FEDERAL REGISTER

Vol. 88 Monday,

No. 165 August 28, 2023

Pages 58495–59438

OFFICE OF THE FEDERAL REGISTER

The **FEDERAL REGISTER** (ISSN 0097–6326) is published daily, Monday through Friday, except official holidays, by the Office of the Federal Register, National Archives and Records Administration, under the Federal Register Act (44 U.S.C. Ch. 15) and the regulations of the Administrative Committee of the Federal Register (1 CFR Ch. I). The Superintendent of Documents, U.S. Government Publishing Office, is the exclusive distributor of the official edition. Periodicals postage is paid at Washington, DC.

The **FEDERAL REGISTER** provides a uniform system for making available to the public regulations and legal notices issued by Federal agencies. These include Presidential proclamations and Executive Orders, Federal agency documents having general applicability and legal effect, documents required to be published by act of Congress, and other Federal agency documents of public interest.

Documents are on file for public inspection in the Office of the Federal Register the day before they are published, unless the issuing agency requests earlier filing. For a list of documents currently on file for public inspection, see *www.federalregister.gov.*

The seal of the National Archives and Records Administration authenticates the Federal Register as the official serial publication established under the Federal Register Act. Under 44 U.S.C. 1507, the contents of the **Federal Register** shall be judicially noticed.

The **Federal Register** is published in paper and on 24x microfiche. It is also available online at no charge at *www.govinfo.gov*, a service of the U.S. Government Publishing Office.

The online edition of the **Federal Register** is issued under the authority of the Administrative Committee of the Federal Register as the official legal equivalent of the paper and microfiche editions (44 U.S.C. 4101 and 1 CFR 5.10). It is updated by 6:00 a.m. each day the **Federal Register** is published and includes both text and graphics from Volume 1, 1 (March 14, 1936) forward. For more information, contact the GPO Customer Contact Center, U.S. Government Publishing Office. Phone 202-512-1800 or 866-512-1800 (toll free). E-mail, *gpocusthelp.com.*

The annual subscription price for the **Federal Register** paper edition is $860 plus postage, or $929, for a combined **Federal Register, Federal Register** Index and List of CFR Sections Affected (LSA) subscription; the microfiche edition of the **Federal Register** including the **Federal Register** Index and LSA is $330, plus postage. Six month subscriptions are available for one-half the annual rate. The prevailing postal rates will be applied to orders according to the delivery method requested. The price of a single copy of the daily **Federal Register,** including postage, is based on the number of pages: $11 for an issue containing less than 200 pages; $22 for an issue containing 200 to 400 pages; and $33 for an issue containing more than 400 pages. Single issues of the microfiche edition may be purchased for $3 per copy, including postage. Remit check or money order, made payable to the Superintendent of Documents, or charge to your GPO Deposit Account, VISA, MasterCard, American Express, or Discover. Mail to: U.S. Government Publishing Office—New Orders, P.O. Box 979050, St. Louis, MO 63197-9000; or call toll free 1-866-512-1800, DC area 202-512-1800; or go to the U.S. Government Online Bookstore site, see *bookstore.gpo.gov.*

There are no restrictions on the republication of material appearing in the **Federal Register.**

How To Cite This Publication: Use the volume number and the page number. Example: 88 FR 12345.

Postmaster: Send address changes to the Superintendent of Documents, Federal Register, U.S. Government Publishing Office, Washington, DC 20402, along with the entire mailing label from the last issue received.

SUBSCRIPTIONS AND COPIES

PUBLIC

Subscriptions:

Paper or fiche	**202–09512—1800**
Assistance with public subscriptions	**202–512–1806**
General online information	**202–512–1530; 1–888–293–6498**

Single copies/back copies:

Paper or fiche	**202–512–1800**
Assistance with public single copies	**1–866–512–1800 (Toll-Free)**

FEDERAL AGENCIES

Subscriptions:

Assistance with Federal agency subscriptions:

Email	*FRSubscriptions@nara.gov*
Phone	**202–741–6000**

The Federal Register Printing Savings Act of 2017 (Pub. L. 115-120) placed restrictions on distribution of official printed copies of the daily **Federal Register** to members of Congress and Federal offices. Under this Act, the Director of the Government Publishing Office may not provide printed copies of the daily **Federal Register** unless a Member or other Federal office requests a specific issue or a subscription to the print edition. For more information on how to subscribe use the following website link: *https://www.gpo.gov/frsubs.*

Contents

Federal Register

Vol. 88, No. 165

Monday, August 28, 2023

Reader Aids

Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents electronic mailing list, go to https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new, enter your e-mail address, then follow the instructions to join, leave, or manage your subscription.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

9 CFR

Proposed Rules:

57 58524
161 58524

14 CFR

97 (2 documents) 58945, 58946

15 CFR

Proposed Rules:

705 58525

21 CFR

Ch. I 58498

33 CFR

165 58500

36 CFR

1280 58502

40 CFR

180 (2 documents) 58503, 58506

Proposed Rules:

52 58538

42 CFR

411 58640
412 58640
419 58640
488 58640
489 58640
495 58640

47 CFR

54 58509

Proposed Rules:

25 58540

50 CFR

223 58511
648 58521
660 58522

Rules and Regulations

Federal Register
Vol. 88, No. 165
Monday, August 28, 2023

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31503; Amdt. No. 4075]

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

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

DATES: This rule is effective August 28, 2023. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of August 28, 2023.

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

For Examination:

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

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

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

4. The National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fr.inspection@nara.gov* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

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

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

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

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

Availability and Summary of Material Incorporated by Reference

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

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

The Rule

This amendment to 14 CFR part 97 is effective upon publication of each separate SIAP, Takeoff Minimums and ODP as amended in the transmittal. Some SIAP and Takeoff Minimums and textual ODP amendments may have been issued previously by the FAA in a Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flights safety relating directly to published aeronautical charts.

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

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

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

Lists of Subjects in 14 CFR Part 97

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

Issued in Washington, DC, on August 18, 2023.

Thomas J. Nichols,

Aviation Safety, Flight Standards Service, Manager, Standards Section, Flight Procedures & Airspace Group, Flight Technologies & Procedures Division.

Adoption of the Amendment

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

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

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

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

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

Effective 5 October 2023

Fairbanks, AK, PAFA, ILS OR LOC RWY 2L, ILS RWY 2L (SA CAT I), ILS RWY 2L (CAT II), ILS RWY 2L (CAT III), Amdt 11
Fairbanks, AK, PAFA, RNAV (RNP) Z RWY 2L, Amdt 2
Fairbanks, AK, PAFA, RNAV (RNP) Z RWY 20R, Amdt 2
Shishmaref, AK, PASH, NDB RWY 5, Amdt 1A, CANCELED
Shishmaref, AK, PASH, RNAV (GPS) RWY 5, Amdt 1
Shishmaref, AK, PASH, RNAV (GPS) RWY 23, Amdt 1
Shishmaref, AK, PASH, Takeoff Minimums and Obstacle DP, Amdt 1
Manila, AR, KMXA, RNAV (GPS) RWY 36, Amdt 1
Lancaster, CA, KWJF, PALMDALE ONE, Graphic DP
Lancaster, CA, KWJF, RNAV (GPS) RWY 24, Orig-B
Lancaster, CA, KWJF, Takeoff Minimums and Obstacle DP, Amdt 1
Colorado Springs, CO, KFLY, FALCON ONE, Graphic DP
Colorado Springs, CO, KFLY, RNAV (GPS) RWY 15, Orig
Colorado Springs, CO, KFLY, RNAV (GPS) RWY 33, Orig
Colorado Springs, CO, KFLY, Takeoff Minimums and Obstacle DP, Orig
Arcadia, FL, X06, RNAV (GPS)–A, Amdt 1
Arcadia, FL, X06, RNAV (GPS)–B, Amdt 1
Elberton, GA, KEBA, RNAV (GPS) RWY 11, Amdt 2
Elberton, GA, KEBA, RNAV (GPS) RWY 29, Amdt 1B
Elberton, GA, KEBA, VOR RWY 11, Amdt 5
Nahunta, GA, 4J1, RNAV (GPS) RWY 1, Amdt 1
Nahunta, GA, 4J1, RNAV (GPS) RWY 19, Amdt 1
Nahunta, GA, 4J1, RNAV (GPS) Y RWY 1, Orig-B, CANCELED
Nahunta, GA, 4J1, RNAV (GPS) Z RWY 19, Orig-B, CANCELED
Kahului, HI, PHOG, ILS Y OR LOC Y RWY 2, Orig-A
Kahului, HI, PHOG, ILS Z OR LOC Z RWY 2, Amdt 26A
Kahului, HI, PHOG, NDB RWY 2, Orig-B, CANCELED
Kahului, HI, PHOG, VOR Y RWY 20, Amdt 1, CANCELED
South Bend, IN, KSBN, RNAV (GPS) RWY 9R, Amdt 1C
South Bend, IN, KSBN, RNAV (GPS) RWY 36, Amdt 1C
Vidalia, LA, 0R4, RNAV (GPS) RWY 14, Amdt 1
Sandusky, MI, Y83, RNAV (GPS) RWY 10, Orig
Sandusky, MI, Y83, RNAV (GPS) RWY 28, Orig
Sandusky, MI, Y83, Takeoff Minimums and Obstacle DP, Orig
Natchez, MS, KHEZ, ILS OR LOC RWY 14, Amdt 3
Natchez, MS, KHEZ, VOR RWY 18, Amdt 11A, CANCELED
Oxford, MS, KUOX, RNAV (GPS) RWY 9, Amdt 2
Oxford, MS, KUOX, RNAV (GPS) RWY 27, Amdt 2
Oxford, MS, KUOX, VOR–A, Amdt 5B
Winnemucca, NV, KWMC, FESKO ONE, Graphic DP
Winnemucca, NV, KWMC, Takeoff Minimums and Obstacle DP, Amdt 3
Winnemucca, NV, KWMC, WINNEMUCCA ONE, Graphic DP, CANCELED
Miller, SD, KMKA, RNAV (GPS) RWY 33, Amdt 1C
Alice, TX, KALI, LOC/DME RWY 31, Orig-F
Alice, TX, KALI, RNAV (GPS) RWY 31, Amdt 1G
Alice, TX, KALI, VOR RWY 31, Amdt 13G
Milwaukee, WI, KMKE, Takeoff Minimums and Obstacle DP, Amdt 9
Buckhannon, WV, W22, RNAV (GPS) RWY 11, Amdt 2E

[FR Doc. 2023–18462 Filed 8–25–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 97

[Docket No. 31504; Amdt. No. 4076]

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

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

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

DATES: This rule is effective August 28, 2023. The compliance date for each SIAP, associated Takeoff Minimums, and ODP is specified in the amendatory provisions.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of August 28, 2023.

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

For Examination:

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

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

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

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

For information on the availability of this material at NARA, email

fr.inspection@nara.gov or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

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

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

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

Availability and Summary of Material Incorporated by Reference

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

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

The Rule

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

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

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

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

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

List of Subjects in 14 CFR Part 97

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

Issued in Washington, DC, on August 18, 2023.

Thomas J. Nichols,

Aviation Safety, Flight Standards Service, Manager, Standards Section, Flight Procedures & Airspace Group, Flight Technologies & Procedures Division.

Adoption of the Amendment

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

PART 97—STANDARD INSTRUMENT APPROACH PROCEDURES

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

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

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

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

** * * Effective Upon Publication*

AIRAC date	State	City	Airport name	FDC No.	FDC date	Procedure name
5-Oct-23	WV	Charleston	West Virginia Intl Yeager	3/0120	8/11/23	ILS OR LOC RWY 5, Orig-A.
5-Oct-23	PA	Reading	Reading Rgnl/Carl A Spaatz Fld.	3/2093	8/10/23	RNAV (GPS) RWY 31, Orig.
5-Oct-23	OH	Washington Court House.	Fayette County	3/2336	8/11/23	RNAV (GPS) RWY 23, Amdt 1A.
5-Oct-23	OH	Coshocton	Richard Downing	3/2817	8/11/23	RNAV (GPS) RWY 4, Orig.
5-Oct-23	WI	Mosinee	Central Wisconsin	3/3041	7/27/23	RNAV (GPS) RWY 17, Amdt 1C.
5-Oct-23	GA	Americus	Jimmy Carter Rgnl	3/3101	6/21/23	RNAV (GPS) RWY 23, Amdt 1C.
5-Oct-23	AR	Fayetteville	Drake Fld	3/7177	8/9/23	RNAV (GPS) RWY 16, Amdt 1B.

AIRAC date	State	City	Airport name	FDC No.	FDC date	Procedure name
5-Oct-23	AR	Fayetteville	Drake Fld	3/7180	8/9/23	LOC RWY 16, Orig.
5-Oct-23	AR	Fayetteville	Drake Fld	3/7182	8/9/23	RNAV (GPS) RWY 34, Amdt 1C.

[FR Doc. 2023–18463 Filed 8–25–23; 8:45 a.m.]

BILLING CODE 4910–13–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Chapter I

[Docket No. FDA–2023–D–1909]

Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act—Compliance Policies; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, Department of Health and Human Services (HHS).

ACTION: Notification of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a final guidance for industry entitled ''Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act—Compliance Policies.'' This guidance describes FDA's compliance policies regarding enforcement of requirements for the interoperable, electronic, package level product tracing (referred to as enhanced drug distribution security requirements) under the Federal Food, Drug, and Cosmetic Act (FD&C Act) that will go into effect on November 27, 2023. FDA believes the compliance policies outlined in this guidance will help supply chain stakeholders, particularly trading partners, by accommodating the additional time that may be needed to continue to develop and refine appropriate systems and processes to conduct interoperable, electronic tracing at the package level, to achieve robust supply chain security under the Drug Supply Chain Security Act (DSCSA) while helping ensure continued patient access to prescription drugs.

DATES: The announcement of the guidance is published in the **Federal Register** on August 28, 2023.

ADDRESSES: You may submit either electronic or written comments on Agency guidances at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–D–1909 for ''Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act—Compliance Policies.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002 or to the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm.

3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Pepinsky, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4258, Silver Spring, MD 20993–0002, 301–796–3130, email: *drugtrackandtrace@fda.hhs.gov;* or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act—Compliance Policies.'' This guidance describes FDA's compliance policies regarding enforcement of requirements for the interoperable, electronic, package level product tracing (referred to as enhanced drug distribution security requirements) under section 582(g)(1) of the FD&C Act (21 U.S.C. 360eee-1(g)(1)) that will go into effect on November 27, 2023. FDA believes that these compliance policies will facilitate the continued use of product tracing and verification methods currently being used while accommodating the additional time that may be needed by trading partners to continue to develop and refine the systems and processes for such activities required under section 582(g)(1) of the FD&C Act.

We are issuing this guidance consistent with our good guidance practices (GGP) regulation (21 CFR 10.115). We are implementing this guidance without prior public comment because we have determined that prior public participation is not feasible or appropriate (21 CFR 10.115(g)(2)). The Agency made this determination because the Agency needs to communicate its compliance policy in a timely manner and provide stakeholders notice of the compliance policy ahead of the effective date of the enhanced distribution security requirements. Although this guidance document is being implemented immediately, it remains subject to comment in accordance with FDA's GGP regulation and the Agency will consider all comments received and determine whether revisions to the guidance document are appropriate.

The DSCSA, enacted on November 27, 2013, outlines critical steps for building an electronic, interoperable system by November 27, 2023, that will identify and trace certain prescription drugs as they are distributed within the United States. Since the enactment of DSCSA, FDA and trading partners have been preparing for the implementation of the enhanced drug distribution security requirements imposed by section 582(g)(1) of the FD&C Act. Trading partners are continuing to work to have the necessary systems and processes in place in anticipation of the November 27, 2023, effective date for these requirements. While trading partners have the obligation to comply with section 582 requirements, including for enhanced drug distribution security, there are other stakeholders involved and affected, including but not limited to: solution providers, standards organizations, trade and professional organizations, state authorities, and other Federal authorities.

FDA understands that collaboration and alignment among trading partners and other stakeholders throughout the supply chain are critical for achieving interoperability under the DSCSA. FDA has heard from stakeholders, including a broad representation of trading partners, about concerns regarding trading partner readiness and the need for clarity and flexibility to ensure trading partners can continue to move product through the supply chain when the enhanced drug distribution security requirements under section 582(g)(1) of the FD&C Act take effect. Most recently, at a virtual public meeting on DSCSA Implementation and Readiness Efforts for 2023 held on December 7 and 8, 2022 (87 FR 67047, November 7, 2022), stakeholders indicated that trading partners throughout the supply chain are at different stages of readiness, with some trading partners being further behind not only in terms of understanding their obligations under section 582(g)(1) of the FD&C Act, but also being aware of the time and resources necessary to meet those obligations. Stakeholders also expressed a need for clarity with respect to treatment of product that is already in the supply chain on November 27, 2023, and the need for flexibility when the requirements under section 582(g)(1) take effect, to minimize potential disruptions in the supply chain. In addition, stakeholders are experiencing challenges with predicting and planning for the possible volume of requests for product tracing information from Federal and State authorities and other trading partners, and the resources needed to respond to such requests, in accordance with section 582(g)(1) of the FD&C Act.

While FDA generally expects trading partners to have the systems and processes in place to meet the enhanced drug distribution security requirements of section 582(g)(1) as of November 27, 2023, we recognize that some technical and operational issues, including issues involving trading partners and other affected stakeholders, may not be fully resolved by that time. The Agency also understands that additional time beyond November 27, 2023, may be needed for systems to stabilize and be fully interoperable for accurate, secure, and timely electronic data exchange. This guidance is intended to provide clarity and flexibility to trading partners to help ensure continued patient access to prescription drugs as the supply chain transitions to the interoperable, electronic product tracing at the package level under the DSCSA. The compliance policies in this guidance can help trading partners throughout the supply chain implement the requirements under section 582(g)(1) of the FD&C Act by accommodating the additional time that may be needed to implement, troubleshoot, and mature their systems and processes while supporting the continued availability of products to patients.

The guidance represents the current thinking of FDA on ''Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act—Compliance Policies.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.[1]

II. Paperwork Reduction Act

FDA concludes that this guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/*

[1] The Office of the Federal Register has published this document under the category ''Rules and Regulations'' pursuant to its interpretation of 1 CFR 5.9(b). We note that the categorization as such for purposes of publication in the **Federal Register** does not affect the content or intent of the document. See 1 CFR 5.1(c).

vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents, or *https://www.regulations.gov.*

Dated: August 22, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–18359 Filed 8–25–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[USCG–USCG–2023–0043]

RIN 1625–AA00

Safety Zone, Illinois River MM 165.5 Peoria, IL

AGENCY: Coast Guard, Department of Homeland Security (DHS).

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for all navigable waters within a half mile radius of a crane boom located in the Illinois River at Mile Marker (MM) 165.5. The safety zone is needed to protect personnel, vessels, and the marine environment from all potential hazards associated with a crane boom blocking the navigable channel and the salvage operation for its removal. Entry of vessels or persons into this zone is prohibited unless specifically authorized by the Captain of the Port Sector Upper Mississippi River (COTP) or a designated representative.

DATES: This rule is effective without actual notice from August 28, 2023, through August 29, 2023. For the purposes of enforcement, actual notice will be used from August 23, 2023, until August 28, 2023.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *https://www.regulations.gov,* type USCG–2023–0043 in the search box and click ''Search.'' Next, in the Document Type column, select ''Supporting & Related Material.''

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email MSTC Nathaniel Dibley, Sector Upper Mississippi River Waterways Management Division, U.S. Coast Guard; telephone 314–269–2560, email *Nathaniel.D.Dibley@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

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

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because a temporary safety zone must be established immediately to protect personnel, vessels, and the marine environment from potential hazards created by a crane boom protruding into the navigable channel and lack sufficient time to provide a reasonable comment period and then consider those comments before issuing the rule. It is impracticable to publish an NPRM because we must establish this safety zone by August 23, 2023.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be impracticable because immediate action is needed to respond to the potential safety hazards associated with a crane boom blocking the navigable channel.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 46 U.S.C. 70034. The Captain of the Port Sector Upper Mississippi River (COTP) has determined that potential hazards associated with a crane boom blocking the navigable channel and the salvage operation taking place to remove it will be a safety concern for anyone operating or transiting within the Illinois River at MM 165.5. This rule is needed to protect personnel, vessels, and the marine environment in the navigable waters within the safety zone until the crane boom has been removed from the waterway.

IV. Discussion of the Rule

The salvaging of the crane boom will occur at MM 165.5 beginning August 23, 2023. The safety zone is designed to protect waterway users until work is complete.

No vessel or person will be permitted to enter the safety zone without obtaining permission from the COTP or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of USCG Sector Upper Mississippi River. To seek permission to enter, contact the COTP or a designated representative via VHF–FM channel 16, or through USCG Sector Upper Mississippi River at 314–269–2332. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative. The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement, as well as reductions in the size of the safety zone through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Safety Marine Information Broadcast (SMIB), as appropriate.

V. Regulatory Analyses

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

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. This rule has not been designated a ''significant regulatory action,'' under section 3(f) of Executive Order 12866, as amended by Executive Order 14094 (Modernizing Regulatory Review). Accordingly, this rule has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on a safety zone located within a half mile radius of a crane boom on the Illinois River at MM 165.5, near Peoria, IL. The safety zone is expected to be active until the crane boom has been salvaged and the channel cleared.

B. Impact on Small Entities

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

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

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

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

C. Collection of Information

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

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has 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. We have analyzed this rule under that order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, 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.

E. Unfunded Mandates Reform Act

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

F. Environment

We have analyzed this rule under Department of Homeland Security Directive 023–01, Rev. 1, associated implementing instructions, and Environmental Planning COMDTINST 5090.1 (series), which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a safety zone encompassing the width of the Illinois River at MM 165.5. It is categorically excluded from further review under paragraph L60(d) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places, or vessels.

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 46 U.S.C. 70034, 70051, 70124; 33 CFR 1.05–1, 6.04–1, 6.04–6, and 160.5; Department of Homeland Security Delegation No. 00170.1, Revision No. 01.3.

■ 2. Add § 165.T08–0043 to read as follows:

§ 165.T08–0043 Safety Zone; Illinois River, Mile Marker 165.5, Peoria, IL.

(a) *Location.* The following area is a safety zone: all navigable waters within a half mile radius of a crane barge on the Illinois River, Mile Marker 165.5, Peoria, IL.

(b) *Enforcement period.* This section will be subject to enforcement from August 23, 2023, until August 29, 2023, or until the hazard has been cleared.

(c) *Regulations.* (1) In accordance with the general safety zone regulations in § 165.23, entry of persons or vessels into the safety zone described in paragraph (a) of this section is prohibited unless authorized by the Captain of the Port Sector Upper Mississippi River (COTP) or a designated representative. A designated representative is a commissioned, warrant, or petty officer of the U.S. Coast Guard (USCG) assigned to units under the operational control of USCG Sector Upper Mississippi River.

(2) To seek permission to enter, contact the COTP or a designated representative via VHF–FM channel 16, or through USCG Sector Upper Mississippi River at 314–269–2332. Persons and vessels permitted to enter the safety zone must comply with all lawful orders or directions issued by the COTP or designated representative.

(d) *Informational broadcasts.* The COTP or a designated representative will inform the public of the effective period for the safety zone as well as any changes in the dates and times of enforcement, as well as reductions in size or scope of the safety zone through Local Notice to Mariners (LNMs), Broadcast Notices to Mariners (BNMs), and/or Safety Marine Information Broadcast (SMIB) as appropriate.

Dated: August 23, 2023.

D.J. Every,

Commander, U.S. Coast Guard, Acting Captain of the Port Sector Upper Mississippi River.

[FR Doc. 2023–18555 Filed 8–24–23; 11:15 am]

BILLING CODE 9110–04–P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

36 CFR Part 1280

[FDMS No. NARA–23–0008; NARA–2023–034]

RIN 3095–AC13

Use of NARA Facilities: Rules for Filming, Photographing, or Videotaping on NARA Property for Personal Use

AGENCY: National Archives and Records Administration (NARA).

ACTION: Direct final rule.

SUMMARY: The National Archives and Records Administration (NARA) is amending our regulations on the Use of NARA Facilities to allow personal, non-flash photography throughout NARA exhibition galleries.

DATES: This rule is effective October 10, 2023, without further action, unless we receive actionable adverse comments by September 18, 2023. If we receive such comments, we will publish a withdrawal of the rule in the **Federal Register**.

ADDRESSES: You may submit comments, identified by RIN 3095–AC13 by the following method:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov.* Follow the online instructions for submitting comments. All submissions must include NARA's name and the regulatory information number for this rulemaking (RIN 3095–AC13). We may publish any comments we receive without changes, including any personal information you include.
- *Mail (for paper, flash drive, or CD–ROM submissions. Include ''RIN 3095–AC13'' on the submission):* National Archives and Records Administration; Regulation Comments Desk, Suite 4100; 8601 Adelphi Road; College Park, MD 20740–6001.

FOR FURTHER INFORMATION CONTACT: Kimberly Richardson, Strategy and Performance Division, by email at *regulation_comments@nara.gov,* by email at *kimberly.richardson@nara.gov,* or by phone at 301–837–2902. Contact *https://museum.archives.gov/contact-us* with any questions on photography in NARA facilities.

SUPPLEMENTARY INFORMATION: The National Archives and Records Administration (NARA) is amending our regulations on the use of NARA facilities to allow personal photography throughout NARA exhibition galleries, including the Rotunda in the National Archives Museum, unless otherwise posted. Direct photography of the display of the founding documents in the Rotunda will continue to be prohibited; however, visitors are allowed to take selfies and other photographs that include the Rotunda as background. Research shows that most museums allow non-flash photography. By expanding the use of photography, we will enhance the visitor experience and raise awareness of our mission, while continuing to maintain preservation and security needs.

Regulatory Analysis

Review Under Executive Order 12866, Regulatory Planning and Review, 58 FR 51735; Executive Order 13563, Improving Regulation and Regulation Review, 76 FR 23821; and Executive Order 14094 Modernizing Regulatory Review, 88 FR 21879.

The Office of Management and Budget (OMB) has reviewed this rulemaking and determined it is not ''significant'' under section 3(f) of Executive Order 12866. It is not significant because it consists of administrative and minor revisions, involves agency organization and management, does not change substantive requirements, and imposes no costs on the public.

Review Under the Regulatory Flexibility Act (5 U.S.C. 601, et seq.)

This review requires an agency to prepare an initial regulatory flexibility analysis and publish it when the agency publishes the proposed rule. This requirement does not apply if the agency certifies that the rulemaking will not, if promulgated, have a significant economic impact on a substantial number of small entities (5 U.S.C. 603). We certify, after review and analysis, that this rulemaking will not have a significant adverse economic impact on small entities.

Review Under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This rulemaking does not impose additional information collection requirements on the public that are subject to the Paperwork Reduction Act.

Review Under Executive Order 13132, Federalism, 64 FR 43255

Review under Executive Order 13132 requires that agencies review regulations for federalism effects on the institutional interest of states and local governments, and, if the effects are sufficiently substantial, prepare a Federal assessment to assist senior policy makers. This rulemaking will not have any effects on state and local governments within the meaning of the Executive order. Therefore, no federalism assessment is required.

Review Under the Unfunded Mandates Reform Act (Sec. 202, Pub. L. 104–4; 2 U.S.C. 1532)

Review under the Unfunded Mandates Reform Act requires that agencies determine whether any Federal mandate in the rulemaking may result in state, local, and tribal governments, in the aggregate, or the private sector, expending $100 million in any one year. NARA certifies that this rulemaking does not contain a Federal mandate that may result in such an expenditure, and this rulemaking is therefore not subject to this requirement.

List of Subjects in 36 CFR Part 1280

Archives and records, Federal buildings and facilities.

For the reasons stated in the preamble, NARA amends 36 CFR part 1280 as follows:

PART 1280—USE OF NARA FACILITIES

■ 1. The authority citation for part 1280 continues to read as follows:

Authority: 44 U.S.C. 2102 notes, 2104(a), 2112, 2903.

■ 2. Revise § 1280.46 to read as follows:

§ 1280.46 Filming, photographing, or videotaping for personal use.

(a) You may film, photograph, or videotape on NARA property outside a NARA facility so long as you do not impede vehicular or pedestrian traffic.

(b) You may film, photograph, or videotape inside a NARA facility during regular business hours in public areas, including research rooms and exhibition areas, unless otherwise posted, under the following conditions:

(1) You may not use a flash or other supplemental lighting; and

(2) You may not use a selfie stick, monopod, tripod, or similar equipment.

■ 3. In § 1280.84, revise paragraph (a) to read as follows:

§ 1280.84 Using the Rotunda.

(a) We do not allow private group event activities (*e.g.,* dinner/reception, program) to be held in the Rotunda or the exhibit galleries in the National Archives Museum. We may, at our discretion, allow attendees at private group events to enter the Rotunda and

other Museum areas in conjunction with their event to view the exhibits, but the event activities themselves may not be held in those spaces. Whether during or outside of regular business hours, event attendees may film, photograph, or videotape in the Rotunda or other Museum areas, including group photographs or videos, for personal use only, in accordance with all applicable regulations contained in this part and unless otherwise posted.

* * * * *

Colleen J. Shogan,

Archivist of the United States.

[FR Doc. 2023–18465 Filed 8–25–23; 8:45 am]

BILLING CODE 7515–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2022–0386; FRL–11036–01–OCSPP]

Spinosad; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of spinosad in or on Spice group 26, and Stalk and stem vegetable subgroup 22A. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 28, 2023. Objections and requests for hearings must be received on or before October 27, 2023, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2022–0386, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets.*

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

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

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

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2022–0386 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before October 27, 2023. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2022–0386, by one of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets.*

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of January 3, 2023 (88 FR 38) (FRL–9410–08–OCSPP), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 2E8993) by IR–4, North Carolina State University, 1730 Varsity Drive, Venture IV, Suite 210, Raleigh, NC 27606. The petition requested to amend 40 CFR part 180 by establishing tolerances for residues of spinosad in or on the raw agricultural commodities Stalk and stem vegetable subgroup 22A at 0.4 parts per million (ppm), and Spice group 26 at 1.7 ppm.

The petition also proposed to remove established tolerances for residues of spinosad in or on the following: Asparagus, and Spice, subgroup 19B, except black pepper.

That document referenced a summary of the petition, which is available in the docket, *https://www.regulations.gov.* There were no comments received in response to the proposed rule.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the

pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

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

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

EPA has previously published several tolerance rulemakings for spinosad, in which EPA concluded, based on the available information, that there is a reasonable certainty that no harm would result from aggregate exposure to spinosad and established tolerances for residues of that chemical. EPA is incorporating previously published sections of those rulemakings that remain unchanged, as described further in this rulemaking. Specific information on the risk assessment conducted in support of this action, including on the studies received and the nature of the adverse effects caused by spinosad, can be found in the document titled ''Spinosad and Spinetoram: Human Health Risk Assessment in Support of Proposed Uses on Stalk and Stem Vegetables (22A) and Greenhouse-Grown Cucumbers, Lettuce, Pepper, and Tomato; and Crop Group Conversion for Spice Group 26'' (hereinafter ''Spinosad and Spinetoram Human Health Risk Assessment'') which is available in the docket for this action at *https://www.regulations.gov.*

Toxicological profile. For a discussion of the Toxicological Profile of spinosad, see Unit III.A. of the rulemaking published in the **Federal Register** of September 19, 2019 (84 FR 49195) (FRL–9995–90).

Toxicological points of departure/Levels of concern. For a summary of the Toxicological Points of Departure/Levels of Concern used for the safety assessment of spinosad, see Unit III.B. of the September 19, 2019, rulemaking.

Exposure assessment. Much of the exposure assessment remains unchanged from the September 19, 2019, rulemaking, although the new exposure assessment incorporates the additional dietary exposure from the petitioned-for tolerances. Other changes are described below.

A chronic dietary exposure assessment was conducted using DEEM–FCID Version 4.02. This software uses 2005–2010 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America, (NHANES/WWEIA). Acute and cancer analyses were not conducted as toxicological effects attributable to a single dose were not identified and spinosad is classified as not likely to be carcinogenic. The chronic dietary analysis assumed 100 percent crop treated (PCT), average field-trial residues or tolerance-level residues for crop commodities, average residues from the livestock feeding studies, residue estimates for fish/shellfish, experimental processing factors when available, and modeled drinking water estimates.

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

Drinking water and non-occupational exposures. The estimated drinking water concentrations (EDWCs) of spinosad have been modified since the last assessment. Based on the Tier I Rice Model and Pesticide Root Zone Model Ground Water (PRZM GW), the EDWCs of spinosad for chronic exposures are estimated to be 38 parts per billion (ppb) for surface water and below the levels of detection for ground water.

Modeled estimates of drinking water concentration were directly entered into the dietary exposure model. For the chronic dietary risk assessment, the water concentration value of 38 ppb was used to assess the contribution to drinking water.

There have been no changes to residential exposures since the September 19, 2019, rulemaking. For calculation of aggregate short-term exposure, residential exposure to adults (residential handler exposure from applying spinosad to turf/ornamentals/home garden), children 3 to less than 6 years old (combined post-application inhalation and ingestion of water exposure during recreational swimming), and children 1 to less than 2 years old (post-application exposure resulting from the application of spinosad to turf/ornamentals/home gardens) yield the highest residential short-term exposure and were therefore used in calculation of aggregate exposure.

Cumulative exposure. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to spinosad and any other substances and spinosad does not appear to produce a toxic metabolite produced by other substances. For the purposes of this action, therefore, EPA has not assumed that spinosad has a common mechanism of toxicity with other substances.

Safety factor for infants and children. EPA continues to conclude that there is reliable data showing that the safety of infants and children would be adequately protected if the Food Quality Protection Act (FQPA) safety factor were reduced from 10X to 1X. The reasons for that decision are articulated in Unit III.D. of the September 19, 2019, rulemaking.

Aggregate risks and determination of safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing dietary exposure estimates to the acute population-

adjusted dose (aPAD) and chronic population-adjusted dose (cPAD). Short-, intermediate-, and chronic-term aggregate risks are evaluated by comparing the estimated total food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists.

An acute assessment was not conducted because toxicological effects attributable to a single dose were not identified. Chronic dietary (food and drinking water) risks are below the Agency's level of concern of 100% of the cPAD: they are 73% of the cPAD for children 1 to 2 years old, which is the population subgroup with the highest exposure estimate.

The short-term aggregate risks combine chronic dietary (food and drinking water) and residential exposures. The short-term aggregate risk for adults is an aggregate MOE of 740; for children aged 3 to less than 6, the aggregate MOE is 330; and for children 1 to less than 2 years old, the aggregate MOE is 200. MOEs below 100 are of concern; these MOEs are above 100 and therefore are not of concern. Short-term aggregate risk calculations are protective of the intermediate-term duration of exposure.

Because spinosad is classified as ''not likely to be carcinogenic to humans'', EPA has concluded that aggregate exposure to spinosad is not likely to pose a cancer risk.

Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to spinosad residues. More detailed information about the Agency's analysis can be found at *https://www.regulations.gov* in the Spinosad and Spinetoram Human Health Risk Assessment in docket ID EPA–HQ–OPP–2022–0386.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the September 19, 2019, rulemaking.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4).

There are currently no established Codex MRLs for residues of spinosad in or on Stalk and stem vegetable subgroup 22A or Spice Group 26.

V. Conclusion

Therefore, tolerances are established for residues of spinosad in or on Spice group 26 at 1.7 ppm, and Stalk and stem vegetable subgroup 22A at 0.4 ppm.

Additionally, the established tolerances on Asparagus, and Spice, subgroup 19B, except black pepper, are removed as unnecessary.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), or to Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule 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**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

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

Dated: August 21, 2023.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter 1 as follows:

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

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

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

■ 2. In § 180.495, amend Table 1 to paragraph (a) by:

■ a. Removing the commodity ''Asparagus''.

■ b. Adding the commodity ''Spice group 26''.

■ c. Removing the commodity ''Spice, subgroup 19B, except black pepper''; and
■ d. Adding the commodity ''Stalk and stem vegetable subgroup 22A''.

The additions read as follows:

§ 180.495 Spinosad; tolerances for residues.

* * * * *

TABLE 1 TO PARAGRAPH (a)

Commodity	Parts per million
* * * * *	
Spice group 26	1.7
Stalk and stem vegetable subgroup 22A	0.4
* * * * *	

* * * * *

[FR Doc. 2023–18346 Filed 8–25–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2022–0139; FRL–11276–01–OCSPP]

Methoxyfenozide; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of methoxyfenozide in or on coffee bean, sugar cane, and sugar cane molasses. There are no U.S. registrations associated with these tolerances. Corteva Agrisciences, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective August 28, 2023. Objections and requests for hearings must be received on or before October 27, 2023, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2022–0139, is available at *https://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566–1744. For the latest status information on EPA/DC services, docket access, visit *https://www.epa.gov/dockets.*

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

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

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

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

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

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

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

Under FFDCA section 408(g), 21 U.S.C. 346a(g), any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2022–0139 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before October 27, 2023. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2022–0139, by one of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/contacts.html.*

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

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of July 5, 2023 (88 FR 42935) (FRL–10579–05), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 1E8910) by Corteva Agriscience LLC, 9330 Zionsville Rd., Indianapolis, IN 46268. The petition requested that 40 CFR 180.544 be amended by establishing tolerances for residues of the insecticide methoxyfenozide, including its metabolites and degradates, in or on coffee at 0.15 parts per million (ppm) and sugarcane at 0.03 ppm and in the processed commodity sugarcane molasses at 0.1 ppm. Compliance with the tolerance levels is to be determined by measuring only methoxyfenozide (3-methoxy-2-methylbenzoic acid 2-(3,5-dimethylbenzoyl)-2-(1,1-dimethylethyl) hydrazide). That document referenced a summary of the petition prepared by Corteva Agrisciences, LLC, which is available in the docket, *https://www.regulations.gov.* There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has recommended revisions in commodity definitions. The reasons for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

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

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

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

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

Toxicological profile. For a discussion of the Toxicological Profile of methoxyfenozide, see Unit III.A. of the methoxyfenozide tolerance rulemaking published in the **Federal Register** of March 12, 2019 (84 FR 8820) (FRL–9985–06).

Toxicological points of departure/Levels of concern. For a summary of the Toxicological Points of Departure/Levels of Concern for methoxyfenozide used for human health risk assessment, see Unit III.B. of the March 12, 2019, rulemaking.

Exposure assessment. Much of the exposure assessment for methoxyfenozide remains unchanged from the discussions in Unit III.C. of the March 12, 2019, rulemaking and Unit III.C. of the methoxyfenozide tolerance rulemaking published in the **Federal Register** of October 11, 2022 (87 FR 61259) (FRL–9525–01), except as described below.

Dietary exposure from food and feed uses. The exposure assessment has been updated to include the additional dietary exposure from the new tolerances for residues of methoxyfenozide on coffee bean and sugar cane commodities using the same previous assumptions of tolerance level residues and 100 percent crop treated (PCT) described in Unit III.C.1. of the March 12, 2019, rulemaking.

Dietary exposure from drinking water. Because the requested tolerances for residues of methoxyfenozide in or on coffee bean and sugar cane commodities do not include registrations for use on coffee bean and sugar cane commodities in the United States, the estimated drinking water concentrations have not changed. For a detailed summary of the drinking water analysis for methoxyfenozide used for the human health risk assessment, see Unit III.C.2. of the March 12, 2019, rulemaking and Unit III.C. of the October 11, 2022, rulemaking.

Non-occupational exposure. As described in Unit III.C. of the October 11, 2022, rulemaking, the Agency assumes that when labels require specific clothing and/or personal protective equipment (PPE) such products are not for residential use. The methoxyfenozide label requires specific clothing and/or PPE; therefore, the Agency has made the assumption that the registered methoxyfenozide labels are not intended for use by residential handlers and a quantitative residential handler assessment has not been conducted. The approach to assessing post-application exposure is the same as described in Unit III.C.3 of the March 12, 2019, rulemaking.

Cumulative effects from substances with a common mechanism of toxicity. Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.'' In 2016, EPA's Office of Pesticide Programs released a guidance document entitled Pesticide Cumulative Risk Assessment: ''Framework for Screening Analysis'' (*https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/pesticide-cumulative-risk-assessment-framework*). This document provides guidance on how to screen groups of pesticides for cumulative evaluation using a two-step approach beginning with the evaluation of available toxicological information and, if necessary, followed by a risk-based screening approach. This framework supplements the existing guidance documents for establishing common mechanism groups (CMGs) and conducting cumulative risk assessments (CRA).

The Agency has utilized this framework for methoxyfenozide and determined that the diacylhydrazine class of insecticides (methoxyfenozide, halofenozide and tebufenozide) form a candidate CMG. This group of pesticides is considered a candidate CMG because they share characteristics to support a testable hypothesis for a common mechanism of action.

Following this determination, the Agency conducted a screening-level cumulative risk assessment consistent with the 2016 guidance document. This assessment included only methoxyfenozide and tebufenozide since there are no registered uses for halofenozide. The current screening assessments for methoxyfenozide and tebufenozide are below the Agency's levels of concern. No further cumulative evaluation is necessary for methoxyfenozide.

For more information, see Appendix E of the document titled ''Methoxyfenozide. Human Health Risk Assessment for the Petition to Establish Permanent Tolerances without a U.S. Registration on Coffee Beans and Sugar Cane,'' available at docket ID number EPA–HQ–OPP–2022–0139.

Safety factor for infants and children. EPA continues to conclude that there are reliable data to support the reduction of the Food Quality Protection

Act (FQPA) safety factor from 10X to 1X. See Unit III.D. of the March 12, 2019, rulemaking for a discussion of the Agency's rationale for that determination.

Aggregate risks and determination of safety. EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute population adjusted dose (aPAD) and chronic population adjusted dose (cPAD). Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate points of departure to ensure that an adequate margin of exposure (MOE) exists. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure.

An acute dietary risk assessment was not needed for methoxyfenozide since no toxic effects attributable to a single dose were identified in the toxicity database. Chronic dietary risks are below the Agency's level of concern of 100% of the cPAD; they are 78% of the cPAD for children 1 to 2 years old, the group with the highest exposure. There are currently no residential handler uses for methoxyfenozide, and none are pending before the Agency. Therefore short- and intermediate-term exposure to methoxyfenozide is not expected, and the short- and intermediate-term risk is equivalent to the chronic dietary risk, which is not of concern. Methoxyfenozide is classified as ''Not Likely to Be Carcinogenic to Humans''; therefore, EPA does not expect methoxyfenozide exposures to pose an aggregate cancer risk.

Determination of safety. Therefore, based on the risk assessments and information described above, EPA concludes there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to methoxyfenozide residues. More detailed information on this action can be found in the document titled ''Methoxyfenozide. Human Health Risk Assessment for the Petition to Establish Permanent Tolerances without a U.S. Registration on Coffee Beans and Sugar Cane,'' available at docket ID number EPA–HQ–OPP–2022–0139.

IV. Other Considerations

A. Analytical Enforcement Methodology

For a discussion of the available analytical enforcement method, see Unit IV.A. of the March 12, 2019, rulemaking.

B. International Residue Limits

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

The Codex has not established a MRL for methoxyfenozide in/on coffee bean or sugar cane commodities.

C. Revisions to Petitioned-For Tolerances

EPA is changing the commodity definitions from coffee to coffee bean, sugarcane to sugar cane, and sugarcane, molasses to sugar cane, molasses to be consistent with Agency nomenclature.

V. Conclusion

Therefore, tolerances are established for residues of methoxyfenozide, in or on coffee bean at 0.15 ppm, sugar cane at 0.03 ppm, and sugar cane, molasses at 0.1 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001), or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

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

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the National Government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule 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**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides

and pests, Reporting and recordkeeping requirements.

Dated: August 18, 2023.

Charles Smith,

Director, Registration Division, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

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

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

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

■ 2. In § 180.544, in paragraph (a)(1) amend the table by:
■ a. Adding in alphabetical order the entries ''Coffee bean''; ''Sugar cane''; and ''Sugar cane, molasses''; and
■ b. Adding footnote 2 at the end of the table.

The additions read as follows:

§ 180.544 Methoxyfenozide; tolerances for residues.

(a) * * *
(1) * * *

TABLE 1 TO PARAGRAPH (a)(1)

Commodity	Parts per million
* * * * *	
Coffee bean[2]	0.15
* * * * *	
Sugar cane[2]	0.03
Sugar cane, molasses[2]	0.1
* * * * *	

* * * * *

[2] There are no U.S. registrations as of August 28, 2023.

[FR Doc. 2023–18410 Filed 8–25–23; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket No. 21–93; DA 23–669; FR ID 164624]

Establishing Emergency Connectivity Fund To Close the Homework Gap

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: In this document, the Wireline Competition Bureau (Bureau) grants a petition for limited waiver of the Emergency Connectivity Fund (ECF) program's invoice filing deadline submitted by T-Mobile USA, Inc. (T-Mobile). The Bureau waives the Federal Communications Commission's (Commission) rules to provide an automatic, one-time extension of the invoicing filing deadline to October 30, 2023, for any funding requests with an invoice filing deadline date occurring before October 30, 2023. The Bureau finds that a one-time extension of the invoice filing deadline for applicants and service providers will provide them with sufficient flexibility to complete and submit their invoicing forms and necessary supporting documentation to the Universal Service Administrative Company (USAC) and the Bureau directs USAC to provide an automatic, one-time extension of the invoice filing deadline to October 30, 2023, for any funding requests with an invoice filing deadline occurring before October 30, 2023.

DATES: Effective August 28, 2023.

FOR FURTHER INFORMATION CONTACT: Molly O'Conor, Wireline Competition Bureau, (202) 418–7400 or by email at *Molly.OConor@fcc.gov.* The Commission asks that requests for accommodations be made as soon as possible in order to allow the agency to satisfy such requests whenever possible. Send an email to *fcc504@fcc.gov* or call the Consumer and Governmental Affairs Bureau at (202) 418–0530.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Bureau's In the Matter of Request for Waiver by T-Mobile USA, Inc., Establishing Emergency Connectivity Fund to Close the Homework Gap, Order in WC Docket No. 21–93; DA 23–669, adopted August 14, 2023, and released August 14, 2023 (Order). The full text of this document is available at the following internet address: *https://www.fcc.gov/document/wcb-grants-limited-waiver-ecf-invoice-filing-deadline.*

I. Introduction

1. In the Order, the Bureau grants a petition for limited waiver of the Emergency Connectivity Fund (ECF) program's invoice filing deadline submitted by T-Mobile USA, Inc. Specifically, the Bureau waives § 54.1711(d) of the Commission's rules to provide an automatic, one-time extension of the invoicing filing deadline to October 30, 2023 for any funding requests with an invoice filing deadline date occurring before October 30, 2023. The Bureau recognizes that many participants with a service delivery deadline of June 30, 2023, or a service delivery deadline that occurs shortly thereafter as a result of the Bureau's *May 2023 Service Delivery Deadline Extension Order,* In the Matter of Establishing Emergency Connectivity Fund to Close the Homework Gap, WC Docket No. 21–93, Order, rel. May 12, 2023, DA 23–405, 88 FR 36510 (June 5, 2023), may require additional time to complete the invoicing process for eligible equipment and services that have already been delivered and provided to students, school staff, and library patrons with unmet needs. The Bureau finds that a one-time extension of the invoice filing deadline for applicants and service providers with an invoice filing deadline that falls before October 30, 2023 (Affected Participants), will provide them with sufficient flexibility to complete and submit their invoicing forms and necessary supporting documentation to USAC, the Administrator of the ECF program, in order to receive their committed funding. Accordingly, the Bureau directs USAC to provide an automatic, one-time extension of the invoice filing deadline to October 30, 2023 for any funding requests with an invoice filing deadline occurring before October 30, 2023, and the Bureau modifies § 54.1711(d) of the Commission's rules to provide 60 days to submit invoices from the date of the notification by USAC that a refund request is processed by USAC.

II. Discussion

2. Generally, the Commission's rules may be waived for good cause shown. The Commission may exercise its discretion to waive a rule where the particular facts make strict compliance inconsistent with the public interest. In addition, the Commission may take into account considerations of hardship, equity, or more effective implementation of overall policy on an individual basis.

3. To ensure ECF program participants can seek reimbursement for all of their approved ECF funding used to connect students, school staff, and library patrons with unmet needs, the Bureau finds good cause exists to waive and extend the invoice filing deadline until October 30, 2023, for applicants and service providers with invoice filing deadlines occurring before that date. In addition, the Bureau also modifies § 54.1711(d) of the Commission's rules to allow invoices to be submitted within 60 days from the date that USAC issues a notification that a refund request submitted by an ECF participant has been processed. In particular, the Bureau recognizes that due to the evolving and emergent nature of this program, complexities in the invoicing

process, and the impact of recent service delivery deadline extensions provided by the Bureau, some program participants may have difficulty timely submitting invoices by their current invoice filing deadlines that fall before October 30, 2023, despite every attempt to comply with the program's rules. The Bureau also understands that at times, ECF funds must be returned (*e.g.,* to correct entity information) and USAC must process the refund request first, before the party is able to submit a corrected invoice for a funding request. Furthermore, although the Commission leveraged existing E-Rate processes and forms in the ECF program, including invoicing, the Bureau understands that the ECF program has a shorter invoice filing period than the E-Rate program and that this is the first time some applicants and service providers are submitting invoices using USAC's system, the ECF Portal, altogether. The Bureau also acknowledges the coinciding timing of the invoicing process for Affected Participants with many schools' summer vacations and start of the school year. Taken together, the Bureau finds that such factors have contributed to the need for additional time to file invoices and present compelling and unique circumstances that merit a waiver and modification of § 54.1711(d) of the Commission's rules.

4. Moreover, The Bureau finds that a waiver and modification of § 54.1711(d) will not lead to any undue advantage in funding as the Affected Participants will not receive more funding than allowed under the ECF program rules, and their equipment and services have already been received and delivered. In addition, the Bureau finds that the public interest would not be served were these otherwise eligible ECF participants to lose ECF funding for eligible equipment and services needed to connect students, school staff, and library patrons with unmet needs who otherwise are not able to fully engage in remote learning because of their inability to submit invoices by their current invoice filing deadline or because of the delay in the processing of their refund request. Thus, the Bureau finds that providing an automatic, one-time extension of the invoice filing deadline to October 30, 2023, for Affected Participants and a modification of § 54.1711(d) to account for the processing of refund requests strikes the right balance between the need for efficient administration of the ECF program and allowing applicants and service providers adequate time to receive their approved and committed ECF funding pursuant to the Commission's rules. The Bureau therefore grants T-Mobile's request for limited waiver and modification of § 54.1711(d) of the Commission's rules, and direct USAC to provide Affected Participants with an automatic, one-time extension to submit their invoices to USAC no later than October 30, 2023.

5. In granting the requested relief, the Bureau emphasizes that the Order does not extend ECF program participants' service delivery deadlines, nor does it alter the obligation of participants to comply with the other program requirements set out in the Commission's rules, including their obligation to certify to receipt of eligible equipment and/or services and that they are not willfully or knowingly requesting reimbursement for equipment or services that are not being used on their ECF FCC Forms 472 and 474 (*i.e.,* the requests for reimbursement). As such, the Bureau reminds applicants that all eligible equipment and services, including funding requests for special construction, must be delivered by their service delivery date. The Bureau also reminds applicants that, unlike E-Rate program rules, ECF program rules do not permit any invoice filing extensions. For this reason, any ECF program participant that requires additional time to submit their requests for reimbursement beyond the relief granted herein must file a request for waiver directly with the Commission and demonstrate good cause.

6. This document does not contain proposed information collection(s) subject to the Paperwork Reduction Act of 1995 (PRA), Public Law 104–13. In addition, therefore, it does not contain any new or modified information collection burden for small business concerns with fewer than 25 employees, pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, *see* 44 U.S.C. 3506(c)(4).

7. The Bureau also modifies § 54.1711(d) of the Commission's rules to reflect the updated invoice filing deadline rule adopted herein. The Bureau makes this change without notice and comment in accordance with the exception to the Administrative Procedure Act (APA) for procedural rules. The updated rule will become effective August 28, 2023.

8. The Commission will not send a copy of the Order to Congress and the Government Accountability Office pursuant to the Congressional Review Act, *see* 5 U.S.C. 801(a)(1)(A), because the adopted rule is a rule of agency organization, procedure, or practice that does not ''substantially affect the rights or obligations of non-agency parties.''

9. Finally, waiving the invoice filing deadline does not increase the risk of waste, fraud, or abuse. The Bureau emphasizes that the Commission is committed to protecting the integrity of the ECF program and ensuring that funds disbursed through the program are used for their intended purposes to provide broadband connectivity and connected devices to students, school staff, and library patrons with unmet needs. Although the Bureau grants a limited waiver of the Commission's invoice filing deadline for certain ECF funding requests, this action does not affect the authority of the Commission or USAC to conduct audits or investigations to determine compliance with ECF program rules and requirements. The Commission is also required to recover funds determined to be disbursed in violation of statutory and/or rule requirements.

III. Ordering Clauses

10. *Accordingly, it is ordered,* pursuant to the authority contained in sections 1–4 and 254 of the Communications Act of 1934, as amended, 47 U.S.C. 151–154 and 254, and §§ 0.91, 0.291, and 1.3 of the Commission's rules, 47 CFR 0.91, 0.291, and 1.3, that § 54.1711(d) of the Commission's rules, 47 CFR 54.1711(d), *is waived* and *amended* to the extent provided herein.

11. *It is further ordered,* that pursuant to § 1.102(b)(1) of the Commission's rules, 47 CFR 1.102(b)(1), the Order *shall be effective* upon release.

12. The amended rule adopted in the Order constitutes a rule of agency organization, procedure and practice and is not subject to the Administrative Procedure Act requirements. Accordingly, this amended rule is *effective* August 28, 2023.

List of Subjects in 47 CFR Part 54

Communications common carriers, Health facilities, Infants and children, internet, Libraries, Puerto Rico, Reporting and recordkeeping requirements, Schools, Telecommunications, Telephone, Virgin Islands.

Federal Communications Commission.

Jodie Griffin,

Chief, Telecommunications Access Policy Division, Wireline Competition Bureau.

Final Rule

For the reasons discussed in the preamble, the Federal Communications Commission amends 47 CFR part 54 as follows:

PART 54—UNIVERSAL SERVICE

■ 1. The authority citation for part 54 continues to read as follows:

Authority: 47 U.S.C. 151, 154(i), 155, 201, 205, 214, 219, 220, 229, 254, 303(r), 403, 1004, 1302, 1601–1609, and 1752, unless otherwise noted.

■ 2. Revise § 54.1711(d) to read as follows:

§ 54.1711 Emergency Connectivity Fund requests for reimbursement.

* * * * *

(d) *Invoice filing deadline.* Invoices must be submitted to the Administrator within 60 days from the date of a funding commitment decision letter; a revised funding commitment decision letter approving a post-commitment change or a successful appeal of a previously denied or reduced funding; notification by the Administrator of a processed returned funds (or refund) request; or service delivery date, whichever is later.

* * * * *

[FR Doc. 2023–18464 Filed 8–25–23; 8:45 am]

BILLING CODE 6712–01–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 223

[Docket No. 230822–0202]

RIN 0648–BH85

Endangered and Threatened Species: Designation of Nonessential Experimental Populations of Chinook Salmon Upstream of Shasta Dam, Authorization for Release, and Adoption of Limited Protective Regulations Under the Endangered Species Act Sections 10(j) and 4(d)

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

ACTION: Final rule; notification of availability of a final environmental assessment.

SUMMARY: We, NMFS, designate and authorize the release of nonessential experimental populations (NEPs or experimental populations) of Sacramento River (SR) winter-run Chinook salmon (*Oncorhynchus tshawytscha)* and Central Valley (CV) spring-run Chinook salmon (*O. tshawytscha*) in the McCloud and Upper Sacramento Rivers upstream of Shasta Dam (the NEP Area), California, and, under the Endangered Species Act (ESA), establish a limited set of take exceptions for the experimental populations. Successful reintroduction of populations within the species' historical ranges will contribute to viability and further conservation of these species. The issuance of limited protective regulations for the conservation of these species will provide assurances regarding the regulatory provisions of the ESA as they apply to SR winter-run and CV spring-run Chinook salmon to the people in the Upper Sacramento River and McCloud River watersheds. This final rule also announces the availability of a final environmental assessment (EA) that analyzed the environmental impacts of promulgating the experimental population rule and associated take exceptions.

DATES: The final rule is effective September 27, 2023.

ADDRESSES: The final Environmental Assessment and other reference materials can be obtained at NMFS' National Environmental Policy Act (NEPA) website at: *https://www.westcoast.fisheries.noaa.gov/publications/nepa/nepa_documents.html* or by submitting a request to the Assistant Regional Administrator, California Central Valley Office, West Coast Region, NMFS, 650 Capitol Mall, Suite 5–100, Sacramento, CA 95814.

FOR FURTHER INFORMATION CONTACT: Steve Edmondson, *steve.edmondson@noaa.gov* or by phone at (916) 930–3600, or by mail at National Marine Fisheries Service, 650 Capitol Mall, Suite 5–100, Sacramento, CA 95814.

SUPPLEMENTARY INFORMATION:

Background Information Relevant to Experimental Population Designation

NMFS listed the SR winter-run Chinook salmon Evolutionarily Significant Unit (ESU) as endangered under the ESA, 16 U.S.C. 1531 *et seq.,* on January 4, 1994 (59 FR 440) and reaffirmed this status on June 28, 2005 (70 FR 37159), and 5-year reviews announced on August 15, 2011 (76 FR 50448), April 14, 2014 (79 FR 20802), and May 26, 2016 (81 FR 33468). Section 9 of the ESA prohibits take of the endangered SR winter-run Chinook salmon. The State of California listed SR winter-run Chinook salmon as endangered in 1989 under the California Endangered Species Act (CESA). The federally listed ESU is composed of a single population that includes all naturally spawned SR winter-run Chinook salmon in the Sacramento River and its tributaries (70 FR 37160, June 28, 2005), as well as SR winter-run Chinook salmon that are part of the conservation hatchery program at the Livingston Stone National Fish Hatchery (NFH). Designated critical habitat of SR winter-run Chinook salmon (58 FR 33212, June 16, 1993) includes: (1) the Sacramento River from Keswick Dam, Shasta County (River Mile (RM) 302) to Chipps Island (RM 0) at the westward margin of the delta; (2) all waters from Chipps Island westward to Carquinez Bridge, including Honker Bay, Grizzly Bay, Suisun Bay, and Carquinez Strait; (3) all waters of San Pablo Bay westward of the Carquinez Bridge; and (4) those waters north of San Francisco-Oakland Bay Bridge.

NMFS listed the CV spring-run Chinook salmon ESU as threatened under the ESA on September 16, 1999 (64 FR 50394), and reaffirmed this status in a final rule on June 28, 2005 (70 FR 37160), and 5-year reviews announced on August 15, 2011 (76 FR 50447), and May 26, 2016 (81 FR 33468). The listed ESU of CV spring-run Chinook salmon currently includes all naturally spawned populations of spring-run Chinook salmon in the Sacramento River and its tributaries, as well as the spring-run Chinook salmon from the Feather River Hatchery (FRH) spring-run Chinook salmon program. On January 9, 2002 (67 FR 1116), NMFS issued protective regulations under section 4(d) of the ESA for CV spring-run Chinook salmon that apply the take prohibitions of section 9(a)(1) of the ESA except for listed exceptions (see 50 CFR 223.203). Critical habitat has been designated for CV spring-run Chinook salmon (70 FR 52488, September 2, 2005), and includes most of the occupied riverine habitat within their extant range. CV spring-run Chinook salmon are also listed as a threatened species by the State of California under CESA, California Fish and Game Code, Division 3, Chapter 1.5.

In 2014, we adopted a final recovery plan for the SR winter-run and CV spring-run Chinook salmon ESUs (79 FR 42504, July 22, 2014). The Central Valley Recovery Plan identifies re-establishing populations of SR winter-run and CV spring-run Chinook salmon above impassable barriers to unoccupied historical habitats as an important recovery action (NMFS 2014). More specifically, the Central Valley Recovery Plan explains that re-establishing populations above impassable barriers, such as Shasta Dam, would aid in recovery of the ESUs by increasing abundance, spatial structure and diversity and by reducing the risk of extinction to the ESUs.

This rule designates and authorize the release of NEPs of SR winter-run and CV spring-run Chinook salmon pursuant to ESA section 10(j) in the McCloud and Upper Sacramento Rivers upstream of Shasta Dam, and establishes take prohibitions for the NEPs and exceptions for particular activities.

This is a final rule stemming from a proposed rule published on May 11, 2023 (88 FR 30690). The NEP Area extends from Shasta Dam up to Pit 7 Dam on the Pit River, McCloud Dam on the McCloud River, and Box Canyon Dam on the upper Sacramento River. All other tributaries flowing into Shasta Reservoir up to the ridge line, including tributaries below Pit 7 Dam, McCloud Dam, and Box Canyon Dam, up to the ridge line would be included in the NEP Area. All other areas above Pit 7 Dam on the Pit River, McCloud Dam on the McCloud River, and Box Canyon Dam on the upper Sacramento River would not be part of the NEP Area. The NEP Area extends up to the ridgelines to account for watershed processes and ends at the aforementioned dams because these dams lack fish passage facilities. The NEP Area is part of the species' historical range. The NEPs are all SR winter-run and CV spring-run Chinook salmon, including fish released or propagated, naturally or artificially, within the NEP Area.

Figure 1—The NEP Area above Shasta Dam for SR winter-run and CV spring-run Chinook salmon

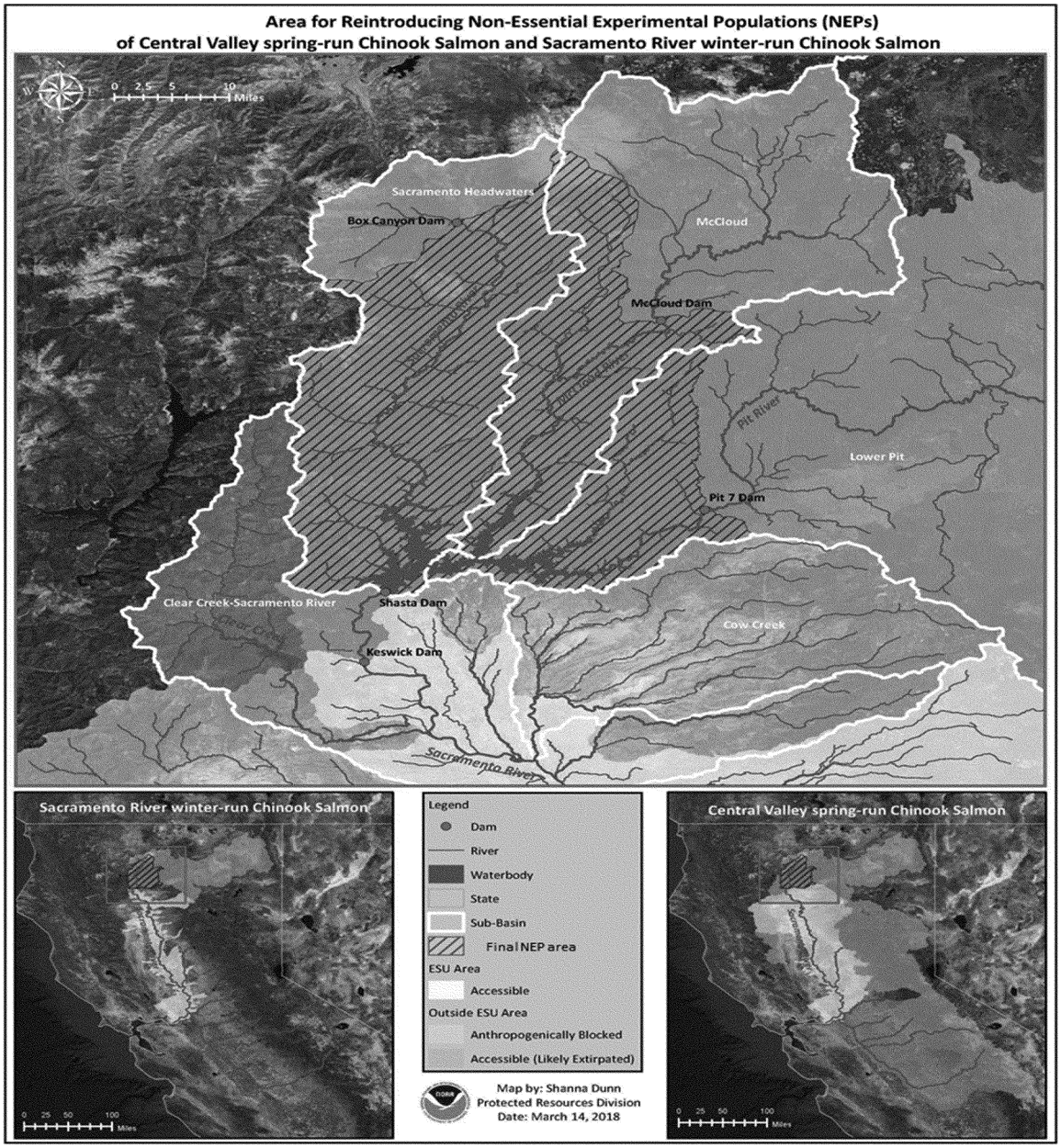


Figure 1 -- The NEP Area above Shasta Dam for SR winter-run and CV spring-run Chinook salmon

Statutory and Regulatory Framework for Experimental Population Designations

Section 10(j) of the ESA (16 U.S.C. 1539(j)) allows the Secretary of Commerce to authorize the release of any population of a listed species outside their current range if the release ''will further the conservation'' of that species. An experimental population is a population that is geographically separate from nonexperimental populations of the same species.

Before authorizing the release of an experimental population, section 10(j)(2)(B) requires that the Secretary must ''by regulation identify the population and determine, on the basis of the best available information, whether or not the population is essential to the continued existence of the listed species.''

An experimental population is treated as a threatened species, except that non-essential populations do not receive the benefit of certain protections normally applicable to threatened species (ESA section 10(j)(2)(C)). Below we discuss the impact of treating experimental populations as threatened species and of exceptions that apply to experimental populations.

For endangered species, section 9 of the ESA prohibits take of those species. For a threatened species, ESA section 9 does not specifically prohibit take of those species, but the ESA instead authorizes NMFS to adopt regulations under section 4(d) to prohibit take or that it deems necessary and advisable for species conservation. The experimental populations of SR winter-run and CV spring-run Chinook salmon we are designating must generally be treated as threatened species. Therefore, we issue tailored protective regulations under ESA section 4(d) for the experimental populations of SR winter-run and CV spring-run Chinook salmon to identify take prohibitions necessary to provide for the conservation of the species with exceptions for particular activities.

Section 7 of the ESA provides for Federal interagency cooperation and consultation on Federal agency actions. Section 7(a)(1) directs all Federal agencies, in consultation with NMFS as applicable depending on the species, to use their authorities to further the purposes of the ESA by carrying out programs for the conservation of listed species. Section 7(a)(2) requires all Federal agencies, in consultation with NMFS as applicable depending on the species, to ensure any action they authorize, fund or carry out is not likely to jeopardize the continued existence of a listed species or result in the destruction or adverse modification of designated critical habitat. Section 7 applies equally to endangered and threatened species.

Although ESA section 10(j) provides that an experimental population must generally be treated as a threatened species, for the purposes of ESA section 7, if the experimental population is determined to be a NEP, section 10(j)(C)(i) requires that we treat the experimental population as a species proposed to be listed, rather than a species that is listed (except when it occurs within a National Wildlife Refuge or National Park, in which case it is treated as listed). Section 7(a)(4) of the ESA requires Federal agencies to confer (rather than consult under ESA section 7(a)(2)) with NMFS on actions likely to jeopardize the continued existence of a species proposed to be listed. The results of a conference are advisory recommendations, if any, on ways to minimize or avoid adverse effects rather than mandatory terms and conditions under ESA section 7(a)(2) consultations (compare 50 CFR 402.10(c) with 402.14(i)(1)(iv)).

NMFS has previously designated four experimental populations (78 FR 2893, January 15, 2013; 78 FR 79622, December 31, 2013; 79 FR 40004, July 11, 2014; 87 FR 79808, December 28, 2022) and promulgated regulations, codified at 50 CFR part 222, subpart E, to implement section 10(j) of the ESA (81 FR 33416, May 26, 2016). NMFS' implementing regulations include the following provisions:

The provision at 50 CFR 222.501(b) defines an ''essential experimental population'' as an experimental population that, if lost, the survival of the species in the wild would likely be appreciably reduced. All other experimental populations are classified as nonessential.

The provision at 50 CFR 222.502(b) provides that, before authorizing the release of an experimental population, the Secretary must find by regulation that such release will further the conservation of the species. In addition, 50 CFR 222.502(b) provides that, in making such a finding, the Secretary shall utilize the best scientific and commercial data available to consider:

- Any possible adverse effects on extant populations of a species as a result of removal of individuals, eggs, or propagules for introduction elsewhere;
- The likelihood that any such experimental population will become established and survive in the foreseeable future;
- The effects that establishment of an experimental population will have on the recovery of the species; and
- The extent to which the introduced population may be affected by existing or anticipated Federal or state actions or private activities within or adjacent to the experimental population area.

The provision at 50 CFR 222.502(c) describes 4 components that must be provided in any NMFS regulations designating an experimental population under ESA section 10(j):

- Appropriate means to identify the experimental population, including, but not limited to, its actual or proposed location; actual or anticipated migration; number of specimens released or to be released; and other criteria appropriate to identify the experimental population(s);
- A finding, based solely on the best scientific and commercial data available, and the supporting factual basis, on whether the experimental population is, or is not, essential to the continued existence of the species in the wild;
- Management restrictions, protective measures, or other special management concerns of that population, as appropriate, which may include, but are not limited to, measures to isolate and/or to contain the experimental population designated in the regulation from non-experimental populations and protective regulations established pursuant to section 4(d) of the ESA; and
- A process for periodic review and evaluation of the success or failure of the release and the effect of the release on the conservation and recovery of the species.

In addition, as described above, ESA section 10(j)(1) defines an ''experimental population'' as any population authorized for release but only when, and at such times as, the population is wholly separate geographically from the non-experimental populations of the same species. Accordingly, we must establish that there are such times and places when the experimental population is wholly geographically separate. Similarly, the statute requires that we identify the experimental population; the legislative history indicates that the purpose of this requirement is to provide notice as to which populations of listed species are experimental (see Joint Explanatory Statement of the Committee of Conference, H.R. Conf. Rep No. 97–835, at 34 (1982)).

We discuss in more detail below how we considered each of these elements.

Status of the Species

Life history and the historical population trends of SR winter-run and CV spring-run Chinook salmon are summarized by Healy (1991), U.S. Fish

and Wildlife Service (USFWS) (1995), Yoshiyama *et al.* (1998), Yoshiyama *et al.* (2001), and Moyle (2002). Section 4(f) of the ESA requires the Secretary of Commerce to develop recovery plans for all listed species unless the Secretary determines that such a plan will not promote the conservation of a listed species. Prior to developing the Central Valley Recovery Plan (NMFS 2014), we assembled a team of scientists from Federal and State agencies, consulting firms, non-profit organizations and academia. This group, known as the Central Valley Technical Recovery Team (CVTRT), was tasked with identifying population structure and recommending recovery criteria (also known as delisting criteria) for ESA-listed salmon and steelhead in the Sacramento River and San Joaquin Rivers and their tributaries. The CVTRT recommended biological viability criteria at the ESU level and population level (Lindley *et al.,* 2007) for recovery planning consideration. The CVTRT identified the current risk level of each population based on the gap between recent abundance and productivity and the desired recovery goals. The CVTRT concluded that the greatest risk facing the ESUs resulted from the loss of historical diversity following the construction of major dams that blocked access to historical spawning and rearing habitat (Lindley *et al.,* 2007).

The CVTRT also recommended spatial structure and diversity metrics for each population (Lindley *et al.,* 2004). Spatial structure refers to the geographic distribution of a population and the processes that affect the distribution. Populations with restricted distribution and few spawning areas are at a higher risk of extinction from catastrophic environmental events (*e.g.,* a volcanic eruption) than are populations with more widespread and complex spatial structure. A population with complex spatial structure typically has multiple spawning areas which allows the expression of diverse life history characteristics. Diversity is the combination of genetic and phenotypic characteristics within and between populations (McElhany *et al.,* 2000). Phenotypic diversity allows more diverse populations to use a wider array of environments and protects populations against short-term temporal and spatial environmental changes. Genotypic diversity, on the other hand, provides populations with the ability to survive long-term changes in the environment by providing genetic variations that may prove successful under different situations. The combination of phenotypic and genotypic diversity, expressed in a natural setting, provides populations with the ability to utilize the full range of habitat and environmental conditions and to have the resiliency to survive and adapt to long-term changes in the environment.

In 2016, NMFS completed a periodic review as required by ESA section 4(c)(2)(A) and on May 26, 2016 (81 FR 33468), announced the SR winter-run Chinook salmon ESU would remain listed as endangered. In 2023, NMFS completed the 2022 review of SR winter-run Chinook salmon that indicates the biological status of the SR winter-run Chinook salmon ESU has declined since the 2016 viability assessment (Williams *et al.,* 2016), with the single spawning population on the mainstem Sacramento River now at a high risk of extinction (Southwest Fisheries Science Center (SWFSC) 2022). Updated information indicates an increased extinction risk due to the larger influence of the hatchery broodstock and low numbers of natural-origin returns in two consecutive years (SWFSC 2022). NMFS determined that the viability of the ESU would be improved by re-establishing this species in their historical spawning and rearing habitats through reintroduction efforts in Battle Creek and upstream from Shasta Reservoir.

In 2016, NMFS completed a periodic review as required by the ESA section 4(c)(2)(A), and concluded that the CV spring-run Chinook salmon ESU should remain listed as threatened (81 FR 33468, May 26, 2016). As part of the periodic review, NMFS' Southwest Fisheries Science Center conducted an analysis (Johnson and Lindley 2016) that indicated the extant independent populations of the CV spring-run Chinook salmon ESU remained at a moderate to low extinction risk. The NMFS Southwest Fisheries Science Center's recent viability analysis (2022) noted some improvements in the viability of the ESU, particularly with the increased spatial diversity of the dependent Battle Creek and Clear Creek populations. However, the analysis also identified as key threats recent catastrophic declines of many of the extant populations, high pre-spawn mortality during the 2012–2015 drought in California, uncertain juvenile survival as a result of drought and ocean conditions, as well as straying of CV spring-run Chinook salmon from the Feather River Fish Hatchery.

Analysis of the Statutory Requirements

1. Will release of experimental populations further the conservation of these species?

Section 3(3) of the ESA, 16 U.S.C. 1532(3), defines ''conservation'' as ''the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to this [Act] are no longer necessary.'' We discuss in more detail below each of the factors we considered in determining whether release of experimental populations in the NEP Area would further the conservation of SR winter-run and CV spring-run Chinook salmon.

Under 50 CFR 222.502(b), NMFS must consider several factors in finding whether release of an experimental population will further the conservation of the species, including any possible adverse effects on extant populations of the species as a result of removal of individuals for introduction elsewhere; the likelihood that the experimental population will become established and survive in the foreseeable future; the effects that establishment of the experimental population will have on the recovery of the species; and the extent to which the experimental populations may be affected by existing or anticipated Federal or state actions or private activities within or adjacent to the experimental population area.

Regarding the likelihood that reintroduction efforts will be successful in the foreseeable future, an important question is: what are the most appropriate sources of broodstock to establish the experimental population, and are the sources available? Reintroduction efforts have the best chance for success when the donor population has life-history characteristics compatible with the anticipated environmental conditions of the habitat into which fish will be reintroduced (Araki *et al.,* 2008). Populations found in watersheds closest to the NEP Area are most likely to have adaptive traits that will lead to a successful reintroduction. Therefore, only SR winter-run and CV spring-run Chinook salmon populations found in the Central Valley would be used in establishing the experimental populations in the NEP Area.

We have preliminarily identified donor sources for reintroduction into the NEP Area as SR winter-run from Livingston Stone NFH and CV spring-run Chinook salmon produced from the FRH. These fish are the geographically closest donor sources that could be used with minimal impact to the wild

populations for reintroduction into the NEP Area. NMFS, in consultation with the California Department of Fish and Wildlife (CDFW), may later consider diversifying the donor stocks from other nearby streams if those populations can sustain removal of fish. Any collection of Chinook salmon would be subject to a Hatchery and Genetic Management Plan (HGMP) in relation to a hatchery source and approval of a permit under ESA section 10(a)(l)(A), which includes analysis under NEPA and ESA section 7.

Use of donor stocks from Livingston Stone NFH and the FRH for the initial phases of a reintroduction program will minimize the number of individuals needed from existing populations. Supplementation to the donor stock, if necessary, would be dependent upon genetic diversity needs and the extent of adverse effects to other populations. It is anticipated that over time, the Livingston Stone NFH and FRH would produce juveniles and adults in sufficient numbers to enable the return of a sufficient number of adults to establish a self-sustaining population in the NEP Area. Once self-sustaining populations are established, it is anticipated that contributions of SR winter-run Chinook salmon from Livingston Stone NFH and CV spring-run Chinook salmon from FRH would be phased out.

We also consider the suitability of habitat available to the experimental populations. In 2014, the U.S. Bureau of Reclamation initiated a habitat assessment of the NEP Area and found conditions were suitable for Chinook salmon spawning, adult holding, and juvenile rearing. Habitat conditions in the Upper Sacramento and McCloud Rivers are described in the EA.

In addition, there are Federal and State laws and regulations that will help ensure the establishment and survival of the experimental populations by protecting aquatic and riparian habitat in the NEP Area. Section 404 of the Clean Water Act (CWA), 33 U.S.C. 1344, establishes a program to regulate the discharge of dredged or fill material into waters of the United States, which generally requires avoidance, minimization, and mitigation for potential adverse effects of dredge and fill activities within the Nation's waterways. Under CWA section 401, 33 U.S.C. 1341, a Federal agency may not issue a permit or license to conduct any activity that may result in any discharge into waters of the United States unless a state or authorized tribe where the discharge would originate issues a section 401 water quality certification verifying compliance with existing water quality requirements or waives the certification requirement. In addition, construction and operational storm water runoff is subject to restrictions under CWA section 402, 33 U.S.C. 1342, which establishes the National Pollutant Discharge Elimination System permit program, and state water quality laws.

The Federal Energy Regulatory Commission (FERC), pursuant to the Federal Power Act (FPA) and the U.S. Department of Energy Organization Act, is authorized to issue licenses for up to 50 years for the construction and operation of non-Federal hydroelectric developments subject to its jurisdiction. The FPA authorizes NMFS to issue mandatory prescriptions for fish passage and recommend other measures to protect salmon, steelhead, and other anadromous fish.

The Magnuson-Stevens Fishery Conservation and Management Act (MSA) (16 U.S.C. 1801 *et seq.*) is the principal law governing marine fisheries conservation and management in the United States. Chinook salmon Essential Fish Habitat (EFH) is identified and described to include all water bodies currently or historically occupied by Chinook salmon in California. Under the MSA, Federal agencies are required to determine whether a Federal action they authorize, fund, or undertake may adversely affect EFH (16 U.S.C. 1855(b)). Chinook salmon EFH does not occur in the NEP Area.

At the State level, the California Fish and Game Code (CFGC) Fish and Wildlife Protection and Conservation provisions (CFGC section 1600, *et seq.*), the CESA (CFGC section 2050, *et seq.*), and the California Environmental Quality Act (CEQA) (Public Resources Code section 21000, *et seq.*) set forth criteria for the incorporation of avoidance, minimization, and feasible mitigation measures for ongoing activities as well as for individual projects. The CFGC Fish and Wildlife Protection and Conservation provisions were enacted to provide conservation for the State's fish and wildlife resources and include requirements to protect riparian habitat resources on the bed, channel, or bank of streams and other waterways. The CESA prohibits the taking of listed species except as otherwise provided in state law. Under the CEQA, no public agency shall approve or carry out a project without identifying all feasible mitigation measures necessary to reduce impacts to a less than significant level, and public agencies shall incorporate such measures absent overriding consideration.

Regarding the effects that establishment of experimental populations will have on the recovery of the species, the Central Valley Recovery Plan (NMFS 2014) characterizes the NEP Area as having the potential to support viable populations of Chinook salmon. The Central Valley Recovery Plan establishes a framework for reintroduction of Chinook salmon and steelhead to historical habitats upstream of dams. The framework recommends that a reintroduction program should include feasibility studies, habitat evaluations, fish passage design studies, and a pilot reintroduction phase prior to implementation of the long-term reintroduction program. In addition, the Central Valley Recovery Plan contains specific management strategies for recovering SR winter-run and CV spring-run Chinook salmon that include securing existing populations and reintroducing these species into historically occupied habitats above rim dams in the Central Valley of California (NMFS 2014). The Central Valley Recovery Plan concludes, and we continue to agree, that establishing experimental populations in the NEP Area that persist into the foreseeable future is expected to reduce extinction risk from natural and anthropogenic factors by increasing abundance, productivity, spatial structure, and diversity within California's Central Valley. These expected improvements in the overall viability of SR winter-run and CV spring-run Chinook salmon, in addition to other actions being implemented throughout the Central Valley, which are described next, will contribute to SR winter-run and CV spring-run Chinook salmon near-term viability and recovery.

Across the Central Valley, a number of actions are being undertaken to improve habitat quality and quantity for SR winter-run and CV spring-run Chinook salmon. Collectively, implementation of these will result in many projects that will improve habitat conditions. The San Joaquin River Restoration Program will improve passage survival and spatial distribution for CV spring-run Chinook salmon in the San Joaquin River corridor. The Battle Creek Salmon and Steelhead Restoration Project will improve passage and rearing survival, spawning opportunities and spatial distribution in Battle Creek. The Central Valley Flood Protection Plan (California Department of Water Resources (DWR) 2011) will improve juvenile rearing conditions during outmigration by creating and improving access to high quality floodplain habitats.

Action items identified in NMFS 2022 5-year review and in the Species in the Spotlight 2021–2025 Priority Action Plan for SR winter-run Chinook salmon (NMFS 2021) include improving management of Shasta Reservoir cold-water storage to reduce water temperatures and provide flows to improve SR winter-run Chinook salmon productivity; restoring Battle Creek habitats and reintroducing SR winter-run Chinook salmon to historical spawning areas; reintroducing SR winter-run Chinook salmon into historical habitats above Shasta Dam; improving Yolo Bypass fish habitat and passage to increase juvenile survival and rearing opportunities; improving management of winter and early spring Delta conditions to improve juvenile survival; and continuing collaboration on science and fostering partnerships to build greater capacity to address recovery challenges. Implementation of these action items will advance the conservation of the species.

Climate change is expected to exacerbate existing habitat stressors in California's Central Valley and increase threats to Chinook salmon and steelhead by reducing the quantity and quality of freshwater habitat (Lindley *et al.,* 2007). Significant contraction of thermally suitable habitat is predicted, and as cold-water sources contract, access to cooler headwater streams is expected to become increasingly important for CV spring-run Chinook salmon in the Central Valley (Crozier *et al.,* 2018). For this reason and other reasons described above, we anticipate reintroduction of SR winter-run and CV spring-run Chinook salmon into headwater streams upstream of Shasta Dam will contribute to their conservation and recovery.

Existing or anticipated Federal or State actions or private activities within or adjacent to the NEP Area may affect the experimental populations. The NEP Area is sparsely populated and ongoing State, Federal, and local activities include forest management, limited mining, highways and road maintenance, residential and municipal development, grazing, tourism, and recreation. These activities will likely continue into the future and are anticipated to have minor impacts to SR winter-run and CV spring-run Chinook salmon in the NEP Area and adjacent areas. Potential impacts from these and other activities are further minimized through application of the aforementioned State and Federal regulations. Dams and water diversions in the NEP Area currently limit fish populations in some parts of the NEP Area. NMFS anticipates releases of SR winter-run and CV spring-run Chinook salmon will be specifically targeted into riverine reaches with abundant high-quality habitats that are not blocked by barriers to fish passage, or impaired by high water temperatures or inadequate flows. The habitat improvement actions called for in the Central Valley Recovery Plan, as well as compliance with existing Federal, State, and local laws, statutes, and regulations, including those mentioned above, are expected to contribute to the establishment and survival of the experimental populations in the NEP Area in the foreseeable future. Although the donor sources for reintroduction are anticipated to include hatchery-origin individuals from the Livingston Stone NFH and FRH, based on the factors discussed above, we conclude it is probable that self-sustaining experimental populations of SR winter-run and CV spring-run Chinook salmon will become established and survive in the NEP Area. Furthermore, we conclude that self-sustaining experimental populations of genetically compatible individuals will likely further the conservation of these species, as discussed above.

2. Identification of the Experimental Populations and Geographic Separation From Nonexperimental Populations of the Same Species

ESA section 10(j)(2)(B) requires that we identify experimental populations by regulation. ESA section 10(j)(1) also provides that a population is considered an experimental population only when, and at such times as, it is wholly separate geographically from the nonexperimental population of the same species. The NEP Area extends upstream from Shasta Dam in the McCloud and Upper Sacramento Rivers as described above. Under this rule, experimental populations are identified as SR winter-run and CV spring-run Chinook salmon populations when geographically located anywhere in the NEP Area. Reintroduced SR winter-run and CV spring-run Chinook salmon are only part of the experimental populations when they are present in the NEP Area, and are not part of the experimental populations when they are outside the NEP Area, even if they originated within the NEP Area. When reintroduced juvenile SR winter-run and CV spring-run Chinook salmon pass downstream of Shasta and Keswick Dams into the Sacramento River, and when they migrate further downstream to the Sacramento River Delta and the Pacific Ocean, they would no longer be geographically separated from other extant SR winter-run and CV spring-run Chinook salmon populations, and thus the ''experimental population'' designations would not apply, unless and until they re-enter the NEP Area.

The NEP Area provides the requisite level of geographic separation because SR winter-run and CV spring-run Chinook salmon are currently extirpated from this area due to the presence of Shasta and Keswick Dams, which block their upstream migration. Straying of fish from other Chinook populations into the NEP Area is not likely due to the presence of these dams. As a result, the geographic description of the extant SR winter-run and CV spring-run Chinook salmon ESUs does not include the NEP Area.

NMFS anticipates that SR winter-run and CV spring-run Chinook salmon used for the initial stages of a reintroduction program would be marked, for example, with specific fin clips and/or coded-wire tags to evaluate stray rates and allow for brood stock collection of returning adults that originated from the experimental populations. Any marking of individuals of the experimental populations, such as clips or tags, would be for the purpose of evaluating the effectiveness of a near-term and long-term fish passage program, and would not be for the purpose of identifying fish from the NEP Area other than for brood stock collection of returning adults. As discussed above, the experimental populations are identified based on the geographic location of the fish. Indeed, if the reintroductions are successful as expected, and fish begin reproducing naturally, their offspring would not be distinguishable from fish from other Chinook salmon populations. Outside of the NEP Area, *e.g.,* downstream of Shasta and Keswick Dams in the Sacramento River, or in the ocean, any such unmarked fish (juveniles and adults alike) would not be considered members of the experimental populations. They would be considered part of the SR winter-run Chinook salmon ESU or the CV spring-run Chinook salmon ESU currently listed under the ESA. Likewise, any fish that were marked for reintroduction in the NEP Area will not be considered part of the experimental populations once they left the NEP Area; rather, they would be considered part of the ESUs currently listed under the ESA.

3. Is the experimental population essential to the continued existence of the species?

As discussed above, ESA section 10(j)(2)(B) requires the Secretary to determine whether experimental populations would be ''essential to the

continued existence'' of the listed species. The statute does not elaborate on how this determination is to be made. However, as noted above, Congress gave some further attention to the term when it described an essential experimental population as one whose loss ''would be likely to appreciably reduce the likelihood of survival of that species in the wild.'' (Joint Explanatory Statement, supra, at 34). NMFS regulations incorporated this concept into its definition of an essential experimental population at 50 CFR 222.501(b), which is an experimental population that, if lost, the survival of the species in the wild would likely be substantially reduced.

In determining whether the experimental populations of SR winter-run and CV spring-run Chinook salmon are essential, we used the best available information as required by ESA section 10(j)(2)(B). Furthermore, we considered the geographic location of the experimental populations in relation to other populations of SR winter-run and CV spring-run Chinook salmon, and the likelihood of survival of these populations without the existence of the experimental populations.

The SR winter-run Chinook salmon ESU consists of a single extant population in the Sacramento River downstream of Shasta and Keswick Dams. The CV spring-run Chinook salmon ESU includes four independent populations and several dependent or establishing populations. Given current protections and restoration efforts, these populations are persisting without the presence of a population in the NEP Area. It is expected that the experimental populations will exist as separate populations from those in the Sacramento River basin and will not be essential to the survival of those populations. Based on these considerations, we conclude the loss of experimental populations of SR winter-run or CV spring-run Chinook salmon in the NEP Area is not likely to appreciably reduce the likelihood of the survival of these species in the wild. Accordingly, NMFS designates the experimental populations as nonessential. Under section 10(j)(2)(C)(ii) of the ESA we cannot designate critical habitat for nonessential experimental populations.

Additional Management Restrictions, Protective Measures, and Other Special Management Considerations

As indicated above, ESA section 10(j)(2)(C) requires that experimental populations be treated as threatened species, except that, for nonessential experimental populations, certain portions of ESA section 7 do not apply and critical habitat cannot be designated. Congress intended that the Secretary would issue regulations deemed necessary and advisable to provide for the conservation of experimental populations just as he or she does under ESA section 4(d) for any threatened species (Joint Explanatory Statement, supra, at 34). In addition, when amending the ESA to add section 10(j), Congress specifically intended to provide broad discretion and flexibility to the Secretary in managing experimental populations so as to reduce opposition to releasing listed species outside their current range (H.R. Rep. No. 567, 97th Cong. 2d Sess. 34 (1982)). Therefore, we have exercised that authority to issue protective regulations under ESA section 4(d) for the experimental populations of SR winter-run and CV spring-run Chinook salmon to identify take prohibitions necessary to provide for the conservation of these species and otherwise provide assurances to the people of the Upper Sacramento and McCloud River watersheds.

The ESA defines ''take'' to mean harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct (16 U.S.C. 1532(19)). Concurrent with the ESA section 10(j) experimental population designation, we are adopting protective regulations under ESA section 4(d) for the experimental populations that would prohibit take of SR winter-run and CV spring-run Chinook salmon in the NEP Area that are part of the experimental populations, except in the following circumstances:

1. Any take by authorized governmental entity personnel acting in compliance with 50 CFR 223.203(b)(3) to aid a sick, injured or stranded fish; dispose of a dead fish; or salvage a dead fish which may be useful for scientific study;

2. Any take that is incidental [1] to an otherwise lawful activity and is unintentional, not due to negligent conduct. Otherwise lawful activities include, but are not limited to, recreation, forestry, water management, agriculture, power production, mining, transportation management, rural development, or livestock grazing, when such activities are in full compliance with all applicable laws and regulations; and

3. Any take that is pursuant to a permit issued by NMFS under section 10 of the ESA (16 U.S.C. 1539) and regulations in 50 CFR part 222 applicable to such a permit.

Process for Periodic Review

Evaluation of the success of experimental populations will require new monitoring programs developed specifically for this purpose. To gauge the success of the program, NMFS anticipates that it will be necessary to monitor in the NEP Area for fish passage efficiency, spawning success, adult and smolt injury and mortality rates, juvenile salmon collection efficiencies, competition with resident species, predation, and disease among other things. We anticipate the status of reintroduced populations of SR winter-run and CV spring-run Chinook salmon in the NEP Area would be evaluated during NMFS' 5-year review process under ESA 4(c)(2). During the 5-year review, NMFS may evaluate whether the current designation under ESA section 10(j) as nonessential experimental populations is still warranted.

Summary of Comments and Responses

The draft EA and proposed rule were made available for a 30-day public comment period. NMFS received comments on the proposed rule and draft EA, which are addressed in Appendix A of the final EA and as changes to the final EA as appropriate. The purpose of the comment period is to help us better understand the concerns of the public on the experimental population designations, take and take exceptions, and associated draft EA. During the comment period, NMFS received 6 comment letters germane to the proposed rulemaking, from entities representing various agencies, nongovernmental organizations, tribes, and individuals. Five comment letters were supportive of the proposed rule. One letter, from Pacific Gas and Electric Company (PG&E), although supportive of designating SR winter-run and CV spring-run Chinook salmon as nonessential experimental populations contained several criticisms and objections. EA Appendix A contains the public comment letters received and our responses. A summary of PG&E's comments and our responses to those comments are presented here.

Comment 1. The proposed exemption from section 9 take prohibitions requires additional detail in which PG&E requested specific language detailing activities associated with its McCloud-

[1] Incidental take refers to takings that result from, but are not the purpose of, carrying out an otherwise lawful activity conducted by the Federal agency or applicant. 50 CFR 402.02.

Pit Hydroelectric Project (Project, FERC Project No. 2106).

Response. The examples in the **Federal Register** notice represent a broad, but non-comprehensive subset of the types of otherwise legal activities that may occur in the NEP area that are exempted from section 9 take prohibitions. The list is intended to be illustrative rather than all-inclusive. Regardless of the types of activities listed as examples in the 4(d) rule, if a legal activity results in incidental take and the take is not due to negligence, then the activity is exempted from take prohibitions, even if not included in the list of examples.

Comment 2. PG&E stated that the level of consultation with stakeholders was inadequate.

Response. NMFS disagrees. Over the past 12 years (starting in 2010) NMFS' public outreach and engagement strategy for both reintroduction and this 10(j) rule has been extensive, comprehensive and sustained. This includes public meetings, landowner and stakeholder meetings, briefings and updates with tribes, local, State, and Federal government representatives and government groups, webinars, podcasts and electronically posting web stories, fact sheets, videos and Frequently Asked Questions (FAQ) documents on NMFS' website. Further, in response to concerns raised by stakeholders as a result of the above outreach efforts, NMFS worked with the California Board of Forestry to amend the California Forest Practice Rules to better align with the 10(j) rule; worked with the CDFW to address concerns over their freshwater fishing regulations and the California Endangered Species Act; and entered into a formal co-stewardship agreement with CDFW and the Winnemem Wintu Tribe to jointly pursue reintroduction. This also includes partnering and participation in several multi-agency and multi-stakeholder technical committees.

Comment 3. PG&E requested ''unambiguous exclusion of hydropower'' to be consistent with NMFS' 2013 Middle Columbia River Steelhead rule.

Response. See response to Comment #1. As stated in PG&E's letter, ''the proposed rule would exclude all lawful activities from the take prohibition . . . including the operation and maintenance of hydroelectric facilities.'' PG&E also noted that its request would be consistent with the Middle Columbia River Steelhead 10(j) and 4(d) rule (see 78 FR 2893—2907 (January 15, 2013)). However, in the case of the Middle Columbia River Steelhead rule, the inclusion of hydropower was explicitly related to a requirement of the new hydropower license for the Pelton Round Butte Project stipulating reintroduction. There is no similar license requirement or final plan to reintroduce SR winter-run Chinook salmon or CV spring-run Chinook salmon upstream of Shasta Dam.

Comment 4. Regarding the congressional history and intent, PG&E claimed that subsequent to the 1982 amendments of the Endangered Species Act (ESA), the Secretary is not authorized to reintroduce eggs, propagules, or individuals outside of the current range of the species without first making the determinations required under section 10(j).

Response. PG&E's interpretation of section 10(j) of the ESA is inconsistent with the statute, congressional history and intent. Section 10(j) does not limit or restrict any previously held authority on the part of the Secretary to authorize or reintroduce species outside their current range. On the contrary, section 10(j) expands the Secretaries' authorities, in this case, to designate and authorize the release of nonessential experimental populations (NEPs or experimental populations) of Sacramento River (SR) winter-run Chinook salmon (*Oncorhynchus tshawytscha)* and Central Valley (CV) spring-run Chinook salmon (*O. tshawytscha*) in the McCloud and Upper Sacramento Rivers upstream of Shasta Dam (the NEP Area), California, and, under the ESA, establish a limited set of take exceptions for the experimental populations.

Comment 5. Regarding the congressional history and intent, PG&E claimed that the key mechanism in section 10(j) to afford landowner cooperation is the provision providing that endangered experimental populations can be treated as threatened species, which consequently authorizes NMFS to relax incidental take prohibitions for endangered experimental populations. Further, they asserted that this reflects the congressional intent that species reintroductions should be accomplished with the support of affected stakeholders.

Response. See response to Comment #2; and section 1.2.4.1. of the EA. Further, Congress viewed ESA section 10(j) as an opportunity ''to encourage the recovery of species through population re-establishment with the cooperation of, not despite, state and local groups'' (Wolok 1996). Congress intended that regulations promulgated by the Services to designate experimental populations ''should be viewed as an agreement among the Federal agencies, the state fish and wildlife agencies and any landowners involved'' (Wolok 1996 quoting H.R. Rep. No. 567, 97th Cong., 2d Sess. 34 (1982)). We note that designation and release of NEPs of Sacramento River (SR) winter-run and Central Valley (CV) spring-run Chinook salmon in the McCloud and Upper Sacramento Rivers above Shasta Dam under section 10(j) of the ESA was formally requested by the U.S. Forest Service (primary landowner in the NEP area) and generally supported by other landowners.

Findings

Based on the best available scientific information, we have determined that the designations and release of NEPs of SR winter-run and CV spring-run Chinook salmon in the NEP Area upstream of Shasta Dam will further the conservation of SR winter-run and CV spring-run Chinook salmon. SR winter-run Chinook salmon used to initiate the reintroduction are anticipated to come from Livingston Stone NFH. CV spring-run Chinook salmon used to initiate the reintroduction are anticipated to come from the FRH. The collection of donor stock will be permitted only after issuance of permits under section 10(a)(1)(A) of the ESA, which includes analysis under NEPA and ESA section 7. The experimental population fish are expected to remain geographically separate from fish in other populations of the SR winter-run and CV spring-run Chinook salmon ESUs during the life stages in which they remain in, or are returned to, the NEP Area. At all times when members of the experimental populations are downstream of Shasta and Keswick Dams, the experimental population designations will not apply. Establishing experimental populations of SR winter-run and CV spring-run Chinook salmon in the NEP Area would likely contribute to the viability of the ESUs. Reintroduction is a recommended recovery action in the Central Valley Recovery Plan (NMFS 2014). Designation of SR winter-run and CV spring-run Chinook salmon in the NEP Area as nonessential experimental populations would ensure that their reintroduction does not impose undue regulatory restrictions on landowners and others because this final rule would apply only limited take prohibitions as compared to the prohibitions that typically apply to SR winter-run and CV spring-run Chinook salmon. In particular, this rule expressly provides an exception for take of NEP fish in the NEP Area provided that the take is incidental to otherwise lawful activities and is unintentional, rather than due to negligent conduct.

We further determine, based on the best scientific and commercial data available, that the experimental populations would not be essential to the continued existence of the SR winter-run Chinook salmon ESU or the CV spring-run Chinook salmon ESU, because absence of the experimental populations would not be likely to appreciably reduce the likelihood of the survival of the ESUs in the wild. However, as described above, the experimental populations are expected to contribute to the recovery of the SR winter-run and CV spring-run Chinook salmon ESUs if reintroduction is successful. We therefore designate the released populations as nonessential experimental populations.

Information Quality Act and Peer Review

Pursuant to the Information Quality Act (section 515 of Pub. L. 106–554), the Office of Management and Budget (OMB) issued a Final Information Quality Bulletin for Peer Review, which was published in the **Federal Register** on January 14, 2005 (70 FR 2664). The Bulletin established minimum peer review standards, a transparent process for public disclosure of peer review planning, and opportunities for public participation with regard to certain types of information disseminated by the Federal Government. The peer review requirements of the OMB Bulletin apply to influential or highly influential scientific information disseminated on or after June 16, 2005. There are no documents supporting this rule that meet these criteria.

Classification

Executive Order 12866

This final rule has been determined to be not significant under Executive Order 12866.

Regulatory Flexibility Act

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. As a result, a final regulatory flexibility analysis was not required and none was prepared.

Executive Order 12630

In accordance with Executive Order 12630, the final rule does not have significant takings implications. A takings implication assessment is not required because this final rule: (1) would not effectively compel a property owner to have the government physically invade their property, and (2) would not deny all economically beneficial or productive use of the land or aquatic resources. This final rule would substantially advance a legitimate government interest (conservation and recovery of a listed fish species) and would not present a barrier to all reasonable and expected beneficial use of private property.

Executive Order 13132

In accordance with Executive Order 13132, we have determined that this final rule does not have federalism implications as that term is defined in Executive Order 13132.

Paperwork Reduction Act of 1995

OMB regulations at 5 CFR part 1320, which implement provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*), require that Federal agencies obtain approval from OMB before collecting information from the public. A Federal 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. This final rule does not include any new collections of information that require approval by OMB under the Paperwork Reduction Act.

National Environmental Policy Act

In compliance with all provisions of the National Environmental Policy Act of 1969 (NEPA), we have analyzed the impact on the human environment and considered a reasonable range of alternatives for this final rule. We made the draft EA and rule available for comments, received comments, and responded to those comments. We have prepared a final EA and Finding of No Significant Impact (FONSI) on this action and have made these documents available for public inspection (see **ADDRESSES** section above).

Government-to-Government Relationship With Tribes (Executive Order 13175)

Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, outlines the responsibilities of the Federal Government in matters affecting tribal interests. If we issue a regulation with tribal implications (defined as having a substantial direct effect on one or more Indian tribes, 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) we must consult with those governments or the Federal Government must provide funds necessary to pay direct compliance costs incurred by tribal governments.

There are no tribally owned or managed lands in the NEP Area. As part of NMFS's obligations under the National Historic Preservation Act, NMFS inquired with federally recognized and non-federally recognized tribes with potential interest in the NEP Area to inform them of the proposed rule and solicit information on cultural resources eligible for listing on the National Register of Historic Places (letters dated Feb. 5, July 14, and July 27, 2016, from Maria Rea, Central Valley Office Supervisor, NMFS). NMFS invites tribes to meet with us to have detailed discussions that could lead to government-to-government consultation meetings with tribal governments. We will continue to coordinate with potentially affected tribes.

References Cited

A complete list of all references cited in this final rule is available upon request from the National Marine Fisheries Service office (see **FOR FURTHER INFORMATION CONTACT**).

List of Subjects in 50 CFR Part 223

Endangered and threatened species.

Dated: August 22, 2023.

Samuel D. Rauch, III,

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

For the reasons set out in the preamble, NMFS amends 50 CFR part 223 as follows:

PART 223—THREATENED MARINE AND ANADROMOUS SPECIES

■ 1. The authority citation for part 223 continues to read as follows:

Authority: 16 U.S.C. 1531–1543; subpart B, § 223.201–202 also issued under 16 U.S.C. 1361 *et seq.;* 16 U.S.C. 5503(d) for § 223.206(d)(9).

■ 2. In § 223.102, amend the table in paragraph (e) by adding entries for ''Salmon, Chinook (Central Valley spring-run ESU–XN Shasta)'' and ''Salmon, Chinook (Sacramento winter-run ESU–XN Shasta)'' under ''Fishes'' in alphabetical order by common name to read as follows:

§ 223.102 Enumeration of threatened marine and anadromous species.

* * * * *

(e) * * *

Species [1]			Citation(s) for listing determinations(s)	Critical habitat	ESA rules
Common name	Scientific name	Description of listed entity			
* * * * * * *			*	*	
FISHES					
* * * * * * *			*	*	
Salmon, Chinook (Central Valley spring-run ESU–XN Shasta).	*Oncorhynchus tshawytscha*.	Central Valley spring-run Chinook salmon only when, and at such times as, they are found in the NEP Area (from Shasta Dam up to Pit 7 Dam on the Pit River, McCloud Dam on the McCloud River, and Box Canyon Dam on the upper Sacramento River. All other tributaries flowing into Shasta Reservoir up to the ridge line, including tributaries below Pit 7 Dam, McCloud Dam, and Box Canyon Dam, up to the ridge line would be included in the NEP Area).	[INSERT **FEDERAL REGISTER** CITATION], 8/28/2023.	NA	.....
* * * * * * *			*	*	
Salmon, Chinook (Sacramento winter-run ESU–XN Shasta).	*Oncorhynchus tshawytscha*.	Sacramento winter-run Chinook salmon only when, and at such times as, they are found in the NEP Area (from Shasta Dam up to Pit 7 Dam on the Pit River, McCloud Dam on the McCloud River, and Box Canyon Dam on the upper Sacramento River. All other tributaries flowing into Shasta Reservoir up to the ridge line, including tributaries below Pit 7 Dam, McCloud Dam, and Box Canyon Dam, up to the ridge line would be included in the NEP Area).	[INSERT **FEDERAL REGISTER** CITATION], 8/28/2023.	NA	.....
* * * * * * *			*	*	

[1] Species includes taxonomic species, subspecies, distinct population segments (DPSs) (for a policy statement, see 61 FR 4722, February 7, 1996), and evolutionarily significant units (ESUs) (for a policy statement, see 56 FR 58612, November 20, 1991).

* * * * *

■ 3. In § 223.301, add paragraph (e) to read as follows:

§ 223.301 Special rules—marine and anadromous fishes.

* * * * *

(e) *McCloud and Upper Sacramento Rivers Sacramento River winter-run and* Central *Valley spring-run Chinook salmon experimental populations* (*Oncorhynchus tshawytscha*)—(1) *Status of McCloud and Upper Sacramento Rivers Sacramento River winter-run and Central Valley spring-run Chinook salmon under the ESA.* The McCloud and Upper Sacramento Rivers Sacramento River winter-run and Central Valley spring-run Chinook salmon populations identified in paragraph (e)(2) of this section are designated as nonessential experimental populations under section 10(j) of the ESA and shall be treated as a ''threatened species'' pursuant to 16 U.S.C. 1539(j)(2)(C).

(2) *McCloud and Upper Sacramento Rivers Sacramento River winter-run and Central Valley spring-run Chinook salmon experimental populations.* All Sacramento River winter-run and Central Valley spring-run Chinook salmon within the experimental population area in the McCloud and Upper Sacramento Rivers upstream of Shasta Dam (the NEP Area), as defined in this paragraph (e)(2), are considered part of the McCloud and Upper Sacramento Rivers Sacramento River winter-run and Central Valley spring-run Chinook salmon experimental populations. The NEP Area extends from Shasta Dam up to Pit 7 Dam on the Pit River, McCloud Dam on the McCloud River, and Box Canyon Dam on the upper Sacramento River. All other tributaries flowing into Shasta Reservoir up to the ridge line, including tributaries below Pit 7 Dam, McCloud Dam, and Box Canyon Dam, up to the ridge line are included in the NEP Area. All other areas above Pit 7 Dam on the Pit River, McCloud Dam on the McCloud River, and Box Canyon Dam on the upper Sacramento River are not part of the NEP Area. The NEP Area extends up to the ridgelines to account for watershed processes and ends at the aforementioned dams because these dams lack fish passage facilities. The NEP Area is part of the species' historical range. The NEPs are all SR winter-run and CV spring-run Chinook salmon, including fish released or propagated, naturally or artificially, within the NEP Area.

(3) *Prohibitions.* Except as expressly allowed in paragraph (e)(4) of this section, all prohibitions of section 9(a)(1) of the ESA (16 U.S.C. 1538 (a)(1)) apply to fish that are part of the McCloud and Upper Sacramento Rivers Sacramento River winter-run and Central Valley spring-run Chinook

salmon nonessential experimental populations identified in paragraph (e)(2) of this section.

(4) *Exceptions to the application of section 9 take prohibitions in the experimental population area.* The following forms of take in the experimental population area identified in paragraph (e)(2) of this section are not prohibited by this section:

(i) Any taking of experimental populations of Sacramento River winter-run or Central Valley spring-run Chinook salmon by authorized governmental entity personnel acting in compliance with § 223.203(b)(3) to aid a sick, injured or stranded fish; dispose of a dead fish; or salvage a dead fish which may be useful for scientific study.

(ii) Any taking of experimental populations of Sacramento River winter-run or Central Valley spring-run Chinook salmon that is unintentional, not due to negligent conduct, and incidental to, and not the purpose of, the carrying out of an otherwise lawful activity.

(iii) Any taking of experimental populations of Sacramento River winter-run or Central Valley spring-run Chinook salmon pursuant to a permit issued by NMFS under section 10 of the ESA (16 U.S.C. 1539) and regulations in part 222 of this chapter applicable to such a permit.

[FR Doc. 2023–18474 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 230821–0201]

RIN 0648–BL61

Fisheries of the Northeastern United States; Improvement and Modernization of Atlantic Surfclam and Ocean Quahog Vessel Reporting Regulations

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

ACTION: Final rule.

SUMMARY: NMFS is implementing regulation changes to integrate the vessel reporting requirements for the Atlantic surfclam and ocean quahog fisheries with the reporting requirements for all other commercial fisheries in the Greater Atlantic Region. These changes are intended to simplify the regulations and make it easier for surfclam and ocean quahog vessel operators to submit the required fishing trip reports electronically. This action will result in improved administration and management of the surfclam and ocean quahog fisheries.

DATES: Effective September 27, 2023.

ADDRESSES: Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this final rule may be submitted to the Greater Atlantic Regional Fisheries Office and to *https://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 Office of Management and Budget (OMB) Control Number 0648–0212.

FOR FURTHER INFORMATION CONTACT: Douglas Potts, Fishery Policy Analyst, (978) 281–9341, *douglas.potts@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Mid-Atlantic Fishery Management Council manages the Atlantic surfclam and ocean quahog fisheries under the Atlantic Surfclam and Ocean Quahog Fishery Management Plan (FMP). The FMP has included a requirement for fishing vessels to maintain and submit a log of fishing operations since it was first implemented (42 FR 60438, November 25, 1977). Over the years, other species also became subject to management under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) and additional fishing vessel reporting requirements were added to the regulations. To cover the reporting requirements of these other fisheries, a standardized fishing vessel trip report (VTR) form was developed. For a number of reasons, including the specific requirements of the Atlantic Surfclam and Ocean Quahog Individual Transferable Quota (ITQ) management system, the surfclam and ocean quahog vessel reporting regulations have remained separate from the vessel reporting regulations that apply to all other commercial fisheries in the Greater Atlantic Region. Surfclam and ocean quahog vessels have used a form separate from the VTR, often referred to as the clam logbook, to report fishing trips that specifically target surfclam or ocean quahog.

Detailed information about the drawbacks of separate trips reports, the benefits of having a single report for all fishing trips, and the development of electronic VTR (eVTR) in the Greater Atlantic Region was provided in the proposed rule for this action (88 FR 20115, April 5, 2023) and is not repeated here.

This action eliminates the requirement for a separate surfclam/ocean quahog logbook and requires surfclam and ocean quahog vessel operators to complete the standard eVTR instead. When a fishing trip includes surfclams or ocean quahogs, the eVTR application will automatically present additional fields to collect the required information specific to the ITQ fishery, including the ITQ allocation number, the cage tag numbers for all cages being landed, and price per bushel. This information has previously been reported by the fishery on the surfclam/ocean quahog logbook, so there is no additional reporting burden on fishermen. Overall, the reporting burden would decrease because surfclam and ocean quahog trips that also land other regulated species will no longer be required to submit two reports, instead fulfilling all reporting requirements through a single electronic submission.

Comments

On April 5, 2023, we published a proposed rule (88 FR 20115) requesting comments on changes to the regulations to eliminate the separate surfclam and ocean quahog vessel logbook and require all vessels fishing for these species to report trips using the standard eVTR. The comment period was open through May 5, 2023. We received no comments on the proposed regulatory changes or on the impact of those changes on the public reporting burden in the existing information collection approved under the Paperwork Reduction Act (PRA).

Changes From the Proposed Rule

There are no changes to the proposed regulatory updates. However, this final rule corrects a minor typographical error in the first sentence of the introductory text in 50 CFR 648.7(b)(1), changing the word ''and'' to ''an.''

Classification

NMFS is issuing this rule pursuant to section 305(d) of the Magnuson-Stevens Act. Pursuant to that section, this action is necessary to carry out the provisions of the Atlantic Surfclam and Ocean Quahog FMP because the initial reporting provisions adopted in 1977 have become inconsistent with other reporting requirements in the Greater Atlantic Region. This inconsistency has led to an unnecessary additional reporting burden on the fishing industry. The NMFS Assistant

Administrator has determined that this final rule is consistent with the Atlantic Surfclam and Ocean Quahog FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration after public comment.

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

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. As a result, a regulatory flexibility analysis was not required and none was prepared.

This final rule contains a collection-of-information requirement subject to review and approval by OMB under the PRA. This rule revises the existing requirements for the collection of information under the following OMB Control Number: 0648–0212, Greater Atlantic Region Logbook Family of Forms, by eliminating the shellfish log (NOAA Form 88–140). All respondents and responses that would have used this form would use the Fishing Vessel Trip Report (NOAA Form 88–30) instead. This form takes less time to complete and is submitted electronically, resulting in a small decrease in estimated time burden and the elimination of postage costs. Public reporting burden for the Fishing Vessel Trip Report is estimated to average five minutes, including the time taken to review the instructions, search existing data sources, gather and maintain the data needed, and to complete and review the information collected.

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: *https://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 0648–0212.

Notwithstanding any other provisions 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, Reporting and recordkeeping requirements.

Dated: August 22, 2023.

Samuel D. Rauch, III,

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

For the reasons set out in the preamble, NMFS amends 50 CFR part 648 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 § 648.7, revise paragraphs (b)(1) introductory text, (b)(1)(i) introductory text, and (b)(1)(iii) to read as follows:

§ 648.7 Recordkeeping and reporting requirements.

* * * * *

(b) * * *

(1) *Fishing Vessel Trip Reports.* The owner or operator of any vessel issued a valid permit or eligible to renew a limited access permit under this part must maintain on board the vessel and submit an accurate fishing log report for each fishing trip, regardless of species fished for or taken, by electronic means. This report must be entered into and submitted through a software application approved by NMFS.

(i) *Vessel owners or operators.* At least the following information as applicable and any other information required by the Regional Administrator must be provided:

* * * * *

(iii) *Surfclam and ocean quahog owners or operators.* In addition to the information listed under paragraph (b)(1)(i) of this section, the owner or operator of any vessel conducting any surfclam or ocean quahog fishing operations in the ITQ program must provide at least the following information and any other information required by the Regional Administrator:

(A) Total amount in bushels of surfclams and/or ocean quahogs taken;

(B) Price per bushel;

(C) Tag numbers from cages used; and

(D) Allocation permit number.

* * * * *

[FR Doc. 2023–18414 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 660

[Docket No. 230508–0124; RTID 0648–XD191]

Fisheries Off West Coast States; Modification of the West Coast Salmon Fisheries; Inseason Action #18

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

ACTION: Inseason modification of 2023 management measures.

SUMMARY: NMFS announces one inseason action for the 2023–2024 ocean salmon fishing season. This inseason action modifies the commercial salmon fisheries in the area from the U.S./Canada border to Cape Falcon, Oregon.

DATES: The effective date for this inseason action is set out in this document under the heading ''Inseason Action'' and the action remains in effect until superseded or modified.

FOR FURTHER INFORMATION CONTACT: Shannon Penna, 562–980–4239, *Shannon.Penna@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Background

The annual management measures for the 2023 and early 2024 ocean salmon fisheries (88 FR 30235, May 11, 2023) govern the commercial and recreational fisheries in the area from the U.S./Canada border to the U.S./Mexico border, effective from 0001 hours Pacific Daylight Time (PDT), May 16, 2023, until the effective date of the 2024 management measures, as published in the **Federal Register**. NMFS is authorized to implement inseason management actions to modify fishing seasons and quotas as necessary to provide fishing opportunity while meeting management objectives for the affected species (50 CFR 660.409). Inseason actions in the salmon fishery may be taken directly by NMFS (50 CFR 660.409(a)—Fixed inseason management provisions) or upon consultation with the Chairman of the Pacific Fishery Management Council (Council), and the appropriate State Directors (50 CFR 660.409(b)—Flexible inseason management provisions).

Management of the salmon fisheries is divided into two geographic areas: north of Cape Falcon (NOF) (U.S./Canada border to Cape Falcon, OR), and south of Cape Falcon (SOF) (Cape Falcon, OR,

to the U.S./Mexico border). The actions described in this document affect the NOF commercial salmon troll fisheries, as set out under the heading Inseason Action below.

Consultation with the Council Chairperson on this inseason action occurred on July 19, 2023. This consultation included representatives from NMFS, Washington Department of Fish and Wildlife, Oregon Department of Fish and Wildlife, and California Department of Fish and Wildlife. Representatives from the Salmon Advisory Subpanel and Salmon Technical Team were also present.

This inseason action was announced on NMFS' telephone hotline and U.S. Coast Guard radio broadcast on the date of the consultations (50 CFR 660.411(a)(2)).

Inseason Action

Inseason Action #18

Description of the action: Inseason action #18 modifies the NOF ocean salmon troll commercial fishery.

Effective dates: Inseason action #18 takes effect for the following areas and dates, and remains in effect until superseded.

- Effective July 20, 2023, at 12:01 a.m., through Wednesday, July 26, 2023, at 11:59 p.m., in the area between the U.S./Canada border and Cape Falcon, the landing possession limit is decreased from 35 Chinook salmon and 150 adipose marked coho salmon per vessel per landing week to 30 Chinook salmon and 150 adipose marked coho salmon per vessel per landing week (Thursday–Wednesday).
- Effective July 27, 2023, at 12:01 a.m., through August 2, 2023, at 11:59 p.m., in the area between the U.S./Canada border and Cape Falcon, the landing and possession limit is decreased from 30 Chinook salmon and 150 adipose marked coho salmon per vessel per landing week to 20 Chinook salmon and 150 adipose marked coho salmon per vessel per landing week (Thursday–Wednesday).
- Effective August 3, 2023, at 12:01 a.m., the area between the U.S./Canada border and Cape Falcon is closed.

Reason and authorization for the action: Inseason action #18 was necessary to progressively slow the rate of Chinook salmon catch in order to preserve the length of the salmon fishing season by setting lower landing and possession limits. The NMFS West Coast Regional Administrator (RA) determined that this inseason action is necessary to meet management and conservation goals for the 2023–2024 management measures after considering the best available information on the 2023 abundance forecasts for Chinook salmon stocks, landings and effort patterns to date, anticipated fishery effort and projected catch, the timing of the action relative to the length of the season, and the other factors and considerations set forth in 50 CFR 660.409. This inseason action modified quotas and/or fishing seasons under 50 CFR 660.409(b)(1)(i).

All other restrictions and regulations remain in effect as announced for the 2023 ocean salmon fisheries (88 FR 30235, May 11, 2023; 88 FR 44737, July 13, 2023, 88 FR 51250, August 3, 2023; 88 FR 53813, August 9, 2023) except as previously modified by inseason actions.

The states and tribes manage the fisheries in state waters adjacent to the areas of the U.S. exclusive economic zone (3–200 nautical miles; 5.6–370.4 kilometers) off the coasts of the States of Washington, Oregon, and California consistent with these Federal actions. As provided by the inseason notice procedures at 50 CFR 660.411, actual notice of the described regulatory actions was given, prior to the time the actions became effective, by telephone hotline numbers 206–526–6667 and 800–662–9825, and by U.S. Coast Guard Notice to Mariners broadcasts on Channel 16 VHF–FM and 2182 kHz.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Fishery Conservation and Management Act (MSA). This action is authorized by 50 CFR 660.409, which was issued pursuant to section 304(b) of the MSA, and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(3)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest. Prior notice and opportunity for public comment on this action was impracticable because NMFS had insufficient time to provide for prior notice and the opportunity for public comment between the time Chinook and coho salmon abundance, catch, and effort information were developed and fisheries impacts were calculated, and the time the fishery modifications had to be implemented in order to ensure that fisheries are managed based on the best scientific information available. As previously noted, actual notice of the regulatory action was provided to fishers through telephone hotlines and radio notifications. These actions comply with the requirements of the annual management measures for ocean salmon fisheries (88 FR 30235, May 11, 2023), the Pacific Salmon Fishery Management Plan (FMP), and regulations implementing the FMP under 50 CFR 660.409 and 660.411.

There is good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effective date, as a delay in effectiveness of this action would allow fishing at levels inconsistent with the goals of the FMP and the current management measures.

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

Dated: August 23, 2023.

Jennifer M. Wallace,

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

[FR Doc. 2023–18512 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 88, No. 165
Monday, August 28, 2023

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 AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Parts 57 and 161

[Docket No. APHIS–2017–0002]

RIN 0579–AE39

National List of Reportable Animal Diseases; Revising Proposed Rule, and Reopening of Comment Period

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; revisions and reopening of comment period.

SUMMARY: We are reopening the comment period for our proposed rule that would amend disease regulations to provide a National List of Reportable Animal Diseases (NLRAD). Our proposed rule would have required animal health professionals suspecting or diagnosing incidences of animal diseases or disease agents classified as ''notifiable'' in the NLRAD to immediately report to both State and Federal officials. During the comment period for the proposed rule, however, several commenters raised concerns regarding the confidentiality of information reported under NLRAD, and that the Animal and Plant Health Inspection Service does not have the ability to provide Federal assurances of such confidentiality for information reported to States. In light of the validity of this concern, we are proposing a possible modification to our proposed rule to no longer require reporting to State officials; other existing Federal, State, and local disease reporting requirements would be unaffected, however. We are reopening the comment period for our proposed rule to provide interested persons with an opportunity to prepare and submit comments regarding this possible modification to the proposed rule.

DATES: The comment period for the proposed rule published on April 2, 2020 (85 FR 18471–18477) is reopened. We will consider all comments that we receive on or before September 27, 2023.

ADDRESSES: You may submit comments by either of the following methods:

- *Federal eRulemaking Portal:* Go to *https://www.regulations.gov* and enter APHIS–2017–0002 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2017–0002, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

The proposed rule and any comments we receive on this docket may be viewed at *www.regulations.gov* or in our reading room, which is located in Room 1620 of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m. EST, Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Jane Rooney, NLRAD Coordinator, Center for Epidemiology and Animal Health, Strategy and Policy, VS, APHIS, USDA 2150 Centre Ave., Building B, Mail Stop 2E6, Fort Collins, CO 80526–8117; 301–789–3064; *NLRAD.NAHRS@usda.gov*.

SUPPLEMENTARY INFORMATION: On April 2, 2020, we published in the **Federal Register** (85 FR 18471–18477, Docket No. APHIS–2017–0002) [1] a proposed rule to amend the animal disease regulations to provide for a national list of reportable animal diseases (NLRAD), as well as disease reporting requirements for animal health professionals identifying or suspecting NLRAD-listed diseases or conditions.

In our proposed rule, we proposed to classify reportable diseases as either monitored or notifiable. We proposed to define *notifiable disease* as ''a disease or condition that requires immediate notification to Federal and State veterinary authorities,'' and proposed to require any animal health professional with knowledge of occurrence or suspected occurrence of an animal disease, disease agent, or condition listed as notifiable in the NLRAD to immediately report such identification or suspicion to both the Animal and Plant Health Inspection Service (APHIS) and the State where the livestock is located.

Commenters on the proposed rule noted that some of the information reported could be personally identifiable or confidential, and they requested assurances from APHIS that the data would remain protected from third-party distribution.

While processes and procedures exist at the Federal level to protect confidential information to the extent allowable under Federal law, APHIS, as a Federal agency, cannot control the release of information reported under NLRAD to a State. Instead, State and local laws and regulations regarding the release of the information would be operative.

Accordingly, we are proposing to modify our proposed rule to no longer require reporting to States under NLRAD. Other Federal, State, and local disease reporting requirements would be unaffected.

Lists of Subjects

9 CFR Part 57

Animal diseases, Reporting, and recordkeeping requirements.

9 CFR Part 161

Reporting and recordkeeping requirements, Veterinarians.

Proposed Regulation Promulgation

Accordingly, we propose to further amend 9 CFR part 57, as proposed to be amended at 85 FR 18476 (April 2, 2020) as set forth below:

PART 57—ANIMAL HEALTH DIAGNOSTICS AND TESTING

■ 1. The authority for part 57 continues to read as follows:

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

§ 57.1 [Amended]

■ 2. Amend § 57.1, as proposed to be amended at 85 FR 18476, in the proposed definition of ''Notifiable disease,'' by removing the words ''and State''.

■ 3. Amend § 57.2, as proposed to be amended at 85 FR 18476, by revising paragraph (d)(1) to read as follows:

[1] To view the proposed rule, go to *www.regulations.gov*. Enter APHIS–2017–0002 in the Search field.

§ 57.2 National List of Reportable Animal Diseases.

* * * * *

(d) * * *

(1) *Notifiable diseases.* Any animal health professional with knowledge of occurrence or suspected occurrence of an animal disease, disease agent, or condition listed as notifiable in the NLRAD must immediately report such identification or suspicion to APHIS. Reporting to APHIS may be accomplished as described on the NLRAD website available at: *https://www.aphis.usda.gov/aphis/ourfocus/animalhealth/monitoring-and-surveillance/nlrad/ct_national_list_reportable_animal_diseases,* or by contacting a local APHIS office.[1]

[1] Contact information for APHIS offices can be found on the APHIS website at *https://www.aphis.usda.gov/aphis/banner/contactus,* or in the local phone directory (listed under Animal and Plant Health Inspection Service (APHIS), Veterinary Services).

* * * * *

Done in Washington, DC, this 18th day of August 2023.

Michael Watson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2023–18379 Filed 8–25–23; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 705

[Docket No. 230810–0188]

RIN 0694–AJ27

Revisions of the Section 232 Steel and Aluminum Tariff Exclusions Process

AGENCY: Bureau of Industry and Security, U.S. Department of Commerce.

ACTION: Proposed rule.

SUMMARY: This proposed rule revises aspects of the process for requesting exclusions from the duties and quantitative limitations on imports of aluminum and steel discussed in five previous Bureau of Industry and Security (''BIS'') interim final rules implementing the exclusion process authorized by the President under section 232 of the Trade Expansion Act of 1962, as amended (''Section 232''). The changes in this proposed rule are also informed by a notice of request for public comments on the Section 232 exclusions process that was published by BIS on February 10, 2022 (February Notice). The February Notice was directed by Proclamation 10328 of December 27, 2021, that directed BIS to review the Section 232 exclusions process to make improvements, including soliciting public comments as part of the review process. Based on a BIS review of the existing Section 232 exclusion process for areas of improvement and public comments on the current process for submissions to BIS, BIS is publishing this proposed rule to propose revisions to the Section 232 exclusions process, including to the Section 232 Exclusions Portal. As part of this proposed rule, BIS requests public comments on the proposed changes.

DATES: Comments on this proposed rule must be received by BIS no later than October 12, 2023.

ADDRESSES: See **SUPPLEMENTARY INFORMATION** section for information on submitting exclusion requests, objections thereto, rebuttals, and surrebuttals.

You may submit comments, identified by docket number BIS–2023–0021 or RIN 0694–AJ27, through the *Federal eRulemaking website: http://www.regulations.gov.* No other submission methods are being used for submitting comments on this proposed rule. Follow the instructions for submitting comments.

All filers using the portal should use the name of the person or entity submitting comments as the name of their files, in accordance with the instructions below. Anyone submitting business confidential information should clearly identify the business confidential portion at the time of submission, file a statement justifying nondisclosure and referring to the specific legal authority claimed, and provide a non-confidential version of the submission.

For comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters ''BC.'' Any page containing business confidential information must be clearly marked ''BUSINESS CONFIDENTIAL'' on the top of that page. The corresponding non-confidential version of those comments must be clearly marked ''PUBLIC.'' The file name of the non-confidential version should begin with the character ''P.'' The ''BC'' and ''P'' should be followed by the name of the person or entity submitting the comments or rebuttal comments. Any submissions with file names that do not begin with a ''BC'' or ''P'' will be assumed to be public and will be made publicly available through *http://www.regulations.gov.* Commenters submitting business confidential information are encouraged to scan a hard copy of the non-confidential version to create an image of the file, rather than submitting a digital copy with redactions applied, to avoid inadvertent redaction errors which could enable the public to read business confidential information.

FOR FURTHER INFORMATION CONTACT: For questions regarding this proposed rule, contact Erika Maynard at 202–482–5572 or via email *Erika.Maynard@bis.doc.gov,* or email *Steel232@bis.doc.gov* regarding provisions in this proposed rule specific to steel exclusion requests and *Aluminum232@bis.doc.gov* regarding provisions in this proposed rule specific to aluminum exclusion requests.

SUPPLEMENTARY INFORMATION:

Background

On March 8, 2018, Presidential Proclamations 9704, *Adjusting Imports of Aluminum Into the United States* (83 FR 13267), and 9705, *Adjusting Imports of Steel Into the United States* (83 FR 11625), imposed duties on imports of aluminum and steel. The Proclamations also authorized the Secretary of Commerce to grant exclusions from the duties if the Secretary determines the steel or aluminum article for which the exclusion is requested is not ''produced in the United States in a sufficient and reasonably available amount or of a satisfactory quality'' or should be excluded ''based upon specific national security considerations,'' and provided authority for the Secretary to issue procedures for exclusion requests. On April 30, 2018, Proclamations 9739 and 9740, and on May 31, 2018, Proclamations 9758 and 9759, set quantitative limitations on the import of steel and aluminum from certain countries in lieu of the duties. On August 29, 2018, Proclamations 9776 and 9777 also authorized the Secretary to grant exclusions from quantitative limitations based on the same standards applicable to exclusions from the tariffs.

The Section 232 Exclusions Process

Since March 19, 2018, BIS has published five interim final rules (IFRs) that established and made various revisions to the Section 232 exclusions process, as well as a Notice of Inquiry seeking public comment on certain aspects of the Section 232 exclusions process.

On March 19, 2018, BIS issued an IFR, *Requirements for Submissions Requesting Exclusions from the Remedies Instituted in Presidential*

Proclamations Adjusting Imports of Steel into the United States and Adjusting Imports of Aluminum into the United States; and the Filing of Objections to Submitted Exclusion Requests for Steel and Aluminum (83 FR 12106), establishing the Section 232 exclusions process in supplements no. 1 and 2 to 15 CFR part 705.

On September 11, 2018, BIS issued a second IFR, *Submissions of Exclusion Requests and Objections to Submitted Requests for Steel and Aluminum* (83 FR 46026), which revised the exclusions process to increase transparency, fairness, and efficiency.

On June 10, 2019, BIS issued a third IFR, *Implementation of New Commerce Section 232 Exclusions Portal* (84 FR 26751), that revised the two supplements to part 705 to grant the public the ability to submit new exclusion requests through the Section 232 Exclusions Portal while still allowing the opportunity for public comment on the portal.

On May 26, 2020, BIS issued a notice of inquiry with request for comment, *Notice of Inquiry Regarding the Exclusions Process for Section 232 Steel and Aluminum Import Tariffs and Quotas* (85 FR 31441), that sought public comment on the appropriateness of the information requested and considered in applying the exclusion criteria and the efficiency and transparency of the process employed.

On December 14, 2020, BIS issued a fourth IFR, *Section 232 Steel and Aluminum Tariff Exclusions Process* (85 FR 81060), which established General Approved Exclusions (GAEs) to reduce the number of exclusion requests for products consistently found not to be produced in the United States, reducing the submission burden on both industry and the Section 232 exclusions process. The December 14 IFR identified 123 GAEs that had generally never received an objection or very few objections via the Section 232 exclusions process. GAEs are available to all would-be requesters for steel and aluminum products imported under 10-Digit Harmonized Tariff Schedule of the United States (HTSUS) classifications without quantity limit or expiration date.

On December 9, 2021, BIS subsequently suspended 30 GAEs in its fifth IFR, *Removal of Certain General Approved Exclusions Under the Section 232 Steel and Aluminum Tariff Exclusion Process* (86 FR 70003), on the Section 232 Exclusions process because they were determined by BIS to no longer fit the criteria of a GAE.

On January 3, 2022, Presidential Proclamations 10327 (87 FR 1) and 10328 (87 FR 11) were published. These Proclamations implemented an understanding reached between the United States and the European Union including the establishment of tariff rate quotas for steel and aluminum articles imported from the European Union member countries. Proclamation 10328 also directed the Secretary of Commerce to seek public comment on the Section 232 exclusions process, including the responsiveness of the exclusions process to market demand and enhanced consultation with U.S. firms and labor organizations.

On February 10, 2022, BIS published *Request for Public Comments on the Section 232 Exclusions Process* (87 FR 7777) (February 2022 Notice), as directed by Presidential Proclamation 10328. The notice sought public comment on a variety of topics regarding the responsiveness of the exclusions process to market demand and enhanced consultation with U.S. firms and labor organizations. The notice comment period closed in March 2022, having received nearly 100 comments. Information about the comments received, along with BIS's responses, are detailed below.

Why is BIS publishing this proposed rule?

BIS is publishing this proposed rule to seek public comment on changes the Department believes will further improve the Section 232 exclusions process, following the receipt of comments from the February 2022 notice and then making any refinements in the changes proposed in this proposed rule in response to the comments received. BIS believes these changes will make important improvements and is requesting public comments to further evaluate how effective these changes will be in improving the Section 232 exclusions process. This action is consistent with the Department's approach of continually working to improve the process and obtain public feedback.

This proposed rule serves two functions. First, it seeks comments, as required by Proclamation 10328. Second, it responds to the outstanding comments received in the broader Section 232 exclusions process IFRs detailed above. As a matter of rulemaking, an IFR is generally followed by a final rule. Therefore, this proposed rule finalizes the Section 232 exclusions process IFRs. Any further action to modify the Section 232 exclusions process will be taken through issuance of a final rule.

What are the key changes included in this proposed rule?

This proposed rule makes the following four changes to the Section 232 exclusions process:

First, it creates a more efficient GAE process. BIS is committed to maintaining GAEs as a policy matter and is using this proposed rule to further clarify the general process by which GAEs are identified. As noted above, BIS issued an initial list of GAEs in December 2020 and modified the list of GAEs in December 2021. Originally, GAEs had been noted by commenters who submit exclusion requests, and by trade associations that represent those companies, as one of the most important changes that could be made to improve the efficiency of the Section 232 exclusions process. Their creation was estimated to result in an immediate decrease of 5,000 exclusion requests annually, resulting in a significant improvement in efficiency, with the possibility of more in the future. GAEs were identified at the ten-digit statistical reporting number of the HTSUS that had generally received no objections.

BIS proposes changing the criteria that has generally been used for GAEs from the HTSUS statistical reporting number that have received no objections to HTSUS classification codes (or subproducts) with very low rates of successful objections. The current criteria have focused most heavily on whether an HTSUS code has received objections. One of the problems with this past approach is that any party opposed to certain GAEs could submit objections regardless of the merits of those objections, which would make those HTSUS categories ineligible for GAE status. This undermines the effectiveness of the Section 232 exclusions process, creates unnecessary burdens on BIS and industry, and reduces the fairness and efficiency of the process. BIS still believes that the number of objections received is generally the right criterion to use; however, that criterion needs to be updated to focus on the number of substantiated objections, which is a better metric to use and should deter objections only submitted to prevent specific GAEs. BIS believes that the low rates of successful objections for specific 10-digit HTSUS classification codes shows that U.S. industry does not produce the products or subproducts in question in a sufficient and reasonably available amount or of a satisfactory quality. New GAEs will continue to be identified following a thorough analysis of objections. As described below, BIS proposes these actions to ensure the

process for identifying future GAEs is efficient and fair. BIS estimates that this change could result in up to a twenty percent reduction in the total number of exclusion requests submitted in the 232 Exclusions Portal, depending on the ultimate objection rate threshold and application used by the Department.

Second, and relatedly, this proposed rule addresses the need to create a more efficient Section 232 exclusions process by introducing a General Denied Exclusions (GDE) process. GDEs have been requested by commenters, who submit objection requests, as an important change that could be made to improve the efficiency of the Section 232 exclusions process and provide a balance to the GAE process. While it is difficult to estimate the expected annual reduction in exclusion requests, BIS anticipates an improvement in efficiency as well as increasing fairness in the process by providing a process comparable to the GAE process. Like BIS's proposed GAE evaluation, GDEs will generally be implemented if, among other things, the HTSUS classification code (or subproducts) have very high rates of successful, substantiated objections. BIS has added various requirements, such as certifications, over the years to limit voluminous exclusion requests that may exceed potential objectors' ability to fairly assess the requests and their ability to satisfy the requests, which has helped improve the efficiency of the Section 232 exclusions process. The addition of the GDEs will further enhance the efficiency of the Section 232 exclusions process by reducing the burden on objectors and requesters with respect to Section 232 exclusion requests that historically have had a very low likelihood of being approved. As with GAEs, GDEs would be applied in a manner that would increase efficiency and have little impact on which products are ultimately subject to or excepted from the tariffs. New GDEs would be identified following an analysis of substantiated objections and exclusion requests that have generally been consistently denied. As described below, BIS introduces GDEs in this proposed rule.

Third, BIS is using this proposed rule as an opportunity to modify the existing certification language and introduce new certification requirements for exclusion requests. Volume certifications were introduced onto the Exclusion Request Form in December 2020 in the Section 232 Exclusions Portal. Volume certification requirements were established after data reviewed by BIS indicated that some exclusion requesters were submitting exclusion requests for high volumes of product not ultimately imported. Continual processing of high volumes of exclusions not utilized decreases the efficiency of the Section 232 exclusions process and reduces the accuracy of data used by BIS to generate informed policy decisions on the Section 232 national security measures. The certification process further ensures that the requested volume in exclusion requests is consistent with the past and future use of steel or aluminum by an exclusion requester. Currently, requesters certify that their business ''expects to consume, sell, or otherwise use the total volume of product . . . within the next calendar year'' across their requests, which is subject to a verification by BIS.

BIS proposes modifications to the existing certification on the Exclusion Request Form. With the proposed changes, before filing an exclusion request, requesters would also need to certify that they have first made reasonable efforts to source their product from the United States and then, if unsuccessful in sourcing from the United States, that they have made reasonable efforts to source their product from a country with which the United States has arrived at a satisfactory alternative means to address the threat to the national security under Section 232. In addition to the certification, requesters would be required to file, simultaneously with their request submission, evidence of the certified sourcing attempts. These can be filed publicly as an attachment to the request submission, or if the information is claimed to be confidential then requesters can submit information to an email address similar to the process by which requesters currently submit confidential information linked to their rebuttals. These sourcing attempts need to have been made within 12 months from the date of submission of the request. BIS is seeking comments (see below) regarding what the evidence supporting sourcing attempts should be and how it should be defined. The United States has alternative arrangements with several other markets, including Argentina, Australia, Brazil, Canada, the European Union, Japan, Mexico, South Korea, and the United Kingdom. Therefore, requiring certification for attempting to source from the United States or an identified partnered country ensures that an attempt was made to first procure from those partner countries. If the sourcing attempts evidence is not provided simultaneously with the request submission, then the request will be rejected. BIS is seeking comments (see below) regarding the appropriate form and substance of evidence that must be provided by requestors to support their certification of such sourcing attempts.

Fourth, BIS is proposing similar certification language on the objection form to further ensure objectors can supply comparable quality and quantity steel or aluminum and make it ''immediately available'' to requestors in line with the standards described in the previous Section 232 IFRs referenced above. BIS welcomes comments from the public on whether this standard is appropriate for the certification or if a different time period should be specified. BIS is also interested in comments on how to address differences between different types of products, which may require longer periods, if a commenter suggests a different time period be specified. With this proposed change, objectors would certify their intent and ability to provide the requested product to the requester if successful in their objection. In addition to the certification, objectors would be required to file, simultaneously with their objection submission, evidence that it has commercially sold the same product as that which is being requested within the last 12 months, or evidence that it has engaged in sales discussions with this requesting company or another company requesting the same product within the last 12 months. This evidence can be filed publicly as an attachment to the objection submission, or if the information is claimed to be confidential then requesters can submit information to an email address similar to the process by which objectors currently submit confidential information linked to their surrebuttals. If the evidence described above is not provided simultaneously with the objection submission, then the objection will be rejected. BIS is seeking comments (see below) regarding the appropriate form and substance of evidence that must be provided by objectors to support their certification of such sales discussions. This proposed change will reduce cases where objections to an exclusion are made but the objector fails to follow through on supplying the material.

Each of the four proposed changes above would add additional features to the Section 232 exclusions process to better ensure that participants in the Section 232 exclusions process further focus their requests and objections as well as make important changes to improve the efficiency of the Section 232 exclusions process. The proposed requirements to provide certain

evidence upon submission, as opposed to later upon request of BIS, will enable BIS to conduct more timely and accurate certification reviews and enhance fairness, transparency, and efficiency in the Section 232 exclusions process for all involved parties.

Public Comments and BIS Responses

The public comment period on the February 2022 Notice closed in March 2022. BIS received nearly 100 public comments on the notice of inquiry, with one comment being deemed unresponsive. Several commenters referenced the imposition of duties and quantitative limitations, questioning the benefit of such regulations. Those comments are outside the scope of the February 2022 Notice that solicited comments on the Section 232 exclusions process. BIS has previously provided responses on these types of comments in the Section 232 rules cited in this proposed rule; therefore, BIS is generally not summarizing or providing responses to those general comments on the duties and quantitative limitations in this proposed rule. Some subject matter in the comments below may overlap generally with comments received in response to previous BIS Section 232 exclusions process publications that solicited public comments and that garnered BIS response or were still being considered under the last administration. However, they were overtaken by the larger review of the Section 232 exclusions process that is being undertaken by the current administration and the February 2022 Notice that provided a new opportunity for the public to identify what remaining issues needed to be improved under the Section 232 exclusions process.

The comments BIS received in response to the February 2022 Notice cover the same topics as the comments from previous Section 232 exclusion process publications. So, this proposed rule is responsive to all those comments. The comments described in this proposed rule are either different enough from comments previously responded to in past Section 232 exclusions process publications to warrant response or that they warrant additional comment due to an ever-changing industrial landscape and the continuing effort to ensure that administration of the Section 232 exclusions process remains fair, efficient, and transparent.

Based on the comments received in response to February 2022 Notice, BIS is proposing additional steps to increase the fairness, efficiency, and transparency of the Section 232 exclusions process. BIS has combined comments with similar subject matter such that the BIS response to those comments in this proposed rule is more efficient. As part of this proposed rule, BIS welcomes comments from the public, particularly those that participate in the Section 232 exclusions process, on whether the changes included in this proposed rule achieve the stated objectives; at the same time, BIS also welcomes any other comments or suggestions from the public regarding the fairness, efficiency, and transparency of the Section 232 exclusions process.

Transparency

General Concerns

Comment (a)(1): Several commentors suggested that BIS should require public summaries of confidential business information (CBI) in exclusions requests and objections. This would be similar to the existing requirements for rebuttals and surrebuttals.

BIS response: BIS agrees that this improves transparency in the request and objection stages. In fact, the system already requires that parties submit public summaries of CBI for rebuttals and surrebuttal. Expanding this requirement to requests and objections is in line with the existing requirements for rebuttals and surrebuttals. Submissions of such information should be in sufficient detail to permit a reasonable understanding of the substance of the information to allow rebuttal. A party's failure to timely and properly provide and summarize its CBI detracts from transparency and fairness and can result in BIS not considering a party's CBI. The regulations regarding CBI for the Section 232 exclusions process and the submission of CBI are found in paragraph (b)(5)(iii) of supplement no. 1 to part 705.

Comment (a)(2): Commenters provided input on requiring public disclosure of delivery times on the exclusion request and objection forms. One commentor suggested that they should be required.

BIS response: This is already explicitly required under paragraphs (c)(6) *Criteria used to review exclusion requests* and (d)(4) *Substance of objections to submitted exclusion requests* in supplement no. 1 to part 705. Paragraphs (c)(6) and (d)(4) note that it is incumbent upon both the exclusion requester and objecting producers to provide evidence supporting their claimed delivery times, from the receipt of a binding purchase order to ultimate delivery of the material to the domestic facility of the requester. BIS is further proposing language, including additional text to paragraph (d)(4), to clarify that all delivery and production times requested in the objection form are not considered CBI and must be included in the objection form for any product that is the subject of the request and objection. Objections that do not appropriately include delivery times where requested in the public version will be rejected by BIS.

Comment (a)(3): Multiple commenters suggested that delivery time should require certification.

BIS response: BIS agrees with this suggestion. The current system already requires certification that information provided within an objection is factual and supported by documentation as needed, as referenced above in response to comment (a)(2). BIS also notes that everything reported by all party involved in the Section 232 exclusions process is certified as true under penalty of perjury.

Comment (a)(4): One commentor suggested that BIS should consider the logistical challenges and other supply chain issues facing imports in evaluating delivery times; and that BIS should seek clarification from relevant parties when necessary to ensure an accurate determination when comparing to domestic delivery timetables.

BIS response: BIS disagrees with this suggestion because market conditions are constantly changing; using relative measures for delivery time would prevent BIS from fairly applying the same standard across all parties to the Section 232 exclusions process. BIS also stresses that seeking clarification with relevant parties would by necessity occur through private communications; however, it is critical that all relevant information, including accurate delivery timeframes, be provided in the public record for all parties to have an opportunity to comment on or contest such claims. Requesters with unique delivery challenges have repeated opportunities throughout the process to provide additional information in the public record and/or could submit a new exclusion request if facts of the case change.

Comment (a)(5): One commentor suggested that BIS should verify with objectors that the products are available on a ''turnkey'' basis in a commercially reasonable time and noted that this process may include calling consumers or asking the objector directly about how quickly they can fulfill a request.

BIS response: BIS does not agree with this suggestion. This information is provided in the record. While this information is subject to change, BIS

evaluates the provided information based on conditions at the time of submission. BIS also notes that the rebuttal process, as well as the surrebuttal process are intended to allow the parties involved, to provide updated information as the parties respond to each other in the Section 232 exclusions process.

Comment (a)(6): Similarly, one commentor stated that objectors who are already operating at full capacity should not be allowed to object.

BIS response: BIS does not agree with this suggestion because market conditions can and do change. For example, an objector may be in the process of adding capacity, so BIS does not want to impose a restriction that would prohibit such producers from being able to submit objections. The expansion of domestic industrial capacity for aluminum and steel is key to achieve the national security objectives of the tariffs and the Section 232 exclusions process, so adopting this type of a restriction would run counter to that objective.

Certification for Objectors and Requesters

Comment (b)(1): Several commentors suggested that objectors and requesters should both be required to submit ''substantive evidence regarding these claims [the assertions they make in Section 232 submissions].''

BIS response: BIS agrees that claims made by objectors and requesters must be adequately supported. BIS is introducing additional certification requirements on objection forms as well as evidence requirements for objection submissions. These certifications and additional evidentiary requirements are designed to address concerns of objectors filing objections when they cannot or will not provide the requested product. Under the proposed certification of objection submitted requirement pursuant to paragraph (d)(5) in supplement no. 1 to part 705, the objector must certify that they currently manufacture the requested product at a facility in the United States. They must also certify that in response to a written request by the requester during the next year they will offer to sell and timely deliver to the requester the full quantity of the product at then-existing market rates and terms and in accordance with the other terms specified in the objection that they are submitting. Ensuring that all parties involved in the process substantiate their claims facilitates achieving the Section 232 exclusions process objectives. As for the requesters, imports from countries with which the United States has an alternative means to address the national security threat already make up roughly 70% of steel and aluminum imports. Therefore, adding this certification statement not only better balances requirements for requesters and objectors, but will not significantly increase the regulatory burden on requesters.

Comment (b)(2): At least one commenter requested BIS institute the same additional certification requirements for rebuttals, as is done for exclusion requests.

BIS response: BIS does not agree that this is necessary. In addition to the unique certification requirements for requesters and objectors, parties must certify under the threat of criminal prosecution that all information contained in all their submissions are complete and correct to the best of their knowledge. As a result, any statement made in a rebuttal or surrebuttal needs to be consistent with the certifications already made by the organization in the exclusion request or objection—meaning that including any additional unique certification requirements in the rebuttal or surrebuttal forms is not necessary.

Exclusion Requests

Timeline for Requests

Comment (c)(1): BIS received a comment suggesting that exclusions for new requests continue to be for up to one year, but up to two years if it is an existing request that has previously been granted, due to the current global supply chain issues.

BIS response: BIS is considering this as market conditions are constantly changing. This change would not require a regulatory change. Under the existing paragraph (h)(2)(iv) to supplement no. 1 to part 705, BIS already specifies that exclusions will generally be approved for one year from the date of the signature on the decision memo, but may be valid for shorter or longer than one year depending on the specifics of the exclusion request. So, exclusion requesters already can request longer periods for exclusion requests and BIS already has the regulatory authority to approve longer exclusion requests when warranted. However, the circumstances under which BIS would approve a longer exclusion request must be unique to require such an action. Currently, the conditions are not unique such that they require a longer exclusion request. Also, exclusion requesters should also be aware that approving multiyear exclusion requests could run counter to the objectives of trying to encourage increased capacity utilization in the United States. BIS would also take that into account when considering a longer period for an exclusion request than one year.

Comment (c)(2): BIS received a comment suggesting that one way to reduce the burden on all parties involved in the process would be to implement a limited period each year where exclusions can be requested for the following calendar year.

BIS response: BIS is not making those changes at this time, given the dynamic nature of the markets at this time. In addition, BIS questions whether compressing all reviews into a short time period would improve the overall efficiency and burdens associated with administering the Section 232 exclusions process.

Comment (c)(3): A commenter suggested that BIS should collaborate with Customs and Border Protection (CBP) to implement a system to automatically register granted exclusions with CBP to help streamline the Section 232 exclusion process and reduce unnecessary administrative work for both agencies.

BIS response: BIS already works closely with CBP to quickly report granted exclusions on a weekly basis and ensure they are programmed accurately into the Automated Commercial Environment (ACE). BIS and CBP continue to make improvements in this area within their existing program constraints and are currently considering further potential programmatic enhancements to the data transfers between BIS and CBP. CBP recently revised and streamlined its procedures for activating granted exclusions and parties should continue to confer directly with CBP about the procedures for utilizing a granted exclusion.

Information Provided in Requests

Comment (d)(1): A commentor suggested that information collected in the exclusion process does not allow for requesters to provide information related to objections on their products in previous requests. If it did, the commenter notes, requesters would be able to address those objections before they occur again and BIS would have that information at the outset, allowing faster decisions.

BIS response: BIS disagrees with this comment. BIS already encourages requesters to submit this type of information in their exclusion requests or the related supplements. BIS also encourages requestors to submit this type of information as relevant when filing rebuttals to objections received against their exclusion requests.

However, BIS maintains that all requests are reviewed solely based on the information provided in each individual record of exclusion requests, objections, rebuttals, and surrebuttals, as well as any associated public or CBI attachments.

Comment (d)(2): One commenter suggested that BIS should eliminate redundant or superfluous parts in the forms.

BIS response: BIS generally agrees with this, however, has concerns with this suggestion in practice. Obtaining the necessary physical, mechanical and chemical characteristics on the requested products ensures that an accurate description of the products is provided that is subject to a request. However, BIS acknowledges that the ''full, complete description of the product'' sought in the noted up-front section of the questionnaire, if properly provided, provides the necessary characteristics of the product. The additional specific characteristics provide further clarification on the products but may not further the ability of parties to review the material subject to the request or provide further insight into the government's ability to implement decisions on products subject to the requests. Also, some fields, such as names of ports of entry and number of shipments may be possibly reexamined. So, BIS will seek public comment on this matter. *See* the Request for Public Comments section for specific information sought.

Other General Requester Comments

Comment (e)(1): A commenter suggested that before considering any new product exclusion request, BIS should require: (1) evidence that the requested product cannot be sourced either from U.S. producers or from any of the countries with an alternative arrangement to the tariffs; (2) detailed documentation that the exclusion can only be obtained from a country subject to the tariffs; and (3) that a good faith effort was conducted to check availability from both domestic producers and from all countries not subject to the tariffs. Absent this showing, Commerce should decline to process and post the exclusion request.

BIS response: BIS agrees with this suggested change and has added new certification and evidentiary requirements on exclusion requesters in this proposed rule. Requesters must now before filing an exclusion request, certify that they have first made reasonable efforts to source their product from the United States and then, if unsuccessful in sourcing from the United States, that they have made reasonable efforts to source their product from a country with which the United States has arrived at a satisfactory alternative means to address the threat to the national security under Section 232, and provide evidence of those sourcing attempts simultaneously with the request submission. The process is intended to treat each party as fairly as possible given complex global market conditions and specialized production unique to individual countries.

General Approved Exclusions (GAEs) and General Denied Exclusions (GDEs)

Comment (f)(1): Some commenters raised concerns about whether the adoption of GAEs made the Section 232 exclusions process too much in favor of exclusion requesters and whether similar changes should be extended to objectors in the Section 232 exclusions process.

BIS response: BIS is committed to ensuring that the Section 232 exclusions process is fair and efficient. That is why BIS established the GAEs. BIS is proposing the concept of the GDEs for the same reason. While no specific commenter suggested the adoption of GDEs, *per se,* some commented on related topics regarding creating a concept, such as the GDEs. The creation of the GDE process would ease the bureaucratic burden in the Section 232 exclusions process for all parties and improve the overall efficiency of the Section 232 exclusions process. Additional General Approved (GAEs) and Denied (GDEs) Exclusions would further streamline the existing Section 232 Exclusions Process.

Comment (f)(2): Another commenter suggested that semi-finished steel should be removed from the list of products eligible for an exclusion.

BIS response: BIS will consider this further; it is possible that this product could be a GDE. To reduce public burden and increase efficiency, and thus be considered as a possible GDE, it would need to fit the criteria established by BIS for GDEs. However, BIS is not proposing the establishment of specific GDEs with this proposed rule.

Comment (f)(3): Several commenters suggested specific items that should be used as a GAE.

BIS response: All GAEs are determined based on an internal analysis of data regarding the items and selection criterion to achieve the intended policy objectives.

Comment (f)(4): One commenter suggested that when a GAE is activated or deactivated, there should be notification period before change is implemented to allow exclusion requesters and objectors to adapt to the change.

BIS response: BIS agrees with this suggestion. BIS intends to adopt fifteen-day delayed effective date before implementing such changes to give the public an opportunity to adjust as needed. BIS welcomes further comments on whether more time is required as a notification period before implementing changes to GAEs.

Comment (f)(5): A commenter suggested that BIS allow for objections to GAEs.

BIS response: BIS does not agree with this suggestion. The public is already permitted to provide specific information regarding the inclusion or deletion of GAEs to Section 232-related rules and notices for public comment. This will inform BIS going forward on the changing availability of domestic production. Additionally, BIS will conduct regular analysis of existing GAEs. The purpose of the GAEs is to ensure that the Section 232 exclusions process is as efficient as possible, while also ensuring that BIS does not discourage the domestic production of any item subject to the process.

Comment (f)(6): Several commenters suggested that because there is not a review process, the GAEs essentially cede entire product segments to foreign competitors.

BIS response: BIS disagrees with this suggestion. BIS plans to more routinely issue periodic requests for public comments on proposed changes to GAEs, and when appropriate can remove GAE eligibility in a subsequent regulatory action. GAEs are issued based on sustained lack of successful objections in the Section 232 exclusions process, which indicates that U.S. industry does not produce the products or subproducts in question in a sufficient and reasonably available amount or of a satisfactory quality. GAEs are based on the record of filings in the Section 232 exclusions process, which provides ample opportunity for domestic industry to contest such exclusions prior to their identification as GAEs. Thus, GAEs are meant to cover product segments for which there is insufficient domestic availability.

Comment (f)(7): A commentor noted that there should be more transparency in the process by which BIS determines the products to remove from the GAE list.

BIS response: BIS provides a rationale for the decision to remove or add a GAE in the preamble of the proposed rule announcing any change. In addition, and as described above, the opportunity for public participation and clarification of the criteria for the addition or

removal of certain GAEs provides transparency and would be further improved if the changes in this proposed rule are adopted in final form.

Comment (f)(8): One comment suggested that BIS should incorporate the use of ranges for dimensions of material across HTS codes when necessary to simplify the process for BIS. while also providing GAEs for these commonly used imports.

BIS response: The Section 232 Exclusions Process is based on unique products within HTSUS codes. However, BIS is open to exploring the possibility of further incorporating or changing the use of ranges for dimensions of material in a single exclusion request. BIS will seek public comment on this matter. *See* the Request for Public Comments section for specific information sought.

Section 232 Exclusions Portal

Portal and Form Functionality

Comment (g)(1): BIS received several comments regarding the functionality of the Section 232 Exclusions Portal. These included the use of an auto-fill feature for information and the ability for requesters to save drafts.

BIS response: BIS agrees that these are useful suggestions. The cloning feature addresses the auto-fill request. BIS has now implemented a draft saving feature.

Comment (g)(2): Several comments suggested that BIS release more detailed analyses of exclusion requests, particularly in the event of a denial, and any relevant internal analysis or communication related to such requests.

BIS response: BIS assesses the currently available public information regarding decisions as adequate, however, BIS is looking at further ways that additional information can be procured for public consumption. BIS is committed to transparency in the Section 232 exclusion process decisions.

Comment (g)(3): At least one comment requested the introduction of an appeals process to prevent requesters from having to file a new exclusion and repeat the protracted Section 232 exclusion process.

BIS response: BIS disagrees with this suggestion. BIS already provides opportunities for requestors and objectors to expand upon their claims through rebuttals and surrebuttals. Ultimately, BIS must enforce a point at which new collection of information ends and a final decision is rendered by BIS. Requesters who believe they have new and relevant information can refile without prejudice in the Section 232 Exclusions Portal.

Processing Times

Comment (h)(1): One commentor suggested that BIS should allow domestic industry to file requests based on a 6-digit HTSUS classification number. They noted that BIS previously started allowing domestic industry to file requests for products that cover a range of dimensions within a 10-digit HTSUS statistical reporting number. They assert that this requirement should be loosened to allow requests for a range of products within a 6-digit HTSUS classification number.

BIS response: BIS does not agree with this suggestion. The current Section 232 exclusions process is product based and uses the 10-digit HTSUS statistical reporting number because that level of specificity is needed to administer the granted exclusions and analyze the submissions to the Section 232 exclusions process. It would likely be difficult to implement and monitor exclusions based on the 6-digit HTSUS classification number without undergoing a fundamental change to the Section 232 exclusions process. However, BIS has allowed Requesters to bundle different products, so long as their technical specifications fall within a single 10-digit HTSUS statistical reporting number. The more-general 6-digit HTSUS classification number encompasses so many products that it would be too prohibitive to administer and not targeted enough for use under the Section 232 exclusions process.

Comment (h)(2): Several commentors suggested that if objections including all necessary public information regarding capacity, lead time, and quality and a rebuttal is not filed within the seven-day rebuttal window, BIS should consider the relevant product to be domestically available and promptly deny the exclusion request. Put more simply, an objection that does not receive a rebuttal should see the original exclusion request be automatically denied.

BIS response: BIS does not agree with this suggestion. BIS is required to analyze all the information in relation to claims made by both the requester and objector.

Comment (h)(3): A commenter suggested that BIS should allow requesters and those submitting a rebuttal to present a full and factual account of their efforts to source domestically, including providing evidence of lack of responsiveness for repeated request for quotes from domestic producers who continue to file objections.

BIS response: BIS agrees with this suggestion and encourages companies to submit such information as part of their exclusion request or subsequent rebuttal filings whenever they deem such information relevant. The additional certification for objectors proposed in this rule also addresses the substance of this comment (described further below).

Comment (h)(4): A commenter suggested that BIS should deny exclusion requests for material that are already available through a tariff-rate quota (TRQ) or country with an existing agreement in place.

BIS response: While BIS does not agree with this suggestion, the addition of new certification language in this proposed rule would require that, before filing an exclusion request, requesters would need to certify that they have first made reasonable efforts to source their product from the United States and then, if unsuccessful in sourcing from the United States, that they have made reasonable efforts to source their product from a country with which the United States has arrived at a satisfactory alternative means to address the threat to the national security under Section 232.

Comment (h)(5): BIS received several additional comments regarding streamlining of the forms or otherwise reducing the administrative burden associated with the Section 232 exclusions process, such as including notifications emails from the Section 232 Exclusions Portal as Section 232 submissions are working their way through the process. Some of these offered suggestions to alleviate the issue, while others did not.

BIS response: BIS is working to reduce the administrative burden where possible. This feature is already in development. BIS seeks to have notification emails operational in the coming months and is continuing to review other ideas for reducing the administrative burden associated with the Section 232 process.

Comment (h)(6): One commenter suggested updating several fields in the portal.

BIS response: BIS intends to make further changes to the portal, such as automated notification emails for filing status changes, fields to input additional importers of record, and internal process improvements to expedite the administration of decisions. Some of the requested changes would require resources beyond the Department's staffing, time, and budget constraints. BIS is currently working to implement changes in the portal that can be made without costly programming changes and will roll those out as soon as they are available.

Comment (h)(7): A commenter said that BIS should split the Section 232 portal into separate portals for steel and aluminum.

BIS response: BIS does not agree with this suggestion. Companies can already filter between steel and aluminum requests with ease. The BIS website also includes guidance on how to use the portal that helps provide guidance on these types of questions.

Comment (h)(8): One commenter stated that BIS should add an option in the exclusion request form to include multiple residents and non-resident importers of record to reduce the need for, and volume of, importer of record change requests.

BIS response: BIS is currently developing the ability to do this. BIS anticipates this new feature should be available in the next few months.

Regulatory Changes

As detailed above, BIS has outlined the proposed changes as well as the comments responsible for their proposal. In this section, BIS will describe the specific changes to the regulatory text, as proposed in this rule.

Under paragraphs (c) and (d) to supplement no. 1 to part 705, BIS is proposing additional certification text. Under paragraph (c)(5)(ii), certification for volume requested by requesters, BIS is proposing to revise the introductory paragraph. This proposed change would reduce the (c)(5)(ii) introductory paragraph to just two sentences with the substance of the text removed to be added to paragraphs (c)(5)(ii)(A) through (E), as needed. Under paragraph (c)(5)(ii)(A), BIS is proposing additional certification text that requesters have first attempted in good faith in the past calendar year to ''source the requested product from the United States and then, if unsuccessful in sourcing from the United States, made reasonable efforts to source the requested product from a country with which the United States has arrived at a satisfactory alternative means to address the threat to the national security under Section 232.'' Also, under paragraph (c)(5)(ii)(A), BIS proposes text for requesters to certify that they will provide all documentation justifying the above quoted text simultaneously with the request submission. This requirement will enable BIS to conduct more timely and accurate certification reviews and enhance fairness, transparency, and efficiency in the Section 232 exclusions process for all parties. Similarly, BIS proposes creating a paragraph (d)(5), certification of objections submitted. This new paragraph (d)(5) would add an introductory paragraph to (d)(5), as well as paragraphs (d)(5)(i) and (ii). These two proposed paragraphs, similar to the requester certification process review mechanism, would establish a BIS review mechanism in (d)(5)(ii), like that proposed in (c)(5)(ii)(A).

This rule also proposes modifying paragraph (d)(4) to specify as noted above that delivery times are not considered CBI and must be included in the objection form. The revisions to paragraph (d)(4) also specify that objections that do not include delivery times in the public version will be rejected by BIS.

Much like supplements no. 2 and 3 to part 705 that created GAE tables for steel and aluminum articles, respectively, this rule proposes the creation of new supplements no. 4 and 5 to part 705. Supplement no. 4 would list General Denied Exclusions (GDEs) for steel articles under the Section 232 exclusions process and supplement no. 5 would list GDEs for aluminum articles under the Section 232 exclusions process.

This rule proposes adding a new supplement no. 4 to part 705—General Denied Exclusions (GDEs) For Steel Articles Under The Section 232 Exclusions Process. This rule also proposes adding a new supplement no. 5 to part 705—General Denied Exclusions (GDEs) For Aluminum Articles Under The Section 232 Exclusions Process. Both supplements would have the same format. Each of the two supplements would include introductory text to explain the selection process and the role of the GDEs in the Section 232 exclusions process. Any steel or aluminum articles identified as a GDE in one of these two supplements must not be included and would not be considered by BIS in an exclusion request. Like the GAEs, the steel and aluminum GDEs will be identified in a table under the respective supplement. Also, like the two GAE supplements, these two GDE supplements would permit BIS, on behalf of the Secretary of Commerce, to periodically publish notices of inquiry in the **Federal Register** soliciting public comments on potential removals, revisions or additions to this supplement.

BIS encourages the public to participate and request changes to GAEs and GDEs when notices are published seeking comments on GAEs or GDEs. In other times when a member of the Department of Commerce receives comments from a party, either verbally or in writing, regarding requested changes to GAEs or GDEs, it is the practice of the Department of Commerce to document those interactions publicly so there is a public record of such interactions. The public record of such interactions will include a log of the person(s) that petitioned the Department of Commerce, the date on which the interaction occurred, the names and title of all persons that were met with at the Department of Commerce, the mode of communication used (*e.g.,* by email, phone, video conference, or in person), a copy of any written documents submitted as part of the interaction, and for verbal communications done over the phone, internet, or in person, a summary transcript of the interaction will be included as part of the public record. The public record for such interactions will be made available to the public.

At this time, BIS is proposing the framework for identifying GDEs, but not proposing any specific articles that would qualify for GDE status.

BIS is also proposing technical regulatory changes with this proposed rule. BIS proposes the deletion of examples found in paragraph (c) of supplement no. 1 to part 705. Given how long the Section 232 exclusions process has been effective, these examples are likely no longer necessary or useful to the public. As a conforming proposed change to supplement no. 1, BIS proposes adding a paragraph (h)(v) for regulations regarding the standard and scope of review for supplement no. 1 to part 705. The proposed text for paragraph (h)(v) is mostly made up of text removed from paragraph (c)(6). BIS proposes this change because they apply to all Section 232 submissions, not just exclusions requests, as they did under paragraph (c)(6).

With the proposed addition of supplements nos. 4 and 5, BIS is proposing changes to the introductory text to supplements nos. 2 and 3. These proposed changes are to align the introductory text of supplements nos. 2, 3, 4, and 5 more closely, such that they are more easily understood by the public. BIS is also proposing revisions throughout part 705. These revisions make the regulations easier to understand. These revisions are in paragraphs (c) and (d) in supplement no. 1 to part 705. Specifically, BIS proposes: (1) adding references to aluminum products in paragraph (c)(1) and (d)(1), which had been inadvertently left out; (2) removing ''either'' from (c)(5)(ii)(D), making it easier to read; (3) adding citations to supplements nos. 2 through 5, a reference to the case-by-case basis of review of exclusions requests and a sentence noting that the burden is on the requester to show that the requests

article is ''not produced in the United States in a sufficient and reasonably available amount or of a satisfactory quality'' to paragraph (c)(6); (4) in paragraphs (c)(6)(i) and (ii), the term ''end user'' is being changed to ''user requesting the exclusion,'' a change BIS deems is a needed clarification, not a policy change; (5) adding more expansive language to account for single and multiple exclusion requests, as well as possible approvals and denials of requests to paragraph (c)(6)(iii); and (6) removing superfluous language and adding additional specific language to paragraph (d)(4), making it easier to understand, and by adding a sentence stating that delivery times are not considered confidential business information and that objections that do not include delivery times in the public version will be rejected. These revisions do not alter 232 exclusions policy.

Request for Public Comment

BIS is seeking public comments on the following issues:

- Changing the Requester Certification Text;
- Requiring Objector Certification;
- Additional evidence requirements for new requester and objector certifications (*i.e.,* what form should this evidence take and how should the evidence be defined as sufficient);
- Change in methodology that requires the consolidation of multiple sizes of a specific product within a specific HTS number and providing relief for sizes with no objection (comments on this issue should be specific to the merits and issues associated with this, as well as how it could be administered);
- Eliminating redundancies in the request and objection forms by removing the charts and tables on product characteristics and chemical composition and require a ''full, complete description of the product'' be provided by the requestor in the noted section of the questionnaire;
- Clarifying the criteria used for identifying GAEs;
- Whether specific products (*e.g.,* aluminum extrusions; boxed aluminum foil; flat-rolled stainless steel of a width of less than 600 millimeters, not further worked than hot-rolled, of a thickness of less than 4.75 millimeters; and flat wire plated or coated in zinc) should continue to qualify for a GAE;
- Creating a GDE process;
- The process and frequency with which reviews of the GAE and GDE processes will undergo, including comments on how often these reviews should be conducted and the types of information that should be requested when the reviews are being conducted.

See the **DATES** and **ADDRESSES** of this proposed rule for guidance on submitting comments.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 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). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This proposed rule has been determined to be a ''significant regulatory action,'' although not economically significant, under section 3(f) of Executive Order 12866. Pursuant to Proclamations 9704 and 9705 of March 8, 2018, and Proclamations 9776 and 9777 of August 29, 2018, the establishment of procedures for an exclusions process under each Proclamation shall be published in the **Federal Register**.

2. The Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA) provides that an agency generally cannot conduct or sponsor a collection of information, and no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information, unless that collection has obtained Office of Management and Budget (OMB) approval and displays a currently valid OMB Control Number.

This final regulation involves three collections currently approved by OMB with the following control numbers:

- Exclusions from the Section 232 National Security Adjustments of Imports of Steel and Aluminum (control number 0694–0139).
- Objections from the Section 232 National Security Adjustments of Imports of Steel and Aluminum (control number 0694–0138).
- Procedures for Submitting Rebuttals and Surrebuttals Requests for Exclusions from and Objections to the Section 232 Adjustments for Steel and Aluminum (OMB control number 0694–0141).

This proposed rule is expected to reduce the overall burden hours and cost associated with the following collections: OMB control numbers 0694–0139, 0694–0138, and 0694–0141. This reduction is expected because of the revised General Approved Exclusions (GAEs) criteria and the addition of General Denied Exclusions GDEs for steel and aluminum, which are expected to result in a decrease of 5,946 exclusion requests under 0694–0139, 2,806 objection requests under 0694–0138, and 1,946 rebuttals, and surrebuttals under 0694–0141 per year for a total burden hour savings of 36,954 and 1,367,298 dollars to the public.

BIS is making a change to the collection for OMB control number 0694–0139 to account for a revised certification under paragraph (c)(5)(ii) introductory text and one new certification that needs to be made in the Section 232 Exclusions Portal under paragraph (c)(5)(ii). These certification changes are expected to be an increase of 4,460 burden hours and an increase of $165,020 dollars to the public. Lastly, BIS is making a change to the collection for OMB control number 0694–0138 to account for two new certifications that need to be made in the Section 232 Exclusions Portal for certifications for objections under paragraph (d)(5)(i) and (ii). These certification changes are expected to be an increase of 2,806 burden hours and an increase of $155,733 to the public. This increase in the burden under OMB control numbers 0694–0139 and 0694–0138 considers the decreases described above in the total overall numbers.

3. This proposed rule does not contain policies with federalism implications as that term is defined in Executive Order 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public comment, and a delay in effective date are inapplicable because this regulation involves a military or foreign affairs function of the United States. (*See* 5 U.S.C. 553(a)(1)). As explained in the reports submitted by the Secretary to the President, steel and aluminum are being imported into the United States in such quantities or under such circumstances as to threaten to impair the national security of the United States, and therefore the President is implementing these remedial actions (as described Proclamations 9704 and 9705 of March 8, 2018) to protect U.S. national security interests. That implementation includes the creation of an effective process by which affected domestic parties can obtain exclusion requests ''based upon specific national security considerations.'' BIS started this process with the publication of the March 19 rule and refined the process with the publication of the September 11 and June 10 rules and is continuing this process with the publication of this proposed rule. The revisions to the

exclusion request process are informed by the comments received in response to the March 19 rule and BIS's experience with managing the Section 232 exclusions process. Commenters on the past rules (March 19, September 11, and June 10 rules) were generally supportive and welcomed the idea of creating an exclusion process, but most of the commenters believe the exclusion process, although improving over time, still could be significantly improved for it to achieve the intended purpose. The commenters identified several areas where transparency, effectiveness, and fairness of the process could be improved. BIS understands the importance of having a transparent, fair, and efficient product exclusion request process, consistent with the directive provided by the President to create this type of process to mitigate any unintended consequences of imposing the tariffs on steel and aluminum to protect critical U.S. national security interests. The publication of this rulemaking should make further improvements in all three respects, but because of the scope of this new process, BIS is publishing this rule as a proposed rule with a request for comments.

Consistent with the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 601 *et seq.*), BIS has prepared the following initial regulatory flexibility analysis (IRFA) of the impact that this proposed rule, if adopted, would have on small businesses.

Description of the Reasons Why Action Is Being Considered

The policy reasons for issuing this proposed rule are discussed in the background section of the preamble of this document and, consequently, are not repeated here.

Statement of the Objectives of, and Legal Basis for, the Proposed Rule; Identification of All Relevant Federal Rules Which May Duplicate, Overlap or Conflict With the Proposed Rule

The objective of this proposed rule, and all other Section 232-related rules published by BIS, are discussed in the background section of the preamble of this document and, consequently, are not repeated here. The legal basis for this proposed rule is as follows: Section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862) and Reorg. Plan No. 3 of 1979 (44 FR 69273, December 3, 1979).

No other Federal rules duplicate, overlap, or conflict with this proposed rule.

Number and Description of Small Entities Regulated by the Proposed Action

This proposed rule would apply to all persons engaged in the Section 232 exclusions process. BIS does not collect or maintain the data necessary to determine exactly how many of the affected persons are small entities as that term is used by the Small Business Administration. However, BIS does ask requestors of the Section 232 exclusions process to self-identify if they are a small business as defined by the Small Business Administration. From this data, BIS has estimated the total number of requestors and objectors who are likely to be small businesses that would be impacted by changes identified in this proposed rule.

Roughly 380 requestors self-identified as small businesses, filing roughly 27,000 exclusion requests in the Section 232 exclusions portal since March 2022, when we began including the option for requestors to self-identify as a small business. BIS does not have the same self-identification option for objectors. However, over the same period, roughly 100 objectors filed objections in the Section 232 exclusions portal; many of these are easily identifiable as being large corporations, not small businesses. Therefore, somewhere between 380 and 500 small businesses could be impacted by these proposed changes. Specific burden estimates for OMB under control numbers 0694–0139 (Exclusions from the Section 232 National Security Adjustments of Imports of Steel and Aluminum), 0694–0138 (Objections from the Section 232 National Security Adjustments of Imports of Steel and Aluminum), and 0694–0141 (Procedures for Submitting Rebuttals and Surrebuttals Requests for Exclusions from and Objections to the Section 232 Adjustments for Steel and Aluminum) are detailed in paragraph 2 of the Rulemaking Requirements section above.

Based on the analysis provided above, the amendments proposed in this rule would not impose a significant economic impact on a substantial number of small businesses.

Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule

The changes proposed in this rule and the corresponding reporting, recordkeeping, and other compliance requirements are discussed in the background section of the preamble of this document and, consequently, are not repeated here. To the extent that compliance with the changes proposed in this rule would impose a burden on persons, including small businesses, BIS believes the burden would be minimal.

Significant Alternatives and Underlying Analysis

As noted above, BIS does not believe that the amendments proposed in this rule, if published in a final rule, would have a significant economic impact on small businesses. Nevertheless, consistent with 5 U.S.C. 603(c), BIS considered significant alternatives to these proposed amendments to assess whether the alternatives would: (1) accomplish the stated objectives of this proposed rule (consistent with the objectives of the Section 232 exclusions process); and (2) minimize any significant economic impact of this proposed rule on small entities. BIS has determined that proposals detailed above are the least disruptive alternative for implementing changes to the Section 232 exclusions process.

Lastly, consistent with 5 U.S.C. 603(c), BIS assessed the use of performance standards rather than design standards and considered whether an exemption for small businesses was practical under the circumstances (*i.e.,* within the context of the changes proposed in this rule).

This proposed rule does not contain an exemption for small businesses from the proposed Section 232 exclusions process changes because these controls are essential to U.S. national security and BIS' regulations apply to all parties. An exemption for small businesses would undermine the effectiveness of these proposed changes.

Conclusion

BIS has identified proposed changes to the Section 232 exclusions process. Consequently, consistent with the Regulatory Flexibility Act, BIS has prepared this IRFA addressing the impact that this proposed rule, if adopted, would have on small entities. BIS's assessment indicates that the amendments proposed in this rule would not have a significant economic impact on a substantial number of small entities.

Please submit any comments concerning this IRFA in accordance with the instructions provided in the **ADDRESSES** section of this proposed rule.

List of Subjects in 15 CFR Part 705

Administrative practice and procedure, Business and industry, Classified information, Confidential business information, Imports, Investigations, National security.

For the reasons set forth in the preamble, part 705 of subchapter A of

15 CFR chapter VII is amended as follows:

PART 705—EFFECT OF IMPORTED ARTICLES ON THE NATIONAL SECURITY

■ 1. The authority citation for part 705 continues to read as follows:

Authority: Section 232 of the Trade Expansion Act of 1962, as amended (19 U.S.C. 1862) and Reorg. Plan No. 3 of 1979 (44 FR 69273, December 3, 1979).

■ 2. Section 705.1 is revised to read as follows:

§ 705.1 Definitions.

Applicant means the person or entity submitting a request or application for an investigation pursuant to this part.

Department means the United States Department of Commerce and includes the Secretary of Commerce and the Secretary's designees.

Secretary means the Secretary of Commerce or the Secretary's designees.

■ 3. Supplement no. 1 to part 705 is amended by:

■ a. Revising paragraphs I and (d);

■ b. Revising paragraph (h) introductory text; and

■ c. Adding paragraph (h)(2)(v).

The revisions and addition read as follows:

Supplement No. 1 to Part 705—Requirements for Submissions Requesting Exclusions From the Adjustment of Imports of Aluminum and Steel Imposed Pursuant to Section 232 of the Trade Expansion Act of 1962, as Amended

* * * * *

(c) *Exclusion requests*—(1) *Who may submit an exclusion request?* Only directly affected individuals or organizations located in the United States may submit an exclusion request. An individual or organization is ''directly affected'' if they are using aluminum or steel in business activities (*e.g.,* construction, manufacturing, or supplying aluminum or steel product to users) in the United States.

(2) *Identification of exclusion requests.* Separate exclusion requests must be submitted for steel products with chemistry by percentage breakdown by weight, metallurgical properties, surface quality (*e.g.,* galvanized, coated), and critical dimensions covered by a common HTSUS statistical reporting number. Separate exclusion requests must be submitted for aluminum products with critical dimensions covered by a common HTSUS statistical reporting number. The exclusion request forms allow for minimum and maximum dimensions. A permissible range must be within the minimum and maximum range that is specified in the HTSUS statistical reporting number and applicable notes. Separate exclusion requests must also be submitted for products falling in more than one ten-digit HTSUS statistical reporting number. BIS will approve exclusions on a product basis, and the approvals will be limited to the individual or organization that submitted the specific exclusion request, unless BIS approves a broader application of the product-based exclusion request to apply to additional importers. Other directly affected individuals or organizations located in the United States that wish to submit an exclusion request for a steel or aluminum product that has already been the subject of an approved exclusion request may submit an exclusion request under this supplement. These additional exclusion requests by other directly affected individuals or organizations in the United States are not required to reference the previously approved exclusion but are advised to do so if they want BIS to take that exclusion into account when reviewing a subsequent exclusion request. Directly affected individuals and organizations in the United States will not be precluded from submitting a request for exclusion of a product even though an exclusion request submitted for that product by another requester or that requester was denied or is no longer valid.

(3) *Where to submit exclusion requests?* All exclusion requests must be submitted directly on the Section 232 Exclusions Portal (*https://www.commerce.gov/page/section-232-investigations*).

(4) *No time limit for submitting exclusion requests.* Exclusion requests may be submitted at any time.

(5)(i) *Substance of exclusion requests.* An exclusion request must specify the business activities in the United States within which the requester is engaged that qualify the individual or organization to be directly affected and thus eligible to submit an exclusion request. The request should clearly identify, and provide support for, the basis upon which the exclusion is sought. An exclusion will only be granted if an article is not produced in the United States in a sufficient and reasonably available amount, or of a satisfactory quality, or based upon specific national security considerations.

(ii) *Certification for volume requested.* Effective for all Exclusion Requests, the undersigned certifies in the Section 232 Exclusions Portal that the information herein supplied in response to this questionnaire is complete and correct to the best of his/her knowledge. By signing the certification below, I attest that:

(A) My organization intends to manufacture, process, or otherwise transform the imported product for which I have filed an exclusion request, or I have a purchase order or orders for such products;

(B) I have personal knowledge or a well-informed basis to state that my organization has in good faith, within the past 12 months from submission of this request, first made reasonable efforts to source the requested product from the United States and then, if unsuccessful in sourcing from the United States, made reasonable efforts to source the requested product from a country with which the United States has arrived at a satisfactory alternative means to address the threat to the national security under Section 232. Simultaneously with this submission, my organization is providing evidence of these sourcing attempts.

(C) My organization does not intend to use the exclusion for which I have filed an exclusion request, if granted, solely to hedge or arbitrage the price;

(D) My organization expects to consume, sell, or otherwise use the total volume of product across all my active exclusions and pending exclusion requests during my organization's business activities within the next calendar year;

(E) If my organization is submitting an exclusion request for a product for which we previously received an exclusion, I certify that my organization imported the full amount of our approved exclusion(s) last year or intended to import the full amount but could not due to one of the following reasons:

(1) Loss of contract(s);

(2) Unanticipated business downturns; or

(3) Other factors that were beyond my organization's control that directly resulted in less need for steel or aluminum articles; and

(F) I certify that the exclusion amount requested this year is the amount that my organization expects to import based on our current business outlook. If requested by the Department of Commerce, my organization shall provide documentation that justifies its assertions in this certification regarding its past and projected imports of steel or aluminum articles related to the past and current calendar year exclusion requests.

Note to paragrapI(c)(5)(i) and (ii): Any exclusion request that does not include

a certification made in accordance with paraIph (c)(5)(ii) or fully respond to a request for verification will be treated as an incomplete submission and will therefore be rejected.

(6) *Criteria used to review exclusion requests.* Except as provided for under supplements nos. 2 through 5 to this part, the U.S. Department of Commerce will review each exclusion request on a case-by-case basis to determine whether an article described in an exclusion request meets any of the following three criteria: the article is not produced in the United States in an amount that can be delivered in a time period equal to or less than the time needed for the requester to obtain the product from their foreign supplier, is not produced in the United States in a satisfactory quality, or for specific national security considerations. The burden is on the requester to show that the article is not produced in the United States in a sufficient and reasonably available amount or of a satisfactory quality. To provide additional context on the meaning and application of the criteria, paIraphs (c)(6)(i) through (iii) of this supplement define keys terms used in the review criteria. The U.S. Department of Commerce will use the same criteria identified inIragraphs (c)(6)(i) through (iii) of this supplement when determining whether it is warranted to approve broader product-based exclusions based on trends the Department may see over time with Section 232 submissions. Items for which a broader determination has been made will be identified in supplements no. 2 or 3 to part 705.

(i) *Not produced in the United States in a sufficient and reasonably available amount.* The exclusion review criterion ''Not produced in the United States in a sufficient and reasonably available amount'' means that the amount that is needed by the user requesting the exclusion is not available immediately in the United States to meet its specified business activities. Available ''immediately'' means that a product (whether it is currently being produced in the United States, or could be produced in the United States) can be produced and delivered by a U.S. producer ''within eight weeks'' from the receipt of a binding purchase order, or, if that is not possible, by a date earlier than the time required for the requester to obtain the entire quantity of the product from the requester's foreign supplier. Furthermore, to the extent that an objector can produce and deliver a portion, which is less than 100 percent, but ten percent or more, of the amount of steel or aluminum needed in the business activities of the user requesting the exclusion in the United States described in the exclusion request, the Department of Commerce may deny a requested exclusion for that percentage of imported steel or aluminum. It is incumbent upon both the exclusion requester, and objecting producers, to provide evidence supporting their claimed delivery times.

(ii) *Not produced in the United States in a satisfactory quality.* The exclusion review criterion ''not produced in the United States in a satisfactory quality'' does not mean the steel or aluminum needs to be identical, but it does need to be equivalent as a substitute product. ''Substitute product'' for purposes of this review criterion means that the steel or aluminum being produced by an objector can meet ''immediately'' I*e* paragraph (c)(6)(i) of this supplement) the quality, regulatory, or testing standards for the U.S.-produced steel to be used in the business activity in the United States of the user requesting the exclusion.

(iii) *For specific national security considerations.* The exclusion review criterion ''or for specific national security considerations'' is intended to allow the U.S. Department of Commerce, in consultation with other parts of the U.S. Government as warranted, to make determinations whether a particular exclusion request or class of exclusion requests should be approved or denied based on specific national security considerations.

(d) *Objections to submitted exclusion requests*—(1) *Who may submit an objection to a submitted exclusion request?* Any individual or organization that manufactures steel or aluminum articles in the United States may file objections to steel or aluminum exclusion requests, but the U.S. Department of Commerce will only consider information directly related to the submitted exclusion request that is the subject of the objection.

(2) *Identification of objections to submitted exclusion requests.* When submitting an objection to a submitted exclusion request, the objector must locate the exclusion request and submit the objection in response to the request directly in the Section 232 Exclusions Portal. Once the relevant exclusion request has been located, an individual or organization that would like to submit an objection will access the objection form by scrolling to the bottom of the exclusion request form and then fill out the web-based form for submitting their objection to the exclusion request in the Section 232 Exclusions Portal (*https://www.commerce.gov/page/section-232-investigations*).

(3) *Time limit for submitting objections to submitted exclusions requests.* All objections to submitted exclusion requests must be submitted directly on the Section 232 Exclusions Portal (*https://www.commerce.gov/page/section-232-investigations*) no later than 30 days after the related exclusion request is posted, with the 30-day clock starting at 11:59 p.m. Eastern Time on the calendar day an exclusion request is posted.

(4) *Substance of objections to submitted exclusion requests.* The objection should clearly identify, and provide support for, its opposition to the proposed exclusion, with reference to the specific basis identified in, and the support provided for, the submitted exclusion request. The objector must be able to specifically identify from where and in what timeframe it can produce and deliver the requested product or a suitable substitute in the quantity requested and whether it can produce and deliver such product ''immediately'' with reference to the time required for the requester to obtain the product from its foreign suppliers. The objector must specifically identify from where and in what timeframe it will be able to produce and deliver to the requester the quantity of steel or aluminum requested. It is incumbent on both the exclusion requester, and the objecting producers, to accurately set forth the time needed for themselves or their supplier to produce and deliver the product or a suitable substitute product, from the receipt of a binding purchase order to ultimate delivery of the material to the domestic facility of the requester, and to provide supplemental evidence supporting these claimed timeframes. If the objector does not currently produce the requested steel or aluminum product, but anticipates starting or restarting production of the product or its substitute in the future, the objector must provide as part of the objection a summary timeline that specifies the steps that will occur over the time needed to produce that steel or aluminum product. This information will assist not only the Department of Commerce in its review of the objection, but also the requester of the exclusion in determining whether to file a rebuttal to the objection. The above-specified timeframes are not considered CBI and must be reported where requested in the public objection form. Objections that do not include these timeframes in the public version will be rejected by BIS.

(5) *Certification of objection submitted.* Effective for all Objections, the undersigned certifies in the Section 232 Exclusions Portal that the

information herein supplied in response to this questionnaire is complete and correct to the best of his/her knowledge. By signing the certification below, I attest that:

(i) My organization currently manufactures the requested product at a facility in the United States and, in response to a written request by the requester occurring within the year, will offer to sell and make 'immediately available' to the requester the full quantity of the product at then-existing market rates and terms and in accordance with the other terms in this Objection.

(ii) Simultaneously with this objection, my organization is submitting evidence that it has commercially sold the same product as that which is being requested within the last 12 months, or evidence that it has engaged in sales discussions with this requesting company or company requesting the same product within the last 12 months.

* * * * *

(h) Disposition of Section 232 submissions—

* * * * *

(2) * * *

(v) *Standard and scope of review.* The review of individual exclusion requests for products not covered by the categorical authorizations under supplements nos. 2 or 3, by exclusions denials under supplements nos. 4 and 5, or decided for national security considerations, will be made on a case-by-case basis to determine whether, consistent with these regulations, the requester has shown that the subject article should be excluded from the tariffs imposed by Section 232.

* * * * *

■ 4. Supplement No. 4 to part 705 is added to read as follows:

Supplement No. 4 to Part 705—General Denied Exclusions (GDEs) for Steel Articles Under the Section 232 Exclusions Process

This supplement identifies certain steel articles for import for which no request for exclusion from the Section 232 tariffs will be granted or considered by Commerce because requests to exclude these articles are covered by a General Denied Exclusion (GDE). The Secretary of Commerce, in consultation with the Secretary of Defense, the Secretary of the Treasury, the Secretary of State, the United States Trade Representative, the Assistant to the President for Economic Policy, the Assistant to the President for National Security Affairs, and other senior Executive Branch officials as appropriate, makes these determinations that certain steel articles may be excluded from the Section 232 exclusions process under a GDE consistent with the objectives of the Section 232 Exclusions Process as outlined in supplement no. 1 to this part. The GDEs described in this supplement apply to any exclusion requester. GDEs do not include quantity limits. Each GDE identifier will be effective fifteen calendar days after publication of a **Federal Register** notice either adding or revising a specific GDE identifier. For exclusion requests already in the portal at the time a **Federal Register** notice is published identifying a new GDE and up until the effective date of the new GDE, the Section 232 Exclusions Portal will still allow for the submission of objections for these steel articles. The Commerce review of such exclusion requests will be informed by the fact that these steel articles will soon be identified as GDEs. Once a GDE becomes effective, the Section 232 Exclusion Portal will prohibit persons from being able to submit exclusion requests for these identified GDEs. These GDEs are indefinite in length, but the Department of Commerce on behalf of the Secretary of Commerce may at any time issue a **Federal Register** notice removing, revising or adding to an existing GDE in this supplement as warranted to align with the objectives of the Section 232 exclusions process as described in supplement no. 1 to this part. GDEs are limited to steel articles that have consistently not been approved for exclusions under the Section 232 exclusions. The Department of Commerce on behalf of the Secretary of Commerce may periodically publish notices of inquiry in the **Federal Register** soliciting public comments on potential removals, revisions or additions to this supplement.

GDE Identifier.	Description of Steel That May Not Be Requested in an Exclusion Request (at 10-digit Harmonized Tariff Schedule of the United States (HTSUS) statistical reporting number or more narrowly defined at product level).	Other Limitations.	**Federal Register** Citation.

■ 4. Supplement No. 5 to part 705 is added to read as follows:

Supplement No. 5 to Part 705—General Denied Exclusions (GDEs) for Aluminum Articles Under the Section 232 Exclusions Process

This supplement identifies aluminum articles that may not be included in the Section 232 exclusion requests because these articles have been denied from import under a General Denied Exclusion (GDE). The Secretary of Commerce, in consultation with the Secretary of Defense, the Secretary of the Treasury, the Secretary of State, the United States Trade Representative, the Assistant to the President for Economic Policy, the Assistant to the President for National Security Affairs, and other senior Executive Branch officials as appropriate, makes these determinations that certain aluminum articles are excluded from the Section 232 exclusions process by being identified under a GDE consistent with the objectives of the Section 232 exclusions process as outlined in supplement no. 1 to this part. GDEs are limited to aluminum articles that have consistently not been approved for exclusions under the Section 232 exclusions. Because these aluminum articles have consistently not been approved, it has been determined by the relevant agencies to be warranted to exclude these identified articles from the Section 232 exclusions process. Inclusion of these articles as GDEs will ease the burden on objectors from having to review exclusions requesters where it has already been demonstrated consistently that such articles should not be approved in exclusion requests. The GDEs described in this supplement apply to any exclusion requester. GDEs do not include quantity limits. Each GDE identifier will be effective fifteen calendar days after publication of a **Federal Register** notice either adding or revising a specific GDE identifier. For exclusion requests already in process at the time a **Federal Register** notice is published identifying a new GDE and up until the effective date of the new GDE, the Section 232 Exclusions Portal will still allow for the submission of exclusion requests for these aluminum articles. The Commerce review of such exclusion requests will be informed by the fact that these aluminum articles will soon be identified as GDEs. Once a GDE becomes effective, the Section 232

Exclusion Portal will prohibit persons from being able to submit exclusion requests for these identified GDEs. These GDEs are indefinite in length, but the Department of Commerce on behalf of the Secretary of Commerce may at any time issue a **Federal Register** notice removing, revising or adding to an existing GDE in this supplement as warranted to align with the objectives of the Section 232 exclusions process as described in supplement no. 1 to this part. The Department of Commerce on behalf of the Secretary of Commerce may periodically publish notices of inquiry in the **Federal Register** soliciting public comments on potential removals, revisions or additions to this supplement.

GDE Identifier.	Description of Aluminum That May Not Be Requested in an Exclusion Request (at 10-digit Harmonized Tariff Schedule of the United States (HTSUS) statistical reporting number or more narrowly defined at product level).	Other Limitations.	**Federal Register** Citation.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2023–18328 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–33–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2022–0925; FRL–10943–01–R9]

Air Quality Implementation Plan; California; Great Basin Unified Air Pollution Control District; Stationary Source Permits

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the Great Basin Unified Air Pollution Control District (GBUAPCD or ''District'') portion of the California State Implementation Plan (SIP). In this action, we are proposing to approve one rule governing the issuance of permits for new and modified major sources in nonattainment areas under part D of title I of the Clean Air Act (CAA or ''the Act'') in the District. We are also proposing to find that PM_{10} precursors are not significant contributors to PM_{10} levels in the Mono Basin, as the majority of direct PM emissions come from dry lake beds. We are taking comments on this proposal and a final action will follow.

DATES: Written comments must be received on or before September 27, 2023.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R09–OAR–2022–0925 at *https://www.regulations.gov*. For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be removed or edited from *Regulations.gov*. For either manner of submission, the EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.,* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section. For the full EPA public comment policy, information about CBI and multimedia submissions, and general guidance on making effective comments, please visit *https://www2.epa.gov/dockets/commenting-epa-dockets*. 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: Nidia Trejo, EPA Region IX, 75 Hawthorne St., San Francisco, CA 94105. By phone: (415) 972–3968, or by email at *trejo.nidia@epa.gov*.

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

Table of Contents

I. The State's Submittal

A. What rule did the State submit?

Table 1 lists the rule addressed by this proposal including the date it was adopted by the District and the date on which it was submitted to the EPA by the California Air Resources Board (CARB or ''the State'').

TABLE 1—SUBMITTED RULE

Rule No.	Rule title	Adopted	Submitted
Rule 222	NSR Requirements for New and Modified Major Sources in Nonattainment Areas.	01/06/22	07/05/22

On January 5, 2023, the submittal for District Rule 222 was deemed by operation of law to meet the completeness criteria in 40 CFR part 51, appendix V, which must be met before formal EPA review.

B. Is there another version of this rule?

There is no previous version of Rule 222 in the California SIP.

C. What is the purpose of the submitted rule?

Rule 222 is intended to address the CAA's statutory and regulatory requirements for Nonattainment New Source Review (NNSR) permit programs for major sources emitting nonattainment air pollutants and their precursors.

II. The EPA's Evaluation

A. What is the background for this proposal?

Historically, the District had four designated PM_{10} nonattainment areas, including the Owens Valley and Coso Junction Planning Areas in Inyo County, CA, and the Mono Basin and Mammoth Lake Planning Areas in Mono County, CA. Currently, however, only the Mono Basin and Owens Valley Planning Areas are designated nonattainment for PM_{10}. The designation of the Mono Basin and Owens Valley Planning Areas as federal PM_{10} nonattainment areas triggered the requirement for the District to develop and submit an NNSR program to the EPA for approval into the California SIP. The District's NNSR program must satisfy the NNSR requirements applicable to a Moderate PM_{10} nonattainment area for the Mono Basin and a Serious PM_{10} nonattainment area for the Owens Valley.

Our Technical Support Document (TSD) for this action contains additional information regarding the history of the District's PM_{10} nonattainment areas. The District is designated attainment/unclassifiable for all other NAAQS.

B. How is the EPA evaluating the rule?

The EPA reviewed Rule 222 for compliance with CAA requirements for: (1) stationary source preconstruction permitting programs as set forth in CAA part D, including CAA sections 172(c)(5) and 173; (2) the review and modification of major sources in accordance with 40 CFR 51.160–51.165 as applicable in Moderate and Serious PM_{10} nonattainment areas; (3) the review of new major stationary sources or major modifications in a designated nonattainment area that may have an impact on visibility in any mandatory Class I Federal area in accordance with 40 CFR 51.307; (4) SIPs in general as set forth in CAA sections 110(a)(2), including 110(a)(2)(A) and 110(a)(2)(E)(i);[1] and (5) SIP revisions as set forth in CAA section 110(l)[2] and 193.[3] Our review evaluated the submittals for compliance with the NNSR requirements applicable to nonattainment areas designated Moderate and Serious, and ensured that the submittals addressed the NNSR requirements for the 1987 PM_{10} NAAQS.

C. Does the rule meet the evaluation criteria?

With respect to procedural requirements, CAA sections 110(a)(2) and 110(l) require that revisions to a SIP be adopted by the state after reasonable notice and public hearing. Based on our review of the public process documentation included in the July 5, 2022 submittal of Rule 222, we find that the District has provided sufficient evidence of public notice, opportunity for comment, and a public hearing prior to adoption and submittal of this rule to the EPA.

With respect to the substantive requirements found in CAA sections 172(c)(5), 173, 189 and 40 CFR 51.160–51.165, we have evaluated Rule 222 in accordance with the applicable CAA and regulatory requirements that apply to NNSR permit programs under part D of title I of the Act for the 1987 PM_{10} NAAQS. We find that Rule 222 satisfies these requirements as they apply to sources subject to NNSR permit program requirements applicable to Moderate and Serious PM_{10} nonattainment areas. As part of our determination, we relied on a previous finding from our 2016 final action approving the Owens Valley 1987 PM_{10} attainment plan that PM_{10} precursors are not significant contributors to PM_{10} in the area,[4] and a comparative analysis of emission sources in the Mono Basin to determine that PM_{10} precursors are also not significant contributors to PM_{10} in the Mono Basin.[5]

We have also determined that this rule satisfies the related visibility requirements in 40 CFR 51.307. In addition, we find that Rule 222 satisfies the requirement in CAA section 110(a)(2)(A) that regulations submitted to the EPA for SIP approval be clear and legally enforceable and that the submittal demonstrates in accordance with CAA section 110(a)(2)(E)(i) that the Districts have adequate personnel, funding, and authority under state law to carry out the proposed SIP revision.

Regarding the additional substantive requirements of CAA sections 110(l) and 193, our action will result in a more stringent SIP, while not relaxing any existing provision contained in the SIP. We have concluded that our action would comply with section 110(l) because our approval of Rule 222 will not interfere with any applicable requirement concerning attainment and reasonable further progress, or any other CAA applicable requirement. In addition, our approval of Rule 222 will not relax any pre-November 15, 1990 requirement in the SIP, and therefore changes to the SIP resulting from this action ensure greater or equivalent emission reductions of PM_{10} and its precursors in the District; accordingly, our action is consistent with the requirements of CAA section 193.

Our TSD, which can be found in the docket for this rule, contains a more detailed discussion of our analysis of Rule 222.

D. EPA Recommendations To Further Improve the Rule

The TSD also includes recommendations for an additional clarifying revision to consider for adoption when the District next modifies Rule 222.

III. Proposed Action and Public Comment

As authorized in sections 110(k)(3) and 301(a) of the Act, the EPA is proposing approval of the submitted rule because it fulfills the relevant CAA requirements and strengthens the SIP. We have concluded that our approval of the submitted rule would comply with the relevant provisions of CAA sections 110(a)(2), 110(l), 172(c)(5), 173, 189, and 193, and 40 CFR 51.160–51.165 and 40 CFR 51.307.

If we finalize this action as proposed, our action will be codified through revisions to 40 CFR 52.220a (Identification of plan—in part). This action would incorporate the submitted rule into the SIP. In conjunction with the EPA's SIP approval of the District's visibility provisions for sources subject to the NNSR program as meeting the relevant requirements of 40 CFR 51.307, this action would also revise the

[1] CAA section 110(a)(2)(A) requires that regulations submitted to the EPA for SIP approval be clear and legally enforceable, and CAA section 110(a)(2)(E)(i) requires that states have adequate personnel, funding, and authority under state law to carry out their proposed SIP revisions.

[2] CAA section 110(l) requires SIP revisions to be subject to reasonable notice and public hearing prior to adoption and submittal by states to EPA and prohibits EPA from approving any SIP revision that would interfere with any applicable requirement concerning attainment and reasonable further progress, or any other applicable requirement of the CAA.

[3] CAA section 193 prohibits the modification of any SIP-approved control requirement in effect before November 15, 1990, in a nonattainment area, unless the modification ensures equivalent or greater emission reductions of the relevant pollutants.

[4] 82 FR 13390, (March 13, 2017). *See* also 81 FR 89407, (December 12, 2016).

[5] See GBUAPCD 1995 PM_{10} State Implementation Plan for Mono Basin Planning Area, Table 4.1—PM_{10} Emissions Summary; see also 82 FR 13390 (Mar. 13, 2017).

regulatory provision at 40 CFR 52.281(d) concerning the applicability of the visibility Federal Implementation Plan (FIP) at 40 CFR 52.28 as it pertains to California, to provide that this FIP does not apply to sources subject to review under the District's SIP-approved NNSR program.

We will accept comments from the public on this proposal until September 27, 2023.

IV. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the GBUAPCD rule listed in Table 1 of this preamble, which regulates the issuance of permits for new and modified major sources in nonattainment areas in the District. The EPA has made, and will continue to make, this document available electronically through *https://www.regulations.gov* and in hard copy 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

Under the Clean Air Act, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the Clean Air Act. Accordingly, this proposed action merely proposes to approve state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed 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 14094 (88 FR 21879, April 11, 2023);
- 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 subject to Executive Order 13045 (62 FR 19885, April 23, 1997) because it proposes to approve a state program;
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001); and
- 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 Clean Air Act.

In addition, 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. 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).

Executive Order 12898 (Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations, 59 FR 7629, Feb. 16, 1994) directs Federal agencies to identify and address ''disproportionately high and adverse human health or environmental effects'' of their actions on minority populations and low-income populations to the greatest extent practicable and permitted by law. The EPA defines environmental justice (EJ) as ''the fair treatment and meaningful involvement of all people regardless of race, color, national origin, or income with respect to the development, implementation, and enforcement of environmental laws, regulations, and policies.'' The EPA further defines the term fair treatment to mean that ''no group of people should bear a disproportionate burden of environmental harms and risks, including those resulting from the negative environmental consequences of industrial, governmental, and commercial operations or programs and policies.''

The District did not evaluate environmental justice considerations as part of its SIP submittal; the CAA and applicable implementing regulations neither prohibit nor require such an evaluation. The EPA did not perform an EJ analysis and did not consider EJ in this action. Consideration of EJ is not required as part of this action, and there is no information in the record inconsistent with the stated goals of E.O. 12898 of achieving environmental justice for people of color, low-income populations, and indigenous peoples.

List of Subjects in 40 CFR Part 52

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

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

Dated: August 17, 2023.

Cheree Peterson,

Deputy Regional Administrator, Region IX.

[FR Doc. 2023–18401 Filed 8–25–23; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 25

[IB Docket No. 21–456; Report No. 3200; FR ID 166483]

Petition for Reconsideration of Action in Rulemaking Proceeding

AGENCY: Federal Communications Commission.

ACTION: Petition for Reconsideration.

SUMMARY: Petition for Reconsideration (Petition) has been filed in the Commission's proceeding by Kimberly Baum, on behalf of WorldVu Satellites Limited.

DATES: Oppositions to the Petition must be filed on or before September 12, 2023. Replies to oppositions must be filed on or before September 22, 2023.

ADDRESSES: Federal Communications Commission, 45 L Street NE, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Clay DeCell at (202) 418–0803 or *Clay.DeCell@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, Report No. 3200, released August 22, 2023. The full text of the Petition can be accessed online via the Commission's Electronic Comment Filing System at: *https://apps.fcc.gov/ecfs/*. The Commission will not send a Congressional Review Act (CRA) submission to Congress or the Government Accountability Office pursuant to the CRA, 5 U.S.C. 801(a)(1)(A), because no rules are being adopted by the Commission.

Subject: In the Matter of Revising Spectrum Sharing Rules for Non-Geostationary Orbit, Fixed-Satellite Service Systems (IB Docket No. 21–456).

Number of Petitions filed: 1.

Federal Communications Commission.

Katura Jackson,

Federal Register Liaison Officer.

[FR Doc. 2023–18417 Filed 8–25–23; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 88, No. 165
Monday, August 28, 2023

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.

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

The Department of Agriculture has submitted the following information collection requirement(s) to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. Comments are requested regarding: whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; ways to enhance the quality, utility and clarity of the information to be collected; and ways to 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 Comments regarding these information collections are best assured of having their full effect if received by September 27, 2023. Written comments and recommendations for the proposed information collection should be submitted within 30 days of the publication of this notice on the following website *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.

An agency may not conduct or sponsor a collection of information unless the collection of information displays a currently valid OMB control number and the agency informs potential persons who are to respond to the collection of information that such persons are not required to respond to the collection of information unless it displays a currently valid OMB control number.

Agricultural Marketing Service

Title: Tobacco Reports.

OMB Control Number: 0581–0004.

Summary of Collection: The authority for the mandatory collection of information on Form TB–26, Tobacco Stocks Report, is Public Law 661, commonly known as the Tobacco Statistics Act (7 U.S.C. 501–508) enacted in 1929. The Act directs the Department of Agriculture (USDA), to collect statistics on the quantities of leaf tobacco held by dealers and manufacturers in the United States and Puerto Rico.

The Agricultural Marketing Act of 1946 (7 U.S.C. 1621–1627) directs and authorizes USDA to collect, tabulate, and disseminate statistics on marketing agricultural products including market supplies, storage stocks, quantity, quality and condition of such products in various positions in the marketing channel, utilization of sub-products, shipment, and unloads.

Need and Use of the Information: The basic purpose of the information collection is to ascertain the total supply of unmanufactured tobacco available to domestic manufacturers and to calculate the amount consumed in manufactured tobacco products. This data is also used for the calculation of production quotas for individual types of tobacco and for price support calculations. Without the information, USDA would not be able to disseminate marketing information as directed and authorized in the Act.

Description of Respondents: Business or other for-profit.

Number of Respondents: 44.

Frequency of Responses: Reporting: Quarterly; Annually.

Total Burden Hours: 156.

Levi S. Harrell,

Departmental Information Collection Clearance Officer.

[FR Doc. 2023–18467 Filed 8–25–23; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2021–0075]

Notice of Availability of Pest Risk Analysis for the Importation of Ugu Leaves (Telfairia occidentalis Hook.f.) From Nigeria Into the Continental United States

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: We are advising the public that we have prepared a pest risk analysis that evaluates the risks associated with importation of fresh Ugu leaves (*Telfairia occidentalis* Hook.f) from Nigeria into the continental United States. Based on the analysis, we have determined that the application of one or more designated phytosanitary measures will be sufficient to mitigate the risks of introducing or disseminating plant pests or noxious weeds via the importation of fresh Ugu leaves from Nigeria. We are making the pest risk analysis available to the public for review and comment.

DATES: We will consider all comments that we receive on or before October 27, 2023.

ADDRESSES: You may submit comments by either of the following methods:

- *Federale Rulemaking Portal:* Go to *www.regulations.gov.* Enter APHIS–2021–0075 in the Search field. Select the Documents tab, then select the Comment button in the list of documents.
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2021–0075, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road, Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at*www.regulations.gov*or in our reading room, whichis located inroom 1620of the USDA South Building, 14th Street and Independence Avenue SW, Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Mr. Hesham Abuelnaga, Senior Regulatory Policy Specialist, Regulatory Coordination and Compliance, PPQ, APHIS, 4700 River Road, Unit 133, Riverdale, MD 20737–1231; (301) 851–2010; email: *Hesham.A.Abuelnaga@usda.gov.*

SUPPLEMENTARY INFORMATION:

Background

Under the regulations in ''Subpart L–Fruits and Vegetables'' (7 CFR 319.56–1 through 319.56–12, referred to below as the regulations), the Animal and Plant Health Inspection Service (APHIS) prohibits or restricts the importation of fruits and vegetables into the United States from certain parts of the world to prevent plant pests from being introduced into or disseminated within the United States.

Section 319.56–4 contains a performance-based process for approving the importation of fruits and vegetables that, based on the findings of a pest risk analysis, can be safely imported subject to one or more of the five designated phytosanitary measures listed in paragraph (b) of that section.

APHIS received a request from the national plant protection organization of Nigeria to allow importation of fresh Ugu leaves (*Telfairia occidentalis* Hook.f) from Nigeria into the continental United States. As part of our evaluation of Nigeria's request, we have prepared a pest risk assessment (PRA) to identify the pests of quarantine significance that could follow the pathway of the importation of fresh Ugu leaves from Nigeria into the continental United States. Based on the PRA, a risk management document (RMD) was prepared to identify phytosanitary measures that could be applied to the fresh Ugu leaves to mitigate the pest risk.

Therefore, in accordance with § 319.56–4(c), we are announcing the availability of our PRA and RMD for public review and comment. Those documents, as well as a description of the economic considerations associated with the importation of fresh Ugu leaves (*Telfairia occidentalis* Hook.f) from Nigeria, may be viewed on the *Regulations.gov* website or in our reading room (see **ADDRESSES** above for a link to *Regulations.gov* and information on the location and hours of the reading room). You may request paper copies of the PRA and RMD by calling or writing to the person listed under **FOR FURTHER INFORMATION CONTACT**. Please refer to the subject of the analysis you wish to review when requesting copies.

After reviewing any comments we receive, we will announce our decision regarding the import status of fresh Ugu leaves from Nigeria in a subsequent notice. If the overall conclusions of our analysis and the Administrator's determination of risk remain unchanged following our consideration of the comments, then we will authorize the importation of fresh Ugu leaves from Nigeria into the continental United States subject to the requirements specified in the RMD.

Authority: 7 U.S.C. 1633, 7701–7772, and 7781–7786; 21 U.S.C. 136 and 136a; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 23rd day of August 2023.

Michael Watson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2023–18521 Filed 8–25–23; 8:45 am]

BILLING CODE 3410–34–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Texas Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of virtual business 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 (FACA) that the Texas Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a series virtual business meeting via ZoomGov on the following dates listed below. These virtual business meetings are for the purpose of discussing the full report on mental health care in the Texas Juvenile Justice Department.

DATES: These meetings will take place on:

- Wednesday, October 11, 2023, from 12:00 p.m.–1:00 p.m. CT
- Tuesday, November 14, 2023, from 12:00 p.m.–1:00 p.m. CT
- Wednesday, December 6, 2023, from 12:00 p.m.–1:00 p.m. CT

Link to Join *(Audio/Visual):*

- Wednesday, October 11 *https://www.zoomgov.com/meeting/register/vJIsc--gqz0sHW0jtmQOTViKkuZUxISqCrA*
- Tuesday, November 14 *https://www.zoomgov.com/meeting/register/vJIscumorzIvG-XIS06yLZrunTp6mhst8zw*
- Wednesday, December 6 *https://www.zoomgov.com/meeting/register/vJIsceioqz8tHrU83OV83jfcAsmVjo0CyWA*

FOR FURTHER INFORMATION CONTACT: Brooke Peery, Designated Federal Officer (DFO) at *bpeery@usccr.gov* or by phone at (202) 701–1376.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the videoconference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Per the Federal Advisory Committee Act, public minutes of the meeting will include a list of persons who are present at the meeting. If joining via phone, 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. Closed captioning will be available for individuals who are deaf, hard of hearing, or who have certain cognitive or learning impairments. To request additional accommodations, please email Angelica Trevino, Support Services Specialist, *atrevino@usccr.gov* at least 10 business days prior to the meeting.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be emailed to Brooke Peery (DFO) at *bpeery@usccr.gov.*

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzkoAAA.*

Please click on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome & Roll Call

II. Approval of Minutes

III. Committee Discussion

IV. Public Comment

V. Adjournment

Dated: August 22, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–18418 Filed 8–25–23; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Texas Advisory Committee

AGENCY: Commission on Civil Rights.

ACTION: Announcement of virtual business meeting.

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 (FACA) that the Texas Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a virtual business meeting via ZoomGov on Tuesday, September 12, 2023, from 12:00 p.m.–1:00 p.m. Central Time, for the purpose of discussing the full report on mental health care in the Texas Juvenile Justice Department.

DATES: The meeting will take place on:

• Tuesday, September 12, 2023, from 12:00 p.m.–1:00 p.m. CT.

Link to Join *(Audio/Visual)https://www.zoomgov.com/meeting/register/vJIscemoqTsjGs5PRglrjEkuLv4vgrYP3Pg.*

FOR FURTHER INFORMATION CONTACT: Brooke Peery, Designated Federal Officer (DFO) at *bpeery@usccr.gov* or by phone at (202) 701–1376.

SUPPLEMENTARY INFORMATION: Committee meetings are available to the public through the videoconference link above. Any interested member of the public may listen to the meeting. An open comment period will be provided to allow members of the public to make a statement as time allows. Per the Federal Advisory Committee Act, public minutes of the meeting will include a list of persons who are present at the meeting. If joining via phone, 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. Closed captioning will be available for individuals who are deaf, hard of hearing, or who have certain cognitive or learning impairments. To request additional accommodations, please email Angelica Trevino, Support Services Specialist, *atrevino@usccr.gov* at least 10 business days prior to the meeting.

Members of the public are entitled to make comments during the open period at the end of the meeting. Members of the public may also submit written comments; the comments must be received in the Regional Programs Unit within 30 days following the meeting. Written comments may be emailed to Brooke Peery (DFO) at *bpeery@usccr.gov.*

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at *https://www.facadatabase.gov/FACA/FACAPublicViewCommitteeDetails?id=a10t0000001gzkoAAA.*

Please click on the ''Meeting Details'' and ''Documents'' links. Records generated from this meeting may also be inspected and reproduced at the Regional Programs Unit, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's website, *https://www.usccr.gov,* or may contact the Regional Programs Unit at the above email or street address.

Agenda

I. Welcome & Roll Call

II. Approval of Minutes

III. Committee Discussion

IV. Public Comment

V. Adjournment

Dated: August 22, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–18422 Filed 8–25–23; 8:45 am]

BILLING CODE P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Arizona Advisory Committee; Correction

AGENCY: Commission on Civil Rights.

ACTION: Notice; update meeting date.

SUMMARY: The Commission on Civil Rights published a notice in the **Federal Register** on Monday, August 7, 2023, concerning a meeting of the Arizona Advisory Committee. The meeting date has since changed.

FOR FURTHER INFORMATION CONTACT: Kayla Fajota (DFO), *kfajota@usccr.gov,* (312) 353–8311.

Correction: In the **Federal Register** on Monday, August 7, 2023, in FR Document Number 2023–16718, on page 52113, first and second columns, change the meeting date from August 24, 2023, to September 29, 2023.

In addition, the link to join will remain the same: *https://www.zoomgov.com/meeting/register/vJItduqtqD0rE4n GesqlMb5mPc5Zrgawg2w.*

Dated: August 22, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–18423 Filed 8–25–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–30–2023]

Foreign-Trade Zone (FTZ) 7; Authorization of Production Activity; AbbVie Ltd.; (Pharmaceutical Products); Barceloneta, Puerto Rico

On April 25, 2023, AbbVie Ltd., submitted a notification of proposed production activity to the FTZ Board for its facility within Subzone 7I, in Barceloneta, Puerto Rico.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (88 FR 27860—27861, May 3, 2023). On August 23, 2023, the applicant was notified of the FTZ Board's decision that no further review of the activity is warranted at this time. The production activity described in the notification was authorized, subject to the FTZ Act and the FTZ Board's regulations, including section 400.14.

Dated: August 23, 2023.

Elizabeth Whiteman,

Executive Secretary.

[FR Doc. 2023–18466 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

In the Matter of:

Esteban Andres Alexander,
Inmate Number: 25471–509,
FCI El Reno,
Federal Correctional Institution,
P.O. Box 1500,
El Reno, OK 73036; Order Denying Export Privileges

On March 8, 2022, in the U.S. District Court for the Eastern District of Texas, Esteban Andres Alexander (''Alexander'') was convicted of violating 18 U.S.C. 371. Specifically, Alexander was convicted of conspiring to export firearms and firearms parts from the United States to Mexico without first having obtained the required export license and authorization from the U.S. Department of State or U.S. Department of Commerce. As a result of his conviction,

the Court sentenced Alexander to 46 months of imprisonment, three years of supervised release, $10,000 criminal fine and a $100 assessment.

Pursuant to Section 1760(e) of the Export Control Reform Act (''ECRA''),[1] the export privileges of any person who has been convicted of certain offenses, including, but not limited to, 18 U.S.C. 371, may be denied for a period of up to ten (10) years from the date of his/her conviction. 50 U.S.C. 4819(e). In addition, any Bureau of Industry and Security (''BIS'') licenses or other authorizations issued under ECRA, in which the person had an interest at the time of the conviction, may be revoked. *Id.*

BIS received notice of Alexander's conviction for violating 18 U.S.C. 371. As provided in Section 766.25 of the Export Administration Regulations (''EAR'' or the ''Regulations''), BIS provided notice and opportunity for Alexander to make a written submission to BIS. 15 CFR 766.25.[2] BIS has not received a written submission from Alexander.

Based upon my review of the record and consultations with BIS's Office of Exporter Services, including its Director, and the facts available to BIS, I have decided to deny Alexander's export privileges under the Regulations for a period of 10 years from the date of Alexander's conviction. The Office of Exporter Services has also decided to revoke any BIS-issued licenses in which Alexander had an interest at the time of his conviction.[3]

Accordingly, it is hereby ordered:

First, from the date of this Order until March 8, 2032, Esteban Andres Alexander, with a last known address of Inmate Number: 25471–509, FCI El Reno, Federal Correctional Institution, P.O. Box 1500, El Reno, OK 73036, and when acting for or on his behalf, his successors, assigns, employees, agents or representatives (''the Denied Person''), may not directly or indirectly participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or engaging in any other activity subject to the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or from any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:

A. Export, reexport, or transfer (in-country) to or on behalf of the Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, pursuant to section 1760(e) of ECRA and sections 766.23 and 766.25 of the Regulations, any other person, firm, corporation, or business organization related to Alexander by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order in order to prevent evasion of this Order.

Fourth, in accordance with part 756 of the Regulations, Alexander may file an appeal of this Order with the Under Secretary of Commerce for Industry and Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of part 756 of the Regulations.

Fifth, a copy of this Order shall be delivered to Alexander and shall be published in the **Federal Register**.

Sixth, this Order is effective immediately and shall remain in effect until March 8, 2032.

John Sonderman,

Director, Office of Export Enforcement.

[FR Doc. 2023–18442 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–DT–P

[1] ECRA was enacted on August 13, 2018, as part of the John S. McCain National Defense Authorization Act for Fiscal Year 2019, and as amended is codified at 50 U.S.C. 4801–4852.

[2] The Regulations are currently codified in the Code of Federal Regulations at 15 CFR parts 730–774 (2022).

[3] The Director, Office of Export Enforcement, is the authorizing official for issuance of denial orders pursuant to amendments to the Regulations (85 *FR* 73411, November 18, 2020).

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Order Denying Export Privileges

On March 30, 2022, in the U.S. District Court for the Northern District of Illinois, Tuqiang Xie (''Xie'') was convicted of violating section 38 of the Arms Export Control Act (22 U.S.C. 2778) (''AECA''). Specifically, Xie was convicted of knowingly and willfully engaging in brokering activities involving the People's Republic of China in negotiating and arranging purchases, sales, transfers, export, and import of a defense article, namely an eyepiece assembly, National Stock Number 1240–01–063–1352, without first registering with, and obtaining a license or written approval from the U.S. Department of State. As a result of his conviction, the Court sentenced Xie to one year and one day in prison, one year of supervised release, an assessement of $200 and a preliminary order of forfeiture in the amount of $200,027.

Pursuant to section 1760(e) of the Export Control Reform Act (''ECRA''), the export privileges of any person who has been convicted of certain offenses, including, but not limited to, section 38 of the AECA, may be denied for a period of up to ten (10) years from the date of his/her conviction. *See* 50 U.S.C. 4819(e). In addition, any Bureau of Industry and Security (''BIS'') licenses or other authorizations issued under ECRA, in which the person had an

interest at the time of the conviction, may be revoked. *Id.*

BIS received notice of Xie's conviction for violating section 38 of the AECA. BIS provided notice and opportunity for Xie to make a written submission to BIS, as provided in section 766.25 of the Export Administration Regulations (''EAR'' or the ''Regulations''). 15 CFR 766.25.[2] BIS has not received a written submission from Xie.

Based upon my review of the record and consultations with BIS's Office of Exporter Services, including its Director, and the facts available to BIS, I have decided to deny Xie's export privileges under the Regulations for a period of 10 years from the date of Xie's conviction. The Office of Exporter Services has also decided to revoke any BIS-issued licenses in which Xie had an interest at the time of his conviction.[3]

Accordingly, it is hereby *ordered:*

First, from the date of this Order until March 30, 2032, Tuqiang Xie, with a last known address of 110 Espina, Irvine, CA 92620, and when acting for or on his behalf, his successors, assigns, employees, agents or representatives (''the Denied Person''), may not directly or indirectly participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or engaging in any other activity subject to the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or from any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:

A. Export, reexport, or transfer (in-country) to or on behalf of the Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, pursuant to section 1760(e) of ECRA (50 U.S.C. 4819(e)) and sections 766.23 and 766.25 of the Regulations, any other person, firm, corporation, or business organization related to Xie by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order in order to prevent evasion of this Order.

Fourth, in accordance with part 756 of the Regulations, Xie may file an appeal of this Order with the Under Secretary of Commerce for Industry and Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of part 756 of the Regulations.

Fifth, a copy of this Order shall be delivered to Xie and shall be published in the **Federal Register**.

Sixth, this Order is effective immediately and shall remain in effect until March 30, 2032.

John Sonderman,

Director, Office of Export Enforcement.

[FR Doc. 2023–18439 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–DT–P

[2] The Regulations are currently codified in the Code of Federal Regulations at 15 CFR parts 730–774 (2022).

[3] The Director, Office of Export Enforcement, is the authorizing official for issuance of denial orders, pursuant to amendments to the Regulations (85 *FR* 73411, November 18, 2020).

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

Materials and Equipment Technical Advisory Committee; Revised: Notice of Partially Closed Meeting

The Materials and Equipment Technical Advisory Committee will meet on September 7 and 8, 2023, at 1:00 p.m., Eastern Daylight Time, at the AC Hotel, 1333 Veterans Boulevard, South San Francisco, CA 94080. The Committee advises the Office of the Assistant Secretary for Export Administration with respect to technical questions that affect the level of export controls applicable to transportation and related equipment or technology. The purpose of the meeting is to have Committee members and U.S. Government representatives mutually review updated technical data and policy-driving information that has been gathered.

Agenda

September 7, 2023–1:00 p.m.–5:00 p.m. EST

Open Session

1. Opening Remarks and Introduction by BIS Senior Management.
2. Report from working groups.
3. Report by regime representatives.

September 8, 2023–1:00 p.m.–5:00 p.m. EST

Closed Session

4. Discussion of matters determined to be exempt from the open meeting and public participation requirements found in sections 1009(a)(1) and 1009(a)(3) of the Federal Advisory Committee Act (FACA) (5 U.S.C. 1001–1014). The exemption is authorized by section 1009(d) of the FACA, which permits the closure of advisory committee meetings, or portions thereof, if the head of the agency to which the advisory committee reports determines such meetings may be closed to the public in accordance with subsection (c) of the Government in the Sunshine Act (5 U.S.C. 552b(c)). In this case, the applicable provisions of 5 U.S.C. 552b(c) are subsection 552b(c)(4), which permits closure to protect trade secrets and commercial or financial information that is privileged

or confidential, and subsection 552b(c)(9)(B), which permits closure to protect information that would be likely to significantly frustrate implementation of a proposed agency action were it to be disclosed prematurely. The closed session of the meeting will involve committee discussions and guidance regarding U.S. Government strategies and policies.

The open session will be accessible via teleconference. To join the conference, submit inquiries to Yvette Springer at *Yvette.Springer@bis.doc.gov,* no later than September 4, 2023.

A limited number of seats will be available for the public session. Reservations are not accepted. To the extent time permits, members of the public may present oral statements to the Committee. The public may submit written statements at any time before or after the meeting. However, to facilitate distribution of public presentation materials to Committee members, the Committee suggests that presenters forward the public presentation materials prior to the meeting to Ms. Springer.

The Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on April 12, 2023, pursuant to 5 U.S.C. chapter 10 of the FACA, (5 U.S.C. 1009(d)), that the portion of the meeting dealing with pre-decisional changes to the Commerce Control List and the U.S. export control policies shall be exempt from the provisions relating to public meetings found in 5 U.S.C. 1009(a)(1) and 1009(a)(3). The remaining portions of the meeting will be open to the public.

For more information, contact Ms. Springer.

Yvette Springer,

Committee Liaison Officer.

[FR Doc. 2023–18440 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–JT–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

In the Matter of: Naomi Natal Haynes, Inmate Number: 19838–104, FCI Aliceville, P.O. Box 4000, Aliceville, AL 35442; Order Denying Export Privileges

On January 11, 2021, in the U.S. District Court for the Southern District of Florida, Naomi Natal Haynes (''Haynes'') was convicted of violating 18 U.S.C. 371. Specifically, Haynes was convicted of conspiring to fraudulently and knowingly export and send firearms from the United States to Canada without the required license. As a result of her conviction, the Court sentenced her to 84 months in prison, three years of supervised release, a $200 assessment and $18,240.18 Restitution.

Pursuant to Section 1760(e) of the Export Control Reform Act (''ECRA''),[1] the export privileges of any person who has been convicted of certain offenses, including, but not limited to, 18 U.S.C 371, may be denied for a period of up to ten (10) years from the date of his/her conviction. 50 U.S.C. 4819(e). In addition, any Bureau of Industry and Security (''BIS'') licenses or other authorizations issued under ECRA, in which the person had an interest at the time of the conviction, may be revoked. *Id.*

BIS received notice of Haynes conviction for violating 18 U.S.C 371. As provided in Section 766.25 of the Export Administration Regulations (''EAR'' or the ''Regulations''), BIS provided notice and opportunity for Haynes to make a written submission to BIS. 15 CFR 766.25.[2] BIS has not received a written submission from Haynes.

Based upon my review of the record and consultations with BIS's Office of Exporter Services, including its Director, and the facts available to BIS, I have decided to deny Haynes's export privileges under the Regulations for a period of 10 years from the date of Haynes's conviction. The Office of Exporter Services has also decided to revoke any BIS-issued licenses in which Haynes had an interest at the time of her conviction.[3]

Accordingly, it is hereby *ordered:*

First, from the date of this Order until January 11, 2031, Naomi Natal Haynes, with a last known address of Inmate Number: 19838–104, FCI Aliceville, P.O. Box 4000, Aliceville, AL 35442 and when acting for or on her behalf, her successors, assigns, employees, agents or representatives (''the Denied Person''), may not directly or indirectly participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as ''item'') exported or to be exported from the United States that is subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, license exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or engaging in any other activity subject to the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or from any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:

A. Export, reexport, or transfer (in-country) to or on behalf of the Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, pursuant to section 1760(e) of ECRA and sections 766.23 and 766.25 of the Regulations, any other person, firm, corporation, or business organization related to Haynes by ownership, control,

[1] ECRA was enacted on August 13, 2018, as part of the John S. McCain National Defense Authorization Act for Fiscal Year 2019, and as amended is codified at 50 U.S.C. 4801–4852.

[2] The Regulations are currently codified in the Code of Federal Regulations at 15 CFR parts 730–774 (2022).

[3] The Director, Office of Export Enforcement, is the authorizing official for issuance of denial orders pursuant to amendments to the Regulations (85 *FR* 73411, November 18, 2020).

position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order in order to prevent evasion of this Order.

Fourth, in accordance with part 756 of the Regulations, Haynes may file an appeal of this Order with the Under Secretary of Commerce for Industry and Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of part 756 of the Regulations.

Fifth, a copy of this Order shall be delivered to Haynes and shall be published in the **Federal Register**.

Sixth, this Order is effective immediately and shall remain in effect until January 11, 2031.

John Sonderman,

Director, Office of Export Enforcement.

[FR Doc. 2023–18437 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–DT–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–471–807]

Certain Uncoated Paper From Portugal: Final Results of Antidumping Duty Administrative Review; 2021–2022

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The U.S. Department of Commerce (Commerce) determines that The Navigator Company, S.A. (Navigator) made sales of certain uncoated paper (uncoated paper) from Portugal in the United States at less than normal value during the period of review (POR) March 1, 2021, through February 28, 2022.

DATES: Applicable August 28, 2023.

FOR FURTHER INFORMATION CONTACT: Eric Hawkins, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230; telephone: (202) 482–1988.

SUPPLEMENTARY INFORMATION:

Background

On April 6, 2023, Commerce published the preliminary results of this administrative review covering one producer/exporter, Navigator.[1] We invited interested parties to comment on the *Preliminary Results.* On August 2, 2023, Commerce extended the time period for issuing the final results of this review until August 22, 2023.[2] For a complete description of the events that occurred since the *Preliminary Results, see* the Issues and Decision Memorandum.[3]

Commerce conducted this administrative review in accordance with section 751 of the Tariff Act of 1930, as amended (the Act).

Scope of the Order [4]

The product covered by this *Order* is certain uncoated paper from Portugal. For a full description of the scope of the *Order, see* the Issues and Decision Memorandum.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs are addressed in the Issues and Decision Memorandum. A list of the issues that parties raised and to which we responded in the Issues and Decision Memorandum is attached to this notice as an appendix. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at *https://access.trade.gov.* In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *https://access.trade.gov/public/FRNoticesListLayout.aspx.*

Changes Since the Preliminary Results

Based on a review of the record and comments received from interested parties, we have recalculated the weighted-average dumping margin for Navigator. Specifically, we have used weight-averaged quarterly costs in determining Navigator's dumping margin. We also made changes in calculating certain rebate caps for Navigator's home market sales. For a more detailed discussion of these changes, *see* the Issues and Decision Memorandum.

Final Results of Review

Commerce determines that the following weighted-average dumping margin exists for the period March 1, 2021, through February 28, 2022:

Exporter/producer	Weighted-average dumping margin (percent)
The Navigator Company, S.A	7.11

Disclosure

Commerce intends to disclose to interested parties the calculations performed in connection with the final results within five days of any public announcement or, if there is no public announcement, within five days of the date of publication of the notice of final determination in the **Federal Register**, in accordance with 19 CFR 351.224(b).

Assessment Rate

Pursuant to section 751(a)(2)(C) of the Act, and 19 CFR 351.212(b)(1), Commerce shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review.

Because Navigator's weighted-average dumping margin is not zero or *de minimis* (*i.e.,* less than 0.5 percent), Commerce has calculated importer-specific antidumping duty assessment rates. We calculated importer-specific *ad valorem* assessment rates based on the ratio of the total amount of dumping calculated for the examined sales to the total entered value of the sales. Where an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties.

For entries of subject merchandise during the POR produced by Navigator for which it did not know its merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction.[5]

Commerce intends to issue assessment instructions to CBP no earlier than 35 days after the date of publication of the final results of this review in the **Federal Register**. If a timely summons is filed at the U.S.

[1] *See Certain Uncoated Paper from Portugal: Preliminary Results of the Administrative Review of the Antidumping Duty Order; 2021–2022,* 88 FR 20484 (April 6, 2023) (*Preliminary Results*), and accompanying Preliminary Decision Memorandum (PDM).

[2] *See* Memorandum, ''Extension of Deadline for Final Results of Antidumping Duty Administrative Review,'' dated August 2, 2023.

[3] *See* Memorandum, ''Issues and Decision Memorandum for the Final Results of the Administrative Review of the Antidumping Duty Order: Certain Uncoated Paper from Portugal; 2021–2022,'' dated concurrently with and hereby adopted by this notice (Issues and Decision Memorandum).

[4] *See Certain Uncoated Paper from Australia, Brazil, Indonesia, the People's Republic of China, and Portugal: Amended Final Affirmative Antidumping Determinations for Brazil and Indonesia and Antidumping Duty Orders,* 81 FR 11174 (March 3, 2016) (*Order*).

[5] For a full discussion of this practice, *see Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties,* 68 FR 23954 (May 6, 2003).

Court of International Trade, the assessment instructions will direct CBP not to liquidate relevant entries until the time for parties to file a request for a statutory injunction has expired (*i.e.,* within 90 days of publication).

Cash Deposit Requirements

The following cash deposit requirements will be effective for all shipments of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication date of the final results of this administrative review, as provided by section 751(a)(2)(C) of the Act: (1) the cash deposit rate for Navigator will be the rate established in the final results of this administrative review; (2) for merchandise exported by producers or exporters not covered in this administrative review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding; (3) if the exporter is not a firm covered in this review, a prior review, or the original less-than-fair-value (LTFV) investigation, but the producer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the producer of the subject merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 7.80 percent, the all-others rate established in the LTFV investigation.[6] These cash deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in Commerce's presumption that reimbursement of antidumping duties has occurred and the subsequent assessment of double antidumping duties.

Administrative Protective Order

This notice also serves as a final reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return/destruction of APO materials, or conversion to judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this notice in accordance with sections 751(a)(1) and 777(i)(1) of the Act, and 19 CFR 351.221(b)(5) and 19 CFR 351.213(h)(1).

Dated: August 22, 2023.

Abdelali Elouaradia,

Deputy Assistant Secretary for Enforcement and Compliance.

Appendix—List of Topics Discussed in the Issues and Decision Memorandum

[FR Doc. 2023–18522 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–DS–P

[6] *See Certain Uncoated Paper from Portugal: Final Determination of Sales at Less than Fair Value and Final Negative Determination of Critical Circumstances,* 81 FR 3105 (January 20, 2016).

DEPARTMENT OF COMMERCE

International Trade Administration

United States Travel and Tourism Advisory Board: Meeting of the United States Travel and Tourism Advisory Board

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice of an open meeting.

SUMMARY: The United States Travel and Tourism Advisory Board (Board or TTAB) will hold a meeting on Wednesday, September 13, 2023. The Board advises the Secretary of Commerce on matters relating to the U.S. travel and tourism industry. The main purpose of this meeting is for Board members to deliberate and potentially adopt five letters of recommendation for the Secretary of Commerce. The final agenda will be posted on the Department of Commerce website for the Board at *https://www.trade.gov/ttab-meetings* at least two days prior to the meeting.

DATES: Wednesday, September 13, 2023, 1:00 p.m.–2:00 p.m. EDT. The deadline for members of the public to register for the meeting or to submit written comments for dissemination prior to the meeting is 5:00 p.m. EDT on Monday, September 11, 2023.

ADDRESSES: The meeting will be held virtually. The access information will be provided by email to registrants. Requests to register (including to speak or for auxiliary aids) and any written comments should be submitted by email to *TTAB@trade.gov.*

FOR FURTHER INFORMATION CONTACT: Jennifer Aguinaga, the United States Travel and Tourism Advisory Board, National Travel and Tourism Office, U.S. Department of Commerce; telephone: 202–482–2404; email: *TTAB@trade.gov.*

SUPPLEMENTARY INFORMATION:

Public Participation: The meeting will be open to the public and will be accessible to people with disabilities. Any member of the public requesting to join the meeting is asked to register in advance by the deadline identified under the DATES caption. Requests for auxiliary aids must be submitted by the registration deadline. Last minute requests will be accepted but may not be possible to fill. There will be fifteen (15) minutes allotted for oral comments from members of the public joining the meeting. To accommodate as many speakers as possible, the time for public comments may be limited to three (3) minutes per person. Members of the public wishing to reserve speaking time during the meeting must submit a request at the time of registration, as well as the name and address of the proposed speaker. If the number of registrants requesting to make statements is greater than can be reasonably accommodated during the meeting, the International Trade Administration may conduct a lottery to determine the speakers. Speakers are requested to submit a written copy of their prepared remarks by 5:00 p.m. EDT on Monday, September 11, 2023, for inclusion in the meeting records and for circulation to the members of the Board.

In addition, any member of the public may submit pertinent written comments concerning the Board's affairs at any time before or after the meeting. Comments may be submitted to Jennifer Aguinaga at the contact information indicated above. To be considered during the meeting, comments must be received no later than 5:00 p.m. EDT on Monday, September 11, 2023, to ensure transmission to the Board prior to the meeting. Comments received after that

date and time will be transmitted to the Board but may not be considered during the meeting. Copies of Board meeting minutes will be available within 90 days of the meeting.

This Notice is published pursuant to the Federal Advisory Committee Act, as amended (FACA), 5 U.S.C., app., 10(a)(2). The Committee was established pursuant to section 607 of the Visit America Act, Subtitle A of title VI of division BB of the Consolidated Appropriations Act, 2023, Public Law. 117–328, and in accordance with the provisions of the FACA, 5 U.S.C. 1001 *et seq.*

Jennifer Aguinaga,

Designated Federal Officer, United States Travel and Tourism Advisory Board.

[FR Doc. 2023–18456 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD217]

Fisheries of the Gulf of Mexico; 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 87 Data Workshop for Gulf of Mexico White, Pink, and Brown Shrimp.

SUMMARY: The SEDAR 87 assessment process of Gulf of Mexico white, pink, and brown shrimp will consist of a Data Workshop, a series of assessment webinars, and a Review Workshop. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 87 Data Workshop will be held September 18–22, 2023, in Tampa, FL. The workshop will be held September 18, from 1 p.m. to 6 p.m.; September 19, from 8:30 a.m. to 6 p.m.; September 20, from 8:30 a.m. to 3 p.m.; September 21, from 8:30 a.m. to 6 p.m.; and September 22, from 8:30 a.m. to 12 p.m. The established times may be adjusted as necessary to accommodate the timely completion of discussion relevant to the assessment process. Such adjustments may result in the meeting being extended from or completed prior to the time established by this notice.

ADDRESSES:

Meeting address: The SEDAR 87 Data Workshop will be held at the Hilton Tampa Airport Westshore, 2225 N. Lois Avenue, Tampa, FL 33607.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571–4366; email: *Julie.neer@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 multi-step process including: (1) Data/Assessment Workshop, and (2) a series of webinars. The product of the Data/Assessment Workshop is a report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses, and describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, HMS 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 NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion in the Data Workshop:

An assessment data set and associated documentation will be developed during the workshop. Participants will evaluate proposed data and select appropriate sources for providing information on life history characteristics, catch statistics, discard estimates, length and age composition, and fishery dependent and fishery independent measures of stock abundance.

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 these meetings. 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

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 5 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: August 22, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–18432 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD268]

Fisheries of the Gulf of Mexico; 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 85 Data Topical Working Group Webinar I for Gulf of Mexico Yellowedge Grouper.

SUMMARY: The SEDAR 85 assessment of Gulf of Mexico yellowedge grouper will consist of a series of webinars. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 85 Data Topical Working Group Webinar will be held September 15, 2023, from 1 p.m. to 3 p.m., Eastern.

ADDRESSES: *Meeting address:* The meeting will be held via webinar. The webinar is open to members of the public. Those interested in participating should contact Julie A. Neer at SEDAR (see **FOR FURTHER INFORMATION CONTACT**) to request an invitation providing webinar access information. Please request webinar invitations at least 24 hours in advance of each webinar.

SEDAR address: 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405.

FOR FURTHER INFORMATION CONTACT: Julie A. Neer, SEDAR Coordinator; (843) 571–4366; email: *Julie.neer@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 multi-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 that 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 that 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, HMS 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 NGO's; International experts; and staff of Councils, Commissions, and state and federal agencies.

The item of discussion in the webinar is as follows:

Participants will discuss what data may be available for use in the assessment of Gulf of Mexico yellowedge grouper.

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

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to the Council office (see **ADDRESSES**) at least 10 business days prior to each workshop.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: August 22, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–18435 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Agency Information Collection Activities; Submission to the Office of Management and Budget (OMB) for Review and Approval; Comment Request; Papahanaumokuakea Marine National Monument Permit Application and Reports for Permits

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 the agency [or department] to 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 October 27, 2023.

ADDRESSES: Interested persons are invited to submit written comments to Adrienne Thomas, NOAA PRA Officer, at *NOAA.PRA@noaa.gov.* Please reference OMB Control Number 0648–0548 in the subject line of your comments. Do not submit Confidential Business Information or otherwise sensitive personally identifiable information or any other type of protected information.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or specific questions related to collection activities should be directed to Phillip Howard, Permit Specialist, NOAA Office of National Marine Sanctuaries, 1845 Wasp Blvd., Building 176 Honolulu, HI 96818, (808–725–5800), and *phillip.howard@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

On June 15, 2006, President Bush established the Papahanaumokuakea Marine National Monument by issuing Presidential Proclamation 8031 (71 FR 36443, June 26, 2006), as amended on February 28, 2007 by Presidential Proclamation 8112 (72 FR 10031, March 6, 2007), under the authority of the Antiquities Act (54 U.S.C. 320301 *et seq.*). The Secretary of Commerce, through the National Oceanic and Atmospheric Administration (NOAA), has primary responsibility regarding the management of the marine areas of the Monument, in consultation with the Secretary of the Interior. Similarly, the Secretary of the Interior, through the Fish and Wildlife Service (FWS), has sole responsibility for management of the areas of the Monument that overlay the Midway Atoll National Wildlife Refuge, the Battle of Midway National Memorial, and the Hawaiian Islands National Wildlife Refuge, in consultation with the Secretary of Commerce.

Presidential Proclamations 8031 and 8112 include restrictions and prohibitions regarding activities in the Monument. Specifically, the Proclamations prohibit access to the Monument except when passing through without interruption or as allowed under a permit issued by NOAA and the FWS. Vessels passing through the Monument without interruption are required to notify NOAA and FWS upon entering into and leaving the monument. Individuals wishing to access the Monument to conduct certain regulated activities must first apply for and be granted a permit issued by NOAA and FWS.

On August 29, 2006, NOAA and FWS published a final rule codifying the provisions of Presidential Proclamation 8031 (71 FR 51134). These agencies have since worked extensively with the State of Hawaii to ensure the permitting requirements and processes of all three entities are sufficiently coordinated and to ensure applicants for permits for Monument activities require only a single application and receive one, combined agency permit.

The information submitted by permit applicants will be used to decide

whether to approve or deny a permit application. In making this decision, the agencies will consider such factors as:

- the professional qualifications and financial ability of the applicant as related to the proposed activity;
- the duration of the activity and its effects;
- the appropriateness of the methods and procedures proposed by the applicant for the conduct of the activity;
- the extent to which the conduct of the activity may diminish or enhance the qualities for which the Monument was designated;
- the end value of the activity; and
- other such matters as agency staff deem appropriate.

In addition to informing the agencies' decisions on permit applications, information submitted in permit applications and reports submitted pursuant to permit conditions may also be used by the agencies to inform—

- administrative appeals of permit decisions;
- decision making on a permit amendment request or another permit application; or
- other management actions (*e.g.,* emergency response and enforcement).

In terms of frequency of use, the information submitted in permit applications will, in general, only be used at the time the application is submitted to make a final decision on the application. Some of the information may also be used subsequent to the initial decision making to inform management actions or decision making. For example, a survey of a project location by one permit applicant may be used by the agencies in the future to respond to a vessel grounding in the same area to facilitate the agencies' decision in response to that matter. Information submitted in a report will be used to periodically assess the permittee's compliance with permit terms and conditions and to assist in evaluating the appropriateness of the permitted activity.

II. Method of Collection

Respondents have a choice of either electronic or paper forms. Methods of submittal include email of electronic forms, and mail and facsimile transmission of paper forms.

III. Data

OMB Control Number: 0648–0548.

Form Number(s): None.

Type of Review: Regular submission, extension of a current information collection.

Affected Public: Individuals, non-profit institutions; Federal, State, local, government, Native Hawaiian organizations; business or other for-profit organizations.

Estimated Number of Respondents: 411.

Estimated Time per Response: Conservation and Management and Education (''general'' permits), 5 hours; Special Ocean Use permits, 10 hours; Native Hawaiian Practices permits, 8 hours; Recreation permits, 6 hours; permit modification requests and final reports, 10 hours; and annual reports, 5 hours.

Estimated Total Annual Burden Hours: 1,343.

Estimated Total Annual Cost to Public: $61,783 in recordkeeping/reporting costs and vessel monitoring system installation and maintenance.

Respondent's Obligation: Required to Obtain or Retain Benefits, or Mandatory.

Legal Authority: 54 U.S.C. 320301 *et seq.;* 16 U.S.C. 1801 *et seq.;* 16 U.S.C. 742f, 16 U.S.C. 742l; 16 U.S.C. 1431 *et seq.*

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 Information Collection Review. 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 Under Secretary for Economic Affairs, Commerce Department.

[FR Doc. 2023–18477 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–NK–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD249]

Schedules for Atlantic Shark Identification Workshops and Protected Species Safe Handling, Release, and Identification Workshops

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

ACTION: Notice of public workshops.

SUMMARY: Free Atlantic Shark Identification Workshops and Safe Handling, Release, and Identification Workshops will be held in October, November, and December of 2023. Certain fishermen and shark dealers are required to attend a workshop to meet regulatory requirements and to maintain valid permits. Specifically, the Atlantic Shark Identification Workshop is mandatory for all federally permitted Atlantic shark dealers. The Safe Handling, Release, and Identification Workshop is mandatory for vessel owners and operators who use bottom longline, pelagic longline, or gillnet gear, and who have also been issued shark or swordfish limited access permits. Additional free workshops will be conducted in 2024 and will be announced in a future notice. In addition, NMFS has implemented online recertification workshops for persons who have already taken an in-person training.

DATES: The Atlantic Shark Identification Workshops will be held on October 12, 2023 and November 9, 2023. The Safe Handling, Release, and Identification Workshops will be held on October 19, 2023, November 7, 2023, and December 5, 2023.

ADDRESSES: The Atlantic Shark Identification Workshops will be held in Mount Pleasant, SC and Largo, FL. The Safe Handling, Release, and Identification Workshops will be held in Warwick, RI, Kitty Hawk, NC, and Manahawkin, NJ.

FOR FURTHER INFORMATION CONTACT: Peter Cooper by email at *peter.cooper@noaa.gov* or by phone at 301–427–8503.

SUPPLEMENTARY INFORMATION: Atlantic highly migratory species (HMS) fisheries are managed under the authority of the Atlantic Tunas Convention Act (16 U.S.C. 971 *et seq.*) and the Magnuson-Stevens Fishery Conservation and Management Act (16 U.S.C. 1801 *et seq.*). The 2006 Consolidated Atlantic HMS Fishery Management Plan and its amendments are implemented by regulations at 50 CFR part 635. Section 635.8 describes the requirements for the Atlantic Shark Identification Workshops and Safe Handling, Release, and Identification Workshops. The workshop schedules, registration information, and a list of frequently asked questions regarding the Atlantic Shark Identification and Safe Handling, Release, and Identification workshops are available online at: *https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/atlantic-shark-identification-workshops* and *https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/safe-handling-release-and-identification-workshops.*

Atlantic Shark Identification Workshops

Since January 1, 2008, Atlantic shark dealers have been prohibited from receiving, purchasing, trading, or bartering for Atlantic sharks unless a valid Atlantic Shark Identification Workshop certificate is on the premises of each business listed under the shark dealer permit that first receives Atlantic sharks (71 FR 58057, October 2, 2006). Dealers who attend and successfully complete a workshop are issued a certificate for each place of business that is permitted to receive sharks. These certificate(s) are valid for 3 years. Thus, certificates that were initially issued in 2020 will expire in 2023.

Currently, permitted dealers may send a proxy to an Atlantic Shark Identification Workshop. However, if a dealer opts to send a proxy, the dealer must designate a proxy for each place of business covered by the dealer's permit that first receives Atlantic sharks. Only one certificate will be issued to each proxy. A proxy must be a person who is currently employed by a place of business covered by the dealer's permit; is a primary participant in the identification, weighing, and/or first receipt of fish as they are offloaded from a vessel; and who fills out dealer reports. Atlantic shark dealers are prohibited from renewing a Federal shark dealer permit unless a valid Atlantic Shark Identification Workshop certificate for each business location that first receives Atlantic sharks has been submitted with the permit renewal application. Additionally, a copy of a valid dealer or proxy Atlantic Shark Identification Workshop certificate must be in any trucks or other conveyances that are extensions of a dealer's place of business.

Workshop Dates, Times, and Locations

1. October 12, 2023, 12 p.m.–4 p.m., Holiday Inn Express Charleston NE Mount Pleasant, 1104 Stockade Lane, Mount Pleasant, SC 29466.

2. November 9, 2023, 12 p.m.–4 p.m., Hampton Inn & Suites Largo, 100 East Bay Drive, Largo, FL 33770.

Registration

To register for a scheduled Atlantic Shark Identification Workshop, please contact Eric Sander at *ericssharkguide@yahoo.com* or at 386–852–8588. Pre-registration is highly recommended, but not required.

Registration Materials

To ensure that workshop certificates are linked to the correct permits, participants will need to bring the following specific items to the workshop:

- Atlantic shark dealer permit holders must bring proof that the attendee is an owner or agent of the business (such as articles of incorporation), a copy of the applicable permit, and proof of identification; and
- Atlantic shark dealer proxies must bring documentation from the permitted dealer acknowledging that the proxy is attending the workshop on behalf of the permitted Atlantic shark dealer for a specific business location, a copy of the appropriate valid permit, and proof of identification.

Workshop Objectives

The Atlantic Shark Identification Workshops are designed to reduce the number of unknown and improperly identified sharks reported in the dealer reporting form and increase the accuracy of species-specific dealer-reported information. Reducing the number of unknown and improperly identified sharks will improve quota monitoring and the data used in stock assessments. These workshops will train shark dealer permit holders or their proxies to properly identify Atlantic shark carcasses.

Safe Handling, Release, and Identification Workshops

Since January 1, 2007, shark limited access and swordfish limited access permit holders who fish with longline or gillnet gear have been required to submit a copy of their Safe Handling, Release, and Identification Workshop certificate in order to renew either permit (71 FR 58057, October 2, 2006). These certificate(s) are valid for 3 years. Certificates issued in 2020 will expire in 2023. As such, vessel owners who have not already attended a workshop and received a NMFS certificate, or vessel owners whose certificate(s) will expire prior to the next permit renewal, must attend a workshop to fish with, or renew, their swordfish and shark limited access permits. Additionally, new shark and swordfish limited access permit applicants who intend to fish with longline or gillnet gear must attend a Safe Handling, Release, and Identification Workshop and submit a copy of their workshop certificate before either of the permits will be issued.

In addition to vessel owners, at least one operator on board vessels issued a limited access swordfish or shark permit that uses longline or gillnet gear is required to attend a Safe Handling, Release, and Identification Workshop and receive a certificate. Vessels that have been issued a limited access swordfish or shark permit and that use longline or gillnet gear may not fish unless both the vessel owner and operator have valid workshop certificates on board at all times. Vessel operators who have not already attended a workshop and received a NMFS certificate, or vessel operators whose certificate(s) will expire prior to their next fishing trip, must attend a workshop to operate a vessel with swordfish and shark limited access permits on which longline or gillnet gear is used.

Workshop Dates, Times, and Locations

1. October 19, 2023, 9 a.m.–5 p.m., Hilton Garden Inn, 1 Thurber Street, Warwick, RI 02886.

2. November 7, 2023, 9 a.m.–5 p.m., Hilton Garden Inn/Outer Banks-Kitty Hawk, 5353 North Virginia Dare Trail, Kitty Hawk, NC 27949.

3. December 5, 2023, 9 a.m.–5 p.m., The Mainland 151 Route 72 East, Manahawkin, NJ 08050.

Registration

To register for a scheduled Safe Handling, Release, and Identification Workshop, please contact Angler Conservation Education at 386–682–0158. Pre-registration is highly recommended, but not required.

Registration Materials

To ensure that workshop certificates are linked to the correct permits, participants will need to bring the

following specific items with them to the workshop:

- Individual vessel owners must bring a copy of the appropriate swordfish and/or shark permit(s), a copy of the vessel registration or documentation, and proof of identification;
- Representatives of a business-owned or co-owned vessel must bring proof that the individual is an agent of the business (such as articles of incorporation), a copy of the applicable swordfish and/or shark permit(s), and proof of identification; and
- Vessel operators must bring proof of identification.

Workshop Objectives

The Safe Handling, Release, and Identification Workshops are designed to teach the owner and operator of a vessel that fisheries with longline or gillnet gear the required techniques for the safe handling and release of entangled and/or hooked protected species, such as sea turtles, marine mammals, smalltooth sawfish, Atlantic sturgeon, and prohibited sharks. In an effort to improve reporting, the proper identification of protected species and prohibited sharks will also be taught at these workshops. Additionally, individuals attending these workshops will gain a better understanding of the requirements for participating in these fisheries. The overall goal of these workshops is to provide participants with the skills needed to reduce the mortality of protected species and prohibited sharks, which may prevent additional regulations on these fisheries in the future.

Online Recertification Workshops

NMFS implemented an online option for shark dealers and owners and operators of vessels that fish with longline and gillnet gear to renew their certificates in December 2021. To be eligible for online recertification workshops, dealers and vessel owners and operators need to have previously attended an in-person workshop. Information about the courses is available online at *https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/atlantic-shark-identification-workshops* and *https://www.fisheries.noaa.gov/atlantic-highly-migratory-species/safe-handling-release-and-identification-workshops.* To access the course please visit: *https://hmsworkshop.fisheries.noaa.gov/start.*

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

Dated: August 23, 2023.

Jennifer M. Wallace,

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

[FR Doc. 2023–18493 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD277]

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod Trawl Cooperative Program; Public Workshop

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

ACTION: Notification of public workshop.

SUMMARY: NMFS will present a public workshop on the implementation of the Pacific cod Trawl Cooperative Program (PCTC Program or Program) for potentially eligible participants and other interested parties. The PCTC Program allocates Pacific cod harvest quota to qualifying groundfish License Limitation Program (LLP) license holders and qualifying processors and requires participants to form cooperatives to harvest the quota. At the workshop, NMFS will provide an overview of the PCTC Program, discuss the key PCTC Program elements, describe the process for participating in the Program, and answer questions. NMFS is conducting this public workshop to provide assistance to fishery participants in understanding and reviewing this Program.

DATES: The same workshop will be presented in Seattle and then via webinar. The first workshop will be held in-person on Wednesday, September 20, 2023 from 5:30 to 7:30 p.m. Pacific Standard Time in Seattle, Washington and will not have a webinar option. The second workshop will be held via webinar on Wednesday, September 27, 2023 from 5:30 to 7:30 p.m. Alaska Standard Time.

ADDRESSES: The first workshop on September 20 will be held in Seattle, Washington at The Mountaineers Seattle Program Center, 7700 Sand Point Way NE, Seattle, WA 98115. The second workshop will be held via webinar and the link to the meeting is: *https://meet.google.com/oky-ajgw-nhm.* A phone connect is also available by calling +1 502–518–3401 and entering the following pin number: 163 659 782#.

FOR FURTHER INFORMATION CONTACT: Stephanie Warpinski, *stephanie.warpinski@noaa.gov,* (907)-586–7234.

SUPPLEMENTARY INFORMATION: NMFS published a final rule that implements Amendment 122 to the Bering Sea and Aleutian Islands Management Area (BSAI) Groundfish Fishery Management Plan (FMP) on (88 FR 53704, August 8, 2023). The PCTC Program assigns Pacific cod harvest quota to qualifying groundfish LLP license holders and qualifying processors. The Program is a limited access privilege program for the harvest of Pacific cod in the BSAI trawl catcher vessel (CV) sector. Under the Program, participants holding quota share (QS) form harvesting cooperatives in association with a processor to harvest the annual harvest privilege of Pacific cod.

The PCTC Program implements a complex suite of measures to improve fishery conditions for all participants. This Program establishes criteria for harvesters and processors in the BSAI trawl CV sector Pacific cod fishery to qualify for and receive QS, criteria for allocating QS in the initial year of implementation, and criteria for the transfer of QS. QS holders are required to join a cooperative (harvesters) or associate with a cooperative (processors). The aggregate QS of cooperative members and associated processors yields an exclusive harvest privilege for PCTC Program cooperatives, which NMFS will issue as cooperative quota (CQ) each year. CQ represents a portion of the A and B season BSAI trawl CV sector Pacific cod Directed Fishing Allowance (DFA). Of the total annual CQ, 77.5 percent is derived from QS issued to LLP licenses, and 22.5 percent is derived from QS issued to processors. The DFA for the C season remains available for harvest as a limited access fishery open to all CVs with the required trawl gear and area endorsements on the LLP license assigned to the vessel.

As required under Magnuson-Stevens Act section 303A(c)(5)(D), the PCTC Program includes ownership and use caps to prevent a permit holder from acquiring an excessive share of the fishery. No person is permitted to hold more than 5 percent of harvester-issued QS or 20 percent of processor-issued QS. In addition, no vessel is allowed to harvest more than 5 percent of the annual CQ, and no company is allowed to process more than 20 percent of the annual CQ. The PCTC Program also includes legacy exemptions for persons over these ownership and use caps at the time of PCTC Program

implementation, allowing participants to maintain levels of historical participation rather than forcing divestiture.

The PCTC Program reduces the halibut and crab Prohibited Species Catch (PSC) limits for participating trawl CVs during the A and B seasons. NMFS will apportion halibut and crab PSC limits to PCTC Program cooperatives during the annual harvest specifications process based on the percentage of total BSAI Pacific cod CQ allocated to each cooperative.

To support the sustained participation of AI communities in the Pacific cod trawl CV fishery, cooperatives are required to collectively set-aside 12 percent of the A season CQ for delivery to an Aleutian Islands shoreplant (AI CQ set-aside) during years in which an AI community representative notifies NMFS of their intent to process Pacific cod.

At this time, NMFS mailed out official records to eligible participants who have until October 10, 2023 to submit the Application for PCTC Program QS to NMFS. Any participants who do not join or associate with a cooperative by November 1 will not receive benefits from their QS for the 2024 fishing season. On November 1, 2023, all cooperatives must submit Applications for PCTC Program Cooperative Quota to NMFS. For the calendar year 2023, to provide for implementation of the Program during its first year, NMFS will allow each cooperative to submit the inter-cooperative agreement on or before December 31, 2023, after the November 1 deadline for the Application for PCTC Program CQ.

NMFS is conducting two public workshops to provide assistance to fishery participants in reviewing the requirements of the Program. At the workshops, NMFS will provide an overview of the Program, and discuss the key Program elements, including the process to apply for QS; cooperative and limited access participation provisions; cooperative quota transfer provisions; the appeals process; monitoring and enforcement; and electronic reporting. Additionally, NMFS will answer questions from workshop participants. For further information on the Program, please visit the NMFS Alaska Region website here: *https://www.fisheries.noaa.gov/action/amendment-122-fishery-management-plan-groundfish-bering-sea-and-aleutian-islands-management.*

Special Accommodations

Requests for sign language interpretation or other auxiliary aids should be directed to Stephanie Warpinski, *stephanie.warpinski@noaa.gov,* at least 5 working days prior to the meeting date.

Dated: August 23, 2023.

Jennifer M. Wallace,

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

[FR Doc. 2023–18530 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD285]

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 (Council) Scientific and Statistical Committee (SSC) will hold a meeting.

DATES: The meeting will be held on Tuesday, September 12, 2023, starting at 10 a.m. and continuing through 1 p.m. on Wednesday, September 13, 2023. See **SUPPLEMENTARY INFORMATION** for agenda details.

ADDRESSES: This will be an in-person meeting with a virtual option. SSC members, other invited meeting participants, and members of the public will have the option to participate in person or virtually via Webex webinar. Webinar connection instructions and briefing materials will be available at: *www.mafmc.org/ssc.*

Meeting address: Royal Sonesta Harbor Court Baltimore, 550 Light Street, Baltimore, MD.

Council address: Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; website: *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: During this meeting, the SSC will discuss recent research that evaluates the science implications and fishery interactions associated with offshore wind development. The SSC will receive an update on the Council's development of the Recreational Measures Setting Process Framework, including anticipated model development and management strategy evaluation analysis to support the action. The SSC will review and provide feedback on the updated Scup discard report and Gear Restricted Area (GRA) analysis. The SSC will get an overview of the Northeast commercial port sampling program and an update on Atlantic Mackerel management track stock assessment and projection scenarios. The SSC will also receive updates from the SSC ecosystem work group and the SSC overfishing limit (OFL) coefficient of variation (CV) subgroup. The SSC may take up any other business as necessary.

A detailed agenda and background documents will be made available on the Council's website (*www.mafmc.org*) prior to the meeting.

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: August 22, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–18431 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD292]

Western Pacific Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The Western Pacific Fishery Management Council (Council) will hold its 149th Scientific and Statistical Committee (SSC) and its 196th Council meeting to take actions on fishery management issues in the Western Pacific Region. The Council will also hold meetings of the following standing committees: Pelagic and International Standing Committee (SC); Program Planning SC; Fishing Rights of Indigenous Peoples SC; and Executive and Budget SC.

DATES: The meetings will be held between September 12 and September 20, 2023. For specific times and

agendas, see **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The 149th SSC meeting will be held as a hybrid meeting for SSC members and the public, with a remote participation option available via WebEx. In-person attendance will be hosted at the Council office, 1164 Bishop Street, Suite 1400, Honolulu, HI 96813.

The Pelagic and International SC, Program Planning SC, Fishing Rights of Indigenous Peoples SC, and Executive and Budget SC meetings will be held in-person at the Council office, 1164 Bishop Street, Suite 1400, Honolulu, HI 96813.

The 196th Council Meeting will be held as a hybrid meeting for Council members and the public, with a remote participation option available via Webex. In-person attendance will be hosted at the Ala Moana Hotel, Hibiscus Ballroom, 410 Atkinson Drive, Honolulu, HI 96814.

Specific information on joining the meeting, connecting to the web conference and providing oral public comments will be posted on the Council website at *www.wpcouncil.org.* For assistance with the web conference connection, contact the Council office at (808) 522–8220.

Council address: Western Pacific Fishery Management Council, 1164 Bishop Street, Suite 1400, Honolulu, HI 96813.

FOR FURTHER INFORMATION CONTACT: Kitty M. Simonds, Executive Director, Western Pacific Fishery Management Council; phone: (808) 522–8220.

SUPPLEMENTARY INFORMATION: The 149th SSC meeting will be held between 9 a.m. and 5 p.m. Hawaii Standard Time (HST) on September 12–13, and 9 a.m. and 1 p.m. on September 14, 2023. The Pelagic and International SC meeting will be held between 9 a.m. and 11 a.m. HST on September 15, 2023. The Program Planning SC meeting will be held between 11:30 a.m. and 1:30 p.m. HST on September 15, 2023. The Fishing Rights of Indigenous Peoples SC meeting will be held between 2 p.m. and 4 p.m. on September 15, 2023. The Executive and Budget SC meeting will be held between 4:30 p.m. and 6:30 p.m. HST on September 15, 2023. The 196th Council Meeting will be held between 9 a.m. and 5 p.m. HST on September 18–20, 2023. Public Comment on Non-Agenda Items will be held between 4 p.m. and 4:30 p.m. HST on September 18, 2023. The Fishers Forum will be held between 6 p.m. and 9 p.m. HST on September 18, 2023.

Agenda items noted as ''Final Action'' refer to actions that may result in Council transmittal of a proposed fishery management plan, proposed plan amendment, or proposed regulations to the U.S. Secretary of Commerce, under Sections 304 or 305 of the MSA. In addition to the agenda items listed here, the Council and its advisory bodies will hear recommendations from Council advisors. An opportunity to submit public comment will be provided throughout the agendas. The order in which agenda items are addressed may change and will be announced in advance at the Council meeting. The meetings will run as late as necessary to complete scheduled business.

Background documents for the 196th Council meeting will be available at *www.wpcouncil.org.* Written public comments on final action items at the 196th Council meeting should be received at the Council office by 5 p.m. HST, Thursday, September 14, 2023, and should be sent to Kitty M. Simonds, Executive Director; Western Pacific Fishery Management Council, 1164 Bishop Street, Suite 1400, Honolulu, HI 96813, phone: (808) 522–8220 or fax: (808) 522–8226; or email: *info@wpcouncil.org.* Written public comments on all other agenda items may be submitted for the record by email throughout the duration of the meeting. Instructions for providing oral public comments during the meeting will be posted on the Council website. This meeting will be recorded (audio only) for the purposes of generating the minutes of the meeting.

Agenda for the 149th SSC Meeting

Tuesday, September 12, 2023, 9 a.m. to 5 p.m. HST

1. Introductions
2. Approval of Draft Agenda and Assignment of Rapporteurs
3. Status of the 148th SSC Meeting Recommendations
4. Pacific Islands Fisheries Science Center (PIFSC) Director Report
5. Island Fisheries
   - A. American Samoa Bottomfish Management Unit Species
   - A.1. P* and SEEM Working Group Reports
   - A.2. Discontinuing the Rebuilding Plan and Setting Acceptable Biological Catch for 2024–2026 (Action Item)
   - B. Main Hawaiian Islands (MHI) Deep 7 Bottomfish Stock Assessment Western Pacific Stock Assessment Review (WPSAR) Terms of Reference
   - C. MHI Uku Ecosystem and Socioeconomic Profile Report Cards
   - D. Public Comment
   - E. SSC Discussion and Recommendations
6. Pelagic and International Fisheries
   - A. American Samoa Longline Fishery Report
   - B. Hawaii Longline Fishery Report
   - C. 2024 U.S. Territorial Bigeye Tuna Catch Limit and Allocation Specifications (Action Item)
   - D. Scenarios for Implementation of Electronic Monitoring in Western Pacific Longline Fisheries
   - E. Feasibility of Stock Assessments for Incidental Pelagic MUS
   - F. International Fisheries
   - F.1. Western and Central Pacific Ocean (WCPO) Longline Management Workshop
   - F.2. 19th Western and Central Pacific Fisheries Commission (WCPFC) Science Committee
   - F.3. 19th International Scientific Committee (ISC) Meeting
   - G. Public Comment
   - H. SSC Discussion and Recommendations

Wednesday, September 13, 2023, 9 a.m. to 5 p.m. HST

7. Protected Species
   - A. Green Sea Turtle Critical Habitat Proposed Designations
   - B. Update on the Hawaii Pelagic False Killer Whale Assessment Approach
   - C. Public Comment
   - D. SSC Discussion and Recommendations
8. Program Planning and Research
   - A. NMFS Draft Climate Governance Policy
   - B. Inflation Reduction Act Overview
   - C. Priorities for Addressing Climate Change in Fishery Management
   - C.1. NMFS National Activities and Priorities (including Ocean Climate Action Plan)
   - C.2. NMFS Regional Activities and Priorities (including Pacific Islands Regional Action Plan & Climate, Ecosystem and Fisheries Initiative)
   - C.3. PIFSC Funding Priorities for Climate-Ready Fisheries (including Inflation Reduction Act)
   - C.4. Council Management Priorities for Addressing Climate ChangeC.5 SSC Discussion on Climate Change and Fisheries Science Priorities for Management
   - D. Proposed Designation of a Pacific Remote Islands National Marine Sanctuary
   - D.1. Updates from Federal Agencies
   - D.2. Review of Existing Fishing Regulations and Options for Developing Fishing Regulations (Action Item)
   - E. Council five-year Program Plan Updates
   - F. Review of Council Research

Priorities
G. Review of SSC Plan 2021–2023 and Development of 2024–2026 Plan
H. National Standards 4, 8 and 9 Review Working Group Report
I. National Academies of Sciences, Engineering, and Medicine (NASEM) Committee on Assessing Equity in the Distribution of Fisheries Management Benefits
J. Public Comment
K. SSC Discussion and Recommendations

Thursday, September 14, 2023, 9 a.m. to 1 p.m. HST

9. Other Business
A. December SSC Meetings Dates
10. Summary of SSC Recommendations to the Council

Agenda for the Pelagic and International SC Meeting

Friday, September 15, 2023, 9 a.m. to 11 a.m. HST

1. Hawaii and American Samoa Longline Fishery Updates
2. 2024 U.S. Territorial Bigeye Tuna Catch Limit and Allocation Specification (Action Item)
3. Scenarios for Implementing Electronic Monitoring in Western Pacific Longline Fisheries
4. Pacific Remote Island Areas Proposed Sanctuary Updates
5. Updates from the U.S. Department of State
6. 19th Scientific Committee of the WCPFC
7. Issues Leading into U.S. Permanent Advisory Committee to WCPFC
8. Advisory Group Report and Recommendations
7. Other Business
8. Public Comment
9. Discussion and Recommendations

Agenda for the Program Planning SC Meeting

Friday, September 15, 2023, 11:30 a.m. to 1:30 p.m. HST

1. Welcome and Introductions
2. Addressing Climate Change in Fishery Management
A. NMFS National and Regional Activities and Priorities
B. Ocean Climate Action Plan
3. Inflation Reduction Act
A. Council Management Priorities for Addressing Climate Change
B. Council Program Planning and Multi-year Priorities
4. Advisory Group Reports and Recommendations
5. Other Business
6. Public Comment
7. Discussion and Recommendations

Agenda for the Fishing Rights of Indigenous Peoples SC Meeting

Friday, September 15, 2023, 2 p.m. to 4 p.m. HST

1. Welcome and Introductions
2. Addressing Equity and Environmental Justice in Fisheries Management
A. Report on NASEM's Committee on Assessing Equity in the Distribution of Fisheries Management Benefits
B. Updates on NMFS EEJ Regional Implementation Plan
C. Report out on NMFS engagement in the Territories
D. Updates on Marine Resource Education Program (MREP)
3. Council Program Planning and Multi-year Priorities
4. Advisory Group Reports and Recommendations
5. Other Business
6. Public Comment
7. Discussion and Recommendations

Agenda for the Executive and Budget SC Meeting

Friday, September 15, 2023, 4:30 p.m. to 6:30 p.m. HST

1. Introductions and Approval of Agenda
2. Financial Reports
3. Administrative Reports
4. Inflation Reduction Act
5. Update on Program Planning
6. Climate Change Governance Policy
7. Council Family Changes
8. Territorial Fishery Management Plan Development
9. Meetings and Workshops
10. Other Business
11. Public Comment
12. Discussion and Recommendations

Agenda for the 196th Council Meeting

Monday, September 18, 2023, 9 a.m. to 5 p.m. HST

1. Welcome and Introductions
2. Oath of Office—New Council Members
3. Approval of the 196th CM Agenda
4. Approval of the 195th CM Meeting Minutes
5. Executive Director's Report
6. Agency Reports
A. National Marine Fisheries Service
A.1. Pacific Islands Regional Office
A.2. Pacific Islands Fisheries Science Center
B. NOAA Office of General Counsel Pacific Islands Section
C. Enforcement
C.1. U.S. Coast Guard
C.2. NOAA Office of Law Enforcement
C.3. NOAA Office of General Counsel Enforcement Section
D. U.S. State Department
E. U.S. Fish and Wildlife Service
F. Public Comment
G. Council Discussion and Action
7. Hawai'i Archipelago & Pacific Remote Island Areas (PRIA)
A. Moku Pepa
B. Department of Land and Natural Resources/Division of Aquatic Resources Report
C. Review of Fishing Regulations in the Pacific Remote Island Areas
D. Options for Developing Fishing Regulations in the Proposed Pacific Remote Islands National Marine Sanctuary (Initial Action)
E. MHI Deep 7 Bottomfish Stock Assessment WPSAR Terms of Reference
F. Hawaii Uku Fishery
F.1. Uku EBFM Project
F.2. MHI Uku Ecosystem and Socioeconomic Profile Report Card
G. Advisory Group Report and Recommendations
G.1. Advisory Panel
G.2. Pelagic Plan Team
G.3. Fishing Industry Advisory Committee
G.4. Scientific & Statistical Committee
H. Public Comment
I. Council Discussion and Action

Monday, September 18, 2023, 4 p.m. to 4:30 p.m. HST

Public Comment on Non-Agenda Items

Monday, September 18, 2023, 6 p.m. to 9 p.m. HST

Fishers Forum: What's in the Gut?

Tuesday, September 19, 2023, 9 a.m. to 5 p.m. HST

8. American Samoa Archipelago
A. Motu Lipoti
B. Department of Marine and Wildlife Resources Report
C. American Samoa Bottomfish
C.1. P* and SEEM Working Group Reports
C.2. Discontinuing the Rebuilding Plan and Annual Catch Limit Specifications for 2024–2026 (Initial Action)
D. Advisory Group Report and Recommendations
D.1. Advisory Panel
D.2. Fishing Industry Advisory Committee
D.3. Scientific & Statistical Committee
E. Public Comment
F. Council Discussion and Action
9. Mariana Archipelago
A. Guam
A.1. Department of Agriculture/ Division of Aquatic and Wildlife Resources Report
A.2. Isla Informe
A.3. Review of the Guam Marine

Conservation Plan (Action Item)
B. CNMI
B.1. Arongol Falú
B.2. Department of Land and Natural Resources/Division of Fish and Wildlife Report
B.3. Review of the CNMI Marine Conservation Plan (Action Item)
C. Advisory Group Report and Recommendations
C.1. Advisory Panel
C.2. Fishing Industry Advisory Committee
C.3. Scientific and Statistical Committee
D. Public Comment
E. Council Discussion and Action
10. Protected Species
A. Endangered Species Act and Marine Mammal Protection Act Updates
A.1. Green Sea Turtle Critical Habitat Proposed Designations
A.2. Other Updates
B. Update on the Hawaii Pelagic False Killer Whale Assessment Approach
C. Advisory Group Report and Recommendations
C.1. Advisory Panel
C.2. Fishing Industry Advisory Committee
C.3. Pelagic Plan Team
C.4. Scientific & Statistical Committee
D. Public Comment
E. Council Discussion and Action

Wednesday, September 20, 2023, 9 a.m. to 5 p.m. HST

11. Program Planning and Research
A. Climate Change Governance Policy
B. Inflation Reduction Act Overview
C. NMFS Priorities for Addressing Climate Change in Fishery Management
C.1. National Activities and Priorities (including Ocean Climate Action Plan)
C.2. Regional Activities and Priorities (including Pacific Islands Regional Action Plan and CEFI)
D. Council Program Planning and Multi-Year Priorities
D.1. Council Management Priorities for Addressing Climate Change
D.2. Inflation Reduction Act Planning
E. National Legislative Report
F. Report on National Standard 4, 8, & 9 Review
G. NASEM Committee on Assessing Equity in the Distribution of Fisheries Management Benefits
H. National Seafood Strategy
I. Regional Communications & Outreach Report
J. Advisory Group Report and Recommendations
J.1. Advisory Panel
J.2. Fishing Industry Advisory Committee
J.3. Pelagic Plan Team
J.4. Education Committee
J.5. Scientific & Statistical Committee
K. Program Planning Standing Committee Report
L. Fishing Rights of Indigenous People Standing Committee Report
M. Public Comment
N. Council Discussion and Action
12. Pelagic & International Fisheries
A. American Samoa Longline Fishery Report
B. Hawaii Longline Fishery Report
C. 2024 U.S. Territorial Bigeye Tuna Catch Limit and Allocation Specification (Final Action)
D. Scenarios for Implementing Electronic Monitoring in Western Pacific Longline Fisheries
E. International Fisheries
E.1. 19th Meeting of the ISC
E.2. 19th Scientific Committee of the WCPFC
E.3. 3rd Western and Central Pacific Ocean Longline Management Workshop
F. Advisory Group Report and Recommendations
F.1. Advisory Panel
F.2. Fishing Industry Advisory Committee
F.3. Pelagic Plan Team
F.4. Scientific & Statistical Committee
G. Pelagic and International Standing Committee Report
H. Public Comment
I. Council Discussion and Action
13. Administrative Matters
A. Financial Reports
B. Administrative Reports
C. Council Family Changes
D. Meetings and Workshops
E. Report on Program Plan
F. Executive and Budget Standing Committee Report
G. Public Comment
H. Council Discussion and Action
14. Other Business

Non-emergency issues not contained in this agenda may come before the Council for discussion and formal Council action during its 196th meeting. However, Council action on regulatory issues will be restricted to those issues specifically listed in this document and any regulatory issue arising after publication of this document that requires emergency action under section 305(c) of the Magnuson-Stevens Act, provided the public has been notified of the Council's intent to take action to address the emergency.

Special Accommodations

These meetings are accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522–8220 (voice) or (808) 522–8226 (fax), at least 5 days prior to the meeting date.

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

Dated: August 23, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–18492 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD286]

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 (MAFMC) Ecosystem and Ocean Planning Advisory Panel and Committee will hold a meeting. See **SUPPLEMENTARY INFORMATION** for agenda details.

DATES: The meeting will take place from Wednesday, September 13, 2023, at 1:30 p.m. to Thursday, September 14, 2023 at 4 p.m.

ADDRESSES: This will be an in-person meeting with a virtual option. Advisory Panel and Committee members, other invited meeting participants, and members of the public will have the option to participate in person at the Royal Sonesta Harbor Court, 550 Light Street, Baltimore, MD 21202, or virtually via Webex webinar. Webinar connection instructions and briefing materials will be available at *www.mafmc.org/ssc.*

Council address: Mid-Atlantic Fishery Management Council, 800 N State Street, Suite 201, Dover, DE 19901; telephone: (302) 674–2331; website: *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: During this meeting, the Ecosystem and Ocean Planning Advisory Panel and Committee will review a draft policy/process for MAFMC review of exempted fishing permit applications for species listed as ecosystem components under the MAFMC's Unmanaged Forage Omnibus Amendment. The Advisory Panel and Committee will then provide

recommendations to the MAFMC for revisions to or adoption of this policy. The Advisory Panel and Committee will also discuss an ongoing comprehensive review of the MAFMC Ecosystem Approach to Fisheries Management (EAFM) risk assessment. The Advisory Panel and Committee will review all components of the risk assessment, including elements, definitions, indicators, and risk ranking criteria. They will then develop recommendations for MAFMC consideration for revisions to the EAFM risk assessment and potential opportunities to apply the risk assessment in the management process. A detailed agenda and background documents will be made available on the Council's website (*www.mafmc.org*) prior to the meeting.

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: August 23, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–18491 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD273]

Endangered and Threatened Species; Take of Anadromous Fish

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

ACTION: Notice of issuance of 17 scientific research permits.

SUMMARY: Notice is hereby given that NMFS has issued 17 scientific research permits under the Endangered Species Act (ESA) to the individuals and organizations listed in Table 1. The research is intended to increase knowledge of species listed under the ESA and to help guide management and conservation efforts.

ADDRESSES: The permits and related documents are available for review upon written request via email to *nmfs.wcr-apps@noaa.gov* (please include the permit number in the subject line of the email).

FOR FURTHER INFORMATION CONTACT: Shivonne Nesbit, Portland, OR ((ph.: 541–805–5320), email: *Shivonne.Nesbit@noaa.gov*).

SUPPLEMENTARY INFORMATION: Notice was published in the **Federal Register** on the dates listed below that requests for permits and permit modifications had been submitted by the below-named applicants. To locate the **Federal Register** notice that announced our receipt of the applications and a complete description of the research, go to *https://www.federalregister.gov* and search on the permit number and **Federal Register** notice information provided in the table below.

TABLE 1—ISSUED PERMITS AND PERMIT MODIFICATIONS

Permit No.	RTID	Applicant	Previous **Federal Register** notice	Issuance date
1134–8R	0648–XC771 ...	Columbia River Inter-Tribal Fish Commission; 729 NE Oregon Street, Suite 200, Portland, OR 97232–2107 (Responsible Party: Robert Lothrop).	88 FR 10295, February 17, 2023	April 21, 2023.
15573–4R ...	0648–XC771 ...	Glenn-Colusa Irrigation District; P.O. Box 150, Willows, CA 95988 (Responsible party: Thad Bettner).	88 FR 10295, February 17, 2023	March 31, 2023.
15824–3R ...	0648–XC771 ...	County of Santa Cruz, Environmental Health Services; 701 Ocean Street, Room 312, Santa Cruz, CA 95060 (Responsible party: Sierra Ryan).	88 FR 10295, February 17, 2023	March 31, 2023.
16303–3R ...	0648–XC771 ...	USGS Western Fisheries Research Center; 6505 NE 65th Street, Seattle, WA 98115 (Responsible party: Michael Schmidt).	88 FR 10295, February 17, 2023	April 6, 2023.
21061–2R ...	0648–XC771 ...	Windward Environmental; 200 W Mercer St. Suite 401, Seattle, WA 98119 (Responsible party: Thai Do).	88 FR 10295, February 17, 2023	April 5, 2023.
22093–2R ...	0648–XC771 ...	Snoqualmie Valley Watershed Improvement District; PO Box 1148, Carnation, WA 98014 (Responsible party: Andrea Obst).	88 FR 10295, February 17, 2023	April 6, 2023.
22998–2R ...	0648–XC771 ...	U.S. Fish and Wildlife Service, Western Washington Fish and Wildlife Conservation; 510 Desmond Dr SE 102, Lacey, WA 98503 (Responsible party: Jeffery Johnson).	88 FR 10295, February 17, 2023	April 6, 2023.
26368–2M ..	0648–XC771 ...	Idaho State University; 1856 S 3rd Ave, Pocatello, ID 83201 (Responsible party: Tyler Breech).	88 FR 10295, February 17, 2023	April 4, 2023.
26714	0648–XC771 ...	Oregon Department of Fish and Wildlife; 65495 Alder Slope Rd., Enterprise, OR 97828 (Responsible party: Michael Lance).	88 FR 10295, February 17, 2023	April 4, 2023.
26766	0648–XC771 ...	Washington Department of Natural Resources, Small Forest Landowners Office; PO Box 544, Twisp, WA 98856 (Responsible party: Brent Haverkamp).	88 FR 10295, February 17, 2023	April 4, 2023.
26968	0648–XC771 ...	California Department of Fish and Wildlife, Aquatic Bioassessment Lab; 2005 Nimbus Rd, Rancho Cordova, CA 95670 (Responsible party: Alison Furler).	88 FR 10295, February 17, 2023	March 31, 2023.
27069	0648–XC771 ...	Thomas Gast & Associates Environmental Consultants; PO Box 1137, Arcata, CA 95518 (Responsible party: Thomas Gast).	88 FR 10295, February 17, 2023	June 20, 2023.
27091	0648–XC771 ...	Port of Seattle, Maritime Environment & Sustainability; PO Box 1209, Seattle, WA 98111 (Responsible party: Sloan Jon).	88 FR 10295, February 17, 2023	April 6, 2023.
27098	0648–XC771 ...	WA Department of Natural Resources, Aquatic Resources; 1111 Washington St SE, Olympia, WA 98504 (Responsible party: Ron Coleman).	88 FR 10295, February 17, 2023	April 6, 2023.
27129	0648–XC771 ...	United States Geological Survey; 10615 SE Cherry Blossom Dr., Portland, OR 97216 (Responsible party: Ian Waite).	88 FR 10295, February 17, 2023	April 7, 2023.
27162	0648–XC771 ...	Washington Department of Natural Resources, Olympic Region; 411 Tillicum Lane, Forks, WA 98331 (Responsible party: Drew Rosanbalm).	88 FR 10295, February 17, 2023	August 14, 2023.
27212	0648–XC771 ...	Oregon State University, Department of Fisheries and Wildlife; 104 Nash Hall, Corvallis, OR 97330 (Responsible party: Brian Sidlauskas).	88 FR 10295, February 17, 2023	April 4, 2023.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activities proposed are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Authority

Scientific research permits are issued in accordance with section 10(a)(1)(A) of the ESA (16 U.S.C. 1531 *et seq.*) and regulations governing listed fish and wildlife permits (50 CFR 222–226). NMFS issues permits based on finding that such permits: (1) are applied for in good faith; (2) if granted and exercised, would not operate to the disadvantage of the listed species that are the subject of the permit; and, (3) are consistent with the purposes and policy of section 2 of the ESA. The authority to take listed species is subject to conditions set forth in the permits.

Dated: August 22, 2023.

Angela Somma,

Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2023–18420 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Request for Public Comment on Draft Hydrographic Survey Specifications and Deliverables

AGENCY: Office of Coast Survey, National Ocean Service, National Oceanic and Atmospheric Administration, Department of Commerce.

ACTION: Request for comments.

SUMMARY: National Oceanic and Atmospheric Administration's (NOAA's) Office of Coast Survey (OCS) requests public comment from all interested parties on a draft of the newly-revised Hydrographic Survey Specifications and Deliverables document (HSSD). The HSSD has been rewritten to be more forward looking with respect to new and developing technologies, best facilitate the use of automated tools, and better integrate with the S–100 based products and the National Bathymetric Source (NBS), which is the OCS database for best-available bathymetry. Additionally, the revised HSSD will better accommodate the increasing amounts of hydrographic data obtained from external sources, with metadata tags to denote data quality and universal data licenses to define terms of use, which will result in more streamlined, standardized workflows. Numerous subject matter experts collaborated to modernize the HSSD so that it best supports OCS as a data-driven organization.

DATES: Comments must be received via email by 5 p.m. ET on October 12, 2023.

ADDRESSES: A copy of the revised HSSD may be downloaded or viewed at: *https://nauticalcharts.noaa.gov/publications/docs/standards-and-requirements/specs/HSSD_2023-2-02.pdf.*

All comments must be submitted by email to *hssd.staff@noaa.gov* by 5 p.m. ET on October 12, 2023.

Instructions: Please include ''Public Comment on Revised HSSD'' in the subject line of the email message. If applicable, clearly indicate the HSSD section and page number to which submitted comments pertain. All submissions must be in English. Email attachments will be accepted in plain text, Microsoft Word, or Adobe PDF formats only. Each individual or institution is requested to submit only one comment. Please note that the U.S. Government will not pay for response preparation or the use of any information contained in the response.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Matt Wilson, NOAA Office of Coast Survey, at *hssd.staff@noaa.gov,* (757) 828–6915.

SUPPLEMENTARY INFORMATION: In accordance with the Coast and Geodetic Survey Act, 33 U.S.C. 883 *et seq.,* and the Hydrographic Services Improvement Act, 33 U.S.C. 892 *et seq.,* NOAA promulgates standards and specifications for hydrographic data in the HSSD in order to ensure safe and efficient navigation in support of our maritime economy. NOAA has revised the HSSD to better accommodate new and developing technologies and increasing amounts of externally-sourced hydrographic data submissions. The revised HSSD facilitates more streamlined workflows via critical metadata tags and universal data licenses, and is better integrated with the NBS program, for a more efficient means of product generation and public access to our national bathymetry.

Authority: 33 U.S.C. 883 *et seq.;* 33 U.S.C. 892 *et seq.*

RDML Benjamin K. Evans,

Director, Office of Coast Survey, National Ocean Service, National Oceanic and Atmospheric Administration.

[FR Doc. 2023–18525 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–JE–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XD239]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of a public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a public meeting of its Monkfish 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 Wednesday, September 13, 2023, from 9 a.m. to 1 p.m.

ADDRESSES:

Webinar registration URL information: https://attendee.gotowebinar.com/register/7745832846565589 33.

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 Monkfish Committee will meet to receive Advisory Panel comments on fishery performance and outlook for the remainder of fishing year 2023, as well as reviewing the outcomes and recommendations of the Monkfish Research-Set-Aside (RSA) Working Group and make recommendations to the Council on next steps with the RSA program. They will make recommendations to the Council for monkfish-related work in 2024, which could include developing regulatory changes to the RSA program.

Other business will be discussed as 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: August 22, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–18434 Filed 8–25–23; 8:45 am]

BILLING CODE 3510–22–P

CONSUMER PRODUCT SAFETY COMMISSION

[CPSC Docket No. 23–C0003]

Whirlpool Corporation

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: The Commission publishes in the **Federal Register** any settlement that it provisionally accepts under the Consumer Product Safety Act. Published below is a provisionally accepted Settlement Agreement with Whirlpool Corporation containing a civil penalty in the amount of $11,500,000, subject to the terms and conditions of the Settlement Agreement. The Commission voted unanimously (4–0) to provisionally accept the proposed Settlement Agreement and Order pertaining to Whirlpool Corporation.

DATES: Any interested person may ask the Commission not to accept this agreement or otherwise comment on its contents by filing a written request with the Office of the Secretary by September 12, 2023.

ADDRESSES: Persons wishing to comment on this Settlement Agreement should send written comments to Comment 23–C0003, Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (240) 863–8938 (mobile), (301) 504–7479 (office); email: *cpsc-os@cpsc.gov.*

FOR FURTHER INFORMATION CONTACT: Joseph Kessler, Trial Attorney, Division of Enforcement and Litigation, Office of Compliance and Field Operations, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, Maryland 20814; *jkessler@cpsc.gov,* 301–504–7602 (office).

SUPPLEMENTARY INFORMATION: The text of the Settlement Agreement and Order appear below.

Dated: August 23, 2023.

Alberta E. Mills,

Secretary.

United States of America

Consumer Product Safety Commission

In the Matter of: Whirlpool Corporation CPSC Docket No.: 23–C0003

Settlement Agreement

1. In accordance with the Consumer Product Safety Act, 15 U.S.C. 2051–2089 (''CPSA''), and 16 CFR 1118.20, Whirlpool Corporation (''Whirlpool'' or the ''Firm''), and the United States Consumer Product Safety Commission (''Commission''), through its staff, hereby enter into this Settlement Agreement (''Agreement''). The Agreement and the incorporated attached Order resolve staff's charges set forth below.

The Parties

2. The Commission is an independent federal regulatory agency, established pursuant to, and responsible for, the enforcement of the CPSA, 15 U.S.C. 2051–2089. By executing the Agreement, staff is acting on behalf of the Commission, pursuant to 16 CFR 1118.20(b). The Commission issues the Order under the provisions of the CPSA.

3. Whirlpool is a corporation, organized and existing under the laws of the state of Delaware, with its principal place of business in Benton Harbor, Michigan.

Staff Charges

4. Between December 2016 and July 2019, Whirlpool manufactured and distributed in the United States approximately 20,000 units of various KitchenAid, Whirlpool, and JennAir electric radiant heat glass cooktops, model numbers KCES950HSS, KCES950HBL, KCES956HSS, KCES956HBL, WCE97US0HS, WCE97US0HB, WCE97US6HS, WCE97US6HB, JEC4430HS, JEC4430HB, JEC4536HS, JEC4536HB, JEC4424HB, JED4430GB, JED4430GS, JED4536GB, and JED4536GS (''Subject Products'').

5. The Subject Products are ''consumer products'' that were ''manufactured'' and ''distribut[ed] in commerce,'' as those terms are defined or used in sections 3(a)(5), (7), and (10) of the CPSA, 15 U.S.C. 2052(a)(5), (8), and (10). Whirlpool is a ''manufacturer'' of the Subject Products, as such term is defined in section 3(a)(11) of the CPSA, 15 U.S.C. 2052(a)(11).

Violation of CPSA Section 19(a)(4)

6. The Subject Products contain a defect which could create a substantial product hazard or create an unreasonable risk of serious injury or death because one or more cooktop surface elements can turn on by themselves, posing a fire and burn hazard.

7. Beginning in November 2017 and continuing into 2019, Whirlpool received numerous reports from consumers that cooktop surface elements turned on by themselves.

8. Between 2007 and 2015, CPSC had publicly announced at least five recalls involving gas or electric cooktops manufactured by other firms reportedly turning on by themselves or not turning off, with each recall announcement warning that the defect presented a fire or burn hazard.

9. Despite possessing information that reasonably supported the conclusion that the Subject Products contained a defect that could create a substantial product hazard or created an unreasonable risk of serious injury or death, Whirlpool did not immediately report to the Commission.

10. By the time Whirlpool filed an initial report with the Commission under 15 U.S.C. 2064(b) concerning the Subject Products, the Firm had received at least 157 reports of Subject Products turning on by themselves, including 14 reports of property damage, four reports of objects igniting, and two reports of minor burns.

11. The Commission and Whirlpool jointly announced the recall of the Subject Products on August 28, 2019.

Failure to Timely Report

12. Despite having information reasonably supporting the conclusion that the Subject Products contained a defect or created an unreasonable risk of serious injury or death, Whirlpool did not notify the Commission immediately of such defect or risk, as required by section 15(b)(4) of the CPSA, 15 U.S.C.

2064(b)(4), in violation of section 19(a)(4) of the CPSA, 15 U.S.C. 2068(a)(4).

13. Because the information in Whirlpool's possession about the Subject Products constituted actual and presumed knowledge, Whirlpool knowingly violated section 19(a)(4) of the CPSA, 15 U.S.C. 2068(a)(4), as the term ''knowingly'' is defined in section 20(d) of the CPSA, 15 U.S.C. 2069(d).

14. Pursuant to section 20 of the CPSA, 15 U.S.C. 2069, Whirlpool is subject to civil penalties for its knowing violation of section 19(a)(4) of the CPSA, 15 U.S.C. 2068(a)(4).

Response of Whirlpool

15. This agreement does not constitute an admission by Whirlpool to the staff's charges as set forth in paragraphs 4 through 14 above, including without limitation that the Subject Products contained a defect that could create a substantial product hazard or created an unreasonable risk of serious injury or death; that Whirlpool failed to notify the Commission in a timely matter in accordance with section 15(b) of the CPSA, 15 U.S.C. 2064(b); and that Whirlpool knowingly violated section 19(a)(4) of the CPSA, 15 U.S.C. 2068(a)(4), as the term ''knowingly'' is defined in section 20(d) of the CPSA, 15 U.S.C. 2069(d).

16. Whirlpool enters into this Agreement to settle this matter and to avoid the cost, distraction, delay, uncertainty, and inconvenience of protracted litigation or other proceedings. Whirlpool does not admit that it violated the CPSA or any other law, and Whirlpool's willingness to enter into this Agreement and Order does not constitute, nor is it evidence of, an admission by Whirlpool of liability or violation of any law.

17. At all relevant times, Whirlpool has had a product safety compliance program, both to help ensure the safety of its products before they are marketed and to identify, monitor and evaluate potential product safety issues on an ongoing basis. Whirlpool maintains that upon identifying the reported issue, Whirlpool promptly notified CPSC and voluntarily recalled the Subject Products pursuant to CPSC's Fast Track recall program.

Agreement of the Parties

18. Under the CPSA, the Commission has jurisdiction over the matter involving the Subject Products and over Whirlpool.

19. The parties enter into the Agreement for settlement purposes only. The Agreement does not constitute an admission by Whirlpool or a determination by the Commission that Whirlpool violated the CPSA.

20. In settlement of staff's charges, Whirlpool shall pay a civil penalty in the amount of eleven million, five hundred thousand dollars ($11,500,000) (''Total Civil Penalty Amount''). The $11,500,000 payment shall be paid within thirty (30) calendar days after receiving service of the Commission's final Order accepting the Agreement. All payments to be made under the Agreement shall constitute debts owing to the United States and shall be made by electronic wire transfer to the United States via *http://www.pay.gov,* for allocation to, and credit against, the payment obligations of Whirlpool under this Agreement. Failure to make such payment by the date specified in the Commission's final Order shall constitute Default.

21. The Commission or the United States may seek enforcement for any breach of, or any failure to comply with, any provision of this Agreement and Order in United States District Court, to seek relief including, but not limited to, collecting amounts due.

22. All unpaid amounts, if any, due and owing under the Agreement, shall constitute a debt due and immediately owing by Whirlpool to the United States, and interest shall accrue and be paid by Whirlpool at the federal legal rate of interest set forth at 28 U.S.C. 1961(a) and (b) from the date of Default, until all amounts due have been paid in full (hereinafter ''Default Payment Amount'' and ''Default Interest Balance''). Whirlpool shall consent to a Consent Judgment in the amount of the Default Payment Amount and Default Interest Balance, and the United States, at its sole option, may collect the entire Default Payment Amount and Default Interest Balance, or exercise any other rights granted by law or in equity, including, but not limited to, referring such matters for private collection, and Whirlpool agrees not to contest, and hereby waives and discharges any defenses to, any collection action undertaken by the United States, or its agents or contractors, pursuant to this paragraph. Whirlpool shall pay the United States all reasonable costs of collection and enforcement under this paragraph, respectively, including reasonable attorney's fees and expenses.

23. After staff receives this Agreement executed on behalf of Whirlpool, staff shall promptly submit the Agreement to the Commission for provisional acceptance. Promptly following provisional acceptance of the Agreement by the Commission, the Agreement shall be placed on the public record and published in the **Federal Register**, in accordance with the procedures set forth in 16 CFR 1118.20(e). If the Commission does not receive any written request not to accept the Agreement within fifteen (15) calendar days, the Agreement shall be deemed finally accepted on the 16th calendar day after the date the Agreement is published in the **Federal Register**, in accordance with 16 CFR 1118.20(f).

24. This Agreement is conditioned upon, and subject to, the Commission's final acceptance, as set forth above, and it is subject to the provisions of 16 CFR 1118.20(h). Upon the later of: (i) Commission's final acceptance of this Agreement and service of the accepted Agreement upon Whirlpool, and (ii) the date of issuance of the final Order, this Agreement shall be in full force and effect, and shall be binding upon the parties.

25. Effective upon the later of: (1) the Commission's final acceptance of the Agreement and service of the accepted Agreement upon Whirlpool and (2) and the date of issuance of the final Order, for good and valuable consideration, Whirlpool hereby expressly and irrevocably waives and agrees not to assert any past, present, or future rights to the following, in connection with the matter described in this Agreement:

(i) an administrative or judicial hearing;

(ii) judicial review or other challenge or contest of the Commission's actions;

(iii) a determination by the Commission of whether Whirlpool failed to comply with the CPSA and the underlying regulations;

(iv) a statement of findings of fact and conclusions of law; and

(v) any claims under the Equal Access to Justice Act.

26. Whirlpool shall maintain its compliance program (''Compliance Program'') designed to ensure compliance with the CPSA (''applicable law'') with respect to any consumer product imported, manufactured, distributed or sold by Whirlpool, which shall contain the following elements:

(i) written standards, policies, and procedures, including those designed to ensure that information that may relate to or impact CPSA compliance are conveyed effectively to personnel responsible for CPSA compliance, whether or not an injury has been reported;

(ii) procedures and systems for tracking and reviewing claims, including warranty claims, and reports for safety concerns and for implementing corrective and preventive

actions when compliance deficiencies or violations are identified;

(iii) procedures requiring that information required to be disclosed by Whirlpool to the Commission is recorded, processed, and reported in accordance with applicable law;

(iv) procedures requiring that all reporting made to the Commission is timely, truthful, complete, accurate, and in accordance with applicable law;

(v) procedures requiring that prompt disclosure is made to Whirlpool's management of any significant deficiencies or material weaknesses in the design or operation of such internal controls that are reasonably likely to affect adversely, in any material respect, Whirlpool's ability to record, process and report to the Commission in accordance with applicable law;

(vi) mechanisms to effectively communicate to all applicable Whirlpool employees, through training programs or other means, compliance-related company policies and procedures to prevent violations of the CPSA;

(vii) a mechanism for confidential employee reporting of compliance-related questions or concerns to either a compliance officer or to another senior manager with authority to act as necessary;

(viii) Whirlpool's senior management responsibility for, and general board oversight of, CPSA compliance, including enhancements to the Firm's compliance program to ensure that incident and injury data are reviewed and analyzed for purposes of CPSA Section 15(b) reporting;

(ix) for at least three (3) years, an annual internal audit of the effectiveness of policies, procedures, systems, and training related to CPSA compliance that evaluates opportunities for improvement, deficiencies or weaknesses, and the Firm's overall culture of compliance; and

(x) retention of all CPSA compliance-related records for at least five (5) years, and availability of such records to CPSC staff upon request.

27. Whirlpool shall submit a report under CPSA Section 16(b), sworn to under penalty of perjury:

(i) describing in detail its compliance program and internal controls and the actions Whirlpool has taken to comply with each subparagraph of paragraph 26;

(ii) affirming that during the reporting period, Whirlpool has reviewed its compliance program and internal controls, including the actions referenced in subparagraph (i) of this paragraph, for effectiveness, and that it complies with each subparagraph of paragraph 26, or describing in detail any non-compliance with any such subparagraph; and

(iii) identifying the results of the annual internal audit referenced in paragraph 26(ix) and any changes or modifications made during the reporting period to Whirlpool's compliance program or internal controls to ensure compliance with the terms of the CPSA and, in particular, the requirements of CPSA Section 15 related to timely reporting.

Such reports shall be submitted annually to the Director, Office of Compliance, Division of Enforcement and Litigation, for a period of three (3) years. The first report shall be submitted 30 days after the close of the first 12-month reporting period, which begins on the date of the Commission's Final Order of Acceptance of the Agreement, and successive reports shall be due annually on the same date thereafter. Whirlpool is aware of the Commission's position that failure to make such timely and accurate reports as required by this Agreement and Order may, without limitation, constitute a violation of Section 19(a)(3) of the CPSA and may subject the Firm to enforcement under Section 22 of the CPSA.

28. Notwithstanding and in addition to the above, upon request of staff, Whirlpool shall promptly provide written documentation of any changes or modifications to its compliance program or internal controls and procedures, including the effective dates of the changes or modifications thereto. Whirlpool shall cooperate fully and truthfully with staff and shall make available all non-privileged information and materials and personnel deemed necessary by staff to evaluate Whirlpool's compliance with the terms of the Agreement.

29. The parties acknowledge and agree that the Commission may publicize the terms of the Agreement and the Order.

30. Whirlpool represents that the Agreement:

(i) is entered into freely and voluntarily, without any degree of duress or compulsion whatsoever;

(ii) has been duly authorized; and

(iii) constitutes the valid and binding obligation of Whirlpool, enforceable against Whirlpool in accordance with its terms. The individuals signing the Agreement on behalf of Whirlpool represent and warrant that they are duly authorized by Whirlpool to execute the Agreement.

31. The signatories represent that they are authorized to execute this Agreement.

32. The Agreement is governed by the laws of the United States.

33. The Agreement and the Order shall apply to, and be binding upon, Whirlpool and each of its parents, successors, transferees, and assigns; and a violation of the Agreement or Order may subject Whirlpool, and each of its parents, successors, transferees, and assigns, to appropriate legal action.

34. The Agreement, any attachments, and the Order constitute the complete agreement between the parties on the subject matter contained therein.

35. The Agreement may be used in interpreting the Order. Understandings, agreements, representations, or interpretations apart from those contained in the Agreement and the Order may not be used to vary or contradict their terms. For purposes of construction, the Agreement shall be deemed to have been drafted by both of the parties and shall not, therefore, be construed against any party, for that reason, in any subsequent dispute.

36. The Agreement may not be waived, amended, modified, or otherwise altered, except as in accordance with the provisions of 16 CFR 1118.20(h). The Agreement may be executed in counterparts.

37. If any provision of the Agreement or the Order is held to be illegal, invalid, or unenforceable under present or future laws effective during the terms of the Agreement and the Order, such provision shall be fully severable. The balance of the Agreement and the Order shall remain in full force and effect, unless the Commission and Whirlpool agree in writing that severing the provision materially affects the purpose of the Agreement and the Order.

(Signatures on next page)

Whirlpool Corporation

By: /s/

Dated: August 7, 2023.

Nathan A. Mouw,

Whirlpool Corporation, Senior Director—Global Product Safety and Regulatory Affairs.

Dated: August 7, 2023.

By: /s/

Eric Rubel,

Arnold & Porter Kaye Scholer LLP, Counsel to Whirlpool Corporation.

U.S. Consumer Product Safety Commission

Mary B. Murphy, Director,

Howard Tarnoff, Deputy Director, Division of Enforcement and Litigation.

Dated: August 8, 2023.

By: /s/

Joseph Kessler,

Trial Attorney, Division of Enforcement and Litigation, Office of Compliance and Field Operations.

United States of America

Consumer Product Safety Commission

In the Matter of: WHIRLPOOL CORPORATION

CPSC Docket No.: 23–C0003

Order

Upon consideration of the Settlement Agreement entered into between Whirlpool Corporation (''Whirlpool'') and the U.S. Consumer Product Safety Commission (''Commission'' or ''CPSC''), and the Commission having jurisdiction over the subject matter and over Whirlpool, and it appearing that the Settlement Agreement is in the public interest, the Settlement Agreement is incorporated by reference and it is:

Provisionally accepted and this Order issued on the 22nd day of August, 2023.

By order of the commission.

Alberta E. Mills, Secretary,
U.S. Consumer Product Safety Commission.

[FR Doc. 2023–18460 Filed 8–25–23; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2010–0055]

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Standard for the Flammability of Mattresses and Mattress Pads and Standard for the Flammability (Open Flame) of Mattress Sets

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: As required by the Paperwork Reduction Act of 1995, the Consumer Product Safety Commission (CPSC or Commission) announces that the Commission has submitted to the Office of Management and Budget (OMB) a request for extension of approval for information collection requirements set forth in the Standard for the Flammability of Mattresses and Mattress Pads, and the Standard for the Flammability (Open Flame) of Mattress Sets, approved previously under OMB control number 3041–0014. On June 20, 2023, CPSC published a notice in the **Federal Register** to announce the agency's intention to seek extension of approval of the collection of information. The Commission has received no comments. Therefore, by publication of this notice, the Commission announces that CPSC has submitted to the OMB a request for extension of approval of that collection of information, without change.

DATES: Submit written or electronic comments not later than September 27, 2023.

ADDRESSES: Submit comments about this request by email: *OIRA_submission@omb.eop.gov* or fax: 202–395–6881. Comments by mail should be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the CPSC, Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503. Comments by mail should be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the CPSC, Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503. Written comments that are sent to OMB also should be submitted electronically at: *http://www.regulations.gov,* under Docket No. CPSC–2010–0055.

FOR FURTHER INFORMATION CONTACT: Cynthia Gillham, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504–7791, or by email to: *cgillham@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

In 1972, the Commission promulgated under section 4 of the Flammable Fabrics Act (FFA), 15 U.S.C. 1193, the Standard for the Flammability of Mattresses and Mattresses Pads, 16 CFR part 1632 (part 1632), to reduce the unreasonable risk of burn injuries and deaths from fires associated with mattresses and mattress pads. 49 FR 19796. Part 1632 prescribes requirements to test whether a mattress or mattress pad will resist ignition from a smoldering cigarette. Part 1632 also requires manufacturers to perform successfully prototype tests of each combination of materials and construction methods used to produce their mattresses or mattress pads. Manufacturers and importers must maintain the records and test results specified under the standard for three years.

Also, to reduce deaths and injuries related to mattress fires, particularly those ignited by open-flame sources, such as lighters, candles, and matches, the Commission promulgated the Standard for the Flammability (Open Flame) of Mattress Sets, 16 CFR part 1633 (part 1633), under section 4 of the FFA. Part 1633 requires manufacturers to maintain certain records to document compliance with the standard, including maintaining records concerning prototype testing, pooling, and confirmation testing, and quality assurance procedures and any associated testing. The required records must be maintained for as long as mattress sets based on the prototype are in production and be retained for three years thereafter.

OMB previously approved the collection of information for parts 1632 and 1633 under control number 3041–0014, with an expiration date of August 31, 2023. On June 20, 2023, the Commission published a notice in the **Federal Register** (88 FR 39832), to announce the agency's intention to seek extension of approval of the collection of information for control number 3041–0014. The Commission has received no comments. Therefore, by publication of this notice, the Commission announces that CPSC has submitted to the OMB a request for extension of approval of that collection of information, without change.

B. Burden Hours

Part 1632: Commission staff estimates 403 respondents produce mattresses, and that each respondent will spend 26 hours for testing and record keeping annually, for a total of 10,478 hours (403 establishments × 26 hours = 10,478). The hourly compensation for the time required for record keeping is $72.68 (for management, professional, and related occupations in goods-producing industries, Bureau of Labor Statistics, March 2023). Staff's estimated annualized cost to respondents is approximately $761,541 (10,478 hours × $72.68 per hour).

Part 1633: Part 1633 requires detailed documentation of prototype identification and testing records, model and prototype specifications, inputs used, name and location of suppliers, and confirmation of test records, if establishments choose to pool a prototype. This documentation is in addition to documentation already conducted by mattress manufacturers to meet part 1632. Staff again estimates that there are 403 respondents.

Using these estimates, including records of reported burden hours since 2017, Commission staff estimates the recordkeeping requirements to require about 4 hours and 44 minutes per establishment, per qualified prototype. Most mattress manufacturers base their complying production on 15 to 20 prototypes, although some larger manufacturers reportedly are producing mattresses based on more than 100 prototypes. Assuming that establishments qualify their production with an average of 20 different qualified prototypes, recordkeeping time is about

94.6 hours (4.73 hours × 20 prototypes) per establishment, per year. This translates to an estimated annual recordkeeping time cost to all mattress producers of 38,124 hours (94.6 hours × 403 establishments). The hourly compensation for the time required for record keeping is $72.68 (for management, professional, and related occupations in goods-producing industries, Bureau of Labor Statistics, March 2023).[1] Accordingly, the annual total estimated cost for recordkeeping is approximately $2,770,852 (38,124 hours × $72.68 per hour). Pooling among establishments or using a prototype qualification for longer than 1 year will reduce the hours required and associated cost, however.

The total estimated annual cost to the 403 establishments for the burden hours associated with parts 1632 and 1633 is approximately $3.5 million ($761,541+ $2,770,852 = $3,532,393.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2023–18476 Filed 8–25–23; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2011–0014]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: As required by the Paperwork Reduction Act of 1995, the Consumer Product Safety Commission (CPSC or Commission) requests comment on a proposed extension of approval of a generic clearance for the collection of qualitative feedback on agency service delivery, approved previously under OMB Control No. 3041–0148. CPSC will consider all comments received in response to this notice, before requesting an extension of this collection of information from the Office of Management and Budget (OMB).

DATES: Submit written or electronic comments on the collection of information by October 27, 2023.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2011–0014, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *https://www.regulations.gov.* Follow the instructions for submitting comments. CPSC typically does not accept comments submitted by electronic mail (email), except through *https://www.regulations.gov.* CPSC encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Mail/Hand Delivery/Courier/Confidential Written Submissions: Submit comments by mail, hand delivery, or courier to: Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; telephone: (301) 504–7479. If you wish to submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public, you can submit such material by mail, hand delivery, or courier, or you can email it to: *cpsc-os@cpsc.gov.*

Instructions: All submissions must include the agency name and docket number for this notice. CPSC may post all comments without change, including any personal identifiers, contact information, or other personal information provided, to: *www.regulations.gov.* Do not submit electronically: confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If you wish to submit such information, please submit it according to the instructions for mail/hand delivery/courier/confidential written submissions.

Docket: For access to the docket to read background documents or comments received, go to: *www.regulations.gov.* Insert the docket number, CPSC–2011–0014, into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Cynthia Gillham, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504–7791, or by email to: *cgillham@cpsc.gov.*

SUPPLEMENTARY INFORMATION: CPSC seeks to renew the following currently approved collection of information:

A. Background

Title: Generic Clearance for the Collection of Qualitative Feedback on Agency Service Delivery.

OMB Number: 3041–0148.

Type of Review: Renewal of collection.

Frequency of Response: On occasion.

Affected Public: Individuals and households, businesses and organizations, state, local, or tribal government.

Description of Collection: Executive Order 12862 (Sept. 11, 1993) encourages independent Federal agencies such as CPSC to provide service to the public that matches or exceeds the best service available in the private sector. To that end, CPSC seeks to renew OMB approval of a generic clearance to collect qualitative feedback on CPSC service delivery. Qualitative feedback means information that provides useful insights on perceptions and opinions but does not include statistical surveys that yield quantitative results that can be generalized to the population of study. This collection of information is necessary to enable CPSC to garner customer and stakeholder feedback in an efficient, timely manner, in accordance with CPSC's commitment to improving service delivery.

This feedback will provide insights into customer or stakeholder perceptions, experiences, and expectations; provide an early warning of issues with service; and help focus attention on areas where communication, training, or changes in operations might improve delivery of products or services. These collections will also allow for ongoing, collaborative, and actionable communications between CPSC and its customers and stakeholders.

B. Burden

Estimated Burden: CPSC will use a variety of instruments and platforms to collect information from respondents. CPSC estimates the burden of the collection of information is as follows:

[1] We updated this estimate from the June 20, 2023 notice (88 FR 39833) to use the more recent March 2023 Bureau of Labor Statistics.

ESTIMATED ANNUAL REPORTING BURDEN

Type of collection	Number of respondents	Annual frequency per response	Hours per response	Total hours
Qualitative Surveys (3)	600	1	.25	150
Focus Groups	200	1	4	800
Customer Satisfaction Surveys (3)	600	1	.25	150
Usability Tests	200	1	.5	100

Based on the above numbers, the total estimated burden for surveys, focus groups, and usability tests combined is estimated to be 1,200 hours annually. The total burden hours requested, 3,600, are based on the number of collections CPSC expects to conduct over the requested period for this clearance (1,200 hours annually x 3 years).

Assuming an hourly rate of $43.07 (U.S. Bureau of Labor Statistics, ''Employer Costs for Employee Compensation,'' All Civilian Workers, Total compensation, *https://www.bls.gov/news.release/archives/ecec_06162023.pdf,* March 2023) the estimated total burden cost is $51,684 annually. This collection has no associated operating, maintenance, or capital costs.

If appropriate, CPSC will collect information electronically and/or use online collaboration tools to reduce burden. No similar data are gathered or maintained by CPSC, or available from other sources known to CPSC.

Burden on Small Entities: Small businesses or other small entities may be involved in these efforts, but CPSC will minimize the burden of information collections approved under this clearance by sampling, asking for readily available information, and using short, easy-to-complete information collection instruments.

Costs to Federal Government: The anticipated cost to the Federal Government is approximately $51,574 annually. These costs are comprised of staff time for preparing questions, analyzing the responses, and conducting focus groups. CPSC estimates the total staff time could be four staff months annually. This is based on a GS–12 level salaried employee. The average annual wage rate for a mid-level salaried GS–12 employee in the Washington, DC metropolitan area (effective as of January 2023) is $106,759 (GS–12, step 5). This represents 69.0 percent of total compensation (U.S. Bureau of Labor Statistics, ''Employer Costs for Employee Compensation,'' March 2023, percentage of wages and salaries for all civilian employees, *https://www.bls.gov/news.release/archives/ecec_06162023.pdf*). Adding an additional 31.0 percent for benefits brings average annual compensation for a mid-range salaried GS–12 employee to $154,723. Assuming that approximately four staff months will be required annually, this results in an annual estimated cost of $51,574.

C. Request for Comments

CPSC solicits written comments from all interested persons about the proposed collection of information. CPSC specifically solicits information relevant to the following topics:

- Whether the collection of information described is necessary for the proper performance of CPSC's functions, including whether the information would have practical utility;
- Whether the estimated burden of the proposed collection of information is accurate;
- Whether the quality, utility, and clarity of the information to be collected could be enhanced; and
- Whether the burden imposed by the collection of information could be minimized by use of automated, electronic, or other technological collection techniques, or other forms of information technology.

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2023–18416 Filed 8–25–23; 8:45 am]

BILLING CODE 6355–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2009–0092]

Proposed Extension of Approval of Information Collection; Comment Request—Clothing Textiles, Vinyl Plastic Film

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: As required by the Paperwork Reduction Act of 1995, the Consumer Product Safety Commission (CPSC or Commission) announces that the Commission has submitted to the Office of Management and Budget (OMB) a request for extension of approval of a collection of information associated with the Standard for the Flammability of Clothing Textiles and the Standard for the Flammability of Vinyl Plastic Film, previously approved under OMB control number 3041–0024. OMB's most recent extension of approval will expire on August 31, 2023. On June 20, 2023, CPSC published a notice in the **Federal Register** to announce the Commission's intention to seek extension of approval of the collection of information. The Commission received no comments on the burden estimates contained in that notice.

DATES: Submit written or electronic comments not later than September 27, 2023.

ADDRESSES: Submit comments about this request by email: *OIRA_submission@omb.eop.gov* or fax: 202–395–6881. Comments by mail should be sent to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the CPSC, Office of Management and Budget, Room 10235, 725 17th Street NW, Washington, DC 20503. In addition, written comments that are sent to OMB also should be submitted electronically at: *http://www.regulations.gov,* under Docket No. CPSC–2009–0092.

FOR FURTHER INFORMATION CONTACT: Cynthia Gillham, Consumer Product Safety Commission, 4330 East-West Highway, Bethesda, MD 20814; (301) 504–7791, or by email to: *cgillham@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

The Commission has promulgated several standards under section 4 of the Flammable Fabrics Act (FFA; 15 U.S.C. 1193) to prohibit the use of dangerously flammable textiles and related materials in wearing apparel. Clothing and fabrics intended for use in clothing) are generally subject to the Standard for the Flammability of Clothing Textiles (16 CFR part 1610). Clothing made from vinyl plastic film and vinyl plastic film intended for use in clothing is subject to the Standard for the Flammability of

Vinyl Plastic Film (16 CFR part 1611). These standards prescribe a test to ensure that articles of wearing apparel, and fabrics and film intended for use in wearing apparel, are not dangerously flammable because of rapid and intense burning.[1]

Section 8 of the FFA (15 U.S.C. 1197) provides that a person who receives a guaranty in good faith that a product complies with an applicable flammability standard is not subject to criminal prosecution for a violation of the FFA resulting from the sale of any product covered by the guaranty. CPSC uses the information compiled and maintained by firms that issue these guaranties to help protect the public from risks of injury or death associated with flammable clothing and fabrics and vinyl film intended for use in clothing. In addition, the information helps CPSC to conduct corrective actions if any products covered by a guaranty fail to comply with the applicable standard in a manner that creates a substantial risk of injury or death to the public. Section 8 of the FFA requires that a guaranty must be based on ''reasonable and representative tests.'' The testing and recordkeeping requirements for firms that issue guaranties are set forth under 16 CFR part 1610, subpart B, and 16 CFR part 1611, subpart B.

On June 20, 2023, the CPSC published a notice in the **Federal Register** (88 FR 39833), to announce the agency's intention to seek extension of approval of the collection of information. The Commission received no comments. Therefore, by publication of this notice, the Commission announces that CPSC has submitted to the OMB a request for extension of approval of that collection of information without change.

B. Burden

CPSC staff estimates that approximately 1,000 firms issue guaranties. Although the CPSC's records indicate that approximately 675 firms have filed continuing guaranties with the Commission, staff believes additional guaranties may be issued that are not filed with the Commission, because continuing guaranties are not required to be filed with the Commission. Accordingly, staff has rounded the estimated number of firms upwards to 1,000 to account for those additional guaranties. Staff's estimate is based on the estimated time needed for each firm to conduct testing, issue guaranties, and establish and maintain associated records.

Staff estimates the recordkeeping requirements to require about 5 hours per each test for each firm, using either the test and conditioning procedures in the regulations or alternate methods. Although many firms are exempt from testing to support guaranties under 16 CFR 1610.1(d), CPSC staff does not know the proportion of those firms that are testing versus those that are exempt. Therefore CPSC has calculated its estimate of the annual industry recordkeeping burden based on its estimate that 1,000 firms issue guaranties. Based on, among other things, staff's experience with and expertise in testing requirements and procedures, as well as staff's review of records relating to guaranties that have been filed with the commission, staff estimates that each firm requires approximately 5 hours for testing and issues an average of 20 new guaranties per year, resulting an annual 100 hours (5 hours × 20 guarantees) per firm per year for testing. Staff estimates that each firm requires one hour to create, record, and enter test data into a computerized dataset; 20 minutes (0.3 hours) for annual review/removal of records; 20 minutes (0.3 hours) to respond to one CPSC records request per year, for a total of 1.6 recordkeeping hours (1 hour + 0.3 hours + 0.3 hours = 1.6 hours per firm). This yields a total of 101.6 estimated annual burden hours per firm (100 hours testing + 1.6 hours recordkeeping), and an estimated industry-wide annual recordkeeping burden of 101,600 hours (101.6 hours per firm × 1,000 firms). The hourly compensation for the time required for recordkeeping is $72.91 (for management, professional, and related occupations in goods-producing industries, Bureau of Labor Statistics, September 2022). Accordingly, the total annual estimated costs for testing and recordkeeping to the 1,000 establishments in the industry for the burden hours associated with parts 1610 and 1611 is $7.4 million (101,600 hours × $72.91 = $7,407,656).

Alberta E. Mills,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2023–18475 Filed 8–25–23; 8:45 am]

BILLING CODE 6355–01–P

[1] Children's sleepwear and fabrics and related materials intended for use in children's sleepwear in sizes 0 through 14 are subject to other, more stringent flammability standards codified at 16 CFR parts 1615 and 1616.

DEPARTMENT OF DEFENSE

Department of the Air Force

[Docket ID: USAF–2023–HQ–0013]

Proposed Collection; Comment Request

AGENCY: Department of the Air Force, Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the Department of the Air Force (DAF) Equal Opportunity (EO) Program, announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's 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 through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by October 27, 2023.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title 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 *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to AFPC/DP3DE at 550 C-Street, West Building 667, JBSA

Randolph, TX 78150, ATTN: Mr. Jermey Lawley. Alternatively, you may call 210–565–2056 or email *eo.workflow@us.af.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Air Force Equal Opportunity Data Collection Program; DAF Forms 1271, 1587, and 1587–1; OMB Control Number 0701–AABC.

Needs and Uses: The information collection requirement is necessary for the purpose of counseling, processing, investigating and adjudicating complaints of unlawful discrimination brought by DAF applicants, former DAF employees, contractors, retirees, and military family members. Particularly, the information is used to investigate and resolve complaints of unlawful discrimination and sexual harassment under the DAF EO Program; and to maintain records created because of the filing of allegations and appeals involving unlawful discrimination because of race, color, religion, sex, national origin, age, physical/mental disability, or genetic information.

Affected Public: Individuals or households.

Annual Burden Hours: 150 hours.

Number of Respondents: 75.

Responses per Respondent: 1.

Annual Responses: 75.

Average Burden per Response: 120 minutes.

Frequency: On occasion.

Dated: August 21, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–18419 Filed 8–25–23; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Science Board; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Research and Engineering, Department of Defense (DoD).

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal advisory committee meeting of the Defense Science Board (DSB) will take place.

DATES: Closed to the public Monday, September 11, 2023, from 8:30 a.m. to 5:00 p.m.; Tuesday, September 12, 2023, from 8:30 a.m. to 4:30 p.m.; Wednesday, September 13, 2023, from 8:30 a.m. to 4:30 p.m.; Thursday, September 14, 2023, from 8:30 a.m. to 4:30 p.m.; and Friday, September 15, 2023, from 8:30 a.m. to 12:00 p.m.

ADDRESSES: The address of the closed meeting is the Jack C. Taylor Conference Center, 290 Wood Rd., Naval Academy, MD 21402.

FOR FURTHER INFORMATION CONTACT: Mr. Kevin Doxey, Designated Federal Officer (DFO), (703) 571–0081 (Voice), (703) 697–1860 (Facsimile), *kevin.a.doxey.civ@mail.mil* (Email). Mailing address is Defense Science Board, 3140 Defense Pentagon, Room 3B888A, Washington, DC 20301–3140. Website: *http://www.acq.osd.mil/dsb/.* The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of chapter 10 of title 5, United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act'' or ''FACA''), 5 U.S.C. 552b (commonly known as the ''Government in the Sunshine Act''), and sections 102–3.140 and 102–3.150 of title 41, Code of Federal Regulations (CFR).

Purpose of the Meeting: The mission of the DSB is to provide independent advice and recommendations on matters relating to the DoD's scientific and technical enterprise. The objective of the meeting is to obtain, review, and evaluate classified information related to the DSB's mission. DSB membership will meet to discuss the 2023 DSB Summer Study on Climate Change and Global Security (''the DSB Summer Study'').

Agenda: The meeting will begin on Monday, September 11 at 8:30 a.m. with administrative remarks from Mr. Kevin Doxey, DFO and Executive Director, and opening remarks and a classified overview of the 2023 Summer Study on Climate Change & Global Security to date from Dr. Eric Evans, the DSB Chair. Next, the DSB members will meet as a group in a plenary session to review the generated study briefing materials and engage in classified discussion(s) regarding anticipating the global stresses and possible conflict due to climate change. Following break, the DSB members will meet in smaller breakout groups to review the study briefing materials and engage in classified discussion regarding anticipating the global stresses and possible conflict due to climate change. The meeting will adjourn at 5:00 p.m.

On September 12 at 8:30 a.m., DSB members will meet in smaller breakout groups to review the study briefing materials and engage in classified discussion regarding anticipating the global stresses and possible conflict due to climate change, with a break mid-day. The meeting will adjourn at 4:30 p.m.

On September 13 at 8:30 a.m., the meeting will begin with a plenary session where members will meet as a group to review the generated study briefing materials and engage in classified discussion(s) regarding anticipating the global stresses and possible conflict due to climate change. Following break, the DSB members will meet in a breakout session, wherein smaller breakout groups will review the study briefing materials and engage in classified discussion regarding anticipating the global stresses and possible conflict due to climate. The meeting will adjourn at 4:30 p.m.

On September 14 at 8:30 a.m., DSB members will meet in smaller breakout groups to review the study briefing materials and engage in classified discussion regarding anticipating the global stresses and possible conflict due to climate change, with a break mid-day. The meeting will adjourn at 4:30 p.m.

On September 15, 2023, the final day of the meeting will open at 8:30 a.m. with a plenary session, where members will review the generated study briefing materials and engage in classified discussion(s) regarding anticipating the global stresses and possible conflict due to climate change. The meeting will adjourn at 12:00 p.m.

Meeting Accessibility: In accordance with 5 U.S.C. 1009(d) and 41 CFR 102–3.140 through 102–3.155, the DoD has determined that the DSB meeting will be closed to the public. Specifically, the Under Secretary of Defense for Research and Engineering, in consultation with the DoD Office of the General Counsel, has determined in writing that the meeting will be closed to the public because it will consider matters covered by 5 U.S.C. 552b(c)(1). The determination is based on the consideration that it is expected that discussions throughout will involve classified matters of national security concern. Such classified material is so intertwined with the unclassified material that it cannot reasonably be segregated into separate discussions without defeating the effectiveness and meaning of the overall meeting. To permit the meeting to be open to the public would preclude discussion of such matters and would greatly diminish the ultimate utility of the DSB's findings and recommendations to the Secretary of Defense and to the Under Secretary of Defense for Research and Engineering.

Written Statements: In accordance with 5 U.S.C. 1009(a)(3) and 41 CFR

102–3.105(j) and 102–3.140, interested persons may submit a written statement for consideration by the DSB at any time regarding its mission or in response to the stated agenda of a planned meeting. Individuals submitting a written statement must submit their statement to the DSB DFO at the email address provided in the **FOR FURTHER INFORMATION CONTACT** section at any point; however, if a written statement is not received at least three calendar days prior to the meeting, which is the subject of this notice, then it may not be provided to or considered by the DSB until a later date.

Dated: August 23, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–18470 Filed 8–25–23; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Health Board; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department Defense (DoD).

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal advisory committee meeting of the Defense Health Board (DHB) will take place.

DATES: Open to the public Monday, September 11, 2023 from 9:00 a.m. to 5:30 p.m. Eastern time.

ADDRESSES: The address of the open meeting is River's Edge Community Center, 850 Sterling Cook Street (Bldg. 256), Portsmouth, VA 23708. The meeting will be held both in-person and virtually. To participate in the meeting, see the Meeting Accessibility section for instructions.

FOR FURTHER INFORMATION CONTACT: Ms. Camille Gaviola, 703–275–6047 (voice), *camille.m.gaviola.civ@health.mil* (email). Mailing address is 7700 Arlington Boulevard, Suite 5101, Falls Church, Virginia 22042. Website: *http://www.health.mil/dhb.* The most up-to-date changes to the meeting agenda can be found on the website.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of chapter 10 of title 5, United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act'' or ''FACA''), 5 U.S.C. 552b (commonly known as the ''Government in the Sunshine Act''), and 41 CFR 102–3.140 and 102–3.150.

Availability of Materials for the Meeting: Additional information, including the agenda, is available on the DHB website, *http://www.health.mil/dhb.* A copy of the agenda or any updates to the agenda for the September 11, 2023, meeting will be available on the DHB website. Any other materials presented in the meeting may also be obtained at the meeting.

Purpose of the Meeting: The DHB provides independent advice and recommendations to maximize the safety and quality of, as well as access to, health care for DoD health care beneficiaries. The purpose of the meeting is to provide progress updates on specific tasks before the DHB. In addition, the DHB will receive information briefings on current issues related to military medicine.

Agenda: The DHB anticipates receiving a decision briefing on Eliminating Racial and Ethnic Health Disparities in the Military Health System. The DHB also expects an update from the DHB Public Health Subcommittee's tasking on effective public communication strategies with DoD personnel, a Defense Health Agency Strategy briefing, a DHA Tidewater Market overview, and briefings on Prolonged Field Care and Naval Medical Assets Afloat.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165 and subject to the availability of space, this meeting will be held in-person and virtually and is open to the public from 9:00 a.m. to 5:30 p.m. Seating and virtual participation is limited and is on a first-come basis. All members of the public who wish to participate must register by emailing their name, rank/title, and organization/company to *dha.ncr.dhb.mbx.defense-health-board@health.mil* or by contacting Mr. Rubens Lacerda at (703) 275–6012 no later than Tuesday, September 5, 2023. Additional details will be required from all members of the public attending in-person to accommodate installation access. Once registered, participant access information will be provided.

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact Mr. Rubens Lacerda at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

Written Statements: Any member of the public wishing to provide comments to the DHB related to its current taskings or mission may do so at any time in accordance with section 10(a)(3) of the FACA, 41 CFR 102–3.105(j) and 102–3.140, and the procedures described in this notice. Written statements may be submitted to the DHB's Designated Federal Officer (DFO), Captain Gregory Gorman, at *dha.dhb@health.mil.* Supporting documentation may also be included, to establish the appropriate historical context and to provide any necessary background information. If the written statement is not received at least five (5) business days prior to the meeting, the DFO may choose to postpone consideration of the statement until the next open meeting. The DFO will review all timely submissions with the DHB President and ensure they are provided to members of the DHB before the meeting that is subject to this notice. After reviewing the written comments, the President and the DFO may choose to invite the submitter to orally present their issue during an open portion of this meeting or at a future meeting.

Dated: August 21, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–18459 Filed 8–25–23; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Advisory Committee on Diversity and Inclusion; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense (DoD).

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: The DoD is publishing this notice to announce that the following Federal advisory committee meeting of the Defense Advisory Committee on Diversity and Inclusion (DACODAI) will occur.

DATES: DACODAI will hold an open to the public meeting—Thursday, October 5, 2023, from 11:45 a.m. to 3:30 p.m. (EST) and Friday, October 6, 2023, from 8:15 a.m. to 12:45 p.m.

ADDRESSES: The meeting will be held via videoconference. Participant access information will be provided after registering.

FOR FURTHER INFORMATION CONTACT: Ms. Shirley Raguindin, (571) 645–6952 (voice), *osd.mc-alex.ousd-p-r.mbx.dacodai@mail.mil* (email).

SUPPLEMENTARY INFORMATION: This meeting is being held under the

provisions of chapter 10 of title 5, United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act'' or ''FACA''), 5 U.S.C. 552b (commonly known as the ''Government in the Sunshine Act''), and 41 CFR 102–3.140 and 102–3.150.

Availability of Materials for the Meeting: Additional information, including the agenda or any updates to the agenda, is available on the DACODAI website *https://www.dhra.mil/DMOC/DACODAI.* Materials presented in the meeting may also be obtained on the DACODAI website.

Purpose of the Meeting: The purpose of the meeting is for the DACODAI to receive briefings and have discussions on topics related to racial/ethnic diversity, inclusion, and equal opportunity within the Armed Forces of the United States and for the committee members to vote on the 2023 DACODAI proposed recommendations for the Secretary of Defense.

Agenda: Thursday, October 5, 2023, from 11:45 a.m. to 3:30 p.m. (EST). The Defense Advisory Committee (DACODAI) will begin in open session on October 5, 2023, from 11:45 a.m. to 3:30 p.m. with opening remarks by Ms. Shirley Raguindin, the Designated Federal Officer (DFO) and the DACODAI's Chair, Gen. (Ret.) Lester Lyle, and, if available, additional comments by The Office of the Secretary of Defense. The DACODAI will receive the following briefings: (1) Office of Diversity, Equity, and Inclusion Progress by Dr. Lisa Arfaa, Director, Office for Diversity, Equity, and Inclusion; (2) the Defense Testing and Assessment Center Diversity and Inclusion Efforts by Dr. Matthew Trippe, Defense Testing and Assessment Center and Ms. Mary Pommerich, Defense Testing and Assessment Center. Closing remarks will be provided by the Chair, Gen. (Ret.) Lyles, and Ms. Shirley Raguindin, DACODAI DFO, will adjourn the meeting.

Friday, October 6, 2023, from 8:15 a.m. to 12:45 p.m. The DACODAI will begin in an open session on October 6, 2023, from 8:15 a.m. to 12:45 p.m. with opening remarks by Ms. Shirley Raguindin, the Designated Federal Officer (DFO) and the DACODAI's Chair, Gen. (Ret.) Lester Lyle. The DACODAI will receive a briefing from the Defense Equal Opportunity Management Institute (DEOMI) on Racial/Ethnic Minority Research Capability and Findings by Captain (U.S. Navy) Delmy Robinson, Commandant, DEOMI, and Dr. Daniel McDonald, Deputy Director, DEOMI. After the briefing, the DACODAI members will vote on proposed recommendations for the Secretary of Defense. Closing remarks will be provided by the Chair, Gen. (Ret.) Lyles, and Ms. Shirley Raguindin, DACODAI DFO, will adjourn the meeting.

Meeting Accessibility: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 and 102–3.150, this meeting is open to the public from 11:45 a.m. to 3:30 p.m. (EST) on October 5, 2023; and from 8:15 a.m. to 12:45 p.m. on October 6, 2023. The meeting will be held via videoconference. The number of participants is limited and is on a first-come basis. All members of the public who wish to participate must register by contacting DACODAI at *osd.mc-alex.ousd-p-r.mbx.dacodai@mail.mil* or by contacting Ms. Shirley Raguindin at (571) 645–6952 no later than Friday, September 29, 2023 (by 5:00 p.m. EST). Once registered, the web address and/or audio number will be provided.

Special Accommodations: Individuals requiring special accommodations to access the public meeting should contact Ms. Shirley Raguindin at *osd.mc-alex.ousd-p-r.mbx.dacodai@mail.mil* or (571) 645–6952 no later than Friday, September 29. 2023 (by 5:00 p.m. EST) so appropriate arrangements can be made.

Written Statements: Pursuant to 41 CFR 102–3.140(c) and section 10(a)(3) of the FACA, the public or interested parties may submit written statements to the DACODAI membership about the DACODAI's mission and functions. Written statements may be submitted at any time or in response to the stated agenda of planned meetings of the DACODAI. All written statements shall be submitted to the DFO, Ms. Shirley Raguindin, for the DACODAI, who will ensure that the written statements are provided to the membership for their consideration. All written statements will be submitted to mailing address, 4800 Mark Center Drive, Suite 06E22, Alexandria, VA 22350. Members of the public interested in making an oral statement must submit a written statement. If a statement is not received by Friday, September 29, 2023, it may not be provided to or considered by the DACODAI during this biannual business meeting. After reviewing the written statements, the Chair and the DFO will determine if the requesting person(s) can make an oral presentation. The DFO will review all timely submissions with the DACODAI Chair and ensure they are provided to the members of the DACODAI.

Members of the public may also email written statements at *osd.mc-alex.ousd-p-r.mbx.dacodai@mail.mil.* Written statements pertaining to the meeting agenda for the DACODAI's meeting on October 5, 2023, must be submitted no later than 5:00 p.m. EST, Friday, September 29, 2023, to be considered by the DACODAI membership prior to its October 5, 2023 meeting.

Dated: August 23, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–18518 Filed 8–25–23; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Policy Board: Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Policy, Department of Defense (DoD).

ACTION: Notice of Federal advisory committee meeting.

SUMMARY: The DoD is publishing this notice to announce the following Federal Advisory Committee meeting of the Defense Policy Board (DPB) will take place.

DATES: Closed to the public; Monday, September 11, 2023, from 8:30 a.m. to 5:00 p.m. Closed to the public; Tuesday, September 12, 2023, from 9:30 a.m. to 12:15 p.m.

ADDRESSES: The closed meeting will be held in the Rodman Conference Room, 3D852, at The Pentagon, 2000 Defense Pentagon, Washington, DC 20301–2000.

FOR FURTHER INFORMATION CONTACT: Lt Col Jesse Humpal (U.S. Air Force), (571) 256–8395 (Voice), *osd.pentagon.rsrcmgmt.list.ousd-policy-defense-board-mbx@mail.mil* (Email). Mailing address is 2000 Defense Pentagon, Attn: 5E420, Washington, DC 20301–2000.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of chapter 10 of title 5, United States Code (U.S.C.) (commonly known as the ''Federal Advisory Committee Act'' or ''FACA''), 5 U.S.C. 552b (commonly known as the ''Government in the Sunshine Act''), and sections 102–3.140 and 102–3.150 of title 41, Code of Federal Regulations (CFR). Purpose of the Meeting: To obtain, review, and evaluate classified information related to the DPB's mission to advise on: (a) issues central to strategic DoD planning; (b) policy implications of U.S. force structure and modernization on DoD's ability to execute U.S. defense strategy; (c) U.S. regional defense policies; and (d) other defense policy topics of special interest

to the DoD, as determined by the Secretary of Defense, the Deputy Secretary of Defense, or the Under Secretary of Defense for Policy.

Agenda: On September 11, 2023, and September 12, 2023, the DPB will receive classified briefings regarding the People's Republic of China (PRC) and issues related to regional security; interagency perspectives; capability and posture issues for U.S. forces, resourcing issues, and U.S. industrial base considerations. The DPB will receive briefings from the following: the Hon. Ely Ratner, Assistant Secretary of Defense for Indo-Pacific Security Affairs; the Hon. Michael J. McCord, Under Secretary of Defense (Comptroller)/Chief Financial Officer; the Hon. Susanna V. Blume, Director, Cost Assessment and Program Evaluation (CAPE); Admiral John C. Aquilino, Commander, USINDOPACOM; the Hon. William A. LaPlante, Under Secretary of Defense for Acquisition and Sustainment; and Lieutenant General Dagvin R.M. Anderson, Director for Joint Force Development.

Meeting Accessibility: In accordance with 5 U.S.C. 1009(d) and 41 CFR 102–3.155, the DoD has determined that this meeting shall be closed to the public. The Acting Under Secretary of Defense (Policy), in consultation with the DoD FACA Attorney, has determined in writing that this meeting be closed to the public because the discussions fall under the purview of 5 U.S.C. 552b(c)(1) and are so inextricably intertwined with unclassified material that they cannot reasonably be segregated into separate discussions without disclosing classified material.

Written Statements: In accordance with 5 U.S.C. 1009(a)(3) and 41 CFR 102–3.105(j) and 102–3.140(c), the public or interested organizations may submit written statements to the membership of the DPB at any time regarding its mission or in response to the stated agenda of a planned meeting. Written statements should be submitted to the DPB's DFO, which is listed in this notice or can be obtained from the GSA's FACA Database—*http://www.facadatabase.gov/.* Written statements that do not pertain to a scheduled meeting of the DPB may be submitted at any time. However, if individual comments pertain to a specific topic being discussed at a planned meeting, then these statements must be submitted no later than five business days prior to the meeting in question. The DFO will review all submitted written statements and provide copies to all members.

Dated: August 22, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–18436 Filed 8–25–23; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2023–OS–0074]

Proposed Collection; Comment Request

AGENCY: United States Special Operations Command (USSOCOM), Department of Defense (DoD).

ACTION: 60-Day information collection notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995,* the United States Special Operations Command (USSOCOM) announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; the accuracy of the agency's 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 through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by October 27, 2023.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments.

Mail: Department of Defense, Office of the Assistant to the Secretary of Defense for Privacy, Civil Liberties, and Transparency, 4800 Mark Center Drive, Mailbox #24, Suite 08D09, Alexandria, VA 22350–1700.

Instructions: All submissions received must include the agency name, docket number and title 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 *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to Department of Defense, Washington Headquarters Services, ATTN: Executive Services Directorate, Directives Division, 4800 Mark Center Drive, Suite 03F09–09, Alexandria, VA 22350–3100, Angela Duncan, 571–372–7574.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Optimizing Brain Health by Mitigating Post Traumatic Stress Disorder, OMB Control Number 0704–0654.

Needs and Uses: The objective is to identify barriers and facilitators of accessing PTSD treatment that are most important to the Special Operations Forces (SOF) community via an online confidential survey of all relevant stakeholders in the healthcare delivery process (N=1,536). Stakeholders will include operators/enablers, healthcare providers, leadership, and policy makers from all SOF commands (Army, Air Force, Naval Special Warfare, Marine). We will then conduct qualitative interviews with SOF operators/enablers (N=24) to generate solutions to the barriers identified in the survey.

Affected Public: Individuals and households.

Survey

Annual Burden Hours: 768.

Number of Respondents: 1,536.

Responses per Respondent: 1.

Annual Responses: 1,536.

Average Burden per Response: 30 minutes.

Qualitative Interview

Annual Burden Hours: 24.

Number of Respondents: 24.

Responses per Respondent: 1.

Annual Responses: 24.

Average Burden per Response: 1 Hour.

Frequency: On occasion.

Dated: August 21, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–18405 Filed 8–25–23; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2023–HA–0020]

Submission for OMB Review; Comment Request

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)), Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by September 27, 2023.

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: Angela Duncan, 571–372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Utilization of the Novel ECC Eagle External Condom Catheter System; OMB Control Number 0720–EECC.

Type of Request: New.

ECC Eagle Patient Satisfaction Questionnaire

Number of Respondents: 10.
Responses per Respondent: 1.
Annual Responses: 10.
Average Burden per Response: 5 minutes.
Annual Burden Hours: 0.8.

Male Urinary Symptom Impact Questionnaire (MUSIQ)

Number of Respondents: 10.
Responses per Respondent: 2.
Annual Responses: 20.
Average Burden per Response: 5 Minutes.
Annual Burden Hours: 1.67.

PROMIS General Life Satisfaction Questionnaire

Number of Respondents: 10.
Responses per Respondent: 2.
Annual Responses: 20.
Average Burden per Response: 5 Minutes.
Annual Burden Hours: 1.7.

Needs and Uses: There are numerous methods to manage urinary incontinence, from pads/diapers to condom catheters to invasive urethral foley catheters. Pads or diapers can lead to skin irritation due to their occlusive barriers which can leave skin moist and lead to breakdown. Current condom catheters can be difficult to size and cause skin breakdown and infections. They can also fall off in patients with a large suprapubic fat pad and a shorter penis. Foley catheters can be uncomfortable and can lead to urinary tract infections. Thus, there is a need for a better way to manage urinary incontinence in men. The ECC Eagle is a novel design for a condom catheter that is intended to be more comfortable and secure than current models. We need to ask patients questions on their experience with the ECC Eagle, the degree of urinary symptoms they experience and the impact this has on their lives. This information is vital to the development of this product.

Affected Public: Individuals or households.

Frequency: On occasion.

Respondent's Obligation: Voluntary.

OMB Desk Officer: Mr. Matthew Eliseo.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number, and title 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 *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: August 21, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–18400 Filed 8–25–23; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2023–HA–0059]

Submission for OMB Review; Comment Request

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs (OASD(HA)), Department of Defense (DoD).

ACTION: 30-Day information collection notice.

SUMMARY: The DoD has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by September 27, 2023.

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: Angela Duncan, 571–372–7574, *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: Continued Health Care Benefit Program; DD Form 2837; OMB Control Number 0720–0066.

Type of Request: Extension.

Number of Respondents: 1,475.

Responses per Respondent: 1.

Annual Responses: 1,475.

Average Burden per Response: 15 minutes.

Annual Burden Hours: 369.

Needs and Uses: The information collection requirement is necessary for individuals to apply for enrollment in the continued Health Care Benefit Program (CHCBP). The CHCBP is a program of temporary health care benefit coverage that is made available to eligible individuals who lose health care coverage under the Military Health System (MHS).

Affected Public: Individuals or households.

Frequency: On occasion.

Respondents Obligation: Voluntary.

OMB Desk Officer: Mr. Matthew Eliseo.

You may also submit comments and recommendations, identified by Docket

ID number and title, by the following method:

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

Instructions: All submissions received must include the agency name, Docket ID number, and title 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 *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Ms. Angela Duncan.

Requests for copies of the information collection proposal should be sent to Ms. Duncan at *whs.mc-alex.esd.mbx.dd-dod-information-collections@mail.mil.*

Dated: August 22, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–18397 Filed 8–25–23; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

President's Advisory Commission on Advancing Educational Equity, Excellence, and Economic Opportunity for Hispanics

AGENCY: Department of Education, President's Advisory Commission on Advancing Educational Equity, Excellence, and Economic Opportunity for Hispanics

ACTION: Announcement of an open meeting.

SUMMARY: This notice sets forth the agenda for the September 12, 2023, meeting of the President's Advisory Commission on Advancing Educational Equity, Excellence, and Economic Opportunity for Hispanics (Commission), and how members of the public may attend the meeting and submit written comments pertaining to the work of the Commission. Notice of this meeting is required by 5 U.S.C. chapter 10 (Federal Advisory Committees).

DATES: The meeting of the Commission will be held on Tuesday, September 12, 2023, from 11:00 a.m. to 3:30 p.m. Mountain Standard Time.

ADDRESSES: Arizona State University Downtown Phoenix Campus, Beus Center for Law & Society, Room: Great Hall, 111 E Taylor St., Phoenix, AZ 85004. Members of the public can attend in-person and virtually.

FOR FURTHER INFORMATION CONTACT: Emmanuel Caudillo, Designated Federal Official, President's Advisory Commission on Advancing Educational Equity, Excellence, and Economic Opportunity for Hispanics, U.S. Department of Education, 400 Maryland Avenue SW, Room 7E220, Washington, DC 20202, telephone: (202) 453–5529, or email: *Emmanuel.Caudillo@ed.gov.*

SUPPLEMENTARY INFORMATION:

The Commission's Statutory Authority and Function: The Commission is established by Executive Order 14045 (September 13, 2021) and continued by Executive Order 14048 (September 30, 2021). The Commission is also governed by the provisions of 5 U.S.C. chapter 10 (Federal Advisory Committees), which sets forth standards for the formation and use of advisory committees. The Commission's duties are to advise the President, through the Secretary of Education, on matters pertaining to educational equity and economic opportunity for the Hispanic and Latino community in the following areas: (i) what is needed for the development, implementation, and coordination of educational programs and initiatives at the U.S. Department of Education (Department) and other agencies to improve educational opportunities and outcomes for Hispanics and Latinos; (ii) how to promote career pathways for in-demand jobs for Hispanic and Latino students, including registered apprenticeships, internships, fellowships, mentorships, and work-based learning initiatives; (iii) ways to strengthen the capacity of institutions, such as Hispanic-serving Institutions, to equitably serve Hispanic and Latino students and increase the participation of Hispanic and Latino students, Hispanic-serving school districts, and the Hispanic community in the programs of the Department and other agencies; (iv) how to increase public awareness of and generate solutions for the educational and training challenges and equity disparities that Hispanic and Latino students face and the causes of these challenges; and (v) approaches to establish local and national partnerships with public, private, philanthropic, and nonprofit stakeholders to advance the mission and objectives of this order, consistent with applicable law.

Meeting Agenda: The agenda for the Commission meeting includes: (1) a discussion and vote on recommendations presented by the Commission's four subcommittees: Advancing PreK–12 Educational Equity; Advancing Higher Education and Hispanic Serving Institutions (HSIs); Strengthening Economic Opportunity & Workforce Development; and Strengthening Public Partnerships and Public Awareness; (2) presentations from federal and community leaders on topics related to Executive Order 14045; (3) presentations from leaders to inform the Commission about the critical role, and needs of, HSIs and emerging HSIs in light of it being Hispanic Serving Institutions Week, and (4) and discussion around next steps towards advancing duties of the Commission, as outlined by Executive Order 14045.

Access to the Meeting: Members of the public may register to attend the meeting in-person or virtually by completing the link at *https://www.ed.gov/hispanicinitiative* or emailing *WhiteHouseHispanicInitiative@ed.gov* by 5 p.m. EDT on Monday, September 11, 2023. Instructions on how to access the meeting in-person and virtually will be emailed to members of the public that register to attend and will be posted to *https://www.ed.gov/hispanicinitiative* by Monday, September 11, 2023 by 6 p.m. EDT.

Submission of written public comments: Written comments pertaining to the work of the Commission may be submitted electronically to *WhiteHouseHispanicInitiative@ed.gov* by 5 p.m. EDT on Monday, September 11, 2023. Include in the subject line: ''Written Comments: Public Comment.'' The email must include the name(s), title, organizations/affiliation, mailing address, email address, and telephone number of the person(s) making the comment. Comments should be submitted as a Microsoft Word document or in a medium compatible with Microsoft Word (not a PDF file) that is attached to the electronic mail message (email) or provided in the body of an email message. Please do not send material directly to members of the Commission.

Access to Records of the Meeting: The Department will post the official report of the meeting on the Commission's website, at *https://sites.ed.gov/hispanic-initiative/presidential-advisory-commission* no later than 90 days after the meeting. Pursuant to 5 U.S.C. 1009(b), the public may request to inspect records of the meeting at 400 Maryland Avenue SW, Washington, DC, by emailing *Emmanuel.Caudillo@ed.gov* or by calling (202) 453–5529 to schedule an appointment.

Reasonable Accommodations: The meeting platform and access code are accessible to individuals with

disabilities. If you will need an auxiliary aid or service for the meeting (*e.g.,* interpreting service, assistive listening device, or materials in an alternate format), notify the contact person listed in this notice at least one week before the meeting date. Although we will attempt to meet a request received after that date, we may not be able to make available the requested auxiliary aid or service because of insufficient time to arrange it.

Electronic Access to this Document: The official version of this document is the document published in the **Federal Register**. Free internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* 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 Adobe Portable Document Format (PDF). To use PDF, you must have Adobe Acrobat Reader, which is available free at the site. You also may 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.

Authority: Executive Order 14045 (September 13, 2021) and continued by Executive Order 14048 (September 30, 2021).

Donna Harris-Aikens,

Deputy Chief of Staff for Strategy, Office of the Secretary.

[FR Doc. 2023–18486 Filed 8–25–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2023–SCC–0104]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and approval; Comment Request; Upward Bound (UB) Upward Bound Math Science (UBMS) Annual Performance Report

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a revision of a currently approved information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before September 27, 2023.

ADDRESSES: Written comments and recommendations for proposed information collection requests should be submitted within 30 days of publication of this notice. Click on this link *www.reginfo.gov/public/do/PRAMain* to access the site. Find this information collection request (ICR) by selecting ''Department of Education'' under ''Currently Under Review,'' then check the ''Only Show ICR for Public Comment'' checkbox. *Reginfo.gov* provides two links to view documents related to this information collection request. Information collection forms and instructions may be found by clicking on the ''View Information Collection (IC) List'' link. Supporting statements and other supporting documentation may be found by clicking on the ''View Supporting Statement and Other Documents'' link.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Marie Julienne, (202) 987–1054.

SUPPLEMENTARY INFORMATION: The Department is especially interested in public comment addressing the following issues: (1) is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Upward Bound (UB) Upward Bound Math Science (UBMS) Annual Performance Report.

OMB Control Number: 1840–0831.

Type of Review: Revision of a currently approved ICR.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 1,264.

Total Estimated Number of Annual Burden Hours: 21,488.

Abstract: The purpose of the Upward Bound (UB) and Upward Bound Math Science (UBMS) Program is to generate in the program's participants the skills and motivation necessary to complete a program of secondary education and to enter and succeed in a program of postsecondary education.

Authority for this program is contained in Title IV, Part A, Subpart 2, Chapter 1, Section 402C of the Higher Education Opportunity Act of 2008. Eligible applicants include institutions of higher education, public or private agencies, or organizations, including community-based organizations with experience in serving disadvantaged youth, secondary schools, and combinations of institutions, agencies, organizations and secondary schools.

The UB and UBMS Program's participants must be potential first-generation college students, low-income individuals, or individuals who have high risk of academic failure and have a need for academic support in order to pursue successfully a program of education beyond high school. Required services of the UB–UBMS Program include: (1) academic tutoring; (2) advice and assistance in secondary and postsecondary course selection; (3) preparation for college entrance exams and completing college admission applications; (4) information on federal student financial aid programs including (a) Federal Pell grant awards, (b) loan forgiveness, and (c) scholarships; (5) assistance completing financial aid applications; (6) guidance and assistance in: (a) secondary school reentry, (b) alternative programs for secondary school drop outs that lead to the receipt of a regular secondary school diploma, (c) entry into general educational development (GED) programs or (d) entry into postsecondary education; and (7) education or counseling services designed to improve the financial and economic literacy of students or the students' parents, including financial planning for postsecondary education. (8) Also, projects funded for at least two years under the program must provide instruction in mathematics through pre-calculus; laboratory science; foreign language; composition; and literature.

Dated: August 23, 2023.

Kun Mullan,

PRA Coordinator, Strategic Collections and Clearance, Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2023–18443 Filed 8–25–23; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Savannah River Site

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the Environmental Management Site-Specific Advisory Board (EM SSAB), Savannah River Site. The Federal Advisory Committee Act requires that public notice of this meeting be announced in the **Federal Register**.

DATES: Tuesday, September 26, 2023; 9:00 a.m.–4:30 p.m. EDT

ADDRESSES: Aiken Senior Life Center, 1310 East Pine Log Road, Aiken, SC 29803.

The meeting will also be streamed on YouTube, no registration is necessary; links for the livestream can be found on the following website: *https://cab.srs.gov/srs-cab.html.*

FOR FURTHER INFORMATION CONTACT: Amy Boyette, Office of External Affairs, U.S. Department of Energy (DOE), Savannah River Operations Office, P.O. Box A, Aiken, SC, 29802; Phone: (803) 952–6120; or Email: *amy.boyette@srs.gov.*

SUPPLEMENTARY INFORMATION:

Purpose of the Board: The purpose of the Board is to provide advice and recommendations concerning the following EM site-specific issues: clean-up activities and environmental restoration; waste and nuclear materials management and disposition; excess facilities; future land use and long-term stewardship. The Board may also be asked to provide advice and recommendations on any EM program components.

Tentative Agenda

Chair Update
Agency Updates
Subcommittee Updates
Program Presentations
Public Comments
Board Business

Public Participation: The meeting is open to the public. To provide a safe meeting environment, seating may be limited; attendees should register for in-person attendance by sending an email to *srscitizensadvisoryboard@srs.gov* no later than 4:00 p.m. EDT on Friday, September 22, 2023. The EM SSAB, Savannah River Site, welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Amy Boyette at least seven days in advance of the meeting at the telephone number listed above. Written statements may be filed with the Board via email either before or after the meeting. Individuals who wish to make oral statements pertaining to agenda items should submit their request to *srscitizensadvisoryboard@srs.gov.* Requests must be received five days prior to the meeting and reasonable provision will be made to include the presentation in the agenda. Comments will be accepted after the meeting, by no later than 4:00 p.m. ET on Tuesday, October 3, 2023. Please submit comments to *srscitizensadvisoryboard@srs.gov.* The Deputy Designated Federal Officer is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Individuals wishing to make oral public comments will be provided a maximum of five minutes to present their comments. Individuals wishing to submit written public comments should email them as directed above.

Minutes: Minutes will be available by emailing or calling Amy Boyette at the email address or telephone number listed above. Minutes will also be available at the following website: *https://cab.srs.gov/srs-cab.html.*

Signed in Washington, DC, on August 23, 2023.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2023–18483 Filed 8–25–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Energy Conservation Program for Consumer Products: Representative Average Unit Costs of Energy

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice.

SUMMARY: In this notice, the U.S. Department of Energy (DOE) is forecasting the representative average unit costs of five residential energy sources for the year 2023 pursuant to the Energy Policy and Conservation Act (Act). The five sources are electricity, natural gas, No. 2 heating oil, propane, and kerosene.

DATES: The representative average unit costs of energy contained in this notice will become effective September 27, 2023 and will remain in effect until further notice.

FOR FURTHER INFORMATION CONTACT: Mr. John Cymbalsky, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121, Telephone: (202) 287–1692, Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Ms. Amelia Whiting, U.S. Department of Energy, Office of General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0103, Telephone: (202) 586–2588, Email: *Amelia.Whiting@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: Section 323 of the Energy Policy and Conservation Act requires that DOE prescribe test procedures for the measurement of the estimated annual operating costs or other measures of energy consumption for certain consumer products specified in the Act. (42 U.S.C. 6293(b)(3)) These test procedures are found in title 10 of the Code of Federal Regulations (CFR) part 430, subpart B.

Section 323(b)(3) of the Act requires that the estimated annual operating costs of a covered product be calculated from measurements of energy use in a representative average use cycle or period of use and from representative average unit costs of the energy needed to operate such product during such cycle. (42 U.S.C. 6293(b)(3)) The section further requires that DOE provide information to manufacturers regarding the representative average unit costs of energy. (42 U.S.C. 6293(b)(4)) This cost information should be used by manufacturers to meet their obligations under section 323(c) of the Act. Most notably, these costs are used to comply with Federal Trade Commission (FTC) requirements for labeling. Manufacturers are required to use the revised DOE representative average unit costs when the FTC publishes new ranges of comparability for specific covered products, 16 CFR part 305. Interested parties can also find information covering the FTC labeling requirements at *https://www.ftc.gov/appliances.*

DOE last published representative average unit costs of residential energy in a **Federal Register** notice entitled, ''Energy Conservation Program for Consumer Products: Representative Average Unit Costs of Energy'', dated March 7, 2022, 87 FR 12681.

On September 27, 2023, the cost figures published in this notice will become effective and supersede those cost figures published on March 7, 2022. The cost figures set forth in this notice will be effective until further notice.

DOE's Energy Information Administration (EIA) has developed the 2023 representative average unit after-tax residential costs found in this notice. These costs for electricity, natural gas, and No. 2 heating oil are based on simulations used to produce

the August 2023, EIA *Short-Term Energy Outlook* (EIA releases the *Outlook* monthly). The representative average unit after-tax cost for propane is based on the U.S. residential sector prices found in the *Annual Energy Outlook 2023,* AEO2023) (March 16, 2023). The representative average unit after-tax cost for kerosene is derived from its price relative to that of heating oil, based on the 2010 to 2013 averages of the U.S. refiner price to end users, which include all the major energy-consuming sectors in the U.S. for these fuels. The source for these price data is the July 2023, *Monthly Energy Review* DOE/EIA–0035(2023/7). The *Short-Term Energy Outlook,* the *Monthly Energy Review,* and the *Annual Energy Outlook* are available on the EIA website at *https://www.eia.doe.gov.* For more information on the data sources used in this notice, contact the National Energy Information Center, Forrestal Building, EI–30, 1000 Independence Avenue SW, Washington, DC 20585, Telephone: (202) 586–8800, Email: *infoctr@eia.doe.gov.*

The 2023 representative average unit costs under section 323(b)(4) of the Act are set forth in Table 1, and will become effective September 27, 2023. They will remain in effect until further notice.

Signing Authority

This document of the Department of Energy was signed on August 23, 2023, by Francisco Alejandro Moreno, Acting Assistant Secretary for Energy Efficiency and Renewable Energy, pursuant to delegated authority from the Secretary of Energy. That document with the original signature and date is maintained by DOE. For administrative purposes only, and in compliance with requirements of the Office of the Federal Register, the undersigned DOE Federal Register Liaison Officer has been authorized to sign and submit the document in electronic format for publication, as an official document of the Department of Energy. This administrative process in no way alters the legal effect of this document upon publication in the **Federal Register**.

Signed in Washington, DC, on August 23, 2023.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

TABLE 1—REPRESENTATIVE AVERAGE UNIT COSTS OF ENERGY FOR FIVE RESIDENTIAL ENERGY SOURCES (2023)

Type of energy	Per million Btu [1]	In commonly used terms	As required by test procedure
Electricity	$46.19	15.76¢/kWh [2] [3]	$0.158/kWh.
Natural Gas	13.97	$1.397/therm [4] or $14.49/MCF [5] [6]	$0.00001397/Btu.
No. 2 Heating Oil	28.36	$3.89/gallon [7]	$0.00002836/Btu.
Propane	32.62	$2.98/gallon [8]	$0.00003262/Btu.
Kerosene	33.52	$4.53/gallon [9]	$0.00003352/Btu.

Sources: U.S. Energy Information Administration, *Short-Term Energy Outlook* (August 8, 2023), *Annual Energy Outlook* (March 16, 2023), and *Monthly Energy Review* (July 26, 2023).

Notes: Prices include taxes.

[1] Btu stands for British thermal units.

[2] kWh stands for kilowatt hour.

[3] 1 kWh = 3,412 Btu.

[4] 1 therm = 100,000 Btu.

[5] MCF stands for 1,000 cubic feet.

[6] For the purposes of this table, one cubic foot of natural gas has an energy equivalence of 1,037 Btu.

[7] For the purposes of this table, one gallon of No. 2 heating oil has an energy equivalence of 137,381 Btu.

[8] For the purposes of this table, one gallon of liquid propane has an energy equivalence of 91,333 Btu.

[9] For the purposes of this table, one gallon of kerosene has an energy equivalence of 135,000 Btu.

[FR Doc. 2023–18532 Filed 8–25–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER23–2668–000]

Richfield Solar Energy 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 Richfield Solar Energy 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 September 11, 2023.

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.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: August 22, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–18487 Filed 8–25–23; 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 rate filings:

Docket Numbers: ER23–2358–001.
Applicants: Wildflower Solar, LLC.
Description: Tariff Amendment: Amendment to the Shared Facilities and Co-Tenancy Agreement to be effective 9/6/2023.
Filed Date: 8/22/23.
Accession Number: 20230822–5104.
Comment Date: 5 p.m. ET 9/12/23.

Docket Numbers: ER23–2409–001.
Applicants: The Potomac Edison Company.
Description: The Potomac Edison Company submits an Amendment and Waiver Request to its notice of cancellation of its reactive power tariff submitted on July 14, 2023.
Filed Date: 8/18/23.
Accession Number: 20230818–5224.
Comment Date: 5 p.m. ET 9/8/23.

Docket Numbers: ER23–2428–001.
Applicants: Bucksport Generation LLC.
Description: Tariff Amendment: Bucksport Generation LLC, IROL–CIP Rate Schedule Amendment to be effective 9/29/2023.
Filed Date: 8/22/23.
Accession Number: 20230822–5133.
Comment Date: 5 p.m. ET 9/12/23.

Docket Numbers: ER23–2448–001.
Applicants: Tunica Windpower LLC.
Description: Tariff Amendment: Tunica Windpower LLC Supplement to MBR Application to be effective 9/18/2023.
Filed Date: 8/22/23.
Accession Number: 20230822–5126.
Comment Date: 5 p.m. ET 9/12/23.

Docket Numbers: ER23–2679–000.
Applicants: Duke Energy Progress, LLC.
Description: Notice of Cancellation of Service Agreements of Duke Energy Progress, LLC.
Filed Date: 8/21/23.
Accession Number: 20230821–5185.
Comment Date: 5 p.m. ET 9/11/23.

Docket Numbers: ER23–2680–000.
Applicants: New York Independent System Operator, Inc., New York State Electric & Gas Corporation.
Description: § 205(d) Rate Filing: New York Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: NYISO–NYSEG Joint 205: Scnd Amd LGIA Baron Winds SA2487 (CEII) to be effective 8/8/2023.
Filed Date: 8/22/23.
Accession Number: 20230822–5051.
Comment Date: 5 p.m. ET 9/12/23.

Docket Numbers: ER23–2681–000.
Applicants: Midcontinent Independent System Operator, Inc., Pioneer Transmission, LLC.
Description: § 205(d) Rate Filing: Midcontinent Independent System Operator, Inc. submits tariff filing per 35.13(a)(2)(iii: 2023–08–22_Pioneer Tariff Sheet Consolidation to be effective 1/1/2022.
Filed Date: 8/22/23.
Accession Number: 20230822–5069.
Comment Date: 5 p.m. ET 9/12/23.

Docket Numbers: ER23–2682–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: Att O Sec. 2 Re How Votes are Tallied in Zonal Planning Criteria Voting (RR 557) to be effective 10/22/2023.
Filed Date: 8/22/23.
Accession Number: 20230822–5083.
Comment Date: 5 p.m. ET 9/12/23.

Docket Numbers: ER23–2683–000.
Applicants: Southwest Power Pool, Inc.
Description: § 205(d) Rate Filing: 4126 NPPD and Tri-State G&T Interconnection Agreement to be effective 10/21/2023.
Filed Date: 8/22/23.
Accession Number: 20230822–5085.
Comment Date: 5 p.m. ET 9/12/23.

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, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) 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.

The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: August 22, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–18482 Filed 8–25–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 15229–000]

Alabama Power Company; Notice of Surrender of Preliminary Permit

Take notice that Alabama Power Company, permittee for the proposed Chandler Mountain Pumped Storage Project No. 15229, has requested that its preliminary permit be terminated. The permit was issued on March 24, 2022 [1] and would have expired on February 28, 2026. The project would have been located on Little Canoe Creek, Gulf Creek, and Jake Creek near the town of

[1] 178 FERC ¶ 61,209 (2022).

Steele, in Etowah and St. Clair Counties, Alabama.[2]

The preliminary permit for Project No. 15229 will remain in effect until the close of business, September 21, 2023. But, if the Commission is closed on this day, then the permit remains in effect until the close of business on the next day in which the Commission is open.[3] New applications for this site may not be submitted until after the permit surrender is effective.

Dated: August 22, 2023.

Kimberly D. Bose,

Secretary.

[FR Doc. 2023–18528 Filed 8–25–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas and Oil Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP23–975–000.

Applicants: Southern Natural Gas Company, L.L.C.

Description: § 4(d) Rate Filing: Fuel Retention Rates—Winter 2023 to be effective 10/1/2023.

Filed Date: 8/22/23.

Accession Number: 20230822–5066.

Comment Date: 5 p.m. ET 9/5/23.

Any person desiring to intervene, to protest, or to answer a complaint in any of the above proceedings must file in accordance with Rules 211, 214, or 206 of the Commission's Regulations (18 CFR 385.211, 385.214, or 385.206) 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.

The filings are accessible in the Commission's eLibrary system (*https://elibrary.ferc.gov/idmws/search/fercgensearch.asp*) by querying the docket number.

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.

For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659. The Commission's Office of Public Participation (OPP) supports meaningful public engagement and participation in Commission proceedings. OPP can help members of the public, including landowners, environmental justice communities, Tribal members and others, access publicly available information and navigate Commission processes. For public inquiries and assistance with making filings such as interventions, comments, or requests for rehearing, the public is encouraged to contact OPP at (202) 502–6595 or *OPP@ferc.gov.*

Dated: August 22, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–18484 Filed 8–25–23; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–11288–01–R8]

Clean Air Act Operating Permit Program; Order on Petitions for Objection to State Operating Permit for Terra Energy Partners, Rocky Moutain LLC, Parachute Water Management Facility

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of final order on petitions.

SUMMARY: The Environmental Protection Agency (EPA) Administrator signed an order dated July 14, 2023, granting in part and denying in part a petition dated November 22, 2022 from WildEarth Guardians and a petition dated November 23, 2022 from the Center for Biological Diversity and Grand Valley Citizens Alliance. The petitions requested that the EPA object to a Clean Air Act (CAA) operating permit issued by the Colorado Department of Public Health and Environment (CDPHE) to Terra Energy Partners, Rocky Moutain LLC for its Parachute Water Management Facility located in Garfield County, Colorado.

FOR FURTHER INFORMATION CONTACT: Donald Law, EPA Region 8, telephone number: (303) 312–7015, email address: *law.donald@epa.gov*. The final order and petition are available electronically at: *https://www.epa.gov/title-v-operating-permits/title-v-petition-database.*

SUPPLEMENTARY INFORMATION: The EPA received appetition from WildEarth Guardians dated November 2, 2022, and a petition from the Center for Biological Diversity and Grand Valley Citizens Alliance dated November 23, 2022, requesting that the EPA object to the issuance of operating permit no. 09OPGA330, issued by CDPHE to Terra Energy Partners, Rocky Mountain LLC in Garfield County, Colorado. On June 14, 2023, the EPA Administrator issued an order granting in part and denying in part the petition. The order itself explains the basis for the EPA's decision.

Sections 307(b) and 505(b)(2) of the CAA provide that a petitioner may request judicial review of those portions of an order that deny issues in a petition. Any petition for review shall be filed in the United States Court of Appeals for the appropriate circuit no later than October 27, 2023.

Dated: August 18, 2023.

KC Becker,

Regional Administrator, Region 8.

[FR Doc. 2023–18454 Filed 8–25–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–ORD–2020–0182; FRL–11281–01–ORD]

Availability of the IRIS Protocol for Vanadium and Compounds (Inhalation)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of public comment period.

SUMMARY: The Environmental Protection Agency (EPA) is announcing a 30-day public comment period associated with release of the document, Protocol for the Vanadium and Compounds (Inhalation) IRIS Assessment. This document communicates the rationale for conducting the Integrated Risk Information System (IRIS) assessment of vanadium and compounds (inhalation), describes screening criteria to identify relevant literature, outlines the approach for evaluating study quality, and describes the methods for dose-response analysis.

DATES: The 30-day public comment period begins August 28, 2023 and ends September 27, 2023. Comments must be received on or before September 27, 2023.

[2] Little Canoe Creek, Gulf Creek, and Jake Creek are tributaries of the Coosa River.

[3] 18 CFR 385.2007(a)(2) (2022).

ADDRESSES: The Protocol for the Vanadium and Compounds (Inhalation) IRIS Assessment will be available via the internet on the IRIS website at *https://www.epa.gov/iris* and in the public docket at *http://www.regulations.gov,* Docket ID: EPA–HQ–ORD–2020–0182.

FOR FURTHER INFORMATION CONTACT: For information on the docket, contact the ORD Docket at the EPA Headquarters Docket Center; email: *Docket_ORD@epa.gov.*

For technical information on the protocol, contact Mr. Dahnish Shams, Center for Public Health & Environmental Assessment; email: *shams.dahnish@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background Information on the IRIS Program and Systematic Review Protocols

EPA's IRIS Program is a human health assessment program that evaluates quantitative and qualitative information on effects that may result from exposure to chemicals found in the environment. Through the IRIS Program, EPA provides high quality science-based human health assessments to support the Agency's regulatory activities and decisions to protect public health.

As part of developing a draft IRIS assessment, EPA presents a methods document, referred to as the protocol, for conducting a chemical-specific systematic review of the available scientific literature. EPA is seeking public comment on components of the protocol including the described strategies for literature searches, criteria for study inclusion or exclusion, considerations for evaluating study methods, information management for extracting data, approaches for synthesis within and across lines of evidence, and methods for derivation of toxicity values. The protocol serves to inform the subsequent development of the draft assessment and is made available to the public. EPA may update the protocol based on the evaluation of the literature, and any updates will be posted to the docket and on the IRIS website.

II. How To Submit Technical Comments to the Docket at *https://www.regulations.gov*

Submit your comments, identified by Docket ID No. EPA–HQ–ORD–2020–0182 for Vanadium and Compounds (Inhalation), by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: Docket_ORD@epa.gov.*
- *Fax:* 202–566–9744.
- *Mail:* U.S. Environmental Protection Agency, EPA Docket Center (ORD Docket), Mail Code: 28221T, 1200 Pennsylvania Avenue NW, Washington, DC 20460. The phone number is 202–566–1752.

For information on visiting the EPA Docket Center Public Reading Room, visit *https://www.epa.gov/dockets.* The telephone number for the Public Reading Room is 202–566–1744. The public can submit comments via *www.regulations.gov* or email.

Instructions: Direct your comments to docket number EPA–HQ–ORD–2020–0182 for vanadium. Please ensure that your comments are submitted within the specified comment period. Comments received after the closing date will be marked ''late,'' and may only be considered if time permits. It is EPA's policy to include all comments it receives in the public docket without change and to make the comments available online at *https://www.regulations.gov,* including any personal information provided, unless a comment includes information claimed to be Confidential Business Information (CBI) or other information for which disclosure is restricted by statute. Do not submit information through *https://www.regulations.gov* or email that you consider to be CBI or otherwise protected. The *https://www.regulations.gov* website is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through *https://www.regulations.gov,* your email address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket, visit the EPA Docket Center homepage at *https://www.epa.gov/dockets.*

Docket: Documents in the docket are listed in the *https://www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other materials, such as copyrighted material, are publicly available only in hard copy. Publicly available docket materials are available either electronically in *https://www.regulations.gov* or as a hard copy at the ORD Docket in the EPA Headquarters Docket Center.

Wayne Cascio,

Director, Center for Public Health & Environmental Assessment.

[FR Doc. 2023–18468 Filed 8–25–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–R05–SFUND–2023–0315; FRL–11033–02-Region 5]

Proposed Prospective Purchaser Agreement for the Buick City Site in Flint, Michigan; Reopening of the Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; request for public comment; reopening of the comment period.

SUMMARY: In the **Federal Register** of June 22, 2023, the Environmental Protection Agency (EPA) announced a proposed administrative settlement; this document reopens the comment period. Additionally, a public meeting will be held in Flint, Michigan prior to the closing of the reopened comment period. The EPA will announce the details of the public meeting in multiple ways, including an ad in the local newspaper.

DATES: The comment period for the noticed published on June 22, 2023, at 88 FR 40821 is re-opened. Comments must be submitted on or before September 13, 2023.

ADDRESSES: You may send comments, identified by Docket ID No. EPA–R05–SFUND–2023–0315, by any of the following methods:

- *Federal eRulemaking Portal: https://www.regulations.gov/* (our preferred method). Follow the online instructions for submitting comments.
- *Mail:* U.S. Environmental Protection Agency, ATTN: Mark Koller, Associate Regional Counsel, Office of Regional Counsel (C–14J), 77 W. Jackson Blvd., Chicago, Illinois 60604.
- *Electronic Mail: koller.mark@epa.gov.*
- Handwritten notes submitted to EPA representatives at the public meeting.

Instructions: All submissions received must include the Docket ID No. for this rulemaking. Comments received may be posted without change to *https://www.regulations.gov/,* including any personal information provided. For detailed instructions on sending comments and additional information on the rulemaking process, see the ''Public Participation'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Mark Koller, Office of Regional Counsel, Environmental Protection Agency, telephone number: (312) 353–2591; email address: *koller.mark@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Written Comments

Submit your comments, identified by Docket ID No. EPA–R05–SFUND–2023–0315, at *https://www.regulations.gov* (our preferred method), or the other methods identified in the **ADDRESSES** section. Once submitted, comments cannot be edited or removed from the docket. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *https://www.epa.gov/dockets/commenting-epa-dockets.*

II. Background Information

The Settling Party proposes to acquire ownership of a portion of the former General Motors Corporation North American operation, at 902 E. Leith St. in Flint, Michigan. The Site is one of the 89 sites that were placed into an Environmental Response Trust (the ''Trust'') as a result of the resolution of the 2009 GM bankruptcy. The Trust is administrated by Revitalizing Auto Communities Environmental Response.

Thomas Short,

Deputy Director, Superfund & Emergency Management Division Region 5.

[FR Doc. 2023–18471 Filed 8–25–23; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL ACCOUNTING STANDARDS ADVISORY BOARD

Notice of Request for Comment on an Exposure Draft Titled Omnibus Amendments: Amending Statements of Federal Financial Accounting Standards 38, 49, and Technical Bulletin 2011–1

AGENCY: Federal Accounting Standards Advisory Board.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Federal Accounting Standards Advisory Board (FASAB) has released an exposure draft titled *Omnibus Amendments: Amending Statements of Federal Financial Accounting Standards 38, 49, and Technical Bulletin 2011–1.* Respondents are encouraged to comment on any part of the exposure draft.

DATES: Written comments are requested by September 21, 2023.

ADDRESSES: Written comments should be sent to *fasab@fasab.gov* or Monica R. Valentine, Executive Director, Federal Accounting Standards Advisory Board, 441 G Street NW, Suite 1155, Washington, DC 20548. The exposure draft is available on the FASAB website at *https://www.fasab.gov/documents-for-comment/.* Copies can be obtained by contacting FASAB at (202) 512–7350.

FOR FURTHER INFORMATION CONTACT: Ms. Monica R. Valentine, Executive Director, 441 G Street NW, Suite 1155, Washington, DC 20548, or call (202) 512–7350.

(Authority: 31 U.S.C. 3511(d); Federal Advisory Committee Act, 5 U.S.C. 1001–1014)

Dated: August 22, 2023.

Monica R. Valentine,

Executive Director.

[FR Doc. 2023–18428 Filed 8–25–23; 8:45 am]

BILLING CODE 1610–02–P

GENERAL SERVICES ADMINISTRATION

[Notice–MA–2023–06; Docket No. 2023–0002; Sequence No. 7]

Federal Travel Regulation (FTR); First Class and Business Class Transportation Reporting Requirements

AGENCY: Office of Government-wide Policy (OGP), General Services Administration (GSA).

ACTION: Notice of GSA Bulletin FTR 23–07, first class and business class transportation reporting requirements.

SUMMARY: FTR Bulletin 23–07 clarifies the information agencies are required to report on the authorized use of first class and business class transportation accommodations and how to determine the comparative coach class accommodations. This bulletin also rescinds FTR Bulletin 20–05.

DATES: *Applicable:* August 28, 2023.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact LaMan Dantzler J.D., Office of Government-wide Policy, Office of Asset and Transportation Management, at 202–615–5399 or *travelpolicy@gsa.gov.* Please cite Notice of GSA Bulletin FTR 23–07.

SUPPLEMENTARY INFORMATION: GSA amended the FTR by introducing premium economy airline accommodations as a class of service, creating management controls related to the use thereof, and changing the deadline for reporting the use of first class and business class transportation accommodations. This rule, titled ''Common Carrier Transportation,'' and published at 87 FR 55699, on September 12, 2022, did not change the requirement for agencies to report the use of all first class and business class transportation accommodations which exceed the coach class fare, nor did it change the requirement for agencies to report the use of extra-fare train service. However, since publishing 87 FR 55699, Common Carrier Transportation, GSA has received questions from agencies on how to determine the comparative cost of a coach class train fare when the use of an extra-fare train is authorized. In accordance with 41 CFR 300–70.101, FTR Bulletin 23–07 clarifies the information agencies are required to report on the authorized use of first class and business class transportation accommodations and how to determine the comparative coach class accommodations. This bulletin also rescinds FTR Bulletin 20–05, published at 85 FR 17890, on March 31, 2020.

GSA Bulletin FTR 23–07 can be viewed in its entirety at *https://www.gsa.gov/ftrbulletins.*

Krystal J. Brumfield,

Associate Administrator, Office of Government-wide Policy.

[FR Doc. 2023–18398 Filed 8–25–23; 8:45 am]

BILLING CODE 6820–14–P

OFFICE OF GOVERNMENT ETHICS

Agency Information Collection Activities; Notice of Approval of Information Collection Requirements

AGENCY: Office of Government Ethics (OGE).

ACTION: Notice of approval of information collection requirements.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the U.S. Office of Government Ethics (OGE) is announcing Office of Management and Budget (OMB) approval of new information collection requirements contained in a final rule published in the **Federal Register** on May 25, 2023, ''Legal Expense Fund Regulation.''

FOR FURTHER INFORMATION CONTACT: McEvan Baum at the U.S. Office of Government Ethics; telephone: 202–482–9287; TTY: 800–877–8339; Email: *usoge@oge.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor a collection of information, and the public is not obligated to respond to a collection of information, unless the collection of information displays a currently valid OMB control number.

On May 25, 2023, OGE published a final rule establishing a framework to govern an executive branch employee's acceptance of payments for legal expenses through a Legal Expense Fund (LEF) for matters arising in connection with the employee's official position, the employee's prior position on a campaign of a candidate for President or Vice President, or the employee's prior position on a Presidential Transition Team. The requirements for establishing and maintaining a LEF are found in 5 CFR part 2635, subpart J (LEF regulation).

The LEF regulation requires that employees who wish to establish a legal expense fund do so through a trust with a single, named employee beneficiary and a trustee. It also requires an employee beneficiary to file quarterly reports that include information (1) regarding members of the public who make financial donations to help pay for the employee beneficiary's legal expenses (donors) and (2) members of the public who receive payments from a legal expense fund (payees). The employee beneficiary must also file a termination report upon the termination of the trust and/or executive branch employment. The trust documents, quarterly reports, and termination reports will be posted directly on OGE's website in accordance with 5 CFR 2635.1007(g). Together, this information collection (IC) is titled ''OGE Legal Expense Fund Information Collection.''

OGE submitted a request for approval of this information collection on May 25, 2023, and OMB approved it on July 21, 2023. It was assigned OMB Control Number 3209–0012. Therefore, in accordance with the PRA, OGE hereby announces OMB approval of the information collection requirements as contained in the final rule, which will be effective November 21, 2023.

Approved: August 23, 2023.

Shelley K. Finlayson,

Acting Director, U.S. Office of Government Ethics.

[FR Doc. 2023–18526 Filed 8–25–23; 8:45 am]

BILLING CODE 6345–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Diagnosis and Management of Obsessive Compulsive Disorders in Children

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Diagnosis and Management of Obsessive Compulsive Disorders in Children,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before September 27, 2023.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Kelly Carper, Telephone: 301–427–1656 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Diagnosis and Management of Obsessive Compulsive Disorders in Children.* AHRQ is conducting this review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on *Diagnosis and Management of Obsessive Compulsive Disorders in Children.* The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/obsessive-compulsive-disorder/protocol.*

This is to notify the public that the EPC Program would find the following information on *Diagnosis and Management of Obsessive Compulsive Disorders in Children* helpful:

- A list of completed studies that your organization has sponsored for this topic. In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*
- *For completed studies that do not have results on ClinicalTrials.gov,* a summary, including the following elements, if relevant: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- *A list of ongoing studies that your organization has sponsored for this topic.* In the list, please provide the

ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including, if relevant, a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.

- Description of whether the above studies constitute *ALL Phase II and above clinical trials* sponsored by your organization for this topic and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on topics not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 45 days.

If you would like to be notified when the draft is posted, please sign up for the email list at: *https://www.effectivehealthcare.ahrq.gov/email-updates.*

The review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

KQ 1: How accurate are assessment tools compared to reference standard methods to identify OCD in symptomatic children and adolescents?

KQ 1a: How does diagnostic accuracy of assessment tools vary by patient, family, social, or other characteristics, or by respondent type?

KQ 2: What are the comparative effects and harms of treatment interventions, used alone or in combination, for OCD in children and adolescents?

KQ 2a: How do the effectiveness and harms vary with patient, family, social, or other characteristics?

Study Eligibility Criteria

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)

	Key Question 1 (diagnosis of OCD)	Key Question 2 (treatment of OCD)
Population	Children and adolescents (<21 years): • in whom there is clinical consideration of OCD. • diagnosed with OCD and/or other conditions which may be either be comorbid with OCD or may present with similar symptoms. *Include:* • Studies evaluating only children and adolescents with OCD (to estimate test sensitivity alone). *Exclude:* • Studies that include both adults and children that do not explicitly report a pediatric or adolescent subgroup in the abstract. • Studies that perform population-based screening (among individuals without a clinical concern for OCD).	Children and adolescents (<21 years) with diagnosed OCD, including those with: • possible PANS/PANDAS (with OCD). • other comorbid conditions (*e.g.,* autism). *Exclude:* • Children and adolescents diagnosed with other OCD-spectrum conditions (*e.g.,* body dysmorphic disorder, body focused repetitive behaviors) without an OCD diagnosis. • Subclinical OCD or obsessive or compulsive symptoms without an OCD diagnosis. • Studies that include both adults and children that do not explicitly report a subgroup by age in the abstract.
Interventions	Index Test(s): • Tools to diagnose OCD in symptomatic patients. For example, ○ Obsessive Compulsive Inventory-Child Version (OCI–CV–R). ○ Toronto Obsessive-Compulsive Scale (TOCS). ○ Short Obsessive-Compulsive Screener (SOCS). • Diagnostic prediction models. • Must report use of specific cut-point(s) to classify an individual as having OCD or a prediction algorithm or model to predict the probability of OCD. • Alternative administration (*e.g.,* child versus parent versus teacher report, in-person versus telehealth). *Exclude:* • Specific individual symptoms, behaviors, or characteristics. • Genetic studies. • Biomarker studies.	Psychological interventions for OCD, alone or in combination with pharmacological and/or other interventions, including: • Cognitive behavioral therapy (CBT). ○ Exposure and response prevention (ERP). ○ Psychoeducation. ○ Coping skills. ○ Cognitive therapy. • Acceptance and commitment therapy (ACT). • Targeted family interventions. • Other psychological interventions. • Delivery method. ○ Therapist led, *e.g.,* scheduled, in-person, or via telephone, video conference. ○ Self-guided, *e.g.,* asynchronous, therapist serves as supportive coach. Pharmacological interventions, alone or in combination with psychological interventions: • Selective serotonin reuptake inhibitors (SSRIs). • Tricyclic antidepressants (TCA), including clomipramine. • Serotonin and norepinephrine reuptake inhibitors (SNRIs). • Medication augmentation strategies: ○ SSRI augmentation with clomipramine, and other medications, including neuroleptics, nonsteroidal anti-inflammatory drugs (NSAIDs). ○ Glutamate modulating agents (*e.g.,* D-cycloserine, riluzole). • Other pharmacologic interventions, alone or in combination with psychological and/or other interventions, including dose escalation, longer treatment duration. Neuromodulation interventions: • Transcranial magnetic stimulation (TMS), • Transcranial direct current stimulation (tDCS), • Transcranial alternating current stimulation (tACS), • Deep brain stimulation (DBS). Complementary/integrative therapies: • Naturopathic interventions. • Mind-body practices (*e.g.,* mindfulness, meditation, yoga). • Sensory integration (*e.g.,* deep pressure).

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)—Continued

	Key Question 1 (diagnosis of OCD)	Key Question 2 (treatment of OCD)
Comparators	Reference standard(s): • Clinical interview. • Validated diagnostic assessment instruments (others may be included). ○ Anxiety Disorders Interview Schedule for DSM–5 child version. ○ (ADIS–C). ○ Kiddie Schedule for Affective Disorders and Schizophrenia, Present and Lifetime version (K–SADS–PL) for DSM–5. ○ Mini-International Neuropsychiatric Interview for Children and Adolescents (MINI–KID). ○ Children's Yale-Brown Obsessive-Compulsive Scale (CY–BOCS). ○ Children's Yale-Brown Obsessive-Compulsive Scale Second Edition (CY–BOCS–II). • Different index tests (if also compared with reference standard). • Different reference standards (i.e., comparison of reference standards). • Different respondents (*e.g.,* clinician, self, parent, educator). • Different methods to give test (*e.g.,* in person vs. via telehealth). • Different populations (see effect modifiers below).	*Exclude:* • Specific treatments for PANS/PANDAS (*e.g.,* antibiotics, immunomodulation, intravenous immunoglobulin). • No treatment (*e.g.,* waitlist control). • Pill placebo or sham control. • Another active intervention or co-intervention (*e.g.,* relaxation therapy). • Alternative delivery methods.
Outcomes (prioritized outcomes have an asterisk and are in bold font).	OCD diagnosis: • Sensitivity/Specificity.* • Positive and negative likelihood ratios. • Accuracy. • Area under the Receiver Operator Characteristic Curve (AUC ROC). • Predicted probability of OCD (model calibration/discrimination). • Time to initiation of treatment (cohort studies). *Exclude:* • Studies not reporting predictive validity that report other psychometric properties of scales: for example, reliability or validity (content, construct, convergent, discriminant, divergent, face).	OCD symptom severity: • Children's Yale-Brown Obsessive Compulsive Scale Total (CY–BOCS).* • Clinical Global Impression–Severity (CGI–S).* Treatment response and remission: • Clinical remission (posttreatment CY–BOCS total score ≤12 as defined by Farhat et. al.23, or as reported).* • Clinical Global Impression–Improvement (CGI–I).* Functional impairment in school, social, and home/family domains: • The Child Obsessive Compulsive Impact Scale—Revised (COIS–R).* ○ Raters: child (COIS–C), parent (COIS–P). Family accommodation: • Family Accommodation Scale (FAS).* Family functioning: • OCD Family Functioning Scale. • Family Environment Scale (FES). • Parental Attitudes and Behaviors Scale (PABS). Patient/parent reported experience measures (PREMs). Patient reported outcome measure (PROMs): • Top Problems assessment (TPA). Quality of Life (QoL) General and Health Related (HRQoL) (validated scales only): * • Quality of Life Enjoyment and Satisfaction Questionnaire-Short Form (QLESQ). Acceptability of treatment: * • Parental satisfaction with services. • Withdrawals/discontinuation. Sleep-related problems. Suicidal thoughts and behavior: • Columbia Suicide Severity Rating Scale Recent Self-Report Screener (C–SSRS). Anxiety and depression. Adverse events related to treatment.* *Exclude:* • Neuroimaging (*e.g.,* functional MRI).
Potential Effect Modifiers/Subgroups of interest.	• Patient, family, social, and other characteristics, including: ○ Race/Ethnicity (racial and ethnic discrimination is the effect modifier of interest but many/most studies will not contain that so we will use race/ethnicity as a marker for likelihood of experience with discrimination and would explicitly discuss this in the review). ○ Identity and Culture (*e.g.,* spiritual and religious beliefs and practices, native language, gender identity, sexual orientation, physical/mental disability status) ○ Age. ○ Age at symptom onset. ○ Social determinants of health, including education level, socioeconomic status, immigration status, refugee status, and geography (*e.g.,* urban vs. rural).	• Patient, family, social, and other characteristics, including: ○ Race/Ethnicity (racial and ethnic discrimination is the effect modifier of interest but many/most studies will not contain that so we will use race/ethnicity as a marker for likelihood of experience with discrimination and would explicitly discuss this in the review). ○ Identity and Culture (*e.g.,* spiritual and religious beliefs and practices, native language, gender identity, sexual orientation, physical/mental disability status). ○ Age. ○ Age at symptom onset. ○ Social determinants of health, including education level, socioeconomic status, immigration status, refugee status, and geography (*e.g.,* urban vs. rural).

PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, AND SETTING)—Continued

	Key Question 1 (diagnosis of OCD)	Key Question 2 (treatment of OCD)
	○ Diagnosis of PANS/PANDAS. ○ OCD in first degree relatives. ○ Level of family accommodation. ○ Co-occurring disorders (*e.g.,* major depressive disorder, anxiety disorders, attention-deficit hyperactivity disorder, conduct disorders, autism spectrum disorder, and Tourette syndrome, other tic disorders). ○ Diagnosis during COVID–19 pandemic (as defined by study authors). ○ Primary versus specialist care. • Respondent type. *Exclude:* • Neuroimaging, *e.g.,* functional MRI.	○ Diagnosis of PANS/PANDAS. ○ OCD in first degree relatives. ○ Level of family accommodation. ○ Co-occurring disorders (*e.g.,* major depressive disorder, anxiety disorders, attention-deficit hyperactivity disorder, conduct disorders, autism spectrum disorder, and Tourette syndrome, other tic disorders). ○ Diagnosis during COVID–19 pandemic (as defined by study authors). ○ Duration of symptoms prior to treatment. ○ Symptom severity. ○ In-session exposure and response prevention. ○ Medication dose. ○ Care settings and care intensities. ▪ Traditional outpatient. ▪ Intensive outpatient. • Day programs (*e.g.,* partial hospitalization). • Residential. ▪ Inpatient. ▪ Other care settings, including school-based settings. ▪ Telehealth (vs. in-person). ▪ Primary versus specialist care.
Design	Cohort or cross-sectional studies: • comparing an index test(s) to a reference standard. • comparing an index test(s) in two or more subgroups of interest. • comparing two or more diagnostic strategies. Randomized controlled trials. Nonrandomized comparative studies: • prospective or retrospective with appropriate adjustment for confounding. Systematic reviews (for reference lists only). *Exclude:* • Prevalence studies. • Qualitative studies. • Case reports and case series. • Unpublished studies, including conference abstracts (but include studies with reported results in the *ClinicalTrials.gov* database).	Comparative trials: • Randomized controlled trials. • Nonrandomized comparative studies. ○ prospective or retrospective with appropriate adjustment for confounding. Single arm studies, N ≥ 50: • with multivariable analyses of potential effect modifiers/subgroups of interest. Systematic reviews (for reference lists only). *Exclude:* • Cross-sectional studies (no longitudinal follow-up). • Qualitative studies. • Case reports and case series. • Unpublished studies, including conference abstracts (but include studies with reported results in the *ClinicalTrials.gov* database).
Timing	Any.	Any.
Setting	Any, including administration of test(s) in-person or via telehealth.	Any.

* Prioritized outcome.

Dated: August 21, 2023.

Marquita Cullom,

Associate Director.

[FR Doc. 2023–18415 Filed 8–25–23; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Clinical Laboratory Improvement Advisory Committee

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with regulatory provisions, the Centers for Disease Control and Prevention (CDC) announces the following meeting of the Clinical Laboratory Improvement Advisory Committee (CLIAC). This is a hybrid meeting, accessible both in person and virtually. It is open to the public, limited only by the in-person space available. The public is also welcome to view the meeting by joining the audio conference (information below). Time will be available for public comment, and the public is also welcome to submit written comments in advance of the meeting (see the public participation section below).

DATES: The meeting will be held on November 8, 2023, from 8:30 a.m. to 5:30 p.m., EST, and November 9, 2023, from 8:30 a.m. to 12 p.m., EST.

ADDRESSES: Centers for Disease Control and Prevention, 2400 Century Parkway NE, Room 1020/1023, Atlanta, Georgia 30345. The conference room will have seating for approximately 60 people.

Meeting Information: All people attending the CLIAC meeting in person are required to register online for the meeting at least five business days in advance for U.S. citizens and at least 20 business days in advance for international registrants. Register at: *https://www.cdc.gov/cliac/upcoming-meeting.html.* Register by scrolling down and clicking the ''Register for this Meeting'' button and completing all forms according to the instructions given. Please complete all the required fields before submitting your registration and submit no later than November 1, 2023, for U.S. registrants and October 11, 2023, for international registrants. The confirmed meeting times, agenda items, and meeting materials, including instructions for accessing the live meeting broadcast, will be available on the CLIAC website at *https://www.cdc.gov/cliac/upcoming-meeting.html.*

FOR FURTHER INFORMATION CONTACT: Heather Stang, MS, Senior Advisor for Clinical Laboratories, Division of Laboratory Systems, Office of Laboratory Science and Safety, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop V24–3, Atlanta, Georgia 30329–4027. Telephone: (404) 498–2769; Email: *HStang@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The Clinical Laboratory Improvement Advisory Committee (CLIAC) is charged with providing scientific and technical advice and guidance to the Secretary, Department of Health and Human Services; the Assistant Secretary for Health; the Director, Centers for Disease Control and Prevention (CDC); the Commissioner, Food and Drug Administration (FDA); and the Administrator, Centers for Medicare & Medicaid Services (CMS). The advice and guidance pertain to general issues related to improvement in clinical laboratory quality and laboratory medicine and specific questions related to possible revision of the Clinical Laboratory Improvement Amendments of 1988 (CLIA) standards. Examples include providing guidance on studies designed to improve quality, safety, effectiveness, efficiency, timeliness, equity, and patient-centeredness of laboratory services; revisions to the standards under which clinical laboratories are regulated; the impact of proposed revisions to the standards on medical and laboratory practice; and the modification of the standards and provision of non-regulatory guidelines to accommodate technological advances, such as new test methods, the electronic transmission of laboratory information, and mechanisms to improve the integration of public health and clinical laboratory practices.

Matters To Be Considered: The agenda will include agency updates from CDC, CMS, and FDA. Presentations and CLIAC discussions will focus on the final report from the CLIA Regulations Assessment Workgroup, efforts to address the CLIA top 10 laboratory deficiencies, standardization of test result communication, and the role of the laboratory in antibiotic stewardship. Agenda items are subject to change as priorities dictate.

Public Participation

It is the policy of CLIAC to accept written public comments and provide a brief period for oral public comments pertinent to agenda items.

Oral Public Comment: Public comment periods for each agenda item are scheduled immediately prior to the Committee discussion period for that item. In general, each individual or group requesting to present an oral comment will be limited to a total time of five minutes (unless otherwise indicated). Speakers should email *CLIAC@cdc.gov* or notify the contact person above (see **FOR FURTHER INFORMATION CONTACT**) at least five business days prior to the meeting date.

Written Public Comment: CLIAC accepts written comments until the date of the meeting (unless otherwise stated). However, it is requested that comments be submitted at least five business days prior to the meeting date so that the comments may be made available to the Committee for their consideration and public distribution. Written comments should be submitted by email to *CLIAC@cdc.gov* or to the contact person above. All written comments will be included in the meeting minutes posted on the CLIAC website.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–18448 Filed 8–25–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Solicitation of Nominations for Appointment to the Lead Exposure and Prevention Advisory Committee

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is soliciting nominations for membership on the Lead Exposure and Prevention Advisory Committee (LEPAC). The LEPAC is composed of 15 members that are Federal and non-Federal experts in fields associated with lead screening, the prevention of lead exposure, and services for individuals and communities affected by lead exposure.

DATES: Nominations for membership on the LEPAC must be received no later than September 30, 2023. Packages received after this time will not be considered for the current membership cycle.

ADDRESSES: All nominations should be emailed to *LEPAC@cdc.gov.*

FOR FURTHER INFORMATION CONTACT: Paul Allwood, Ph.D., M.P.H., Designated Federal Officer, National Center for Environmental Health, Centers for Disease Control and Prevention, 4770 Buford Highway, Atlanta, Georgia 30341. Telephone: 770–488–6774; Email: *PAllwood@cdc.gov.*

SUPPLEMENTARY INFORMATION: Nominations are being sought for individuals with expertise in the fields of epidemiology, toxicology, mental health, pediatrics, early childhood education, special education, diet and nutrition, and environmental health. Members may be invited to serve for three-year terms. Selection of members is based on candidates' qualifications to contribute to the accomplishment of Lead Exposure and Prevention Advisory Committee (LEPAC) objectives.

The members of this Committee are selected by the Secretary of the Department of Health and Human Services (HHS). The committee's objective is to advise the Secretary, HHS and the Director, Centers for Disease Control and Prevention (CDC)/ Administrator, Agency for Toxic Substances and Disease Registry on a range of activities to include: (1) review of Federal programs and services available to individuals and communities exposed to lead; (2) review of the current research on lead exposure to identify additional research needs; (3) review of and identification of best practices, or the need for best practices regarding lead screening and the prevention of lead exposure; (4) identification of effective services, including services relating to healthcare, education, and nutrition for individuals and communities affected by lead exposure and lead poisoning, including in consultation with, as appropriate, the lead exposure registry as established in Public Law 114–322 section 2203(b) (42 U.S.C. 300j–27); and (5) undertaking of any other review or activities that the Secretary determines to be appropriate.

Annually as determined necessary by the Secretary or as required by Congress, the committee shall submit a report to include: (1) an evaluation of the effectiveness of the Federal programs and services available to individuals and communities exposed to lead; (2) an evaluation of additional lead exposure research needs; (3) an assessment of any effective screening methods or best practices used or developed to prevent or screen for lead exposure; (4) input and recommendations for improved access to effective services relating to health care, education, or nutrition for

individuals and communities impacted by lead exposure; and (5) any other recommendations for communities affected by lead exposure, as appropriate.

At least half of the committee will consist of Federal representatives from a range of agencies that may include the Department of Housing and Urban Development; the Environmental Protection Agency; the Consumer Product Safety Commission; the Centers for Medicare and Medicaid Services; the Health Resources and Services Administration; the Food and Drug Administration (FDA); the U.S. Department of Agriculture; the Occupational Safety and Health Administration; the National Institute of Environmental Health Sciences; the U.S. Geological Survey; and such additional Federal, state, tribal, and local public and private officials as the Secretary deems necessary for the committee to carry out its function. The rest of the committee will consist of non-Federal members. Only non-Federal members are being solicited with this announcement.

HHS policy stipulates that committee membership be balanced in terms of points of view represented and the committee's function. Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens and cannot be full-time employees of the U.S. Government. Current participation on Federal workgroups or prior experience serving on a Federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships. Committee members are Special Government Employees, requiring the filing of financial disclosure reports at the beginning and annually during their terms. CDC reviews potential candidates for LEPAC membership each year and provides a slate of nominees for consideration to the Secretary of HHS for final selection. HHS notifies selected candidates of their appointment as soon as the HHS selection process is completed. Note that the need for different expertise varies from year to year and a candidate who is not selected in one year may be reconsidered in a subsequent year.

Candidates should submit the following items:

- Current curriculum vitae, including complete contact information (telephone numbers, mailing address, email address).
- At least one letter of recommendation from person(s) not employed by HHS. Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by an HHS agency (*e.g.,* CDC, National Institutes of Health, FDA).

Nominations may be submitted by the candidate or by the person/organization recommending the candidate.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to *sign* **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–18449 Filed 8–25–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Solicitation of Nominations for Appointment to the Board of Scientific Counselors, Center for Preparedness and Response

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), is seeking nominations for membership on the Board of Scientific Counselors, Center for Preparedness and Response, (BSC, CPR). The BSC, CPR consists of 11 experts in fields associated with business, crisis leadership, emergency response and management, informatics, laboratory science, medicine, mental and behavioral health, public health law, public health practice, risk communication, and social science.

DATES: Nominations for membership on the BSC, CPR must be received no later than October 31, 2023. Packages received after this time will not be considered for the current membership cycle.

ADDRESSES: All nominations should be emailed to *BSC-ORR@cdc.gov.*

FOR FURTHER INFORMATION CONTACT: Dometa Ouisley, Public Health Analyst, Office of Science and Public Health Practice, Office of Readiness and Response, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–6, Atlanta, Georgia 30329–4027. Telephone: (404) 639–7450; Email: *DOuisley@cdc.gov.*

SUPPLEMENTARY INFORMATION: Nominations are sought for individuals who have the expertise and qualifications necessary to contribute to the accomplishment of the objectives of the Board of Scientific Counselors, Center for Preparedness and Response (BSC, CPR). Nominees will be selected based on expertise in the fields of business, crisis leadership, emergency response and management, informatics, laboratory science, medicine, mental and behavioral health, public health law, public health practice, risk communication, and social science. Selection of members is based on candidates' qualifications to contribute to the accomplishment of the BSC, CPR objectives (*https://www.cdc.gov/orr/bsc/index.htm*). Members may be invited to serve for up to four-year terms.

Department of Health and Human Services (HHS) policy stipulates that committee membership be balanced in terms of points of view represented and the committee's function. Appointments shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, gender identity, HIV status, disability, and cultural, religious, or socioeconomic status. Nominees must be U.S. citizens and cannot be full-time employees of the U.S. Government. Current participation on federal workgroups or prior experience serving on a federal advisory committee does not disqualify a candidate; however, HHS policy is to avoid excessive individual service on advisory committees and multiple committee memberships.

Board members are Special Government Employees, requiring the filing of financial disclosure reports at the beginning of and annually during their terms. The Centers for Disease Control and Prevention (CDC) reviews potential candidates for BSC, CPR membership each year and provides a slate of nominees for consideration to the Secretary of HHS for final selection. HHS notifies selected candidates of their appointment near the start of the term in October 2024, or as soon as the HHS selection process is completed.

Note that the need for different expertise varies from year to year and a candidate who is not selected in one year may be reconsidered in a subsequent year. Candidates should submit the following items:

- Cover letter stating area of expertise, your background and experience, and the skills/perspective you would bring to the Board.
- Current curriculum vitae, including complete contact information (telephone numbers, mailing address, email address).
- At least one letter of recommendation from person(s) not employed by HHS. Candidates may submit letter(s) from current HHS employees if they wish, but at least one letter must be submitted by a person not employed by an HHS agency (*i.e.,* CDC, National Institutes of Health, Food and Drug Administration, Substance Abuse and Mental Health Services Administration, etc.).

Nominations may be submitted by the candidate or by the person/organization recommending the candidate.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–18450 Filed 8–25–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health, National Institute for Occupational Safety and Health

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with regulatory provisions, the Centers for Disease Control and Prevention (CDC) announces a meeting of the Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board). This meeting is open to the public, but without a public comment period. The public is welcome to submit written comments in advance of the meeting, to the contact person below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcomed to listen to the meeting by joining the teleconference (information below). The audio conference line has 150 ports for callers.

DATES: The meeting will be held on October 12, 2023, from 11 a.m. to 1 p.m., EDT. Written comments must be received on or before October 5, 2023.

ADDRESSES: You may submit comments by mail to: Rashaun Roberts, National Institute for Occupational Safety and Health, 1090 Tusculum Avenue, MS C–24, Cincinnati, Ohio 45226. *Meeting Information:* Audio Conference Call via FTS Conferencing. The USA toll-free dial-in number is 1–866–659–0537; the pass code is 9933701.

FOR FURTHER INFORMATION CONTACT: Rashaun Roberts, Ph.D., Designated Federal Officer, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1090 Tusculum Avenue, Mailstop C–24, Cincinnati, Ohio 45226. Telephone: (513) 533–6800, Email: *ocas@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Advisory Board was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines which have been promulgated by the Department of Health and Human Services (HHS) as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program, and advice on petitions to add classes of workers to the Special Exposure Cohort (SEC). In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the Centers for Disease Control and Prevention (CDC). The National Institute for Occupational Safety and Health implements this responsibility for CDC.

The charter was issued on August 3, 2001, renewed at appropriate intervals, and rechartered under Executive Order 13889 on March 22, 2022, and will terminate on March 22, 2024.

Purpose: This Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters To Be Considered: The agenda will include discussions on the following: Update on Cybersecurity Modernization Initiative; Work Group and Subcommittee Reports; Update on the Status of SEC Petitions; and plans for the December 2023 Advisory Board Meeting. Agenda items are subject to change as priorities dictate. For additional information, please contact Toll Free 1(800) 232–4636.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–18451 Filed 8–25–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health, Subcommittee on Procedures Reviews, National Institute for Occupational Safety and Health

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting.

SUMMARY: In accordance with regulatory provisions, the Centers for Disease Control and Prevention (CDC) announces the following meeting for the Subcommittee on Procedures Reviews (SPR) of the Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board). This meeting is open to the public, but without a public comment period. The public is welcome to submit written comments in advance of the meeting, to the contact person below. Written comments received in advance of the meeting will be included in the official record of the meeting. The public is also welcomed to listen to the meeting by joining the audio conference (information below). The audio conference line has 150 ports for callers.

DATES: The meeting will be held on November 16, 2023, from 11 a.m. to 4:30 p.m., EST. Written comments must be received on or before November 9, 2023.

ADDRESSES: You may submit comments by mail to: Rashaun Roberts, National Institute for Occupational Safety and Health Centers for Disease Control and Prevention, 1090 Tusculum Avenue, MS C–24, Cincinnati, Ohio 45226.

Meeting Information: Audio Conference Call via FTS Conferencing. The USA toll-free dial-in number is 1–866–659–0537; the pass code is 9933701.

FOR FURTHER INFORMATION CONTACT: Rashaun Roberts, Ph.D., Designated Federal Officer, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1090 Tusculum Avenue, MS C–24, Cincinnati, Ohio 45226. Telephone: (513) 533–6800; Email: *ocas@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Advisory Board on Radiation and Worker Health (ABRWH or the Advisory Board) was established under the Energy Employees Occupational Illness Compensation Program Act of 2000 to advise the President on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Advisory Board include providing advice on the development of probability of causation guidelines that have been promulgated by the Department of Health and Human Services (HHS) as a final rule; advice on methods of dose reconstruction, which have also been promulgated by HHS as a final rule; advice on the scientific validity and quality of dose estimation and reconstruction efforts being performed for purposes of the compensation program; and advice on petitions to add classes of workers to the Special Exposure Cohort. In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to the Centers for Disease Control and Prevention (CDC). The National Institute for Occupational Safety and Health (NIOSH) implements this responsibility for CDC.

The charter was issued on August 3, 2001, renewed at appropriate intervals, and rechartered under Executive Order 13889 on March 22, 2022, and will terminate on March 22, 2024.

Purpose: The Advisory Board is charged with (a) providing advice to the Secretary, HHS, on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS, on the scientific validity and quality of dose reconstruction efforts performed for this program; and (c) upon request by the Secretary, HHS, advising the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class. The ABRWH Subcommittee on Procedures Reviews (SPR) is responsible for overseeing, tracking, and participating in the reviews of all procedures used in the dose reconstruction process by the NIOSH Division of Compensation Analysis and Support (DCAS) and its dose reconstruction contractor (Oak Ridge Associated Universities—ORAU).

Matters to be Considered: The agenda will include discussions on the following: 1. Carry-over items from June 21, 2023, SPR Meeting including a. Sandford Cohen & Associates (SC&A) follow-up review of PER–049 (Paducah Gaseous Diffusion Plant) internal dose assessment using hypothetical intakes versus bioassay data and b. SC&A's Peek Street memo on the review of two additional cases provided by NIOSH; 2. Newly issued SC&A reviews including a. DCAS–PER–040 ''Mallinckrodt TBD Revisions,'' b. DCAS–PER–051 ''Weldon Spring Plant,'' c. DCAS–PER–083 ''Weldon Spring Plant TBD Revision,'' d. DCAS–PER–067 ''Allegheny Ludlum Appendix Q Revisions,'' and e. ORAUT–RPRT–0097 ''Breathing Zone to General Area Air Concentration Ratios in Small Workrooms''; 3. Preparation for the December 2023 Full ABRWH Meeting: Review of SPR accomplishments and current activities; 4. Preparation for the April 2024 Full ABRWH Meeting: Review of technical guidance documents ready for full Board approval; and 5. Newly Issued Guidance and Supplemental Topics. Agenda items are subject to change as priorities dictate. For additional information, please contact Toll Free 1(800) 232–4636.

The Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Office of Strategic Business Initiatives, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–18452 Filed 8–25–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–10553, CMS–10554, CMS–10856 and CMS–R–305]

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 collect information from the public. 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 October 27, 2023.

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, please access the CMS PRA website by copying and pasting the following web address into your web browser: *https://www.cms.gov/Regulations-and-Guidance/Legislation/PaperworkReductionActof1995/PRA-Listing.*

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–10553 Medicaid Managed Care Quality including Supporting Regulations.

CMS–10554 Children's Health Insurance Program Managed Care and Supporting Regulations.

CMS–10856 Medicaid Managed Care and Supporting Regulations.

CMS–R–305 External Quality Review (EQR) of Medicaid and Children's Health Insurance Program (CHIP) Managed Care, EQR Protocols, and Supporting Regulations.

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:* Medicaid Managed Care Quality including Supporting Regulations; *Use:* States are required to develop quality strategies and quality strategy effectiveness evaluations. States use the information from these documents to help monitor and assess the performance of their Medicaid managed care programs. When developing these documents, States must engage stakeholders and make the documents available for public comment. Medicaid beneficiaries and stakeholders use the reported information to understand the state's quality improvement goals and objectives, and to understand how the state is measuring progress of its goals. States must submit these documents to CMS for review at least once every three years, or when substantial changes are made to their quality strategies, or State Medicaid programs. CMS uses this information as a part of its oversight responsibilities. The Medicaid and CHIP (MAC) QRS requirements currently include public posting of quality ratings on the State's website, which is intended to provide beneficiaries and their caregivers with a web-based interface to compare Medicaid and CHIP managed care plans based on assigned ratings. *Form Number:* CMS–10553 (OMB control number: 0938–1281); *Frequency:* Annually, triennial, and one-time.; *Affected Public:* Private sector (business or other for-profits) and State, local or Tribal governments; *Number of Respondents:* 673; *Number of Responses:* 6,087; *Total Annual Hours:* 1,441,211. (For policy questions regarding this collection contact Carlye Burd at 720–853–2780.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Children's Health Insurance Program Managed Care and Supporting Regulations; *Use:* States must provide information obtained through methods consistent with the Protocols specified by CMS to External Quality Review Organization (EQRO). States must post the EQR technical reports on their websites to help enrollees and potential enrollees make informed choices when selecting providers. It also gives advocacy organizations, researchers, and other interested parties access to information pertaining to: the quality of care provided to beneficiaries enrolled in CHIP managed care organizations (MCO), prepaid inpatient health plans (PIHP), and prepaid ambulatory health plans (PAHP). The quality ratings system (QRS) provides beneficiaries with information that allows them to make an informed choice when comparing and selecting managed care plans. The information also provides a better understanding of the state's quality improvement goals and objectives, and how the state is measuring the progress of its goals. The information may assist states in comparing the outcomes of different delivery systems and can assist them in identifying future performance improvement subjects. *Form Number:* CMS–10554 (OMB control number: 0938–1282); *Frequency:* Annually and one-time; *Affected Public:* Private sector (business or other for-profits and not-for-profit institutions) and State, local, and Tribal governments; *Number of Respondents:* 62; Number of Responses: 2,735,906; *Total Annual Hours:* 365,310. (For policy questions regarding this collection contact Joshua Bougie at 410–786–8117.)

3. *Type of Information Collection Request:* New; *Title of Information Collection:* Medicaid Managed Care and Supporting Regulations; *Use:* Provides reporting and third-party disclosure requirements pertaining to State program administration and CMS compliance monitoring. *Form Number:* CMS–10856 (OMB control number: 0938–TBD); *Frequency:* Annually and one-time; *Affected Public:* Private sector (business or other for-profits) and State, local or Tribal governments; *Number of Respondents:* 679; *Number of Responses:* 14,313; *Total Annual Hours:* 255,384. (For policy questions regarding this collection contact Amy Gentile at 410–786–3499.)

4. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* External Quality Review (EQR) of Medicaid and Children's Health Insurance Program (CHIP) Managed Care, EQR Protocols, and Supporting Regulations; *Use:* Most contracts between a state Medicaid agency and their managed care plan

must provide for an annual External Quality Review (EQR). The annual EQR is conducted by an independent external quality review organization (EQRO). States must provide the EQRO with information obtained through methods consistent with the protocols specified by CMS. The information is used by the EQRO to determine the quality of care furnished by the managed care plans in the state. The publicly posted EQR results allows Medicaid/CHIP enrollees and potential enrollees to make informed choices regarding the selection of their providers. It also provides advocacy organizations, researchers, and other interested parties access to information on the quality of care provided to Medicaid beneficiaries enrolled in Medicaid/CHIP managed care. States use the information during their oversight of these organizations. *Form Number:* CMS–R–305 (OMB control number: 0938–0786); *Frequency:* Annually and one-time; *Affected Public:* Private sector (business or other for-profits) and State, local or Tribal governments; *Number of Respondents:* 698; *Number of Responses:* 10,249; *Total Annual Hours:* 483,784. (For policy questions regarding this collection contact Carlye Burd at 720–853–2780.)

Dated: August 23, 2023.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2023–18520 Filed 8–25–23; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 1009 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 Center for Advancing Translational Sciences Special Emphasis Panel; NCATS SBIR Basket Clinical Trials.

Date: September 21, 2023.

Time: 11:30 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Center for Advancing Translational Sciences, 6701 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Nakia C Brown, Ph.D., Scientific Review Officer, Office of Grants Management and Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1037, Bethesda, MD 20892, (301) 827–3484, *brownnac@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: August 23, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–18490 Filed 8–25–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development.

FOR FURTHER INFORMATION CONTACT: Licensing information may be obtained by communicating with Vidita Choudhry, Ph.D., Office of Technology Transfer and Development, National Heart, Lung, and Blood Institute, 31 Center Drive Room 4A29, MSC2479, Bethesda, MD 20892–2479; telephone: 301–594–4095; email: *vidita.choudhry@nih.gov.* A signed Confidential Disclosure Agreement may be required to receive any unpublished information.

SUPPLEMENTARY INFORMATION: Technology description follows.

Apparatus for Cryogenic-Electron Microscopy Sample Preparation

Cryo-Electron Microscopy (cryo-EM) is used to obtain high-resolution structural images of macromolecular structures. Samples must be purified and loaded onto cryo-EM grids before imaging. The ideal cryo-EM grid consists of particles that are evenly and richly distributed in a broad distribution of orientations throughout the holes of the support film. Current techniques to prepare cryo-EM grids are performed manually and require trial and error, resulting in a bottleneck in cryo-EM workflows.

Researchers have developed a device and method for time-resolved preparation of liquid samples for cryo-EM experiments. In particular, the mixing and dispensation of liquid samples is achieved by electrical signals that are transduced into specific acoustic frequencies to mix the liquid samples (low frequency) and then dispense the mixture (high frequency) in small, nanoliter volumes onto a cryo-EM grid. This novel apparatus and method provides more precise control over liquid sample mixing and dispensing, and improved dispensation of the mixture onto the EM grid. Also, the improved quality of captured images of homogeneous macromolecular structures is achieved due to a uniformly mixed and dispensed sample on the EM grid. This allows electrons to be transmitted through the very thin liquid film in the holes of the cryo-EM grid to form an image.

Potential Commercial Applications

- Automation of cryo-EM experiments aimed at Structure-based Drug Design by examining macromolecular structure and its interactions with ligands.
- Kits with hardware and software components to setup robotic automation of cryo-EM sample preparation, dispensation, plunging and storage.

Competitive Advantages

- Automated workflow eliminates the guesswork out of cryo-EM sample preparation.
- Increases sample prep success rate and decreases the need to screen repeated trials.
- Using acoustic-based, multiple-sample mixing enables homogeneous mixing and facilitates the observation of transient molecular interactions with high time resolution.
- Python code is available for command and control of a robot that manipulates the cryo-EM grid.

Development Stage

- Prototype.

Inventors

Venkata M. Dandey (NIEHS), Mario J. Borgnia (NIEHS), Wyatt Peele (NIEHS), Tony J. Huang (Duke), and Kaichun Yang (Duke).

Intellectual Property

HHS Reference No. E–184–2023–0; U.S Provisional Patent Application 63/472,113 filed June 09, 2023.

Licensing Contact

Vidita Choudhry, Ph.D.; 301–594–4095; *vidita.choudhry@nih.gov. This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404.*

Dated: August 22, 2023.

Vidita Choudhry,

Senior Technology Transfer Manager, National Heart, Lung, and Blood Institute, Office of Technology Transfer and Development.

[FR Doc. 2023–18438 Filed 8–25–23; 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 1009 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; NIH Research Enhancement Award (R15) in Oncological Sciences.

Date: September 20, 2023.

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: Byung Min Chung, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496–4056, *justin.chung@nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR 22–104: Fogarty NCD–LIFESPAN Panel.

Date: September 22, 2023.

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: Jeanne M McCaffery, Ph.D., Scientific Review Officer, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–594–3854, *jeanne.mccaffery@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: August 23, 2023.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–18489 Filed 8–25–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health and Human Development; Notice of Closed Meetings

Pursuant to section 1009 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: Eunice Kennedy Shriver National Institute of Child Health and Human Development Special Emphasis Panel; Population Dynamics Centers Research Infrastructure Program FY 2024 (P2C).

Date: November 8–9, 2023.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Room 2131D, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Anita Szajek, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2131D, Bethesda, MD 20892, *anita.szajek@nih.gov.*

Name of Committee: Eunice Kennedy Shriver National Institute of Child Health and Human Development Special Emphasis Panel; Opportunities for Advancing Limb Regeneration Research (R01).

Date: November 17, 2023.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Eunice Kennedy Shriver National Institute of Child Health and Human Development, 6710B Rockledge Drive, Room 2131B, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jolanta Maria Topczewska, Ph.D., Scientific Review Officer, Scientific Review Branch, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, 6710B Rockledge Drive, Room 2131B, Bethesda, MD 20892, (301) 451–0000, *jolanta.topczewska@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children, National Institutes of Health, HHS)

Dated: August 23, 2023.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–18488 Filed 8–25–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2011–0351]

Consolidated Port Approaches Port Access Route Studies (CPAPARS) Final Notice

AGENCY: Coast Guard, DHS.

ACTION: Notification.

SUMMARY: The Coast Guard published a document on March 10, 2023, that announced the availability of the final Consolidated Port Approaches Port Access Route Studies. In addition, the Coast Guard requested comments concerning the final report. After a review of the comments received, the Coast Guard has determined that it is not necessary to revise the final report, and therefore considers it to be complete as published.

FOR FURTHER INFORMATION CONTACT: For information about this document call or email Maureen Kallgren, Coast Guard; telephone 202–372–1561, email *maureen.r.kallgren2@uscg.mil.*

SUPPLEMENTARY INFORMATION:

Background and Purpose

On April 5, 2017, the Coast Guard announced the completion of the Atlantic Coast Port Access Route Study in the **Federal Register** (82 FR 16510), which is available for viewing and download from the Coast Guard Navigation Center's website at *https://www.navcen.uscg.gov/port-access-route-studies.*

The ACPARS identified navigation safety corridors along the Atlantic Coast based on the predominant two-way vessel traffic and customary routes confirmed with AIS data for offshore deep draft and coastal seagoing tug/tow vessels. The study recommended using these corridor locations to establish shipping safety fairways or other appropriate vessel routing measures.

Recognizing the ACPARS only analyzed coastal, longshore, and predominantly north/south vessel transit routes along the Atlantic Coast, the Coast Guard announced new studies focused on port approaches and international entry and departure areas along the Atlantic Coast to supplement the ACPARS on March 15, 2019 (84 FR 9541). On September 9, 2022, the Coast Guard announced the availability of the Consolidated Port Approaches and International Entry and Departure Transit Areas Port Access Route Studies, (CPAPARS) (87 FR 55449). The CPAPARS summarizes the findings of four regional port access route studies: the Northern New York Bight; Seacoast of New Jersey Including Offshore Approaches to the Delaware Bay, Delaware; Approaches to the Chesapeake Bay, Virginia; and the Seacoast of North Carolina; as well as ongoing dialogue with the maritime industry.

To provide continued engagement with stakeholders, the Coast Guard announced the availability of an updated CPAPARS report and provided a ninety-day comment period (88 FR 15055).

Discussion of Comments

Comments were submitted by representatives of the maritime community, wind energy developers, a state government agency, and private citizens.

Most comments were concerned with the recommended shipping safety fairways' proximity to and impact on potential offshore wind energy areas. To address these concerns, the Coast Guard has been working extensively with the Bureau of Ocean Energy management (BOEM) throughout the development of the incoming Notice of Proposed Rulemaking (NPRM) proposing fairways along the Atlantic Coast.[1] The forthcoming NPRM will outline the adjustments that have been made to the fairway dimensions and the work we have done with BOEM to identify and resolve any conflicts.

One commenter urged the Coast Guard to consider underwater cables when designing the fairways. We have considered all known underwater cables and their potential impacts on the proposed fairways, TSS, and precautionary areas. None were found to restrict, endanger, or interfere with navigation.

Another commenter asked us to consider the impacts on the fairways on the White House's offshore wind development goals. We do, and we believe that these goals are best served by the establishment of consistent and well-defined fairways.

One commenter recommended that the Coast Guard coordinate with the Department of Defense to ensure that the fairways would have no impact on national security. We have and will continue to do so throughout the fairway establishment process.

One commenter requested that the Coast Guard acknowledge that vessels in the U.S. EEZ are permitted to navigate through wind farms in contrast to Europe, where vessels must avoid wind energy areas wholesale. We acknowledge this but believe that protecting these wind energy areas from the hazards associated with navigating vessels is the best way to help The White House achieve its renewable energy goals.

One commenter believed that the PARS methodology could be improved using a more granular approach and challenged the Coast Guard's use of the World Association for Waterborne Transport Infrastructure (PIANC) methodology. The USCG uses the PIANC as a starting place to determine widths for historic shipping routes. Marine planners review and adjust the widths based on input from stakeholders, AIS data sets broken down by ship type, and through collaboration with other ocean users (*e.g.,* renewable energy lessees). The final fairway widths are finalized based on this collaboration among all parties to ensure safe and equitable design of fairways on the OCS.

This commenter also requested an explanation for the variability in fairway width. The fairways vary in width because they have been intentionally designed to accommodate OCS development. The fairways have been designed in coordination with BOEM and the relevant stakeholders and the variability is a result of this coordination.

This notice is being issued under authority located in 5 U.S.C. 552(a) as well as 46 U.S.C. 70003.

The Coast Guard.

Dated: August 21, 2023.

Michael D. Emerson,

Director, Marine Transportation Systems, U.S. Coast Guard.

[FR Doc. 2023–18444 Filed 8–25–23; 8:45 am]

BILLING CODE 9110–04–P

[1] *https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=1625-AC57.* Last visited July 20, 2023.

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7070–N–49]

30-Day Notice of Proposed Information Collection: Distressed Cities Technical Assistance NOFO; OMB Control No.: 2528–0326

AGENCY: Office of Policy Development and Research, Chief Data Officer, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* September 27, 2023.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. 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. Interested persons are also invited to submit comments regarding this proposal and comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Anna Guido, Clearance Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000; email *PaperworkReductionActOffice@hud.gov.*

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410; phone number 202–402–5535 or email: *PaperworkReductionActOffice@hud.gov.* This is not a toll-free number, HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit: *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

Copies of available documents submitted to OMB may be obtained from Ms. Guido.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on May 4, 2023 at 88 FR 28598.

A. Overview of Information Collection

Title of Information Collection: Distressed Cities Technical Assistance NOFO.

OMB Approval Number: 2528–0326.

Type of Request: Revision of a currently approved collection.

Form Number: SF–424, SF–LLL, HUD–2880. HUD–424–B.

Description of the need for the information and proposed use: Application information is needed to determine the competition winners, *i.e.,* the technical assistance providers best able to help distressed communities adopt effective, efficient, and sustainable financial management practices, build capacity for financial management, economic revitalization, affordable housing, and disaster recovery, and improve knowledge of federal development programs.

Respondents: Organizations.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
Pre-Award+							
Narrative Response to Rating Factors	5	1	5	20.00	100.00	$28.53	$2,853.00
SF–424							
HUD–424–B	5	1	5	0.25	1.25	28.53	35.66
HUD–2880 Applicant/Recipient Disclosure/Update Report	5	1	5	0.25	1.25	28.53	35.66
SF–LLL Disclosure of Lobbying Activities							
Total				20.5	102.5	28.53	2,924.33

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) 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) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(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 those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

(5) 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. HUD encourages interested parties to submit comments in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Anna P. Guido,

Department Reports Management Office, Office of Policy Development and Research, Chief Data Officer.

[FR Doc. 2023–18445 Filed 8–25–23; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7077–N–15]

Privacy Act of 1974; System of Records

AGENCY: Office of Multifamily Housing, HUD.

ACTION: Rescindment of a system of records notice.

SUMMARY: The Department of the Housing and Urban Development (HUD) is issuing a public notice of its intent to rescind the Integrated Real Estate Management System (iREMS). During a routine review of Multifamily Housing system of records notices, it was determined that this system of records is no longer necessary because personally identifiable information is not used in the retrieval process of the iREMS system.

DATES: This proposed action will be effective immediately upon publication.

ADDRESSES: You may submit comments, identified by one of the following methods:

Federal e-Rulemaking Portal: http://www.regulations.gov. Follow the instructions provided on that site to submit comments electronically.

Fax: 202–619–8365.

Email: www.privacy@hud.gov.

Mail: Attention: Privacy Office; LaDonne White, Chief Privacy Officer; The Executive Secretariat; 451 Seventh Street SW, Room 10139; Washington, DC 20410–0001.

Instructions: All submissions received must include the agency name and docket number for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov* including any personal information provided.

Docket: For access to the docket to read background documents or comments received go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: LaDonne White; 451 Seventh Street SW, Room 10139; Washington, DC 20410–0001; telephone number 202–708–3054 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication

disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs* .

SUPPLEMENTARY INFORMATION: The Integrated Real Estate Management System (iREMs) is being provided for rescindment from the HUD Office of Multifamily Housing (MFH) system of records inventory. The SORN was identified for rescindment for the following reason: the records are not Privacy Act records. This rescindment will have no impact to the records as it pertains only to the retrievability of the records. Records in this system are stored securely electronically or on paper in secure facilities in a locked drawer behind a locker door. A description of each rescindment justification, the applicable SORN, and an account of what happened to the records is as follows:

Integrated Real Estate Management System (iREMS) is a system of systems that aggregates data from multiple sources. Personal Identifiers do not originate in iREMS. The retrievability section of the current iREMS SORN states the system can use Property Participant data such as their Taxpayer Identification number (TIN) and the participants name to retrieve a record. iREMS users are unable to retrieve a record using Property Participant personally identifiable information (PII) from the user interface. Records are retrieved mainly based on the property identification number, Federal Housing Authority (FHA) Identification Number or the contract identification number associated with the record.

SYSTEM NAME AND NUMBER:

Integrated Real Estate Management System (iREMS), *HSNG.MF/HTS.01*

HISTORY:

The previously published notice published in the **Federal Register** [Docket Number FR–5921–N–13] on August 22, 2016, at 81 FR 56684.

LaDonne White,

Chief Privacy Officer, Office of Administration.

[FR Doc. 2023–18446 Filed 8–25–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–6415–D–01]

Order of Succession for the Office of Public and Indian Housing

AGENCY: Office of Public and Indian Housing, U.S. Department of Housing and Urban Development (HUD).

ACTION: Notice of order of succession.

SUMMARY: In this notice, the Principal Deputy Assistant Secretary designates the order of succession for the Office of Public and Indian Housing (PIH). This order of succession revokes and supersedes all prior orders of succession for the Office of Public and Indian Housing, including the Order of Succession published in the **Federal Register** on April 7, 2015.

DATES: Applicable Date: TBD.

FOR FURTHER INFORMATION CONTACT: Michael Stettes, Office of Policy, Program and Legislative Initiatives, Office of Public and Indian Housing, Department of Housing and Urban Development, 451 7th St. SW, Washington, DC 20410, email address *Michael.C.Stettes@hud.gov,* telephone 202–402–5983. HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit: *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

SUPPLEMENTARY INFORMATION: The Principal Deputy Assistant Secretary is issuing this order of succession of officials authorized to perform the duties and functions of the Office of the Assistant Secretary for Public and Indian Housing when the Assistant Secretary is not available to exercise the powers or perform the duties of the office. This Order of Succession is subject to the provisions of the Federal Vacancies Reform Act of 1998 (5 U.S.C. 3345–3349d). This publication revokes and supersedes all prior orders of succession for the Office of Public and Indian Housing, including the order of succession published in the **Federal Register** on April 7, 2015 (80 FR 18644).

Section A. Order of Succession

Subject to the provisions of the Federal Vacancies Reform Act of 1998 (5 U.S.C. 3345 *et seq.,*) during any period when, by reason of absence, disability, or vacancy in office, the Assistant Secretary for PIH is not available to exercise the powers or perform the duties of the Assistant Secretary for PIH, the following officials within PIH are hereby designated to exercise the powers and perform the duties of the Assistant Secretary for PIH. These officials shall perform the functions and duties of the office in the order specified herein, and no official shall serve unless all the other officials, whose position precedes theirs in this order, are not available to act by reason of absence, disability or vacancy in office. No individual who is serving in an office listed below in an acting capacity may act as the Assistant Secretary for Public and Indian Housing pursuant to this Order of Succession.

(1) Principal Deputy Assistant Secretary for Public and Indian Housing;

(2) General Deputy Assistant Secretary for Public and Indian Housing;

(3) Deputy Assistant Secretary for Public Housing and Voucher Programs;

(4) Deputy Assistant Secretary for Public Housing Investments;

(5) Deputy Assistant Secretary for Field Operations;

(6) Deputy Assistant Secretary for Real Estate Assessment Center;

(7) Deputy Assistant Secretary for Office of Native American Programs;

(8) Deputy Assistant Secretary for Operations

(9) Chief for Office of Policy, Programs and Legislative Initiatives

(10) Public Housing Director, Atlanta Field Office

(11) Director of the Financial Management Center, Kansas City

(12) Network Director for the Northeast for Regions I, II, III

Section B. Authority Superseded

This order of succession supersedes all prior orders of succession for the Office of Public and Indian Housing, including the order of succession published in the **Federal Register** on April 7, 2015, (80 FR 18644).

Authority: Section 7(d), Department of Housing and Urban Development Act, (42 U.S.C. 3535(d)).

Principal Deputy Assistant Secretary for Public and Indian Housing, Richard J. Monocchio, having reviewed and approved this document, is delegating the authority to electronically sign this document to submitter, Aaron Santa Anna, who is the Federal Register Liaison for HUD, for purposes of publication in the **Federal Register**.

Aaron Santa Anna,

Federal Register Liaison for the Department of Housing and Urban Development.

[FR Doc. 2023–18461 Filed 8–25–23; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7077–N–16]

Privacy Act of 1974; System of Records

AGENCY: Office of Single-Family Program, HUD.

ACTION: Notice of a new system of records.

SUMMARY: Pursuant to the provisions of the Privacy Act of 1974, as amended, the Department of Housing and Urban Development (HUD) is issuing a public notice of its intent to create the Office of Single Family Program Development Privacy Act system of records, ''Credit Alert Reporting Verification System (CAIVRS)'', CAIVRS was developed by the HUD in June 1987 as a shared database of defaulted Federal debtors and enables processors of applications for Federal credit benefit to identify individuals who are in default or have had claims paid on direct or guaranteed Federal loans or are delinquent on other debts owed to Federal agencies. The purpose of this system is to enable program agencies to prescreen their borrowers and to broaden the Federal Government's base in determining an applicant's creditworthiness. Some of these factors include: verifying loan applicants are not in default or delinquent on direct or guaranteed loans of participating Federal programs, providing authorized users with a means to prescreen applicants for Federal credit benefit in order to avoid extending benefits to individuals who are considered credit risks, and demonstrating to the public the importance of meeting Federal obligations and its commitment to collecting delinquent debt. CAIVRS is included in the HUD's inventory of record systems.

DATES: Comments will be accepted on or before September 27, 2023. This proposed action will be effective on the date following the end of the comment period unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments identified by docket number or by any of the following methods:

Federal e-Rulemaking Portal: http://www.regulations.gov. Follow the instructions provided on that site to submit comments electronically.

Fax: 202–619–8365.

Email: www.privacy@hud.gov.

Mail: Attention: Ladonne White; Department of Housing and Urban Development, 451 Seventh Street SW, Room 10139, Washington, DC 20410–0001.

Instructions: All submissions received must include the agency name and docket number [Insert Docket Number] for this rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Ladonne White; 451 Seventh Street SW, Room 10139, Washington, DC 20410–0001; telephone number 202–708–3054 (this is not a toll-free number). HUD welcomes and is prepared to receive calls from individuals who are deaf or hard of hearing, as well as individuals with speech or communication disabilities. To learn more about how to make an accessible telephone call, please visit *https://www.fcc.gov/consumers/guides/telecommunications-relay-service-trs.*

SUPPLEMENTARY INFORMATION: Single Family Program Development maintains the ''CAIVRS (F57)'' system of records. The purpose of this system is to enable program agencies to prescreen their borrowers and to broaden the Federal Government's base in determining an applicant's creditworthiness. Some of these factors include: verifying loan applicants are not in default or delinquent on direct or guaranteed loans of participating Federal programs, providing authorized users with a means to prescreen applicants for Federal credit benefit in order to avoid extending benefits to individuals who are considered credit risks, and demonstrating to the public the importance of meeting Federal obligations and its commitment to collecting delinquent debt. CAIVRS is included in the HUD's inventory of record systems. The system contains borrowers with delinquent Federal debt and allows Federal agencies to reduce the risk of future credit default to Federal insured or guaranteed loan programs.

SYSTEM NAME AND NUMBER:

Credit Alert Reporting Verification System (CAIVRS)—HUD/HOU–04.

SECURITY CLASSIFICATION:

Unclassified.

SYSTEM LOCATION:

CAIVRS is located and operated at NASA's John C. Stennis Space Flight Center, located at 1100 Balch Boulevard, Stennis Space Center, MS 39529–0001.

SYSTEM MANAGER(S):

Elissa Saunders, Director, Office of Single-Family Program Development, United States Department of Housing and Urban Development, 451 7th St. SW, Washington, DC 20410–1000; Phone (202) 402–2378; Email: *Elissa.O.Saunders@hud.gov.*

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Section 203, National Housing Act, Public Law 73–479 (12 U.S.C. 1709); section 255, National Housing Act, Public Law 73–479 (12 U.S.C. 1701z–20); section 165, Housing and Community Development Act of 1987, Public Law 100–242 (42 U.S.C. 3543); section 31001, Debt Collection Act of 1996 as amended, Public Law 104–134 (31 U.S.C. 7701); and section 31001, Debt Collection Act of 1996 as amended, Public Law 104–134 (31 U.S.C. 3720B). Office of Management and Budget (OMB) Circulars A–129 (Policies for Federal Credit Programs and Non-Tax Receivables); the Budget and Accounting Acts of 1921 and 1950, as amended; the Debt Collection Act of 1982, as amended; the Deficit Reduction Act of 1984, as amended, and the Debt Collection Improvement Act of 1996, as amended.

PURPOSE(S) OF THE SYSTEM:

The purpose of CAIVRS is to ensure participating Federal agencies and their authorized lenders will comply with the legal requirement to verify individuals applying for a federally backed loan, or other aid, are not presently delinquent on another Federal obligation. CAIVRS is a shared, inter-agency database managed by HUD where participating agencies are required to report delinquent federal debt.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Individual borrowers who have applied for Federal housing loans and have fallen delinquent.

CATEGORIES OF RECORDS IN THE SYSTEM:

Full Name, Social Security Number/Taxpayer ID number (SSNs/TINs), Date of Birth, Email Addresses, Work address, Employee Identification Number, Home Address, Mother's Maiden Name, and FHA Case Number.

RECORD SOURCE CATEGORIES:

F17C–FHA Connection (User ID and Password management), F71-Debt Collection and Asset Management System—Title I, F71A-Debt Collection and Asset Management System—Generic Debt, P278-Lender Electronic Assessment Portal, A75R—Financial Data Mart, VA-Department of Veteran Affairs Accounts Receivable Records

88VA244, SBA-Small Business Administration Disaster Loan Case File and Loan System, ED-Department of Education Common Services for Borrowers, USDA-United States Department of Agriculture Applicant, Borrower, Grantee, or Tenant File (Rural Development), DOJ-Department of Justice Debt Collection Enforcement System.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:

(A) To a congressional office from the record of an individual, in response to an inquiry from the congressional office made at the request of that individual.

(B) To Federal, State, and local agencies, their employees, and agents to conduct computer matching programs as regulated by the Privacy Act of 1974, as amended (5 U.S.C. 552a).

(C) To Federal agencies, non-Federal entities, their employees, and agents (including contractors, their agents or employees; employees or contractors of the agents or designated agents); or contractors, their employees or agents with whom HUD has a contract, service agreement, grant, cooperative agreement, or computer matching agreement for: (1) detection, prevention, and recovery of improper payments; (2) detection and prevention of fraud, waste, and abuse in major Federal programs administered by a Federal agency or non-Federal entity; (3) detection of fraud, waste, and abuse by individuals in their operations and programs, but only if the information shared is necessary and relevant to verify pre-award and prepayment requirements before the release of Federal funds, prevent and recover improper payments for services rendered under programs of HUD or of those Federal agencies and non-Federal entities to which HUD provides information under this routine use.

(D) To contractors, grantees, experts, consultants, Federal agencies, and non-Federal entities, including, but not limited to, State and local governments and other research institutions or their parties, and entities and their agents with whom HUD has a contract, service agreement, grant, or cooperative agreement, when necessary to accomplish an agency function, related to a system of records, for the purposes of statistical analysis and research in support of program operations, management, performance monitoring, evaluation, risk management, and policy development, or to otherwise support the Department's mission. Records under this routine use may not be used in whole or in part to make decisions that affect the rights, benefits, or privileges of specific individuals. The results of the matched information may not be disclosed in identifiable form.

(b) To a recipient who has provided the agency with advance, adequate written assurance that the record provided from the system of records will be used solely for statistical research or reporting purposes. Records under this condition will be disclosed or transferred in a form that does not identify an individual.

(E) To contractors, grantees, experts, consultants and their agents, or others performing or working under a contract, service, grant, or cooperative agreement with HUD, when necessary to accomplish an agency function related to a system of records. Disclosure requirements are limited to only those data elements considered relevant to accomplishing an agency function. Individuals provided information under these routine use conditions are subject to Privacy Act requirements and disclosure limitations imposed on the Department.

(F) To contractors, experts, and consultants with whom HUD has a contract, service agreement, or other assignment of the Department, when necessary to utilize data to test new technology and systems designed to enhance program operations and performance.

(G) To appropriate agencies, entities, and persons when (1) HUD suspects or has confirmed there has breached the system of records; (2) HUD has determined that because of the suspected or confirmed breach there is a risk of harm to individuals, HUD (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 HUD'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 HUD determines that information from this system of record 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) (a) To appropriate Federal, State, local, tribal, or governmental agencies or multilateral governmental organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license, where HUD determines that the information would help to enforce civil or criminal laws.

(b) To third parties during a law enforcement investigation, to the extent to obtain information pertinent to the investigation, disclosed such information is appropriate to the proper performance of the official duties of the officer making the disclosure.

(J) (a) To a court, magistrate, administrative tribunal, or arbitrator while presenting evidence, including disclosures to opposing counsel or witnesses in civil discovery, litigation, mediation, or settlement negotiations; or in connection with criminal law proceedings; or in response to a subpoena or to a prosecution request when such records to be released are specifically approved by a court provided order.

(b) To appropriate Federal, State, local, Tribal, or governmental agencies or multilateral governmental organizations responsible for investigating or prosecuting the violations of, or for enforcing or implementing, a statute, rule, regulation, order, or license, where HUD determines that the information would help to enforce civil or criminal laws.

(c) To third parties during a law enforcement investigation to the extent to obtain information pertinent to the investigation, provided disclosure is appropriate to the proper performance of the official duties of the officer making the disclosure.

(d) To another agency or to an instrumentality of any governmental jurisdiction within or under the control of the United States for a civil or criminal law enforcement activity if the activity is authorized by law, and if the head of the agency or instrumentality has made a written request to the agency that maintains the record, specifying the particular portion desired and the law enforcement activity for which the record is sought.

(K) To any component of the Department of Justice or other Federal agency conducting litigation or in proceedings before any court, adjudicative, or administrative body, when HUD determines that the use of such records is relevant and necessary to the litigation and when any of the following is a party to the litigation or have an interest in such litigation: (1) HUD, or any component thereof; or (2) any HUD employee in his or her official capacity; or (3) any HUD employee in

his or her individual capacity where the Department of Justice or agency conducting the litigation has agreed to represent the employee; or (4) the United States, or any agency thereof, where HUD determines that litigation is likely to affect HUD or any of its components.

(L) To match system users for security purposes. User-provided PII may be shared with HUD departmental enforcement offices and other Federal, State, local or Tribal law enforcement agencies if there is reason to believe that a user provided false information to obtain access to the system, and that providing such information would help enforce civil or criminal laws.

(M) With the United States Department of Veterans Affairs (VA), to pre-screen applicants to determine if they are presently delinquent on any Federal debt reported by a participating agency, and to determine if they are eligible for a new federally backed loan or grant.

With the United States Small Business Administration (SBA) to pre-screen applicants to determine if they are presently delinquent on any Federal debt reported by a participating agency, and to determine if they are eligible for a new federally backed loan or grant.

With the United States Department of Education to pre-screen applicants to determine if they are presently delinquent on any Federal debt reported by a participating agency, and to determine if they are eligible for a new federally backed loan or grant.

With the United States Department of Agriculture (USDA) to pre-screen applicants to determine if they are presently delinquent on any Federal debt reported by a participating agency, and to determine if they are eligible for a new federally backed loan or grant.

With the United States DOJ to pre-screen applicants to determine if they are presently delinquent on any Federal debt reported by a participating agency, and to determine if they are eligible for a new federally backed loan or grant.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Electronic only.

POLICIES AND PRACTICES FOR RETRIEVAL OF RECORDS:

Name and Social Security Number/ Taxpayer ID Number (SSNS and TINS).

POLICIES AND PRACTICIES FOR RENTENTION AND DISPOSAL OF RECORDS:

All records related to Federal Housing Administration (FHA) Mortgage Credit Alert report will be destroyed according to HUD Schedule Appendix 20 Single Family Home Mortgage Insurance Program Records, item 13B6 which states the following, destroy when superseded or obsolete. All records related to FHA Mortgage Credit Verification will be destroyed according to HUD Schedule Appendix 5 Technical Support Records, item 7 which states the following, destroy when superseded or obsolete.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

CAIVRS and its data are located on centralized servers within Federal facilities with access control in place. Physical controls include cypher and combination locks, key card-controlled access, security guards, closed circuit TV, identification badges, and safes. Administrative controls include encryption of back-up data, back-ups secured off-site, methods to ensure only authorized users have access to PII, periodic security audits, regular monitoring of system users' behavior. Technical controls include encryption of Data at Rest and in Transit, firewalls at HUD and each reporting agency, role-based access controls, user IDs and passwords, Least Privileged access, elevated and/or administrative privileged access, PIV cards, intrusion detection systems. Additional measures to safeguard the system include role-based Privacy Act training required for HUD personnel responsible for CAIVRS system program management, IT security monitoring by the Department of Housing and Urban Development and the Department of Homeland Security.

RECORD ACCESS PROCEDURES:

Individuals requesting records of themselves should address written inquiries to the Department of Housing Urban and Development 451 7th Street SW, Washington, DC 20410–0001. For verification, individuals should provide their full name, current address, and telephone number. In addition, the requester must provide either a notarized statement or an unsworn declaration made under 24 CFR 16.4

CONTESTING RECORD PROCEDURES:

The HUD rule for contesting the content of any record pertaining to the individual by the individual concerned is published in 24 CFR 16.8 or may be obtained from the system manager.

NOTIFICATION PROCEDURES:

Individuals requesting notification of records of themselves should address written inquiries to the Department of Housing Urban Development, 451 7th Street SW, Washington, DC 20410–0001. For verification purposes, individuals should provide their full name, office or organization where assigned, if applicable, and current address and telephone number. In addition, the requester must provide either a notarized statement or an unsworn declaration made under 24 CFR 16.4.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

N/A.

HISTORY:

N/A.

LaDonne White,

Chief Privacy Officer, Office of Administration.

[FR Doc. 2023–18447 Filed 8–25–23; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R3–ES–2023–N069; FXES11130300000–234–FF03E00000]

Endangered and Threatened 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 or threatened species under the ESA. We invite the public and local, State, Tribal, and Federal agencies to comment on these applications. Before issuing any of 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 September 27, 2023.

ADDRESSES: *Document availability and comment submission:* Submit requests for copies of the applications and related documents, as well as any comments, by one of the following methods. All requests and comments should specify the applicant name(s) and application number(s) (*e.g.,* ESXXXXXX; see table in **SUPPLEMENTARY INFORMATION**):

- *Email (preferred method): permitsR3ES@fws.gov.* Please refer to the respective application number (*e.g.,* Application No. ESXXXXXX) in the subject line of your email message.
- *U.S. Mail:* Regional Director, Attn: Nathan Rathbun, U.S. Fish and Wildlife Service, Ecological Services, 5600 American Blvd. West, Suite 990, Bloomington, MN 55437–1458.

FOR FURTHER INFORMATION CONTACT: Nathan Rathbun, 612–713–5343 (phone); *permitsR3ES@fws.gov* (email). Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service, invite review and comment from the public and local, State, Tribal, and Federal agencies on applications we have received for permits to conduct certain activities with endangered and threatened species under section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and our regulations in the Code of Federal Regulations (CFR) at 50 CFR part 17. Documents and other information submitted with the applications are available for review, subject to the requirements of the Privacy Act and the Freedom of Information Act.

Background

The ESA prohibits certain activities with endangered and threatened species unless authorized by a Federal permit. The ESA and our implementing regulations in part 17 of title 50 of the Code of Federal Regulations (CFR) provide for the issuance of such permits and require that we invite public comment before issuing permits for activities involving endangered species.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to conduct activities with endangered 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

The ESA requires that we invite public comment before issuing these permits. Accordingly, we invite local, State, Tribal, and Federal agencies and the public to submit written data, views, or arguments with respect to these applications. The comments and recommendations that will be most useful and likely to influence agency decisions are those supported by quantitative information or studies. Proposed activities in the following permit requests are for the recovery and enhancement of propagation or survival of the species in the wild.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
ES98298A	Ohio Environmental Protection Agency, Columbus, OH.	Add new species—round hickorynut (*Obovaria subrotunda*), pink mucket (*Lampsilis abrupta*), and longsolid (*Fusconaia subrotunda*)—to existing authorized 10 freshwater mussel species.	OH	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture, handle, release.	Amend.
ES206781	EcoAnalysts, Inc., O'Fallon, MO.	Add new species—round hickorynut (*Obovaria subrotunda*) and longsolid (*Fusconaia subrotunda*)—to existing authorized 60 freshwater mussel species.	AR, CO, CT, DE, IA, IN, IL, KS, KY, MA, MD, ME, MI, MN, MO, NE, NH, NJ, NY, OH, OK, PA, RI, SD, TN, TX, VA, VT, WI, WV.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture, handle, release, and relocate under special circumstances.	Amend.
ES48835A	Applied Science & Technology, Inc., Brighton, MI.	Add new species—round hickorynut (*Obovaria subrotunda*) and longsolid (*Fusconaia subrotunda*)—to existing authorized eight freshwater mussel species.	MI, OH	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture, handle, release, and relocate under special circumstances.	Amend.
ES53616C	Illinois Natural History Survey, Champaign, IL.	Rusty patched bumble bee (*Bombus affinis*).	IL	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture, handle, sample, salvage, and release.	Renew and amend.
PER3213383	Heidi McMullin, Poplar Bluff, MO.	Indiana bat (*Myotis sodalis*), northern long-eared bat (*Myotis septentrionalis*), gray bat (*Myotis grisescens*), Virginia big-eared bat (*Corynorhinus townsendii virginianus*), and Ozark big-eared bat (*Corynorhinus townsendii ingens*).	AL, AR, CT, DE, FL, GA, IA, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MS, MO, NC, NE, NH, NJ, NY, OH, OK, PA, RI, SC, TN, TX, VA, VT, WI, WV.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture with mist nets or harp traps, identify, handle, collect non-intrusive measurements, band, radio-tag, and release.	New.
ESPER0011986	Lindsey Jakovljavic, Kirtland, OH.	Add new species—round hickorynut (*Obovaria subrotunda*) and longsolid (*Fusconaia subrotunda*)—to existing authorized 20 freshwater mussel species.	OK, IL, IN, IA, MI, MN, MO, OH, WI, AL, AR, KY, MS, TN, NJ, NY, PA, WV, KS.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture, handle, release, and relocate under special circumstances.	Amend.

Application No.	Applicant	Species	Location	Activity	Type of take	Permit action
PER3542792	Burke Engineering, Rosemont, IL.	Sheepnose mussel (*Plethobasus cyphyus*).	IL	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture, handle, release, and relocate under special circumstances.	New.
ESPER1224186	Greg Gaulke, Madison, WI.	Add new species—sheepnose (*Plethobasus cyphyus*), clubshell, (*Pleurobema clava*), fanshell (*Cyprogenia stegaria*), northern riffleshell (*Epioblasma rangiana*), purple cat's paw pearlymussel (*Epioblasma obliquata*), rayed bean (*Villosa fabalis*), white cat's paw (*Epioblasma perobliqua*), round hickorynut (*Obovaria subrotunda*), pyramid pigtoe (*Pleurobema rubrum*), longsolid (*Fusconaia subrotunda*)—to six existing authorized freshwater mussel species.	IL, IN, IA, MI, MN, MO, OH, WI.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture, handle, release, and relocate under special circumstances.	Amend.
ES81968B	Curtis Hart, Hudson, MI.	Indiana bat (*Myotis sodalis*), northern long-eared bat (*M. septentrionalis*), gray bat (*M. grisescens*), Virginia big-eared bat (*Corynorhinus townsendii virginianus*), and Ozark big-eared bat (*C. townsendii ingens*).	OK, IL, IN, IA, MI, MN, MO, OH, WI, AL, AR, FL, GA, KY, LA, MS, NC, SC, TN, CT, DE, DC, MD, MA, NH, NJ, NY, PA, RI, VT, VA, WV, KS, MT, NE, ND, SD, WY.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Add New Activities—Collect wing punches and tissue samples—to existing authorized activities: Capture with mist nets, identify, handle, collect non-intrusive measurements, band, radio-tag, and release.	Amend.
ES70488C	Scott Bergeson, Fort Wayne, IN.	Add new species—tri-colored bat (*Perimyotis subflavus*)—to existing authorized species: Indiana bat (*Myotis sodalis*), northern long-eared bat (*Myotis septentrionalis*), and gray bat (*Myotis grisescens*).	AL, AR, CT, FL, GA, IA, IL, IN, KS, KY, LA, MA, MD, MI, ME, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NY, OH, OK, PA, RI, SC, SD, TN, VT, VA, WI, WV.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture with mist-nets and harp traps, handle, identify, radio-tag, band, enter hibernacula, collect nonintrusive measurements, and release.	Amend.
ES62048D	Carly Kalina, Des Moines, IA.	Indiana bat (*Myotissodalis*), northern long-eared bat (*Myotis septentrionalis*), and gray bat (*Myotis grisescens*).	AL, AR, CT, DC, DE, GA, IA, IL, IN, KS, KY, LA, MA, MD, MI, ME, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NY, OH, OK, PA, RI, SC, SD, TN, VT, VA, WI, WV, WY.	Conduct presence/absence surveys, document habitat use, conduct population monitoring, and evaluate impacts.	Capture with mist-nets, handle, identify, radio-tag, band, enter hibernacula, collect nonintrusive measurements, collect tissue/fecal samples, and release.	Amend.

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 any of the applicants listed in this notice, we will publish a notice in the **Federal Register**.

Authority

We publish this notice under section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Lori Nordstrom,

Assistant Regional Director, Ecological Services, Midwest Region.

[FR Doc. 2023–18481 Filed 8–25–23; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–ES–2023–N072; FXES11130800000–234–FF08E00000]

Endangered and Threatened Wildlife and Plants; Initiation of 5-Year Status Reviews of 47 Species in California, Nevada, and Oregon; Correction

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of initiation of reviews; correction.

SUMMARY: We, the U.S. Fish and Wildlife Service, published a notice in the **Federal Register** of August 17, 2023, initiating 5-year status reviews of 47 species in California, Nevada, and Oregon under the Endangered Species Act. We inadvertently included one species in error. We are correcting the notice to remove that species.

DATES: Interested persons are invited to submit comments on or before October 16, 2023.

SUPPLEMENTARY INFORMATION: On August 17, 2023, we, the U.S. Fish and Wildlife Service, published a notice initiating 5-year status reviews of 47 species in California, Nevada, and Oregon under the Endangered Species Act. We inadvertently included one species, the southern sea otter (*Enhydra lutris nereis*), in error. We are correcting the notice to remove that species. For how to comment, see our August 17, 2023, notice (88 FR 56042).

Correction

In the **Federal Register** of August 17, 2023, in FR Doc. 2023–17728, please make the following correction:

On page 56043, remove the ''Otter, southern sea'' entry from the table.

Jill Russi,

Acting Regional Director, California Great Basin Region, U.S. Fish and Wildlife Service.

[FR Doc. 2023–18479 Filed 8–25–23; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R4–ES–2023–N070; FXES11140400000–234–FF04E00000]

Endangered Species; 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 any of the requested permits, we will take into consideration any information that we receive during the public comment period.

DATES: We must receive written data or comments on the applications by September 27, 2023.

ADDRESSES: *Reviewing Documents:* Submit requests for copies of applications and other information submitted with the applications to Karen Marlowe (see **FOR FURTHER INFORMATION CONTACT**). All requests and comments should specify the applicant name and application number (*e.g.,* Mary Smith, ESPER0001234).

Submitting Comments: If you wish to comment, you may submit comments by one of the following methods:

- *Email (preferred method): permitsR4ES@fws.gov.* Please include your name and return address in your email message. If you do not receive a confirmation from the U.S. Fish and Wildlife Service that we have received your email message, contact us directly at the telephone number listed in **FOR FURTHER INFORMATION CONTACT**.
- *U.S. mail:* U.S. Fish and Wildlife Service Regional Office, Ecological Services, 1875 Century Boulevard, Atlanta, GA 30345 (Attn: Karen Marlowe, Permit Coordinator).

FOR FURTHER INFORMATION CONTACT: Karen Marlowe, Permit Coordinator, 404–679–7097 (telephone) or *karen_marlowe@fws.gov* (email). Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service, invite review and comment from the public and local, State, Tribal, and Federal agencies on applications we have received for permits to conduct certain activities with endangered and threatened species under section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and our regulations in the Code of Federal Regulations (CFR) at 50 CFR part 17. Documents and other information submitted with the applications are available for review, subject to the requirements of the Privacy Act of 1974, as amended (5 U.S.C. 552a), and the Freedom of Information Act (5 U.S.C. 552).

Background

With some exceptions, the ESA prohibits take of listed species unless a Federal permit is issued that authorizes such take. The ESA's definition of ''take'' includes hunting, shooting, harming, wounding, or killing, and also such activities as pursuing, harassing, trapping, capturing, or collecting.

A recovery permit issued by us under section 10(a)(1)(A) of the ESA authorizes the permittee to take endangered or threatened species while engaging in activities that are conducted for scientific purposes that promote recovery of species or for enhancement of propagation or survival of species. These activities often include the capture and collection of species, which would result in prohibited take if a permit were not issued. 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

The ESA requires that we invite public comment before issuing these permits. Accordingly, we invite local, State, Tribal, and Federal agencies, and the public to submit written data, views, or arguments with respect to these applications. The comments and recommendations that will be most useful and likely to influence agency decisions are those supported by quantitative information or studies. Proposed activities in the following permit requests are for the recovery and enhancement of propagation or survival of the species in the wild.

Permit application number	Applicant	Species	Location	Activity	Type of take	Permit action
PER4098933–0	Robert Stinson; Knoxville, TN.	Gray bat (*Myotis grisescens*), Indiana bat (*Myotis sodalis*), northern long-eared bat (*Myotis septentrionalis*), tricolored bat (*Perimyotis subflavus*), and Virginia big-eared bat (*Corynorhinus townsendii virginianus*).	Alabama, Georgia, Kentucky, Mississippi, North Carolina, South Carolina, Tennessee, and Virginia.	Presence/probable absence surveys, studies to document habitat use, population monitoring, and studies to evaluate potential impacts of white-nose syndrome and other threats.	Enter hibernacula or maternity roost caves, capture with mist nets or harp traps, handle, identify, band, radio tag, and release.	New.
PER3404461–0	Megan Wallrichs; Knoxville, TN.	Florida bonneted bat (*Eumops floridanus*), gray bat (*Myotis grisescens*), Indiana bat (*Myotis sodalis*), northern long-eared bat (*Myotis septentrionalis*), and tricolored bat (*Perimyotis subflavus*).	Alabama, Arkansas, Colorado, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming.	Presence/probable absence surveys, studies to document habitat use, population monitoring, and studies to evaluate potential impacts of white-nose syndrome and other threats.	Enter hibernacula or maternity roost caves, capture with mist nets or harp traps, handle, identify, band, radio tag, swab, and release.	New.
ES81430B–2 ...	Heather Wallace; Raleigh, NC.	Tricolored bat (*Perimyotis subflavus*).	Alabama, Arkansas, Georgia, Kentucky, Louisiana, Mississippi, North Carolina, South Carolina, and Tennessee.	Presence/probable absence surveys, population monitoring, genetic analyses, and studies to evaluate potential impacts of white-nose syndrome and other threats.	Enter hibernacula, capture with mist nets or harp traps, handle, identify, band, radio tag, and release.	Amendment.
ES102292–14 ..	Jeremy Jackson; Richmond, KY.	Gray bat (*Myotis grisescens*), Indiana bat (*Myotis sodalis*), northern long-eared bat (*Myotis septentrionalis*), tricolored bat (*Perimyotis subflavus*), and Virginia big-eared bat (*Corynorhinus townsendii virginianus*).	Alabama, Arkansas, Connecticut, Delaware, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Montana, Nebraska, New Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming.	Presence/probable absence surveys, studies to document habitat use, and population monitoring.	Enter hibernacula or maternity roost caves, capture with mist nets or harp traps, handle, identify, collect hair samples, band, radio tag, and release.	Renewal and amendment.
PER3535456–0	Mirabeau Dudley; Pittsview, AL.	Red-cockaded woodpecker (*Picoides borealis*).	Alabama	Population management and monitoring.	Capture, band, construct and monitor artificial nest cavities and restrictors, translocate, recapture, and release.	New.

Permit application number	Applicant	Species	Location	Activity	Type of take	Permit action
PER3726625–0	Kelly Stewart; La Jolla, CA.	Green sea turtle (*Chelonia mydas*), hawksbill sea turtle (*Eretmochelys imbricata*), leatherback sea turtle (*Dermochelys coriacea*), and loggerhead sea turtle (*Caretta caretta*).	U.S. Virgin Islands	Nest monitoring and protection, and habitat use, demographic, and genetic studies.	Capture; handle; measure; collect tissue and blood; flipper, satellite, and PIT tag; salvage dead hatchlings and nonviable eggs; and examine and relocate nests.	New.
ES57873C–1 ...	Arkansas Natural Heritage Commission; Little Rock, AR.	Yellowcheek darter (*Etheostoma moorei*).	Arkansas	Presence/probable absence surveys.	Capture, identify, and release.	Renewal.
ES62778B–3 ...	Chanston Osborne; Aberdeen, NC.	Tricolored bat (*Perimyotis subflavus*).	Alabama, Arkansas, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Texas, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming.	Presence/probable absence surveys.	Capture with mist nets and harp traps, handle, identify, band, radio tag, and release.	Amendment.
ES022468–6	Endangered Species Branch, Department of Defense; Ft. Bragg, NC.	Red-cockaded woodpecker (*Picoides borealis*).	North Carolina	Population management and monitoring..	Capture, band, construct, and monitor artificial nest cavities and restrictors, and translocate.	Renewal.
ES02167C–1 ...	James Gore; Columbia, SC.	Tricolored bat (*Perimyotis subflavus*).	Alabama, Arkansas, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Illinois, Indiana, Iowa, Kansas, Kentucky, Louisiana, Maine, Maryland, Massachusetts, Michigan, Minnesota, Mississippi, Missouri, Nebraska, New Hampshire, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, South Carolina, South Dakota, Tennessee, Vermont, Virginia, West Virginia, Wisconsin, and Wyoming.	Presence/probable absence surveys, population monitoring, and stable isotope analyses..	Enter hibernacula and maternity roost caves, capture with mist nets or harp traps, handle, identify, band, radio tag, and collect hair samples..	Renewal and amendment.

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 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. 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 a permit to an applicant listed in this notice, we will publish a notice in the **Federal Register**.

Authority

We publish this notice under section 10(c) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

Lourdes Mena,

Acting Deputy Assistant Regional Director, Ecological Services, Southeast Region.

[FR Doc. 2023–18523 Filed 8–25–23; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R8–ES–2023–0124; FXES11140800000–234–FF08EVEN00]

Endangered and Threatened Wildlife and Plants; Three Draft Habitat Conservation Plans and Associated Draft Categorical Exclusions for Development of Single-Family Residences; Los Osos, San Luis Obispo County, CA

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), have received three applications for incidental take permits (ITPs) for the federally threatened Morro shoulderband snail under the Endangered Species Act of 1973, as amended. Each of three applicants submitted a permit application which, if issued, would authorize take of the Morro shoulderband snail incidental to activities associated with development of a single-family residence in Los Osos, San Luis Obispo County, California. As part of the application for an ITP, each applicant submitted a draft habitat conservation plan for their respective project. For each proect, The Service prepared a draft low-effect screening form and environmental action statement in accordance with the National Environmental Policy Act to evaluate the potential effects to the natural and human environment resulting from issuing an ITP to each applicant for their project. We invite the public and local, State, Tribal, and Federal agencies to comment on these documents.

DATES: Written comments should be received on or before September 27, 2023.

ADDRESSES: *Obtaining Documents:* The documents this notice announces, as well as any comments and other materials that we receive, will be available for public inspection online in Docket No. FWS–R8–ES–2023–0124 at *https://www.regulations.gov. Submitting Written Comments:* Please send us your written comments using one of the following methods:

- *Online: https://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–R8–ES–2023–0124.
- *U.S. mail:* Public Comments Processing; Attn: FWS–R8–ES–2023–0124; U.S. Fish and Wildlife Service; MS: PRB/3W; 5275 Leesburg Pike; Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: Rachel Henry, Fish and Wildlife Biologist, by email at *rachel_henry@fws.gov* or via phone at (805) 448–7484. Individuals in the United States who are deaf, deafblind, hard of hearing, or have a speech disability may dial 711 (TTY, TDD, or TeleBraille) to access telecommunications relay services. Individuals outside the United States should use the relay services offered within their country to make international calls to the point-of-contact in the United States.

SUPPLEMENTARY INFORMATION: We, the U.S. Fish and Wildlife Service (Service), have received three applications for incidental take permits (ITPs) under the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*). The applicants have developed draft habitat conservation plans (HCPs) for the respective projects that include measures to mitigate and avoid/minimize impacts to the federally threatened Morro shoulderband snail (*Helminthoglypta walkeriana*). Each of the permits, if granted, would authorize take of the Morro shoulderband snail incidental to otherwise lawful activities associated with construction of single-family residences within the community of Los Osos in San Luis Obispo County, California. In addition, two of the HCPs anticipate impacts to the federally threatened Morro manzanita (*Arctostaphylos morroensis*). The Service prepared three draft screening forms in accordance with the National Environmental Policy Act of 1969 (NEPA; 42 U.S.C. 4321 *et seq.*) to evaluate the potential effects to the natural and human environment resulting from issuing the ITPs and implementing the draft HCPs, in order to determine if the actions fit within the criteria for categorical exclusions under NEPA. We invite public comment on all of these documents.

Background

The Service listed the Morro manzanita as threatened on December 15, 1994 (59 FR 64613), and listed the Morro shoulderband snail as endangered on December 15, 1994 (65 FR 64613), and reclassified the Morro shoulderband snail from endangered to threatened on February 3, 2022 (87 FR 6063). Section 9 of the ESA prohibits ''take'' of fish and wildlife species listed as endangered (16 U.S.C. 1538), where take is defined to include the following activities: ''to harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or to attempt to engage in any such conduct'' (16 U.S.C. 1532). The take prohibitions of section 9 are extended to species listed as threatened at the discretion of the Secretary of the Department of the Interior, and were extended to Morro shoulderband snail with exceptions. The Service published a 4(d) rule that includes exceptions to incidental take associated with native habitat enhancement and fire reduction activities (87 FR 6063).

Under section 10(a)(1)(B) of the ESA (16 U.S.C. 1539(a)(1)(B)), we may issue permits to authorize take of listed fish and wildlife species that is incidental to, and not the purpose of, carrying out an otherwise lawful activity. Regulations governing incidental take permits for endangered and threatened species are in the Code of Federal Regulations (CFR) at 50 CFR 17.22 and 17.32, respectively. Issuance of an ITP also must not jeopardize the existence of federally listed fish, wildlife, or plant species, pursuant to section 7 of the ESA and 50 CFR 402.02. The permittee would receive assurances under our ''No Surprises'' regulations (50 CFR 17.22(b)(5) and 17.32(b)(5)).

Proposed Activities

Each applicant has applied for a permit for incidental take of the Morro shoulderband snail. The take would occur in association with activities associated with development of single-family residences and ancillary features on lots zoned for residential use within the community of Los Osos in San Luis Obispo County, California.

The respective HCPs include avoidance and minimization measures for the Morro shoulderband snail and mitigation for unavoidable loss of habitat that is occupied by the species. As mitigation for the loss of suitable habitat, the applicants propose mitigation that will support the recovery goals of the species such as restoration and protection of habitat.

Public Availability 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 view, we cannot guarantee that we will be able to do so.

Authority

We provide this notice under section 10(c) of the Endangered Species Act (16 U.S.C. 1531 *et seq.*) and its implementing regulations (50 CFR 17.22 and 17.32) and National Environmental Policy Act (42 U.S.C. 4321 *et seq.*) and its implementing regulations (40 CFR 1506.6).

Stephen Henry,

Field Supervisor, Ventura Fish and Wildlife Office, Ventura, California.

[FR Doc. 2023–18480 Filed 8–25–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036466; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Gilcrease Museum, Tulsa, OK

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Gilcrease Museum has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice. The human remains and associated funerary objects were removed from Clark, Garland, Lafayette, Miller, Ouachita, and Union Counties, AR.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after September 27, 2023.

ADDRESSES: Laura Bryant, Gilcrease Museum, 800 S Tucker Drive, Tulsa, OK 74104, telephone (918) 596–2747, email *laura-bryant@utulsa.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Gilcrease Museum. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the Gilcrease Museum.

Description

Human remains representing, at minimum, one individual were removed from Clark County, AR. In December of 1938, avocational archeologists Harry J. Lemley and S.D. Dickinson excavated these human remains at the Kirkham Place (3CL29). The 27 associated funerary objects are 20 lots consisting of sherds; one lot consisting of faunal remains, including antlers; two lots consisting of faunal bone tools; two lots consisting of lithic tools, including projectile points, scrapers, flakes, and knives; one lot consisting of pipe fragments; and one lot consisting of celts.

Human remains representing, at minimum, one individual were removed from Garland County, AR. In 1929, Reverend O.N. Wehunt removed these human remains from the Jim Williamson Place, and at an unknown date, Harry J. Lemley acquired them from Wehunt. The one associated funerary object is a ceramic vessel.

Human remains representing, at minimum, three individuals were removed from Lafayette County, AR. In 1900, H.A. McCants removed these human remains from the Joe Russell Place (3LA91, 3LA245, 3LA246), and at an unknown date, Harry J. Lemley acquired them. The one associated funerary object is a ceramic vessel.

Human remains representing, at minimum, one individual were removed from Lafayette County, AR. Sometime in the early 20th century, Gamel Smith removed these human remains from Lester's Brother's Place (3LA38, 3LA48), and at an unknown date, Harry J. Lemley acquired them. The one associated funerary object is a ceramic vessel.

Human remains representing, at minimum, two individuals were removed from Lafayette County, AR. During the early 20th century, various individuals, including Dan Jenkins, removed items from the Battle Place/William Handy Place (3LA0001), and at different times during the early-to-mid-20th century, Harry J. Lemley acquired them. The five associated funerary objects are one lot consisting of sherds, one lot consisting of faunal remains, two lots consisting of lithic tools, and one ceramic vessel.

Human remains representing, at minimum, one individual were removed from Miller County, AR. In 1935, Harry J. Lemley removed these human remains from the Crenshaw Place (3MI6). No associated funerary objects are present.

In 1955, the Gilcrease Foundation purchased the human remains and associated funerary objects listed above from Harry J. Lemley. In 1963–1964, the Foundation transferred this collection to the City of Tulsa.

Human remains representing, at minimum, one individual were removed from Miller County, AR. In 1967, Gregory Perino, a curator at Gilcrease Museum at the time, removed these human remains from the Haley Place (3MI11). The three associated funerary objects are two ceramic vessels and one ceramic pipe bowl.

The human remains and associated funerary objects listed below were part of Frank and Norma Soday's collection. In 1982, the Thomas Gilcrease Museum Association purchased this collection and gifted it to the Gilcrease Museum.

Human remains representing, at minimum, one individual were removed from Ouachita County, AR. In 1950, Frank Soday, an avocational archeologist, removed these human remains from Carroll Givens Mound (3OU27, Soday site 380). No associated funerary objects are present.

Human remains representing, at minimum, one individual were removed from Ouachita County, AR. Sometime between 1948 and 1950, Frank Soday removed these human remains from Hindman Mound (Soday site 306). The two associated funerary objects are two lots consisting of faunal remains.

Human remains representing, at minimum, three individuals were removed from Ouachita County, AR. In 1949, Frank Soday removed these human remains from Bacon Mound #3 (3OU131, Soday site 360). The four associated funerary objects are one lot consisting of lithic tools, one lot consisting of pottery sherds, one lot consisting of faunal remains, and one lot consisting of daub.

Human remains representing, at minimum, seven individuals were removed from Ouachita County, AR. In 1950, Frank Soday removed these human remains from Freo Island (Soday site 371). The eight associated funerary objects are three lots consisting of faunal remains, one lot consisting of pottery sherds and daub, one lot consisting of shell beads and lithics, one ceramic vessel, one lot consisting of lithic tools, and one lot consisting of antlers.

Human remains representing, at minimum, 10 individuals were removed from Ouachita County, AR. In 1951, Frank Soday removed these human remains from Matkins Bee Ranch/Stone Trestle Mound (3OU005, Soday sites 369 and 378). The one associated funerary object is one lot consisting of faunal remains.

Human remains representing, at minimum, one individual were removed from Ouachita County, AR. In 1948, Frank Soday removed these human remains from Paw Paw Mound (3OU22, Soday site 316). The two associated funerary objects are one lot consisting of pottery sherds and one lot consisting of faunal remains.

Human remains representing, at minimum, one individual were removed from Ouachita County, AR. In 1950, Frank Soday removed these human remains from the Ritchie Place (Soday site 367). No associated funerary objects are present.

Human remains representing, at minimum, one individual were removed from Union County, AR. In 1947, Frank Soday removed these human remains from Harper Mound (3UN41, Soday site 333). The three associated funerary objects are one lot consisting of faunal remains, one lot consisting of pottery sherds, and one lot consisting of lithic tools.

Human remains representing, at minimum, 18 individuals were removed from Union County, AR. Sometime between 1948 and 1950, Frank Soday removed these human remains from the J. M. Nelson Farm (3UN8, Soday site 325). The 39 associated funerary objects are nine lots consisting of faunal remains, antlers, and bone tools; one lot consisting of burned faunal remains; 17 lots consisting of pottery sherds; four lots consisting of lithic tools; five ceramic vessels; and three lots consisting of shells.

Human remains representing, at minimum, two individuals were removed from Union County, AR. In 1955, Frank Soday removed these human remains from Lapile Mound Village (Soday site 551). The four associated funerary objects are one lot consisting of faunal bone tools, one lot consisting of lithic flakes, one lot consisting of wood and burnt faunal remains, and one lot consisting of pottery sherds.

Human remains representing, at minimum, one individual were removed from Union County, AR. In 1949, Frank Soday removed these human remains from Watt Mound (3UN18 or 3UN22, Soday site 342). The one associated funerary object is one lot consisting of faunal remains.

Cultural Affiliation

The human remains and associated funerary objects in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: archeological, geographical, oral traditional, and museum records.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the Gilcrease Museum has determined that:

- The human remains described in this notice represent the physical remains of 56 individuals of Native American ancestry.
- The 102 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a relationship of shared group identity that can be reasonably traced between the human remains and associated funerary objects described in this notice and the Caddo Nation of Oklahoma.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the Responsible Official identified in ADDRESSES. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains and associated funerary objects in this notice to a requestor may occur on or after September 27, 2023. If competing requests for repatriation are received, the Gilcrease Museum must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The Gilcrease Museum is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: August 18, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18503 Filed 8–25–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036471; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: California State University, Los Angeles, Los Angeles, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), California State University, Los Angeles has completed an inventory of human remains (hereafter referred to as ''ancestors'') in consultation with the appropriate Indian Tribes or Native Hawaiian organizations and has determined that there is a cultural affiliation between the ancestors and Indian Tribes or Native Hawaiian organizations in this notice. The ancestors were removed from Clark County, NV.

DATES: Repatriation of the ancestors in this notice will occur on or after September 27, 2023.

ADDRESSES: Michele Bleuze, California State University, 5151 State University Drive, Los Angeles, CA 90032, telephone (323) 343–2440, email *mbleuze@calstatela.edu;* Amira Ainis, California State University, 5151 State University Drive, Los Angeles, CA 90032, telephone (323) 343–2449, email *aainis2@calstatela.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of California State University, Los Angeles. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found

in the inventory or related records held by California State University, Los Angeles.

Description

A minimum of two ancestors were removed from Clark County, NV. Sometime in the mid-1970s (the exact date is unclear), California State University, Los Angeles conducted excavations at the CK2003 Mill Point #1 site, also referred to as the Fremont Point site. The descriptions of the two burials are based on a 1994 osteological report from Judy M. Suchey of the Department of Anthropology at California State University, Fullerton and a 2005 NAGPRA inventory, likely completed by Patricia Martz of the Department of Anthropology at California State University, Los Angeles. Burial 1 is a nearly complete burial of an estimated female over 30 years of age who was between 4′ 11″ and 5′ 2″ in stature. Marked vertebral lipping and heavy dental attrition and alveolar resorption were noted. Burial 2 is a nearly complete burial of an estimated female over 30 years of age who was between 5′ 4″ and 5′ 7″ in stature. Heavy vertebral lipping on the lower thoracic and lumbar vertebrae and minimal dental attrition on the maxillary teeth were noted. None of the current faculty at California State University, Los Angeles has conducted any analyses on these ancestors. No associated funerary objects are present.

Based on documentation in the Department of Anthropology, California State University, Los Angeles, officials at California State University, Fullerton determined that the CK2003 Mill Point #1 site dates to A.D. 530–1070. A site report from 1979 by R.F. Perkins indicates a radiocarbon-14 date of A.D. 680.

Cultural Affiliation

The ancestors in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: geographical, archeological, expert opinion, and other information.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, California State University, Los Angeles has determined that:

- Pursuant to 25 U.S.C. 3001(9), the ancestors described in this notice represent the physical remains of two individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American ancestors described in this notice and the Colorado River Indian Tribes of the Colorado River Indian Reservation, Arizona and California; Confederated Tribes of the Warm Springs Reservation of Oregon; Fort Independence Indian Community of Paiute Indians of the Fort Independence Reservation, California; Fort Mojave Indian Tribe of Arizona, California & Nevada; Hualapai Indian Tribe of the Hualapai Indian Reservation, Arizona; Kaibab Band of Paiute Indians of the Kaibab Indian Reservation, Arizona; Las Vegas Tribe of Paiute Indians of the Las Vegas Indian Colony, Nevada; Moapa Band of Paiute Indians of the Moapa River Indian Reservation, Nevada; and the Paiute Indian Tribe of Utah (Cedar Band of Paiutes, Kanosh Band of Paiutes, Koosharem Band of Paiutes, Indian Peaks Band of Paiutes, and Shivwits Band of Paiutes).

Requests for Repatriation

Written requests for repatriation of the ancestors in this notice must be sent to the Responsible Officials identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the ancestors in this notice to a requestor will occur on or after September 27, 2023. If competing requests for repatriation are received, California State University, Los Angeles must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the ancestors are considered a single request and not competing requests. California State University, Los Angeles is responsible for sending a copy of this notice to the Indian Tribes identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: August 18, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18508 Filed 8–25–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036467; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Gilcrease Museum, Tulsa, OK

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Gilcrease Museum has completed an inventory of human remains and associated funerary objects and has determined that there is no cultural affiliation between the human remains and associated funerary objects and any Indian Tribe. The human remains and associated funerary objects were removed from Calhoun and Ashley Counties, AR.

DATES: Disposition of the human remains and associated funerary objects in this notice may occur on or after September 27, 2023.

ADDRESSES: Laura Bryant, Gilcrease Museum 800 S Tucker Drive, Tulsa, OK 74104, telephone (918) 596–2747, email *laura-bryant@utulsa.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Gilcrease Museum. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the Gilcrease Museum.

Description

The human remains and associated funerary objects listed below were collected by Frank Soday, an avocational archeologist. In 1980, the Thomas Gilcrease Association purchased Frank Soday's entire collection from him and donated it to Gilcrease Museum.

Human remains representing, at minimum, two individuals were removed from Bang's Slough in Calhoun County, AR. On June 19–20, 1950, Frank Soday excavated at the site with Jerry

Carr (his nephew) and Ray Hammons. The three associated funerary objects are one lot consisting of pottery sherds and two lots consisting of worked stone.

Human remains representing, at minimum, two individuals were removed from the Stringfellow Farm in Calhoun County, AR. On November 19, 1949, Frank Soday excavated at the site. The five associated funerary objects are one lot consisting of pottery sherds, one lot consisting of grinding stones, one lot consisting of lithic tools, one lot consisting of worked stone, and one lot consisting of awls.

Human remains representing, at minimum, one individual were removed from Sweitzer's Mound in Ashley County, AR. On November 13, 1949, Frank Soday excavated at the site with Richard Franz. The two associated funerary objects are one lot consisting of pottery sherds and one lot consisting of lithic tools.

Aboriginal Land

The human remains and associated funerary objects in this notice were removed from known geographic locations. These locations are the aboriginal lands of one or more Indian Tribes. The following information was used to identify the aboriginal land: a treaty.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes, the Gilcrease Museum has determined that:

- The human remains described in this notice represent the physical remains of five individuals of Native American ancestry.
- The 10 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- No relationship of shared group identity can be reasonably traced between the human remains and associated funerary objects and any Indian Tribe.
- The human remains and associated funerary objects described in this notice were removed from the aboriginal land of the Quapaw Nation.

Requests for Disposition

Written requests for disposition of the human remains and associated funerary objects in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for disposition may be submitted by:

1. Any one or more of the Indian Tribes identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization, or who shows that the requestor is an aboriginal land Indian Tribe.

Disposition of the human remains and associated funerary objects described in this notice to a requestor may occur on or after September 27, 2023. If competing requests for disposition are received, the Gilcrease Museum must determine the most appropriate requestor prior to disposition. Requests for joint disposition of the human remains and associated funerary objects are considered a single request and not competing requests. The Gilcrease Museum is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9 and 10.11.

Dated: August 18, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18504 Filed 8–25–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036460; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Peabody Museum of Archaeology and Ethnology, Harvard University (PMAE) has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice. The human remains were collected at the U.S. Indian Vocational School in Bernalillo County, NM; the University of New Mexico in Bernalillo County, NM; and the Pueblo of Jemez in Sandoval County, NM.

DATES: Repatriation of the human remains in this notice may occur on or after September 27, 2023.

ADDRESSES: Jane Pickering, Peabody Museum of Archaeology and Ethnology, Harvard University, 11 Divinity Avenue, Cambridge, MA 02138, telephone (617) 496–2374, email *jpickering@fas.harvard.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the PMAE. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the PMAE.

Description

Human remains representing, at minimum, 10 individuals were collected at the Pueblo of Jemez in Sandoval County, NM. The human remains are hair clippings collected from two individuals who were recorded as being 17 years old, one individual who was recorded as being 18 years old, one individual who was recorded as being 19 years old, one individual who was recorded as being 23 years old, two individuals who were recorded as being 24 years old, one individual who was recorded as being 27 years old, one individual who was recorded as being 35 years old, and one individual who was recorded as being 38 years old. All 10 individuals were identified as ''Jemez.'' Mamie Tanquist took the hair clippings at the Jemez Pueblo between 1930 and 1933. Tanquist sent the hair clippings to George Woodbury, who donated the hair clippings to the PMAE in 1935. No associated funerary objects are present.

Human remains representing, at minimum, eight individuals were collected at the U.S. Indian Vocational School in Bernalillo County, NM. The human remains are hair clippings collected from three individuals who were recorded as being 15 years old, four individuals who were recorded as being 16 years old, and one individual who was recorded as being 18 years old. All eight individuals were identified as ''Jemez.'' Reuben Perry took the hair clippings at the Jemez Pueblo between 1930 and 1933. Perry sent the hair clippings to George Woodbury, who donated the hair clippings to the PMAE in 1935. No associated funerary objects are present.

Human remains representing, at minimum, two individuals were collected at the University of New Mexico in Bernalillo County, NM. The human remains are hair clippings collected from two individuals who were recorded as being 16 years old and identified as ''Jemez.'' Clyde Kay Maben Kluckhohn took the hair clippings at the University of New Mexico between 1930 and 1933. Kluckhohn sent the hair clippings to George Woodbury, who donated the hair clippings to the PMAE in 1935. No associated funerary objects are present.

Cultural Affiliation

The human remains in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: kinship and anthropological.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate lineal descendants, Indian Tribes, and Native Hawaiian organizations, the PMAE has determined that:

- The human remains described in this notice represent the physical remains of 20 individuals of Native American ancestry.
- There is a relationship of shared group identity that can be reasonably traced between the human remains described in this notice and the Pueblo of Jemez, New Mexico.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains in this notice to a requestor may occur on or after September 27, 2023. If competing requests for repatriation are received, the PMAE must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The PMAE is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: August 18, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18497 Filed 8–25–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036462; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Peabody Museum of Archaeology and Ethnology, Harvard University (PMAE) has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice. The human remains were collected at the Fort Sill Indian School in Comanche County, OK, and the Sherman Institute in Riverside County, CA.

DATES: Repatriation of the human remains in this notice may occur on or after September 27, 2023.

ADDRESSES: Jane Pickering, Peabody Museum of Archaeology and Ethnology, Harvard University, 11 Divinity Avenue, Cambridge, MA 02138, telephone (617) 496–2374, email *jpickering@fas.harvard.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the PMAE. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the PMAE.

Description

Human remains representing, at minimum, one individual were collected at the Sherman Institute in Riverside County, CA. The human remains are hair clippings collected from an individual who was recorded as being 18 years old and identified as ''Comanche.'' Samuel R. Gilliam took the hair clippings at the Sherman Institute between 1930 and 1933. Gilliam sent the hair clippings to George Woodbury, who donated the hair clippings to the PMAE in 1935. No associated funerary objects are present.

Human remains representing, at minimum, 14 individuals were collected at the Fort Sill Indian School in Comanche County, OK. The human remains are hair clippings collected from one individual recorded as being 13 years old, seven individuals recorded as being 14 years old, four individuals recorded as being 15 years old, and two individuals recorded as being 16 years old. All 14 individuals were identified as ''Comanche.'' An unknown collector took the hair clippings at the Fort Sill Indian School between 1930 and 1933, and sent the hair clippings to George Woodbury, who donated the hair clippings to the PMAE in 1935. No associated funerary objects are present.

Cultural Affiliation

The human remains in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: kinship and anthropological.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate lineal descendants, Indian Tribes, and Native Hawaiian organizations, the PMAE has determined that:

- The human remains described in this notice represent the physical remains of 15 individuals of Native American ancestry.
- There is a relationship of shared group identity that can be reasonably traced between the human remains described in this notice and the Comanche Nation, Oklahoma.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains in this notice to a requestor may occur on or after September 27, 2023. If competing requests for repatriation are received, the PMAE must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The PMAE is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: August 18, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18499 Filed 8–25–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036469; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: California State University, Sacramento, Sacramento, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), California State University, Sacramento has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice. The human remains and associated funerary objects were removed from Sacramento County, CA.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after September 27, 2023.

ADDRESSES: Dr. Dianne Hyson, Dean of the College of Social Sciences and Interdisciplinary Studies, California State University, Sacramento, 6000 J Street, Sacramento, CA 95819, telephone (916) 278–6504, email *dhyson@csus.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of California State University, Sacramento. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by California State University, Sacramento.

Description

In 1984 and 1994, human remains representing, at minimum, eight individuals were removed from site CA–SAC–42 (also known as Souza Mound) in Sacramento County, CA, by Peak & Associates and Far Western Anthropological Research Group. Occupation of this site is estimated to have occurred during the Middle and Late Periods. In 1995 and 1998, Far Western Anthropological Research Group and the City of Sacramento donated collections from these excavations to California State University, Sacramento. No human remains were thought to be present in either donation. In 2011, during analysis of the faunal material, these human remains were discovered. The 18,006 associated funerary objects include baked clay objects; flaked and ground stones; floral and faunal remains; historic materials; modified bones, stones, and shells; unmodified stones; soil samples; and column samples.

Cultural Affiliation

The human remains and associated funerary objects in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: anthropological, archeological, folkloric, geographical, historical, kinship, linguistic, oral traditional, and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, California State University, Sacramento has determined that:

- The human remains described in this notice represent the physical remains of eight individuals of Native American ancestry.
- The 18,006 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a relationship of shared group identity that can be reasonably traced between the human remains and associated funerary objects described in this notice and the Buena Vista Rancheria of Me-Wuk Indians of California; Chicken Ranch Rancheria of Me-Wuk Indians of California; Ione Band of Miwok Indians of California; Jackson Band of Miwuk Indians; Shingle Springs Band of Miwok Indians, Shingle Springs Rancheria (Verona Tract), California; United Auburn Indian Community of the Auburn Rancheria of California; and the Wilton Rancheria, California.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains and associated funerary objects in this notice to a requestor may occur on or after September 27, 2023. If competing requests for repatriation are received, California State University, Sacramento must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. California State

University, Sacramento is responsible for sending a copy of this notice to the Indian Tribes identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: August 18, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18506 Filed 8–25–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036464; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Peabody Museum of Archaeology and Ethnology, Harvard University (PMAE) has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice. The human remains were collected at the Sherman Institute in Riverside County, CA.

DATES: Repatriation of the human remains in this notice may occur on or after September 27, 2023.

ADDRESSES: Jane Pickering, Peabody Museum of Archaeology and Ethnology, Harvard University, 11 Divinity Avenue, Cambridge, MA 02138, telephone (617) 496–2374, email *jpickering@fas.harvard.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the PMAE. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the PMAE.

Description

Human remains representing, at minimum, one individual were collected at the Sherman Institute in Riverside County, CA. The human remains are hair clippings collected from an individual who was recorded as being 18 years old and identified as ''Paiute.'' Samuel R. Gilliam took the hair clippings at the Sherman Institute between 1930 and 1933, and sent the hair clippings to George Woodbury, who donated the hair clippings to the PMAE in 1935. No associated funerary objects are present.

Cultural Affiliation

The human remains in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: kinship and anthropological.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate lineal descendants, Indian Tribes, and Native Hawaiian organizations, the PMAE has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- There is a relationship of shared group identity that can be reasonably traced between the human remains described in this notice and the Pyramid Lake Paiute Tribe of the Pyramid Lake Reservation, Nevada.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains in this notice to a requestor may occur on or after September 27, 2023. If competing requests for repatriation are received, the PMAE must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The PMAE is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: August 18, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18501 Filed 8–25–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036468; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Gilcrease Museum, Tulsa, OK

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Gilcrease Museum has completed an inventory of human remains and associated funerary objects and has determined that there is a cultural affiliation between the human remains and associated funerary objects and Indian Tribes or Native Hawaiian organizations in this notice. The human remains and associated funerary objects were removed from Crittenden, Cross, Mississippi, and Poinsett Counties in Arkansas.

DATES: Repatriation of the human remains and associated funerary objects in this notice may occur on or after September 27, 2023.

ADDRESSES: Laura Bryant, Gilcrease Museum, 800 S Tucker Drive, Tulsa, OK 74104, telephone (918) 596–2747, email *laura-bryant@utulsa.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the Gilcrease Museum. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the Gilcrease Museum.

Description

Human remains representing, at minimum, 25 individuals were removed from Crittenden County, AR. Between 1957 and 1959, Gregory Perino removed these human remains from the Banks site. The 400 associated funerary objects are 90 lots consisting of ceramic vessels, four lots consisting of broken vessels, 247 lots consisting of pottery sherds, one lot consisting of ceramic plugs, 10 lots consisting of lithic points, one lot consisting of lithic flakes, one lot consisting of chunkey stones, eight lots consisting of worked stone, three lots consisting of shell ornaments and worked shell, one lot consisting of pigments and ochre, eight lots consisting of daub, two lots consisting of pipes, 13 lots consisting of faunal remains and fish scales, one lot consisting of beads, three lots consisting of bone tools, two lots consisting of charcoal, four lots consisting of sediment, and one lot consisting of corn fragments.

Human remains representing, at minimum, one individual were removed from Crittenden County, AR. In 1958, Gregory Perino removed these human remains from the Bradley site. The six associated funerary objects are three lots consisting of ceramic vessels, one lot consisting of copper beads, one lot consisting of chunkey stones, and one lot consisting of stone tools, including projectile points and hoes.

Human remains representing, at minimum, 23 individuals were removed from Cross County, AR. In 1958, Gregory Perino removed these human remains from the Cherry Valley site. The 36 associated funerary objects are 14 lots consisting of intact ceramic vessels, 13 lots consisting of broken ceramic vessels, two lots consisting of ceramic sherds and earspools, one lot consisting of worked lithics, two lots consisting of charcoal, two lots consisting of wood, and two lots consisting of shell beads.

Human remains representing, at minimum, three individuals were removed from Cross County, AR. In 1957, Gregory Perino removed these human remains from Rose Mound. The nine associated funerary objects are five lots consisting of ceramic vessels, two lots consisting of stone tools, one lot consisting of faunal remains, and one lot consisting of worked shell, including ear plugs and beads.

Human remains representing, at minimum, one individual were removed from Mississippi County, AR. In 1960, Gregory Perino removed these human remains from the Shawnee Village Site (3MS7). The one associated funerary object is one lot consisting of corn cobs.

Human remains representing, at minimum, five individuals were removed from Poinsett County, AR. These human remains were removed from the Stott Site (3PO26), likely by Elbert Hawkins sometime in the 1970s. The eight associated funerary objects are three lots consisting of pottery sherds, one lot consisting of ceramic vessels, one lot consisting of lithic tools, two lots consisting of faunal remains, and one lot consisting of shells.

Human remains representing, at minimum, one individual were removed from Poinsett County, AR, likely by Frank Soday sometime in the mid-20th century. No associated funerary objects are present.

Cultural Affiliation

The human remains and associated funerary objects in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: archeological, geographical, historical, oral traditional, and other relevant information.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the Gilcrease Museum has determined that:

- The human remains described in this notice represent the physical remains of 59 individuals of Native American ancestry.
- The 460 objects described in this notice are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony.
- There is a relationship of shared group identity that can be reasonably traced between the human remains and associated funerary objects described in this notice and the Quapaw Nation.

Requests for Repatriation

Written requests for repatriation of the human remains and associated funerary objects in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains and associated funerary objects in this notice to a requestor may occur on or after September 27, 2023. If competing requests for repatriation are received, the Gilcrease Museum must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains and associated funerary objects are considered a single request and not competing requests. The Gilcrease Museum is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: August 18, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18505 Filed 8–25–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036461; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Peabody Museum of Archaeology and Ethnology, Harvard University (PMAE) has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice. The human remains were collected at the Sherman Institute in Riverside County, CA.

DATES: Repatriation of the human remains in this notice may occur on or after September 27, 2023.

ADDRESSES: Jane Pickering, Peabody Museum of Archaeology and Ethnology, Harvard University, 11 Divinity Avenue, Cambridge, MA 02138, telephone (617)

496–2374, email *jpickering@fas.harvard.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the PMAE. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the PMAE.

Description

Human remains representing, at minimum, one individual were collected at the Sherman Institute in Riverside County, CA. The human remains are hair clippings collected from one individual who was recorded as being 18 years old and identified as ''Paiute.'' Samuel R. Gilliam took the hair clippings at the Sherman Institute between 1930 and 1933. Gilliam sent the hair clippings to George Woodbury, who donated the hair clippings to the PMAE in 1935. No associated funerary objects are present.

Cultural Affiliation

The human remains in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: kinship and anthropological.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate lineal descendants, Indian Tribes, and Native Hawaiian organizations, the PMAE has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- There is a relationship of shared group identity that can be reasonably traced between the human remains described in this notice and the Fort Independence Indian Community of Paiute Indians of the Fort Independence Reservation, California.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains in this notice to a requestor may occur on or after September 27, 2023. If competing requests for repatriation are received, the PMAE must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The PMAE is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: August 18, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18498 Filed 8–25–23; 8:45 am]

BILLING CODE 4321–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036465; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Peabody Museum of Archaeology and Ethnology, Harvard University (PMAE) has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice. The human remains were collected at the Chilocco Indian Agricultural School in Kay County, OK.

DATES: Repatriation of the human remains in this notice may occur on or after September 27, 2023.

ADDRESSES: Jane Pickering, Peabody Museum of Archaeology and Ethnology, Harvard University, 11 Divinity Avenue, Cambridge, MA 02138, telephone (617) 496–2374, email *jpickering@fas.harvard.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the PMAE. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the PMAE.

Description

Human remains representing, at minimum, three individuals were collected at the Chilocco Indian Agricultural School in Kay County, OK. The human remains are hair clippings collected from three individuals, all of whom are recorded as being 17 years old and identified as ''Choctaw.'' Lawrence E. Correll took the hair clippings at the Chilocco Indian Agricultural School between 1930 and 1933, and sent the hair clippings to George Woodbury, who donated the hair clippings to the PMAE in 1935. No associated funerary objects are present.

Cultural Affiliation

The human remains in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: kinship and anthropological.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate lineal descendants, Indian Tribes, and Native Hawaiian organizations, the PMAE has determined that:

- The human remains described in this notice represent the physical remains of three individuals of Native American ancestry.
- There is a relationship of shared group identity that can be reasonably traced between the human remains described in this notice and The Choctaw Nation of Oklahoma.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains in this notice to a requestor may occur on or after September 27, 2023. If competing requests for repatriation are received, the PMAE must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The PMAE is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: August 18, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18502 Filed 8–25–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036472; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: California State University, Los Angeles, Los Angeles, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), California State University, Los Angeles has completed an inventory of human remains (hereafter referred to as ''ancestors'') in consultation with the appropriate Indian Tribes or Native Hawaiian organizations and has determined that there is a cultural affiliation between the ancestors and Indian Tribes or Native Hawaiian organizations in this notice. The ancestors were removed from Los Angeles County, CA.

DATES: Repatriation of the ancestors in this notice will occur on or after September 27, 2023.

ADDRESSES: Michele Bleuze, California State University, 5151 State University Drive, Los Angeles, CA 90032, telephone (323) 343–2440, email *mbleuze@calstatela.edu;* Amira Ainis, California State University, 5151 State University Drive, Los Angeles, CA 90032, telephone (323) 343–2449, email *aainis2@calstatela.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of California State University, Los Angeles. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by California State University, Los Angeles.

Description

A minimum of two ancestors were removed from Los Angeles County, CA. Located in the City of Carson, CA–LAN–98 is the site of Suangna, a known Gabrielino-Tongva village. According to one source, it may have been occupied as late as 1813 (McCawley, 1996). Another source notes that, based on artifact comparisons, CA–LAN–98 was occupied for approximately 600 years, from A.D. 1200–1800 (Eggers, 1977:44). It was first excavated by Racer in 1910. In the late 1960s and early 1970s, Hal Eberhart from LA City College and Ken Kuykendall and A. Van D. Eggers from Dominquez College conducted excavations there, as did Charles Irwin of the Bowers Museum in 1972–1973. The collection from CA–LAN–98 at California State University, Los Angeles is assumed to have arrived in the late 1960s or early 1970s with Hal Eberhart, at that time a faculty member. (No reports or documents regarding this collection have been found at California State University, Los Angeles.) As no current faculty have examined the human remains, the following descriptions derive solely from box and bag labels. One bag is labeled ''Watson Site, Burial #1'' and another is labeled ''Watson Site, Burial #2.'' There is also one small bag labeled ''Skull fragments, no location, Watson'' along with what appears to be added, in faint pencil, ''associated with Burial #1.'' No associated funerary objects are present. (Additional collections from CA–LAN–98 are housed at California State University, Dominguez Hills, and a master's thesis from California State University, Fullerton indicates that additional materials from this site are curated with the Pacific Coast Archaeological Society (Graling, 2004).)

Cultural Affiliation

The ancestors in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: geographical, archeological, and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, California State University, Los Angeles has determined that:

- Pursuant to 25 U.S.C. 3001(9), the ancestors described in this notice represent the physical remains of at least two individuals of Native American ancestry.
- Pursuant to 25 U.S.C. 3001(2), there is a relationship of shared group identity that can be reasonably traced between the Native American ancestors described in this notice and the Santa Rosa Band of Cahuilla Indians, California and the Soboba Band of Luiseno Indians, California.

Requests for Repatriation

Written requests for repatriation of the ancestors in this notice must be sent to the Responsible Officials identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice and, if joined to a request from one or more of the Indian Tribes, the following non-federally recognized Indian groups: the Gabrieleno Band of Mission Indians-Kizh Nation; Gabrieleno/Tongva San Gabriel Band of Mission Indians; Gabrielino/Tongva Nation; Gabrielino Tongva Indians of California Tribal Council (Bellflower and Simi Valley); and the Gabrielino-Tongva Tribe.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the ancestors in this notice to a requestor will occur on or after September 27, 2023. If competing requests for repatriation are received, California State University, Los Angeles must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the ancestors are considered a single request and not competing requests. California State University, Los Angeles is responsible for sending a copy of this notice to the Indian Tribes identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: August 18, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18509 Filed 8–25–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036459; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Peabody Museum of Archaeology and Ethnology, Harvard University (PMAE) has completed an inventory of human remains and has determined that there is no cultural affiliation between the human remains and any Indian Tribe. The human remains were removed from Worcester County, MA.

DATES: Disposition of the human remains in this notice may occur on or after September 27, 2023.

ADDRESSES: Patricia Capone, Peabody Museum of Archaeology and Ethnology, 11 Divinity Avenue, Cambridge, MA 02138, telephone (617) 496–3702, email *pcapone@fas.harvard.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the PMAE. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the PMAE.

Description

In 1909, human remains representing, at minimum, one individual were removed by Samuel Kirkland Lothrop from the land of S.K. Warren in Harvard, Worcester County, MA. Lothrop donated the human remains to the PMAE in 1919. No associated funerary objects are present.

In 1857, human remains representing, at minimum, one individual were removed by John White from the area of Wachusett in Westminster, Worcester County, MA. White presented the human remains to the Warren Anatomical Museum, Harvard University (WAM) at an unknown date, and the WAM sent the human remains to the PMAE on permanent loan in May of 1959. No associated funerary objects are present.

On October 12, 1885, human remains representing, at minimum, one individual were removed by Dr. W.H. Raymenton from William U. Maynard's farm in the town of Northborough, near the town boundary with Shrewsbury, in Worcester County, MA. Raymenton collected the human remains as part of an excavation with the Worcester Society of Natural History. The Worcester Society of Natural History donated the human remains to the PMAE later in 1885. The human remains were found in a peat bog, under approximately five feet of soil and on solid bedrock, near where the teeth and tusks of a mastodon were excavated in 1884. No associated funerary objects are present.

On June 25, 1891, human remains representing, at minimum, one individual were removed by an unknown person from an ''Indian Burial Place'' in Winchendon, Worcester County, MA. The Massachusetts Historical Society donated the human remains to the PMAE, likely in 1891. No associated funerary objects are present.

Aboriginal Land

The human remains in this notice were removed from known geographic locations. These locations are the aboriginal lands of one or more Indian Tribes. Historical documents and other information obtained through consultation show that Worcester County, MA, was aboriginally occupied by the Wampanoag people. These types of information also show that Worcester County, MA, was aboriginally occupied by the Nipmuc people, who are not represented by any federally recognized Indian Tribe. The following information was used to identify the aboriginal land: treaties.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes, the PMAE has determined that:

- The human remains described in this notice represent the physical remains of four individuals of Native American ancestry.
- No relationship of shared group identity can be reasonably traced between the human remains and any Indian Tribe.
- The human remains described in this notice were removed from the aboriginal land of the Mashpee Wampanoag Tribe and the Wampanoag Tribe of Gay Head (Aquinnah).

Requests for Disposition

Written requests for disposition of the human remains in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for disposition may be submitted by:

1. Any one or more of the Indian Tribes identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization, or who shows that the requestor is an aboriginal land Indian Tribe.

Disposition of the human remains described in this notice to a requestor may occur on or after September 27, 2023. If competing requests for disposition are received, the PMAE must determine the most appropriate requestor prior to disposition. Requests for joint disposition of the human remains are considered a single request and not competing requests. The PMAE is responsible for sending a copy of this notice to the Indian Tribes identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9 and 10.11.

Dated: August 18, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18496 Filed 8–25–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036458; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Klamath County Museum, Klamath Falls, OR

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Klamath County Museum has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice. The human remains were removed from Siskiyou County, CA, and Klamath County, OR.

DATES: Repatriation of the human remains in this notice may occur on or after September 27, 2023.

ADDRESSES: Todd Kepple, Klamath County Museum, 1451 Main Street, Klamath Falls, OR 97601, telephone (541) 882–1000, email *museum@klamathcounty.org.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of Klamath County Museum. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by Klamath County Museum.

Description

All the human remains described below were collected by the Frank and Doris Payne family and became part of their collection of artifacts from the Upper Klamath Basin region. The Payne Collection was acquired by a group of local businessmen around 1944, when the Paynes moved away from Klamath Falls, and in 1965, it was transferred to the Klamath County Museum. No associated funerary objects are present.

In April of 1938, human remains representing, at minimum, two individuals were removed from Lower Klamath Lake in Siskiyou County, CA. These fragmentary human remains (designated SK–13 and SK–22) belong to two individuals of unknown age and sex. The human remains of one of them (SK–13) are in a mineralized state, which suggests they are several thousand years old.

In March of 1941, human remains representing, at minimum, one individual were removed from Tule Lake in Siskiyou County, CA. These fragmentary human remains (designated SK–28B) belong to an individual of unknown age and sex.

Sometime in 1941, human remains representing, at minimum, one individual were removed from Lower Klamath Lake in Siskiyou County, CA. These fragmentary human remains (designated SK–30) belong to an individual of unknown age and sex.

Sometime prior to 1944, human remains representing, at minimum, one individual were removed from an unknown location. These fragmentary human remains belong to an individual of unknown age and sex.

Sometime prior to 1944, human remains representing, at minimum, one individual were removed from Lower Klamath Lake in Siskiyou County, CA. These fragmentary human remains belong to an individual of unknown age and sex.

Sometime prior to 1944, human remains representing, at minimum, one individual were removed from an unknown location. These fragmentary human remains (designated BA–76) belong to an individual of unknown age and sex.

Sometime prior to 1944, human remains representing, at minimum, one individual were removed from an unknown location. These human remains (designated 220g–1) consist of a mandible belonging to a mature individual of unknown age and sex.

Sometime prior to 1944, human remains representing, at minimum, one individual were removed from an unknown location. These human remains (designated 413–7 (1341)) consist of a pear-shaped skull fragment belonging to an individual of unknown age and sex.

Cultural Affiliation

The human remains in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following type of information was used to reasonably trace the relationship: historical.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the Klamath County Museum has determined that:

- The human remains described in this notice represent the physical remains of nine individuals of Native American ancestry.
- There is a relationship of shared group identity that can be reasonably traced between the human remains described in this notice and the Klamath Tribes.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains in this notice to a requestor may occur on or after September 27, 2023. If competing requests for repatriation are received, the Klamath County Museum must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The Klamath County Museum is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: August 18, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18495 Filed 8–25–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036463; PPWOCRADN0–PCU00RP14.R50000]

Notice of Inventory Completion: Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), the Peabody Museum of Archaeology and Ethnology, Harvard University (PMAE) has completed an inventory of human remains and has determined that there is a cultural affiliation between the human remains and Indian Tribes or Native Hawaiian organizations in this notice. The human remains were collected at the Pawnee Indian Reservation in Pawnee County, OK.

DATES: Repatriation of the human remains in this notice may occur on or after September 27, 2023.

ADDRESSES: Jane Pickering, Peabody Museum of Archaeology and Ethnology, Harvard University, 11 Divinity Avenue, Cambridge, MA 02138, telephone (617) 496–2374, email *jpickering@fas.harvard.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of the PMAE. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the inventory or related records held by the PMAE.

Description

Human remains representing, at minimum, one individual were collected at the Pawnee Indian Reservation in Pawnee County, OK. The human remains are hair clippings collected from an individual recorded as 13 years old and identified as ''Cheyenne, Pawnee.'' Arvel R. Snyder took the hair clippings at the Pawnee Indian Reservation between 1930 and 1933. And sent the hair clippings to George Woodbury, who donated the hair clippings to the PMAE in 1935. No associated funerary objects are present.

Cultural Affiliation

The human remains in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian organizations. The following types of information were used to reasonably trace the relationship: kinship and anthropological.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate lineal descendants, Indian Tribes, and Native Hawaiian organizations, the PMAE has determined that:

- The human remains described in this notice represent the physical remains of one individual of Native American ancestry.
- There is a relationship of shared group identity that can be reasonably traced between the human remains described in this notice and the Cheyenne and Arapaho Tribes, Oklahoma.

Requests for Repatriation

Written requests for repatriation of the human remains in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by:

1. Any one or more of the Indian Tribes or Native Hawaiian organizations identified in this notice.

2. Any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the human remains in this notice to a requestor may occur on or after September 27, 2023. If competing requests for repatriation are received, the PMAE must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the human remains are considered a single request and not competing requests. The PMAE is responsible for sending a copy of this notice to the Indian Tribes identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.9, 10.10, and 10.14.

Dated: August 18, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18500 Filed 8–25–23; 8:45 am]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–WASO–NAGPRA–NPS0036470; PPWOCRADN0–PCU00RP14.R50000]

Notice of Intent To Repatriate Cultural Items: California State University, Sacramento, Sacramento, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

SUMMARY: In accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), California State University, Sacramento, Sacramento, CA intends to repatriate certain cultural items that meet the definition of unassociated funerary objects and that have a cultural affiliation with the Indian Tribes or Native Hawaiian organizations in this notice. The cultural items were removed from Sacramento County, CA.

DATES: Repatriation of the cultural items in this notice may occur on or after September 27, 2023.

ADDRESSES: Dr. Dianne Hyson, Dean of the College of Social Sciences and Interdisciplinary Studies, California State University, Sacramento, 6000 J Street, Sacramento, CA 95819, telephone (916) 278–6504, email *dhyson@csus.edu.*

SUPPLEMENTARY INFORMATION: This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA. The determinations in this notice are the sole responsibility of California State University, Sacramento. The National Park Service is not responsible for the determinations in this notice. Additional information on the determinations in this notice, including the results of consultation, can be found in the summary or related records held by California State University, Sacramento.

Description

At an unknown date, two cultural items were removed from CA–SAC–159 in Sacramento County, CA. How this collection came into the possession of California State University, Sacramento is unknown. The two unassociated funerary objects are flaked stones.

Cultural Affiliation

The cultural items in this notice are connected to one or more identifiable earlier groups, tribes, peoples, or cultures. There is a relationship of shared group identity between the identifiable earlier groups, tribes, peoples, or cultures and one or more Indian Tribes or Native Hawaiian

organizations. The following types of information were used to reasonably trace the relationship: anthropological, archeological, folkloric, geographical, historical, kinship, linguistic, oral traditional, other relevant information, and expert opinion.

Determinations

Pursuant to NAGPRA and its implementing regulations, and after consultation with the appropriate Indian Tribes and Native Hawaiian organizations, the California State University, Sacramento has determined that:

- The two cultural items described above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of a Native American individual.
- There is a relationship of shared group identity that can be reasonably traced between the cultural items and the Wilton Rancheria, California.

Requests for Repatriation

Additional, written requests for repatriation of the cultural items in this notice must be sent to the Responsible Official identified in **ADDRESSES**. Requests for repatriation may be submitted by any lineal descendant, Indian Tribe, or Native Hawaiian organization not identified in this notice who shows, by a preponderance of the evidence, that the requestor is a lineal descendant or a culturally affiliated Indian Tribe or Native Hawaiian organization.

Repatriation of the cultural items in this notice to a requestor may occur on or after September 27, 2023. If competing requests for repatriation are received, California State University, Sacramento must determine the most appropriate requestor prior to repatriation. Requests for joint repatriation of the cultural items are considered a single request and not competing requests. California State University, Sacramento is responsible for sending a copy of this notice to the Indian Tribe identified in this notice.

Authority: Native American Graves Protection and Repatriation Act, 25 U.S.C. 3003, and the implementing regulations, 43 CFR 10.8, § 10.10, and § 10.14.

Dated: August 18, 2023.

Melanie O'Brien,

Manager, National NAGPRA Program.

[FR Doc. 2023–18507 Filed 8–25–23; 8:45 am]

BILLING CODE 4312–52–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–891 (Fourth Review)]

Foundry Coke From China; Scheduling of an Expedited Five-Year Review

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the scheduling of an expedited review pursuant to the Tariff Act of 1930 (''the Act'') to determine whether revocation of the antidumping duty order on foundry coke from China would be likely to lead to continuation or recurrence of material injury within a reasonably foreseeable time.

DATES: July 7, 2023.

FOR FURTHER INFORMATION CONTACT: (Nitin Joshi 202–708–1669), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for this proceeding may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—On July 7, 2023, the Commission determined that the domestic interested party group response to its notice of institution (88 FR 19674, April 3, 2023) of the subject five-year review was adequate and that the domestic interested party group response was inadequate. The Commission did not find any other circumstances that would warrant conducting a full review.[1] Accordingly, the Commission determined that it would conduct an expedited review pursuant to section 751(c)(3) of the Act (19 U.S.C. 1675(c)(3)).

For further information concerning the conduct of this review and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A, D, E, and F (19 CFR part 207).

Staff report.—A staff report containing information concerning the subject matter of the review has been placed in the nonpublic record, and will be made available to persons on the Administrative Protective Order service list for this review on September 13, 2023. A public version will be issued thereafter, pursuant to § 207.62(d)(4) of the Commission's rules.

Written submissions.—As provided in § 207.62(d) of the Commission's rules, interested parties that are parties to the review and that have provided individually adequate responses to the notice of institution,[2] and any party other than an interested party to the review may file written comments with the Secretary on what determination the Commission should reach in the review. Comments are due on or before 5:15 p.m. on September 21, 2023 and may not contain new factual information. Any person that is neither a party to the five-year review nor an interested party may submit a brief written statement (which shall not contain any new factual information) pertinent to the review by September 21, 2023. However, should the Department of Commerce (''Commerce'') extend the time limit for its completion of the final results of its review, the deadline for comments (which may not contain new factual information) on Commerce's final results is three business days after the issuance of Commerce's results. If comments contain business proprietary information (BPI), they must conform with the requirements of §§ 201.6, 207.3, and 207.7 of the Commission's rules. The Commission's *Handbook on Filing Procedures,* available on the Commission's website at *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf,* elaborates upon the Commission's procedures with respect to filings.

In accordance with §§ 201.16(c) and 207.3 of the rules, each document filed by a party to the review must be served on all other parties to the review (as identified by either the public or BPI service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Determination.—The Commission has determined this review is extraordinarily complicated and

[1] A record of the Commissioners' votes, the Commission's statement on adequacy, and any individual Commissioner's statements will be available from the Office of the Secretary and at the Commission's website.

[2] The Commission has found the responses submitted on behalf of ABC Coke (a division of Drummond Company, Inc.), and SunCoke Energy, Inc., to be individually adequate. Comments from other interested parties will not be accepted (*see* 19 CFR 207.62(d)(2)).

therefore has determined to exercise its authority to extend the review period by up to 90 days pursuant to 19 U.S.C. 1675(c)(5)(B).

Authority: This review being conducted under authority of title VII of the Act; this notice is published pursuant to § 207.62 of the Commission's rules.

By order of the Commission.

Issued: August 23, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–18511 Filed 8–25–23; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Vaporizer Devices, Cartridges Used Therewith, and Components Thereof, DN 3691;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing pursuant to the Commission's Rules of Practice and Procedure.

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (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 United States International Trade Commission (USITC) at *https://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at *https://edis.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 has received a complaint and a submission pursuant to § 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of NJOY, LLC on August 22, 2023. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain vaporizer devices, cartridges used therewith, and components thereof. The complaint names as a respondent: JUUL Labs, Inc. of Washington, DC. The complainant requests that the Commission issue a limited exclusion order, a cease and desist order, and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j). Proposed respondents, other interested parties, and members of the public are invited to file comments on any public interest issues raised by the complaint or § 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions on the public interest must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation. Any written submissions on other issues must also be filed by no later than the close of business, eight calendar days after publication of this notice in the **Federal Register**. Complainant may file replies to any written submissions no later than three calendar days after the date on which any initial submissions were due, notwithstanding § 201.14(a) of the Commission's Rules of Practice and Procedure. No other submissions will be accepted, unless requested by the Commission. Any submissions and replies filed in response to this Notice are limited to five (5) pages in length, inclusive of attachments.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. Submissions should refer to the docket number (''Docket No. 3691'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures [1]). Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov.*) No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice. Persons with questions regarding filing should contact the Secretary at *EDIS3Help@usitc.gov.*

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. appendix 3; or (ii) by U.S. government employees and contract

[1] Handbook for Electronic Filing Procedures: *https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf.*

personnel,[2] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[3]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of §§ 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

By order of the Commission.

Issued: August 22, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–18406 Filed 8–25–23; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–388, 389, and 391 and 731–TA–817, 818, and 821 (Fourth Review)]

Cut-to-Length Carbon-Quality Steel Plate From India, Indonesia, and South Korea Determinations

On the basis of the record [1] developed in the subject five-year reviews, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that revocation of the antidumping duty and countervailing duty orders on cut-to-length carbon-quality steel plate (''CTL plate'') from India, Indonesia, and South Korea would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.

Background

The Commission instituted these reviews on February 1, 2023 (88 FR 6781) and determined on May 8, 2023 that it would conduct expedited reviews (88 FR 37098, June 6, 2023).

The Commission made these determinations pursuant to section 751(c) of the Act (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on August 23, 2023. The views of the Commission are contained in USITC Publication 5455 (August 2023), entitled *Cut-to-Length Carbon-Quality Steel Plate from India, Indonesia, and South Korea: Investigation Nos. 701–TA–388, 389, and 391 and 731–TA–817, 818, and 821 (Fourth Review).*

By order of the Commission.

Issued: August 23, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–18524 Filed 8–25–23; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2010–0041]

Logging Operations Standard; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning the proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements specified in its Standard on Logging Operations.

DATES: Comments must be submitted (postmarked, sent, or received) by October 27, 2023.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov.* Documents in the docket are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download from the website. All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2350 (TTY (877) 889–5627) for assistance in locating docket submissions.

Instructions: All submissions must include the agency name and OSHA docket number (OSHA–2010–0041) for the Information Collection Request (ICR). OSHA will place all comments, including personal information, in the public docket, which may be available online. Therefore, OSHA cautions interested parties about submitting personal information such as social security numbers and birthdates.

For further information on submitting comments, see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Seleda Perryman or Theda Kenney, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of effort in obtaining information (29 U.S.C. 657).

The following sections describe who uses the information collected under each requirement, as well as how they use it. The paperwork provisions of this standard specify requirements for developing, maintaining, and disclosing inspection records and written reports associated with logging operations.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the agency's functions to protect workers, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

[1] The record is defined in § 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

information collection requirements, including the validity of the methodology and assumptions used;

- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection, and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend the approval of the information collection requirements contained in the Standard on Logging Operations. The agency is requesting an adjustment decrease in the number of burden hours for the information collection requirements in the standard from 1,507 hours to 1,387 hours for a total decrease of 120 burden hours.

OSHA will summarize the comments submitted in response to this notice and will include this summary in the request to OMB to extend the approval of the information collection requirements.

Type of Review: Extension of a currently approved collection.

Title: Logging Operations Standard.

OMB Control Number: 1218–0198.

Affected Public: Business or other for-profits; Federal Government; State, Local, or Tribal Government.

Number of Respondents: 7,559.

Number of Responses: 46,859.

Frequency of Responses: On occasion.

Average Time per Response: Varies.

Estimated Total Burden Hours: 1,387.

Estimated Cost (Operation and Maintenance): $0.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile (fax), if your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648; or (3) by hard copy. All comments, attachments, and other material must identify the agency name and the OSHA docket number for the ICR (Docket No. OSHA–2010–0041). You may supplement electronic submissions by uploading document files electronically.

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download from this website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* website to submit comments and access the docket is available at the website's ''User Tips'' link.

Contact the OSHA Docket Office at (202) 693–2350 (TTY (877) 889–5627) for information about materials not available from the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 8–2020 (85 FR 58393).

Signed in Washington, DC, on August 21, 2023.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2023–18408 Filed 8–25–23; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2010–0038]

Rigging Equipment and Material Handling Standard; Extension of the Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning the proposal to extend the Office of Management and Budget's (OMB) approval of the information collection requirements specified in its Standard on Rigging Equipment and Material Handling.

DATES: Comments must be submitted (postmarked, sent, or received) by October 27, 2023.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov. D*ocuments in the docket are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download from the website. All submissions, including copyrighted material, are available for inspection through the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2350 (TTY (877) 889–5627) for assistance in locating docket submissions.

Instructions: All submissions must include the agency name and OSHA docket number (OSHA–2010–0038) for the Information Collection Request (ICR). OSHA will place all comments, including personal information, in the public docket, which may be available online. Therefore, OSHA cautions interested parties about submitting personal information such as social security numbers and birthdates.

For further information on submitting comments, see the ''Public Participation'' heading in the section of this notice titled **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: Seleda Perryman or Theda Kenney, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor; telephone: (202) 693–2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork and respondent (*i.e.,* employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by employers as necessary or appropriate for enforcement of the OSH Act or for developing information regarding the causes and prevention of occupational injuries, illnesses, and accidents (29 U.S.C. 657). The OSH Act also requires

that OSHA obtain such information with minimum burden upon employers, especially those operating small businesses, and to reduce to the maximum extent feasible unnecessary duplication of effort in obtaining information (29 U.S.C. 657).

The following sections describe who uses the information collected under each requirement, as well as how they use it. The collection of information provisions of the standard specify affixing identification tags or markings on rigging equipment, marking special custom design lifting accessories, shift inspections, periodic inspections, developing and maintaining inspection records, and maintaining dates and results of certain shackle/hook load tests.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection requirements are necessary for the proper performance of the agency's functions to protect workers, including whether the information is useful;
- The accuracy of OSHA's estimate of the burden (time and costs) of the information collection requirements, including the validity of the methodology and assumptions used;
- The quality, utility, and clarity of the information collected; and
- Ways to minimize the burden on employers who must comply; for example, by using automated or other technological information collection, and transmission techniques.

III. Proposed Actions

OSHA is requesting that OMB extend the approval of the information collection requirements contained in the Standard on Rigging Equipment and Material Handling. The agency is requesting maintenance in the number of burden hours for the information collection requirements in the standard of 49,160 hours.

OSHA will summarize the comments submitted in response to this notice and will include this summary in the request to OMB to extend the approval of the information collection requirements.

Type of Review: Extension of a currently approved collection.

Title: Rigging Equipment and Material Handling Standard.

OMB Control Number: 1218–0233.

Affected Public: Business or other for-profits; Federal Government; State, Local, or Tribal Government.

Number of Respondents: 115,829.

Number of Responses: 263,953.

Frequency of Responses: On occasion.

Average Time per Response: Varies.

Estimated Total Burden Hours: 49,160.

Estimated Cost (Operation and Maintenance): $0.

IV. Public Participation—Submission of Comments on This Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) electronically at *http://www.regulations.gov,* which is the Federal eRulemaking Portal; (2) by facsimile (fax), if your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648; or (3) by hard copy. All comments, attachments, and other material must identify the agency name and the OSHA docket number for the ICR (Docket No. OSHA–2010–0038). You may supplement electronic submissions by uploading document files electronically.

Comments and submissions are posted without change at *http://www.regulations.gov.* Therefore, OSHA cautions commenters about submitting personal information such as social security numbers and dates of birth. Although all submissions are listed in the *http://www.regulations.gov* index, some information (*e.g.,* copyrighted material) is not publicly available to read or download from this website. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the *http://www.regulations.gov* website to submit comments and access the docket is available at the website's ''User Tips'' link. Contact the OSHA Docket Office at (202) 693–2350 (TTY (877) 889–5627) for information about materials not available from the website, and for assistance in using the internet to locate docket submissions.

V. Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 8–2020 (85 FR 58393).

Signed in Washington, DC, on August 21, 2023.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2023–18409 Filed 8–25–23; 8:45 am]

BILLING CODE 4510–26–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Proposed Collection

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice and request for comments.

SUMMARY: The National Credit Union Administration (NCUA), as part of a continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to comment on the following new collection, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments should be received on or before October 27, 2023 to be assured consideration.

ADDRESSES: Interested persons are invited to submit written comments on the information collection to Rena Y. Kim, National Credit Union Administration, 1775 Duke Street, Suite 6032, Alexandria, Virginia 22314; email at *PRAComments@NCUA.gov.*

FOR FURTHER INFORMATION CONTACT: Address requests for additional information to Rena Y. Kim at the address above or telephone 703–548–2398.

SUPPLEMENTARY INFORMATION:

OMB Number: 3133–NEW.

Title: NCUA Speaker and Chairman Request Forms.

Type of Review: New collection.

Abstract: The Federal Credit Union (FCU) Act of 1970 (12 U.S.C. 1752) established the National Credit Union Administration (NCUA) as an independent agency, in control of regulating and supervising Federal credit unions. This mission requires coordination and collaboration with credit unions, other Federal agencies, and consumers to provide a safe and sound credit union system. As part of its collaboration efforts, the NCUA receives requests annually for NCUA leadership and staff to participate in speaking engagements at various events. This digital collection of information is necessary to ensure an efficient and timely process to schedule outreach and engagement with NCUA stakeholders. As a result of the requests received for speaking engagements, the NCUA has developed two forms, (1) the Speaker Request Form and, (2) the Chairman Request Form; and is requesting approval from the Office of Management and Budget (OMB) for a new information collection. The forms collect information regarding the requested speaking engagement to

include, the host organization, the speaking topic, agenda, and additional event details. The information is used to determine if accepting the request will further NCUA's mission.

Affected Public: Private and Public Sectors: NCUA Stakeholders potentially including credit unions and credit union organizations, other Federal and state agencies, and consumers groups.

Estimated Number of Respondents: 152.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Responses: 152.

Estimated Hours per Response: 0.25.

Estimated Total Annual Burden Hours: 38.

Request for Comments: Comments submitted in response to this notice will be summarized and included in the request for OMB approval. All comments will become a matter of public record. The public is invited to submit comments concerning: (a) whether the collection of information is necessary for the proper execution of the function of the agency, including whether the information will have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information, 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 the information on the respondents, including the use of automated collection techniques or other forms of information technology.

By the National Credit Union Administration Board.

Melane Conyers-Ausbrooks,

Secretary of the Board.

[FR Doc. 2023–18404 Filed 8–25–23; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request; Medical Clearance Process for Deployment to the Polar Regions.

AGENCY: National Science Foundation.

ACTION: Notice.

SUMMARY: The National Science Foundation (NSF) is announcing plans to renew this collection. In accordance with the requirements of the Paperwork Reduction Act of 1995, we are providing opportunity for public comment on this action. After obtaining and considering public comment, NSF will prepare the submission requesting Office of Management and Budget (OMB) clearance of this collection for no longer than 3 years.

DATES: Written comments on this notice must be received by October 27, 2023 to be assured consideration. Comments received after that date will be considered to the extent practicable. Send comments to the address below.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 2415 Eisenhower Avenue, Suite E7400, Alexandria, Virginia 22314; telephone (703) 292–7556; or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including Federal holidays).

SUPPLEMENTARY INFORMATION:

Title of Collection: Medical Clearance Process for Deployment to the Polar Regions.

OMB Number: 3145–0177.

Expiration Date of Approval: October 31, 2023.

Type of Request: Revision to and extension of approval of an information collection.

Proposed Project: Presidential Memorandum No. 6646 (February 5, 1982) (available from the National Science Foundation, Office of Polar Programs, Office 7100, 2415 Eisenhower Avenue, Alexandria, VA 22314) sets forth the National Science Foundation's overall management responsibilities for the entire United States national program in Antarctica. Section 107(a) of Public Law 98–373 [July 31, 1984; amended as Public Law 101–609-November 16, 1990] [available from the National Science Foundation, Office of Polar Programs, Office 7100, 2415 Eisenhower Avenue, Alexandria, VA 22314] designates the National Science Foundation as the lead agency responsible for implementing Arctic research policy, and the Director of the National Science Foundation shall ensure that the requirements of section 108 are fulfilled.

NSF Form 1700, Medical Clearance Process for Deployment to the Polar Regions furnishes information to the NSF regarding the physical, mental, and dental health status for all individuals (except DoD-uniformed service personnel) who anticipate deploying to Antarctica under the auspices of the United States Antarctic Program or to certain regions of the Arctic sponsored by the NSF/GEO/Office of Polar Programs. The information is used to determine whether an individual is physically and mentally suited to endure the extreme hardships imposed by the Arctic and Antarctic continents, while also performing specific duties as specified by their employers.

Respondents: All non-DoD uniformed personnel planning to deploy to U.S. stations in the Antarctic or to specified regions of the Arctic that are sponsored by the National Science Foundation's Office of Polar Programs.

The number of annual respondents: 3,500 to the Antarctic and 150 to the Arctic.

Estimated Total Annual Burden on Respondents: 36,500 hours.

Frequency of Responses: This form is submitted upon an individual's first deployment to Antarctica (below 60° South) or to specified regions of the Arctic and annually thereafter for the duration of the individual's deployments.

Dated: August 23, 2023.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2023–18516 Filed 8–25–23; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2023–0001]

Sunshine Act Meetings

TIME AND DATE: Weeks of August 28, September 4, 11, 18, 25, October 2, 2023. The schedule for Commission meetings is subject to change on short notice. The NRC Commission Meeting Schedule can be found on the internet at: *https://www.nrc.gov/public-involve/public-meetings/schedule.html.*

PLACE: The NRC provides reasonable accommodation to individuals with disabilities where appropriate. If you need a reasonable accommodation to participate in these public meetings or need this meeting notice or the transcript or other information from the public meetings in another format (*e.g.,* braille, large print), please notify Anne Silk, NRC Disability Program Specialist, at 301–287–0745, by videophone at 240–428–3217, or by email at *Anne.Silk@nrc.gov.* Determinations on requests for reasonable accommodation will be made on a case-by-case basis.

STATUS: Public and closed.

Members of the public may request to receive the information in these notices electronically. If you would like to be added to the distribution, please contact the Nuclear Regulatory Commission, Office of the Secretary, Washington, DC

20555, at 301–415–1969, or by email at *Wendy.Moore@nrc.gov.*

MATTERS TO BE CONSIDERED:

Week of August 28, 2023

There are no meetings scheduled for the week of August 28, 2023.

Week of September 4, 2023—Tentative

There are no meetings scheduled for the week of September 4, 2023.

Week of September 11, 2023—Tentative

Tuesday, September 12, 2023

10:00 a.m. All Employees Meeting (Public Meeting), (Contact: Anthony de Jesus: 301–287–9219; Adrienne Brown: 301–415–3764)

Additional Information: The meeting will be held in the Two White Flint North auditorium, 11555 Rockville Pike, Rockville, Maryland. The public is invited to attend the Commission's meeting live by webcast at the Web address—*https://video.nrc.gov/.*

Thursday, September 14, 2023

10:00 a.m. Briefing on NRC International Activities (Closed—Ex. 1 & 9)

Week of September 18, 2023—Tentative

There are no meetings scheduled for the week of September 18, 2023.

Week of September 25, 2023—Tentative

There are no meetings scheduled for the week of September 25, 2023.

Week of October 2, 2023—Tentative

There are no meetings scheduled for the week of October 2, 2023.

CONTACT PERSON FOR MORE INFORMATION: For more information or to verify the status of meetings, contact Wesley Held at 301–287–3591 or via email at *Wesley.Held@nrc.gov.*

The NRC is holding the meetings under the authority of the Government in the Sunshine Act, 5 U.S.C. 552b.

Dated: August 24, 2023.

For the Nuclear Regulatory Commission.

Monika G. Coflin,

Technical Coordinator, Office of the Secretary.

[FR Doc. 2023–18610 Filed 8–24–23; 4:15 pm]

BILLING CODE 7590–01–P

PUBLIC BUILDINGS REFORM BOARD

Notice of Public Meeting by the Public Buildings Reform Board

AGENCY: Public Buildings Reform Board.

ACTION: Notice of public meeting.

SUMMARY: As provided by the Federal Assets Sale and Transfer Act of 2016 (FASTA), the Public Buildings Reform Board (PBRB) is holding its eighth public meeting. At this meeting, the Board will discuss the progress of past rounds and well as plans for the second round to be submitted in late 2024.

DATES: The meeting is scheduled for Thursday, September 28, 2023 from 11 a.m. to 12 noon (eastern daylight time).

ADDRESSES: The meeting will be held at the JLL offices at 2020 K St. NW, Washington, DC 20006. Registration for the meeting is required: *https://forms.gle/DoXvky7Br5XxErVH9.*

FOR FURTHER INFORMATION CONTACT: Paul Walden, PBRB, at (202) 716–8165, or questions and comments can be forwarded to the PBRB Team by email at *fastainfo@pbrb.gov.*

SUPPLEMENTARY INFORMATION:

Background: FASTA created the PBRB as an independent Board to identify opportunities for the Federal government to significantly reduce its inventory of civilian real property and thereby reduce costs. The Board is directed, within 6 months of its formation, to recommend to the Office of Management and Budget (OMB) the sale of not fewer than five properties not on the list of surplus or excess with a fair market value of not less than $500 million and not more than $750 million. In two subsequent rounds over a five-year period, the Board is responsible for making recommendations for other sales, consolidations, property disposals or redevelopment of up to $7.25 billion.

Format and Registration: The format for the meeting will be panel discussions with appropriate time allowed for a Q&A segment. Interested participants must register for the public meeting via this link: *https://forms.gle/DoXvky7Br5XxErVH9.*

Individuals wishing to attend who require special assistance or accommodations must contact the PBRB Team at *fastainfo@pbrb.gov* at least 12 days prior to the event.

Portions of the meeting may be held in executive session if the Board is considering issues involving classified or proprietary information.

A transcript of the public meeting will be uploaded to *pbrb.gov* shortly after the session. If you have any additional questions, please email *fastainfo@pbrb.gov.*

Authority: Public Law 114–287, 130 Stat 1463.

Paul Walden,

Executive Director, Federal Register Liaison, Public Buildings Reform Board.

[FR Doc. 2023–17586 Filed 8–25–23; 8:45 am]

BILLING CODE P

PENSION BENEFIT GUARANTY CORPORATION

Submission of Information Collection for OMB Review; Comment Request; Generic Clearance for the Collection of Qualitative and Quantitative Feedback on Agency Service Delivery

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of request for extension of OMB approval.

SUMMARY: The Pension Benefit Guaranty Corporation is requesting that the Office of Management and Budget (OMB) extend approval, under the Paperwork Reduction Act, of the collection of information on qualitative and quantitative feedback on PBGC's service delivery (OMB Control Number 1212–0066; expires October 31, 2023). This notice informs the public of PBGC's request and solicits comments on the proposed information collection. This collection of information was developed as part of a Federal Government-wide effort to streamline the process for seeking feedback from the public on service delivery.

DATES: Comments must be received on or before September 27, 2023 to be assured of consideration.

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. All comments received will be posted without change to PBGC's website, *http://www.pbgc.gov,* including any personal information provided. Do not submit comments that include any personally identifiable information or confidential business information.

A copy of the request will be posted on PBGC's website at *https://www.pbgc.gov/prac/laws-and-regulation/federal-register-notices-open-for-comment.* It may also be obtained without charge by writing to the Disclosure Division, *disclosure@pbgc.gov,* Office of the General Counsel of PBGC, 445 12th Street SW, Washington, DC 20024–2101; or, calling 202–229–4040 during normal business hours. If you are deaf or hard of hearing or have a speech disability, please dial 7–1–1 to access telecommunications relay services.

FOR FURTHER INFORMATION CONTACT: Melissa Rifkin (*rifkin.melissa@pbgc.gov*), Attorney, Regulatory Affairs

Division, Office of the General Counsel, Pension Benefit Guaranty Corporation, 445 12th Street SW, Washington, DC 20024–2101; 202–229–6563. (If you are deaf or hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services.)

SUPPLEMENTARY INFORMATION: This information collection activity will gather qualitative and quantitative customer and stakeholder feedback in an efficient, timely manner, in accordance with PBGC's commitment to improving service delivery. By qualitative feedback we mean information that provides useful insights on the public's perceptions and opinions. By quantitative feedback we mean numeric scores evaluating PBGC services and customer satisfaction using the American Customer Satisfaction Index (ACSI) methodology. This feedback provides insights into customer or stakeholder perceptions, experiences and expectations, provides early warnings of issues with service, and focuses attention on areas where changes in PBGC's communication with the public, in training of staff, or in operations might improve the delivery of products or services. These collections will allow for ongoing, collaborative and actionable communications between PBGC and its customers and stakeholders. These collections also allow feedback to contribute directly to the improvement of program management.

The solicitation of feedback targets 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 were not collected, vital feedback from customers and stakeholders on PBGC's services would be unavailable.

PBGC only submits a collection for approval under this generic clearance if it meets the following conditions:

- 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;
- Personally identifiable information (PII) is collected only to the extent necessary and is not retained;
- Except for information that will be included in PBGC's annual report, 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; and
- Information from qualitative surveys gathered will yield qualitative results; the collections will not be designed or expected to yield statistically reliable results or be used as though the results are generalizable to the population of interest;
- Information from quantitative surveys will be based on statistical methods and will yield quantitative results, such as satisfaction scores that can be generalized to the population.

As a general matter, these 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.

Annually, over the next three years, PBGC estimates that it will conduct three activities involving about 2,430 respondents, each of whom will provide one response. The number of respondents will vary by activity: 80 for usability testing, 50 for focus groups (5 groups of 10 respondents), and 2,300 for customer satisfaction surveys.

PBGC estimates the annual burden of this collection of information as 755 hours: one hour per response for usability testing (total 80 hours); 2 hours per response for focus groups (total 100 hours); and 15 minutes per response for customer satisfaction surveys (total 575 hours). No cost burden to the public is anticipated.

The existing collection of information was approved under OMB control number 1212–0066 (expires October 31, 2023). On May 16, 2023, PBGC published in the **Federal Register** a notice at 88 FR 31289 informing the public of its intent to request an extension of this collection of information and solicited public comment. No comments were received. 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.

Issued in Washington, DC.

Stephanie Cibinic,

Deputy Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation.

[FR Doc. 2023–18458 Filed 8–25–23; 8:45 am]

BILLING CODE 7709–02–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2023–235 and CP2023–238; MC2023–236 and CP2023–239; MC2023–238 and CP2023–241]

New Postal Products

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing for the Commission's consideration concerning a negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* August 29, 2023.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at *http://www.prc.gov.* Those who cannot submit comments electronically should contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section by telephone for advice on filing alternatives.

FOR FURTHER INFORMATION CONTACT: David A. Trissell, General Counsel, at 202–789–6820.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction

The Commission gives notice that the Postal Service filed request(s) for the Commission to consider matters related to negotiated service agreement(s). The request(s) may propose the addition or removal of a negotiated service agreement from the Market Dominant or the Competitive product list, or the modification of an existing product currently appearing on the Market Dominant or the Competitive product list.

Section II identifies the docket number(s) associated with each Postal Service request, the title of each Postal Service request, the request's acceptance date, and the authority cited by the Postal Service for each request. For each request, the Commission appoints an officer of the Commission to represent the interests of the general public in the

proceeding, pursuant to 39 U.S.C. 505 (Public Representative). Section II also establishes comment deadline(s) pertaining to each request.

The public portions of the Postal Service's request(s) can be accessed via the Commission's website (*http://www.prc.gov*). Non-public portions of the Postal Service's request(s), if any, can be accessed through compliance with the requirements of 39 CFR 3011.301.[1]

The Commission invites comments on whether the Postal Service's request(s) in the captioned docket(s) are consistent with the policies of title 39. For request(s) that the Postal Service states concern Market Dominant product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3622, 39 U.S.C. 3642, 39 CFR part 3030, and 39 CFR part 3040, subpart B. For request(s) that the Postal Service states concern Competitive product(s), applicable statutory and regulatory requirements include 39 U.S.C. 3632, 39 U.S.C. 3633, 39 U.S.C. 3642, 39 CFR part 3035, and 39 CFR part 3040, subpart B. Comment deadline(s) for each request appear in section II.

II. Docketed Proceeding(s)

1. *Docket No(s).:* MC2023–235 and CP2023–238; *Filing Title:* USPS Request to Add Priority Mail Express, Priority Mail & USPS Ground Advantage Contract 5 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* August 21, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Jennaca D. Upperman; *Comments Due:* August 29, 2023.

2. *Docket No(s).:* MC2023–236 and CP2023–239; *Filing Title:* USPS Request to Add Priority Mail & USPS Ground Advantage Contract 31 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* August 21, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* August 29, 2023.

3. *Docket No(s).:* MC2023–238 and CP2023–241; *Filing Title:* USPS Request to Add USPS Ground Advantage Contract 2 to Competitive Product List and Notice of Filing Materials Under Seal; *Filing Acceptance Date:* August 21, 2023; *Filing Authority:* 39 U.S.C. 3642, 39 CFR 3040.130 through 3040.135, and 39 CFR 3035.105; *Public Representative:* Kenneth R. Moeller; *Comments Due:* August 29, 2023.

This Notice will be published in the **Federal Register**.

Erica A. Barker,

Secretary.

[FR Doc. 2023–18473 Filed 8–25–23; 8:45 am]

BILLING CODE 7710–FW–P

[1] *See* Docket No. RM2018–3, Order Adopting Final Rules Relating to Non-Public Information, June 27, 2018, Attachment A at 19–22 (Order No. 4679).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98197; File No. SR–NYSEAMER–2023–41]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of Proposed Change To Modify Rule 928NYP

August 22, 2023.

Pursuant to section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on August 17, 2023, NYSE American LLC (''NYSE American'' or ''Exchange'') filed with the Securities and Exchange Commission (''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 to modify Rule 928NYP (Pre-Trade and Activity-Based Risk Controls) to allow certain order types to be excluded from the Activity-Based Risk Controls. 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 to modify Rule 928NYP (Pre-Trade and Activity-Based Risk Controls) to allow certain order types to be excluded from the Activity-Based Risk Controls.[4] Specifically, the Exchange proposes to allow ATP Holders[5] the ability to exclude orders marked as GTX[6] from counting towards the limits established by the Activity-Based Risk Controls and to exclude GTX orders from cancellation when an Activity-Based Risk Limit is breached.[7] The Exchange notes that a substantively similar change was recently adopted on its affiliated exchange, NYSE Arca, Inc. (''NYSE Arca'') and therefore this proposal raises no new or novel issues not previously considered by the Commission.[8]

The Exchange offers ATP Holders the option of utilizing Activity-Based Risk Controls to assist ATP Holders in managing risk related to submitting orders during periods of increased and significant trading activity.[9] ATP

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange notes that this proposed change modifies a Pillar rule (*i.e.,* with a ''P'' modifier) that has not yet been implemented. The Exchange anticipates migrating to its Pillar trading platform beginning on October 23, 2023. As is the case with all Pillar rules, this proposed rule change (as well as the entire Rule 928NYP) will not be implemented until all other Pillar-related rule filings are approved or operative, as applicable, and the Exchange announces the migration of underlying symbols to Pillar by Trader Update.

[5] An ATP Holder is a natural person, sole proprietorship, partnership, corporation, limited liability company or other organization, in good standing, which has been issued an ATP, and references to ''member'', and ''member organization'' as those terms are used in the Rules of the Exchange should be deemed to be references to ATP Holders. *See* Rule 900.2NY. An ATP is an American Trading Permit issued by the Exchange for effecting approved securities transactions on the Exchange's Trading Facilities. *See id.* The Exchange notes that an ATP may be acting as a Specialist, which market participant is subject to heightened requirements. *See, e.g.,* Rule 925.1NYP(b), (c).

[6] *See infra* note 17 (for description of orders marked as GTX).

[7] *See* proposed Rules 928NYP(c)(2)(B) and (c)(2)(C)(iii).

[8] *See* Securities Exchange Act Release No. 98038 (August 1, 2023), 88 FR 52231 (Augst 7, 2023) (SR–NYSEARCA–2023–49) (immediately effective rule change to allow market participants to exclude orders marked as GTX from the Activity-Based Risk Controls, per Rule 6.40P–O).

[9] *See* Rule 928NYP(a)(3)(A)–(C) (describing the three potential Activity-Based Risk Controls: Transaction-Based Risk Limit; Volume-Based Risk Limit; and Percentage-Based Risk Limit).

Holders acting as Specialist must apply one of the Activity-Based Risk Controls to all of its orders and quotes, whereas an ATP Holder not acting as a Specialist may, but is not required to, apply one of the Activity-Based Risk Controls to its orders.[10] To determine when an Activity-Based Risk Control has been breached, the Exchange will maintain a Trade Counter that will be incremented every time an order (or quote) trades, including any leg of a Complex Order, and will aggregate the number of contracts traded during each such execution.[11] When designating one of the three Activity-Based Risk Controls, an ATP Holder must indicate the action that it would like the Exchange to take if an Activity-Based Risk Limit is exceeded.[12] Currently, the Exchange affords ATP Holders the ability to exclude certain orders from being considered by a Trade Counter.[13] The order types that an ATP Holder may opt to exclude are orders designated as IOC or FOK, which order types are designed to cancel if not executed on arrival.[14] In addition, the Exchange exempts certain orders from being cancelled or blocked—specifically Auction-Only orders (submitted solely for the purpose of being executed in an opening auction) and GTC Orders, which by their terms are meant to eventually execute unless specifically cancelled by the order-sender.[15]

The Exchange proposes to modify Rule 928NYP(c)(2)(B) to add GTX to the order types that may be excluded by Trade Counters in tracking Activity-Based Risk Controls.[16] In addition, for ATP Holders that select the automated breach action of ''Cancel and Block,'' the Exchange proposes to modify Rule 928NYP(c)(2)(C)(iii) to provide ATP Holders the option of instructing the Exchange not to cancel unexecuted GTX orders in the event of a breach.[17]

An order marked GTX, such as a GTX order submitted in response to a CUBE Order (''CUBE GTX'') or a COA GTX Order submitted in response to a Complex Order Auction (or COA), will cancel after executing to the extent possible with a CUBE Order, or a COA Order in a Complex Order Auction, as applicable (collectively, ''GTX orders'').[18] As such, GTX orders are never ranked (as resting interest) in the Consolidated Book. Because GTX orders are submitted for the sole purposes of executing (to the extent possible) with either a CUBE Order or a COA Order before cancelling, the Exchange believes providing ATP Holders the option of exempting these orders from the Activity-Based Risk Controls would enable these ATP Holders to exclude GTX orders from being counted and avoid potentially triggering their risk settings (prematurely), resulting in the cancellation of open orders. Likewise, the Exchange believes that allowing ATP Holders to instruct the Exchange not to cancel any unexecuted GTX orders if their risk setting is breached would likewise afford such ATP Holders additional flexibility. This proposed handling of GTX orders is consistent with how the Exchange currently handles GTX orders per (pre-Pillar) Commentary .01 to Rule 928NY (Risk Limitation Mechanism).[19]

The Exchange believes that providing ATP Holders this additional flexibility may encourage more ATP Holders to utilize the risk settings, which benefits all market participants. The Exchange also believes that the proposed change would result in risk settings that may be better calibrated to suit the needs of certain ATP Holders (*i.e.,* those that routinely utilize GTX orders) and should encourage ATP Holders to direct additional order flow and liquidity to the Exchange.

Implementation

This proposed change modifies a Pillar rule (*i.e.,* with a ''P'' modifier). As is the case with all Pillar rules, this proposed rule change (as well as the entire Rule 928NYP) will not be implemented until all other Pillar-related rule filings are approved or operative, as applicable, and the Exchange announces the migration of underlying symbols to Pillar by Trader Update.

2. Statutory Basis

The Exchange believes that its proposal is consistent with section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[20] in general, and furthers the objectives of section 6(b)(5) of the Act,[21] in particular, in that 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 regulating, clearing, settling, processing information with respect to, and 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.

The Exchange believes that the proposed rule change removes impediments to and perfects the mechanism of a free and open market by providing ATP Holders greater control and flexibility over setting their risk tolerance, which may enhance the efficacy of the risk settings. Orders marked GTX, including CUBE GTX Orders and COA GTX Orders, will cancel after executing to the extent possible with a COA Order as part of a Complex Order Auction. As such, GTX orders are never ranked (as resting interest) in the Consolidated Book. The Exchange believes that certain market participants utilize GTX orders to access liquidity on the Exchange. Thus, the proposed change is designed to accommodate participants that utilize GTX orders in this manner by enabling them to exclude GTX orders from being counted and avoid potentially triggering their risk settings (prematurely), resulting in the cancellation of open orders. In addition, allowing ATP Holders the option to exclude unexecuted GTX orders from being cancelled in the event of a breach would allow ATP Holders to utilize this order type without fear of such orders being cancelled before having the opportunity to trade in a Complex Order Auction. As noted herein, this proposed handling of

[10] *See* Rule 928NYP(c)(2)(A).

[11] *See* Rule 928NYP(c)(2)(B).

[12] *See* Rule 928NYP(c)(2)(C) (describing the potential automated breach actions of Notification Only, Block Only, and Cancel and Block).

[13] *See* Rule 928NYP(c)(2)(B).

[14] *See id. See* also Rule 900.3NYP(b)(2) (IOC) and (3) (FOK).

[15] *See* Rule 928NYP(c)(2)(C)(iii).

[16] *See* proposed Rule 928NYP(c)(2)(B) (providing, in relevant part, that an ATP Holder ''may opt to exclude any orders designated IOC, FOK, or GTX from being considered by a Trade Counter.'')

[17] *See* proposed Rule 928NYP(c)(2)(C)(iii) (providing, in relevant part, that an ATP Holder ''may opt to exclude orders designated as GTX from being cancelled.'').

[18] Per Rule 971.1NYP regarding Single-Leg CUBE Auctions, an ATP Holder may respond to a CUBE Auction (''Auction'') with an order marked as GTX, which order is not displayed and which must be entered during the Response Time Interval of the Auction and may include an AuctionID to specify the CUBE Order with which it would like to trade. *See* Rule 971.1NYP(c)(1)(C)(i). A CUBE GTX Order will cancel after executing with the CUBE Order to the extent possible. Similarly, per Rule 980NYP(b)(2), an ATP Holder may designate an Electronic Complex Order (or ECO) as GTX. A ''COA GTX Order'' is an order sent in response to a Complex Order Auction (or COA), which order is not displayed and which must be entered during the Response Time Interval of a COA. The COA GTX Order will cancel after executing with the COA Order to the extent possible. *See* Rule 980NYP(b)(2)(C). The Exchange notes that NYSE Arca does not offer the CUBE Auction or CUBE GTX Orders.

[19] *See* (pre-Pillar) Rule 928NY, Commentary .01 (providing, in relevant part, that upon the triggering of an established risk limit, the Exchange would cancel all open orders and quotes in the affected series but would exclude from such cancellation any ''orders entered in response to an electronic auction that are valid only for the duration of the auction ('GTX')'', which includes CUBE GTX Orders and COA GTX Orders).

[20] 15 U.S.C. 78f(b).

[21] 15 U.S.C. 78f(b)(5).

GTX orders (*i.e.,* excluding such orders from cancellation upon triggering of a risk setting) is consistent with how the Exchange currently handles GTX orders per (pre-Pillar) Commentary .01 to Rule 928NY (Risk Limitation Mechanism).

The Exchange believes that providing ATP Holders this additional flexibility may encourage more ATP Holders to utilize the risk settings, which benefits all market participants. Further, the proposed change would promote just and equitable principles of trade because it would result in risk settings that may be better calibrated to suit the needs of certain ATP Holders (*i.e.,* those that routinely utilize GTX orders) and should encourage ATP Holders to direct additional order flow and liquidity to the Exchange. To the extent additional order flow is submitted to the Exchange as a result of the proposed change, all market participants stand to benefit from increased trading. The Exchange notes that an ATP Holder has the option of utilizing risk settings for all orders submitted to the Exchange and, as proposed, would have the additional option of excluding from these risk settings any GTX orders in a given options class submitted to the Exchange.

This proposed change, which was specifically requested by some ATP Holders, would foster cooperation and coordination with persons engaged in regulating, clearing, settling, and processing information with respect to, and facilitating transactions in, securities as it will be available to all ATP Holders and may encourage more ATP Holders to utilize this enhanced functionality to the benefit of all market participants.

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 that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange is proposing a market enhancement that would provide ATP Holders with greater control and flexibility over setting their risk tolerance and, potentially, more protection over risk exposure. The proposal is structured to offer the same enhancement to all ATP Holders and would not impose a competitive burden on any participant. The Exchange does not believe that the proposed enhancement to the existing Activity-Based Risk Controls would impose a burden on competing options exchanges. Rather, the availability of these controls may foster more competition. Specifically, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. When an exchange offers enhanced functionality that distinguishes it from the competition and participants find it useful, it has been the Exchange's experience that competing exchanges will move to adopt similar functionality. Thus, the Exchange believes that this type of competition amongst exchanges is beneficial to the marketplace as a whole as it can result in enhanced processes, functionality, and technologies.

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

Because the foregoing 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 for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to section 19(b)(3)(A)(iii) of the Act [22] and subparagraph (f)(6) of Rule 19b–4 thereunder.[23]

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.

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 (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–NYSEAMER–2023–41 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–2023–41. 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 (*https://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 a.m. and 3 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to file number SR–NYSEAMER–2023–41 and should be submitted on or before September 18, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[24]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–18430 Filed 8–25–23; 8:45 am]

BILLING CODE 8011–01–P

[22] 15 U.S.C. 78s(b)(3)(A)(iii).

[23] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires the Exchange to give the Commission written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[24] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–98200; File No. SR–ICC–2023–013]

Self-Regulatory Organizations; ICE Clear Credit LLC; Notice of Filing of Proposed Rule Change Relating to ICC's Treasury Operations Policies and Procedures

August 22, 2023.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934,[1] and Rule 19b–4,[2] notice is hereby given that on August 15, 2023, ICE Clear Credit LLC (''ICC'') filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been primarily prepared by ICC. 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

The principal purpose of the proposed rule change is to revise the ICC Treasury Operations Policies and Procedures (''Treasury Policy''). These revisions do not require any changes to the ICC Clearing Rules (the ''Rules'').

II. Clearing Agency's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, ICC included statements concerning the purpose of and basis for the proposed rule change, security-based swap submission, or advance notice and discussed any comments it received on the proposed rule change, security-based swap submission, or advance notice. The text of these statements may be examined at the places specified in Item IV below. ICC 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

(a) Purpose

ICC proposes to revise its Treasury Policy. The purpose of the Treasury Policy is to articulate the policies and procedures used to support the ICC Treasury Department, which is responsible for daily cash and collateral management of margin and guaranty fund assets, including Client-Related Initial Margin assets. The proposed changes consist of clarifications and updates with respect to collateral asset haircuts, and additional details on ICC's foreign exchange conversion methods should British pound sterling (''GBP'') cash need to be converted to another currency in the context of a Clearing Participant default. ICC believes that such revisions will facilitate the prompt and accurate clearance and settlement of securities transactions and derivative agreements, contracts, and transactions for which it is responsible. ICC proposes to make such changes effective following Commission approval of the proposed rule change. The proposed revisions are described in detail as follows.

ICC proposes to revise the 'Collateral Valuation' section of the Treasury Policy [3] to clarify the description of ICC's collateral valuation process across all collateral types. The ICC collateral valuation process is based on accurately and effectively pricing the assets posted as collateral and appropriately haircutting the assets for their native market risks (*i.e.,* the risk of a decrease in value of the asset posted as collateral) as well as related cross-currency risk (*i.e.,* the risk of the change in value of one currency as compared to the value of another currency) when the collateral is to be used to cover an obligation denominated in a different currency. All such proposed changes are non-material and clarifying, except for the haircut process for GBP cash posted as Client-Related Initial Margin [4] used to cover a Euro denominated product requirement. Currently, with respect to GBP cash used to cover a Euro denominated product requirement, ICC first converts the GBP cash value to its USD value. The USD value is haircut at the GBP currency haircut. Then, the EUR denominated product requirement is converted to the USD value. The resulting USD requirement is grossed up by the EUR currency haircut. The effect of the current approach is to haircut GBP cash margin twice, which ICC believes is unnecessary as a matter of risk management and inefficient.[5] Under the proposed changes, the value of GBP cash posted to cover a Euro denominated obligation will no longer be subjected to two currency haircuts. Rather, GBP cash posted to cover a Euro obligation, will first be converted to its Euro value and then haircut to capture the potential foreign exchange risk between GBP and Euro. ICC believes the proposed revised treatment of GBP cash posted to cover a Euro obligation is more efficient while still maintaining ICC's conservative collateral valuation practices.

Along with this specific change for GBP cash, relevant language in the Collateral Valuation section is being clarified and simplified to apply generally without need to refer to specific currencies. Thus, consistent with the above, the revised section would state generally that cash posted in one currency to cover an obligation denominated in another currency is first converted to its value in the currency of the obligation, and then haircut to capture the potential foreign exchange risk. References to specific currencies (which note for example that Euro and GBP cash used to cover a USD denominated product requirement are first converted to USD value and then the USD value is haircut) would be removed as they are unnecessary. Similarly, the revised section would state generally that cash posted to cover an obligation in the same currency will not be subject to a haircut, rather than include multiple currency specific statements to the same effect. ICC also is proposing non-material drafting changes to the description of the valuation process for collateral posted in the form of U.S. Treasuries. ICC is not proposing in those amendments to change the currencies that are currently accepted as margin or collateral.

Also, ICC proposes the addition of Section III.G., ''Non-Committed FX Facility'' to the Treasury Policy. Such proposed section would reflect that ICC has access to non-committed foreign exchange facilities with a diverse set of commercial counterparties. Such facilities may be used to convert one currency to another for same day settlement, on a non-committed basis. Such section would provide additional details with respect to Client-Related Initial Margin posted by Clearing Participants in GBP cash. The amendments would note that the circumstances where ICC would need to convert such GBP cash collateral to another currency are very narrow (as no ICC contracts are settled in GBP, and GBP would not be needed for daily settlement). In addition, such section would be amended to further note that as ICC accepts GBP cash collateral only

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Treasury Policy section V.B.2.

[4] GBP cash currently is only accepted as Client-Related Initial Margin (a/k/a ''Client Margin''). GBP cash collateral is not accepted by ICC with respect to (i) House Margin (*i.e.,* margin posted by an ICC Clearing Participant to support their proprietary positions cleared at ICC) or (ii) General Guaranty Fund contributions.

[5] ICC recently completed a system change to modify its clearing system business logic so that it is no longer necessary from a systems standpoint for GBP cash posted to cover a EUR denominated to be subjected to two currency haircuts. Due to the completed system change, ICC is now in the position to propose this rule change to eliminate the inefficient double haircut.

with respect to Client-Related Initial Margin, and that use of Client-Related Initial Margin by ICC in the context of a Clearing Participant default is very limited, the circumstances where ICC would need to covert GBP cash collateral into another currency is further limited. However, if the narrow circumstances did arise and ICC needed to convert GBP cash collateral to either USD or EUR in the context of a Clearing Participant default, ICC would use one of its existing non-committed foreign exchange arrangements to convert the GBP into the applicable currency.

Certain other typographical and similar non-substantive corrections are made throughout the Treasury Policy, including references to ''haircuts.'' Lastly, ICC proposes amending Appendix X., Revision History, to reflect the changes and approvals of the Treasury Policy.

(b) Statutory Basis

Section 17A(b)(3)(F) of the Act[6] 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, and to the extent applicable, derivative agreements, contracts and 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 to protect investors and the public interest. ICC believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to ICC, in particular, Section 17(A)(b)(3)(F),[7] because ICC believes that the proposed rule change will promote the prompt and accurate clearance and settlement of securities transactions, derivatives agreements, contracts, and transactions, and contribute to the safeguarding of securities and funds associated with security-based swap transactions in ICC's custody or control, or for which ICC is responsible. As described above, the proposed rule change would make certain clarifications and updates to the Treasury Policy, in particular to avoid an unnecessary double haircut that currently applies to GBP cash posted to cover a Euro denominated obligation, which may currently disadvantage those customers of Clearing Participants that post such cash. The amendments would simplify and clarify the description of cross-currency haircuts generally, without need for references to specific currencies. The proposed updates would also add additional details on ICC's non-committed foreign exchange facilities, which would be used, among other purposes, if necessary to convert GBP cash posted as Client-Related Initial Margin to cover Euro or USD obligations. Taken together, the amendments promote overall clarity in the Treasury Policy regarding foreign exchange conversion and the cross-currency haircut process. The proposed updates thus ensure that the documentation of ICC's Treasury Policy remains up-to-date, transparent, and focused on clearly articulating the policies and procedures used to support ICC's treasury functions, which promotes the prompt and accurate clearance and settlement of securities transactions, derivatives agreements, contracts, and transactions, contributes to the safeguarding of securities and funds which are in the custody or control of ICC or for which it is responsible, and generally promotes the protection of investors and the public interest. As such, the proposed rule changes are consistent with the requirements of Section 17A(b)(3)(F) of the Act.[8]

Rule 17Ad–22(e)(5)[9] requires each covered clearing agency to ''establish, implement, maintain, and enforce written policies and procedures reasonably designed to, as applicable . . . [l]imit the assets it accepts as collateral to those with low credit, liquidity, and market risks, and set and enforce appropriately conservative haircuts and concentration limits if [it] requires collateral to manage its or its participants' credit exposure. . . .'' As described above, ICC accounts for the risk associated with fluctuations in the value of collateral assets by applying haircuts under the Treasury Policy. The amendments would revise the cross-currency haircut applicable to GBP cash posted to cover Euro obligations to eliminate an unnecessary double haircut. ICC believes the amendments would result in a more efficient, yet appropriately conservative, haircut level for such GBP cash. The amendments would also make a number of other non-substantive revisions to clarify the discussion of cross-currency haircuts generally and ensure that the Treasury Policy remains effective and clear. As such, the amendments would satisfy the requirements of Rule 17Ad–22(e)(5).[10]

(B) Clearing Agency's Statement on Burden on Competition

ICC does not believe the proposed rule change would have any impact, or impose any burden, on competition not necessary or appropriate in furtherance of the purposes of the Act. As discussed above, the amendments would revise the haircut applicable to GBP cash posed to cover Euro obligations to avoid a double haircut. ICC believes this change will improve efficiency and benefit market participants that may choose to post GBP cash as Client-Related Initial Margin. Other changes would generally improve the clarity of the Treasury Policy. The proposed changes to ICC's Treasury Policy will apply uniformly across all market participants. ICC does not believe the amendments would adversely affect the costs of clearing for market participants, or otherwise affect the ability of market participants to access clearing or the market for clearing services generally. Therefore, ICC does not believe the proposed rule change imposes any burden on competition that is inappropriate in furtherance of the purposes of the Act.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments relating to the proposed rule change have not been solicited or received. ICC will notify the Commission of any written comments received by ICC.

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.

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:

[6] 15 U.S.C. 78q–1(b)(3)(F).

[7] *Id.*

[8] *Id.*

[9] 17 CFR 240.17Ad–22(e)(5).

[10] *Id.*

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include file number SR–ICC–2023–013 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–ICC–2023–013. 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 (*https://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 a.m. and 3 p.m. Copies of such filings will also be available for inspection and copying at the principal office of ICE Clear Credit and on ICE Clear Credit's website at *https://www.theice.com/clear-credit/regulation.*

Do not include personal identifiable information in submissions; you should submit only information that you wish to make available publicly. We may redact in part or withhold entirely from publication submitted material that is obscene or subject to copyright protection. All submissions should refer to File Number SR–ICC–2023–013 and should be submitted on or before September 18, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–18429 Filed 8–25–23; 8:45 am]

BILLING CODE 8011–01–P

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2:00 p.m. on Thursday, August 31, 2023.

PLACE: The meeting will be held via remote means and/or at the Commission's headquarters, 100 F Street NE, Washington, DC 20549.

STATUS: This meeting will be closed to the public.

MATTERS TO BE CONSIDERED: Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the closed meeting. Certain staff members who have an interest in the matters also may be present.

In the event that the time, date, or location of this meeting changes, an announcement of the change, along with the new time, date, and/or place of the meeting will be posted on the Commission's website at *https://www.sec.gov.*

The General Counsel of the Commission, or her designee, has certified that, in her opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (6), (7), (8), 9(B) and (10) and 17 CFR 200.402(a)(3), (a)(5), (a)(6), (a)(7), (a)(8), (a)(9)(ii) and (a)(10), permit consideration of the scheduled matters at the closed meeting.

The subject matter of the closed meeting will consist of the following topics:

Institution and settlement of injunctive actions;

Institution and settlement of administrative proceedings;

Resolution of litigation claims; and

Other matters relating to examinations and enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting agenda items that may consist of adjudicatory, examination, litigation, or regulatory matters.

CONTACT PERSON FOR MORE INFORMATION: For further information; please contact Vanessa A. Countryman from the Office of the Secretary at (202) 551–5400.

Authority: 5 U.S.C. 552b.

Dated: August 24, 2023.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2023–18623 Filed 8–24–23; 4:15 pm]

BILLING CODE 8011–01–P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #18092 and #18093; TEXAS Disaster Number TX–00660]

Administrative Declaration of a Disaster for the State of Texas

AGENCY: U.S. Small Business Administration.

ACTION: Notice.

SUMMARY: This is a notice of an Administrative declaration of a disaster for the State of Texas dated 08/22/2023.

Incident: Tornado.

Incident Period: 06/15/2023.

DATES: Issued on 08/22/2023.

Physical Loan Application Deadline Date: 10/23/2023.

Economic Injury (EIDL) Loan Application Deadline Date: 05/22/2024.

ADDRESSES: Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

FOR FURTHER INFORMATION CONTACT: A. Escobar, Office of Disaster Recovery & Resilience, U.S. Small Business Administration, 409 3rd Street SW, Suite 6050, Washington, DC 20416, (202) 205–6734.

SUPPLEMENTARY INFORMATION: Notice is hereby given that as a result of the Administrator's disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

Primary Counties: Ochiltree.

Contiguous Counties:

Texas: Hansford, Hutchinson, Lipscomb, Roberts.

Oklahoma: Beaver, Texas.

The Interest Rates are:

	Percent
For Physical Damage:	
Homeowners with Credit Available Elsewhere	5.000
Homeowners without Credit Available Elsewhere	2.500
Businesses with Credit Available Elsewhere	8.000
Businesses without Credit Available Elsewhere	4.000
Non-Profit Organizations with Credit Available Elsewhere	2.375
Non-Profit Organizations without Credit Available Elsewhere	2.375
For Economic Injury:	
Businesses & Small Agricultural Cooperatives without Credit Available Elsewhere	4.000

	Percent
Non-Profit Organizations without Credit Available Elsewhere	2.375

The number assigned to this disaster for physical damage is 18092 C and for economic injury is 18093 0.

The States which received an EIDL Declaration # are Oklahoma, Texas.

(Catalog of Federal Domestic Assistance Number 59008)

Isabella Guzman,

Administrator.

[FR Doc. 2023–18478 Filed 8–25–23; 8:45 am]

BILLING CODE 8026–09–P

DEPARTMENT OF STATE

[Public Notice: 12163]

U.S. Department of State Advisory Committee on Private International Law: Public Meeting on the Hague Conference on Private International Law (HCCH), Eighth Meeting Special Commission on Practical Operations 1980 Child Abduction Convention

The Department of State's Advisory Committee on Private International Law (ACPIL) will hold a virtual meeting to discuss the Hague Special Commission on the Eighth Meeting of the Practical Operation on the 1980 Child Abduction Convention on September 12, 2023. The meeting will be held in WebEx. The program is scheduled to run from 1:00 p.m. to 3:00 p.m. Eastern Daylight Time.

The meeting will discuss the reports and documents completed concerning the Practical Operations of the 1980 Child Abduction Convention and 1996 Child Protection Convention regarding the feasibility of one or more private international law instruments. The purpose of the public meeting is to obtain the views of concerned stakeholders on the matters presented in the relevant documents, which will be made available by the HCCH at *https://www.hcch.net/en/publications-and-studies/details4/?pid=8488&dtid=57.*

Members of the public may attend this virtual session and will be permitted to participate in the discussion. Virtual attendance is limited to 100 persons, so each member of the public that wishes to attend this session must provide: Name, contact information, and affiliation to *pil@state.gov,* not later than September 8, 2023. When you register, please indicate whether you require captioning. The WebEx site and agenda will be forwarded to individuals who register. Requests made after that date will be considered but might not be able to be fulfilled.

Karin Kizer,

Attorney-Adviser, Office of Private International Law, Office of the Legal Adviser, Department of State.

[FR Doc. 2023–18510 Filed 8–25–23; 8:45 am]

BILLING CODE 4710–08–P

DEPARTMENT OF STATE

[Public Notice: 12156]

Notice of Determinations; Culturally Significant Objects Being Imported for Exhibition—Determinations: "Africa & Byzantium" Exhibition

SUMMARY: Notice is hereby given of the following determinations: I hereby determine that certain objects being imported from abroad pursuant to agreements with their foreign owners or custodians for temporary display in the exhibition ''Africa & Byzantium'' at The Metropolitan Museum of Art, New York, New York; the Cleveland Museum of Art, Cleveland, Ohio; and at possible additional exhibitions or venues yet to be determined, are of cultural significance, and, further, that their temporary exhibition or display within the United States as aforementioned is in the national interest. I have ordered that Public Notice of these determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Reed Liriano, Program Coordinator, Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, 2200 C Street NW (SA–5), Suite 5H03, Washington, DC 20522–0505.

SUPPLEMENTARY INFORMATION: The foregoing determinations were made pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), E.O. 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000, and Delegation of Authority No. 523 of December 22, 2021.

Nicole L. Elkon,

Deputy Assistant Secretary for Professional and Cultural Exchanges, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2023–18403 Filed 8–25–23; 8:45 am]

BILLING CODE 4710–05–P

DEPARTMENT OF STATE

[Public Notice: 12162]

Notice of Public Meeting in Preparation for International Maritime Organization TC 73 Meeting

The Department of State will conduct a public meeting at 10:00 a.m. on Thursday, October 12, 2023, both in-person at Coast Guard Headquarters in Washington, DC, and via teleconference. The primary purpose of the meeting is to prepare for the 73rd session of the International Maritime Organization's (IMO) Technical Cooperation Committee (TC 73) to be held at the IMO Headquarters in London, United Kingdom from Monday, October 16, to Thursday, October 19, 2023.

Members of the public may participate up to the capacity of the teleconference phone line, which can handle 500 participants or up to the seating capacity of the room if attending in-person. The meeting location will be the United States Coast Guard Headquarters, 5PS Conference Room, and the teleconference line will be provided to those who RSVP. To RSVP, participants should contact the meeting coordinator, LT Emily Rowan, by email at *Emily.K.Rowan@uscg.mil.* LT Rowan will provide access information for in-person and virtual attendance.

The agenda items to be considered at this meeting mirror those to be considered at TV 73, and include:

—Adoption of the agenda
—Work of other bodies and organizations
—Technical Cooperation Planning and Reporting
—Resource mobilization and partnerships:
—The 2030 Agenda for Sustainable Development
—The Capacity-Building Decade 2021–2030 Strategy
—Regional presence and coordination
—IMO Member State Audit Scheme
—Capacity-building: Strengthening the impact of women in the maritime sector
—Global maritime training institution
—Status of implementation of the recommendations from the report of the evaluation of the ITCP activities for the period 2016–2019
—Application of the document on the *Organization and method of work of the Technical Cooperation Committee*
—Work programme
—Election of Chair and Vice-Chair for 2023 and 2024
—Any other business
—Consideration of the report of the Committee on its seventy-third session

Please note: The IMO may, on short notice, adjust the TC 73 agenda to accommodate the constraints associated with the virtual meeting format. Any changes to the agenda will be reported to those who RSVP and those in attendance at the meeting.

Those who plan to participate may contact the meeting coordinator, LT Emily Rowan, by email at *Emily.K.Rowan@uscg.mil,* by phone at (202) 372–1376, or in writing at United States Coast Guard (CG–5PS), ATTN: LT Emily Rowan, 2703 Martin Luther King Jr. Ave. SE, Stop 7509, Washington, DC 20593–7509. Members of the public needing reasonable accommodation should advise LT Emily Rowan no later than September 28, 2023. Requests made after that date will be considered but might not be possible to fulfill.

Additional information regarding this and other IMO public meetings may be found at: *https://www.dco.uscg.mil/IMO.*

(Authority: 22 U.S.C. 2656 and 5 U.S.C. 552)

Leslie W. Hunt,

Coast Guard Liaison Officer, Office of Ocean and Polar Affairs, Department of State.

[FR Doc. 2023–18453 Filed 8–25–23; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF STATE

[Public Notice: 12161]

Notice of Public Meeting in Preparation for International Maritime Organization Carriage of Cargoes and Containers Sub-Committee Meeting

The Department of State will conduct a public meeting at 10:00 a.m. on Tuesday, September 12, 2023, both in-person at Coast Guard Headquarters in Washington, DC, and via teleconference. The primary purpose of the meeting is to prepare for the 9th session of the International Maritime Organization's (IMO) Carriage of Cargoes and Containers Sub-Committee (CCC 9) to be held at the IMO Headquarters in London, United Kingdom from Wednesday, September 20, to Friday, September 29, 2023. Members of the public may participate up to the capacity of the teleconference phone line, which can handle 500 participants or up to the seating capacity of the room if attending in-person. The meeting location will be the United States Coast Guard Headquarters, 5Q23–06, and the teleconference line will be provided to those who RSVP. To RSVP, participants should contact the meeting coordinator, Dr. Amy Parker, by email at *Amy.M.Parker@uscg.mil.* Dr. Parker will provide access information for in-person and virtual attendance.

The agenda items to be considered at this meeting mirror those to be considered at CCC 9, and include:

—Adoption of the agenda
—Decisions of other IMO bodies
—Amendments to the IGF Code and development of guidelines for alternative fuels and related technologies
—Review of the IGC Code
—Amendments to the IMSBC Code and supplements
—Amendments to the IMDG Code and supplements
—Revision of the Interim recommendations for carriage of liquefied hydrogen in bulk
—Revision of resolution A.1050(27) to ensure the safety of personnel entering enclosed spaces on board ships
—Consideration of reports of incidents involving dangerous goods or marine pollutants in packaged form on board ships or in port areas
—Unified interpretation of provisions of IMO safety, security, and environment-related conventions
—Biennial status report and provisional agenda for CCC 10
—Election of Chair and Vice-Chair for 2024
—Any other business
—Report to the Committees

Please note: The IMO may, on short notice, adjust the CCC 9 agenda to accommodate the constraints associated with the virtual meeting format. Any changes to the agenda will be reported to those who RSVP and those in attendance at the meeting.

Those who plan to participate may contact the meeting coordinator, Dr. Amy Parker, by email at *Amy.M.Parker@uscg.mil,* by phone at (202) 372–1423, or in writing at United States Coast Guard (CG–ENG–5), ATTN: Dr. Amy Parker, 2703 Martin Luther King Jr. Ave. SE, Stop 7509, Washington, DC 20593–7509. Members of the public needing reasonable accommodation should advise Dr. Amy Parker no later than August 29, 2023. Requests made after that date will be considered but might not be possible to fulfill. Additional information regarding this and other IMO public meetings may be found at: *https://www.dco.uscg.mil/IMO.*

(Authority: 22 U.S.C. 2656 and 5 U.S.C. 552.)

Leslie W. Hunt,

Coast Guard Liaison Officer, Office of Ocean and Polar Affairs, Department of State.

[FR Doc. 2023–18433 Filed 8–25–23; 8:45 am]

BILLING CODE 4710–09–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No.: FAA–2023–1328; Summary Notice No. 2023–27]

Petition for Exemption; Summary of Petition Received; IHC Health Services, Inc./dba Intermountain Life Flight

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

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion nor omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before September 18, 2023.

ADDRESSES: Send comments identified by docket number FAA–2023–1328 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://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, 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 20590–0001, 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: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time.

Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Andrew Thai at (202) 267–0175, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC.

Angela O. Anderson,

Director, Regulatory Support Division, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2023–1328.

Petitioner: IHC Health Services, Inc./dba Intermountain Life Flight.

Section(s) of 14 CFR Affected: § 135.271.

Description of Relief Sought: The petitioner seeks an exemption to conduct air medical airplane operations under 14 CFR 135.271 in lieu of § 135.267. In addition, the petitioner seeks to increase flight time limits of 14 CFR 135.271 from 8 hours to 10 hours when using a flight crew consisting of two pilots within the United States.

[FR Doc. 2023–18426 Filed 8–25–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. 2013–0259]

Agency Information Collection Activities: Requests for Comments; Clearance of Renewed Approval of Information Collection: Advisory Circular: Reporting of Laser Illumination of Aircraft

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (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 renew information collection. Advisory Circular 70–2B provides guidance to civilian air crews on the reporting of laser illumination incidents and recommended mitigation actions to be taken in order to ensure continued safe and orderly flight operations.

DATES: Written comments should be submitted by October 27, 2023.

ADDRESSES: Please send written comments:

By Electronic Docket: *www.regulations.gov* (Enter docket number into search field)

By mail: Nicholas Torgerson, Federal Aviation Administration, AJR–223, 800 Independence Ave. SW, Washington, DC 20591.

FOR FURTHER INFORMATION CONTACT: Nicholas Torgerson, by email at: *Nicholas.d.torgerson@faa.gov;* phone: 202–322–4157

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. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

OMB Control Number: 2120–0698.

Title: Advisory Circular (AC): Reporting of Laser Illumination of Aircraft.

Form Numbers: Advisory Circular 70–2B, Reporting of Laser Illumination of Aircraft.

Type of Review: Renewal of an information collection.

Background: Advisory Circular 70–2B provides guidance to civilian air crews on the reporting of laser illumination incidents and recommended mitigation actions to be taken in order to ensure continued safe and orderly flight operations. Information is collected from pilots and aircrews that are affected by an unauthorized illumination by lasers. The requested reporting involves an immediate broadcast notification to Air Traffic Control (ATC) when the incident occurs, as well as a broadcast warning of the incident if the aircrew is flying in uncontrolled airspace. In addition, the AC requests that the aircrew supply a written report of the incident and send it by fax or email to the Washington Operations Control Complex (WOCC) as soon as possible.

Respondents: Approximately 1,100 pilots and crewmembers.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: 10 minutes.

Estimated Total Annual Burden: 183 hours.

Issued in Washington, DC, on August 23, 2023.

Sandra L. Ray,

Aviation Safety Inspector, AFS–260.

[FR Doc. 2023–18517 Filed 8–25–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2023–1718]

Notice of Intent To Designate as Abandoned Supplemental Type Certificate No. SA1201GL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of intent to designate Supplemental Type Certificate as abandoned; request for comments.

SUMMARY: This Notice announces the FAA's intent to designate Supplemental Type Certificate (STC) No. SA1201GL as abandoned and make the related engineering data available upon request. The FAA has received a request to provide engineering data concerning this STC. The FAA has been unsuccessful in contacting the STC holder concerning the STC. This action is intended to enhance aviation safety.

DATES: We must receive all comments by February 26, 2024.

ADDRESSES: You may send comments on this notice by any of the following methods:

- *Federal eRulemaking Portal:* Go to *regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* JoWanna Jenkins, Program Management Specialist, Central Certification Branch, 2300 East Devon Avenue, Room 107, Des Plaines, IL 60018.
- *Email: jowanna.jenkins@faa.gov.* Include ''Docket No. FAA–2023–1718'' in the subject line of the message.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: JoWanna Jenkins, Program Management Specialist, Central Certification Branch, 2300 East Devon Avenue, Room 107, Des Plaines, IL 60018; telephone 847–294–7145; email *jowanna.jenkins@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

The FAA invites interested parties to provide comments, written data, views, or arguments relating to this notice. Send your comments to an address

listed under the **ADDRESSES** section. Include ''Docket No. FAA–2023–1718'' at the beginning of your comments. The FAA will consider all comments received on or before the closing date. All comments received will be available in the docket for examination by interested persons.

Background

The FAA is posting this notice to inform the public of the intent to designate as abandoned STC No. SA1201GL, which authorized a gross weight increase for Aeronca Model 65–C and S–65–C airplanes, and subsequently release the related engineering data.

The FAA has received a third-party request for the release of the aforementioned engineering data under the provisions of the Freedom of Information Act (FOIA), 5 U.S.C. 552. The FAA cannot release commercial or financial information under FOIA without the permission of the data owner. However, in accordance with title 49 of the United States Code § 44704(a)(5), the FAA can provide STC ''engineering data'' it possesses for STC maintenance or improvement, upon request, if the following conditions are met:

1. The FAA determines the STC has been inactive for three years or more;
2. Using due diligence, the FAA is unable to locate the owner of record or the owner of record's heir; and
3. The availability of such data will enhance aviation safety.

There has been no activity with this STC holder for more than three years.

On September 23, 2022, the FAA sent a registered letter to the STC holder, Lawrence F. Diedrich, at his last known address, Route 3, Box 279, Lodi, WI 53555. The letter informed Mr. Diedrich that the FAA had received a request for engineering data related to STC No. SA1201GL and was conducting a due diligence search to determine whether the STC was inactive and may be considered abandoned. The letter further requested Mr. Diedrich to respond in writing within 60 days and state whether he is the holder of the STC.

Information Requested

If you are the owner or heir or a transferee of STC No. SA1201GL or have any knowledge regarding who may now hold STC No. SA1201GL, please contact JoWanna Jenkins using a method described in this notice under **FOR FURTHER INFORMATION CONTACT.** If you are the heir of the owner, or the owner by transfer, of STC No. SA1201GL, you must provide a notarized copy of your government-issued identification with a letter and background establishing your ownership of the STC and, if applicable, your relationship as the heir to the deceased holder of the STC.

Conclusion

If the FAA does not receive any response by February 26, 2024, the FAA will consider STC No. SA1201GL abandoned, and the FAA will proceed with the release of the requested data. This action is for the purpose of maintaining the airworthiness of an aircraft and enhancing aviation safety.

Issued on August 21, 2023.

Victor Wicklund,

Deputy Director, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2023–18472 Filed 8–25–23; 8:45 am]

BILLING CODE 4210–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No.: FAA–2023–1240; Summary Notice No. 2023–31]

Petition for Exemption; Summary of Petition Received; Gregory D. Kruse

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

ACTION: Notice.

SUMMARY: This notice contains a summary of a petition seeking relief from specified requirements of Federal Aviation Regulations. The purpose of this notice is to improve the public's awareness of, and participation in, the FAA's exemption process. Neither publication of this notice nor the inclusion nor omission of information in the summary is intended to affect the legal status of the petition or its final disposition.

DATES: Comments on this petition must identify the petition docket number and must be received on or before September 18, 2023.

ADDRESSES: Send comments identified by docket number FAA–2023–1240 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://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, 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 20590–0001, 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: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to *http://www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *http://www.dot.gov/privacy.*

Docket: Background documents or comments received may be read at *http://www.regulations.gov* at any time. Follow the online instructions for accessing the docket or go to the Docket Operations in Room W12–140 of the West Building Ground Floor at 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Andrew Thai at (202) 267–0175, Office of Rulemaking, Federal Aviation Administration, 800 Independence Avenue SW, Washington, DC 20591.

This notice is published pursuant to 14 CFR 11.85.

Issued in Washington, DC.

Angela O. Anderson,

Director, Regulatory Support Division, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA–2023–1240.

Petitioner: Gregory D. Kruse.

Section(s) of 14 CFR Affected: § 65.71(a)(2).

Description of Relief Sought: The petitioner seeks relief from the basic eligibility 14 CFR 65.71(a)(2) that requires a person to be able to read the English language to be eligible for a mechanic certificate and associated ratings. As the petitioner is blind, he intends to utilize various technologies and applications in order to read.

[FR Doc. 2023–18424 Filed 8–25–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Transit Administration

Rescinding Notice of Intent To Prepare an Environmental Impact Statement for the Restoration of Rail Service in the Northern Branch Corridor, Hudson and Bergen Counties, New Jersey

AGENCY: Federal Transit Administration (FTA), Department of Transportation (DOT).

ACTION: Rescind notice of intent to prepare an environmental impact statement.

SUMMARY: The FTA, in cooperation with the New Jersey Transit Corporation (NJ TRANSIT), is issuing this Notice to advise the public that we are rescinding the 2007 Notice of Intent (NOI) to prepare an Environmental Impact Statement (EIS) for a previous proposal for the Restoration of Rail Service in the Northern Branch Corridor Project from North Bergen to Englewood in Hudson and Bergen Counties, New Jersey.

FOR FURTHER INFORMATION CONTACT: Donald Burns, FTA Director of Planning and Program Development. Address: One Bowling Green, Room 429, New York, New York, 10004–1415; Email: *Donald.Burns@dot.gov;* Telephone: (212) 668–2203.

SUPPLEMENTARY INFORMATION: The FTA, as the lead Federal agency, in cooperation with the NJ TRANSIT, published an NOI in the **Federal Register** on October 2, 2007 (72 FR 56123) to prepare an EIS for the proposed Northern Branch Project. The Northern Branch Project EIS was being advanced to study the restoration of rail passenger service on the Northern Branch rail corridor between North Bergen, Hudson County, and Englewood, Bergen County. Based on FTA's most recent review of the Project, FTA has decided to rescind the NOI due to all-encompassing changes in the Project design and environmental impacts in the following areas: floodplains, stormwater management, cultural resources, hazardous materials, traffic and parking, and air quality, all of which have occurred since 2007.

Comments and questions concerning the proposed action should be directed to FTA at the address provided above.

Donald Burns,

Director of Planning and Program Development Federal Transit Administration—Region II.

[FR Doc. 2023–18485 Filed 8–25–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

[Docket ID OCC–2023–0013]

Minority Depository Institutions Advisory Committee

AGENCY: Office of the Comptroller of the Currency (OCC), Treasury.

ACTION: Notice of Federal Advisory Committee meeting.

SUMMARY: The OCC announces a meeting of the Minority Depository Institutions Advisory Committee (MDIAC).

DATES: The OCC MDIAC will hold a public meeting on Tuesday, September 12, 2023, beginning at 1:00 p.m. Eastern Daylight Time (EDT). The meeting will be in person and virtual.

ADDRESSES: The OCC will hold the September 12, 2023 meeting of the MDIAC at the OCC's offices at 400 7th Street SW, Washington, DC 20219 and virtually.

FOR FURTHER INFORMATION CONTACT: André King, Designated Federal Officer and Assistant Deputy Comptroller, (202) 649–5420, Office of the Comptroller of the Currency, 400 Seventh Street SW, Washington, DC 20219. If you are deaf, hard of hearing, or have a speech disability, please dial 7–1–1 to access telecommunications relay services. You may also access prior MDIAC meeting materials on the MDIAC page of OCC's website.[1]

SUPPLEMENTARY INFORMATION: Under the authority of the Federal Advisory Committee Act (the Act), 5 U.S.C. 1001 *et seq,* and the regulations implementing the Act at 41 CFR part 102–3, the OCC is announcing that the MDIAC will convene a public meeting at 1:00 p.m. EDT on Tuesday, September 12, 2023. Agenda items will include current topics of interest to the industry. The purpose of the meeting is for the MDIAC to advise the OCC on steps the agency may be able to take to ensure the continued health and viability of minority depository institutions and other issues of concern to minority depository institutions. In addition to attending the meeting, members of the public may submit written statements to the MDIAC by email to: *MDIAC@occ.treas.gov.*

The OCC must receive any written statements no later than 5:00 p.m. EDT on Thursday, September 7, 2023.

[1] *https://www.occ.gov/topics/supervision-and-examination/bank-management/minority-depository-institutions/minority-depository-institutions-advisory-committee.html.*

Members of the public who plan to attend the public meeting should contact the OCC by 5:00 p.m. EDT on Thursday, September 7, 2023—to indicate whether they will attend in person or virtually, and to obtain information about participating in the meeting—via email at *MDIAC@occ.treas.gov* or by telephone at (202) 649–5420. Attendees should provide their full name, email address, and organization, if any. Members of the public who are deaf, hard of hearing, or have a speech disability, should dial 7–1–1 to access telecommunications relay services for this meeting.

Benjamin W. McDonough,

Senior Deputy Comptroller and Chief Counsel.

[FR Doc. 2023–18427 Filed 8–25–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Notice of OFAC Sanctions Actions

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The U.S. Department of the Treasury's Office of Foreign Assets Control (OFAC) is publishing the names of one or more persons that have been placed on OFAC's Specially Designated Nationals and Blocked Persons List (SDN List) based on OFAC's determination that one or more applicable legal criteria were satisfied. All property and interests in property subject to U.S. jurisdiction of these persons are blocked, and U.S. persons are generally prohibited from engaging in transactions with them.

DATES: See **SUPPLEMENTARY INFORMATION** section for applicable date(s).

FOR FURTHER INFORMATION CONTACT: OFAC: Associate Director for Global Targeting, tel.: 202–622–2420; Assistant Director for Licensing, tel.: 202–622–2480; Assistant Director for Regulatory Affairs, tel.: 202–622–4855; or Assistant Director for Sanctions Compliance & Evaluation, tel.: 202–622–2490.

SUPPLEMENTARY INFORMATION:

Electronic Availability

The SDN List and additional information concerning OFAC sanctions programs are available on OFAC's website (*https://www.treasury.gov/ofac*).

Notice of OFAC Actions

On August 23, 2023, OFAC determined that the property and interests in property subject to U.S.

jurisdiction of the following persons are blocked under the relevant sanctions authority listed below.

Individuals:

1. TUN, Zaw Min (a.k.a. HTUN, Zaw Min), Burma; DOB 20 Jul 2001; POB Burma; nationality Burma; Gender Male; National ID No. 9/PABATHA(N)010135 (Burma) (individual) [BURMA–EO14014].

Designated pursuant to section 1(a)(i) of Executive Order 14014 of February 10, 2021, ''Blocking Property With Respect to the Situation in Burma'', 86 FR 9429 (''E.O. 14014'') for operating in the jet fuel sector of the Burmese economy.

2. WIN, Khin Phyu (a.k.a. SHUI, Zhao Jia; a.k.a. SHWE, Kyauk Kyar; a.k.a. WIN, Kin Phyu), 1002, Shwe Than Lwin Condo, New University Avenue, Bahan Township, Yangon, Burma; No. 218, Building No. A, Level 16 A, No. 13 Ward, Insein Road, Hlaing Township, Yangon, Burma; DOB 10 Nov 1960; nationality Burma; Gender Female; National ID No. 13/THAPANA(AEI)000103 (Burma) (individual) [BURMA–EO14014].

Designated pursuant to section 1(a)(i) of E.O. 14014 for operating in the jet fuel sector of the Burmese economy.

Entities:

3. SHOON ENERGY PTE. LTD. (f.k.a. ASIA SUN AVIATION PTE. LTD.), Singapore; Organization Established Date 27 Jun 2018; Organization Type: Activities of holding companies; Registration Number 201821798H (Singapore) [BURMA–EO14014] (Linked To: WIN, Khin Phyu).

Designated pursuant to section 1(a)(i) of E.O. 14014 for operating in the jet fuel sector of the Burmese economy and for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Khin Phyu Win, a person whose property and interests in property are blocked pursuant to E.O. 14014.

4. PEIA PTE. LTD. (f.k.a. PUMA ENERGY IRRAWADDY AVIATION PTE. LTD.), Singapore; Organization Established Date 30 Oct 2014; Organization Type: Activities of holding companies; Registration Number 201432465N (Singapore) [BURMA–EO14014] (Linked To: WIN, Khin Phyu).

Designated pursuant to section 1(a)(vii) of E.O. 14014 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Khin Phyu Win, a person whose property and interests in property are blocked pursuant to E.O. 14014.

5. P.E.I ENERGY PTE. LTD. (f.k.a. PUMA ENERGY MYANMAR PTE. LTD.; f.k.a. PUMA ENERGY BENGALE GULF PTE. LTD.; f.k.a. PUMA ENERGY IRRAWADDY PTE. LTD.), Singapore; Organization Established Date 17 Aug 2012; Organization Type: Activities of holding companies; Registration Number 201220511D (Burma) [BURMA–EO14014] (Linked To: WIN, Khin Phyu).

Designated pursuant to section 1(a)(vii) of E.O. 14014 for being owned or controlled by, or having acted or purported to act for or on behalf of, directly or indirectly, Khin Phyu Win, a person whose property and interests in property are blocked pursuant to E.O. 14014.

Authority: E.O. 14014, 86 FR 9429.

Dated: August 23, 2023.

Bradley T. Smith,

Deputy Director, Office of Foreign Assets Control, U.S. Department of the Treasury.

[FR Doc. 2023–18469 Filed 8–25–23; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900–0325]

Agency Information Collection Activity: Certificate of Delivery of Advance Payment and Enrollment

AGENCY: Veterans Benefits Administration, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: Veterans Benefits Administration, Department of Veterans Affairs (VA), is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (PRA) of 1995, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed revision of a currently approved collection, and allow 60 days for public comment in response to the notice.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before October 27, 2023.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at *www.Regulations.gov* or to Nancy J. Kessinger, Veterans Benefits Administration (20M33), Department of Veterans Affairs, 810 Vermont Avenue NW, Washington, DC 20420 or email to *nancy.kessinger@va.gov.* Please refer to ''OMB Control No. 2900–0325'' in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Maribel Aponte, Office of Enterprise and Integration, Data Governance Analytics (008), 810 Vermont Ave. NW, Washington, DC 20420, (202) 266–4688 or email *maribel.aponte@va.gov.* Please refer to ''OMB Control No. 2900–0325'' in any correspondence.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995, Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. This request for comment is being made pursuant to section 3506(c)(2)(A) of the PRA.

With respect to the following collection of information, VBA invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of VBA's functions, including whether the information will have practical utility; (2) the accuracy of VBA's estimate of the burden of the proposed collection of information; (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 or the use of other forms of information technology.

Authority: 38 U.S.C. 3034, 3241, 3531, 3680(d), 3684,10 U.S.C. 16136(b), 38 CFR 21.4138a, 21.4203(a), 21.5135, 21.5200(d), 21.5292(e)(2), 21.7151(b), and 21.7640(d).

Title: Certificate of Delivery of Advance Payment and Enrollment, VA Form 22–1999v.

OMB Control Number: 2900–0325.

Type of Review: Revision of a currently approved collection.

Abstract: The VA uses information from the current collection at the beginning of the school term to ensure that advance payments have been delivered, and to determine whether the student has increased, reduced, or terminated training. School Certifying Officials (SCOs) completes this form and returns it to VA when delivery of the advance payment check is made to students upon registration for their period of enrollment. If this student fails to register within 30 days after the commencement date of the enrollment period, the advance payment check must be returned to the Department of the Treasury. Advance payments are not available under the Post-9/11 GI Bill (Chapter 33) benefit program.

Affected Public: State, Local and Tribal Governments.

Estimated Annual Burden: 23 hours.

Estimated Average Burden Time per Respondent: 5 minutes.

Frequency of Response: On occasion.

Estimated Number of Respondents: 63.

By direction of the Secretary.

Maribel Aponte,

VA PRA Clearance Officer, Office of Enterprise and Integration/Data Governance Analytics, Department of Veterans Affairs.

[FR Doc. 2023–18399 Filed 8–25–23; 8:45 am]

BILLING CODE 8320–01–P

DEPARTMENT OF VETERANS AFFAIRS

Advisory Committee: National Academic Affiliations Council, Notice of Meeting

The Department of Veterans Affairs (VA) gives notice under the Federal Advisory Committee Act, 5 U.S.C. ch. 10, that a meeting of VA's National Academic Affiliations Council (Council) will be held September 27, 2023–September 28, 2023. The meetings will begin and end as follows:

Public participation will commence as follows:

Date	Time	Location	Open session
September 27, 2023 ..	9:00 a.m. to 4:00 p.m. Central Standard Time (CST).	Ernest Childers VA Outpatient Clinic, 8921 South Mingo Road, Tulsa, OK, 74133–5841.	Yes.
September 28, 2023 ..	9:30 a.m. to 2:15 p.m. CST	Ernest Childers VA Outpatient Clinic, 8921 South Mingo Road, Tulsa, OK, 74133–5841.	No.

Sessions are open to the public, except when the Council is conducting tours of VA facilities. Tours of VA facilities are closed to protect Veterans' privacy and personal information, by 5 U.S.C. 552b(c)(6).

The purpose of the Council is to advise the Secretary on matters affecting partnerships between VA and its academic affiliates.

On September 27, 2023, the Council will convene an open session and receive presentations and updates. The morning agenda will include a presentation from Oklahoma VA on Academic Relationships and Accomplishments, a presentation and update of Communities Helping Invest through Property and Improvements Needed for Veterans Act, discussions with the Tribal Advisory Committee and Office of Tribal and Government relations, and a comprehensive MISSON ACT Section 403 presentation. In the afternoon, the Council will continue discussions with VA leadership including a panel discussion with Oklahoma VA trainees as it relates to diversity and rural health, and will receive updates from the Strategic Academic Advisory Council (SAAC). The Council will receive public comments from 3:40 p.m. to 4:00p.m. CST. The meeting will adjourn day one at 4:00 p.m. CST.

On September 28, 2023, at 9:30 a.m. CST, the Council will reconvene for day two. Day two of the meeting will be closed to the public, as the council will tour Indian Health Service (IHS) medical facilities. Tours of medical facilities are closed to protect privacy and personal information, in accordance with 5 U.S.C. 552b(c)(6). The meeting will adjourn at 2:15 p.m. CST.

Interested persons may attend and present oral statements to the Council on day 1 during the public comment period. A sign-in sheet for those who want to give comments will be available at the meeting. Individuals who speak are invited to submit a 1–2-page summary of their comments at the time of the meeting for inclusion in the official meeting record. Oral presentations will be limited to three to five minutes, depending on the number of participants. Interested parties may also provide written comments for review by the Council prior to the meeting, or at any time via email to *nellie.mitchell@va.gov.*

Any member of the public seeking additional information should contact Ms. Mitchell via email or by phone at (608) 358–9902. Because the meeting will be held in a government building, anyone attending must be prepared to submit to security screening and present a valid photo I.D. Please allow at least 30 minutes prior to the meeting for this process.

Dated: August 22, 2023.

Jelessa M. Burney,

Federal Advisory Committee Management Officer.

[FR Doc. 2023–18412 Filed 8–25–23; 8:45 am]

BILLING CODE P

FEDERAL REGISTER

Vol. 88 Monday,
No. 165 August 28, 2023

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 411, 412, 419, et al.

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician-Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership; and Medicare Disproportionate Share Hospital (DSH) Payments: Counting Certain Days Associated With Section 1115 Demonstrations in the Medicaid Fraction; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 411, 412, 419, 488, 489, and 495

[CMS–1785–F and CMS–1788–F]

RINs 0938–AV08 and 0938–AV17

Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2024 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Rural Emergency Hospital and Physician-Owned Hospital Requirements; and Provider and Supplier Disclosure of Ownership; and Medicare Disproportionate Share Hospital (DSH) Payments: Counting Certain Days Associated With Section 1115 Demonstrations in the Medicaid Fraction

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Final rules.

SUMMARY: This final rule will: revise the Medicare hospital inpatient prospective payment systems (IPPS) for operating and capital-related costs of acute care hospitals; make changes relating to Medicare graduate medical education (GME) for teaching hospitals; update the payment policies and the annual payment rates for the Medicare prospective payment system (PPS) for inpatient hospital services provided by long-term care hospitals (LTCHs); and make other policy-related changes. This final rule also revises our regulations on the counting of days associated with individuals eligible for certain benefits provided by section 1115 demonstrations in the Medicaid fraction of a hospital's disproportionate patient percentage (DPP) used in the disproportionate share hospital (DSH) calculation.

DATES: This final rule is effective October 1, 2023. The amendments to 42 CFR 488.18(d), published at 59 FR 32120, June 22, 1994, is effective August 1, 2023.

FOR FURTHER INFORMATION CONTACT:

Donald Thompson, and Michele Hudson, (410) 786–4487 or *DAC@cms.hhs.gov*, Operating Prospective Payment, MS–DRG Relative Weights, Wage Index, Hospital Geographic Reclassifications, Graduate Medical Education, Capital Prospective Payment, Excluded Hospitals, Medicare Disproportionate Share Hospital (DSH) Payment Adjustment, Sole Community Hospitals (SCHs), Medicare-Dependent Small Rural Hospital (MDH) Program, Low-Volume Hospital Payment Adjustment, and Inpatient Critical Access Hospital (CAH) Issues.

Emily Lipkin, and Jim Mildenberger, *DAC@cms.hhs.gov*, Long-Term Care Hospital Prospective Payment System and MS–LTC–DRG Relative Weights Issues.

Adina Hersko, *NewTech@cms.hhs.gov*, New Technology Add-On Payments and New COVID–19 Treatments Add-on Payments Issues.

Mady Hue, *marilu.hue@cms.hhs.gov*, and Andrea Hazeley, *andrea.hazeley@cms.hhs.gov*, MS–DRG Classifications Issues.

Siddhartha Mazumdar, *siddhartha.mazumdar@cms.hhs.gov*, Rural Community Hospital Demonstration Program Issues.

Jeris Smith, *jeris.smith@cms.hhs.gov*, Frontier Community Health Integration Project (FCHIP) Demonstration Issues.

Lang Le, *lang.le@cms.hhs.gov*, Hospital Readmissions Reduction Program—Administration Issues.

Ngozi Uzokwe, *ngozi.uzokwe@cms.hhs.gov*, Hospital Readmissions Reduction Program—Measures Issues.

Jennifer Tate, *jennifer.tate@cms.hhs.gov*, Hospital-Acquired Condition Reduction Program—Administration Issues.

Ngozi Uzokwe, *ngozi.uzokwe@cms.hhs.gov*, Hospital-Acquired Condition Reduction Program—Measures Issues.

Julia Venanzi, *julia.venanzi@cms.hhs.gov*, Hospital Inpatient Quality Reporting Program and Hospital Value-Based Purchasing Program—Administration Issues.

Melissa Hager, *melissa.hager@cms.hhs.gov* and Ngozi Uzokwe, ngozi.uzokwe@cms.hhs.gov—Hospital Inpatient Quality Reporting Program and Hospital Value-Based Purchasing Program—Measures Issues Except Hospital Consumer Assessment of Healthcare Providers and Systems Issues.

Elizabeth Goldstein, *elizabeth.goldstein@cms.hhs.gov*, Hospital Inpatient Quality Reporting and Hospital Value-Based Purchasing—Hospital Consumer Assessment of Healthcare Providers and Systems Measures Issues.

Ora Dawedeit, *ora.dawedeit@cms.hhs.gov*, PPS-Exempt Cancer Hospital Quality Reporting—Administration Issues.

Leah Domino, *leah.domino@cms.hhs.gov*, PPS-Exempt Cancer Hospital Quality Reporting Program-Measure Issues.

Ariel Cress, *ariel.cress@cms.hhs.gov*, Lorraine Wickiser, Lorraine, *Wickiser@cms.hhs.gov*, Long-Term Care Hospital Quality Reporting Program—Data Reporting Issues.

Jessica Warren, *jessica.warren@cms.hhs.gov* and Elizabeth Holland, *elizabeth.holland@cms.hhs.gov*, Medicare Promoting Interoperability Program.

Jennifer Milby, *jennifer.milby@cms.hhs.gov* and Sara Brice-Payne, *sara.brice-payne@cms.hhs.gov*, Special Requirements for Rural Emergency Hospitals (REHs).

Lisa O. Wilson, *Lisa.Wilson2@cms.hhs.gov*, Physician-Owned Hospital Issues.

Frank Whelan, *Frank.Whelan@cms.hhs.gov*, Disclosure of Ownership.

SUPPLEMENTARY INFORMATION:

Tables Available on the CMS Website

The IPPS tables for this fiscal year (FY) 2024 final rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled ''FY 2024 IPPS Final Rule Home Page'' or ''Acute Inpatient—Files for Download.'' The LTCH PPS tables for this FY 2024 final rule are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1785–F. For further details on the contents of the tables referenced in this final rule, we refer readers to section VI. of the Addendum to this FY 2024 IPPS/LTCH PPS final rule.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites, as previously identified, should contact Michael Treitel, *DAC@cms.hhs.gov*.

Table of Contents

I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This FY 2024 IPPS/LTCH PPS final rule makes payment and policy changes under the Medicare inpatient prospective payment system (IPPS) for operating and capital-related costs of acute care hospitals as well as for certain hospitals and hospital units excluded from the IPPS. In addition, it makes payment and policy changes for inpatient hospital services provided by long-term care hospitals (LTCHs) under the long-term care hospital prospective payment system (LTCH PPS). This final rule also makes policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs. In this FY 2024 final rule, we are finalizing our proposal to continue policies to address wage index disparities impacting low wage index hospitals. We are also finalizing our proposed changes relating to Medicare graduate medical education (GME) for teaching hospitals and new technology add-on payments.

In this FY 2024 final rule, we are finalizing our changes to the regulation governing the counting of days associated with individuals eligible for certain benefits provided by section 1115 demonstrations in the Medicaid fraction of a hospital's DPP that were proposed in CMS 1788–P, *Medicare Program; Medicare Disproportionate Share Hospital (DSH) Payments: Counting Certain Days Associated With Section 1115 Demonstrations in the Medicaid Fraction* (88 FR 12623).

We are finalizing our proposals to establish new requirements and revise existing requirements for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program.

In the Hospital VBP Program, we are finalizing our proposals to add one new measure, substantively modify two existing measures, add technical changes to the administration of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey, change the scoring policy to include a health equity scoring adjustment, and modify the Total Performance Score (TPS) maximum to be 110, resulting in a numeric score range of 0 to 110. We are also providing estimated and newly established performance standards for the FY 2026 through FY 2029 program years for the Hospital VBP Program.

In the HAC Reduction Program, we are finalizing our proposals to establish a validation reconsideration process for data validation and to add an additional targeting criterion for validation. We did not propose any changes and are not finalizing any changes for the Hospital Readmissions Reduction Program.

In the Hospital IQR Program, we are finalizing our proposals to add three new measures, to modify three existing measures, and to remove three measures. We are also finalizing our proposed changes to add technical changes to the administration of the HCAHPS Survey and to add an additional targeting criterion for validation.

In the PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR), we are finalizing our proposals to add four new measures and to modify an existing measure. We are also finalizing our proposed changes to add technical changes to the administration of the HCAHPS Survey and to begin public reporting of one measure.

In the LTCH QRP, we are finalizing our proposals to add two new measures, modify an existing measure, remove two measures, and increase the LTCH QRP data completion thresholds for LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS) items. Additionally, we provide a summary of the comments received to our request for information on principles for selecting and prioritizing LTCH QRP quality measures and concepts under consideration for future years and our update on CMS' continued efforts to close the health equity gap.

Under various statutory authorities, we either discuss continued program implementation or make changes to the Medicare IPPS, the LTCH PPS, other related payment methodologies and programs for FY 2024 and subsequent fiscal years, and other policies and provisions included in this rule. These statutory authorities include, but are not limited to, the following:

- Section 1886(d) of the Social Security Act (the Act), which sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires that, instead of paying for capital-related costs of inpatient hospital services on a reasonable cost basis, the Secretary use a prospective payment system (PPS).
- Section 1886(d)(1)(B) of the Act, which specifies that certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: rehabilitation hospitals and units; LTCHs; psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals; and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS.
- Sections 123(a) and (c) of the Balanced Budget Refinement Act of 1999 (BBRA) (Public Law (Pub. L.) 106–113) and section 307(b)(1) of the Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554) (as codified under section 1886(m)(1) of the Act), which provide for the development and implementation of a prospective payment system for payment for inpatient hospital services of LTCHs described in section 1886(d)(1)(B)(iv) of the Act.
- Section 1814(l)(4) of the Act requires downward adjustments to the applicable percentage increase, beginning with FY 2015, for CAHs that do not successfully demonstrate meaningful use of certified electronic health record technology (CEHRT) for an EHR reporting payment for a payment adjustment year.
- Section 1814(l)(4) of the Act, which requires downward adjustments to the applicable percentage increase, beginning with FY 2015, for CAHs that do not successfully demonstrate meaningful use of certified electronic health record technology (CEHRT) for an electronic health record (EHR) reporting payment for a payment adjustment year.
- Section 1886(a)(4) of the Act, which specifies that costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. Hospitals paid under the IPPS with approved GME programs are paid for the indirect costs of training residents in accordance with section 1886(d)(5)(B) of the Act.
- Section 1886(d)(5)(F) of the Act provides for additional Medicare IPPS payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. These payments are known as the Medicare disproportionate share hospital (DSH) adjustment. Section 1886(d)(5)(F) of the Act specifies the methods under which a hospital may qualify for the DSH payment adjustment.
- Section 1886(b)(3)(B)(viii) of the Act, which requires the Secretary to reduce the applicable percentage increase that would otherwise apply to the standardized amount applicable to a subsection (d) hospital for discharges occurring in a fiscal year if the hospital does not submit data on measures in a form and manner, and at a time, specified by the Secretary.
- Section 1886(b)(3)(B)(ix) of the Act, which requires downward adjustments to the applicable percentage increase, beginning with FY 2015 (and beginning with FY 2022 for subsection (d) Puerto Rico hospitals), for eligible hospitals that do not successfully demonstrate meaningful use of CEHRT for an EHR reporting period for a payment adjustment year.
- Section 1866(k) of the Act, which provides for the establishment of a quality reporting program for hospitals described in section 1886(d)(1)(B)(v) of the Act, referred to as ''PPS-exempt cancer hospitals.''
- Section 1886(n) of the Act, which establishes the requirements for an eligible hospital to be treated as a meaningful EHR user of CEHRT for an EHR reporting period for a payment year or, for purposes of subsection (b)(3)(B)(ix) of the Act, for a fiscal year.
- Section 1886(o) of the Act, which requires the Secretary to establish a Hospital Value- Based Purchasing (VBP) Program, under which value-based incentive payments are made in a fiscal year to hospitals meeting performance standards established for a performance period for such fiscal year.
- Section 1886(p) of the Act, which establishes a Hospital-Acquired Condition (HAC) Reduction Program, under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions.
- Section 1886(q) of the Act, as amended by section 15002 of the 21st Century Cures Act, which establishes the Hospital Readmissions Reduction Program. Under the program, payments for discharges from an applicable hospital as defined under section 1886(d) of the Act will be reduced to account for certain excess readmissions. Section 15002 of the 21st Century Cures Act directs the Secretary to compare hospitals with respect to the number of their Medicare-Medicaid dual-eligible beneficiaries in determining the extent of excess readmissions.
- Section 1886(r) of the Act, as added by section 3133 of the Affordable Care Act, which provides for a reduction to disproportionate share hospital (DSH) payments under section 1886(d)(5)(F) of the Act and for an additional

uncompensated care payment to eligible hospitals. Specifically, section 1886(r) of the Act requires that, for fiscal year 2014 and each subsequent fiscal year, subsection (d) hospitals that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act will receive two separate payments: (1) 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act (''the empirically justified amount''), and (2) an additional payment for the DSH hospital's proportion of uncompensated care, determined as the product of three factors. These three factors are: (1) 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act, in the absence of section 1886(r) of the Act; (2) 1 minus the percent change in the percent of individuals who are uninsured; and (3) the hospital's uncompensated care amount relative to the uncompensated care amount of all DSH hospitals expressed as a percentage.

- Section 1886(m)(5) of the Act, which requires the Secretary to reduce by two percentage points the annual update to the standard Federal rate for discharges for a long-term care hospital (LTCH) during the rate year for LTCHs that do not submit data in the form, manner, and at a time, specified by the Secretary.
- Section 1886(m)(6) of the Act, as added by section 1206(a)(1) of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67) and amended by section 51005(a) of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which provided for the establishment of site neutral payment rate criteria under the LTCH PPS, with implementation beginning in FY 2016. Section 51005(b) of the Bipartisan Budget Act of 2018 amended section 1886(m)(6)(B) by adding new clause (iv), which specifies that the IPPS comparable amount defined in clause (ii)(I) shall be reduced by 4.6 percent for FYs 2018 through 2026.
- Section 1899B of the Act, as added by section 2(a) of the Improving Medicare Post-Acute Care Transformation Act of 2014 (IMPACT Act) (Pub. L. 113–185), which provides for the establishment of standardized data reporting for certain post-acute care providers, including LTCHs.
- Section 1861(kkk) of the Act requires the Secretary to establish the conditions REHs must meet in order to participate in the Medicare program and which are considered necessary to ensure the health and safety of patients receiving services at these entities.
- Section 1877(i) of the Act, as added by section 6001(a)(3) of the Patient Protection and Affordable Care Act of 2010 (Affordable Care Act) (Pub. L. 111–148) and amended by section 1106 of the Health Care and Education Reconciliation Act of 2010 (HCERA) (Pub. L. 111–152), which requires the Secretary to establish and implement a process under which a hospital that is an ''applicable hospital'' or a ''high Medicaid facility'' may apply for an exception from the prohibition on expansion of facility capacity.

2. Summary of the Major Provisions

The following is a summary of the major provisions in this final rule. In general, these major provisions are being finalized as part of the annual update to the payment policies and payment rates, consistent with the applicable statutory provisions. A general summary of the changes in this final rule is presented in section I.D. of the preamble of this final rule.

a. Modification to the Rural Wage Index Calculation Methodology

As discussed in section III.G.1. of this final rule, CMS has taken the opportunity to revisit the case law, prior public comments, and the relevant statutory language with regard to its policies involving the treatment of hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act, as implemented in the regulations under 42 CFR 412.103. After doing so, CMS now agrees that the best reading of section 1886(d)(8)(E) is that it instructs CMS to treat § 412.103 hospitals the same as geographically rural hospitals. Therefore, we believe it is proper to include these hospitals in all iterations of the rural wage index calculation methodology included in section 1886(d) of the Act, including all hold harmless calculations in that provision. Beginning with FY 2024, we will include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations and only exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and Medicare Geographic Classification Review Board (MGCRB) reclassifications) in accordance with the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act.

b. Continuation of the Low Wage Index Hospital Policy

To help mitigate growing wage index disparities between high wage and low wage hospitals, in the FY 2020 IPPS/LTCH PPS rule (84 FR 42326 through 42332), we adopted a policy to increase the wage index values for certain hospitals with low wage index values (the low wage index hospital policy). This policy was adopted in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals. We also indicated our intention that this policy would be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. As discussed in section III.G.4. of the preamble of this final rule, as we only have 1 year of relevant data at this time that we could use to evaluate any potential impacts of this policy, we believe it is necessary to wait until we have useable data from additional fiscal years before making any decision to modify or discontinue the policy. Therefore, for FY 2024, we are finalizing our proposal to continue the low wage index hospital policy and the related budget neutrality adjustment.

c. DSH Payment Adjustment and Additional Payment for Uncompensated Care

Under section 1886(r) of the Act, which was added by section 3133 of the Affordable Care Act, starting in FY 2014, Medicare disproportionate share hospitals (DSHs) receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments in section 1886(d)(5)(F) of the Act. The remaining amount, equal to 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, is paid as additional payments after the amount is reduced for changes in the percentage of individuals that are uninsured. Each Medicare DSH will receive an additional payment based on its share of the total amount of uncompensated care for all Medicare DSHs for a given time period.

In this final rule, we are finalizing our proposal to update our estimates of the three factors used to determine uncompensated care payments for FY 2024. We are also finalizing our proposal to continue to use uninsured estimates produced by CMS' Office of the Actuary (OACT) as part of the development of the National Health Expenditure Accounts (NHEA) in conjunction with more recently available data in the calculation of Factor 2. Consistent with the regulation at § 412.106(g)(1)(iii)(C)(*11*), which was

adopted in the FY 2023 IPPS/LTCH PPS final rule, for FY 2024, we will use the 3 most recent years of audited data on uncompensated care costs from Worksheet S–10 of the FY 2018, FY 2019, and FY 2020 cost reports to calculate Factor 3 in the uncompensated care payment methodology for all eligible hospitals.

Beginning with FY 2023, we established a supplemental payment for IHS and Tribal hospitals and hospitals located in Puerto Rico, to help prevent undue long-term financial disruption to these hospitals due to the decision to discontinue use of the low-income insured days proxy in the uncompensated care payment methodology for these providers.

In this final rule we are also finalizing our proposal (88 FR 12623) on counting of days associated with individuals eligible for certain benefits provided by section 1115 demonstrations in the Medicaid fraction of a hospital's disproportionate patient percentage for the purposes of determining Medicare DSH payments to subsection (d) hospitals under section 1886(d)(5)(F) of the Act. Specifically, under our finalized policy, for purposes of the Medicare DSH calculation in section 1886(d)(5)(F)(vi) of the Act we will ''regard as'' ''eligible for medical assistance under a State plan approved under title XIX'' patients who (1) receive health insurance authorized by a section 1115 demonstration or (2) buy health insurance with premium assistance provided to them under a section 1115 demonstration, where State expenditures to provide the health insurance or premium assistance is matched with funds from title XIX. Furthermore, of these expansion groups we regard as eligible for Medicaid, we include in the disproportionate patient percentage (DPP) Medicaid fraction numerator only the days of those patients who receive from the demonstration (1) health insurance that covers inpatient hospital services or (2) premium assistance that covers 100 percent of the premium cost to the patient, which the patient uses to buy health insurance that covers inpatient hospital services, provided in either case that the patient is not also entitled to Medicare Part A. Finally, patients whose inpatient hospital costs are paid for with funds from an uncompensated/undercompensated care pool authorized by a section 1115 demonstration will not be patients ''regarded as'' eligible for Medicaid, and the days of such patients may not be included in the DPP Medicaid fraction numerator.

d. Hospital Readmissions Reduction Program

We did not propose any changes to the Hospital Readmissions Reduction Program. We note that all previously finalized policies under this program will continue to apply and refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49081 through 49094) for information on these policies.

e. Hospital Value-Based Purchasing (VBP) Program

Section 1886(o) of the Act requires the Secretary to establish a Hospital VBP Program under which value-based incentive payments are made in a fiscal year to hospitals based on their performance on measures established for a performance period for such fiscal year. In this final rule, we are finalizing our proposal to adopt modified versions of: (1) the Medicare Spending Per Beneficiary (MSPB) Hospital measure beginning with the FY 2028 program year; and (2) the Hospital-level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure beginning with the FY 2030 program year. In addition, we are finalizing our proposal to adopt the Severe Sepsis and Septic Shock: Management Bundle measure in the Safety Domain beginning with the FY 2026 program year.

We are finalizing our proposal to make technical changes to the form and manner of the administration of the HCAHPS Survey measure under the Hospital VBP Program beginning with the FY 2027 program year in alignment with the Hospital IQR Program. Additionally, we are finalizing our proposal to adopt a health equity scoring change for rewarding excellent care in underserved populations beginning with the FY 2026 program year, as well as the proposal to modify the Total Performance Score (TPS) maximum to be 110, such that the TPS numeric score range would be 0 to 110 in order to afford even top-performing hospitals the opportunity to receive the additional health equity bonus points under the health equity scoring change.

f. Hospital-Acquired Condition Reduction Program

Section 1886(p) of the Act establishes the HAC Reduction Program under which payments to applicable hospitals are adjusted to provide an incentive to reduce hospital-acquired conditions. In this final rule, we are finalizing our proposal to establish a validation reconsideration process for hospitals who fail data validation beginning with the FY 2025 program year, affecting calendar year 2022 discharges. We are also finalizing modification of the validation targeting criteria to include hospitals granted an extraordinary circumstances exceptions (ECEs) beginning with the FY 2027 program year, affecting calendar year 2024 discharges.

g. Modification of the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure in the Hospital IQR Program, PCHQR Program, and LTCH QRP

In the FY 2024 IPPS/LTCH PPS final rule, we are finalizing our proposal to modify the COVID–19 Vaccination Coverage among HCP measure to replace the term ''complete vaccination course'' with the term ''up to date'' with regard to recommended COVID–19 vaccines beginning with the Quarter 4 (Q4) calendar year (CY) 2023 reporting period/FY 2025 payment determination for the Hospital IQR Program, and the FY 2025 program year for the LTCH QRP and the PCHQR Program.

h. Hospital Inpatient Quality Reporting (IQR) Program

Under section 1886(b)(3)(B)(viii) of the Act, subsection (d) hospitals are required to report data on measures selected by the Secretary for a fiscal year in order to receive the full annual percentage increase.

In the FY 2024 IPPS/LTCH PPS final rule, we are finalizing several changes to the Hospital IQR Program. We are finalizing the adoption of three new measures: (1) Hospital Harm—Pressure Injury electronic clinical quality measure (eCQM) beginning with the CY 2025 reporting period/FY 2027 payment determination; (2) Hospital Harm—Acute Kidney Injury eCQM beginning with the CY 2025 reporting period/FY 2027 payment determination; and (3) Excessive Radiation eCQM beginning with the CY 2025 reporting period/FY 2027 payment determination. We are also finalizing the modification of three current measures: (1) Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure beginning with the FY 2027 payment determination; (2) Hybrid Hospital-Wide All-Cause Readmission (HWR) measure beginning with the FY 2027 payment determination; and (3) COVID–19 Vaccination Coverage among HCP measure beginning with the Q4 CY 2023 reporting period/FY 2025 payment determination. We are also finalizing the removal of three current measures: (1) Hospital-level Risk-standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty

(THA) and/or Total Knee Arthroplasty (TKA) measure beginning with the April 1, 2025-March 31, 2028 reporting period/FY 2030 payment determination pursuant to Removal Factor 8; (2) Medicare Spending Per Beneficiary (MSPB) Hospital measure beginning with the CY 2026 reporting period/FY 2028 payment determination pursuant to Removal Factor 8; and (3) Elective Delivery (PC–01) measure beginning with the CY 2024 reporting period/FY 2026 payment determination pursuant to Removal Factor 1. We are finalizing the codification of our Measure Removal Factors.

We are also finalizing two changes to current policies related to data submission, reporting, and validation: (1) Technical changes to the form and manner of the administration of the HCAHPS Survey Measure beginning with the CY 2025 reporting period/FY 2027 payment determination; and (2) Modification of the targeting criteria for hospital validation for extraordinary circumstances exceptions (ECEs) beginning with the FY 2027 payment determination.

i. PPS-Exempt Cancer Hospital Quality Reporting Program

Section 1866(k)(1) of the Act requires, for purposes of FY 2014 and each subsequent fiscal year, that a hospital described in section 1886(d)(1)(B)(v) of the Act (a PPS-exempt cancer hospital, or a PCH) submit data in accordance with section 1866(k)(2) of the Act with respect to such fiscal year. There is no financial impact to PCH Medicare payment if a PCH does not participate.

In the FY 2024 IPPS/LTCH PPS final rule, we are finalizing our proposals to adopt four new measures for the PCHQR Program: (i) three health equity-focused measures: the Facility Commitment to Health Equity measure, the Screening for Social Drivers of Health measure, and the Screen Positive Rate for Social Drivers of Health measure; and (ii) a patient preference-focused measure, the Documentation of Goals of Care Discussions Among Cancer Patients measure. We are also finalizing our proposal to adopt a modified version of the COVID–19 Vaccination Coverage among HCP measure beginning with the FY 2025 program year. We are also finalizing our proposals to publicly report the Surgical Treatment Complications for Localized Prostate Cancer (PCH–37) measure beginning with data from the FY 2025 program year, and technical changes to the form and manner of the administration of the HCAHPS survey measure beginning with the FY 2027 program year.

j. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

We are finalizing several changes to the LTCH QRP. Specifically, we are: (1) adopting a modified version of the COVID–19 Vaccination Coverage among HCP measure beginning with the FY 2025 LTCH QRP; (2) adopting the Discharge Function Score measure beginning with the FY 2025 LTCH QRP; (3) removing the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function measure beginning with the FY 2025 LTCH QRP; (4) removing the Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function measure beginning with the FY 2025 LTCH QRP; (5) adopting the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure beginning with the FY 2026 LTCH QRP; (6) increasing the LTCH QRP data completion thresholds for the LCDS beginning with the FY 2026 LTCH QRP; and (7) beginning public reporting of the Transfer of Health (TOH) Information to the Patient-Post-Acute Care (PAC) and TOH Information to the Provider-PAC measures.

k. Medicare Promoting Interoperability Program

In this final rule, we are finalizing several changes to the Medicare Promoting Interoperability Program. Specifically, we are finalizing our proposals to: (1) amend the definition of ''EHR reporting period for a payment adjustment year'' at 42 CFR 495.4 for eligible hospitals and CAHs participating in the Medicare Promoting Interoperability Program, to define the electronic health record (EHR) reporting period in CY 2025 as a minimum of any continuous 180-day period within CY 2025; (2) update the definition of ''EHR reporting period for a payment adjustment year'' at § 495.4 for eligible hospitals such that, beginning in CY 2025, those hospitals that have not successfully demonstrated meaningful use in a prior year will not be required to attest to meaningful use by October 1st of the year prior to the payment adjustment year; (3) modify our requirements for the Safety Assurance Factors for EHR Resilience (SAFER) Guides measure beginning with the EHR reporting period in CY 2024, to require eligible hospitals and CAHs to attest ''yes'' to having conducted an annual self-assessment of all nine SAFER Guides at any point during the calendar year in which the EHR reporting period occurs; (4) modify the way we refer to the calculation considerations related to unique patients or actions for Medicare Promoting Interoperability Program objectives and measures for which there is no numerator and denominator; and (5) adopt three new eCQMs beginning with the CY 2025 reporting period for eligible hospitals and CAHs to select as one of their three self-selected eCQMs: the Hospital Harm—Pressure Injury eCQM, the Hospital Harm—Acute Kidney Injury eCQM, and the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Inpatient) eCQM.

l. Changes to the Severity Level Designation for Z Codes Describing Homelessness

As discussed in section II.C. of the preamble of this final rule, we are finalizing the proposed change the severity level designation for social determinants of health (SDOH) diagnosis codes describing homelessness from non-complication or comorbidity (NonCC) to complication or comorbidity (CC) for FY 2024. Consistent with our annual updates to account for changes in resource consumption, treatment patterns, and the clinical characteristics of patients, CMS is recognizing homelessness as an indicator of increased resource utilization in the acute inpatient hospital setting.

Consistent with the Administration's goal of advancing health equity for all, including members of historically underserved and under-resourced communities, as described in the President's January 20, 2021 Executive Order 13985 on ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' [1] we also continue to be interested in receiving feedback on how we might otherwise foster the documentation and reporting of the diagnosis codes describing social and economic circumstances to more accurately reflect each health care encounter and improve the reliability and validity of the coded data including in support of efforts to advance health equity.

3. Summary of Costs and Benefits

The following table provides a summary of the costs, savings, and benefits associated with the major

[1] *Available at* 86 FR 7009 (January 25, 2021) (*https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government*).

provisions described in section I.A.2. of the preamble of this final rule.

Provision Description	Description of Costs, Transfers, Savings, and Benefits
Modification to the Rural Wage Index Calculation Methodology	Beginning with FY 2024, we are including hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations and only excluding "dual reclass" hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) in accordance with the hold-harmless provision at section 1886(d)(8)(C)(ii) of the Act. Changes to the rural wage index, which affect the rural floor, are generally implemented in a budget neutral manner.
Continuation of the Low Wage Index Hospital Policy	For FY 2024, we are continuing the low wage index hospital policy and the related budget neutrality adjustment.
Medicare DSH Payment Adjustment and Additional Payment for Uncompensated Care and Supplemental Payment	For FY 2024, we are updating our estimates of the three factors used to determine uncompensated care payments. We are continuing to use uninsured estimates produced by OACT as part of the development of the NHEA in conjunction with more recently available data in the calculation of Factor 2. As provided in the regulation at § 412.106(g)(1)(iii)(C)(*11*), for FY 2024, we are using the 3 most recent years of audited data on uncompensated care costs from Worksheet S–10 of the FY 2018, FY 2019, and FY 2020 cost reports to calculate Factor 3 in the uncompensated care payment methodology for all eligible hospitals.
Update to the IPPS Payment Rates and Other Payment Policies	As discussed in appendix A of this final rule, acute care hospitals are estimated to experience an increase of approximately $2.2 billion in FY 2024, primarily driven by: (1) a combined $2.6 billion increase in FY 2024 operating payments and capital payments, as well as changes in DSH and uncompensated care payments, and (2) a decrease of $364 million resulting from estimated changes in new technology add-on payments, as projected for this final rule.
Update to the LTCH PPS Payment Rates and Other Payment Policies	As discussed in appendix A of this final rule, based on the best available data for the 333 LTCHs in our database, we estimate that the changes to the payment rates and factors that we present in the preamble of and Addendum of the final rule, which reflect the update to the LTCH PPS standard Federal payment rate for FY 2024, will result in an estimated increase in payments in FY 2024 of approximately $6 million.
Changes to the Value-Based Incentive Payments under the Hospital VBP Program	We estimate that there would be no net financial impact to the Hospital VBP Program for the FY 2024 program year in the aggregate because, by law, the amount available for value-based incentive payments under the program in a given year must be equal to the total amount of base operating MS-DRG payment amount reductions for that year, as estimated by the Secretary. The estimated amount of base operating MS-DRG payment amount reductions for the FY 2024 program year and, therefore, the estimated amount available for value-based incentive payments for FY 2024 discharges is approximately $1.7 billion.
Modification of the COVID-19 Vaccination Coverage among Healthcare Personnel Measure in the Hospital IQR Program, PCHQR Program, and LTCH QRP	We estimate that the modified version of this measure will have no financial impact on the LTCH QRP, PCHQR Program, or Hospital IQR Program
Changes to the Hospital-Acquired Condition (HAC) Reduction Program	Across the 400 subsection (d) hospitals selected for validation each year from the HAC Reduction Program, we estimate that our changes in this final rule will not result in a change in information collection burden for the FY 2025 program year and subsequent years.
Changes to the Hospital IQR Program	Across 3,150 IPPS hospitals, we estimate that our changes for the Hospital IQR Program in this final rule will result in a total information collection burden decrease of 144,836 hours associated with our finalized policies,

Provision Description	Description of Costs, Transfers, Savings, and Benefits
	and updated burden estimates and a total cost decrease of approximately $6,834,886 across a 4-year period from the CY 2024 reporting period/FY 2026 payment determination through the CY 2027 reporting period/FY 2029 payment determination.
Changes to the PCHQR Program	Across 11 PCHs, we estimate that our changes for the PCHQR Program in this final rule will result in a total information collection burden increase of 187.2 hours at a cost increase of $6,232. We estimate additional costs of $416,815 annually associated with our adoption of the Documentation of Goals of Care Discussions Among Cancer Patients measure beginning with the FY 2026 program year.
Changes to the LTCH QRP	Across 330 LTCHs, we estimate that our changes for the LTCH QRP in this final rule will result in a total information collection burden decrease of 1,292 hours associated with our policies and updated burden estimates and a total cost decrease of approximately $127,421 across the FY 2025 and FY 2026 LTCH QRP program years.
Changes to the Medicare Promoting Interoperability Program	Across 4,500 eligible hospitals and CAHs, we estimate that our changes for the Medicare Promoting Interoperability Program in this final rule would not result in a change to the information collection burden for the CY 2024 EHR Reporting Period and subsequent years. We estimate additional annual costs associated with our finalized modification to the SAFER Guides measure to range from a minimum of $8,916,278 to a maximum of $108,976,725 beginning with the CY 2024 EHR Reporting Period.

B. Background Summary

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

Section 1886(d) of the Act sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Section 1886(g) of the Act requires the Secretary to use a prospective payment system (PPS) to pay for the capital-related costs of inpatient hospital services for these ''subsection (d) hospitals.'' Under these PPSs, Medicare payment for hospital inpatient operating and capital-related costs is made at predetermined, specific rates for each hospital discharge. Discharges are classified according to a list of diagnosis-related groups (DRGs).

The base payment rate is comprised of a standardized amount that is divided into a labor-related share and a nonlabor-related share. The labor-related share is adjusted by the wage index applicable to the area where the hospital is located. If the hospital is located in Alaska or Hawaii, the nonlabor-related share is adjusted by a cost-of-living adjustment factor. This base payment rate is multiplied by the DRG relative weight.

If the hospital treats a high percentage of certain low-income patients, it receives a percentage add-on payment applied to the DRG-adjusted base payment rate. This add-on payment, known as the disproportionate share hospital (DSH) adjustment, provides for a percentage increase in Medicare payments to hospitals that qualify under either of two statutory formulas designed to identify hospitals that serve a disproportionate share of low-income patients. For qualifying hospitals, the amount of this adjustment varies based on the outcome of the statutory calculations. The Affordable Care Act revised the Medicare DSH payment methodology and provides for an additional Medicare payment beginning on October 1, 2013, that considers the amount of uncompensated care furnished by the hospital relative to all other qualifying hospitals.

If the hospital is training residents in an approved residency program(s), it receives a percentage add-on payment for each case paid under the IPPS, known as the indirect medical education (IME) adjustment. This percentage varies, depending on the ratio of residents to beds.

Additional payments may be made for cases that involve new technologies or medical services that have been approved for special add-on payments. In general, to qualify, a new technology or medical service must demonstrate that it is a substantial clinical improvement over technologies or services otherwise available, and that, absent an add-on payment, it would be inadequately paid under the regular DRG payment. In addition, certain transformative new devices and certain antimicrobial products may qualify under an alternative inpatient new technology add-on payment pathway by demonstrating that, absent an add-on payment, they would be inadequately paid under the regular DRG payment.

The costs incurred by the hospital for a case are evaluated to determine whether the hospital is eligible for an additional payment as an outlier case. This additional payment is designed to protect the hospital from large financial losses due to unusually expensive cases. Any eligible outlier payment is added to the DRG-adjusted base payment rate, plus any DSH, IME, and new technology or medical service add-on adjustments and, beginning in FY 2023 for IHS and Tribal hospitals and hospitals located in Puerto Rico, the new supplemental payment.

Although payments to most hospitals under the IPPS are made on the basis of the standardized amounts, some categories of hospitals are paid in whole or in part based on their hospital-specific rate, which is determined from their costs in a base year. For example, sole community hospitals (SCHs) receive the higher of a hospital-specific rate based on their costs in a base year (the highest of FY 1982, FY 1987, FY 1996, or FY 2006) or the IPPS Federal rate based on the standardized amount. SCHs are the sole source of care in their areas. Specifically, section 1886(d)(5)(D)(iii) of the Act defines an SCH as a hospital that is located more than 35 road miles from another hospital or that, by reason of factors such as an isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of hospital inpatient services reasonably available to Medicare beneficiaries. In addition, certain rural hospitals previously designated by the Secretary as essential access community hospitals are considered SCHs.

Under current law, the Medicare-dependent, small rural hospital (MDH) program is effective through FY 2024. For discharges occurring on or after October 1, 2007, but before October 1, 2024, an MDH receives the higher of the Federal rate or the Federal rate plus 75 percent of the amount by which the Federal rate is exceeded by the highest of its FY 1982, FY 1987, or FY 2002 hospital-specific rate. MDHs are a major source of care for Medicare beneficiaries in their areas. Section 1886(d)(5)(G)(iv) of the Act defines an MDH as a hospital that is located in a rural area (or, as amended by the Bipartisan Budget Act of 2018, a hospital located in a State with no rural area that meets certain statutory criteria), has not more than 100 beds, is not an SCH, and has a high percentage of Medicare discharges (not less than 60 percent of its inpatient days or discharges in its cost reporting year beginning in FY 1987 or in two of its three most recently settled Medicare cost reporting years).

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient hospital services in accordance with a prospective payment system established by the Secretary. The basic methodology for determining capital prospective payments is set forth in our regulations at 42 CFR 412.308 and 412.312. Under the capital IPPS, payments are adjusted by the same DRG for the case as they are under the operating IPPS. Capital IPPS payments are also adjusted for IME and DSH, similar to the adjustments made under the operating IPPS. In addition, hospitals may receive outlier payments for those cases that have unusually high costs.

The existing regulations governing payments to hospitals under the IPPS are located in 42 CFR part 412, subparts A through M.

2. Hospitals and Hospital Units Excluded From the IPPS

Under section 1886(d)(1)(B) of the Act, as amended, certain hospitals and hospital units are excluded from the IPPS. These hospitals and units are: Inpatient rehabilitation facility (IRF) hospitals and units; long-term care hospitals (LTCHs); psychiatric hospitals and units; children's hospitals; cancer hospitals; extended neoplastic disease care hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa). Religious nonmedical health care institutions (RNHCIs) are also excluded from the IPPS. Various sections of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33), the Medicare, Medicaid and SCHIP [State Children's Health Insurance Program] Balanced Budget Refinement Act of 1999 (BBRA, Pub. L. 106–113), and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA, Pub. L. 106–554) provide for the implementation of PPSs for IRF hospitals and units, LTCHs, and

psychiatric hospitals and units (referred to as inpatient psychiatric facilities (IPFs)). (We note that the annual updates to the LTCH PPS are included along with the IPPS annual update in this document. Updates to the IRF PPS and IPF PPS are issued as separate documents.) Children's hospitals, cancer hospitals, hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa), and RNHCIs continue to be paid solely under a reasonable cost-based system, subject to a rate-of-increase ceiling on inpatient operating costs. Similarly, extended neoplastic disease care hospitals are paid on a reasonable cost basis, subject to a rate-of-increase ceiling on inpatient operating costs.

The existing regulations governing payments to excluded hospitals and hospital units are located in 42 CFR parts 412 and 413.

3. Long-Term Care Hospital Prospective Payment System (LTCH PPS)

The Medicare prospective payment system (PPS) for LTCHs applies to hospitals described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002. The LTCH PPS was established under the authority of sections 123 of the BBRA and section 307(b) of the BIPA (as codified under section 1886(m)(1) of the Act). Section 1206(a) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) established the site neutral payment rate under the LTCH PPS, which made the LTCH PPS a dual rate payment system beginning in FY 2016. Under this statute, effective for LTCH's cost reporting periods beginning in FY 2016 cost reporting period, LTCHs are generally paid for discharges at the site neutral payment rate unless the discharge meets the patient criteria for payment at the LTCH PPS standard Federal payment rate. The existing regulations governing payment under the LTCH PPS are located in 42 CFR part 412, subpart O. Beginning October 1, 2009, we issue the annual updates to the LTCH PPS in the same documents that update the IPPS.

4. Critical Access Hospitals (CAHs)

Under sections 1814(l), 1820, and 1834(g) of the Act, payments made to critical access hospitals (CAHs) (that is, rural hospitals or facilities that meet certain statutory requirements) for inpatient and outpatient services are generally based on 101 percent of reasonable cost. Reasonable cost is determined under the provisions of section 1861(v) of the Act and existing regulations under 42 CFR part 413.

5. Payments for Graduate Medical Education (GME)

Under section 1886(a)(4) of the Act, costs of approved educational activities are excluded from the operating costs of inpatient hospital services. Hospitals with approved graduate medical education (GME) programs are paid for the direct costs of GME in accordance with section 1886(h) of the Act. The amount of payment for direct GME (DGME) costs for a cost reporting period is based on the hospital's number of residents in that period and the hospital's costs per resident in a base year. The existing regulations governing payments to the various types of hospitals are located in 42 CFR part 413. Section 1886(d)(5)(B) of the Act provides that prospective payment hospitals that have residents in an approved GME program receive an additional payment for each Medicare discharge to reflect the higher patient care costs of teaching hospitals relative to non-teaching hospitals. The additional payment is based on the indirect medical education (IME) adjustment factor, which is calculated using a hospital's ratio of residents to beds and a multiplier, which is set by Congress. Section 1886(d)(5)(B)(ii)(XII) of the Act provides that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. The regulations regarding the indirect medical education (IME) adjustment are located at 42 CFR 412.105.

C. Summary of Provisions of Recent Legislation That Will Be Implemented in This Final Rule

1. The Consolidated Appropriations Act, 2023 (CAA 2023; Pub. L. 117–328)

Section 4101 of the CAA 2023 extended through FY 2024 the modified definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals in effect for FYs 2019 through 2022. Specifically, under section 1886(d)(12)(C)(i) of the Act, as amended, for FYs 2019 through 2024, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 3,800 total discharges during the fiscal year. Under section 1886(d)(12)(D) of the Act, as amended, for discharges occurring in FYs 2019 through 2024, the Secretary determines the applicable percentage increase using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges to a zero percent additional payment for low-volume hospitals with more than 3,800 discharges in the fiscal year.

Section 4102 of the CAA 2023 amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to provide for an extension of the MDH program through FY 2024.

Section 4143 of the CAA 2023 amended section 1886(l)(2)(B) of the Act to specify that for portions of cost reporting periods occurring in each of calendar years (CYs) 2010 through 2019, the $60 million payment limit specified in that subparagraph is not to apply to the total amount of additional payments for nursing and allied health education to be distributed to hospitals that, as of December 29, 2022, were operating a school of nursing, a school of allied health, or a school of nursing and allied health. In addition, section 4143 of the CAA 2023 provides that in addition to not applying the $60 million limit for each of years 2010 through 2019, the Secretary shall not reduce direct GME payments by such additional payment amounts for such nursing and allied health education for portions of cost reporting periods occurring in the year.

D. Issuance of the Notices of Proposed Rulemaking and Summary of the Proposed Provisions

1. FY 2024 IPPS/LTCH PPS Proposed Rule

In the proposed rule that appeared in the **Federal Register** on May 1, 2023 (88 FR 26658), we set forth proposed payment and policy changes to the Medicare IPPS for FY 2024 operating costs and capital-related costs of acute care hospitals and certain hospitals and hospital units that are excluded from IPPS. In addition, we set forth proposed changes to the payment rates, factors, and other payment and policy-related changes to programs associated with payment rate policies under the LTCH PPS for FY 2024.

The following is a general summary of the changes that we proposed to make.

a. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of the proposed rule, we included the following:

- Proposed changes to MS–DRG classifications based on our yearly review for FY 2024.
- Proposed recalibration of the MS–DRG relative weights.
- A discussion of the proposed FY 2024 status of new technologies

approved for add-on payments for FY 2023, a presentation of our evaluation and analysis of the FY 2024 applicants for add-on payments for high-cost new medical services and technologies (including public input, as directed by Pub. L. 108–173, obtained in a town hall meeting) for applications not submitted under an alternative pathway, and a discussion of the proposed status of FY 2024 new technology applicants under the alternative pathways for certain medical devices and certain antimicrobial products.

- Proposed modifications to the new technology add-on payment application eligibility requirements for technologies that are not already Food and Drug Administration (FDA) market authorized to require such applicants to have a complete and active FDA market authorization request at the time of new technology add-on payment application submission, to provide documentation of FDA acceptance or filing, and to move the deadline for FDA marketing authorization from July 1 to May 1 of the year before the fiscal year for which the applicant applied for new technology add-on payments, beginning with applications for FY 2025 (as discussed in section II.E.9. of the preamble of the proposed rule).

b. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble of the proposed rule, we proposed revisions to the wage index for acute care hospitals and the annual update of the wage data. Specific issues addressed include, but are not limited to, the following:

- The proposed FY 2024 wage index update using wage data from cost reporting periods beginning in FY 2019.
- Calculation, analysis, and implementation of the proposed occupational mix adjustment to the wage index for acute care hospitals for FY 2024 based on the 2019 Occupational Mix Survey.
- Proposed application of the rural, imputed and frontier State floors, and continuation of the low wage index hospital policy.
- Proposed revisions to the wage index for acute care hospitals, based on hospital redesignations and reclassifications under sections 1886(d)(8)(B), (d)(8)(E), and (d)(10) of the Act.
- Proposed adjustment to the wage index for acute care hospitals for FY 2024 based on commuting patterns of hospital employees who reside in a county and work in a different area with a higher wage index.
- Proposed labor-related share for the proposed FY 2024 wage index.

c. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2024

In section IV. of the preamble of the proposed rule, we discuss the following:

- Proposed calculation of Factor 1 and Factor 2 of the uncompensated care payment methodology.
- Proposed methodological approach for determining the additional payments for uncompensated care for FY 2024, which is the same overall approach as was for FY 2023.

d. Other Decisions and Proposed Changes to the IPPS for Operating Costs

In section V. of the preamble of the proposed rule, we discuss proposed changes or clarifications of a number of the provisions of the regulations in 42 CFR parts 412 and 413, including the following:

- Proposed inpatient hospital update for FY 2024.
- Proposed change related to the effective date of sole community hospital (SCH) classification in cases that involve a merger.
- Proposed updated national and regional case-mix values and discharges for purposes of determining RRC status.
- Proposed payment adjustment for low-volume hospitals for FY 2024.
- Discussion of statutory extension of the MDH program through FY 2024.
- Proposed to establish a validation reconsideration process and update the data validation targeting criteria under the HAC Reduction Program for FY 2024.
- Proposed to update the MSPB Hospital and THA/TKA Complications measures, to adopt the new Severe Sepsis and Septic Shock: Management Bundle measure, to update the changes to the data collection and submission requirements for the HCAHPS Survey measure, to revise the scoring methodology to include a health equity scoring adjustment, to modify the Total Performance Score numeric score range to be 0–110, and to codify the measure removal factors, the revised scoring methodology and TPS numeric score range, and the minimum numbers of cases.
- Proposed changes to the regulations for GME payments when training occurs in REHs.
- Discussion of and proposed changes relating to the implementation of the Rural Community Hospital Demonstration Program in FY 2024.
- Proposed nursing and allied health education program Medicare Advantage (MA) add-on rates and direct GME MA percent reductions for CY 2022.
- Proposal to implement section 4143 of the CAA 2023 which waives the $60 million limit on annual nursing and allied health education program MA payments.
- Proposed update to the payment adjustment for certain clinical trial and expanded access use immunotherapy cases.

e. Proposed FY 2024 Policy Governing the IPPS for Capital-Related Costs

In section VI. of the preamble of the proposed rule, we discuss the proposed payment policy requirements for capital-related costs and capital payments to hospitals for FY 2024. In addition, we discuss a proposed change to how hospitals with a rural reclassification are treated for capital DSH payments.

f. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VII. of the preamble of the proposed rule, we discuss the following:

- Proposed changes to payments to certain excluded hospitals for FY 2024.
- Proposed continued implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration.

g. Proposed Changes to the LTCH PPS

In section VIII. of the preamble of the proposed rule, we set forth proposed changes to the LTCH PPS Federal payment rates, factors, and other payment rate policies under the LTCH PPS for FY 2024.

h. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section IX. of the preamble of the proposed rule, we addressed the following:

- Proposed adoption of a modified version of the COVID–19 Vaccination Coverage among Healthcare Personnel Measure in the Hospital IQR Program, PCHQR Program, and LTCH QRP.
- Proposed requirements for the Hospital Inpatient Quality Reporting (IQR) Program.
- Proposed changes to the requirements for the PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR Program).
- Proposed changes to the requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP), and a request for information on principles for selecting and prioritizing LTCH QRP quality measures and concepts under consideration for future years. We also provide an update on health equity.
- Proposed changes to requirements pertaining to eligible hospitals and

CAHs participating in the Medicare Promoting Interoperability Program.

i. Other Proposals and Comment Solicitations Included in the Proposed Rule

Section X. of the preamble of the proposed rule included the following:

- Proposals to establish requirements for additional information that an eligible facility would be required to submit when applying for enrollment as an REH.
- Proposed changes pertaining to the process for hospitals requesting an exception from the prohibition against facility expansion and program integrity restrictions on approved facility expansion.
- Solicitation of comments on potential approaches to address the challenges faced by safety-net hospitals, including an appropriate mechanism for identifying safety-net hospitals for Medicare policy purposes.
- Proposals to apply certain definitions included in the Disclosures of Ownership and Additional Disclosable Parties Information for Skilled Nursing Facilities proposed rule published in the February 15, 2023 **Federal Register** (88 FR 9820) to all provider types that complete the Form CMS–855–A enrollment application.

j. Other Provisions of the Proposed Rule

Section XI.A. of the preamble of the proposed rule includes our discussion of the MedPAC Recommendations.

Section XI.B. of the preamble of the proposed rule includes a descriptive listing of the public use files associated with the proposed rule.

Section XII. of the preamble of the proposed rule includes the collection of information requirements for entities based on our proposals.

Section XIII. of the preamble of the proposed rule includes information regarding our responses to public comments.

k. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In sections II. and III. of the Addendum of the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2024 prospective payment rates for operating costs and capital-related costs for acute care hospitals. We proposed to establish the threshold amounts for outlier cases. In addition, in section IV. of the Addendum of the proposed rule, we address the proposed update factors for determining the rate-of-increase limits for cost reporting periods beginning in FY 2024 for certain hospitals excluded from the IPPS.

l. Determining Prospective Payment Rates for LTCHs

In section V. of the Addendum of the proposed rule, we set forth proposed changes to the amounts and factors for determining the proposed FY 2024 LTCH PPS standard Federal payment rate and other factors used to determine LTCH PPS payments under both the LTCH PPS standard Federal payment rate and the site neutral payment rate in FY 2024. We are proposing to establish the adjustments for the wage index, labor-related share, the cost-of-living adjustment, and high-cost outliers, including the applicable fixed-loss amounts and the LTCH cost-to-charge ratios (CCRs) for both payment rates.

m. Impact Analysis

In appendix A of the proposed rule, we set forth an analysis of the impact the proposed changes would have on affected acute care hospitals, CAHs, LTCHs and other entities.

n. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In appendix B of the proposed rule, as required by sections 1886(e)(4) and (e)(5) of the Act, we provide our recommendations of the appropriate percentage changes for FY 2024 for the following:

- A single average standardized amount for all areas for hospital inpatient services paid under the IPPS for operating costs of acute care hospitals (and hospital-specific rates applicable to SCHs and MDHs).
- Target rate-of-increase limits to the allowable operating costs of hospital inpatient services furnished by certain hospitals excluded from the IPPS.
- The LTCH PPS standard Federal payment rate and the site neutral payment rate for hospital inpatient services provided for LTCH PPS discharges.

o. Discussion of Medicare Payment Advisory Commission Recommendations

Under section 1805(b) of the Act, MedPAC is required to submit a report to Congress, no later than March 15 of each year, in which MedPAC reviews and makes recommendations on Medicare payment policies. MedPAC's March 2023 recommendations concerning hospital inpatient payment policies address the update factor for hospital inpatient operating costs and capital-related costs for hospitals under the IPPS. We address these recommendations in appendix B of the proposed rule. For further information relating specifically to the MedPAC March 2023 report or to obtain a copy of the report, contact MedPAC at (202) 220–3700 or visit MedPAC's website at *https://www.medpac.gov.*

2. Section 1115 Demonstration Disproportionate Share Hospital Proposed Rule

In addition, in the proposed rule that appeared in the **Federal Register** on February 28, 2023 (88 FR 12623), we set forth proposed revisions to the regulations on the counting of days associated with individuals eligible for certain benefits provided by section 1115 demonstrations in the Medicaid fraction of a hospital's disproportionate patient percentage for the purposes of determining Medicare DSH payments to subsection (d) hospitals under section 1886(d)(5)(F) of the Act. Specifically, we proposed for purposes of the Medicare DSH calculation in section 1886(d)(5)(F)(vi) of the Act to ''regard as'' ''eligible for medical assistance under a State plan approved under title XIX'' patients who (1) receive health insurance authorized by a section 1115 demonstration or (2) buy health insurance with premium assistance provided to them under a section 1115 demonstration, where State expenditures to provide the health insurance or premium assistance is matched with funds from title XIX. Furthermore, of these expansion groups we proposed to regard as eligible for Medicaid, we proposed to include in the disproportionate patient percentage (DPP) Medicaid fraction numerator only the days of those patients who receive from the demonstration (1) health insurance that covers inpatient hospital services or (2) premium assistance that covers 100 percent of the premium cost to the patient, which the patient uses to buy health insurance that covers inpatient hospital services, provided in either case that the patient is not also entitled to Medicare Part A. Finally, we proposed specifically that patients whose inpatient hospital costs are paid for with funds from an uncompensated/undercompensated care pool authorized by a section 1115 demonstration would not be patients ''regarded as'' eligible for Medicaid, and the days of such patients may not be included in the DPP Medicaid fraction numerator.

E. Use of the Best Available Data for the FY 2024 IPPS and LTCH PPS Ratesetting

We primarily use two data sources in the IPPS and LTCH PPS ratesetting: claims data and cost report data. The

claims data source is the Medicare Provider Analysis and Review (MedPAR) file, which includes fully coded diagnostic and procedure data for all Medicare inpatient hospital bills for discharges in a fiscal year. The cost report data source is the Medicare hospital cost report data files from the most recent quarterly Healthcare Cost Report Information System (HCRIS) release. Our goal is always to use the best available data overall for ratesetting. Ordinarily, the best available MedPAR data is the most recent MedPAR file that contains claims from discharges for the fiscal year that is 2 years prior to the fiscal year that is the subject of the rulemaking. Ordinarily, the best available cost report data is based on the cost reports beginning 3 fiscal years prior to the fiscal year that is the subject of the rulemaking. However, due to the impact of the COVID–19 public health emergency (PHE) on our ordinary ratesetting data, we finalized modifications to our usual ratesetting procedures in the FY 2022 and FY 2023 IPPS/LTCH PPS final rules.

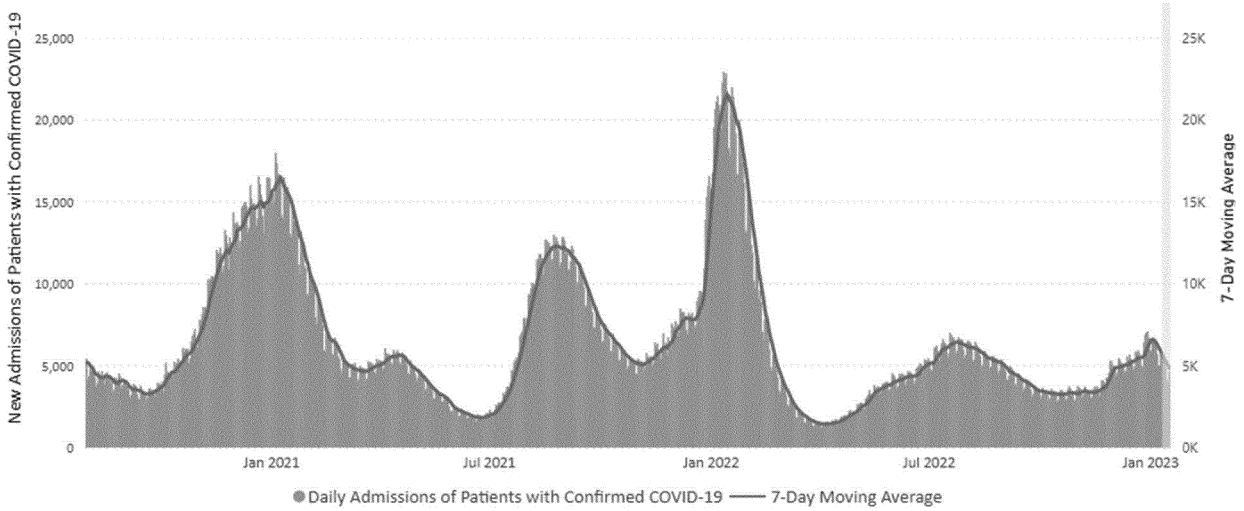
In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44789 through 44793), we discussed that the FY 2020 MedPAR claims file and the FY 2019 HCRIS dataset (the most recently available data at the time of rulemaking) both contained data that was significantly impacted by the COVID–19 PHE, primarily in that the utilization of services at IPPS hospitals and LTCHs was generally markedly different for certain types of services in FY 2020 than would have been expected in the absence of the PHE. We stated that the most recent vaccination and hospitalization data from the Centers for Disease Control and Prevention (CDC) available at the time of development of that rule supported our belief at the time that the risk of COVID–19 in FY 2022 would be significantly lower than the risk of COVID–19 in FY 2020 and there would be fewer COVID–19 hospitalizations for Medicare beneficiaries in FY 2022 than there were in FY 2020. Therefore, we finalized our proposal to use FY 2019 data for the FY 2022 ratesetting for circumstances where the FY 2020 data was significantly impacted by the COVID–19 PHE, based on the belief that FY 2019 data from before the COVID–19 PHE would be a better overall approximation of the FY 2022 inpatient experience at both IPPS hospitals and LTCHs.

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48795 through 48798), we discussed that the FY 2021 MedPAR claims file and the FY 2020 HCRIS dataset (the most recently available data at the time of rulemaking) both contain data that was significantly impacted by the COVID–19 PHE, primarily in that the utilization of services at IPPS hospitals and LTCHs was again generally markedly different for certain types of services in FY 2021 than would have been expected in the absence of the virus that causes COVID–19. Based on review of the most recent hospitalization data and information available from the CDC at the time of development of that rule, we stated our belief that it was reasonable to assume that some Medicare beneficiaries would continue to be hospitalized with COVID–19 at IPPS hospitals and LTCHs in FY 2023. However, we also stated our belief that it would be reasonable to assume based on the information available at the time that there would be fewer COVID–19 hospitalizations in FY 2023 than in FY 2021. Accordingly, because we anticipated Medicare inpatient hospitalizations for COVID–19 would continue in FY 2023 but at a lower level, we finalized our proposal to use FY 2021 data for purposes of the FY 2023 IPPS and LTCH PPS ratesetting but with several modifications to our usual ratesetting methodologies to account for the anticipated decline in COVID–19 hospitalizations of Medicare beneficiaries at IPPS hospitals and LTCHs as compared to FY 2021.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26671), we analyzed the FY 2022 MedPAR claims file and the FY 2021 HCRIS dataset, which are the most recently available data for FY 2024 ratesetting. We observed that certain shifts in inpatient utilization and costs that occurred in FY 2020 continued to persist in FY 2022. Specifically, the share of admissions at IPPS hospitals and LTCHs for MS–DRGs and MS–LTC–DRGs that are associated with the treatment of COVID–19 continued to remain at levels higher than those observed in the pre-pandemic data.

For example, in FY 2019, the share of IPPS cases grouped to MS–DRG 177 (Respiratory Infections and Inflammations with major complication or comorbidity (MCC)) was approximately 1 percent, while in FY 2022 the share of IPPS cases grouped to MS–DRG 177 was approximately 4 percent. Similarly, in FY 2019, the share of LTCH PPS standard Federal payment rate cases grouped to MS–LTC–DRG 207 (Respiratory System Diagnosis with Ventilator Support >96 Hours) was approximately 18 percent, while in FY 2022 the share of LTCH PPS standard Federal payment rate cases grouped to MS–LTC–DRG 207 was approximately 22 percent.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26671), we also reviewed the most recent COVID–19 related data and information released by the CDC. We presented this CDC graph which illustrates new inpatient hospital admissions of patients with confirmed COVID–19 from August 1, 2020 through January 20, 2023. (*https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/01202023/images/hospitalizations.PNG?_=24630,* accessed January 20, 2023).



We stated that the graph shows that in the United States, patients continue to be hospitalized with the virus that causes COVID–19. We also noted that the CDC has stated that new variants will continue to emerge. Viruses constantly change through mutation and sometimes these mutations result in a new variant of the virus. Some variants spread more easily and quickly than other variants, which may lead to more cases of COVID–19. Even if a variant causes less severe disease in general, an increase in the overall number of cases could cause an increase in hospitalizations.[2] In the proposed rule, we concluded that based on the information available at the time, we believe there will continue to be COVID–19 cases treated at IPPS hospitals and LTCHs in FY 2024, such that it is appropriate to use the FY 2022 data, as the most recent available data, for purposes of the FY 2024 IPPS and LTCH PPS ratesetting. We also stated that based on the information available at the time, we do not believe there is a reasonable basis for us to assume that there will be a meaningful difference in the number of COVID–19 cases treated at IPPS hospitals and LTCHs in FY 2024 relative to FY 2022 to the extent that modifications to our usual ratesetting methodologies would be warranted.

As such, we stated our belief that FY 2022 data, as the most recent available data, is the best available data for approximating the inpatient experience at IPPS hospitals and LTCHs in FY 2024. Therefore, we proposed to use the FY 2022 MedPAR claims file and the FY 2021 HCRIS dataset (which contains data from many cost reports ending in FY 2022 based on each hospital's cost reporting period) for purposes of the FY 2024 IPPS and LTCH PPS ratesetting. For the reasons discussed, we did not propose any modifications to our usual ratesetting methodologies to account for the impact of COVID–19 on the ratesetting data.

The comments we received on our proposal to use FY 2022 data for purposes of the FY 2024 IPPS and LTCH PPS ratesetting were focused on the specific use of FY 2022 data when determining the FY 2024 outlier fixed-loss amounts. Therefore, we refer the reader to section II.A.4. of the addendum to this final rule for our summary and response to comments received on our proposal to use FY 2022 data and our usual methodology when determining the FY 2024 outlier fixed-loss amounts for IPPS cases. We refer the reader to section V.D.3. of the Addendum to this final rule for our summary and response to comments received on our proposal to use FY 2022 data and our usual methodology when determining the FY 2024 outlier fixed-loss amounts for LTCH PPS standard Federal payment rate cases.

For the reasons discussed in those sections, we are finalizing our proposal to use FY 2022 data for purposes of the FY 2024 IPPS and LTCH PPS ratesetting. (That is, the FY 2022 MedPAR claims file and the FY 2021 HCRIS dataset (which contains data from many cost reports ending in FY 2022 based on each hospital's cost reporting period).) We also are finalizing, with modification, our proposal to use our usual ratesetting methodologies for purposes of the FY 2024 IPPS and LTCH PPS ratesetting. As discussed in section V.D.3. of the addendum to this final rule, after consideration of the comments received, we are modifying our proposed methodology for establishing the FY 2024 outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases.

F. Potential Payment Under the IPPS for Establishing and Maintaining Access to Essential Medicines

In the CY 2024 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Proposed Rule (CMS 1786–P) issued on July 13, 2023, we included a request for public comments on potential payment under the IPPS for establishing and maintaining access to essential medicines. As discussed in that rule, we are seeking comment on, and may consider finalizing based on the review of comments received, as early as for cost reporting periods beginning on or after January 1, 2024, separate payment under IPPS, for establishing and maintaining access to a buffer stock of essential medicines to foster a more reliable, resilient supply of these medicines. Public comments are being accepted through September 11, 2023.

II. Changes to Medicare Severity Diagnosis-Related Group (MS–DRG) Classifications and Relative Weights

A. Background

Section 1886(d) of the Act specifies that the Secretary shall establish a classification system (referred to as diagnosis-related groups (DRGs)) for inpatient discharges and adjust payments under the IPPS based on appropriate weighting factors assigned to each DRG. Therefore, under the IPPS, Medicare pays for inpatient hospital services on a rate per discharge basis that varies according to the DRG to which a beneficiary's stay is assigned. The formula used to calculate payment for a specific case multiplies an

[2] *https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html*, accessed January 20, 2023.

individual hospital's payment rate per case by the weight of the DRG to which the case is assigned. Each DRG weight represents the average resources required to care for cases in that particular DRG, relative to the average resources used to treat cases in all DRGs.

Section 1886(d)(4)(C) of the Act requires that the Secretary adjust the DRG classifications and relative weights at least annually to account for changes in resource consumption. These adjustments are made to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources.

B. Adoption of the MS–DRGs and MS–DRG Reclassifications

For information on the adoption of the MS–DRGs in FY 2008, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47140 through 47189).

For general information about the MS–DRG system, including yearly reviews and changes to the MS–DRGs, we refer readers to the previous discussions in the FY 2010 IPPS/rate year (RY) 2010 LTCH PPS final rule (74 FR 43764 through 43766) and the FYs 2011 through 2023 IPPS/LTCH PPS final rules (75 FR 50053 through 50055; 76 FR 51485 through 51487; 77 FR 53273; 78 FR 50512; 79 FR 49871; 80 FR 49342; 81 FR 56787 through 56872; 82 FR 38010 through 38085; 83 FR 41158 through 41258; 84 FR 42058 through 42165; 85 FR 58445 through 58596; 86 FR 44795 through 44961; and 87 FR 48800 through 48891, respectively).

For discussion regarding our previously finalized policies (including our historical adjustments to the payment rates) relating to the effect of changes in documentation and coding that do not reflect real changes in case mix, we refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 48799 through 48800).

Comment: Several commenters requested that CMS make a positive adjustment to restore the full amount of the documentation and coding recoupment adjustments in the FY 2024 IPPS final rule which they asserted is required under section (7)(B)(2) and (4) of the TMA [Transitional Medical Assistance], Abstinence Education, and QI [Qualifying Individuals] Programs Extension Act of 2007 (Pub. L. 110–90). Commenters stated that the statute is explicit that CMS may not carry forward any documentation and coding adjustments applied in fiscal years 2010 through 2017 into IPPS rates after FY 2023. Commenters contended that CMS, by its own admission, has restored only 2.9588 percentage points of a total 3.9 percentage point reduction. By not fully restoring the total reductions, commenters believe that CMS is improperly extending payment adjustments beyond the FY 2023 statutory limit. A commenter stated that, even if CMS disputes it is required to make such an adjustment, CMS should use its special exceptions and adjustments authority to address the shortfall.

Response: As of FY 2023, CMS completed the statutory requirements of section 7(b)(1)(B) of Pub. L. 110–90 as amended by section 631 of the American Taxpayer Relief Act of 2012 (ATRA, Pub. L. 112– 240), section 404 of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), and section 15005 of the 21st Century Cures Act (Pub. L. 114–255). As we discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44794 through 44795), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58444 through 58445) and in prior rules, we believe section 414 of the MACRA and section 15005 of the 21st Century Cures Act set forth the levels of positive adjustments for FYs 2018 through 2023. We are not convinced that the adjustments prescribed by MACRA were predicated on a specific adjustment level estimated or implemented by CMS in previous rulemaking. We see no evidence that Congress enacted these adjustments with the intent that CMS would make an additional +0.7 percentage point adjustment in FY 2018 to compensate for the higher than expected final ATRA adjustment made in FY 2017, nor are we persuaded that it would be appropriate to use the Secretary's exceptions and adjustments authority under section 1886(d)(5)(I) of the Act to adjust payments in FY 2024 restore any additional amount of the original 3.9 percentage point reduction, given Congress' directive regarding prescriptive adjustment levels under section 414 of the MACRA and section 15005 of the 21st Century Cures Act. Accordingly, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38009), we implemented the required +0.4588 percentage point adjustment to the standardized amount for FY 2018. In the FY 2019 IPPS/LTCH PPS final rule (FY 2019 final rule) (83 FR 41157), the FY 2020 IPPS/LTCH PPS final rule (FY 2020 final rule) (84 FR 42057), the FY 2021 IPPS/LTCH PPS final rule (FY 2021 final rule) (85 FR 58444 and 58445), the FY 2022 IPPS/LTCH PPS final rule (FY 2022 final rule) (86 FR 44794 and 44795), and the FY 2023 IPPS/LTCH PPS final rule (FY 2023 final rule) (87 FR 48800), consistent with the requirements of section 414 of the MACRA, we implemented 0.5 percentage point positive adjustments to the standardized amount for FY 2019, FY 2020, FY 2021, FY 2022 and FY 2023, respectively. As discussed in the FY 2023 final rule, the finalized 0.5 percentage point positive adjustment for FY 2023 is the final adjustment prescribed by section 414 of the MACRA.

C. Changes to Specific MS–DRG Classifications

1. Discussion of Changes to Coding System and Basis for FY 2024 MS–DRG Updates

a. Conversion of MS–DRGs to the International Classification of Diseases, 10th Revision (ICD–10)

As of October 1, 2015, providers use the International Classification of Diseases, 10th Revision (ICD–10) coding system to report diagnoses and procedures for Medicare hospital inpatient services under the MS–DRG system instead of the ICD–9–CM coding system, which was used through September 30, 2015. The ICD–10 coding system includes the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, as well as the ICD–10–CM and ICD–10–PCS Official Guidelines for Coding and Reporting. For a detailed discussion of the conversion of the MS–DRGs to ICD–10, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56789).

b. Basis for FY 2024 MS–DRG Updates

As discussed in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28127) and final rule (87 FR 48800 through 48801), beginning with FY 2024 MS–DRG classification change requests, we changed the deadline to request changes to the MS–DRGs to October 20 of each year to allow for additional time for the review and consideration of any proposed updates. We also described the new process for submitting requested changes to the MS–DRGs via a new electronic application intake system, Medicare Electronic Application Request Information System™ (MEARIS™), accessed at *https://mearis.cms.gov.* We stated that beginning with FY 2024 MS–DRG classification change requests, CMS will only accept requests submitted via MEARIS™ and will no longer consider

requests sent via email. Additionally, we noted that within MEARIS™, we have built in several resources to support users, including a ''Resources'' section available at *https://mearis.cms.gov/public/resources* with technical support available under ''Useful Links'' at the bottom of the MEARIS™ site. Questions regarding the MEARIS™ system can be submitted to CMS using the form available under ''Contact'', also at the bottom of the MEARIS™ site.

We note that the burden associated with this information collection requirement is the time and effort required to collect and submit the data in the request for MS–DRG classification changes to CMS. The aforementioned burden is subject to the Paperwork Reduction Act (PRA) of 1995 and approved under Office of Management and Budget (OMB) control number 0938–1431 and has an expiration date of 09/30/2025.

As noted previously, interested parties had to submit MS–DRG classification change requests for FY 2024 by October 20, 2022. As we have discussed in prior rulemaking, we may not be able to fully consider all of the requests that we receive for the upcoming fiscal year. We have found that, with the implementation of ICD–10, some types of requested changes to the MS–DRG classifications require more extensive research to identify and analyze all of the data that are relevant to evaluating the potential change. We note in the discussion that follows those topics for which further research and analysis are required, and which we will continue to consider in connection with future rulemaking. Interested parties should submit any comments and suggestions for FY 2025 by October 20, 2023 via MEARIS™ at: *https://mearis.cms.gov/public/home.*

As we did for the FY 2023 IPPS/LTCH PPS proposed rule, for the FY 2024 IPPS/LTCH PPS proposed rule we provided a test version of the ICD–10 MS–DRG GROUPER Software, Version 41, so that the public can better analyze and understand the impact of the proposals included in the proposed rule. We noted that this test software reflected the proposed GROUPER logic for FY 2024. Therefore, it included the new diagnosis and procedure codes that are effective for FY 2024 as reflected in Table 6A.—New Diagnosis Codes—FY 2024 and Table 6B.—New Procedure Codes—FY 2024 that were associated with the proposed rule and does not include the diagnosis codes that are invalid beginning in FY 2024 as reflected in Table 6C.—Invalid Diagnosis Codes—FY 2024 associated with the proposed rule. We noted that at the time of the development of the proposed rule there were no procedure codes designated as invalid for FY 2024, and therefore, there was no Table 6D–Invalid Procedure Codes—FY 2024 associated with the proposed rule. Those tables were not published in the Addendum to the proposed rule, but are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. of the Addendum to the proposed rule. Because the diagnosis codes no longer valid for FY 2024 are not reflected in the test software, we made available a supplemental file in Table 6P.1a that includes the mapped Version 41 FY 2024 ICD–10–CM codes and the deleted Version 40.1 FY 2023 ICD–10–CM codes that should be used for testing purposes with users' available claims data. Therefore, users had access to the test software allowing them to build case examples that reflect the proposals that were included in the proposed rule. In addition, users were able to view the draft version of the ICD–10 MS–DRG Definitions Manual, Version 41.

The test version of the ICD–10 MS–DRG GROUPER Software, Version 41, the draft version of the ICD–10 MS–DRG Definitions Manual, Version 41, and the supplemental mapping files in Table 6P.1a of the FY 2023 and FY 2024 ICD–10–CM diagnosis codes are available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.*

Following are the changes that we proposed to the MS–DRGs for FY 2024. We invited public comments on each of the MS–DRG classification proposed changes, as well as our proposals to maintain certain existing MS–DRG classifications discussed in the proposed rule. In some cases, we proposed changes to the MS–DRG classifications based on our analysis of claims data and clinical appropriateness. In other cases, we proposed to maintain the existing MS–DRG classifications based on our analysis of claims data and clinical appropriateness. As discussed in the FY 2024 IPPS/LTCH PPS proposed rule, our initial MS–DRG analysis was based on ICD–10 claims data from the September 2022 update of the FY 2022 MedPAR file, which contains hospital bills received from October 1, 2021, through September 30, 2022. In our discussion of the proposed MS–DRG reclassification changes, we referred to those claims data as the ''September 2022 update of the FY 2022 MedPAR file.'' Separately, where otherwise indicated, additional analysis was based on ICD–10 claims data from the December 2022 update of the FY 2022 MedPAR file, which contains hospital bills received by CMS through December 31, 2022, for discharges occurring from October 1, 2021, through September 30, 2022. In our discussion of the proposed MS–DRG reclassification changes, we referred to those claims data as the ''December 2022 update of the FY 2022 MedPAR file.'' Specifically, as discussed further in the proposed rule and in this section, we used the additional claims data available in the December 2022 update of the FY 2022 MedPAR file to assess the application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split, as well as to simulate restructuring of any proposed MS–DRGs, to assess the case counts and other criteria for determining whether a proposed new base MS–DRG would satisfy the criteria to create subgroups.

As explained in previous rulemaking (76 FR 51487), in deciding whether to propose to make further modifications to the MS–DRGs for particular circumstances brought to our attention, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients represented in the MS–DRG. We evaluate patient care costs using average costs and lengths of stay and rely on clinical factors to determine whether patients are clinically distinct or similar to other patients represented in the MS–DRG. In evaluating resource costs, we consider both the absolute and percentage differences in average costs between the cases we select for review and the remainder of cases in the MS–DRG. We also consider variation in costs within these groups; that is, whether observed average differences are consistent across patients or attributable to cases that are extreme in terms of costs or length of stay, or both. Further, we consider the number of patients who will have a given set of characteristics and generally prefer not to create a new MS–DRG unless it would include a substantial number of cases.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58448), we finalized our proposal to expand our existing criteria to create a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS–DRG. Specifically, we finalized the expansion of the criteria to include the NonCC subgroup for a three-way severity level split. We stated we

believed that applying these criteria to the NonCC subgroup would better reflect resource stratification as well as promote stability in the relative weights by avoiding low volume counts for the NonCC level MS–DRGs. We noted that in our analysis of MS–DRG classification requests for FY 2021 that were received by November 1, 2019, as well as any additional analyses that were conducted in connection with those requests, we applied these criteria to each of the MCC, CC, and NonCC subgroups. We also noted that the application of the NonCC subgroup criteria going forward may result in modifications to certain MS–DRGs that are currently split into three severity levels and result in MS–DRGs that are split into two severity levels. We stated that any proposed modifications to the MS–DRGs would be addressed in future rulemaking consistent with our annual process and reflected in Table 5.—List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay for the applicable fiscal year.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44798), we finalized a delay in applying this technical criterion to existing MS–DRGs until FY 2023 or future rulemaking, in light of the PHE. Interested parties recommended that a complete analysis of the MS–DRG changes to be proposed for future rulemaking in connection with the expanded three-way severity split criteria be conducted and made available to enable the public an opportunity to review and consider the redistribution of cases, the impact to the relative weights, payment rates, and hospital case mix to allow meaningful comment prior to implementation.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 48803), we also finalized a delay in application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split in light of the ongoing PHE and until such time additional analyses can be performed to assess impacts, as discussed in response to public comments in the FY 2022 and FY 2023 IPPS/LTCH PPS final rules.

In our analysis of the MS–DRG classification requests for FY 2024 that we received by October 20, 2022, as well as any additional analyses that were conducted in connection with those requests, we applied these criteria to each of the MCC, CC, and NonCC subgroups, as described in the following table.

BILLING CODE 4120–01–P

Criteria Number and Description	**Three-Way Split** 123 (MCC vs CC vs NonCC)	**Two-Way Split** 1_23 MCC vs (CC+NonCC)	
1. At least 500 cases in the MCC/CC/NonCC group	500+ cases for MCC group; and 500+ cases for CC group; and 500+ cases for NonCC group	500+ cases for MCC group; and 500+ cases for (CC+NonCC) group	500+ cases for (MCC+CC) group; and 500+ cases for NonCC group
2. At least 5% of the patients are in the MCC/CC/NonCC group	5%+ cases for MCC group; and 5%+ cases for CC group; and 5%+ cases for NonCC group	5%+ cases for MCC group; and 5%+ cases for (CC+NonCC) group	5%+ cases for (MCC+CC) group; and 5%+ cases for NonCC group
3. There is at least a 20% difference in average cost between subgroups	20%+ difference in average cost between MCC group and CC group; and 20%+ difference in average cost between CC group and NonCC group	20%+ difference in average cost between MCC group and (CC+NonCC) group	20%+ difference in average cost between (MCC+ CC) group and NonCC group
4. There is at least a $2,000 difference in average cost between subgroups	$2,000+ difference in average cost between MCC group and CC group; and $2,000+ difference in average cost between CC group and NonCC group	$2,000+ difference in average cost between MCC group and (CC+ NonCC) group	$2,000+ difference in average cost between (MCC+ CC) group and NonCC group
5. The R2 of the split groups is greater than or equal to 3	R2 > 3.0 for the three way split within the base MS-DRG	R2 > 3.0 for the two way 1_23 split within the base MS-DRG	R2 > 3.0 for the two way 12_3 split within the base MS-DRG

In general, once the decision has been made to propose to make further modifications to the MS–DRGs as described previously, such as creating a new base MS–DRG, or in our evaluation of a specific MS–DRG classification request to split (or subdivide) an existing base MS–DRG into severity levels, all five criteria must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. We note that in our analysis of requests to create a new MS–DRG, we typically evaluate the most recent year of MedPAR claims data available. For example, we stated earlier that for the FY 2024 IPPS/LTCH PPS proposed rule, our initial MS–DRG analysis was generally based on ICD–10 claims data from the September 2022 update of the FY 2022 MedPAR file, with the additional claims data

available in the December 2022 update of the FY 2022 MedPAR file used to assess the case counts and other criteria for determining whether a proposed new base MS–DRG would satisfy the criteria to create subgroups. However, in our evaluation of requests to split an existing base MS–DRG into severity levels, as noted in prior rulemaking (80 FR 49368), we typically analyze the most recent two years of data. This analysis includes 2 years of MedPAR claims data to compare the data results from 1 year to the next to avoid making determinations about whether additional severity levels are warranted based on an isolated year's data fluctuation and also, to validate that the established severity levels within a base MS–DRG are supported. The first step in our process of evaluating if the creation of a new CC subgroup within a base MS–DRG is warranted is to determine if all the criteria is satisfied for a three-way split. In applying the criteria for a three-way split, a base MS–DRG is initially subdivided into the three subgroups: MCC, CC, and NonCC. Each subgroup is then analyzed in relation to the other two subgroups using the volume (Criteria 1 and 2), average cost (Criteria 3 and 4), and reduction in variance (Criteria 5). If the criteria fail, the next step is to determine if the criteria are satisfied for a two-way split. In applying the criteria for a two-way split, a base MS–DRG is initially subdivided into two subgroups: ''with MCC'' and ''without MCC'' (1_23) or ''with CC/MCC'' and ''without CC/MCC'' (12_3). Each subgroup is then analyzed in relation to the other using the volume (Criteria 1 and 2), average cost (Criteria 3 and 4), and reduction in variance (Criteria 5). If the criteria for both of the two-way splits fail, then a split (or CC subgroup) would generally not be warranted for that base MS–DRG. If the three-way split fails on any one of the five criteria and all five criteria for both two-way splits (1_23 and 12_3) are met, we would apply the two-way split with the highest R2 value. We note that if the request to split (or subdivide) an existing base MS–DRG into severity levels specifies the request is for either one of the two-way splits (1_23 or 12_3), in response to the specific request, we will evaluate the criteria for both of the two-way splits, however we do not also evaluate the criteria for a three-way split.

As previously noted, to validate whether the established severity levels within a base MS–DRG are supported, we typically analyze the most recent two years of MedPAR claims data. For the FY 2024 IPPS/LTCH PPS proposed rule, using the December 2022 update of the FY 2022 MedPAR file and the March 2022 update of the FY 2021 MedPAR file, we also analyzed how applying the NonCC subgroup criteria to all MS–DRGs currently split into three severity levels would potentially affect the MS–DRG structure in connection with the proposed FY 2024 MS–DRG classification changes. While, as previously noted, our MS–DRG analysis for the FY 2024 IPPS/LTCH PPS proposed rule was otherwise based on ICD–10 claims data from the September 2022 update of the FY 2022 MedPAR file, we utilized the additional claims data available from the December 2022 update of the FY 2022 MedPAR file for purposes of assessing the application of the NonCC subgroup criteria to these existing MS–DRGs as well as to determine whether a proposed new base MS–DRG satisfies the criteria to create subgroups. In the FY 2024 IPPS/LTCH PPS proposed rule, we noted that findings from our analysis indicated that approximately 45 base MS–DRGs would be subject to change based on the three-way severity level split criterion finalized in FY 2021. Specifically, we found that applying the NonCC subgroup criteria to all MS–DRGs currently split into three severity levels would result in the potential deletion of 135 MS–DRGs (45 MS–DRGs × 3 severity levels =135) and the potential creation of 86 new MS–DRGs. We referred the reader to Table 6P.10—Potential MS–DRG Changes with Application of the NonCC Subgroup Criteria and Detailed Data Analysis- FY 2024 associated with the proposed rule and available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* for detailed information, including the criteria to create subgroups in Table 6P.10a (as also set forth in the preceding table) and the list of the 135 MS–DRGs that would potentially be subject to deletion and the list of the 86 MS–DRGs that would potentially be created in Table 6P.10b. We noted that we also identified an additional 12 obstetric MS–DRGs (4 base MS–DRGs × 3 severity levels=12) that would be subject to change based on the application of the three-way severity level split criterion, as reflected in our data analysis in Table 6P.10c associated with the proposed rule. However, in response to prior public comments expressing concern about the historical low volume of the obstetric related MS–DRGs being subject to application of the NonCC subgroup criteria and consistent with our discussion in prior rulemaking regarding this population in our Medicare claims data and the development of these MS–DRGs (83 FR 41210), we stated we believed it may be appropriate to exclude these MS–DRGs from application of the NonCC subgroup criteria. The list of 12 obstetric MS–DRGs is shown in the following table.

List of 12 Obstetric MS-DRGs to Potentially Exclude from Application of the NonCC Subgroup Criteria

MS-DRG	Description
783	Cesarean Section with Sterilization with MCC
784	Cesarean Section with Sterilization with CC
785	Cesarean Section with Sterilization without CC/MCC
796	Vaginal Delivery with Sterilization and/or D&C with MCC
797	Vaginal Delivery with Sterilization and/or D&C with CC
798	Vaginal Delivery with Sterilization and/or D&C without CC/MCC
817	Other Antepartum Diagnoses with O.R. Procedures with MCC
818	Other Antepartum Diagnoses with O.R. Procedures with CC
819	Other Antepartum Diagnoses with O.R. Procedures without CC/MCC
831	Other Antepartum Diagnoses without O.R. Procedures with MCC
832	Other Antepartum Diagnoses without O.R. Procedures with CC
833	Other Antepartum Diagnoses without O.R. Procedures without CC/MCC

BILLING CODE 4120–01–C

We also referred the reader to Table 6P.10d for the data analysis of all 49 base MS–DRGs that would be subject to change based on the application of the three-way severity level split criterion and to Table 6P.10e for the corresponding data dictionary that describes the meaning of the data elements and assists with interpretation of the data related to our analysis with application of the NonCC subgroup criteria. We noted, in our analysis of the claims data and as reflected in Table 6P.10d, we identified four base MS–DRGs currently subdivided with a three-way severity level split (4 base MS–DRGs × 3 severity levels=12 MS–DRGs) that result in the potential creation of a single, base MS–DRG when grouped under the proposed V41 GROUPER software with application of the NonCC subgroup criteria. As shown in Table 6P.10d, the four current base MS–DRGs (excluding the 4 obstetric related base DRGs) are base MS–DRGs 283, 296, 411, and 799. In addition to not satisfying the criterion that there be at least 500 cases in the NonCC subgroup for a three-way severity level split, these four base MS–DRGs also failed one or more of the other criteria to create subgroups. For example, our review of base MS–DRGs 283 and 296 showed they failed the criterion that there be at least 5% or more of the patient cases in the NonCC subgroup. For base MS–DRG 411, we found the criterion that there be at least 500 cases in each subgroup for a three-way severity level split, as well as in each subgroup for both of the two-way severity level splits, was not met. Lastly, for base MS–DRG 799, we found less than 500 cases in at least two of three subgroups for a three-way severity level split, as well as for at least one of the two subgroups for a two-way severity level split, and the R2 value was less than 3.0 for the two-way severity level split.

We also referred the reader to Table 6P.10f for the alternate cost weight analysis with application of the NonCC subgroup criteria that includes transfer-adjusted cases from the December 2022 update of the FY 2022 MedPAR file under the proposed V41 ICD–10 MS–DRG GROUPER Software, the MS–DRG relative weights calculated under the proposed V41 ICD–10 MS–DRG GROUPER Software, the alternate MS–DRG relative weights calculated with application of the NonCC subgroup criteria using an alternate version of the ICD–10 MS–DRG GROUPER Software, Version 41.A (discussed in more detail in this section of the proposed rule), and the change in MS–DRG relative weights between those calculated under the proposed V41 GROUPER Software and those calculated under the alternate V41.A GROUPER Software. We noted that to facilitate the structural comparison between the proposed V41 GROUPER and the alternate V41.A GROUPER, the relative weights calculated using the proposed V41 GROUPER Software (column F) did not reflect application of the 10-percent cap. We further noted that changes in the status for transfer adjusted cases were reflected for the relative weights calculated using the proposed V41 GROUPER Software only and were not reflected for the alternate MS–DRG weights with application of the NonCC subgroup criteria. We noted, as shown in Table 6P.10f, that we found five MS–DRGs for which there appears to be a greater than negative 10% change between the relative weight calculated under the proposed V41 GROUPER Software and the calculated alternate relative weight under the V41.A GROUPER Software with application of the NonCC subgroup criteria. As shown in Table 6P.10f, the five MS–DRGs are existing MS–DRG 021 (potential new MS–DRG 105), existing MS–DRG 411 (potential new MS–DRG 426), existing MS–DRG 573 (potential new MS–DRG 529), existing MS–DRG 574 (potential new MS–DRG 530), and existing MS–DRG 799 (potential new MS–DRG 649). Of the five existing MS–DRGs, two of the MS–DRGs are those for which a new single, base MS–DRG would potentially be created from the current three-way split, as previously described: MS–DRG 411 (potential new MS–DRG 426) and MS–DRG 799 (potential new MS–DRG 649). In the proposed rule, we stated that the findings were consistent with what we would expect given the low volume of cases in the NonCC subgroups compared to the volume of cases in the CC subgroups for these MS–DRGs.

As noted in prior rulemaking, any potential MS–DRG updates to be considered for a future proposal in connection with application of the NonCC subgroup criteria would also involve a redistribution of cases, which would impact the relative weights, and, thus, the payment rates proposed for particular types of cases. As such, and in response to prior public comments requesting that further analysis of the application of the NonCC subgroup criteria be made available, in addition to Table 6P.10f, we made available additional files reflecting application of the NonCC subgroup criteria in connection with the proposed FY 2024 MS–DRG changes, using the December 2022 update of the FY 2022 MedPAR file. These additional files included an alternate Table 5—Alternate List of Medicare Severity Diagnosis Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay, an alternate Length of Stay (LOS) Statistics file, an alternate Case Mix Index (CMI) file, and an alternate After Outliers Removed and Before Outliers Removed (AOR_BOR) file. The files are available in association with the proposed rule on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS.*

For the FY 2024 IPPS/LTCH PPS proposed rule we also provided an alternate test version of the ICD–10 MS–DRG GROUPER Software, Version 41.A, so that the public can better analyze and understand the impact on the proposals included in the proposed rule if the NonCC subgroup criteria were to be applied to existing MS–DRGs with a three-way severity level split. We noted that this alternate test software reflected the proposed GROUPER logic for FY 2024 as modified by the application of the NonCC subgroup criteria. Therefore, it included the new diagnosis and procedure codes that are effective for FY 2024 as reflected in Table 6A.—New Diagnosis Codes—FY 2024 and Table 6B.—New Procedure Codes—FY 2024 associated with the proposed rule and did not include the diagnosis codes that are invalid beginning in FY 2024 as reflected in Table 6C.—Invalid Diagnosis Codes—FY 2024 associated with the proposed rule. As previously noted, at the time of the development of the proposed rule there were no procedure codes designated as invalid for FY 2024, and therefore, there was no Table 6D– Invalid Procedure Codes—FY 2024 associated with the proposed rule. These tables were not published in the Addendum to the proposed rule, but are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. of the Addendum to the proposed rule. Because the diagnosis codes no longer valid for FY 2024 are not reflected in the alternate test software, we made available a supplemental file in Table 6P.1a that includes the mapped Version 41 FY 2024 ICD–10–CM codes and the deleted Version 40.1 FY 2023 ICD–10–CM codes that should be used for testing purposes with users' available claims data. Therefore, users had access to the alternate test software allowing them to build case examples that reflect the proposals included in the proposed rule

with application of the NonCC subgroup criteria. Because the potential MS–DRG changes with application of the NonCC subgroup criteria are available in Table 6P.10b associated with the proposed rule, an alternate version of the ICD–10 MS–DRG Definitions Manual was not developed.

The alternate test version of the ICD–10 MS–DRG GROUPER Software, Version 41.A, and the supplemental mapping files in Table 6P.1a of the FY 2023 and FY 2024 ICD–10–CM diagnosis codes are available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.*

After delaying the application of the NonCC subgroup criteria for two years, and in response to prior public comments, we made available these additional analyses reflecting application of the criteria in connection with the proposed FY 2024 MS–DRG changes for public review and comment, to inform application of the NonCC subgroup criteria for FY 2025 rulemaking.

We proposed to continue to delay application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split for FY 2024. We stated that we were interested in hearing feedback regarding the experience of large urban hospitals, rural hospitals, and other hospital types and will take commenters' feedback into consideration for our development of the FY 2025 proposed rule.

Comment: Commenters expressed appreciation that CMS provided additional files for review and consideration that reflect application of the NonCC subgroup criteria in connection with the FY 2024 proposed MS–DRG changes.

Response: We thank the commenters for their feedback.

Comment: Commenters supported the proposal to delay application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split for FY 2024 and to maintain the current structure of the 45 MS–DRGs that currently have a three-way split (total of 135 MS–DRGs). The commenters also expressed support for the proposal to exclude the 12 obstetric related MS–DRGs from application of the NonCC subgroup criteria in the future. Some commenters stated they agreed with the methodology for creating subgroups and viewed the consolidation as a positive change, however, the commenters also recommended that CMS continue to collect data and identify any unintended impacts to the MS–DRG relative weights because of the redistribution of cases from application of the NonCC subgroup criteria. Other commenters stated that although the COVID–19 PHE has ended, several hospitals are still recovering and further assessment of the impacts for low volume procedures in connection with the potential MS–DRG changes with application of the NonCC subgroup criteria is needed.

A couple commenters specifically requested that CMS provide data analysis by hospital type for FY 2025 rulemaking to afford organizations additional time to review and forecast impacts, as well as to facilitate more informed comments in response to the CMS request for comments related to experiences of large urban hospitals, rural hospitals, and other hospital types.

Response: We appreciate the commenters' support. We will continue to review and consider the feedback we have received for our development of the FY 2025 proposed rule.

Comment: A couple commenters who expressed support for the proposed delay in application of the NonCC subgroup criteria for FY 2024 and appreciation for the additional analysis files that were made available stated that deleting and adding a large volume of MS–DRGs may create additional administrative burden. The commenters stated providers will need more time than is typically provided for implementation of finalized policies under the IPPS. The commenters urged CMS to work with interested parties in developing an appropriate implementation timeline. A commenter suggested that CMS consider implementing application of the NonCC subgroup criteria using a phased approach, over several years, to assist in the transition. This commenter encouraged CMS to continue to provide additional analysis files as was done with the proposed rule and to include the potential effects of a multi-year implementation plan.

Response: We thank the commenters for their support and feedback. We will continue to review and consider the feedback we have received for our development of the FY 2025 proposed rule.

Comment: A commenter who agreed it is appropriate to defer implementation of MS–DRG consolidation based on the three-way severity criteria specifically expressed concern that the policy may result in additional reductions to relative weights for important procedures, including intracranial vascular procedures. According to the commenter, intracranial vascular procedures have already experienced significant cuts in recent years. The commenter stated that based on the data that was made available in connection with the proposed rule, the estimates show that consolidation for five MS–DRGs, including potential new MS–DRG 105 (Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage without MCC) would result in a more than 10 percent relative weight reduction (prior to the application of the current 10-percent cap). To the extent that CMS does adopt such MS–DRG consolidation in the future, the commenter recommended that CMS limit the single-year relative weight reductions resulting from cumulative policy changes to 5 percent.

The commenter also suggested that CMS consider building more flexibility into its assessment of severity level subdivisions for both new and existing MS–DRGs. According to the commenter, the requirement to meet multiple, rigid cost and volume cut-offs may detract from the assessment of important clinical and resource distinctions in patient populations within the MS–DRGs.

A few commenters expressed concern that the criterion of a 500-case volume may be too high, particularly for low volume services and MS–DRGs. The commenters stated that there has been tremendous growth in Medicare Advantage claims with a decrease in fee-for-service (FFS) claims flowing into rate-setting. The commenters stated additional analysis of this criterion is warranted and requested that CMS provide further information about the benefits.

Response: We appreciate the commenters' feedback. We acknowledge the growth in Medicare Advantage claims and will continue to review and consider the feedback we have received for our development of the FY 2025 proposed rule.

In response to the commenter's recommendation that CMS limit the single-year relative weight reductions to 5 percent, we note that there was extensive discussion in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48897 through 48900) regarding the cap for relative weight reductions and refer the reader to that discussion for detailed information. We also refer the reader to the additional discussion in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26774 through 26775) and in section II.D.2.c. of the preamble of this final rule.

With regard to the commenter's suggestion that more flexibility should be built into CMS' assessment of severity level subdivisions for both new

and existing MS–DRGs, we note that currently, the minimum case volume requirements were established to avoid overly fragmenting the MS–DRG classification system. With smaller volumes they will be subject to stochastic (unpredictable) effects that may indicate a cost difference within the data sample. Reevaluation in subsequent years may result in those cost differences being insufficient to support the split.

We do not believe it is in the interest of the Medicare program or providers to establish and then remove MS–DRG splits. We believe that stability of MS–DRG payment is an important objective and therefore, that a volume requirement is a necessary adjunct to cost differentiation. We established a 500-case limit to meet this stability requirement. With this case limit, an MS–DRG split not meeting this minimum volume threshold will have fewer than 0.007% cases from which the MS–DRG RW is constructed. Under application of the NonCC subgroup criteria, hospitals would receive a payment weight that averages the two comorbidity split levels (CC and NonCC) and will thus only experience any potential negative impact to the extent that their case mix is comprised of cases with the (potentially) higher weight. We note, as discussed in prior rulemaking (86 FR 44878), the MS–DRG system is a system of averages and it is expected that within the diagnostic related groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs. We also provide outlier payments to mitigate extreme loss on individual cases.

Comment: A couple commenters requested clarification on how the policy to cap the reductions for MS–DRG relative weights to 10-percent would apply as CMS considers implementation of the NonCC subgroup criteria.

Response: As stated in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48900), the 10- percent cap on reductions to an MS–DRG's relative weight applies to new or modified MS–DRGs after the first fiscal year that the new or modified MS–DRGs take effect. Therefore, the 10-percent cap would not apply to the relative weight for any new or renumbered MS–DRGs for the first fiscal year. However, we recognize that application of the NonCC subgroup criteria may warrant special consideration with respect to the 10-percent cap on reductions to an MS–DRG's relative weight and will continue to consider this issue in connection with our efforts to promote predictability and mitigate financial impacts resulting from significant fluctuations in the relative weights.

Comment: A couple commenters expressed concern that the additional files made available in connection with the proposed rule did not demonstrate how the explanatory power of the potential new MS–DRGs with application of the NonCC subgroup criteria is an improvement over the current MS–DRGs. The commenters expressed concern that the impact of the presence of a CC for MS–DRG assignment appears to be declining because the application of the NonCC subgroup criteria is resulting in fewer MS–DRGs split by the presence of a CC. Specifically, the commenters stated that when the NonCC subgroup criteria were applied to existing MS–DRGs currently split into three severity levels, as well as when the criteria were applied to proposed new MS–DRG classification requests, none of the proposed new MS–DRGs with a two-way severity level split involved a ''with CC/MCC'' and ''without CC/MCC'' split.

Response: As discussed in the FY 2024 IPPS/LTCH proposed rule, we provided both a test version of the ICD–10 MS–DRG GROUPER Software, Version 41 and an alternate version of the ICD–10 MS–DRG GROUPER Software, Version 41.A so that the public could better analyze and understand the impact on the proposals included in the proposed rule if the NonCC subgroup criteria were to be applied to existing MS–DRGs with a three-way severity level split. We noted that this alternate test software reflected the proposed GROUPER logic for FY 2024 as modified by the application of the NonCC subgroup criteria. Overall, we believe the explanatory power (R2) for the V41.A alternate GROUPER yields similar results to the proposed V41 GROUPER. Based on our review, the explanatory power (R2) goes down by 0.04 percent with the V41.A alternate GROUPER, explaining less variation when compared to the V41 notice of proposed rulemaking (NPRM) GROUPER, however this result is as we would expect since the MS–DRGs subject to the NonCC subgroup criteria considered for potential adjustment are low volume to begin with.

GROUPER Version	Number of Cases in Relative Weights Calculation	R2
V41 NPRM	6,916,080	33.1463
V41.A	6,916,081	33.1316

In response to the concerns expressed that application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split appears to result in fewer MS–DRGs split by the presence of a CC, we note that the criteria for the two-way split of ''with CC/MCC'' and ''without CC/MCC'' requires that there be at least 500 cases in the NonCC group, and as discussed in the proposed rule, in applying the criteria for proposed new MS–DRGs, that volume requirement was not met. Alternatively, the criteria for the two-way split of ''with MCC'' and ''without MCC'' was met for specific proposals, and therefore, proposed.

We recognize and acknowledge the concerns raised by the commenters regarding the impact the application of the NonCC subgroup criteria to existing MS–DRGs with a three-way split appears to have on the presence of a CC for MS–DRG assignment. We will continue to examine this issue with respect to the criteria and how it also relates to the comprehensive CC/MCC analysis. We refer the reader to section II.C.12.b. of the preamble of this final rule for additional discussion related to the comprehensive CC/MCC analysis.

Comment: Some commenters requested additional insight and rationale as to why CMS applied the NonCC subgroup criteria to the proposed MS–DRG changes for FY 2024 if the intent is to delay application of the NonCC subgroup criteria until future rulemaking.

Response: As discussed in prior rulemaking, in general, once the decision has been made to propose to make further modifications to the MS–DRGs, such as creating a new base MS–DRG, all five criteria must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. We note that we have applied the criteria to create subgroups, including application of the NonCC subgroup criteria, in our annual analysis of the MS–DRG classification requests

effective FY 2021 (85 FR 58446 through 58448). For example, we applied the criteria to create subgroups, including application of the NonCC subgroup criteria, for a proposed new base MS–DRG as discussed in our finalization of new base MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy), new base MS–DRG 019 (Simultaneous Pancreas and Kidney Transplant with Hemodialysis), new base MS–DRG 140 (Major Head and Neck Procedures), new base MS–DRG 143 (Other Ear, Nose, Mouth and Throat O.R. Procedures), new base MS–DRG 521 (Hip Replacement with Principal Diagnosis of Hip Fracture) and new base MS–DRG 650 (Kidney Transplant with Hemodialysis) for FY 2021. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58448), we finalized our proposal to expand our existing criteria to create a new CC or MCC subgroup within a base MS–DRG. Specifically, we finalized the expansion of the criteria to include the NonCC subgroup for a three-way severity level split.

Similarly, we applied the criteria to create subgroups including application of the NonCC subgroup criteria for MS–DRG classification requests for FY 2022 that we received by November 1, 2020 (86 FR 44796 through 44798), for MS–DRG classification requests for FY 2023 that we received by November 1, 2021 (87 FR 48801 through 48804), and for MS–DRG classification requests for FY 2024 that we received by October 20, 2022 (88 FR 26673 through 26676), as well as any additional analyses that were conducted in connection with those requests.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44798) and FY 2023 IPPS/LTCH PPS final rule (87 FR 48803), we finalized a delay in applying this technical criterion to existing MS–DRGs in light of the PHE. We take this opportunity to clarify that the delay referenced was in applying this technical criterion to existing MS–DRGs with a three-way severity level split. Therefore, while we have made analyses for potential MS–DRG changes with application of the NonCC subgroup criteria publicly available, we have not yet proposed application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split. We note that we will continue to apply the criteria to create subgroups, including application of the NonCC subgroup criteria, in our annual analysis of MS–DRG classification requests, consistent with our approach since FY 2021 when we finalized the expansion of the criteria to include the NonCC subgroup for a three-way severity level split.

Comment: A few commenters expressed concerns about the fluctuations in potential MS–DRG restructuring with application of the NonCC subgroup criteria from FY 2021 through FY 2024 based on different sets of claims data.

Response: We note that we addressed similar comments in detail in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48803 through 48804) and refer the reader to that discussion.

After consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal to delay the application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split until FY 2025 or later, and are finalizing for FY 2024 our proposal to maintain the current structure of the 45 MS–DRGs that currently have a three-way severity level split.

We are making the FY 2024 ICD–10 MS–DRG GROUPER and Medicare Code Editor (MCE) Software Version 41, the ICD–10 MS–DRG Definitions Manual files Version 41 and the Definitions of Medicare Code Edits Manual Version 41 available to the public on our CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

2. Major Diagnostic Category (MDC) 01: (Diseases and Disorders of the Nervous System): Epilepsy With Neurostimulator

The Responsive Neurostimulator (RNS®) System is a cranially implanted neurostimulator and is a treatment option for persons diagnosed with medically intractable epilepsy, a brain disorder characterized by persistent seizure activity which despite maximal medical treatment, remains sufficiently debilitating. In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26676 through 26681), we stated that cases involving the use of the RNS® System are identified by the reporting of an ICD–10–PCS code combination capturing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain and the cases are assigned to MS–DRG 023 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) when reported with a principal diagnosis of epilepsy. We referred the reader to the ICD–10 MS–DRG Definitions Manual Version 40.1, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for MS–DRG 023.

As discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38015 through 38019), we finalized our proposal to reassign all cases with a principal diagnosis of epilepsy and one of the following ICD–10–PCS code combinations capturing cases with a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) to MS–DRG 023 even if there is no MCC reported:

- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H00MZ (Insertion of neurostimulator lead into brain, open approach);
- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H03MZ (Insertion of neurostimulator lead into brain, percutaneous approach); and
- 0NH00NZ (Insertion of neurostimulator generator into skull, open approach), in combination with 00H04MZ (Insertion of neurostimulator lead into brain, percutaneous endoscopic approach).

We also finalized our proposed change to the title of MS–DRG 023 from ''Craniotomy with Major Device Implant or Acute Complex Central Nervous System (CNS) Principal Diagnosis (PDX) with MCC or Chemo Implant'' to ''Craniotomy with Major Device Implant or Acute Complex Central Nervous System (CNS) Principal Diagnosis (PDX) with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator'' to reflect the modifications to the MS–DRG structure.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58459 through 58462), we discussed a request to reassign cases describing the insertion of a neurostimulator generator into the skull in combination with the insertion of a neurostimulator lead into the brain from MS–DRG 023 to MS–DRG 021 (Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage with CC) or to reassign these cases to another MS–DRG for more appropriate payment. We stated that while the results of our claims analysis indicated that the average costs of cases reporting a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator), and a principal diagnosis of epilepsy are higher compared to the average costs for all cases in their assigned MS–DRG, we could not ascertain from the claims data

the resource use specifically attributable to the procedure during a hospital stay. We stated that we believed that further analysis of cases reporting a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator), and a principal diagnosis of epilepsy was needed prior to proposing any further reassignment of these cases to ensure clinical coherence between these cases and the other cases with which they may potentially be grouped and therefore did not propose to reassign cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) from MS–DRG 023 to MS–DRG 021. We also did not propose to reassign Responsive Neurostimulator (RNS®) System cases to another MS–DRG. We stated we expected that, in future years, we would have additional data that could be used to evaluate the potential reassignment of cases reporting a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator), and a principal diagnosis of epilepsy.

In the FY 2024 IPPS/LTCH PPS proposed rule, we stated we received a similar request to reassign cases describing the insertion of a neurostimulator generator into the skull in combination with the insertion of a neurostimulator lead into the brain from MS–DRG 023 to MS–DRG 021 or reassign all cases currently assigned to MS–DRG 023 that involve a craniectomy or a craniotomy with the insertion of device implant and create a new MS–DRG for these cases. The requestor acknowledged both the refinements made to MS–DRG 023 effective for FY 2018 and the discussion in FY 2021 rulemaking, but stated that cases describing the insertion of a neurostimulator generator into the skull in combination with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) are negatively impacted from a payment perspective in their current MS–DRG assignment due to the large number of cases, with a wide range of principal diagnoses, procedures, and procedure approaches, also assigned to MS–DRG 023 and MS–DRG 024 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC) and therefore continue to be underpaid. We stated in the FY 2024 IPPS/LTCH PPS proposed rule that the requestor performed its own analysis of Medicare claims data and stated that it found that the average costs of cases describing the insertion of the RNS® neurostimulator were significantly higher than the average costs of all cases in their current assignment to MS–DRG 023, and as a result, cases describing the insertion of the RNS® neurostimulator are not being adequately reimbursed.

The requestor suggested the following two options for MS–DRG assignment updates: (1) reassign cases describing the insertion of a neurostimulator generator into the skull in combination with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) from MS–DRG 023 to MS–DRG 021 with a change in title to ''Intracranial Vascular Procedures with PDX Hemorrhage with CC or Craniectomy with Neurostimulator;'' or (2) extract all cases from MS–DRG 023 involving a craniectomy/craniotomy with device implant and create a new MS–DRG for these cases.

The requestor acknowledged that the relatively low volume of cases that only involve the insertion of a neurostimulator generator into the skull in combination with the insertion of a neurostimulator lead into the brain in the claims data is likely not sufficient to warrant the creation of a new MS–DRG. The requestor further stated given the limited options within the existing MS–DRG structure that fit from both a cost and clinical cohesiveness perspective, they believe that MS–DRG 021 is the most logical fit in terms of average costs and clinical coherence for reassignment of RNS® System cases even though, according to the requestor, the insertion of a neurostimulator generator into the skull in combination with the insertion of a neurostimulator lead into the brain is technically more complex and involves a higher level of training, extreme precision and sophisticated technology than performing a craniectomy for hemorrhage.

As another option, the requestor identified procedures involving a craniectomy or craniotomy by searching for ICD–10–PCS codes that describe the root operations ''Destruction'', ''Division'', ''Drainage'', ''Excision'', Extirpation'', or ''Insertion'' performed related to the brain or specific brain anatomy (for example, cerebral ventricle, cerebellum) with an ''Open Approach'' in the claims data. The requestor also said they identified claims involving a device implant by searching for ICD–10–PCS codes that describe the root operation ''Insertion'' and stated that they found that the claims they identified had average costs comparable to the average costs of RNS® cases and therefore creating a new MS–DRG for all cases involving a craniectomy/craniotomy with device implant was a reasonable alternative option.

We stated in the proposed rule that to begin our analysis, we identified the ICD–10–CM diagnosis codes that describe a diagnosis of epilepsy. We referred the reader to Table 6P.2a associated with the proposed rule (and available at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps*) for the list of the ICD–10–CM codes that we identified.

We stated in the proposed rule that we then examined the claims data from the September 2022 update of the FY 2022 MedPAR file for all cases in MS–DRG 023 and compared the results to cases reporting a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) that had a principal diagnosis of epilepsy in MS–DRG 023. The following table shows our findings:

BILLING CODE 4120–01–P

MS-DRG 023	Number of Cases	Average Length of Stay	Average Costs
All cases	11,602	10.4	$47,321
Cases with principal diagnosis of epilepsy with neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain	57	3.1	$58,676

As shown in the table, for MS–DRG 023, we identified a total of 11,602 cases, with an average length of stay of 10.4 days and average costs of $47,321. Of those 11,602 cases in MS–DRG 023, there were 57 cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) that had a principal diagnosis of epilepsy. We noted that the 57 cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) and a principal diagnosis of epilepsy had an average length of stay of 3.1 days and average costs of $58,676, as compared to the average length of stay of 10.4 days and average costs of $47,321 for all cases in MS–DRG 023. We stated that while these neurostimulator cases had average costs that were $11,355 higher than the average costs of all cases in MS–DRG 023, there were only a total of 57 cases. We stated we reviewed these data, and agreed with the requestor that the number of cases continued to be too small to warrant the creation of a new MS–DRG for these cases, for the reasons discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38015 through 38019) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58459 through 58462).

As stated in the proposed rule, we examined the reassignment of cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) to MS–DRGs 020, 021, and 022 (Intracranial Vascular Procedures with PDX Hemorrhage with MCC, with CC, and without CC/MCC, respectively). While the request was to reassign these cases to MS–DRG 021, we noted that MS–DRG 021 is specifically differentiated according to the presence of a secondary diagnosis with a severity level designation of a complication or comorbidity (CC). Cases with a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) do not always involve the presence of a secondary diagnosis with a severity level designation of a complication or comorbidity (CC), and therefore we reviewed data for all three MS–DRGs. The following table shows our findings:

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
020	2,016	13.9	$72,776
021	548	9.1	$53,973
022	270	3.9	$31,248

As shown in the table, for MS–DRG 020, there were a total of 2,016 cases with an average length of stay of 13.9 days and average costs of $72,776. For MS–DRG 021, there were a total of 548 cases with an average length of stay of 9.1 days and average costs of $53,973. For MS–DRG 022, there were a total of 270 cases with an average length of stay of 3.9 days and average costs of $31,248.

Because all cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) with a principal diagnosis of epilepsy are assigned MS–DRG 023 even if there is no MCC reported and there is a three-way split within MS–DRGs 020, 021, and 022, in the proposed rule we stated we also analyzed the cases reporting a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) with a principal diagnosis of epilepsy for the presence or absence of a secondary diagnosis designated as a complication or comorbidity (CC) or a major complication or comorbidity (MCC). The following table shows our findings:

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
023	Cases with principal diagnosis of epilepsy with neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain with MCC	8	8.4	$68,486
	Cases with principal diagnosis of epilepsy with neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain with CC	14	2.4	$60,799
	Cases with principal diagnosis of epilepsy with neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain without CC/MCC	35	2.1	$55,585

As noted in the proposed rule, this data analysis shows that, similar to our findings as summarized in the FY 2018 and FY 2021 IPPS/LTCH PPS final rules, on average, the cases in MS–DRG 023 describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) and a principal diagnosis of epilepsy have average costs that are relatively more similar to the average costs of cases in MS–DRG 021 ($58,676 compared to $53,973), while the average length of stay is shorter (3.1 days compared to 9.1 days). However, when distributed based on the presence or absence of a secondary diagnosis designated as a CC or an MCC, the 57 cases in MS–DRG 023 reporting a principal diagnosis of epilepsy with a neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain have higher average costs and shorter lengths of stay than the cases in the FY 2022 MedPAR file for MS–DRGs 021 and 022 while having lower average costs and shorter lengths of stay than the cases in MS–DRG 020. We stated we reviewed the clinical issues and the claims data and continued to not support reassigning the cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) and a principal diagnosis of epilepsy from MS–DRG 023 to MS–DRGs 020, 021, or 022. We noted in the proposed rule that as also discussed in the FY 2018 and FY 2021 IPPS/LTCH PPS final rules, the cases in MS–DRGs 020, 021, and 022 have a principal diagnosis of a hemorrhage. The RNS® neurostimulator generators are not used to treat patients with diagnosis of a hemorrhage. We stated we continued to believe that it is inappropriate to reassign cases representing a principal diagnosis of epilepsy to a MS–DRG that contains cases that represent the treatment of intracranial hemorrhage, as discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38015 through 38019) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58459 through 58462). We noted that the differences in average length of stay and average costs based on the more recent data continued to support this recommendation.

We noted, as discussed in section II.C.1.b of the proposed rule, using the December 2022 update of the FY 2022 MedPAR file, we analyzed how applying the NonCC subgroup criteria to all MS–DRGs currently split into three severity levels would affect the MS–DRG structure beginning in FY 2024. As stated in the proposed rule, findings from our analysis indicated that MS–DRGs 020, 021, and 022 as well as approximately 44 other base MS–DRGs would potentially be subject to change based on the three-way severity level split criterion finalized in FY 2021. We referred the reader to Table 6P.10b associated with the proposed rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for the list of the 135 MS–DRGs that would be subject to deletion and the list of the 86 new MS–DRGs that would potentially be created if the NonCC subgroup criteria were applied.

We stated that we then explored alternative options, as was requested. As stated in the proposed rule, we did not agree that searching for ICD–10–PCS codes that describe the root operations ''Destruction'', ''Division'', ''Drainage'', ''Excision'', Extirpation'', or ''Insertion'' performed related to the brain or specific brain anatomy as suggested by the requestor was a reasonable approach to find cases comparable to cases involving the use of the RNS® System as these root operations all describe procedures performed for distinct and differing objectives. Instead, to review for similar utilization of resources, we stated we further analyzed the data to identify those cases currently reporting a procedure code combination representing neurostimulator generator and lead code combinations that are captured under the list referred to as ''Major Device Implant'' in the GROUPER logic for MS–DRGs 023 and 024 since the ICD–10–PCS code combinations that capture the use of the RNS® neurostimulator generator and leads that would determine an assignment of a case to MS–DRGs 023 are also found on the ''Major Device Implant'' list. The neurostimulator generators on this list are inserted into the skull, as well as into the subcutaneous areas of the chest, back, or abdomen. The leads are all inserted into the brain. The following table shows our findings:

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
023	**All cases**	11,602	10.4	$47,321
	Cases with neurostimulators (Major Device Implant list cases)	90	7.3	$59,733
	Cases with neurostimulators (Major Device Implant list cases) **excluding** cases with principal diagnosis of epilepsy with neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain	33	14.6	$61,559
	Cases with principal diagnosis of epilepsy with neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain	57	3.1	$58,676
024	**All cases**	4,378	5.2	$32,613
	Cases with neurostimulators (Major Device Implant list cases)	395	1.6	$36,147
	Cases with neurostimulators (Major Device Implant list cases) **excluding** cases with principal diagnosis of epilepsy with neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain	395	1.6	$36,147
	Cases with principal diagnosis of epilepsy with neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain	0	0	$0

BILLING CODE 4120–01–C

We noted that the 90 Major Device Implant list cases involving a neurostimulator generator (including cases involving the use of the RNS® neurostimulator and a principal diagnosis of epilepsy) have an average length of stay of 7.3 days and average costs of $59,733 as compared to all 11,602 cases in MS–DRG 023, which have an average length of stay of 10.4 days and average costs of $47,321. In MS–DRG 024, we noted that the 395 Major Device Implant list cases involving a neurostimulator generator have an average length of stay of 1.6 days and average costs of $36,147 as compared to all 4,378 cases in MS–DRG 024, which have an average length of stay of 5.2 days and average costs of $32,613. In the proposed rule, we stated that while these neurostimulator cases have average costs that are higher than the average costs of all cases in their respective MS–DRGs, it was difficult to detect patterns of complexity and resource intensity. Moreover, we stated we were unable to identify another MS–DRG in MDC 01 that would be a more appropriate MS–DRG assignment for these cases based on the indication for and complexity of the procedure.

We noted that while our data findings demonstrated the average costs are higher for the 57 cases with a principal diagnosis of epilepsy with neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain when compared to all cases in MS–DRG 023, these cases represent a small percentage of the total number of cases reported in this MS–DRG. We stated that while we appreciated the requestor's concerns regarding the differential in average costs for cases describing the insertion of a neurostimulator generator into the skull in combination with the insertion of a neurostimulator lead into the brain when compared to all cases in their assigned MS–DRG, we believe additional time is needed to evaluate these cases as part of our ongoing examination of the case logic for MS–DRGs 023 through 027. As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48808 through 48820), in connection with our analysis of cases reporting LITT procedures performed on the brain or brain stem in MDC 01, we have started to examine the logic for case assignment to MS–DRGs 023 through 027 to determine where further refinements could potentially be made to better account for differences in the technical complexity and resource utilization among the procedures that are currently assigned to those MS–DRGs. In the proposed rule, we stated that specifically, we are in the process of evaluating procedures that are performed using an open craniotomy (where it is necessary to surgically remove a portion of the skull) versus a percutaneous burr hole (where a hole approximately the size of a pencil is drilled) to obtain access to the brain in the performance of a procedure. We are also reviewing the indications for these procedures, for example, malignant neoplasms versus epilepsy to consider if there may be merit in considering restructuring the current MS–DRGs to better recognize the clinical distinctions

of these patient populations in the MS–DRGs.

As part of this evaluation, as discussed in the proposed rule, we have begun to analyze the ICD–10 coded claims data from the September 2022 update of the FY 2022 MedPAR file to determine if the patients' diagnoses, the objective of the procedure performed, the specific anatomical site where the procedure is performed or the surgical approach used (for example, open, percutaneous, percutaneous endoscopic, among others) demonstrates a greater severity of illness and/or increased treatment difficulty as we consider restructuring MS–DRGs 023 through 027, including how to better align the clinical indications with the performance of specific intracranial procedures. We refer the reader to Tables 6P.2b through 6P.2f associated with the proposed rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for data analysis findings of cases assigned to MS–DRGs 023 through 027 as we continue to look for patterns of complexity and resource intensity.

In summary, in the proposed rule, we stated we believe that further analysis of cases reporting a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) and a principal diagnosis of epilepsy is needed in connection with our analysis of the claims data for MS–DRGs 023 through 027 prior to proposing any further reassignment of these cases, to ensure clinical coherence between these cases and the other cases with which they may potentially be grouped. Therefore, we did not propose to reassign cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) from MS–DRG 023 to MS–DRG 021. We also did not propose to create a new MS–DRG for cases involving a craniectomy/craniotomy with device implant at this time.

Comment: Some commenters expressed support for CMS' proposal to maintain the assignment of cases reporting procedure codes that describe a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) in MS–DRG 023 and to not propose to create a new MS–DRG for cases involving a craniectomy/craniotomy with device implant. A commenter stated they agreed that it was inappropriate to reassign cases that involve craniectomy or craniotomy with the insertion of neurostimulator into the skull in combination with the insertion of a neurostimulator lead into the brain from MS–DRG 023 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator) to MS–DRG 021 (Intracranial Vascular Procedures with Principal Diagnosis Hemorrhage with CC). This commenter also stated that due to the low volume of total cases, they agreed that creation of a new MS–DRG was not warranted.

Response: We appreciate the commenters' support.

Comment: Another commenter opposed CMS' proposal. The commenter stated CMS' data analysis demonstrated that the average costs of RNS® System cases continue to be substantially higher than the average costs of all cases in their assigned MS–DRG 023. This commenter further stated that they believed the data analysis supports extracting cases reporting procedure codes that describe a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator) (*e.g.,* Major Device Implant list cases) from MS–DRGs 023 and 024 and creating two new MS–DRGs with logic maintained for cases with a principal diagnosis of epilepsy with neurostimulator generator inserted into the skull and insertion of a neurostimulator lead into brain. The commenter stated this refinement would result in a much better alignment of the average costs of these cases compared to their current MS–DRG assignment.

Response: We thank the commenter for their feedback. We continue to be receptive to concerns about payment for cases reporting procedure codes that describe a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator). While we agree these neurostimulator cases can have average costs that are higher than the average costs of all cases in their respective MS–DRGs, in our analysis of this issue, it was difficult to detect patterns of complexity and resource intensity. As discussed in the proposed rule and earlier in this section, to review for similar utilization of resources, we analyzed the data to identify those cases currently reporting a procedure code combination representing neurostimulator generator and lead code combinations that are captured under the list referred to as ''Major Device Implant'' in the GROUPER logic for MS–DRGs 023 and 024 since the ICD–10–PCS code combinations that capture the use of the RNS® neurostimulator generator and leads that would determine an assignment of a case to MS–DRGs 023 are also found on the ''Major Device Implant'' list. In our analysis in MS–DRG 023, we found 90 cases reporting a procedure code combination representing neurostimulator generator and lead code combination captured under the list referred to as ''Major Device Implant'' with the average length of stay ranging from 1 day to 249 days and average costs ranging from $22,717 to $250,272 for these cases. In MS–DRG 024, we found 395 cases reporting a procedure code combination representing neurostimulator generator and lead code combination captured under the list referred to as ''Major Device Implant'' with the average length of stay ranging from 1 day to 12 days and average costs ranging from $16,359 to $70,949 for these cases. We continue to believe that additional time is needed to evaluate these cases as part of our ongoing examination of the case logic for MS–DRGs 023 through 027. As part of our ongoing, comprehensive analysis of the MS–DRGs under ICD–10, we will continue to explore mechanisms to ensure clinical coherence between these cases and the other cases with which they may potentially be grouped.

Therefore, after consideration of the public comments we received, and for the reasons stated earlier, we are finalizing our proposal to maintain the current assignment of cases describing a neurostimulator generator inserted into the skull with the insertion of a neurostimulator lead into the brain (including cases involving the use of the RNS® neurostimulator), without modification, for FY 2024.

As noted in the proposed rule, as we continue this analysis of the claims data with respect to MS–DRGs 023 through 027, we continue to seek public comments and feedback on other factors that should be considered in the potential restructuring of these MS–DRGs. As previously described, we are examining procedures by their approach (open versus percutaneous), clinical indications, and procedures that involve the insertion or implantation of a device. We recognize the logic for MS–DRGs 023 through 027 has grown more complex over the years and believe there is opportunity for further refinement. We refer the reader to the ICD–10 MS–DRG Definitions Manual, version 40.1, which is available on the

CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for MS–DRGs 023 through 027. Feedback and other suggestions may be submitted by October 20, 2023 and directed to the new electronic intake system, Medicare Electronic Application Request Information System™ (MEARIS™), discussed in section II.C.1.b. of the preamble of the proposed rule and this final rule at: *https://mearis.cms.gov/public/home*.

Comment: In response to CMS' request for public comment and feedback on the potential restructuring of the craniotomy MS–DRGs for future consideration, a commenter stated they do not believe there is a need for CMS to re-evaluate the assignment of neurosurgical procedures within the craniotomy MS–DRGs 023 through 027. This commenter stated that the procedures in these MS–DRGs have been well established from a clinical homogeneity perspective, as well as a resource utilization perspective, and the procedures costs have been stable. Another commenter stated they appreciate CMS' willingness to review the craniotomy/craniectomy MS–DRGs to ensure proper alignment of procedures, indications, technical complexity, and resource utilization. This commenter further noted there are a wide array of diagnoses and procedures that fall within this range of MS–DRG and stated they believe there are a variety of ways these MS–DRGs can be classified.

A commenter mentioned that CMS referred the reader to Tables 6P.2b through 6P.2f associated with the proposed rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for the data analysis findings of cases assigned to MS–DRGs 023 through 027 and expressed concern that there was no discussion of these findings or their significance in the proposed rule. This commenter suggested that CMS comment on the following:

- How is CMS defining technical complexity and what factors are being considered in the analysis?
- Are there other data not included in Tables 6P.2b through 6P.2f that CMS is analyzing?
- What is the timing for completion of the full analysis of MS–DRGs 023–027?

Response: We thank the commenters for their feedback and will take these recommendations into consideration as we further examine the logic for case assignment. The data analysis as displayed in Tables 6P.2b through 6P.2f associated with the proposed rule was displayed to provide the public an opportunity to review our examination of the procedures by their approach (open versus percutaneous), clinical indications, and procedures that involve the insertion or implantation of a device and to reflect on what factors should be considered in the potential restructuring of these MS–DRGs. We welcome further feedback on how CMS should define technical complexity, what factors should be considered in the analysis, and whether there are other data not included in Tables 6P.2b through 6P.2f that CMS should analyze.

As discussed in the proposed rule, and earlier in this section, as we continue the analysis of the claims data with respect to MS–DRGs 023 through 027, we are interested in receiving feedback on where further refinements could potentially be made to better account for differences in the technical complexity and resource utilization among the procedures that are currently assigned to these MS–DRGs. Feedback and other suggestions may be submitted by October 20, 2023 and directed to the new electronic intake system, Medicare Electronic Application Request Information System™ (MEARIS™) at *https://mearis.cms.gov/public/home.* We note that we would address any proposed modifications to the existing logic in future rulemaking.

3. MDC 02 (Diseases and Disorders of the Eye): Retinal Artery Occlusion

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 48830 through 48835), we discussed a request we received to reassign cases reporting diagnosis codes describing central retinal artery occlusion, and the closely allied condition, branch retinal artery occlusion, from MS–DRG 123 (Neurological Eye Disorders) in MDC 02 (Diseases and Disorders of the Eye) to MS–DRGs 061, 062, and 063 (Ischemic Stroke Precerebral Occlusion or Transient Ischemia with Thrombolytic Agent with MCC, with CC, and without CC/MCC, respectively) in MDC 01 (Diseases and Disorders of the Nervous System).

Retinal artery occlusion refers to blockage of the retinal artery that carries oxygen to the nerve cells in the retina at the back of the eye, often by an embolus or thrombus. A blockage in the main artery in the retina is called central retinal artery occlusion (CRAO). A blockage in a smaller artery is called branch retinal artery occlusion (BRAO).

Based on the various data analyses we performed to explore the possible reassignment of cases with a principal diagnosis of CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent or a procedure code describing hyperbaric oxygen therapy, and the clinical analysis discussed, for FY 2023 we did not propose any MS–DRG changes for cases with a principal diagnosis of CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent or a procedure code describing hyperbaric oxygen therapy.

In response to this final policy, as discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26681 through 26684), we received a request to again review the MS–DRG assignment of cases involving CRAO. According to the requestor, CRAO is a form of acute ischemic stroke which occurs when a vessel supplying blood to the brain is obstructed and there is growing recognition of this diagnosis as a vascular neurological problem. The requestor stated new evidence outlines treatment of patients with CRAO with acute stroke protocols, specifically with intravenous thrombolysis (IV tPA) or hyperbaric oxygen therapy (HBOT), to improve outcomes. We stated in the proposed rule that the requestor stated they performed an internal analysis of their claims data and found that the average costs of cases reporting a procedure code describing the administration of a thrombolytic agent with a principal diagnosis of CRAO were 2.5 times higher than the average costs of cases with a principal diagnosis of CRAO that did not report the administration of a thrombolytic agent. The requestor further stated the increased utilization of resources of these cases was isolated to be almost entirely due to the cost of the tPA itself based on this review of their internal cost level data. Consequently, the requestor stated the continued assignment of these conditions to MS–DRG 123 does not properly recognize disease complexity and understates the resource utilization associated with administering critical (potentially vision-saving) treatments for these cases.

The requestor suggested that the following three MS–DRGs be created to reflect current standard of care for these patients:

- Suggested New MS–DRG XXX—Neurological Eye Disorders with Thrombolytic Agent with MCC.
- Suggested New MS–DRG XXX—Neurological Eye Disorders with Thrombolytic Agent with CC.

• Suggested New MS–DRG XXX—Neurological Eye Disorders with Thrombolytic Agent without CC/MCC.

We stated in the proposed rule that in reviewing this issue, it was unclear why the requestor did not include branch retinal artery occlusion (BRAO) in their request for FY 2024 rulemaking. As discussed in the FY 2023 IPPS/LTCH PPS final rule, BRAO is a closely allied condition. Therefore, we identified the ICD–10–CM codes found in the following table that describe CRAO and BRAO.

BILLING CODE 4120–01–P

ICD-10-CM Code	Description
H34.10	Central retinal artery occlusion, unspecified eye
H34.11	Central retinal artery occlusion, right eye
H34.12	Central retinal artery occlusion, left eye
H34.13	Central retinal artery occlusion, bilateral
H34.231	Retinal artery branch occlusion, right eye
H34.232	Retinal artery branch occlusion, left eye
H34.233	Retinal artery branch occlusion, bilateral
H34.239	Retinal artery branch occlusion, unspecified eye

We stated in the proposed rule that thrombolytic therapy is identified with the following ICD–10–PCS procedure codes.

ICD-10-PCS Code	Description
3E03017	Introduction of other thrombolytic into peripheral vein, open approach
3E03317	Introduction of other thrombolytic into peripheral vein, percutaneous approach
3E04017	Introduction of other thrombolytic into central vein, open approach
3E04317	Introduction of other thrombolytic into central vein, percutaneous approach
3E05017	Introduction of other thrombolytic into peripheral artery, open approach
3E05317	Introduction of other thrombolytic into peripheral artery, percutaneous approach
3E06017	Introduction of other thrombolytic into central artery, open approach
3E06317	Introduction of other thrombolytic into central artery, percutaneous approach

In this final rule, we would like to correct the statement in the proposed rule and add that thrombolytic therapy is also identified with the following two ICD–10–PCS procedure codes.

3E08017	Introduction of other thrombolytic into heart, open approach
3E08317	Introduction of other thrombolytic into heart, percutaneous approach

We stated in the proposed rule that our analysis of this grouping issue again confirmed that, when a procedure code describing the administration of a thrombolytic agent is reported with principal diagnosis code describing CRAO or BRAO, these cases group to medical MS–DRG 123. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 40.1, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for MS–DRG 123.

To begin our analysis, as discussed in the proposed rule, we examined claims data from the September 2022 update of the FY 2022 MedPAR file for MS–DRG 123 to (1) identify cases reporting a principal diagnosis code describing CRAO or BRAO without a procedure code describing the administration of a thrombolytic agent and (2) identify cases reporting diagnosis codes describing CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent. Our findings are shown in the following table:

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
123	All cases	2,771	2.5	$6,720
	Cases reporting a principal diagnosis of CRAO or BRAO without a procedure code describing the administration of a thrombolytic agent	839	2.2	$5,842
	Cases reporting a principal diagnosis of CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent	38	3.3	$13,302
	All other cases	1,894	2.6	$6,977

As shown in the table, we identified a total of 2,771 cases within MS–DRG 123 with an average length of stay of 2.5 days and average costs of $6,720. Of these 2,771 cases, there are 839 cases that reported a principal diagnosis code describing CRAO or BRAO without a procedure code describing the administration of a thrombolytic agent with an average length of stay of 2.2 days and average costs of $5,842. There are 38 cases that reported a principal diagnosis code describing CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent with an average length of stay of 3.3 days and average costs of $13,302.

We stated in the proposed rule that the data analysis showed that the 839 cases in MS–DRG 123 reporting a principal diagnosis code describing CRAO or BRAO without a procedure code describing the administration of a thrombolytic agent have lower average costs as compared to all cases in MS–DRG 123 ($5,842 compared to $6,720), and a shorter average length of stay (2.2 days compared to 2.5 days). For the 38 cases in MS–DRG 123 reporting a principal diagnosis code describing CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent, however, the average length of stay is longer (3.3 days compared to 2.5 days) and the average costs are higher ($13,302 compared to $6,720) than the average length of stay and average costs compared to all cases in that MS–DRG.

We stated in the proposed rule that we reviewed these data and did not believe that the small subset of cases reporting a principal diagnosis code describing CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent warranted the creation of new MS–DRGs at this time. As stated in prior rulemaking, the MS–DRGs are a classification system intended to group together diagnoses and procedures with similar clinical characteristics and utilization of resources. We generally seek to identify sufficiently large sets of claims data with a resource/cost similarity and clinical similarity in developing diagnostic-related groups rather than smaller subsets. Moreover, in response to the specific request to create new MS–DRGs subdivided into severity levels for the cases reporting a principal diagnosis code describing CRAO with a procedure code describing the administration of a thrombolytic agent, we only identified a total of 38 cases, so the criterion that there are at least 500 or more cases in each subgroup cannot be met. Therefore, for FY 2024, we did not propose to create new MS–DRGs subdivided into severity levels for cases reporting a principal diagnosis code describing CRAO with a procedure code describing the administration of a thrombolytic agent.

We noted in the proposed rule that we recognized however, that the average costs of the small number of cases reporting a principal diagnosis code describing CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent are greater when compared to the average costs of all cases in MS–DRG 123. To explore other mechanisms to address this request, we then reexamined the MS–DRGs within MDC 02 to consider the possibility of reassigning the cases with a principal diagnosis of CRAO or BRAO that receive the administration of a thrombolytic agent to other MS–DRGs within MDC 02. As discussed in the proposed rule, after further consideration, in reviewing the claims data from the September 2022 update of the FY 2022 MedPAR file and examining the clinical considerations, we stated that we believe that the cases reporting a principal diagnosis code describing CRAO or BRAO could more suitably group to MS–DRGs 124 and 125 (Other Disorders of the Eye with MCC, and without MCC, respectively), which contain diagnoses other than neurological conditions that affect the eye, noting the vascular involvement inherent to a diagnosis of CRAO or BRAO. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 40.1, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for MS–DRGs 124 and 125.

To determine how the resources for this subset of cases compared to cases in MS–DRGs 124 and 125 as a whole, we stated we examined the average costs and length of stay for cases in MS–DRGs 124 and 125. Our findings are shown in this table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 124--All cases	889	5.4	$11,922
MS-DRG 125--All cases	2,424	3.3	$7,425

For this subset of cases, the average costs of the 38 cases reporting a principal diagnosis code describing CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent are slightly higher ($13,302 compared to $11,922) and the average length of stay is shorter (3.3 days compared to 5.4 days) than for all cases in MS–DRGs 124. The 839 cases reporting a principal diagnosis code describing CRAO or BRAO without a procedure code describing the administration of a thrombolytic agent have lower average costs ($5,842 compared to $7,425) and a shorter average length of stay (2.2 compared to 3.3 days) than for cases in MS–DRG 125.

We stated in the proposed rule that our analysis demonstrated that while the volume of cases is small, the average costs for the cases reporting a principal diagnosis code describing CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent currently grouping to MS–DRG 123 are more aligned with the average costs of the cases currently grouping to MS–DRG 124. We stated we reviewed these data and supported the addition of the ten diagnosis codes listed previously to the GROUPER logic list for MS–DRGs 124 and 125. While the cases reporting a principal diagnosis code describing CRAO or BRAO without a procedure code describing the administration of a thrombolytic agent have lower costs and a shorter average length of stay than for cases in MS–DRG 125, we stated we believed reassigning these diagnosis codes to MS–DRGs 124 and 125 would better account for the subset of patients who are treated with a thrombolytic agent, and would more appropriately reflect the resources involved in evaluating and treating these patients. We also stated we supported the assignment of the cases reporting procedure codes describing the administration of a thrombolytic agent to the higher (MCC) severity level MS–DRG 124 as an enhancement to better reflect the clinical severity and resource use involved in these cases.

Therefore, we proposed to reassign ICD–10–CM diagnosis codes H34.10, H34.11, H34.12, H34.13, H34.231, H34.232, H34.233, and H34.239 from MDC 02 MS–DRG 123 to MS–DRGs 124 and 125, effective October 1, 2023, for FY 2024. We also proposed to add the procedure codes describing the administration of a thrombolytic agent listed previously to MS–DRG 124. In the proposed rule, we noted that the procedure codes describing the administration of a thrombolytic agent are not designated as operating room procedures for purposes of MS–DRG assignment (''non-O.R. procedures''), therefore, as part of the logic for MS–DRG 124, we also proposed to designate these codes as non-O.R. procedures affecting the MS–DRG. Lastly, for consistency, we also proposed to change the titles of MS–DRGs 124 and 125 from ''Other Disorders of the Eye, with and without MCC, respectively'' to ''Other Disorders of the Eye with MCC or Thrombolytic Agent, and without MCC, respectively'' to better reflect the assigned procedures.

Comment: Commenters agreed with our proposal to reassign ICD–10–CM diagnosis codes H34.10, H34.11, H34.12, H34.13, H34.231, H34.232, H34.233, and H34.239 from MDC 02 MS–DRG 123 to MS–DRGs 124 and 125. A commenter stated that this proposal better aligns with the resource consumption of these cases. Another commenter stated that the proposed MS–DRG assignment of cases reporting a principal diagnosis code describing CRAO or BRAO with a procedure code describing the administration of a thrombolytic agent would more accurately capture the complexity of the condition and the necessary resources associated with administering critical treatments.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to reassign ICD–10–CM diagnosis codes H34.10, H34.11, H34.12, H34.13, H34.231, H34.232, H34.233, and H34.239 from MDC 02 MS–DRG 123 to MS–DRGs 124 and 125, without modification, effective October 1, 2023, for FY 2024. In addition, we are finalizing our proposal to add the procedure codes describing the administration of a thrombolytic agent listed previously to MS–DRG 124. As part of the logic for MS–DRG 124, we are also finalizing our proposal to designate the 10 ICD–10–PCS procedure codes describing the administration of a thrombolytic agent listed previously as non-O.R. procedures affecting the MS–DRG. Lastly, we are finalizing our proposal to change the titles of MS–DRGs 124 and 125 from ''Other Disorders of the Eye, with and without MCC, respectively'' to ''Other Disorders of the Eye with MCC or Thrombolytic Agent, and without MCC, respectively'' to better reflect the assigned procedures for FY 2024.

4. MDC 04 (Diseases and Disorders of the Respiratory System)

a. Ultrasound Accelerated Thrombolysis for Pulmonary Embolism

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26684 through 26691), we received a request to reassign cases reporting ultrasound accelerated thrombolysis (USAT) with the administration of thrombolytic(s) for the treatment of pulmonary embolism (PE) from MS–DRGs 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively).

A pulmonary embolism is an obstruction of pulmonary vasculature most commonly caused by a venous thrombus, and less commonly by fat or tumor tissue or air bubbles or both. Risk factors for a pulmonary embolism include prolonged immobilization from any cause, obesity, cancer, fractured hip or leg, use of certain medications such as oral contraceptives, presence of certain medical conditions such as heart failure, sickle cell anemia, or certain congenital heart defects. Common symptoms of pulmonary embolism include shortness of breath with or without chest pain, tachycardia, hemoptysis, low grade fever, pleural effusion, and depending on the etiology of the embolus, might include lower extremity pain or swelling, syncope, jugular venous distention. Alternatively, a pulmonary embolus could be asymptomatic.

Thrombolysis is a type of treatment where the infusion of thrombolytics (fibrinolytic or ''clot-busting'' drugs) is used to dissolve blood clots that form in the arteries or veins with the goal of

improving blood flow and preventing long-term damage to tissues and organs. When a clot forms in the arteries of the lungs it is known as a pulmonary embolism. In addition, clots in the veins of the legs causing deep venous thrombosis (DVT) may also result in pulmonary embolism if a piece of the clot breaks off and travels to an artery in the lungs. Conventional catheter-directed thrombolysis (CDT) procedures generally rely on a multi-sidehole catheter placed adjacent to the thrombus through which thrombolytics are delivered directly to the thrombus, however, the EKOS™ EkoSonic® Endovascular System (EKOS™ System) employs ultrasound to assist in thrombolysis. The ultrasound does not itself dissolve the thrombus, but pulses of ultrasonic energy temporarily make the fibrin in the thrombus more porous and increase fluid flow within the thrombus. High frequency, low-intensity ultrasonic waves create a pressure gradient that drives the thrombolytic into the thrombus and keeps it in close proximity to the binding sites. USAT is also referred to as ultrasound-assisted thrombolysis or ultrasound-enhanced thrombolysis.

As discussed in the proposed rule, according to the requestor (the manufacturer of the EKOS™ device), USAT with the administration of thrombolytic(s) for the treatment of PE performed using the EKOS™ device utilizes more resources in comparison to other procedures that are currently assigned to MS–DRGs 166, 167, and 168 and is not clinically coherent with the other procedures assigned to those MS–DRGs. The requestor stated that the cases reporting USAT with the administration of thrombolytic(s) for PE are more comparable with and more clinically aligned with the procedures assigned to MS–DRGs 163, 164, and 165. The requestor stated they performed an analysis of cases reporting USAT for PE with the following ICD–10–PCS procedure codes.

ICD-10-PCS Code	Description
02FP3Z0	Fragmentation of pulmonary trunk, percutaneous approach, ultrasonic
02FQ3Z0	Fragmentation of right pulmonary artery, percutaneous approach, ultrasonic
02FR3Z0	Fragmentation of left pulmonary artery, percutaneous approach, ultrasonic
02FS3Z0	Fragmentation of right pulmonary vein, percutaneous approach, ultrasonic
02FT3Z0	Fragmentation of left pulmonary vein, percutaneous approach, ultrasonic
03F23Z0	Fragmentation of innominate artery, percutaneous approach, ultrasonic
03F33Z0	Fragmentation of right subclavian artery, percutaneous approach, ultrasonic
03F43Z0	Fragmentation of left subclavian artery, percutaneous approach, ultrasonic
03F53Z0	Fragmentation of right axillary artery, percutaneous approach, ultrasonic
03F63Z0	Fragmentation of left axillary artery, percutaneous approach, ultrasonic
03F73Z0	Fragmentation of right brachial artery, percutaneous approach, ultrasonic
03F83Z0	Fragmentation of left brachial artery, percutaneous approach, ultrasonic
03F93Z0	Fragmentation of right ulnar artery, percutaneous approach, ultrasonic
03FA3Z0	Fragmentation of left ulnar artery, percutaneous approach, ultrasonic
03FB3Z0	Fragmentation of right radial artery, percutaneous approach, ultrasonic
03FC3Z0	Fragmentation of left radial artery, percutaneous approach, ultrasonic
03FY3Z0	Fragmentation of upper artery, percutaneous approach, ultrasonic

We noted in the proposed rule that the requestor did not include a list of diagnosis codes describing PE or a list of procedure codes describing the administration of thrombolytic(s) in connection with its analysis.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58561 through 85 FR 58579), we summarized and responded to public comments expressing concern with the proposed MS–DRG assignments for the newly created procedure codes describing USAT of several anatomic sites that were effective with discharges on and after October 1, 2020 (FY 2021). We noted in the proposed rule that similar to the current request for FY 2024, for FY 2021, the commenters recommended that USAT procedures performed with the EKOS™ device for the treatment of pulmonary embolism be assigned to MS–DRGs 163, 164, and 165 instead of MS–DRGs 166, 167, and 168. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58561 through 85 FR 58579), available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* for the detailed discussion.

As discussed in the proposed rule, we analyzed claims data from the September 2022 update of the FY 2022 MedPAR file for MS–DRGs 166, 167, and 168 for all cases reporting a principal diagnosis of PE and USAT procedure with and without the administration of thrombolytic(s). We identified claims reporting an USAT procedure, the administration of thrombolytic(s), and a diagnosis of PE with the listed codes shown in the following tables.

List of ICD-10-PCS Procedure Codes Describing Ultrasound Accelerated Thrombolysis (USAT)	
ICD-10-PCS Code	**Description**
02FP3Z0	Fragmentation of pulmonary trunk, percutaneous approach, ultrasonic
02FQ3Z0	Fragmentation of right pulmonary artery, percutaneous approach, ultrasonic
02FR3Z0	Fragmentation of left pulmonary artery, percutaneous approach, ultrasonic
02FS3Z0	Fragmentation of right pulmonary vein, percutaneous approach, ultrasonic
02FT3Z0	Fragmentation of left pulmonary vein, percutaneous approach, ultrasonic

List of ICD-10-PCS Procedure Codes Describing Administration of Thrombolytic(s)	
ICD-10-PCS Code	**Description**
3E03317	Introduction of other thrombolytic into peripheral vein, percutaneous approach
3E04317	Introduction of other thrombolytic into central vein, percutaneous approach
3E05317	Introduction of other thrombolytic into peripheral artery, percutaneous approach
3E06317	Introduction of other thrombolytic into central artery, percutaneous approach

List of ICD-10-CM Diagnosis Codes Describing Pulmonary Embolism	
ICD-10-CM Code	**Description**
I26.01	Septic pulmonary embolism with acute cor pulmonale
I26.02	Saddle embolus of pulmonary artery with acute cor pulmonale
I26.09	Other pulmonary embolism with acute cor pulmonale
I26.90	Septic pulmonary embolism without acute cor pulmonale
I26.92	Saddle embolus of pulmonary artery without acute cor pulmonale
I26.93	Single subsegmental pulmonary embolism without acute cor pulmonale
I26.94	Multiple subsegmental pulmonary emboli without acute cor pulmonale
I26.99	Other pulmonary embolism without acute cor pulmonale
I27.82	Chronic pulmonary embolism

We noted that the listed procedure codes describing USAT identified for our claims analysis differ from the procedure codes identified by the requestor for its analysis. Clinically, we did not agree that thrombolysis of non-pulmonary anatomic sites (for example, subclavian artery, axillary artery, etc.) would be performed for the treatment of a PE. We also noted that the procedure codes describing thrombolysis of non-pulmonary anatomic sites provided by the requestor are assigned to MDC 05 (Diseases and Disorders of the Circulatory System) and not to MDC 04 (Diseases and Disorders of the Respiratory System) where MS–DRGs 163, 164, 165, 166, 167, and 168 are assigned. The findings from our analysis are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
166 – All cases	8,318	11	$31,910
166 – Cases reporting a principal diagnosis of PE and USAT with thrombolytic(s)	826	5.4	$28,912
166 – Cases reporting principal diagnosis of PE and USAT without thrombolytic(s)	161	5.4	$27,897
167 – All cases	4,306	4.7	$16,290
167 – Cases reporting a principal diagnosis of PE and USAT with thrombolytic(s)	316	3.9	$23,240
167 – Cases reporting principal diagnosis of PE and USAT without thrombolytic(s)	52	3.7	$23,608
168 – All cases	1,441	2.3	$12,379
168 – Cases reporting a principal diagnosis of PE and USAT with thrombolytic(s)	65	2.8	$20,156
168 – Cases reporting principal diagnosis of PE and USAT without thrombolytic(s)	15	2.7	$20,112

As shown in the table, we identified a total of 8,318 cases in MS–DRG 166 with an average length of stay of 11 days and average costs of $31,910. Of the 8,318 cases, we found 826 cases reporting a principal diagnosis of PE and USAT with thrombolytic(s) with an average length of stay of 5.4 days and average costs of $28,912 and 161 cases reporting a principal diagnosis of PE and USAT without thrombolytic(s) with an average length of stay of 5.4 days and

average costs of $27,897. The data demonstrate that the cases reporting a principal diagnosis of PE and USAT with or without thrombolytic(s) have a shorter average length of stay compared to the average length of stay of all the cases in MS–DRG 166 (5.4 days and 5.4 days, respectively versus 11 days). Similarly, the average costs for the cases reporting a principal diagnosis of PE and USAT with or without thrombolytic(s) are lower than the average costs of all the cases in MS–DRG 166 ($28,912 and $27,897, respectively versus $31,910). The data indicate that the cases reporting a principal diagnosis of PE and USAT with or without thrombolytic(s) appear to be grouped and paid appropriately, despite the fact the logic for case assignment to MS–DRG 166 requires the reporting of at least one or more secondary MCC diagnoses, and it would not be unreasonable to expect these cases to be more expensive in comparison to all the cases in MS–DRG 166. As the average costs for these cases are lower than the average costs of all the cases in MS–DRG 166, the data appear to reflect that the reporting of at least one or more secondary MCC diagnoses and use of the EKOS™ device technology did not impact consumption of resources for these cases in MS–DRG 166.

For MS–DRG 167, we identified a total of 4,306 cases with an average length of stay of 4.7 days and average costs of $16,290. Of the 4,306 cases, we found 316 cases reporting a principal diagnosis of PE and USAT with thrombolytic(s) with an average length of stay of 3.9 days and average costs of $23,240 and 52 cases reporting a principal diagnosis of PE and USAT without thrombolytic(s) with an average length of stay of 3.7 days and average costs of $23,608. The data demonstrate that the cases reporting a principal diagnosis of PE and USAT with or without thrombolytic(s) have a shorter average length of stay compared to the average length of stay of all the cases in MS–DRG 167 (3.9 days and 3.7 days, respectively versus 4.7 days). Conversely, the average costs for the cases reporting a principal diagnosis of PE and USAT with or without thrombolytic(s) are higher than the average costs of all the cases in MS–DRG 167 ($23,240 and $23,608, respectively versus $16,290) with a corresponding difference in average costs of $6,950 and $7,318, respectively. The data indicate the cases reporting a principal diagnosis of PE and USAT with or without thrombolytic(s) appear to consume more resources in comparison to the other cases in MS–DRG 167, although it is unclear if the higher resource consumption is a direct result of the EKOS™ device technology utilized in the performance of the thrombolysis procedure, or the fact that these cases also include the reporting of at least one or more secondary CC diagnoses, or a combination of both factors.

For MS–DRG 168, we identified a total of 1,441 cases with an average length of stay of 2.3 days and average costs of $12,379. Of the 1,441 cases, we found 65 cases reporting a principal diagnosis of PE and USAT with thrombolytic(s) with an average length of stay of 2.8 days and average costs of $20,156 and 15 cases reporting a principal diagnosis of PE and USAT without thrombolytic(s) with an average length of stay of 2.7 days and average costs of $20,112. The data demonstrate that the cases reporting a principal diagnosis of PE and USAT with or without thrombolytic(s) have a longer average length of stay compared to the average length of stay of all the cases in MS–DRG 168 (2.8 days and 2.7 days, respectively versus 2.3 days). Additionally, the average costs for the cases reporting a principal diagnosis of PE and USAT with or without thrombolytic(s) are higher than the average costs of all the cases in MS–DRG 168 ($20,156 and $20,112, respectively versus $12,379) with a corresponding difference in average costs of $7,777 and $7,733, respectively. Similar to our findings for MS–DRG 167, the data for MS–DRG 168 indicate the cases reporting a principal diagnosis of PE and USAT with or without thrombolytic(s) appear to consume more resources in comparison to the other cases in MS–DRG 168. However, it is unclear if the higher resource consumption is a direct result of the EKOS™ device technology utilized in the performance of the thrombolysis procedure alone, or if there are other contributing factors, since cases grouping to MS–DRG 168 do not include the reporting of at least one or more secondary CC or MCC diagnoses.

We stated in the proposed rule that based on our review of the data for MS–DRGs 166, 167, and 168 and our initial analysis for cases reporting a principal diagnosis of PE and USAT procedure with and without the administration of thrombolytic(s), the findings also suggest that the administration of thrombolytic(s) is not a significant factor in the consumption of resources for these cases in MS–DRGs 166, 167, and 168 where USAT is performed in the treatment of a PE. For example, in MS–DRG 166, there are 826 cases reporting a principal diagnosis of PE and USAT procedure with the administration of thrombolytic(s) and 161 cases reporting a principal diagnosis of PE and USAT procedure without the administration of thrombolytic(s), however, both subsets of cases have an equivalent average length of stay of 5.4 days and a difference in average costs of $1,015 ($28,912 − $27,897 = $1,015). For MS–DRG 167, there are 316 cases reporting a principal diagnosis of PE and USAT procedure with the administration of thrombolytic(s) and 52 cases reporting a principal diagnosis of PE and USAT procedure without the administration of thrombolytic(s), however, both subsets of cases have a similar average length of stay (3.9 days and 3.7 days, respectively) with a difference in average costs of $368 ($23,608 − $23,240 = $368). For MS–DRG 168, there are 65 cases reporting a principal diagnosis of PE and USAT procedure with the administration of thrombolytic(s) and 15 cases reporting a principal diagnosis of PE and USAT procedure without the administration of thrombolytic(s), however, both subsets of cases have a similar average length of stay (2.8 days and 2.7 days, respectively) with a difference in average costs of $44 ($20,156 − $20,112 = $44). Because the administration of thrombolytic(s) would be expected to increase resource consumption, the small difference in average costs between these two sets of cases could also suggest that the administration of thrombolytic(s) was not consistently reported.

We noted in the proposed rule that while the request we received was to reassign cases reporting ultrasound accelerated thrombolysis (USAT) with the administration of thrombolytic(s) for the treatment of pulmonary embolism (PE) from MS–DRGs 166, 167, and 168 to MS–DRGs 163, 164, and 165, based on our findings that suggest the administration of thrombolytic(s) is not a significant factor in the consumption of resources for those cases or that a code describing the administration of thrombolytic(s) may not have been consistently reported on a subset of claims that also reported a code identifying USAT was performed, we then analyzed claims data from the September 2022 update of the FY 2022 MedPAR file for all cases in MS–DRGs 163, 164, and 165 and compared it to the cases reporting a principal diagnosis of PE and USAT procedure with or without thrombolytic(s) in MS–DRGs 166, 167, and 168. The findings from our analysis are shown in the following tables.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
163 – All cases	10,697	10.3	$39,126
164 – All cases	13,384	4.7	$22,040
165 – All cases	6,301	2.7	$16,404

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
166 – All cases	8,318	11	$31,910
166 – Cases with principal diagnosis of PE and USAT with or without thrombolytic(s)	987	5.4	$28,746
167– All cases	4,306	4.7	$16,290
167 – Cases with principal diagnosis of PE and USAT with or without thrombolytic(s)	368	3.9	$23,292
168 – All cases	1,441	2.3	$12,379
168– Cases with principal diagnosis of PE and USAT with or without thrombolytic(s)	80	2.8	$20,148

The average costs of the 987 cases reporting a principal diagnosis of PE and USAT with or without thrombolytic(s) in MS–DRG 166 are $10,380 less than the average costs of all cases in MS–DRG 163 ($39,126-$28,746=$10,380) and have an average length of stay that is approximately half the average length of stay of all cases in MS–DRG 163 (5.4 days versus 10.3 days). As stated previously, our analysis of these cases demonstrate they appear to be grouped and paid appropriately in MS–DRG 166. The 368 cases reporting a principal diagnosis of PE and USAT with or without thrombolytic(s) in MS–DRG 167 have a shorter average length of stay (3.9 days versus 4.7 days) in comparison to all the cases in MS–DRG 164, however, the average costs of the 368 cases reporting a principal diagnosis of PE and USAT with or without thrombolytic(s) in MS–DRG 167 are more comparable to the average costs of all the cases in MS–DRG 164 ($23,292 versus $22,040). Finally, the 80 cases reporting a principal diagnosis of PE and USAT with or without thrombolytic(s) in MS–DRG 168 have an average length of stay that is more comparable to all the cases in the MS–DRG 165 (2.8 days versus 2.7 days), however, the average costs for the 80 cases continue to be higher in comparison to all the cases in MS–DRG 165 ($20,148 versus $16,404).

We stated in the proposed rule that upon analysis of the claims data and our review of the request, we do not agree with reassigning cases reporting an USAT procedure with the administration of thrombolytic(s) and a principal diagnosis of PE from MS–DRGs 166, 167, and 168 to MS–DRGs 163, 164, and 165. As previously noted, the data do not support that cases reporting USAT (with or without thrombolytic(s)) for PE utilize similar resources when compared to other procedures currently assigned to MS–DRGs 163 and 165. Costs were only comparable with procedures currently assigned to MS–DRG 164. Further, we stated we do not agree that cases reporting USAT (with or without thrombolytic(s)) are more comparable with and more clinically aligned with the procedures assigned to MS–DRGs 163, 164, and 165. The vast majority of procedures in these MS–DRGs describe procedures performed on the trachea, bronchus or lungs with either an open approach or a percutaneous endoscopic approach in contrast to the USAT endovascular (percutaneous) procedure performed on the pulmonary trunk, arteries or veins. In addition, the majority of procedures in MS–DRGs 163, 164, and 165 are performed on patients who are not clinically similar to patients who undergo USAT for PE since they describe procedures such as destruction (ablation) or excision performed for patients with conditions other than a PE, such as malignant neoplasm, pneumonia, or pulmonary fibrosis. Lastly, a number of procedures in these MS–DRGs also involve the use of a permanently implanted device while the procedures utilizing USAT do not. Therefore, we stated in the proposed rule that we do not consider USAT procedures to be major chest procedures, nor do we believe the cases reporting USAT with (or without thrombolytic(s)) for PE utilize similar resources when compared to other procedures currently assigned to MS–DRGs 163, 164, and 165.

As stated in the proposed rule, the findings from our analysis suggest that the administration of thrombolytic(s) is not a significant factor in the consumption of resources for cases in MS–DRGs 166, 167, and 168 reporting an USAT procedure performed for the treatment of a PE or that a code describing the administration of thrombolytic(s) may not have been consistently reported on a subset of claims that also reported a code identifying USAT was performed, or a combination of both factors. Based on these findings related to the administration of thrombolytic(s), we stated we believed it would also be beneficial to examine cases reporting standard CDT procedures with or without thrombolytic(s) for the treatment of PE in MS–DRGs 166, 167, and 168, and compare the findings to the cases reporting USAT with or without thrombolytic(s) for the treatment of PE.

Therefore, as discussed in the proposed rule, we conducted additional analyses to determine if there were significant differences in resource utilization for cases reporting standard CDT with or without thrombolytic(s) versus USAT procedures with or without thrombolytic(s) in the treatment of PE, since claims data to compare the two modalities is now available and studies have reported similar clinical outcomes in reducing PE regardless of which thrombolysis modality is utilized.[3] [4]

[3] Rothschild DP, Goldstein JA, Ciacci J, Bowers TR. Ultrasound-accelerated thrombolysis (USAT) versus standard catheter-directed thrombolysis (CDT) for treatment of pulmonary embolism: A retrospective analysis. Vasc Med. 2019 Jun;24(3):234–240.

[4] Sista A, et al. Is it Time to Sunset Ultrasound-Assisted Catheter-Directed Thrombolysis for Submassive PE?*. J Am Coll Cardiol Intv. 2021 Jun, 14 (12) 1374–1375.

In the proposed rule, we stated that we analyzed claims data from the September 2022 update of the FY 2022 MedPAR file for all cases in MS–DRGs 166, 167, and 168 and cases reporting a standard CDT procedure with or without the administration of thrombolytic(s) and a principal diagnosis of PE. We utilized the previously listed procedure codes for the administration of thrombolytic(s) and the previously listed diagnosis codes for a principal diagnosis of PE. We identified cases describing standard CDT procedures performed in the treatment of PE with the following procedure codes.

List of ICD-10-PCS Procedure Codes Describing Standard Catheter-Directed Thrombolysis (CDT)	
ICD-10-PCS Code	**Description**
02FP3ZZ	Fragmentation of pulmonary trunk, percutaneous approach
02FQ3ZZ	Fragmentation of right pulmonary artery, percutaneous approach
02FR3ZZ	Fragmentation of left pulmonary artery, percutaneous approach
02FS3ZZ	Fragmentation of right pulmonary vein, percutaneous approach
02FT3ZZ	Fragmentation of left pulmonary vein, percutaneous approach

The findings from our analysis are shown in the following table. We noted that there were no cases found to report a principal diagnosis of PE and standard CDT with or without thrombolytic(s) in MS–DRGs 168.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
166 – All cases	8,318	11	$31,910
166 – Cases with principal diagnosis of PE and CDT with or without thrombolytic(s)	7	3.3	$18,472
167– All cases	4,306	4.7	$16,290
167 – Cases with principal diagnosis of PE and CDT with or without thrombolytic(s)	6	3.5	$30,928
168 – All cases	1,441	2.3	$12,379

The data shows that the 7 cases reporting a principal diagnosis of PE and standard CDT with or without thrombolytic(s) in MS–DRG 166 have a shorter average length of stay compared to all cases in MS–DRG 166 (3.3 days versus 11 days) and lower average costs ($18,472 versus $31,910). For MS–DRG 167, the data shows that the 6 cases reporting a principal diagnosis of PE and CDT with or without thrombolytic(s) have a shorter average length of stay compared to all cases in MS–DRG 167 (3.5 days versus 4.7 days), however the average costs are higher ($30,928 versus $16,290).

As discussed in the proposed rule, based on our review and the claims data analysis for cases in MS–DRGs 163, 164, and 165, and for MS–DRGs 166, 167, and 168 and cases reporting standard CDT or USAT with or without thrombolytic(s) and a principal diagnosis of PE, we believe that while this subset of cases for patients undergoing a thrombolysis (CDT or USAT) procedure for PE does not clinically align with patients undergoing surgery for malignancy or treatment for infection and does not involve the same level of complexity, monitoring or support as cases grouping to MS–DRGs 163, 164, and 165, the differences in resource consumption warrant proposed reassignment of these cases. Specifically, we believe the clinical and data analyses support creating a new base MS–DRG to distinguish cases reporting a principal diagnosis of PE and USAT or standard CDT procedure with or without thrombolytic(s) from other cases currently grouping to MS–DRGs 166, 167, and 168. We believe a new MS–DRG would reflect more appropriate payment for USAT and standard CDT procedures in the treatment of PE.

We stated in the proposed rule that to compare and analyze the impact of our suggested modifications, we ran a simulation using the most recent claims data from the December 2022 update of the FY 2022 MedPAR file. The following table illustrates our findings for all 1,534 cases reporting procedure codes describing an USAT or CDT procedure with a principal diagnosis of PE.

Proposed new MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed new MS-DRG XXX	1,534	4.8	$26,802

Consistent with our established process as discussed in section II.C.1.b. of the preamble of the proposed rule and this final rule, once the decision has been made to propose to make further modifications to the MS–DRGs, such as creating a new base MS–DRG, all five criteria to create subgroups must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. Therefore, we applied the criteria to create subgroups in a base MS–DRG. We noted that, as shown in the table that follows, a three-way split of this base MS–DRG failed to meet the criterion that there be at least 500 cases in both the CC and the NonCC (without CC/MCC) subgroup and it also failed to

meet the criterion that there be a 20% difference in average costs between the CC and NonCC subgroup.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
With MCC	1,058	5.31	$28,618
With CC	393	3.85	$23,164
Without CC/MCC	83	2.88	$20,886

As also discussed in section II.C.1.b. of the preamble of the proposed rule and this final rule, if the criteria for a three-way split fail, the next step is to determine if the criteria are satisfied for a two-way split. We therefore applied the criteria for a two-way split for the ''with MCC and without MCC'' subgroups. We noted that, as shown in the table that follows, a two-way split of this base MS–DRG failed to meet the criterion that there be at least 500 cases in the without MCC (CC+NonCC) subgroup. The following table illustrates our findings.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
With MCC	1,058	5.31	$28,618
Without MCC	476	3.7	$22,767

We then applied the criteria for a two-way split for the ''with CC/MCC and without CC/MCC'' subgroups. As with the analysis of the three-way severity split as described previously, and as shown in the table that follows, a two-way split of this base MS–DRG failed to meet the criterion that there be at least 500 cases in the without CC/MCC (NonCC) subgroup.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
With CC/MCC	1,451	4.9	$27,141
Without CC/MCC	83	2.88	$20,886

We noted that because the criteria for both of the two-way splits failed, a split (or CC subgroup) is not warranted for the proposed new base MS–DRG. As a result, for FY 2024, we proposed to create new base MS–DRG 173 (Ultrasound Accelerated and Other Thrombolysis with Principal Diagnosis Pulmonary Embolism). The following table reflects a simulation of the proposed new base MS–DRG.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed MS-DRG 173	1,534	4.8	$26,802

BILLING CODE 4120–01–C

We stated we believed the resulting proposed MS–DRG better recognizes the consumption of resources and maintains clinical coherence for both USAT and CDT procedures performed for the treatment of PE.

We proposed to define the logic for the proposed new MS–DRG using the previously listed diagnosis codes for PE and the previously listed procedure codes for USAT and CDT, as identified and discussed in our analysis of the claims data in the proposed rule and in this final rule.

Comment: Commenters supported the proposal to create new MS–DRG 173 (Ultrasound Accelerated and Other Thrombolysis with Principal Diagnosis Pulmonary Embolism) given the data and information provided. A commenter expressed appreciation that CMS has acted to correct payment disparities for these procedures and recommended that CMS also utilize this approach to address other, similar MS–DRG reassignment requests that may involve a component with a lower volume of cases. Another commenter stated the proposal aligns more closely with the resources used, as opposed to the current MS–DRGs 166, 167, and 168. The commenter requested that CMS continue to analyze the data for these cases and consider creating an additional MS–DRG to reflect major complications and comorbidities, if warranted by further analysis. Other commenters who supported the proposal to reassign the cases from their current MS–DRG assignment expressed concern about the proposed single base MS–DRG. Specifically, the commenters stated the proposal does not acknowledge the secondary diagnosis

impact that the CMS analysis recognized may or may not be a contributing factor for the higher average costs of the cases reporting USAT procedures. The commenters also stated that the proposal demonstrates that application of the NonCC Subgroup may not be appropriate for some MS–DRGs since the result in this instance is for a base MS–DRG with a lower relative weight because severity of illness is unable to be recognized.

Response: We thank the commenters for their support. In response to the concerns raised by the commenters regarding the impact application of the NonCC subgroup criteria has on proposed new MS–DRG 173, we note that, as discussed in the proposed rule and in this final rule, we apply the NonCC subgroup criteria once the decision is made to propose to make further modifications to the MS–DRGs. While application of the criteria did not support a severity level split for proposed MS–DRG 173 for FY 2024, we intend to reevaluate for future rulemaking whether the criteria for a potential ''with MCC'' and ''without MCC'' two-way split would be met.

Comment: A couple commenters suggested that the proposal to create new MS–DRG 173 should be delayed until more data can be collected. The commenters stated their belief that it is premature to create this new MS–DRG at this time and that in developing this proposed MS–DRG, CMS relied on recently implemented ICD–10–PCS data. According to the commenters, due to the lengthy processes for hospitals to adopt and accurately implement new coding, and conflicting coding advice for utilization of the ICD–10–PCS procedure codes for CDT and USAT, the number of cases is currently insufficient to support development of a new MS–DRG. The commenters stated that the low volume of cases and related data selected by CMS for analysis, CDT for the treatment of PE, cannot adequately compare to the costs, complexity, and utilization of USAT with a high confidence interval.

Response: We appreciate the commenters' feedback. We disagree with the commenters that it is premature to propose the creation of new MS–DRG 173 based on our review and claims data analysis as discussed in the proposed rule. In response to the commenters' statement that CMS relied on recently implemented ICD–10–PCS data, it is not clear to us what specific ICD–10–PCS data the commenters are referring to since a specific list was not provided, however, we believe the commenters may be suggesting the codes for USAT that were finalized October 1, 2020 (FY 2021), and listed previously in connection with the analysis discussed in the proposed rule. As discussed in the proposed rule and prior rulemaking, our goal is always to use the best available data. We noted in the proposed rule that our initial MS–DRG analysis was based on ICD–10 claims data from the September 2022 update of the FY 2022 MedPAR file, which contains hospital bills received from October 1, 2021, through September 30, 2022, and where otherwise indicated, additional analysis was based on ICD–10 claims data from the December 2022 update of the FY 2022 MedPAR file, which contains hospital bills received by CMS through December 31, 2022, for discharges occurring from October 1, 2021, through September 30, 2022. Therefore, we believe our analysis of claims data in consideration of the MS–DRG request to reassign cases reporting USAT procedures for PE is consistent with our standard process, regardless of the effective date of the coded claims data. We also do not agree with the commenters' assertion that it is a lengthy process for hospitals to adopt and accurately implement new coding. We note that procedure code proposals discussed at the September ICD–10 Coordination and Maintenance Committee meeting and subsequently finalized are typically included in Table 6B.—New Procedure Codes in association with the proposed rule that is made publicly available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*. This table (Table 6B) lists the new procedure codes that have been approved to date that will be effective with discharges on and after October 1 of the upcoming fiscal year. Therefore, information regarding the finalized codes from the September meeting is made publicly available approximately 4–5 months in advance of the implementation date, affording the ability for users of the code set to gain familiarity with the updates. In addition, there are extensive industry-sponsored educational opportunities through various professional associations that introduce and discuss the annual code updates. For example, the American Hospital Association (AHA), American Health Information Management Association (AHIMA), and the American Academy of Professional Coders (AAPC) generally take lead roles in developing detailed technical training materials for coders and other users of the ICD–10 code set. The AHA also includes updates to ICD–10 in its *Coding Clinic® for ICD–10–CM/ICD–10–PCS* publication. Because the codes describing USAT were finalized for implementation October 1, 2020 (FY 2021), we believe sufficient time has elapsed and that providers are successfully coding and reporting the procedure as demonstrated in our claims analysis.

It is also not clear what conflicting coding advice for utilization of the ICD–10–PCS procedure codes for CDT and USAT the commenters are referring to since the commenters did not provide examples or supplemental information for what they believed to be conflicting advice to enable further evaluation.

Comment: A few commenters expressed concern that the inclusion of both conventional CDT, also known as ''standard infusion catheters,'' and USAT in the proposed new MS–DRG disregards fundamental clinical differences between the procedures. According to the commenters, CDT generally relies on a multi-sidehole infusion catheter placed adjacent to the thrombus through which thrombolytics are delivered, typically over the course of 24 hours with the catheter in-dwelling, whereas USAT employs ultrasound to assist in thrombolysis, and the pulses of ultrasonic energy temporarily make the fibrin in the thrombus more porous and increase fluid flow within the thrombus. The commenters stated standard CDT is the simple infusion of liquids into the vessel and should not map to the same root operation fragmentation codes as does USAT. The commenters also stated CDT procedures are generally less complex clinically and consume significantly lower level of hospital resources as a result. The commenters recommended CMS should delay implementation, not finalize the proposed MS–DRG at this time and reconsider at a later date when utilization volumes reach a threshold of significance.

A commenter also indicated that an analysis of cost data was being submitted to CMS to demonstrate that USAT PE cases have total costs that are more than three times the cost of CDT procedures for the sickest patients.

Response: We disagree with the commenters that inclusion of both conventional CDT and USAT in the proposed new MS–DRG disregards fundamental clinical differences between the procedures. We note that while USAT procedures performed utilizing the EKOS™ device employ ultrasound, the objective of both CDT and USAT procedures is to effectuate thrombolysis and reduce clot burden. In response to the commenters' statement that standard CDT is the simple infusion

of liquids into the vessel and should not map to the same root operation fragmentation codes as does USAT, we note that under ICD–10–PCS, both USAT and CDT are reported with the root operation fragmentation, defined as breaking solid matter in a body part into pieces. The procedure may be accomplished by physical force (*e.g.,* manual, ultrasonic) applied directly or indirectly that is used to break the solid matter into pieces. The solid matter may be an abnormal byproduct of a biological function or a foreign body. The pieces of solid matter are not taken out. With respect to the commenters' statement that CDT procedures are generally less complex clinically and consume significantly lower level of hospital resources, we note that any procedure that places a catheter inside a blood vessel carries certain risks, including damage to the blood vessel, bruising or bleeding at the puncture site, and infection. In the treatment of a significant pulmonary embolism, both procedures (USAT and CDT) require a right heart catheterization by either an interventional cardiologist or an interventional radiologist, utilizing the same level of facility resources. In response to the commenters' recommendation that CMS should delay finalization for the proposed MS–DRG and reconsider in the future when utilization volumes reach a threshold of significance, as discussed in the proposed rule, once the decision was made to propose a new base MS–DRG, we applied the criteria to create subgroups and the criteria for both a three-way split and for a two-way split failed, however, we believe the simulated volume of 1,534 cases is sufficient for creation of the proposed new MS–DRG for these procedures.

Finally, in response to the cost data that was submitted by a commenter, we note that it was the same data analysis as reflected and discussed in the proposed rule, and therefore we refer readers to that prior discussion.

Comment: A commenter stated they agreed that fragmentation procedures with or without USAT do not belong in the requested MS–DRGs 163, 164, and 165, and suggested they remain in their current MS–DRGs 166, 167, and 168 based on clinical coherence and resource utilization.

Response: We appreciate the commenter's feedback and agree that fragmentation procedures with or without USAT do not belong in the requested MS–DRGs 163, 164, and 165. However, for reasons discussed in the proposed rule, we believe our review of these procedures and data analysis findings support the proposal to create new MS–DRG 173 for grouping cases reporting the performance of USAT or CDT with a principal diagnosis of pulmonary embolism.

Comment: A couple commenters disagreed with the proposal to create new MS–DRG 173. A commenter stated USAT procedures have been receiving appropriate payment since FY 2021 and the proposed new MS–DRG would create unnecessary administrative burden for established procedure codes that already have appropriate payment. Another commenter stated that fragmentation procedures, with or without ultrasonic assistance to break up blood clots, should stay assigned to the current MS–DRGs 166, 167, and 168 respectively. The commenter stated that the costs and resources for these procedures are consistent with current payment levels when compared to the rest of the procedures assigned to the current MS–DRGs, that the change is not needed or necessary, and that over time may result in overall reduced payment, given that such a low number of procedures would be assigned to their own MS–DRGs.

Response: We appreciate the commenters' feedback, however, based on our review of the procedures and claims data analysis as discussed in the proposed rule, we believe that USAT and CDT procedures performed for PE are clinically distinct and utilize a different pattern of resources than the other procedures in MS–DRGs 166, 167, and 168. We stated in the proposed rule that while we did not agree with the request to reassign cases reporting USAT or CDT for PE from MS–DRGs 166, 167, and 168 to MS–DRGs 163, 164, and 165, we believed the findings from our analysis warranted proposed reassignment of these cases. While we described the findings from our review of the procedures currently assigned to MS–DRGs 163, 164, and 165 to specifically address the MS–DRG request (88 FR 26689), we note that in our review of cases assigned to MS–DRGs 166, 167, and 168, we identified similar findings; the majority of procedures reported are for malignant neoplasms of the trachea, bronchus, and lung, as well as for pneumonia and respiratory failure with either an open or percutaneous endoscopic approach in contrast to the USAT endovascular (percutaneous) procedure performed on the pulmonary trunk, arteries or veins. In addition, the majority of procedures in MS–DRGs 166, 167, and 168 are performed on patients who are not clinically similar to patients who undergo USAT or CDT for PE since they describe procedures such as destruction (ablation) or excision performed for patients with conditions other than a PE, such as malignant neoplasm, pneumonia, or pulmonary fibrosis. Lastly, a number of procedures in these MS–DRGs also involve the use of a permanently implanted device while the procedures utilizing USAT or CDT do not.

As we have also stated in prior rulemaking (86 FR 44808), the ''other'' surgical category contains surgical procedures which, while infrequent, could still reasonably be expected to be performed for a patient in the particular MDC. We note that because MS–DRGs 166, 167, and 168 are classified as an ''other'' surgical category, they are not as precisely defined from a clinical perspective and contain surgical procedures that are not based on any particular organizing principle (*e.g.* anatomy, surgical approach, diagnostic approach, pathology, etiology, or treatment process). However, we also note that the classification of patient cases into the MS–DRGs is a constantly evolving process, therefore, as coding, medical technologies or treatments change and more comprehensive data is collected, the MS–DRG definitions are reviewed, and revisions are proposed. As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44820), we stated we believed further analysis of the procedures assigned to MS–DRGs 163, 164, 165, 166, 167, and 168 was warranted based on the creation of new procedure codes that have been assigned to these MS–DRGs in recent years for which claims data were not yet available and the need for additional time to examine the procedures currently assigned to those MS–DRGs by clinical intensity, complexity of service and resource utilization. We stated we would continue to evaluate the procedures assigned to these MS–DRGs as additional claims data became available.

We also do not agree that the proposed new MS–DRG would create an unnecessary administrative burden for the established procedure codes since providers are accustomed to proposed and finalized changes to the MS–DRG classifications each fiscal year and software vendors incorporate the finalized changes into their products. With respect to the commenter's assertion that a low volume of procedures would be assigned to their own MS–DRG based on the proposal, as previously discussed, once the decision was made to propose a new base MS–DRG, we applied the criteria to create subgroups and the criteria for both a three-way split and for a two-way split failed, however, we believe the simulated volume of 1,534 cases is

sufficient for creation of the proposed new MS–DRG.

Comment: A commenter stated they could not fully understand or evaluate CMS' proposal for proposed new MS–DRG 173 or determine how the data presented in the preamble of the proposed rule related to the proposed reassignment of cases because of inconsistencies in the materials supporting the proposed rule. According to the commenter, CMS referred to one set of ICD–10–PCS codes in the proposed rule and cited a different set of ICD–10–PCS codes mapping to proposed MS–DRG 173 in the proposed ICD–10 MS–DRG V41 Definitions Manual. The commenter stated interested parties are unable to evaluate and comment on proposals complicated by such an important inconsistency.

Response: We appreciate the commenter's feedback, however, it is not clear what inconsistencies in the materials the commenter is specifically referring to since the commenter did not provide a list of codes for evaluation. Upon review of the proposed rule and the proposed ICD–10 MS–DRG V41 Definitions Manual, we did not find discrepancies.

After consideration of the public comments we received, we are finalizing our proposal to create new MS–DRG 173 (Ultrasound Accelerated and Other Thrombolysis with Principal Diagnosis Pulmonary Embolism), without modification, for FY 2024. We are also finalizing our proposal to define the logic for the new MS–DRG using the previously listed diagnosis codes for PE and the previously listed procedure codes for USAT and CDT, as identified and discussed in our analysis of the claims data in association with the proposed rule. We will continue to monitor the claims data for this new MS–DRG after implementation to determine if additional refinements are warranted.

b. Respiratory Infections and Inflammations Logic

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26691), we stated that the logic for case assignment to MS–DRGs 177, 178, and 179 (Respiratory Infections and Inflammations with MCC, with CC, and without CC/MCC, respectively) as displayed in the ICD–10 MS–DRG V40.1 Definitions Manual (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*) is comprised of two logic lists. The first logic list is entitled ''Principal Diagnosis with Secondary Diagnosis'' and is defined by a list of five ICD–10–CM diagnosis codes describing influenza due to other or unidentified influenza virus with pneumonia in combination with a separate list of ten diagnosis codes describing the specific pneumonia infection. When any one of the five listed diagnosis codes from the ''Principal Diagnosis'' logic list is reported as a principal diagnosis in combination with any one of the ten listed diagnosis code from the ''with Secondary Diagnosis'' logic list as a secondary diagnosis, the case results in assignment to MS–DRG 177, 178, or 179 depending on the presence of any additional MCC or CC secondary diagnoses. All 15 of the diagnosis codes included on the first logic list ''Principal Diagnosis with Secondary Diagnosis'' are designated as MCCs.

The second logic list is entitled ''or Principal Diagnosis'' and is defined by a list of 57 diagnosis codes describing various pulmonary infections. When any one of the 57 diagnosis codes from this list is reported as a principal diagnosis, the case results in assignment to MS–DRG 177, 178, or 179 depending on the presence of any additional MCC or CC secondary diagnoses.

We noted in the proposed rule that currently, when a diagnosis code from the second logic list ''or Principal Diagnosis'' is reported as the principal diagnosis and a diagnosis code from the first logic list ''Principal Diagnosis with Secondary Diagnosis'' is reported as a secondary diagnosis, the case is grouping to MS–DRG 177 (Respiratory Infections and Inflammations with MCC). Consistent with how other similar logic lists function in the ICD–10 Grouper software for case assignment to the ''with MCC'' MS–DRG, the logic for case assignment to MS–DRG 177 is intended to require any *other* diagnosis designated as an MCC and reported as a secondary diagnosis for appropriate assignment, and not the diagnoses currently listed in the logic for the definition of the MS–DRG.

Therefore, for FY 2024, we proposed to correct the logic for case assignment to MS–DRG 177 by excluding the 15 diagnosis codes from the first logic list ''Principal Diagnosis with Secondary Diagnosis'' from acting as an MCC when any one of the listed codes is reported as a secondary diagnosis with a diagnosis code from the second logic list ''or Principal Diagnosis'' reported as the principal diagnosis.

Comment: Several commenters expressed support for the proposal to correct the logic for case assignment to MS–DRG 177. However, some commenters stated it was not specifically clear what was changing and requested that CMS provide more transparency with examples.

A couple commenters recommended that when any one of the five influenza codes (J10.00, J10.01, J10.08, J11.00, or J11.08) from the first logic list entitled ''Principal Diagnosis'' in MS–DRGs 177, 178, and 179 is reported as a secondary diagnosis with a principal diagnosis from the second logic list (''or Principal Diagnosis''), that the influenza diagnosis code continue to be allowed to act as an MCC for assignment to MS–DRG 177. According to the commenters, influenza is not inherently related to the principal diagnoses on the second logic list, and, in combination, they have the potential to be more complicated and resource intensive to treat than any of the diagnoses occurring alone. The commenters supported excluding the 10 secondary diagnoses from the first logic list entitled ''with Secondary Diagnosis'' from acting as an MCC when any one of the codes is reported as a secondary diagnosis with a principal diagnosis code from the second logic list.

Response: We thank the commenters for their support. In response to the commenters who requested additional clarification for the proposed changes, we are providing the following case example to demonstrate the intent of the proposed logic changes with application of the V41 ICD–10 MS–DRG test GROUPER that was made publicly available in association with the proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

Case Example: A patient who is admitted with COVID–19 develops influenza due to an unidentified flu virus along with an unspecified type of pneumonia. The principal diagnosis in this case is reported as the COVID–19 (diagnosis code U07.1) and the secondary diagnosis in this case is reported as influenza due to an unidentified flu virus with unspecified type of pneumonia (diagnosis code J11.00). The diagnosis code for COVID–19 (U07.1) is listed as one of the 58 diagnoses in the second logic list entitled ''or Principal Diagnosis'' and the diagnosis code for influenza due to an unidentified flu virus with unspecified type of pneumonia (J11.00) is listed as one of the five diagnoses in the first logic list entitled ''Principal Diagnosis''. When these diagnoses are entered in the V41 ICD–10 MS–DRG test GROUPER, the resulting MS–DRG is 177 (Respiratory infections and inflammations with MCC).

Principal Diagnosis: U07.1 COVID–19 (DRG)
Secondary Diagnoses: J11.00 Flu due to unidentified flu virus w unsp type of pneumonia (MCC)

Additionally, when any one of the other four influenza diagnosis codes (J10.00, J10.01, J10.08, or J11.08) in that first logic list is reported as a secondary diagnosis with a principal diagnosis of U07.1, the resulting MS–DRG is also MS–DRG 177. Therefore, we agree with the commenters that the five influenza codes (J10.00, J10.01, J10.08, J11.00, or J11.08) should continue to be allowed to act as a MCC with a principal diagnosis from the second logic list in specific clinical scenarios.

The following tables illustrate additional examples when the reporting of any one of the five influenza codes (J10.00, J10.01, J10.08, J11.00, or J11.08) from the first logic list entitled ''Principal Diagnosis'' in MS–DRGs 177, 178, and 179 continues to act as an MCC when reported as a secondary diagnosis with certain principal diagnoses from the second logic list (''or Principal Diagnosis'') and to illustrate when any one of the five influenza diagnosis codes is excluded from acting as an MCC when reported as a secondary diagnosis with certain principal diagnoses from the second logic list.

BILLING CODE 4120–01–P

Influenza Codes (J10.00, J10.01, J10.08, J11.00, or J11.08) Acting as an MCC with Certain Principal Diagnoses from Second Logic List in ICD-10 MS-DRG GROUPER Version 41

Principal Diagnosis	Secondary Diagnosis Influenza Code	MCC	MS-DRG
A06.5 Amebic lung disease	J10.00 Influenza due to other identified influenza virus with unspecified type of pneumonia	Yes	177
A15.7 Primary respiratory tuberculosis	J10.01 Influenza due to other identified influenza virus with the same other identified influenza virus pneumonia	Yes	177
B01.2 Varicella pneumonia	J10.08 Influenza due to other identified influenza virus with other specified pneumonia	Yes	177
J85.0 Gangrene and necrosis of lung	J11.00 Influenza due to unidentified influenza virus with unspecified type of pneumonia	Yes	177
J86.0 Pyothorax with fistula	J11.08 Influenza due to unidentified influenza virus with specified pneumonia	Yes	177

Influenza Codes (J10.00, J10.01, J10.08, J11.00 or J11.08) Excluded from Acting as an MCC with Certain Principal Diagnoses from Second Logic List in ICD-10 MS-DRG GROUPER Version 41

Principal Diagnosis	Secondary Diagnosis Influenza Code	MCC	MS-DRG
A15.0 Tuberculosis of lung	J10.00 Influenza due to other identified influenza virus with unspecified type of pneumonia	No	179
A15.8 Other respiratory tuberculosis	J10.01 Influenza due to other identified influenza virus with the same other identified influenza virus pneumonia	No	179
B25.0 Cytomegaloviral pneumonitis	J10.08 Influenza due to other identified influenza virus with other specified pneumonia	No	179
B39.0 Acute pulmonary histoplasmosis capsulati	J11.00 Influenza due to unidentified influenza virus with unspecified type of pneumonia	No	179
B39.1 Chronic pulmonary histoplasmosis capsulati	J11.08 Influenza due to unidentified influenza virus with specified pneumonia	No	179

We note that in the preamble of the proposed rule we stated that we were proposing to exclude the 15 diagnosis codes from the first logic list ''Principal Diagnosis with Secondary Diagnosis'' from acting as an MCC when any one of the listed codes is reported as a secondary diagnosis with a diagnosis code from the second logic list ''or Principal Diagnosis'' reported as the principal diagnosis, however, the proposal was intended to exclude the 11 secondary diagnoses from the first logic list entitled ''with Secondary Diagnosis'' when one of the codes is reported as a secondary diagnosis with a principal diagnosis code from the second logic list, (as reflected in the case example when a diagnosis from each logic list is entered in the V41 ICD–10 MS–DRG test GROUPER).

After consideration of the public comments we received, we are finalizing our proposal to correct the logic for case assignment to MS–DRG 177, with modification, for FY 2024. We are finalizing the exclusion of the following 11 diagnosis codes listed in the first logic list entitled ''with Secondary Diagnosis'' from acting as an MCC when any one of the listed codes is reported as a secondary diagnosis with a diagnosis code from the second logic list entitled ''or Principal Diagnosis'' when reported as the principal diagnosis.

Diagnoses Excluded from Acting as an MCC for MS-DRG 177	
ICD-10-CM Code	**Description**
A48.1	Legionnaires' disease
J15.0	Pneumonia due to Klebsiella pneumoniae
J15.1	Pneumonia due to Pseudomonas
J15.20	Pneumonia due to staphylococcus, unspecified
J15.211	Pneumonia due to Methicillin susceptible Staphylococcus aureus
J15.212	Pneumonia due to Methicillin resistant Staphylococcus aureus
J15.29	Pneumonia due to other staphylococcus
J15.5	Pneumonia due to Escherichia coli
J15.61	Pneumonia due to Acinetobacter baumannii
J15.69	Pneumonia due to other Gram-negative bacteria
J15.8	Pneumonia due to other specified bacteria

BILLING CODE 4120–01–C

5. MDC 05 (Diseases and Disorders of the Circulatory System)

a. Surgical Ablation

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44836 through 44848), we discussed a two-part request we received to review the MS–DRG assignments for cases involving the surgical ablation procedure for atrial fibrillation. The first part of the request was to create a new classification of surgical ablation MS–DRGs to better accommodate the costs of open concomitant surgical ablations. The second part of the request was to reassign cases describing standalone percutaneous endoscopic surgical ablation. In the part of the request relating to the costs of open concomitant surgical ablations, the requestor identified the following potential procedure combinations that would comprise an ''open concomitant surgical ablation'' procedure.

- Open CABG + open surgical ablation
- Open MVR + open surgical ablation
- Open AVR + open surgical ablation
- Open MVR + open AVR + open surgical ablation
- Open MVR + open CABG + open surgical ablation
- Open MVR + open AVR + open CABG + open surgical ablation
- Open AVR + open CABG + open surgical ablation

As discussed in the FY 2022 IPPS/LTCH PPS final rule, we examined claims data from the March 2020 update of the FY 2019 MedPAR file and the September 2020 update of the FY 2020 MedPAR file for cases reporting procedure code combinations describing open concomitant surgical ablations. We refer the reader to Table 6P.1o associated with the FY 2022 final rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for data analysis findings of cases reporting procedure code combinations describing open concomitant surgical ablations. We stated our analysis showed while the average lengths of stay and average costs of cases reporting procedure code combinations describing open concomitant surgical ablations are higher than all cases in their respective MS–DRG, we found variation in the volume, length of stay, and average costs of the cases. We also stated findings from our analysis indicated that MS–DRGs 216, 217, and 218 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively) as well as approximately 31 other MS–DRGs would be subject to change based on the three-way severity level split criterion finalized in FY 2021.

In the FY 2022 final rule, we finalized our proposal to revise the surgical hierarchy for the MS–DRGs in MDC 05 (Diseases and Disorders of the Circulatory System) to sequence MS–DRGs 231–236 (Coronary Bypass, with or without PTCA, with or without Cardiac Catheterization or Open Ablation, with and without MCC, respectively) above MS–DRGs 228 and 229 (Other Cardiothoracic Procedures with and without MCC, respectively), effective October 1, 2021. In addition, we also finalized the assignment of cases with a procedure code describing coronary bypass and a procedure code describing open ablation to MS–DRGs 233 and 234 and changed the titles of these MS–DRGs to ''Coronary Bypass with Cardiac Catheterization or Open Ablation with and without MCC, respectively'' to reflect this reassignment for FY 2022.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 48845 through 48849), we discussed a request we received to again review the MS–DRG assignment of cases involving open concomitant surgical ablation procedures. The requestor stated they continue to believe that the average hospital costs for surgical ablation for atrial fibrillation demonstrates a cost disparity compared to all procedures within their respective MS–DRGs. The requestor suggested that when open surgical ablation is performed with MVR, or AVR or MVR/AVR + CABG that these procedures are either (1) assigned to a different family of MS–DRGs or (2) assigned to MS–DRGs 216 and 217 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC and with CC, respectively) similar to what CMS did with CABG and open ablation procedures in the FY 2022 rulemaking to better accommodate the added cost of open concomitant surgical ablation.

We stated our analysis using the September 2021 update of the FY 2021 MedPAR file reflected that the cases reporting an open concomitant surgical ablation code combination are predominately found in the higher (CC or MCC) severity level MS–DRGs of their current base MS–DRG assignment, suggesting that the patient's co-morbid conditions may also be contributing to the higher costs of these cases. Secondly, for the numerous procedure combinations that would comprise an ''open concomitant surgical ablation'' procedure, the increase in average costs appeared to directly correlate with the number of procedures performed. For example, cases that describe ''Open MVR + Open surgical ablation'' generally demonstrated costs that were lower than cases that describe ''Open MVR + Open AVR + Open CABG + Open surgical ablation.'' We also noted using the September 2021 update of the FY 2021 MedPAR file, we analyzed how applying the NonCC subgroup criteria to all MS–DRGs currently split into three severity levels would affect the MS–DRG structure beginning in FY 2022. Similar to our findings discussed in the FY 2022 IPPS/LTCH final rule, findings

from our analysis using the September 2021 update of the FY 2021 MedPAR file indicated that MS–DRGs 216, 217, 218 as well as approximately 40 other MS–DRGs would be subject to change based on the three-way severity level split criterion finalized in FY 2021.

Therefore, we stated we believe that additional time was needed to allow for further analysis of the claims data to determine to what extent the patient's co-morbid conditions are also contributing to higher costs and to identify other contributing factors that might exist with respect to the increased length of stay and costs of these cases in these MS–DRGs. For the reasons summarized, and after consideration of the public comments we received, we did not make any MS–DRG changes for cases involving the open concomitant surgical ablation procedures for FY 2023.

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26691 through 26695), we again received a request to review the MS–DRG assignment of cases involving open concomitant surgical ablation procedures. The requestor recommended that CMS reassign open concomitant surgical ablation procedures for atrial fibrillation (AF) from MS–DRGs 219, 220, and 221 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 216, 217, and 218. The requestor further recommended that if CMS does not reassign cases involving open concomitant surgical ablation procedures to MS–DRGs 216, 217, and 218, in the alternative, CMS should create new MS–DRGs for all open mitral or aortic valve repair or replacement procedures with concomitant surgical ablation for AF to improve clinical coherence when three to four open heart procedures are performed in one setting.

The requestor suggested that the following three MS–DRGs be created to reflect current standard of care for these patients:

- Suggested New MS–DRG XXX—2 procedures;
- Suggested New MS–DRG XXX—3 procedures; and
- Suggested New MS–DRG XXX—4+ procedures.

The requestor stated that cases reporting open surgical ablation procedures for AF performed during open valve repair/replacement procedures are typically assigned to MS–DRGs 216, 217, 218, 219, 220, and 221, with the majority of the cases being assigned to MS–DRGs 219, 220 and 221 because of the surgical hierarchy in MDC 05 and because there is less of a need for cardiac catheterization in these cases. We stated in the proposed rule that the requestor performed its own data analysis, and stated their analysis showed that the data continues to demonstrate that claims with open surgical ablation procedures for AF are not clinically similar to the remaining cases in MS–DRGs 219, 220, and 221, and there are significant differences in resource utilization that reflect those clinical differences.

To explore mechanisms to address this request, we stated in the proposed rule we began our analysis by examining claims data from the September 2022 update of the FY 2022 MedPAR file for cases reporting procedure code combinations describing open concomitant surgical ablations assigned to MS–DRGs 216, 217, 218, 219, 220, and 221. We referred readers to Tables 6P.3a and 6P.3b associated with the proposed rule (which are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for the data analysis of cases reporting procedure code combinations describing open concomitant surgical ablations in the September 2022 update of the FY 2022 MedPAR file. Table 6P.3a associated with the proposed rule sets forth the list of ICD–10–PCS procedure codes reflecting mitral valve repair or replacement (MVR), aortic valve repair or replacement (AVR), coronary artery bypass grafting (CABG) and surgical ablation procedures that we examined in this analysis. Table 6P.3b associated with the proposed rule shows the data analysis findings of cases reporting procedure code combinations describing open concomitant surgical ablations assigned to MS–DRGs 216, 217, 218, 219, 220, and 221 from the September 2022 update of the FY 2022 MedPAR file.

As shown in Table 6P.3b associated with the proposed rule, while the average lengths of stay and average costs of cases reporting procedure code combinations describing open concomitant surgical ablations are higher than all cases in their respective MS–DRG, we found there is variation in the volume, length of stay, and average costs of the cases. For MS–DRG 216, we found 439 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay ranging from 16.7 days to 20.3 days and average costs ranging from $78,586 to $111,439 for these cases. For MS–DRG 217, we found 92 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay ranging from 8.5 days to 14 days and average costs ranging from $43,221 to $98,001 for these cases. For MS–DRG 218, we found 2 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay of 6.5 days and average cost of $38,519 for these cases. For MS–DRG 219, we found 1,136 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay ranging from 9.5 days to 13.6 days and average costs ranging from $60,495 to $94,572 for these cases. For MS–DRG 220, we found 770 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay ranging from 6.7 days to 9.6 days and average costs ranging from $49,900 to $84,293 for these cases. For MS–DRG 221, we found 38 cases reporting procedure code combinations describing open concomitant surgical ablations with the average length of stay ranging from 4.5 days to 5.8 days and average costs ranging from $30,725 to $59,024 for these cases.

We stated in the proposed rule that similar to our analysis of the data as discussed in the FY 2023 IPPS/LTCH PPS final rule, this data analysis also shows for the numerous procedure combinations that would comprise an ''open concomitant surgical ablation'' procedure, the increase in average costs appears to directly correlate with the number of procedures performed. We stated the data analysis reflects that cases that describe ''Open MVR + Open AVR'' in addition to other concomitant procedures generally demonstrate higher average costs in their respective MS–DRGs. In MS–DRG 216, we identified a total of 439 cases reporting procedure code combinations describing open concomitant surgical ablations with an average length of stay of 17.7 days and average costs of $89,877. Of those 439 cases, there were 40 cases reporting an aortic valve repair/replacement procedure, a mitral valve repair/replacement procedure, and another concomitant procedure with average costs of $106,301 and an average length of stay of 17.9 days. In MS–DRG 217, we identified a total of 92 cases reporting procedure code combinations describing open concomitant surgical ablations with an average length of stay of 10 days and average costs of $60,975. Of those 92 cases, there were 9 cases reporting an aortic valve repair/replacement procedure, a mitral valve repair/

replacement procedure, and another concomitant procedure with average costs of $82,514 and an average length of stay of 12.5 days. In MS–DRG 219, we identified a total of 1,136 cases reporting procedure code combinations describing open concomitant surgical ablations with an average length of stay of 11.2 days and average costs of $70,693. Of those 1,136 cases, there were 102 cases reporting an aortic valve repair/replacement procedure, a mitral valve repair/replacement procedure, and another concomitant procedure with average costs of $85,537 and an average length of stay of 12.8 days. In MS–DRG 220, we identified a total of 770 cases reporting procedure code combinations describing open concomitant surgical ablations with an average length of stay of 7.3 days and average costs of $52,456. Of those 770 cases, there were 48 cases reporting an aortic valve repair/replacement procedure, a mitral valve repair/replacement procedure, and another concomitant procedure with average costs of $67,344 and an average length of stay of 8.4 days. For MS–DRG 218 and MS–DRG 221, we did not identify any cases reporting procedure code combinations describing open concomitant surgical ablations with an aortic valve repair/replacement procedure, a mitral valve repair/replacement procedure, and another concomitant procedure.

In examining this request, we noted in the proposed rule that the requestor suggested that CMS reassign open concomitant surgical ablation procedures for atrial fibrillation (AF) from MS–DRGs 219, 220, and 221 (Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 216, 217 and 218 for FY 2024, however, as discussed in the FY 2023 IPPS/LTCH PPS final rule, MS–DRGs 216, 217 and 218 are defined by the performance of cardiac catheterization. We stated we continue to be concerned about the effect on clinical coherence of assigning cases reporting procedure code combinations describing open concomitant surgical ablations that do not also have a cardiac catheterization procedure reported to MS–DRGs that are defined by the performance of that procedure. We also noted, as discussed in section II.C.1.b of the proposed rule, using the December 2022 update of the FY 2022 MedPAR file, we analyzed how applying the NonCC subgroup criteria to all MS–DRGs currently split into three severity levels would affect the MS–DRG structure beginning in FY 2024. Similar to our findings discussed in the FY 2022 and FY 2023 IPPS/LTCH PPS final rules, findings from our analysis indicate that MS–DRGs 216, 217, 218 as well as approximately 44 other base MS–DRGs would be subject to change based on the three-way severity level split criterion finalized in FY 2021. Specifically, we noted that the total number of cases in MS–DRG 218 is again below 500. We refer the reader to Table 6P.10b associated with the proposed rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for the list of the 135 MS–DRGs that would potentially be subject to deletion and the list of the 86 new MS–DRGs that would potentially be created under this policy if the NonCC subgroup criteria was applied.

As discussed in the proposed rule, to further analyze the claims data to determine to what extent the performance of multiple procedures is contributing to higher costs and to identify other contributing factors that might exist with respect to the increased length of stay and costs of these cases in these MS–DRGs, we analyzed the cases reporting a concomitant procedure code combination without reporting a procedure code describing open surgical ablation assigned to MS–DRGs 216, 217, 218, 219, 220, and 221. We refer readers to Tables 6P.3c associated with the proposed rule (which are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for the data analysis of cases reporting a concomitant procedure code combination without reporting a procedure code describing open surgical ablation assigned to MS–DRGs 216, 217, 218, 219, 220, and 221 from the September 2022 update of the FY 2022 MedPAR file.

We stated that the data analysis as shown in Table 6P.3c associated with the proposed rule, similarly, reflects that cases that report ''Open MVR + Open AVR'' in addition to other concomitant procedures generally demonstrate higher average costs in their respective MS–DRGs, even in instances where an open surgical ablation was not reported. In MS–DRG 216, we identified a total of 2,759 cases reporting a concomitant procedure code combination without reporting a procedure code describing open surgical ablation with an average length of stay of 17.5 days and average costs of $89,334. Of those 2,759 cases, there were 240 cases reporting an aortic valve repair/replacement procedure, a mitral valve repair/replacement procedure, and another concomitant procedure with average costs of $116,611 and an average length of stay of 22.7 days. In MS–DRG 217, we identified a total of 852 cases reporting a concomitant procedure code combination without reporting a procedure code describing open surgical ablation with an average length of stay of 10.7 days and average costs of $56,208. Of those 852 cases, there were 31 cases reporting an aortic valve repair/replacement procedure, a mitral valve repair/replacement procedure, and another concomitant procedure with average costs of $70,831 and an average length of stay of 12.6 days. In MS–DRG 218, we identified a total of 64 cases reporting a concomitant procedure code combination without reporting a procedure code describing open surgical ablation with an average length of stay of 6.5 days and average costs of $39,924, none of which reported an aortic valve repair/replacement procedure, a mitral valve repair/replacement procedure, and another concomitant procedure. In MS–DRG 219, we identified a total of 7,604 cases reporting a concomitant procedure code combination without reporting a procedure code describing open surgical ablation with an average length of stay of 11.1 days and average costs of $66,412. Of those 7,604 cases, there were 579 cases reporting an aortic valve repair/replacement procedure, a mitral valve repair/replacement procedure, and another concomitant procedure with average costs of $85,890 and an average length of stay of 13.7 days. In MS–DRG 220, we identified a total of 6,430 cases reporting a concomitant procedure code combination without reporting a procedure code describing open surgical ablation with an average length of stay of 6.5 days and average costs of $45,472. Of those 6,430 cases, there were 260 cases reporting an aortic valve repair/replacement procedure, a mitral valve repair/replacement procedure, and another concomitant procedure with average costs of $63,761 and an average length of stay of 7.8 days. In MS–DRG 221, we identified a total of 666 cases reporting a concomitant procedure code combination without reporting a procedure code describing open surgical ablation with an average length of stay of 5.0 days and average costs of $39,777. Of those 666 cases, there were 9 cases reporting an aortic valve repair/replacement procedure, a mitral valve repair/replacement procedure, and another concomitant procedure with average costs of $38,156 and an average length of stay of 5.6 days.

We noted in the proposed rule that analysis of the claims data suggested that it is the performance of an aortic valve repair or replacement procedure, a mitral valve repair or replacement procedure plus another concomitant procedure that is associated with increased hospital resource utilization, not solely the performance of open surgical ablation as suggested by the requestor, when compared to other cases in their respective MS–DRGs. We stated we reviewed these data and noted, clinically, the management of mixed valve disease is challenging because patients with mixed valve disease are often frail, elderly, and present with multiple comorbidities. The combination of conditions in mixed valve disease, such as aortic stenosis and mitral stenosis, can result in a greater reduction of cardiac output than in isolated valvular stenosis. Patients requiring an aortic valve procedure and a mitral valve procedure in the same operative session are more complex cases and can be at significant risk for adverse events if there is moderate or severe disease of one or more cardiac valves. In the proposed rule, we stated that the data analysis clearly showed that cases reporting aortic valve repair or replacement procedure, a mitral valve repair or replacement procedure and another concomitant procedure have higher average costs and generally longer lengths of stay compared to all the cases in their assigned MS–DRG. For these reasons, we proposed to create a new MS–DRG for cases reporting an aortic valve repair or replacement procedure, a mitral valve repair or replacement procedure, and another concomitant procedure.

As discussed in the proposed rule, to compare and analyze the impact of our suggested modifications, we ran a simulation using the most recent claims data from the December 2022 update of the FY 2022 MedPAR file. The following table illustrates our findings for all 892 cases reporting procedure codes describing an aortic valve repair or replacement procedure, a mitral valve repair or replacement procedure, and another concomitant procedure. We stated we believed that the resulting proposed MS–DRG assignment is more clinically homogeneous, coherent and better reflects hospital resource use.

Proposed new MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed new MS-DRG XXX Concomitant Aortic and Mitral Valve Procedures	892	15.7	$93,764

We applied the criteria to create subgroups in a base MS–DRG as discussed in section II.C.1.b. of the FY 2024 IPPS/LTCH PPS proposed rule. As shown in the table that follows, a three-way split of the proposed new MS–DRG failed to meet the criterion that there be at least 500 or more cases in each subgroup.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
With MCC	679	17.7	$102,194
With CC	207	9.4	$67,682
Without CC/MCC	6	5	$39,567

We then applied the criteria for a two-way split for the ''with CC/MCC'' and ''without CC/MCC'' subgroups and again found that the criterion that there be at least 500 or more cases in each subgroup could also not be met. The following table illustrates our findings.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
With CC/MCC	886	15.7	$94,131
Without CC/MCC	6	5	$39,567

We also applied the criteria for a two-way split for the ''with MCC'' and ''without MCC'' subgroups and found that the criterion that there be at least 500 or more cases in each subgroup similarly could not be met. The following table illustrates our findings.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
With MCC	679	17.7	$102,194
Without MCC	213	9.2	$66,890

Therefore, for FY 2024, we did not propose to subdivide the proposed new MS–DRG for cases reporting procedure codes describing an aortic valve repair or replacement procedure, a mitral valve repair or replacement procedure, and another concomitant procedure into severity levels.

In summary, for FY 2024, taking into consideration that it clinically requires greater resources to perform an aortic valve repair or replacement procedure, a mitral valve repair or replacement procedure, and another concomitant procedure, we proposed to create a new base MS–DRG for cases reporting an aortic valve repair or replacement procedure, a mitral valve repair or replacement procedure, and another concomitant procedure in MDC 05. The proposed new MS–DRG is proposed new MS–DRG 212 (Concomitant Aortic and Mitral Valve Procedures). We referred the reader to Table 6P.4a associated with the proposed rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index* for the list of procedure codes we proposed to define in the logic for the proposed new MS–DRG. We refer the reader to section II.C.15. of the preamble of this final rule for the discussion of the surgical hierarchy and the complete list of our proposed modifications to the surgical hierarchy as well as our finalization of those proposals.

Comment: Commenters expressed support for the proposal to create new base MS–DRG 212 (Concomitant Aortic and Mitral Valve Procedures) for cases reporting an aortic valve repair or replacement procedure, a mitral valve repair or replacement procedure, and another concomitant procedure in MDC 05. Many commenters stated finalization of this proposal would provide the resources necessary to continue offering these concomitant procedures to Medicare patients with extremely serious, complicated heart conditions, which avoids a future additional surgery down the line. Other commenters stated they agreed with CMS that this proposal would result in more clinically homogenous assignments that better reflect hospital resources. A commenter stated they thank CMS for recognizing the importance of adequate payment for multiple concomitant open valvular procedures. Another commenter stated that without an MS–DRG reflecting the additional costs of performing concomitant procedures, hospitals will continue to be incentivized for multiple admissions for separate cardiac procedures in order to cover the cost of care.

Response: We appreciate the commenters' support.

Comment: Many commenters stated that the proposal to create MS–DRG 212 is a good first step, but urged CMS go a step further and also assign cases reporting a single AVR or MVR procedure and another concomitant procedure in MDC 05 to the proposed new MS–DRG. Commenters stated that this modification to the proposal would better align with the clinical literature and the clinical needs of Medicare beneficiaries by allowing patients to receive lifesaving therapies in one visit, while not incentivizing hospitals to send patients with AF home to return for future procedures. Some commenters stated, based on their analysis, more patients require an open concomitant single AVR or MVR procedure than multiple open valvular procedures with open surgical ablation. These commenters stated that new MS–DRG 212 would only apply to roughly 10 percent of Medicare beneficiaries, while excluding the majority of Medicare beneficiaries who require open heart valve procedures in combination with open surgical ablation treatment for AF. A commenter stated that AF is a complex arrythmia that is present in more than 40 percent of patients undergoing open single or multiple valve procedures and stated that these patients have a two to three times greater risk for hospitalizations and multiple admissions if their AF goes untreated. Commenters stated that treating atrial fibrillation during the same surgical session as a single open valve procedure requires significant device costs, additional operating room time, and specialized staff. Some commenters expressed concern that given the added costs of performing multiple procedures at the same time, hospitals may more likely schedule the patient for separate procedures even though guidelines of the Society for Thoracic Surgeons and the Heart Rhythm Society recommend performing surgical ablation for atrial fibrillation at the time of open-heart procedures when indicated. These commenters further stated a delay in addressing the biggest patient segment with single open valve replacement (MVR or AVR) and other concomitant procedures risks limiting lifesaving access to therapies for CMS beneficiaries. Many commenters stated the proposal would be even more impactful for patients if cases reporting single open valve procedures were included.

Some commenters urged CMS to either (1) assign all cases reporting a single AVR or MVR procedure and another concomitant procedure for the treatment of atrial fibrillation to new proposed MS–DRG 212, (2) create a new MS–DRG for cases reporting a single AVR or MVR procedure for the treatment of atrial fibrillation, or (3) assign cases reporting a single AVR or MVR procedure and a concomitant surgical ablation procedure for the treatment of atrial fibrillation to MS–DRGs 216, 217, and 218 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively) and change the title of the MS–DRGs, while maintaining the relative weight, and then monitor the claims data for two years.

However, other commenters were not supportive of assigning cases reporting a single AVR or MVR procedure and another concomitant procedure to the proposed new MS–DRG 212. These commenters noted that the focus and clinical rationale for CMS' proposal was based on the complex, multiple valve procedures. Commenters stated that assigning cases reporting a single AVR or MVR procedure and another concomitant procedure to new MS–DRG 212 would have a significant negative impact on the remaining MS–DRGs, notably MS–DRG 216. The commenters recommended that CMS continue to carefully review the impacts on the relative weights in these MS–DRGs if CMS finalizes the proposal to move approximately 900 cases out of MS–DRGs 216, 217, 218, 219, 220, and 221. Another commenter requested that CMS delay implementation of proposed new MS–DRG 212 for a year to allow interested parties to fully assess the impact of the proposed changes to MS–DRGs 216, 217, 218, 219, 220, and 221 and to analyze other options to address payment adequacy more broadly across concomitant procedures, particularly given that findings from CMS' analysis indicate that MS–DRGs 216, 217, and 218 as well as approximately 44 other base MS–DRGs would be subject to change based on the NonCC subgroup criteria finalized in FY 2021. This commenter further stated given the relatively small number of cases impacted by the newly proposed MS–DRG 212, additional time would give CMS an opportunity to work with interested parties to consider other concomitant procedures that have similar clinical and cost coherence as the procedures currently proposed for MS–DRG 212, such as concomitant procedures involving the tricuspid and pulmonary valves.

Response: We appreciate the commenters sharing their concerns and

feedback on this proposal. To examine the recommendation that CMS expand MS–DRG 212 to allow cases reporting a single aortic valve repair or replacement procedure or a mitral valve repair or replacement procedure with an open concomitant surgical ablation to be grouped into the proposed new MS–DRG, we further analyzed the September 2022 update of the FY 2022 MedPAR file for cases reporting procedure code combinations describing a single AVR or MVR procedure and a concomitant procedure assigned to MS–DRGs 216, 217, 218, 219, 220 and 221. We also analyzed the September 2022 update of the FY 2022 MedPAR file for cases reporting procedure code combinations describing a single AVR or MVR procedure and a concomitant procedure and a diagnosis of AF. We identified cases reporting AF as a principal or secondary diagnosis with the following ICD–10–CM codes.

BILLING CODE 4120–01–P

ICD-10-CM Code	Description
I48.0	Paroxysmal atrial fibrillation
I48.11	Longstanding persistent atrial fibrillation
I48.19	Other persistent atrial fibrillation
I48.20	Chronic atrial fibrillation, unspecified
I48.21	Permanent atrial fibrillation
I48.91	Unspecified atrial fibrillation

MS-DRGs 216 – 221: Cases Reporting Procedures Describing Concomitant Single Open Valve Procedures

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
216	Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC - ALL CASES	5,311	14.9	$84,327

	-Cases reporting a single AVR or MVR procedure and a concomitant procedure	2,590	17.1	$87,374
	--Cases reporting a single AVR or MVR procedure and a concomitant procedure with diagnosis of AF	1,511	17	$85,840
217	Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with CC - ALL CASES	1,736	7.3	$56,143
	-Cases reporting a single AVR or MVR procedure and a concomitant procedure	808	9.4	$55,593
	--Cases reporting a single AVR or MVR procedure and a concomitant procedure with diagnosis of AF	462	9.8	$56,104
218	Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization without CC/MCC – ALL CASES	309	3.1	$50,208
	-Cases reporting a single AVR or MVR procedure and a concomitant procedure	62	6.6	$38,013
	--Cases reporting a single AVR or MVR procedure and a concomitant procedure with diagnosis of AF	18	6.2	$37,053
219	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC - ALL CASES	12,149	10.8	$65,911
	-Cases reporting a single AVR or MVR procedure and a concomitant procedure	7,400	10.9	$65,489
	--Cases reporting a single AVR or MVR procedure and a concomitant procedure with diagnosis of AF	4,485	11.1	$66,912
220	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with CC - ALL CASES	9,888	6.4	$45,839
	-Cases reporting a single AVR or MVR procedure and a concomitant procedure	6,496	6.5	$45,455
	--Cases reporting a single AVR or MVR procedure and a concomitant procedure with diagnosis of AF	3,645	7	$47,560
221	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization without CC/MCC - ALL CASES	1,402	4	$40,694
	-Cases reporting a single AVR or MVR procedure and a concomitant procedure	650	5	$39,688
	--Cases reporting a single AVR or MVR procedure and a concomitant procedure with diagnosis of AF	239	5.6	$41,903

BILLING CODE 4120–01–C

As shown in the table, in MS–DRG 216, we identified a total of 2,590 cases reporting procedure code combinations describing a single AVR or MVR procedure and a concomitant procedure with an average length of stay of 17.1 days and average costs of $87,374. Of those 2,590 cases, there were 1,511 cases reporting procedure code combinations describing a single AVR or MVR procedure and a concomitant procedure, with a diagnosis of AF with average costs of $85,840 and an average length of stay of 17 days. The data analysis performed indicates that the 1,511 cases in MS–DRG 216 reporting procedure code combinations describing a single AVR or MVR procedure and a concomitant procedure with a diagnosis of AF have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 216 (17.1 days versus 14.9 days) and slightly higher average costs when compared to all the cases in MS–DRG 216 ($85,840 versus $84,327).

In MS–DRG 217, we identified a total of 808 cases reporting procedure code combinations describing a single AVR or MVR procedure and a concomitant procedure with an average length of stay of 9.4 days and average costs of $55,593. Of those 808 cases, there were 462 cases reporting procedure code combinations describing a single AVR or MVR procedure and a concomitant procedure, with a diagnosis of AF with average costs of $56,104 and an average length of stay of 9.8 days. The data analysis performed indicates that the 462 cases in MS–DRG 217 reporting procedure code combinations describing a single

AVR or MVR procedure and a concomitant procedure with a diagnosis of AF have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 217 (9.8 days versus 7.3 days) and similar average costs when compared to all the cases in MS–DRG 217 ($56,104 versus $56,143).

In MS–DRG 218, we identified a total of 62 cases reporting procedure code combinations describing a single AVR or MVR procedure and a concomitant procedure with an average length of stay of 6.6 days and average costs of $38,013. Of those 62 cases, there were 18 cases reporting procedure code combinations describing a single AVR or MVR procedure and a concomitant procedure, with a diagnosis of AF with average costs of $37,053 and an average length of stay of 6.2 days. The data analysis performed indicates that the 18 cases in MS–DRG 218 reporting procedure code combinations describing a single AVR or MVR procedure and a concomitant procedure with a diagnosis of AF have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 218 (6.2 days versus 3.1 days) and lower average costs when compared to all the cases in MS–DRG 218 ($37,053 versus $50,208).

In MS–DRG 219, we identified a total of 7,400 cases reporting procedure code combinations describing a single AVR or MVR procedure and a concomitant procedure with an average length of stay of 10.9 days and average costs of $65,489. Of those 7,400 cases, there were 4,485 cases reporting procedure code combinations describing a single AVR or MVR procedure and a concomitant procedure, with a diagnosis of AF with average costs of $66,912 and an average length of stay of 11.1 days. The data analysis performed indicates that the 4,485 cases in MS–DRG 219 reporting procedure code combinations describing a single AVR or MVR procedure and a concomitant procedure with a diagnosis of AF have an average length of stay that is slightly longer than the average length of stay for all the cases in MS–DRG 219 (11.1 days versus 10.8 days) and slightly higher average costs when compared to all the cases in MS–DRG 219 ($66,912 versus $65,911).

In MS–DRG 220, we identified a total of 6,496 cases reporting procedure code combinations describing a single AVR or MVR procedure and a concomitant procedure with an average length of stay of 6.5 days and average costs of $45,455. Of those 6,496 cases, there were 3,645 cases reporting procedure code combinations describing a single AVR or MVR procedure and a concomitant procedure, with a diagnosis of AF with average costs of $47,560 and an average length of stay of 7 days. The data analysis performed indicates that the 3,645 cases in MS–DRG 220 reporting procedure code combinations describing a single AVR or MVR procedure and a concomitant procedure with a diagnosis of AF have an average length of stay that is slightly longer than the average length of stay for all the cases in MS–DRG 220 (7 days versus 6.4 days) and slightly higher average costs when compared to all the cases in MS–DRG 220 ($47,560 versus $45,839).

In MS–DRG 221, we identified a total of 650 cases reporting procedure code combinations describing a single AVR or MVR procedure and a concomitant procedure with an average length of stay of 5 days and average costs of $39,688. Of those 650 cases, there were 239 cases reporting procedure code combinations describing a single AVR or MVR procedure and a concomitant procedure, with a diagnosis of AF with average costs of $41,903 and an average length of stay of 5.6 days. The data analysis performed indicates that the 239 cases in MS–DRG 221 reporting procedure code combinations describing a single AVR or MVR procedure and a concomitant procedure with a diagnosis of AF have an average length of stay that is longer than the average length of stay for all the cases in MS–DRG 221 (5.6 days versus 4 days) and slightly higher average costs when compared to all the cases in MS–DRG 221 ($41,903 versus $40,694).

The data analysis performed also indicates that the cases in MS–DRGs 219, 220, and 221 reporting procedure code combinations describing a single AVR or MVR procedure and a concomitant procedure have a similar average length of stay and generally lower average costs when compared to all cases in MS–DRGs 216, 217, and 218. As discussed in the proposed rule, to compare and analyze the impact of our suggested modifications, we ran a simulation using the most recent claims data from the December 2022 update of the FY 2022 MedPAR file. We stated we found 892 cases reporting procedure codes describing an aortic valve repair or replacement procedure, a mitral valve repair or replacement procedure, and another concomitant procedure with an average length of stay of 15.7 days and average costs of $93,764. Our additional analysis performed in response to public comments also indicates that the cases reporting procedure code combinations describing a single AVR or MVR procedure and a concomitant procedure have a much shorter average length of stay and much lower average costs when compared to these 892 cases.

Upon analysis of the claims data using our current analytical framework, review of the original request, and review of the public comments, while we agree that there are more cases reporting a single AVR or MVR procedure and another concomitant procedure than cases reporting concomitant aortic and mitral valve procedures, we do not agree with assigning cases reporting a single AVR or MVR procedure and another concomitant procedure for the treatment of atrial fibrillation to new proposed MS–DRG 212. As previously noted, the data do not indicate cases reporting a single AVR or MVR procedure and another concomitant procedure (with or without a diagnosis of AF) utilize similar resources when compared to the cases proposed to be assigned to new MS–DRG 212. The cases are not clinically coherent with regard to resource utilization as reflected in the differences in average costs. Further, the data do not support creating a new MS–DRG for cases reporting a single AVR or MVR procedure for the treatment of atrial fibrillation and instead suggest that cases reporting a single AVR or MVR procedure for the treatment of atrial fibrillation are suitably grouped to MS–DRGs 216, 217, 218, 219, 220, and 221 where they are currently assigned based on the similarities in resource utilization compared to all the cases in their respective MS–DRG.

In response to comments that urged CMS to assign cases reporting procedure code combinations describing open concomitant surgical ablations currently assigned to MS–DRGs 216, 217, 218, 219, 220, and 221 to MS–DRGs 216, 217, and 218, as noted in prior rulemaking, MS–DRGs 216, 217, and 218 are defined by the performance of cardiac catheterization. We continue to express concern about the effect on clinical coherence of assigning cases reporting procedure code combinations describing open concomitant surgical ablations that do not also have a cardiac catheterization procedure reported to MS–DRGs that are defined by the performance of that procedure.

In response to the suggestion that CMS delay implementation of proposed new MS–DRG 212 for a year to allow interested parties to fully assess the impact of the proposed changes to MS–DRGs 216, 217, 218, 219, 220, and 221 and to analyze other options to address payment adequacy more broadly across concomitant procedures, we reviewed the commenters' concern and do not agree that a delay would be prudent. We believe that the data we currently have

available is sufficient to create a new MS–DRG for cases reporting an aortic valve repair or replacement procedure, a mitral valve repair or replacement procedure, and another concomitant procedure. As discussed in the proposed rule, and earlier in this section, the data demonstrate that cases reporting aortic valve repair or replacement procedure, a mitral valve repair or replacement procedure and another concomitant procedure have higher average costs and generally longer lengths of stay compared to all the cases in their assigned MS–DRG.

We appreciate the public comments we received and will continue to monitor for impacts in MDC 05 and across the MS–DRGs to avoid unintended consequences or missed opportunities in most appropriately capturing the resource utilization and clinical coherence for this subset of procedures.

Comment: Some commenters stated the title of proposed new MS–DRG 212 (Concomitant Aortic and Mitral Valve Procedures) is not clear. These commenters stated it was not clear if the logic intent is for cases reporting both a mitral and aortic valve procedure with a concomitant procedure to be assigned to new MS–DRG 212 or if the logic intent is to have cases reporting a mitral valve or an aortic valve procedure with a concomitant procedure to be assigned to new MS–DRG 212. A few commenters suggested that consideration be given to revising the title of the proposed new MS–DRG as it is not intuitive that the list of concomitant procedures in the GROUPER logic list for MS–DRG 212 includes both surgical ablation and CABG procedures. Another commenter stated that the display in the draft Definition Manual, Version 41, for MS–DRG 212 is unclear and observed there are no instructional notes included in the draft Definition Manual to explain the intent of the various lists of procedures.

Response: We appreciate the commenters' feedback. As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26691 through 26695), analysis of the claims data suggests that it is the performance of an aortic valve repair or replacement procedure, a mitral valve repair or replacement procedure plus another concomitant procedure that is associated with increased hospital resource utilization (88 FR 26694). For these reasons, we proposed to create a new MS–DRG for cases reporting an aortic valve repair or replacement procedure, a mitral valve repair or replacement procedure, and another concomitant procedure.

In response to commenters who stated that it was not clear if the logic intent is for cases reporting both a mitral and aortic valve procedure with a concomitant procedure to be assigned to new MS–DRG 212 or if the logic intent is to have cases reporting a mitral valve or an aortic valve procedure with a concomitant procedure to be assigned to new MS–DRG 212, we wish to clarify cases reporting: (1) an aortic valve repair or replacement procedure; (2) a mitral valve repair or replacement procedure; and (3) at least one other concomitant procedure, as defined in the GROUPER logic, would be assigned to proposed new MS–DRG 212 (Concomitant Aortic and Mitral Valve Procedures).

In response to the suggestion that the title of MS–DRG 212 be revised, we reviewed the commenters' concerns and do not believe a modification is warranted. As our analysis of the claims data suggests that it is the performance of an aortic valve repair or replacement procedure, a mitral valve repair or replacement procedure plus another concomitant procedure that is associated with increased hospital resource utilization, we believe the proposed title of the new MS–DRG appropriately characterizes these findings.

In reviewing the comment regarding the draft version of the ICD–10 MS–DRG Definitions Manual, Version 41, (available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*), that was provided so the public can better analyze and understand the impact of the proposals included in the FY 2024 IPPS/LTCH PPS proposed rule, we agree refinements to the display would be helpful to clarify the GROUPER logic for MS–DRG 212. In the final ICD–10 MS–DRG Definitions Manual, Version 41, we will refine the display by adding headers above each of the respective logic lists as follows:

- Select ONE procedure from aortic valve procedures
- Select ONE procedure from mitral valve procedures
- Select at least ONE procedure from concomitant procedures

Comment: Some commenters noted that the list of procedure codes we proposed to define aortic valve procedures and mitral valve procedures in the logic for the proposed new MS–DRG is limited to the root operations ''Repair'' and ''Replacement,'' however there are other valve procedures listed under the ''Concomitant Procedure'' logic list. These commenters suggested that CMS consider moving the aortic and mitral valve procedure codes with the root operations of ''Creation'', ''Release'', ''Restriction'', and ''Supplement,'' that are currently listed under the Concomitant Procedures list in Table 6P.4a and in the draft version of the ICD–10 MS–DRG Definitions Manual to the appropriate logic list of aortic valve or mitral valve procedures. The commenters stated that procedure codes with these other root operations also represent types of valvular repairs and should be included on the aortic valve procedures and mitral valve procedures logic lists rather than the ''Concomitant Procedure'' logic list. A commenter stated that this change would ensure that all of the aortic valve and mitral valve procedures codes are captured as valve procedures instead of concomitant procedures when performed.

Response: We appreciate the feedback and will take these suggestions under consideration. We note that the requestor originally requested that CMS review the MS–DRG assignments for cases involving open surgical ablation performed during another open heart surgical procedure such as mitral valve repair or replacement (MVR), aortic valve repair or replacement (AVR), or coronary artery bypass grafting (CABG). Table 6P.3a associated with the proposed rule sets forth the list of ICD–10–PCS procedure codes reflecting MVR, AVR, CABG, and surgical ablation procedures that we examined in our analysis. We agree with the commenters that there are other valve procedures listed under the ''Concomitant Procedure'' logic list in Table 6P.3a, however, each of these procedures are defined by clinically distinct definitions and objectives, which is why there are separate and unique ICD–10–PCS procedure codes within the classification for reporting purposes. Additional claims analysis is needed to determine if the technical complexity and resource utilization of all, or a subset, of the aortic and mitral valve procedure codes with the root operations of ''Creation'', ''Release'', ''Restriction'', and ''Supplement'' in the ''Concomitant Procedures'' logic list warrant any modifications to the GROUPER logic of proposed new MS–DRGs 212. We believe there may be an opportunity to further refine this MS–DRG as we continue to monitor the claims data and perform additional analysis. We note that we would address any proposed modifications to the logic in future rulemaking.

Comment: Commenters stated they appreciated CMS' willingness to examine how the performance of multiple procedures during the same

operative session contributes to higher hospital costs and patient length of stay. Commenters encouraged CMS to continue to consider options in the MS–DRGs for concomitant procedures with higher hospital resource utilization, given the important patient care benefits and efficiencies associated with performing certain procedures concomitantly in a single encounter rather than staging separate procedures. A commenter stated they recognize that clinical services across many medical specialties may be performed concomitantly to optimize patient outcomes and noted, for example, studies indicate when left atrial appendage closure (LAAC) is performed concomitantly with ablation, the outcomes are at least as comparable as for patients who have undergone these procedures separately. This commenter suggested that CMS conduct comprehensive analysis of all concomitant procedures, similar to the analysis of concomitant aortic and mitral valve procedures, to inform whether CMS should establish a more holistic policy to provide adequate payment for clinical practices that lead to better efficiency and patient outcomes. Another commenter recommended that CMS devise a broader, more inclusive, supplemental mechanism to facilitate incremental payment when two major procedures are performed during the same hospital admission and urged CMS to ensure that the incurred costs are adequately addressed so as to not disincentivize concomitant procedures which can be more cost efficient, more convenient, and provide a better prognosis for the patient than the procedures being performed during different hospital stays.

Response: We appreciate the commenters' support. We also thank the commenters for their recommendations to conduct comprehensive analysis of all concomitant procedures as we agree that the performance of ''concomitant procedures'' may affect the consumption of resources in other clinical scenarios, especially when the use of devices is involved. We continue to be interested in receiving feedback on possible mechanisms through which we can address concomitant procedures. We are also interested in receiving feedback on how CMS can mitigate any unintended negative payment impacts to providers providing concomitant procedures. Commenters can continue to submit their recommendations via the Medicare Electronic Application Request Information System™ (MEARIS™) at: *https://mearis.cms.gov/public/home.* We will consider these public comments for possible proposals in future rulemaking as part of our annual review process.

Comment: While supporting the proposal, a commenter suggested that proposed new MS–DRG 212 be split into two severity levels (with and without MCC). The commenter stated they believe it is mathematically impossible for the proposed new MS–DRG to ever be more than a base MS–DRG, however in their opinion, a base MS–DRG does not take into account the variation in the average costs between cases reporting a secondary diagnosis designated as a MCC compared to cases reporting a secondary diagnosis designated as a CC.

Response: We thank the commenter for their feedback. In response to the suggestion that proposed new MS–DRG 212 for cases describing concomitant aortic and mitral valve procedures be subdivided with a two-way severity level split, we note as discussed in the proposed rule and earlier in this section, in the analysis of the cases describing concomitant aortic and mitral valve procedures, we applied the criteria for a two-way split for the ''with MCC'' and ''without MCC'' subgroups and found that the criterion that there be at least 500 or more cases in each subgroup could not be met and therefore did not propose to subdivide the proposed new MS–DRG for concomitant aortic and mitral valve procedures into severity levels for FY 2024. In response to the concern about variation of costs between cases reporting a secondary diagnosis designated as a MCC compared to cases reporting a secondary diagnosis designated as a CC in a base MS–DRG, we note the MS–DRG system is a system of averages, and it is expected that within the diagnostic related groups, some cases may demonstrate higher than average costs, while other cases may demonstrate lower than average costs.

Therefore, after consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal to create a new MS–DRG 212 (Concomitant Aortic and Mitral Valve Procedures) in MDC 05, without modification, effective October 1, 2023, for FY 2024. We are also finalizing the list of procedure codes to define the logic for the new MS–DRGs as displayed in Table 6P.4a associated with the proposed rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*).

b. External Heart Assist Device

Impella® Ventricular Support Systems are temporary heart assist devices intended to support blood pressure and provide increased blood flow to critical organs in patients with cardiogenic shock, by drawing blood out of the heart and pumping it into the aorta, partially or fully bypassing the left ventricle to provide adequate circulation of blood (replace or supplement left ventricle pumping) while also allowing damaged heart muscle the opportunity to rest and recover in patients who need short-term support.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44820 through 44831), we discussed a request to reassign certain cases reporting procedure codes describing the insertion of a percutaneous short-term external heart assist device from MS–DRG 215 (Other Heart Assist System Implant) to MS–DRGs 216, 217, and 218 (Cardiac Valve and Other Major Cardiothoracic Procedures with Cardiac Catheterization with MCC, with CC, and without CC/MCC, respectively). We stated that our clinical advisors reviewed the clinical issues and the claims data and agreed that cases reporting a procedure code that describes the intraoperative insertion of a short-term external heart assist device are generally less resource intensive and are clinically distinct from other cases reporting procedure codes describing the insertion of other types of heart assist devices currently assigned to MS–DRG 215. We also stated that critically ill patients who are experiencing or at risk for cardiogenic shock from an emergent event such as heart attack or virus that impacts the functioning of the heart and requires longer heart pump support are different from those patients who require intraoperative support only. Patients receiving a short-term external heart assist device intraoperatively during coronary interventions often have an underlying disease pathology such as heart failure related to occluded coronary vessels that is broadly similar in kind to other patients also receiving these interventions without the need for an insertion of a short-term external heart assist device. In the post-operative period, these patients can recover and can be sufficiently rehabilitated prior to discharge. For these reasons, we finalized our proposal to assign ICD–10–PCS codes 02HA0RJ, 02HA3RJ, or 02HA4RJ that describe the intraoperative insertion of a short-term external heart assist device to MS–DRGs 216, 217, 218, 219, 220, and 221.

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26695

through 26700), we received a request to reassign certain cases reporting procedure codes describing the insertion of a short-term external heart assist device using an axillary artery conduit from MS–DRG 215 to MS–DRGs 001 and 002 (Heart Transplant or Implant of Heart Assist System with MCC and without MCC, respectively) and MS–DRG 003 (ECMO or Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedures).

We noted in the proposed rule that the Impella 5.5® with SmartAssist® System is designed for longer-duration support (up to 14 days) than other femoral access percutaneous ventricular assist devices (pVADs) that treat cardiogenic shock (up to 4 days) providing full cardiac and hemodynamic support with 5.5 liters of blood flow per minute. The Impella 5.5® with SmartAssist® System is considered a hybrid procedure of an open vascular exposure and an endovascular procedure. The Impella 5.5® with SmartAssist® System surgical pump can be inserted through an open chest for direct aortic access or a surgical incision that exposes the axillary artery. In the axillary artery approach, a surgical graft conduit is anastomosed to the axillary artery by a surgeon in the operating room. The device is positioned across the aortic valve, with the inlet located in the left ventricle and the outlet in the ascending aorta to allow the device to directly unload via the native pathway and to support coronary perfusion. According to the requestor, the Impella 5.5® with SmartAssist® System is indicated for more complex patients than other femoral artery access pVADs, however the insertion of a short-term external heart assist device using an axillary artery conduit (such as the Impella 5.5® with SmartAssist® System) is reported with the same ICD–10–PCS code that describes insertion of a percutaneous short-term external heart assist device and are therefore also assigned to MS–DRG 215. According to the requestor, Impella 5.5® with SmartAssist® System is more clinically comparable to implantable heart assist systems, such as left ventricular assist devices (LVADs), and like LVADs, the insertion of a short-term external heart assist device using an axillary artery conduit must be performed by a surgeon in the operating room. We stated in the proposed rule that the requestor performed its own data analysis, and stated their analysis showed a significant variation in the resource utilization for patients treated with the Impella 5.5® with SmartAssist® System compared to patients treated with other femoral access pVADs assigned to MS–DRG 215.

In the proposed rule, we also noted that following the submission of the FY 2024 MS–DRG classification change request for certain cases reporting procedure codes describing the insertion of a short-term external heart assist device using an axillary artery conduit, this same requestor (the manufacturer of the Impella® Ventricular Support Systems) submitted a code proposal requesting a new ICD–10–PCS procedure code to describe the Impella 5.5® with SmartAssist® System for consideration as an agenda topic to be discussed at the March 7–8, 2023 ICD–10 Coordination and Maintenance Committee meeting. The proposal was presented and discussed at the March 7–8, 2023 ICD–10 Coordination and Maintenance Committee meeting. We refer the reader to the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials* for additional detailed information regarding the request, including a recording of the discussion and the related meeting materials. Public comments in response to the code proposal were due by April 7, 2023.

In reviewing this MS–DRG reclassification request, in the proposed rule we noted that we agreed with the requestor that the insertion of a short-term external heart assist device using an axillary artery conduit (such as the Impella 5.5® with SmartAssist® System) is not separately identifiable in the claims data. Therefore, in this section, we address the assignment of the existing procedure codes describing the insertion of short-term external heart assist devices, including our proposed reassignment of a subset of these cases for FY 2024.

The following ICD–10–PCS procedure codes describe the insertion of a short-term external heart assist device.

BILLING CODE 4120–01–P

ICD-10-PCS Code	Description
02HA0RZ	Insertion of short-term external heart assist system into heart, open approach
02HA3RZ	Insertion of short-term external heart assist system into heart, percutaneous approach
02HA4RZ	Insertion of short-term external heart assist system into heart, percutaneous endoscopic approach

In the ICD–10 MS–DRG Definitions Manual Version 40.1, procedure codes 02HA0RZ, 02HA3RZ, and 02HA4RZ are currently recognized as extensive O.R. procedures assigned to MS–DRG 215 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 05.

As stated previously and discussed in the proposed rule, the request for FY 2024 rulemaking was to reassign certain cases reporting procedure codes describing the insertion of a short-term external heart assist device using an axillary artery conduit from MS–DRG 215 to MS–DRGs 001 and 002 (Heart Transplant or Implant of Heart Assist System with MCC and without MCC, respectively) and MS–DRG 003 (ECMO or Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedures). During our review of this request, we noted in the proposed rule that the current GROUPER logic for MS–DRGs 001 and 002 is comprised of two lists. The first list includes procedure codes identifying a heart transplant procedure, and the second list includes procedure codes identifying the implantation of a heart assist system (including short-term external heart assist systems) and includes code combinations or procedure code ''clusters'' that, when reported together, satisfy the logic for assignment to MS–DRGs 001 and 002. The code combinations are represented by two procedure codes and include either one code for the insertion of the device with one code for removal of the device or one code for the revision of the device with one code for the removal of the device.

We also noted in the proposed rule that the GROUPER logic for MS–DRG 003 is defined by (1) a procedure code for extracorporeal oxygenation (ECMO), (2) a procedure code for tracheostomy, mechanical ventilation and a procedure code further classified as extensive, or (3) a procedure code for tracheostomy with a procedure code further classified as extensive and a principal diagnosis not assigned to MS–DRGs 011, 012 or 013 as reflected in the logic table:

ECMO	Tracheostomy	MV >96	PDx Except Face, Mouth, Neck	Major O.R. Procedure	MS-DRG
Yes	n/a	n/a	n/a	n/a	003 (ECMO or Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedures)
No	Yes	Yes		Yes	003 (ECMO or Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedures)
No	Yes		Yes	Yes	003 (ECMO or Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck with Major O.R. Procedures)
No	Yes	Yes		No	004 (Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck without Major O.R. Procedures)
No	Yes		Yes	No	004 (Tracheostomy with MV >96 Hours or Principal Diagnosis Except Face, Mouth and Neck without Major O.R. Procedures)

As procedure codes describing the insertion of a short-term external heart assist device are classified as extensive procedures in Version 40.1, specific assignment of these procedure codes to MS–DRG 003 is not required. When the other parameters of the GROUPER logic are met and procedure codes describing the insertion of a short-term external heart assist device are also reported, MS–DRG 003 will be assigned, therefore in the proposed rule we stated we did not include MS–DRG 003 in our analysis. We refer the reader to the ICD–10 MS–DRG Version 40.1 Definitions Manual (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for the listed MS–DRGs and for Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index.

In the proposed rule, we stated that to begin our analysis, we examined claims data from the September 2022 update of the FY 2022 MedPAR file for MS–DRG 215 to identify cases reporting ICD–10–PCS codes 02HA0RZ, 02HA3RZ, and 02HA4RZ. Our findings are shown in the following table:

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
215	All cases	3,587	9	$86,774
	02HA0RZ	60	9.2	$130,153
	02HA3RZ	3,424	8.9	$86,640
	02HA4RZ	6	6.7	$63,923

As shown in the table, we identified a total of 3,587 cases within MS–DRG 215 with an average length of stay of 9 days and average costs of $86,774. Of these 3,587 cases, there are 60 cases reporting a procedure code describing the open insertion of a short-term external heart assist device with an average length of stay of 9.2 days and average costs of $130,153. There are 3,424 cases reporting a procedure code describing a percutaneous insertion of a short-term external heart assist device with an average length of stay of 8.9 days and average costs of $86,640. There are 6 cases reporting a procedure code describing a percutaneous endoscopic insertion of a short-term external heart assist device with an average length of stay of 6.7 days and average costs of $63,923. The data analysis shows that the average length of stay is longer and the average costs are higher for the cases reporting a procedure code describing the open insertion of a short-term external heart assist device compared to all cases in MS–DRG 215, while the average length of stay is shorter and the average costs are lower for the cases reporting a procedure code describing the percutaneous or percutaneous endoscopic insertion of a short-term

external heart assist device compared to all cases in that MS–DRG.

We stated in the proposed rule that we then examined claims data from the September 2022 update of the FY 2022 MedPAR for MS–DRGs 001 and 002. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
001	1,553	40.4	$235,135
002	28	18.3	$108,476

We stated that while the average costs for all cases in MS–DRG 001 are higher than the average costs of the cases reporting a procedure code describing the open insertion of a short-term external heart assist device, the data suggested that overall, cases reporting a procedure code describing the open insertion of a short-term external heart assist device may be more appropriately aligned with the average costs of the cases in MS–DRGs 001 and 002 in comparison to MS–DRG 215, even though the average length of stay is shorter.

In the proposed rule, we stated that we then reviewed the clinical considerations along with this data analysis and agreed that cases reporting a procedure code that describes the open insertion of a short-term external heart assist device are generally more resource intensive and are clinically distinct from other cases reporting procedure codes describing the insertion of short-term external heart devices by other approaches currently assigned to MS–DRG 215. The availability of mechanical circulatory support devices to provide acute hemodynamic support for cardiogenic shock or to support percutaneous coronary intervention (PCI) has expanded over the past decade. We noted that there is now a portfolio of short-term external heart assist devices available that each have different indications for use and techniques for implantation.

We also noted that the percutaneous or percutaneous endoscopic insertion of a short-term external heart assist device involves standard catheterization techniques except for the requirement of a large-bore 13 or 14 Fr sheath. Short-term external heart assist devices inserted in this manner generally provide blood flow up to 2.5 L/min for systemic perfusion and are intended for temporary (≤4 days) use to maintain stable heart function. In contrast, the open insertion of a short-term external heart assist device or the insertion of short-term external heart assist devices using an axillary artery conduit requires a surgical cutdown of the axillary artery to place the larger 23 Fr sheaths of these devices. Short-term external heart assist devices that are inserted via an open approach or using an axillary artery conduit can provide blood flow up to 5.5 L/min for systemic perfusion and are intended for longer use (≤14 days). They are indicated for the treatment of ongoing cardiogenic shock that occurs less than 48 hours following acute myocardial infarction or open-heart surgery or in the setting of cardiomyopathy, including peripartum cardiomyopathy, or myocarditis as a result of isolated left ventricular failure that is not responsive to medical management and conventional treatment measures. We noted in the proposed rule that the indications for the open insertion of a short-term external heart assist device or the insertion of short-term external heart assist devices using an axillary artery conduit are more closely aligned with MS–DRGs 001 and 002 as compared to MS–DRG 215. For these reasons, we stated we believed reassigning ICD–10–PCS code 02HA0RZ that describes the open insertion of a short-term external heart assist device to Pre-MDC MS–DRGs 001 and 002 would improve clinical coherence in these MS–DRGs.

As discussed in the proposed rule, to compare and analyze the impact of these potential modifications, we ran a simulation using the claims data from the September 2022 update of the FY 2022 MedPAR file. The following table reflects our simulation for ICD–10–PCS procedure code 02HA0RZ that describes the open insertion of a short-term external heart assist device if it was moved to MS–DRGs 001 and 002.

MS-DRG		Number of Cases	Average Length of Stay	Average Cost
215	All Cases	3,587	9	$86,774
	without 02HA0RZ	3,534	9	$83,613
001	All Cases	1,553	40.4	$235,135
	with 02HA0RZ	1,606	39.4	$231,677
002	All Cases	28	18.3	$108,476
	with 02HA0RZ	35	15.3	$112,533

We stated in the proposed rule that we believed that this simulation supports that the resulting MS–DRG assignments would be more clinically homogeneous, coherent and better reflect hospital resource use. A review of this simulation shows that this distribution of ICD–10–PCS code 02HA0RZ that describes the open insertion of a short-term external heart assist device if moved to MS–DRGs 001 and 002, slightly decreases the average

costs of the cases remaining in MS–DRG 215 by about $3,000, while similarly having a limited effect on the average costs of MS–DRGS 001 and 002. Therefore, for FY 2024, we proposed to reassign ICD–10–PCS code 02HA0RZ when reported as a standalone procedure from MDC 05 in MS–DRG 215 to Pre-MDC MS–DRGs 001 and 002. We noted that under this proposal, procedure code 02HA0RZ would no longer need to be reported as part of a procedure code combination or procedure code ''cluster'' to satisfy the logic for assignment to MS–DRGs 001 and 002.

As discussed in the proposed rule, we will continue to monitor the clinical cohesiveness of the procedures assigned to MS–DRGs 001 and 002 to assess whether they continue to be aligned on resource use, as well as current shifts in treatment practices, to determine if additional refinements may be warranted in the future. The increased availability of short-term external heart assist devices and their development into low profile, high output pumps has shifted the management of cardiogenic shock that is unresponsive to other interventions in the years since these MS–DRGs were created. These short-term devices can now be used as a bridge to provide the time needed for clinical decision making, native heart recovery, or until another procedure can be performed, such as the insertion of a left ventricular assist device (LVAD) or cardiac transplantation.

As noted previously, this same requestor (the manufacturer of the Impella® Ventricular Support Systems) submitted a code proposal to be discussed at the March 7–8, 2023 ICD–10 Coordination and Maintenance Committee meeting to request a change to how the Impella 5.5® with SmartAssist® System is coded within the ICD–10–PCS classification as there are no unique ICD–10–PCS codes to describe the insertion of a short-term external heart assist system using an axillary artery conduit. In the proposed rule, we noted that because the decisions on the diagnosis and procedure code proposals that were presented at the March 7–8, 2023 ICD–10–CM Coordination and Maintenance Committee meeting for an October 1 implementation (upcoming FY) are not finalized in time to include in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes in association with the FY 2024 IPPS/LTCH PPS proposed rule, as we have noted in prior rulemaking (86 FR 44805), we use our established process to examine the MS–DRG assignment for the predecessor codes to determine the most appropriate MS–DRG assignment. Specifically, we review the predecessor code and MS–DRG assignment most closely associated with the new procedure code, and in the absence of claims data, we consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We have noted in prior rulemaking that this process does not automatically result in the new procedure code being assigned to the same MS–DRG or to have the same designation (O.R. versus Non-O.R.) as the predecessor code.

We noted in the proposed rule that under this established process, the MS–DRG assignment for any new procedure codes describing the Impella 5.5® with SmartAssist® System, if finalized following the March meeting, would be reflected in Table 6B.—New Procedure Codes associated with the final rule for FY 2024. In the event there is not support for the new procedure code as presented at the March 7–8, 2023 ICD–10 Coordination and Maintenance Committee meeting to describe the insertion of a short-term external heart assist system using an axillary artery conduit, the procedure will be reported with current coding that is applicable within the classification as displayed in the ICD–10 Coordination and Maintenance Committee meeting materials (available on the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials*). We refer the reader to section II.C.13. of the preamble of the proposed rule and this final rule for further information regarding Table 6B.

As discussed in prior rulemaking, interested parties may use current coding information to consider the potential MS–DRG assignments for procedure codes that may be finalized after the March meeting and submit public comments for consideration. Specifically, in the ICD–10 Coordination and Maintenance Committee meeting materials (available on the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials*), for each procedure code proposal we provide the current coding that is applicable within the classification and that should be reported in the absence of a more unique code, or until such time a new code is created and becomes effective. The procedure code(s) listed in current coding are generally, but not always, the same code(s) that are considered as the predecessor code(s) for purposes of MS–DRG assignment. As previously noted, our process for determining the MS–DRG assignment for a new procedure code does not automatically result in the new procedure code being assigned to the same MS–DRG or having the same designation (O.R. versus Non-O.R.) as the predecessor code. However, this current coding information can be used in conjunction with the GROUPER logic, as set forth in the ICD–10 MS–DRG Definitions Manual and publicly available on our CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* to review the MS–DRG assignment of the current code(s) and examine the potential MS–DRG assignment of the proposed code(s), to assist in formulating any public comments for submission to CMS for consideration.

In summary, we proposed to reassign ICD–10–PCS code 02HA0RZ (Insertion of short-term external heart assist system into heart, open approach) from MDC 05 in MS–DRG 215 to Pre-MDC MS–DRGs 001 and 002 for FY 2024. Separately, and as previously discussed, a code proposal was discussed at the March 7–8, 2023 ICD–10 Coordination and Maintenance Committee meeting to request a change to how the Impella 5.5® with SmartAssist® System is coded within the ICD–10–PCS classification. In the proposed rule, we noted that if finalized, the new procedure code would be included in the FY 2024 code update files that are made available in late May/early June on the CMS website at: *https://www.cms.gov/medicare/coding/icd10.* In addition, using our established process, if finalized, the MS–DRG assignment for any new procedure codes describing the Impella 5.5® with SmartAssist® System will be displayed in Table 6B.—New Procedure Codes in association with this FY 2024 IPPS/LTCH PPS final rule that will be made publicly available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS.*

Comment: Many commenters expressed support for CMS' proposal to reassign ICD–10–PCS code 02HA0RZ from MDC 05 in MS–DRG 215 to Pre-MDC MS–DRGs 001 and 002 when reported as a standalone procedure. These commenters stated they agreed with the proposal and believed reassigning this procedure to MS–DRGs 001 and 002 aligns more accurately with, and reflects resources used for, these more complex patients and more complex procedures. Commenters stated that they appreciate CMS' continued efforts to ensure appropriate code assignments of surgical approaches for

short-term heart assist devices and to improve clinical consistency and predictability for providers as short-term heart assist devices have evolved with different access procedures to treat hemodynamically compromised patients. Some commenters also stated that streamlining the GROUPER logic so that ICD–10–PCS code 02HA0RZ will no longer need to be reported as part of a procedure code combination or procedure code ''cluster'' to satisfy the logic for assignment to MS–DRGs 001 and 002 will ensure that the cases in these MS–DRGs are more clinically homogeneous and better reflect hospital resource use.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to reassign ICD–10–PCS code 02HA0RZ (Insertion of short-term external heart assist system into heart, open approach) from MDC 05 in MS–DRG 215 to Pre-MDC MS–DRGs 001 and 002 when reported as a standalone procedure, without modification, effective October 1, 2023, for FY 2024. Under this finalization, procedure code 02HA0RZ will no longer need to be reported as part of a procedure code combination or procedure code ''cluster'' to satisfy the logic for assignment to MS–DRGs 001 and 002.

Comment: Many commenters stated that if new ICD–10–PCS procedure codes describing the Impella 5.5® with SmartAssist® System were finalized following the March 7–8, 2023 ICD–10 Coordination and Maintenance Committee meeting, they recommend CMS assign the new codes to MS–DRGs 001 and 002. Some commenters stated that patients treated with the Impella 5.5® with SmartAssist® System have a very similar clinical presentation as patients treated with short-term external heart assist systems inserted via the open approach and utilize approximately the same resources. These commenters stated that they believed that both procedures are clinically coherent with cases currently assigned to MS–DRGs 001 and 002, so it is reasonable that cases reporting the insertion of the Impella 5.5® with SmartAssist® System group to the same MS–DRG as ICD–10–PCS code 02HA0RZ. A commenter further stated that this adjustment would help ensure adequate payment for the resources invested, allowing institutions to maintain high-quality care, and would incentivize the advancement of innovative interventions in the field of cardiovascular medicine.

Response: We thank the commenters for their feedback.

We note that the proposal to change how the Impella® 5.5 with SmartAssist® System is coded within the ICD–10–PCS classification that was discussed at the March 7–8 2023 ICD–10 Coordination and Maintenance Committee meeting was approved and new procedure codes to identify the insertion of a short-term external heart assist system using a conduit attached to the right axillary artery or to the ascending aorta were finalized as reflected in the FY 2024 ICD–10–PCS Code Update files that were made publicly available on the CMS website at *https://www.cms.gov/Medicare/Coding/ICD10* on June 6, 2023. In addition to the new procedure codes describing the Impella 5.5® with SmartAssist® System being made publicly available in the FY 2024 ICD–10–PCS Code Update files on the CMS website, we note that the new procedure codes are also reflected in Table 6B.—New Procedure Codes, in association with this final rule and available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS,* including the MS–DRG assignments for these new codes for FY 2024. We refer the reader to section II.C.13. of the preamble of this final rule for further information regarding the table.

Specifically, using our established process, we examined the MS–DRG assignment for the predecessor code to determine the most appropriate MS–DRG assignment. We reviewed the predecessor code and MS–DRG assignment most closely associated with the new procedure codes, and in the absence of claims data, we considered other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. ICD–10–PCS procedure code 03HY0YZ (Insertion of other device into upper artery, open approach) is the predecessor code that we utilized to inform this analysis.

The MS–DRG assignment for the predecessor code 03HY0YZ and the new procedure codes describing the insertion of a short-term external heart assist system using a conduit attached to the right axillary artery or to the ascending aorta under MDC 05 are identified as follows.

ICD-10-PCS Code	Description	MS-DRG
X2HL0F9	Insertion of conduit to short-term external heart assist system into right axillary artery, open approach, new technology group 9	252-254 (Other Vascular Procedures with MCC, with CC, without MCC respectively)
X2HM0F9	Insertion of conduit to short-term external heart assist system into left axillary artery, open approach, new technology group 9	
X2HX0F9	Insertion of conduit to short-term external heart assist system into thoracic aorta, ascending, open approach, new technology group 9	

While the new procedure codes are being assigned to the same MS–DRG as the predecessor code in this instance, as we have noted in prior rulemaking, and earlier in this section, this process does not automatically result in the new procedure code being assigned to the same MS–DRG or to have the same designation (O.R. versus Non-O.R.) as the predecessor code.

We also note that the finalized procedure codes describing the Impella 5.5® with SmartAssist® System identify the insertion of short-term external heart assist system using a conduit attached to the right axillary artery or to the ascending aorta. To fully describe the procedure, a separate code will continue to be reported for the insertion of the external heart assist system. In addition to the MDC and MS–DRG assignments as reflected in the previous table and in Table 6B.—New Procedure Codes, in association with this final rule, we note the procedure code combinations reflected in the table that follows are assigned to MS–DRGs 001 and 002, for FY 2024. This assignment is also reflected in the final Version 41 ICD–10 MS–DRG GROUPER logic.

ICD-10-PCS Code Pairs Added to Version 41 ICD-10 MS-DRGs 001 and 002: New Short-Term External Heart Assist ICD-10-PCS Combinations				
ICD–10–PCS Code	**Description**		**ICD–10–PCS Code**	**Description**
02HA0RZ	Insertion of short-term external heart assist system into heart, open approach	and	X2HX0F9	Insertion of conduit to short-term external heart assist system into thoracic aorta, ascending, open approach, new technology group 9
02HA3RZ	Insertion of short-term external heart assist system into heart, percutaneous approach	and	X2HL0F9	Insertion of conduit to short-term external heart assist system into right axillary artery, open approach, new technology group 9
02HA3RZ	Insertion of short-term external heart assist system into heart, percutaneous approach	and	X2HM0F9	Insertion of conduit to short-term external heart assist system into left axillary artery, open approach, new technology group 9
02HA0RZ	Insertion of short-term external heart assist system into heart, open approach	and	X2HX0F9	Insertion of conduit to short-term external heart assist system into thoracic aorta, ascending, open approach, new technology group 9
02HA3RZ	Insertion of short-term external heart assist system into heart, percutaneous approach	and	X2HL0F9	Insertion of conduit to short-term external heart assist system into right axillary artery, open approach, new technology group 9
02HA3RZ	Insertion of short-term external heart assist system into heart, percutaneous approach	and	X2HM0F9	Insertion of conduit to short-term external heart assist system into left axillary artery, open approach, new technology group 9

The public may provide feedback on these MS–DRG assignments for FY 2024, which will then be taken into consideration for the following fiscal year.

c. Ultrasound Accelerated Thrombolysis for Deep Venous Thrombosis

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27000 through 26706), we received a request to reassign cases reporting ultrasound accelerated thrombolysis (USAT) of peripheral vascular structures procedures with the administration of thrombolytic(s) for deep venous thrombosis from MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 270, 271, and 272 (Other Major Cardiovascular Procedures with MCC, with CC, and without CC/MCC, respectively).

Deep venous thrombosis (DVT) is caused when a blood clot (or thrombus) forms in a vein, primarily in large veins of the lower leg and thigh, but may also occur in the deep veins of the pelvis and less commonly, in the upper extremities. Risk factors for DVT are similar to those of pulmonary embolism as discussed in section II.C.4.a. of the proposed rule and this final rule, and include prolonged immobilization from any cause, obesity, cancer, fractured hip or leg, use of certain medications such as oral contraceptives, and the presence of certain medical conditions such as heart failure. Common symptoms of DVT include leg (or arm) swelling, pain, cramping, or heaviness, skin discoloration, the feeling of warmth in the affected area, or there may not be any noticeable symptoms.

Thrombolysis is a type of treatment where the infusion of thrombolytics (fibrinolytic or ''clot-busting'' drugs) is used to dissolve blood clots that form in the arteries or veins with the goal of improving blood flow and preventing long-term damage to tissues and organs. Conventional catheter-directed thrombolysis (CDT) procedures generally rely on a multi-sidehole catheter placed adjacent to the thrombus through which thrombolytics are delivered directly to the thrombus, however, the EKOS™ EkoSonic® Endovascular System (EKOS™ System) employs ultrasound to assist in thrombolysis. The ultrasound does not itself dissolve the thrombus, but pulses of ultrasonic energy temporarily make the fibrin in the thrombus more porous and increase fluid flow within the thrombus. High frequency, low-intensity ultrasonic waves create a pressure gradient that drives the thrombolytic into the thrombus and keeps it in close proximity to the binding sites. USAT is also referred to as ultrasound-assisted thrombolysis or ultrasound-enhanced thrombolysis.

We stated in the proposed rule that, according to the requestor (the manufacturer of the EKOS™ device), USAT of peripheral vascular structures with the administration of thrombolytic(s) for the treatment of DVT performed using the EKOS™ device utilizes more resources in comparison to other procedures that are currently assigned to MS–DRGs 252, 253, and 254 and is not clinically coherent with the other procedures assigned to those MS–DRGs. The requestor stated that the cases reporting USAT of peripheral vascular structures with the administration of thrombolytic(s) for DVT are more comparable with and more clinically aligned with the procedures assigned to MS–DRGs 270, 271, and 272. The requestor stated they performed an analysis of cases reporting USAT of peripheral vascular structures

for DVT with the following ICD–10–PCS procedure codes.

ICD-10-PCS Code	Description
04FC3Z0	Fragmentation of right common iliac artery, percutaneous approach, ultrasonic
04FD3Z0	Fragmentation of left common iliac artery, percutaneous approach, ultrasonic
04FE3Z0	Fragmentation of right internal iliac artery, percutaneous approach, ultrasonic
04FF3Z0	Fragmentation of left internal iliac artery, percutaneous approach, ultrasonic
04FH3Z0	Fragmentation of right external iliac artery, percutaneous approach, ultrasonic
04FJ3Z0	Fragmentation of left external iliac artery, percutaneous approach, ultrasonic
04FK3Z0	Fragmentation of right femoral artery, percutaneous approach, ultrasonic
04FL3Z0	Fragmentation of left femoral artery, percutaneous approach, ultrasonic
04FM3Z0	Fragmentation of right popliteal artery, percutaneous approach, ultrasonic
04FN3Z0	Fragmentation of left popliteal artery, percutaneous approach, ultrasonic
04FP3Z0	Fragmentation of right anterior tibial artery, percutaneous approach, ultrasonic
04FQ3Z0	Fragmentation of left anterior tibial artery, percutaneous approach, ultrasonic
04FR3Z0	Fragmentation of right posterior tibial artery, percutaneous approach, ultrasonic
04FS3Z0	Fragmentation of left posterior tibial artery, percutaneous approach, ultrasonic
04FT3Z0	Fragmentation of right peroneal artery, percutaneous approach, ultrasonic
04FU3Z0	Fragmentation of left peroneal artery, percutaneous approach, ultrasonic
04FY3Z0	Fragmentation of lower artery, percutaneous approach, ultrasonic
05F33Z0	Fragmentation of right innominate vein, percutaneous approach, ultrasonic
05F43Z0	Fragmentation of left innominate vein, percutaneous approach, ultrasonic
05F53Z0	Fragmentation of right subclavian vein, percutaneous approach, ultrasonic
05F63Z0	Fragmentation of left subclavian vein, percutaneous approach, ultrasonic
05F73Z0	Fragmentation of right axillary vein, percutaneous approach, ultrasonic
05F83Z0	Fragmentation of left axillary vein, percutaneous approach, ultrasonic
05F93Z0	Fragmentation of right brachial vein, percutaneous approach, ultrasonic
05FA3Z0	Fragmentation of left brachial vein, percutaneous approach, ultrasonic
05FB3Z0	Fragmentation of right basilic vein, percutaneous approach, ultrasonic
05FC3Z0	Fragmentation of left basilic vein, percutaneous approach, ultrasonic
05FD3Z0	Fragmentation of right cephalic vein, percutaneous approach, ultrasonic
05FF3Z0	Fragmentation of left cephalic vein, percutaneous approach, ultrasonic
06FC3Z0	Fragmentation of right common iliac vein, percutaneous approach, ultrasonic
06FD3Z0	Fragmentation of left common iliac vein, percutaneous approach, ultrasonic
06FF3Z0	Fragmentation of right external iliac vein, percutaneous approach, ultrasonic
06FG3Z0	Fragmentation of left external iliac vein, percutaneous approach, ultrasonic
06FH3Z0	Fragmentation of right hypogastric vein, percutaneous approach, ultrasonic
06FJ3Z0	Fragmentation of left hypogastric vein, percutaneous approach, ultrasonic
06FM3Z0	Fragmentation of right femoral vein, percutaneous approach, ultrasonic
06FN3Z0	Fragmentation of left femoral vein, percutaneous approach, ultrasonic
06FP3Z0	Fragmentation of right saphenous vein, percutaneous approach, ultrasonic
06FQ3Z0	Fragmentation of left saphenous vein, percutaneous approach, ultrasonic
06FY3Z0	Fragmentation of lower vein, percutaneous approach, ultrasonic

We noted in the proposed rule that the requestor did not include a list of diagnosis codes describing DVT or a list of procedure codes describing the administration of thrombolytic(s) in connection with its analysis.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58561 through 85 FR 58579), we summarized and responded to public comments expressing concern with the proposed MS–DRG assignments for the newly created procedure codes describing USAT of several anatomic sites that were effective with discharges on and after October 1, 2020 (FY 2021). Similar to the current request for FY 2024, for FY 2021, the commenters recommended that USAT procedures performed with the EKOS™ device for the treatment of DVT be assigned to MS–DRGs 270, 271, and 272 instead of MS–DRGs 252, 253, and 254. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR

58561 through 85 FR 58579), available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* for the detailed discussion.

In the proposed rule, we stated that we analyzed claims data from the September 2022 update of the FY 2022 MedPAR file for MS–DRGs 252, 253, and 254 and cases reporting a principal diagnosis of DVT and USAT of peripheral vascular structures procedure with and without the administration of thrombolytic(s). We noted that we identified claims reporting an USAT of peripheral vascular structures procedure, the administration of thrombolytic(s), and a diagnosis of DVT with the listed codes as shown in Table 6P.5a associated with the proposed rule (and available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*). The findings from our analysis are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
252 – All cases	20,939	8	$29,307
252 – Cases reporting a principal diagnosis of DVT and USAT with thrombolytic(s)	51	6.4	$36,660
252 – Cases reporting principal diagnosis of DVT and USAT without thrombolytic(s)	10	6.7	$21,538
253 – All cases	16,650	5.2	$22,685
253 – Cases reporting a principal diagnosis of DVT and USAT with thrombolytic(s)	80	5.2	$26,471
253 – Cases reporting principal diagnosis of DVT and USAT without thrombolytic(s)	11	3.8	$20,126
254 – All cases	6,707	2.4	$15,438
254 – Cases reporting a principal diagnosis of DVT and USAT with thrombolytic(s)	22	3	$21,867
254 – Cases reporting principal diagnosis of DVT and USAT without thrombolytic(s)	9	2	$17,750

As shown in the table, we identified a total of 20,939 cases in MS–DRG 252 with an average length of stay of 8 days and average costs of $29,307. Of the 20,939 cases, we found 51 cases reporting a principal diagnosis of DVT and USAT with thrombolytic(s) with an average length of stay of 6.4 days and average costs of $36,660 and 10 cases reporting a principal diagnosis of DVT and USAT without thrombolytic(s) with an average length of stay of 6.7 days and average costs of $21,538. The data demonstrate that the cases reporting a principal diagnosis of DVT and USAT with or without thrombolytic(s) have a shorter average length of stay compared to the average length of stay of all the cases in MS–DRG 252 (6.4 days and 6.7 days, respectively versus 8 days). However, the average costs for the cases reporting a principal diagnosis of DVT and USAT with thrombolytic(s) are higher than the average costs of all the cases in MS–DRG 252 ($36,660 versus $29,307) and the average costs for the cases reporting a principal diagnosis of DVT and USAT without thrombolytic(s) are lower than the average costs of all the cases in MS–DRG 252 ($21,538 versus $29,307). The data indicate that the cases reporting a principal diagnosis of DVT and USAT with thrombolytic(s) appear to consume more resources in comparison to the other cases in MS–DRG 252, although it is unclear if the higher resource consumption is a direct result of the EKOS™ device technology utilized in the performance of the thrombolysis procedure, or the fact that these cases also include the reporting of at least one or more secondary MCC diagnoses, or a combination of both factors. Conversely, the data indicate that the cases reporting a principal diagnosis of DVT and USAT without thrombolytic(s) appear to be less resource intensive with a difference in average costs of $7,769 ($29,307 − $21,538 = $7,769). Accordingly, the data appear to reflect that the cases reporting use of the EKOS™ device technology with thrombolytic(s) may have an impact on the consumption of resources when compared to all the cases in MS–DRG 252.

For MS–DRG 253, we identified a total of 16,650 cases with an average length of stay of 5.2 days and average costs of $22,685. Of the 16,650 cases, we found 80 cases reporting a principal diagnosis of DVT and USAT with thrombolytic(s) with an average length of stay of 5.2 days and average costs of $26,471 and 11 cases reporting a principal diagnosis of DVT and USAT without thrombolytic(s) with an average length of stay of 3.8 days and average costs of $20,126. The data demonstrate that the average length of stay for cases reporting a principal diagnosis of DVT and USAT with thrombolytic(s) is the same as the average length of stay for all the cases in MS–DRG 253 (5.2 days). Conversely, the average length of stay for the cases reporting a principal diagnosis of DVT and USAT without thrombolytic(s) is shorter than the average length of stay of all the cases in MS–DRG 253 (3.8 days versus 5.2 days). Similar to MS–DRG 252, the average costs for the cases reporting a principal diagnosis of DVT and USAT with thrombolytic(s) are higher than the average costs of all the cases in MS–DRG 253 ($26,471 versus $22,685) and the average costs for the cases reporting a principal diagnosis of DVT and USAT without thrombolytic(s) are lower than the average costs of all the cases in MS–DRG 253 ($20,126 versus $22,685). The data indicate that the cases reporting a principal diagnosis of DVT and USAT with thrombolytic(s) appear to consume more resources in comparison to the other cases in MS–DRG 253, although it is unclear if the higher resource consumption is a direct result of the EKOS™ device technology utilized in the performance of the thrombolysis procedure, or the fact that these cases also include the reporting of at least one or more secondary CC diagnoses, or a combination of both factors.

For MS–DRG 254, we identified a total of 6,707 cases with an average length of stay of 2.4 days and average costs of $15,438. Of the 6,707 cases, we found 22 cases reporting a principal diagnosis of DVT and USAT with thrombolytic(s) with an average length of stay of 3 days and average costs of $21,867 and 9 cases reporting a principal diagnosis of DVT and USAT without thrombolytic(s) with an average length of stay of 2 days and average costs of $17,750. The data demonstrate that the cases reporting a principal diagnosis of DVT and USAT with thrombolytic(s) have a longer average length of stay compared to the average

length of stay of all the cases in MS–DRG 254 (3 days versus 2.4 days), however, the cases reporting a principal diagnosis of DVT and USAT without thrombolytic(s) have a shorter but comparable average length of stay compared to the average length of stay of all the cases in MS–DRG 254 (2 days versus 2.4 days). Additionally, the average costs for the cases reporting a principal diagnosis of DVT and USAT with or without thrombolytic(s) are higher than the average costs of all the cases in MS–DRG 254 ($21,867 and $17,750 respectively versus $15,438) with a corresponding difference in average costs of $6,429 and $2,312 respectively. Similar to our findings for MS–DRGs 252 and 253, the data for MS–DRG 254 indicate the cases reporting a principal diagnosis of DVT and USAT with thrombolytic(s) appear to consume more resources in comparison to the other cases in their respective MS–DRG. In addition, as noted, for MS–DRG 254, the average costs of cases reporting a principal diagnosis of DVT and USAT without thrombolytic(s) are also higher than the average costs of all the cases in MS–DRG 254. However, it is unclear if the higher resource consumption is a direct result of the EKOS™ device technology utilized in the performance of the thrombolysis procedure alone, or if there are other contributing factors, since cases grouping to MS–DRG 254 do not include the reporting of at least one or more secondary CC or MCC diagnoses.

We stated in the proposed rule that our review of the data for MS–DRGs 252, 253, and 254 and our initial analysis for cases reporting a principal diagnosis of DVT and USAT procedure with and without the administration of thrombolytic(s) suggests that the administration of thrombolytic(s) may be considered a factor in the consumption of resources for these cases in MS–DRGs 252, 253, and 254 where USAT is performed in the treatment of a DVT. For example, in MS–DRG 252, there are 51 cases reporting a principal diagnosis of DVT and USAT procedure with the administration of thrombolytic(s) and 10 cases reporting a principal diagnosis of DVT and USAT procedure without the administration of thrombolytic(s), with both subsets of cases showing a comparable average length of stay of 6.4 and 6.7 days, respectively, however, the difference in average costs for cases with and without thrombolytic(s) is $15,122 ($36,660 − $21,538 = $15,122). For MS–DRG 253, there are 80 cases reporting a principal diagnosis of DVT and USAT procedure with the administration of thrombolytic(s) and 11 cases reporting a principal diagnosis of DVT and USAT procedure without the administration of thrombolytic(s), with both subsets of cases showing a difference in the average length of stay (5.2 days and 3.8 days, respectively) and a difference in average costs of $6,345 ($26,471 − $20,126 = $6,345). For MS–DRG 254, there are 22 cases reporting a principal diagnosis of DVT and USAT procedure with the administration of thrombolytic(s) and 9 cases reporting a principal diagnosis of DVT and USAT procedure without the administration of thrombolytic(s), however, both subsets of cases have a similar average length of stay (3 days and 2 days, respectively) with a difference in average costs of $4,117 ($21,867 − $17,750 = $4,117).

In the proposed rule, we noted that since the request we received was to reassign cases reporting ultrasound accelerated thrombolysis (USAT) with the administration of thrombolytic(s) for the treatment of deep venous thrombosis (DVT) from MS–DRGs 252, 253, and 254 to MS–DRGs 270, 271, and 272, based on our approach utilized in our initial analysis of claims reporting USAT with a principal diagnosis for DVT in MS–DRGs 252, 253, and 254, we then analyzed claims data from the September 2022 update of the FY 2022 MedPAR file for all cases in MS–DRGs 270, 271, and 272 and compared it to the cases reporting a principal diagnosis of DVT and USAT procedure with or without thrombolytic(s) in MS–DRGs 252, 253, and 254. The findings from our analysis are shown in the following tables.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
270 – All cases	15,879	9.5	$42,517
271 – All cases	11,449	5.4	$30,030
272 – All cases	3,832	2.4	$21,556

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
252 – All cases	20,939	8	$29,307
252 – Cases with principal diagnosis of DVT and USAT with or without thrombolytic(s)	61	6.4	$34,181
253– All cases	16,650	5.2	$22,685
253 – Cases with principal diagnosis of DVT and USAT with or without thrombolytic(s)	91	5	$25,704
254 – All cases	6,707	2.4	$15,438
254– Cases with principal diagnosis of DVT and USAT with or without thrombolytic(s)	31	2.7	$20,672

The claims data show that the 61 cases reporting a principal diagnosis of DVT and USAT with or without thrombolytic(s) in MS–DRG 252 have average costs that are lower than the average costs of all cases in MS–DRG 270 ($34,181 versus $42,517) and have a shorter average length of stay compared to all the cases in MS–DRG 270 (6.4 days versus 9.5 days). The 91 cases reporting a principal diagnosis of DVT and USAT with or without thrombolytic(s) in MS–DRG 253 have a comparable average length of stay (5 days versus 5.4 days) in comparison to all the cases in MS–DRG 271 and lower average costs in comparison to all the cases in MS–DRG 271 ($25,704 versus $30,030) with a difference of $4,326. Finally, the 31 cases reporting a principal diagnosis of DVT and USAT with or without thrombolytic(s) in MS–DRG 254 have an average length of stay that is comparable to all the cases in the

MS–DRG 272 (2.7 days versus 2.4 days) and comparable average costs ($20,672 versus $21,556) with a difference of $884.

We stated in the proposed rule that upon analysis of the claims data and our review of the request, we do not agree with reassigning cases reporting an USAT procedure with the administration of thrombolytic(s) and a principal diagnosis of DVT from MS–DRGs 252, 253, and 254 to MS–DRGs 270, 271, and 272. As stated in the proposed rule, the data do not support that cases reporting USAT (with or without thrombolytic(s)) for DVT utilize similar resources when compared to other procedures currently assigned to MS–DRGs 270, 271, and 272. We do not agree that cases reporting USAT (with or without thrombolytic(s)) are more comparable with and more clinically aligned with the procedures assigned to MS–DRGs 270, 271, and 272 because the majority of procedures in these MS–DRGs describe procedures performed on the heart and great vessels with either an open or an endoscopic approach in contrast to the USAT endovascular (percutaneous) procedure performed on the peripheral vascular structures. In addition, the majority of procedures in MS–DRGs 270, 271, and 272 are performed on patients who are not clinically similar to patients who undergo USAT for DVT since they describe procedures such as bypass, occlusion, and restriction that are typically performed for patients with conditions other than a DVT, such as atherosclerosis, aneurysm, and acute myocardial infarction (AMI). Lastly, a number of procedures in these MS–DRGs also involve the use of a permanently implanted device while the procedures utilizing USAT do not. Therefore, we do not consider USAT procedures to be major cardiovascular procedures, nor do we believe the cases reporting USAT with (or without thrombolytic(s)) for DVT demonstrate a similar level of technical complexity when compared to other procedures currently assigned to MS–DRGs 270, 271, and 272.

As noted in the proposed rule, while the average costs are higher for cases reporting the administration of a thrombolytic, we questioned whether the higher average costs may also reflect other factors, such as the use of the EKOS™ device or the performance of other O.R. procedures that also group to MS–DRGs 252, 253, and 254. Consistent with the analysis discussed in section II.C.4.a. of the proposed rule and this final rule for a similar, but separate request related to thrombolysis procedures, we believed it would also be beneficial to examine cases reporting standard CDT procedures with or without thrombolytic(s) for the treatment of DVT in MS–DRGs 252, 253, and 254, and compare the findings to the cases reporting USAT with or without thrombolytic(s) for the treatment of DVT.

Therefore, as discussed in the proposed rule, we conducted additional analyses to determine if there were significant differences in resource utilization for cases reporting standard CDT with or without thrombolytic(s) versus USAT procedures with or without thrombolytic(s) in the treatment of DVT, since claims data to compare the two modalities is now available and studies have reported similar clinical outcomes in reducing DVT regardless of which thrombolysis modality is utilized.[5]

We analyzed claims data from the September 2022 update of the FY 2022 MedPAR file for all cases in MS–DRGs 252, 253, and 254 and cases reporting a standard CDT procedure with or without the administration of thrombolytic(s) and a principal diagnosis of DVT. We utilized the previously listed procedure codes for the administration of thrombolytic(s) and the previously listed diagnosis codes for a principal diagnosis of DVT. We identified cases describing standard CDT procedures performed in the treatment of DVT with the procedure codes listed in Table 6P.5a. associated with the proposed rule and available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*. The findings from our analysis are shown in the following table. We note there were no cases found to report a standard CDT procedure with or without thrombolytic(s) and a principal diagnosis of DVT in MS–DRGs 253 or 254.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
252 – All cases	20,939	8	$29,307
252 – Cases with principal diagnosis of DVT and CDT with or without thrombolytic(s)	3	2.3	$10,603
253– All cases	16,650	5.2	$22,685
254 – All cases	6,707	2.4	$15,438

The data shows that the 3 cases reporting a principal diagnosis of DVT and standard CDT with or without thrombolytic(s) in MS–DRG 252 have a shorter average length of stay compared to all cases in MS–DRG 252 (2.3 days versus 8 days) and lower average costs ($10,603 versus $29,307).

We noted in the proposed rule that, overall, our analysis of the claims data for cases reporting a principal diagnosis of DVT and USAT or standard CDT, with or without thrombolytic(s), demonstrate a low volume of cases, however, the average costs of the cases reporting USAT with thrombolytic(s) reflect a significantly higher consumption of resources than all cases in MS–DRGs 252, 253, and 254. We further noted that because it is also possible that a patient may be admitted to a hospital and receive thrombolysis (USAT or CDT) with a principal diagnosis other than a DVT or the DVT condition may be reported as a secondary diagnosis, we believed additional analysis for cases reporting either USAT or CDT, regardless of the principal diagnosis, would provide us with more beneficial information in our review of these cases.

Therefore, using the September 2022 update of the FY 2022 MedPAR file, we conducted an analysis of MS–DRGs 252, 253, and 254 for cases reporting either USAT or CDT with and without thrombolytic(s) with any principal diagnosis from MDC 5. Our findings are shown in the following table.

[5] Engelberger, Rolf & Stuck, Anna K. & Spirk, David & Willenberg, Torsten & Haine, Axel & Périard, Daniel & Baumgartner, Iris & Kucher, Nils. (2017). Ultrasound-assisted versus conventional catheter-directed thrombolysis for acute ilio-femoral deep vein thrombosis: one-year follow-up data of a randomized-controlled trial. Journal of Thrombosis and Haemostasis. 15. 10.1111/jth.13709.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
252 – All cases	20,939	8	$29,307
252 – Cases with any MDC 05 principal diagnosis and USAT or CDT with or without thrombolytic(s)	468	8.6	$39,181
253– All cases	16,650	5.2	$22,685
253 – Cases with any MDC 05 principal diagnosis and USAT or CDT with or without thrombolytic(s)	722	4.9	$29,663
254 – All cases	6,707	2.4	$15,438
254 – Cases with any MDC 05 principal diagnosis and DVT or CDT with or without thrombolytic(s)	195	2.6	$22,487

The findings from our analysis show a larger volume of cases for each respective MS–DRG (252, 253, and 254) for cases reporting USAT or CDT procedures with any MDC 05 principal diagnosis versus the findings from our earlier analysis involving cases specifically reporting a principal diagnosis of DVT. The claims data also show that the 468 cases reporting any principal diagnosis from MDC 05 and USAT or CDT with or without thrombolytic(s) in MS–DRG 252 have average costs that are higher than the average costs of all cases in MS–DRG 252 ($39,181 versus $29,307) and have a comparable average length of stay (8.6 days versus 8.0 days). The 722 cases reporting any principal diagnosis from MDC 05 and USAT or CDT with or without thrombolytic(s) in MS–DRG 253 have a shorter average length of stay (4.9 days versus 5.2 days) in comparison to all the cases in MS–DRG 253 and higher average costs ($29,663 versus $22,685) with a difference of $6,978. Finally, the 195 cases reporting any principal diagnosis from MDC 05 and USAT or CDT with or without thrombolytic(s) in MS–DRG 254 have an average length of stay that is comparable to all the cases in the MS–DRG 272 (2.6 days versus 2.4 days) and higher average costs ($22,487 versus $15,438) with a difference of $7,049.

As discussed in the proposed rule, based on our review and the claims data analysis for cases in MS–DRGs 252, 253, and 254 and MS–DRGs 270, 271, and 272, and for cases reporting standard CDT or USAT with or without thrombolytic(s) regardless of the principal diagnosis reported from MDC 05, we believe that while the subset of cases for patients undergoing a thrombolysis (CDT or USAT) procedure for DVT does not clinically align with patients undergoing surgery for acute myocardial infarction (AMI) and does not involve the same level of complexity as cases grouping to MS–DRGs 270, 271, and 272, the differences in resource consumption warrant reassignment of these cases. Specifically, we believed the clinical and data analyses support creating a new base MS–DRG to distinguish cases reporting USAT or standard CDT procedure of peripheral vascular structures with or without thrombolytic(s) from other cases currently grouping to MS–DRGs 252, 253, and 254. We stated we believe a new MS–DRG would reflect more appropriate payment for USAT and standard CDT procedures of peripheral vascular structures.

In the proposed rule, we also noted that to compare and analyze the impact of our suggested modifications, we ran a simulation using the most recent claims data from the December 2022 update of the FY 2022 MedPAR file. The following table illustrates our findings for all 1,487 cases reporting procedure codes describing an USAT or CDT procedure with any principal diagnosis from MDC 05.

Proposed new MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed new MS-DRG XXX	1,487	5.8	$31,794

Consistent with our established process as discussed in section II.C.1.b. of the preamble of the proposed rule and this final rule, once the decision has been made to propose to make further modifications to the MS–DRGs, such as creating a new base MS–DRG, all five criteria to create subgroups must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. Therefore, we applied the criteria to create subgroups in a base MS–DRG. We noted in the proposed rule that, as shown in the table that follows, a three-way split of this base MS–DRG failed to meet the criterion that there be at least 500 cases in the NonCC (without CC/MCC) subgroup.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
With MCC	516	8.5	$38,904
With CC	768	4.8	$29,555
Without CC/MCC	203	2.5	$22,188

As discussed in section II.C.1.b. of the preamble of the proposed rule and this final rule, if the criteria for a three-way split fail, the next step is to determine if the criteria are satisfied for a two-way split. We applied the criteria for a two-way split for the ''with MCC and without MCC'' subgroups. We noted that, as shown in the table that follows, a two-way split of this base MS–DRG met all five criteria. For the proposed MS–DRGs, there is at least (1) 500 or more cases in the MCC group and in the without MCC subgroup; (2) 5 percent or more of the cases in the MCC group and

in the without MCC subgroup; (3) a 20 percent difference in average costs between the MCC group and the without MCC group; (4) a $2,000 difference in average costs between the MCC group and the without MCC group; and (5) a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the proposed MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system. The following table illustrates our findings for the suggested MS–DRGs with a two-way severity level split.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
With MCC	516	8.5	$38,904
Without MCC	971	4.3	$28,015

Accordingly, because the criteria for the two-way split were met, we stated we believed a split (or CC subgroup) is warranted for the proposed new base MS–DRG. As a result, for FY 2024, we proposed to create new MS–DRG 278 (Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures with MCC) and new MS–DRG 279 (Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures without MCC).

We proposed to define the logic for the proposed new MS–DRGs using the previously listed procedure codes for USAT and CDT, as identified and discussed in our analysis of the claims data in Table 6P.5a associated with the proposed rule.

Comment: Commenters supported the proposal to create new MS–DRGs 278 and 279 (Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures with and without MCC, respectively) given the data and information provided. A commenter stated the new MS–DRGs will generate more appropriate payment for cases reporting these procedures.

Response: We thank the commenters for their support.

Comment: A couple commenters suggested that the proposal to create the two new MS–DRGs should be delayed until more data can be collected. The commenters stated their belief that it is premature to create these new MS–DRGs at this time and that in developing these proposed MS–DRGs, CMS relied on recently implemented ICD–10–PCS data. According to the commenters, due to the lengthy processes for hospitals to adopt and accurately implement new coding, and conflicting coding advice for utilization of the ICD–10–PCS procedure codes for CDT and USAT, the number of cases is currently insufficient to support development of new MS–DRGs. The commenter stated that the low volume of cases and related data selected by CMS for analysis, CDT for the treatment of DVT, cannot adequately compare to the costs, complexity, and utilization of USAT with a high confidence interval.

Response: We appreciate the commenters' feedback. We disagree with the commenters that it is premature to propose the creation of new MS–DRGs 278 and 279 based on our review and claims data analysis as discussed in the proposed rule. In response to the commenters' statement that CMS relied on recently implemented ICD–10–PCS data, it is not clear to us what specific ICD–10–PCS data the commenters are referring to since a specific list was not provided, however, we believe the commenters may be suggesting the codes for USAT that were finalized October 1, 2020 (FY 2021), and listed previously in connection with the analysis discussed in the proposed rule. As discussed in the proposed rule and prior rulemaking, our goal is always to use the best available data. We noted in the proposed rule that our initial MS–DRG analysis was based on ICD–10 claims data from the September 2022 update of the FY 2022 MedPAR file, which contains hospital bills received from October 1, 2021, through September 30, 2022, and where otherwise indicated, additional analysis was based on ICD–10 claims data from the December 2022 update of the FY 2022 MedPAR file, which contains hospital bills received by CMS through December 31, 2022, for discharges occurring from October 1, 2021, through September 30, 2022. Therefore, we believe our analysis of claims data in consideration of the MS–DRG request to reassign cases reporting USAT of peripheral vascular structures procedures with the administration of thrombolytic(s) for DVT is consistent with our standard process, regardless of the effective date of the coded claims data. We also do not agree with the commenters' assertion that it is a lengthy process for hospitals to adopt and accurately implement new coding. We note that procedure code proposals discussed at the September ICD–10 Coordination and Maintenance Committee meeting and subsequently finalized are typically included in Table 6B.—New Procedure Codes in association with the proposed rule that is made publicly available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*. This table (Table 6B) lists the new procedure codes that have been approved to date that will be effective with discharges on and after October 1 of the upcoming fiscal year. Therefore, information regarding the finalized codes from the September meeting is made publicly available approximately 4–5 months in advance of the implementation date, affording the ability for users of the code set to gain familiarity with the updates. In addition, there are extensive industry-sponsored educational opportunities through various professional associations that introduce and discuss the annual code updates. For example, the American Hospital Association (AHA), American Health Information Management Association (AHIMA), and the American Academy of Professional Coders (AAPC) generally take lead roles in developing detailed technical training materials for coders and other users of the ICD–10 code set. The AHA also includes updates to ICD–10 in its *Coding Clinic® for ICD–10–CM/ICD–10–PCS* publication. Because the codes describing USAT were finalized for implementation October 1, 2020 (FY 2021), we believe sufficient time has elapsed and that providers are successfully coding and reporting the procedure as demonstrated in our claims analysis.

It is also not clear what conflicting coding advice for utilization of the ICD–10–PCS procedure codes for CDT and USAT the commenters are referring to since the commenters did not provide examples or supplemental information for what they believed to be conflicting advice to enable further evaluation.

Comment: A couple commenters expressed concern that the inclusion of both conventional CDT, also known as

''standard infusion catheters,'' and USAT in the proposed new MS–DRGs disregards fundamental clinical differences between the procedures. According to the commenters, CDT generally relies on a multi-sidehole infusion catheter placed adjacent to the thrombus through which thrombolytics are delivered, typically over the course of 24 hours with the catheter in-dwelling, whereas USAT employs ultrasound to assist in thrombolysis, and the pulses of ultrasonic energy temporarily make the fibrin in the thrombus more porous and increase fluid flow within the thrombus. The commenters stated standard CDT is the simple infusion of liquids into the vessel and should not map to the same root operation fragmentation codes as does USAT. The commenters also stated CDT procedures are generally less complex clinically and consume significantly lower level of hospital resources as a result. The commenters recommended CMS should delay implementation, not finalize the proposed MS–DRGs at this time and reconsider at a later date when utilization volumes reach a threshold of significance.

A commenter also indicated that an analysis of cost data was being submitted to CMS to demonstrate that USAT DVT cases have total costs that are more than three times the cost of CDT procedures for the sickest patients.

Response: We disagree with the commenters that inclusion of both conventional CDT and USAT in the proposed new MS–DRGs disregards fundamental clinical differences between the procedures. We note that while USAT procedures performed utilizing the EKOS™ device employ ultrasound, the objective of both CDT and USAT procedures is to effectuate thrombolysis and reduce clot burden. In response to the commenters' statement that standard CDT is the simple infusion of liquids into the vessel and should not map to the same root operation fragmentation codes as does USAT, we note that under ICD–10–PCS, both USAT and CDT are reported with the root operation fragmentation, defined as breaking solid matter in a body part into pieces. The procedure may be accomplished by physical force (*e.g.,* manual, ultrasonic) applied directly or indirectly that is used to break the solid matter into pieces. The solid matter may be an abnormal byproduct of a biological function or a foreign body. The pieces of solid matter are not taken out. With respect to the commenters' statement that CDT procedures are generally less complex clinically and consume significantly lower level of hospital resources, we note that any procedure that places a catheter inside a blood vessel carries certain risks, including damage to the blood vessel, bruising or bleeding at the puncture site, and infection. In response to the commenters' recommendation that CMS should delay finalization for the proposed MS–DRGs and reconsider in the future when utilization volumes reach a threshold of significance, as discussed in the proposed rule, once the decision was made to propose a new base MS–DRG, we applied the criteria to create subgroups and the criteria for a two-way split was met, therefore, we believe sufficient volume does exist for the proposed new MS–DRGs.

Finally, in response to the cost data that was submitted by a commenter, we note that it was the same data analysis as reflected and discussed in the proposed rule, therefore we refer readers to that prior discussion.

Comment: A commenter stated they agreed that fragmentation procedures with or without USAT do not belong in the requested MS–DRGs 270, 271, and 272, and suggested they remain in their current MS–DRGs 252, 253, and 254 based on clinical coherence and resource utilization.

Response: We appreciate the commenter's feedback and agree that fragmentation procedures with or without USAT do not belong in the requested MS–DRGs 270, 271, and 272. However, for reasons discussed in the proposed rule, we believe our review of these procedures and data analysis findings support the proposal to create new MS–DRGs 278 and 279 for grouping cases reporting the performance of USAT or CDT with any principal diagnosis from MDC 05.

Comment: A couple commenters disagreed with the proposal to create new MS–DRGs 278 and 279. A commenter stated USAT procedures have been receiving appropriate payment since FY 2021 and the proposed new MS–DRGs would create unnecessary administrative burden for established procedure codes that already have appropriate payment. Another commenter stated that fragmentation procedures, with or without ultrasonic assistance to break up blood clots in the peripheral vasculature, should stay assigned to the current MS–DRGs 252, 253, and 254, respectively. The commenter stated that the costs and resources for these procedures are consistent with current payment levels when compared to the rest of the procedures assigned to the current MS–DRGs, that the change is not needed or necessary, and that over time may result in overall reduced payment, given that such a low number of procedures would be assigned to their own MS–DRGs.

Response: We appreciate the commenters' feedback, however, based on our review of the procedures and claims data analysis as discussed in the proposed rule, we believe that USAT and CDT procedures performed on peripheral vascular structures are clinically distinct and utilize a different pattern of resources than other procedures in MS–DRGs 252, 253, and 254. We stated in the proposed rule that while we did not agree with the request to reassign cases reporting USAT or CDT for peripheral vascular structures from MS–DRGs 252, 253, and 254 to MS–DRGs 270, 271, and 272, we believed the findings from our analysis warranted proposed reassignment of these cases. While we described the findings from our review of the procedures currently assigned to MS–DRGs 270, 271, and 272 to specifically address the MS–DRG request (88 FR 26704), we note that in our review of cases assigned to MS–DRGs 252, 253, and 254 we identified the majority of procedures reported are for procedures that involve a bypass or dilation procedure that alters the diameter or route of a tubular body part with either an open or percutaneous endoscopic approach in contrast to the USAT endovascular (percutaneous) procedure performed on the peripheral vascular structures. In addition, a number of procedures in these MS–DRGs also involve the use of a permanently implanted device while the procedures utilizing USAT or CDT do not. We also do not agree that the proposed new MS–DRGs would create an unnecessary administrative burden for the established procedure codes since providers are accustomed to proposed and finalized changes to the MS–DRG classifications each fiscal year and software vendors incorporate the finalized changes into their products. With respect to the commenter's assertion that a low volume of procedures would be assigned to their own MS–DRGs based on the proposal, as previously discussed, once the decision was made to propose a new base MS–DRG, we applied the criteria to create subgroups and the criteria for a two-way split was met, therefore, we believe sufficient volume does exist for the proposed new MS–DRGs.

After consideration of the public comments we received, we are finalizing our proposal to create new MS–DRG 278 (Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures with MCC) and new MS–DRG 279 (Ultrasound Accelerated

and Other Thrombolysis of Peripheral Vascular Structures without MCC), without modification, for FY 2024. We are also finalizing our proposal to define the logic for the new MS–DRGs using the previously listed procedure codes for USAT and CDT, as identified and discussed in our analysis of the claims data in Table 6P.5a associated with the proposed rule. We will continue to monitor the claims data for these new MS–DRGs after implementation to determine if additional refinements are warranted.

d. Coronary Intravascular Lithotripsy

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26706 through 26712), we discussed a request we received to review the MS–DRG assignment of cases describing percutaneous coronary intravascular lithotripsy (IVL) involving the insertion of a coronary drug-eluting stent. Coronary IVL is utilized in a subset of percutaneous coronary interventions (PCI) procedures when the artery is severely calcified. The presence of calcium can create various challenges in PCI procedures as it can prevent the optimal deployment of coronary stents and can negatively impact patient outcomes. To fully optimize the PCI for severely calcified arteries, advanced techniques, such as coronary IVL, that utilize specialty devices are often required. In coronary IVL, a lithotripsy device catheter is delivered from a small incision in the patient's arm or leg through to the coronary arterial system of the heart to reach the site of a severely calcified lesion. The lithotripsy emitters at the end of the catheter create acoustic pressure waves that are intended to break up the calcification that is restricting the blood flow in the vessels of the heart to help open the blood vessels when an angioplasty balloon is inflated. After the lithotripsy is performed, the provider can implant an intraluminal device, also called a stent, to keep the vessel open.

According to the requestor, PCIs involving coronary IVL are clinically more complex because coronary IVL is a therapy deployed exclusively in severely calcified coronary lesions, and these lesion types are associated with longer procedure times and increased utilization of hospital resources. The requestor performed its own analysis of claims data for cases reporting procedure codes describing coronary IVL in MS–DRGs 246 and 247 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Arteries or Stents and without MCC, respectively) and stated that their findings showed a significant disparity in total standardized costs for cases in MS–DRG 247. Therefore, according to the requestor, the reassignment of all cases reporting procedure codes describing percutaneous coronary IVL involving the insertion of a drug-eluting intraluminal device from the lower severity level MS–DRG 247 to the higher severity level MS–DRG 246 would be reasonable. The requestor also asked that CMS analyze the cases reporting procedure codes describing percutaneous coronary IVL involving the insertion of a non-drug-eluting intraluminal device to determine if reclassifying cases from the lower severity level MS–DRG 249 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent without MCC) to the higher severity level MS–DRG 248 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent with MCC or 4+ Arteries or Stents) would be warranted.

The four ICD–10–PCS procedure codes that describe percutaneous coronary IVL are shown in the following table.

ICD-10-PCS Code	Description
02F03ZZ	Fragmentation in coronary artery, one artery, percutaneous approach
02F13ZZ	Fragmentation in coronary artery, two arteries, percutaneous approach
02F23ZZ	Fragmentation in coronary artery, three arteries, percutaneous approach
02F33ZZ	Fragmentation in coronary artery, four or more arteries, percutaneous approach

We stated in the proposed rule that the Shockwave C2 Intravascular Lithotripsy System, indicated for lithotripsy-enabled, low-pressure dilation of calcified, stenotic de novo coronary arteries prior to stenting, is identified by the reporting of an ICD–10–PCS code that describes percutaneous coronary IVL shown in the previous table. The Shockwave C2 Intravascular Lithotripsy System was approved for new technology add-on payments for FY 2022 (86 FR 45151 through 45153) and FY 2023 (87 FR 48913). We refer readers to section II.E.5 of the preamble of the proposed rule and this final rule for a discussion regarding the FY 2024 status of technologies approved for FY 2023 new technology add-on payments, including the Shockwave C2 Intravascular Lithotripsy System.

We stated in the proposed rule that the requestor is correct that cases reporting procedure codes that describe percutaneous coronary IVL involving the insertion of a drug-eluting intraluminal device group to MS–DRGs 246 and 247. We also stated the requestor is correct that cases reporting procedure codes that describe percutaneous coronary IVL involving the insertion of a non-drug-eluting intraluminal device group to MS–DRGs 248 and 249. We referred the reader to the ICD–10 MS–DRG Definitions Manual Version 40.1, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for MS–DRGs 246, 247, 248, and 249.

In analyzing this request, we noted in the proposed rule that coronary IVL is a vessel preparation technique and that there may be instances where an intraluminal device is unable to be inserted after the application of the IVL pulses. Therefore, in our analysis of cases reporting procedure codes describing percutaneous coronary IVL involving the insertion of a drug-eluting intraluminal device and non-drug-eluting intraluminal device that group to MS–DRGs 246, 247, 248, and 249, we stated that we included cases reporting percutaneous coronary IVL without procedure codes describing the insertion of a intraluminal device that group to MS–DRGs 250 and 251 (Percutaneous Cardiovascular Procedures without Coronary Artery Stent with MCC and without MCC, respectively) in our examination of claims data from the September 2022

update of the FY 2022 MedPAR file for cases reporting percutaneous coronary IVL and compared the results to all cases in their respective MS–DRG.

The following table shows our findings:

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
246	All cases	40,647	5.2	$25,630
	Cases reporting coronary IVL	2,359	5.7	$35,503
	All other cases	38,288	5.2	$25,022
247	All cases	54,671	2.4	$16,241
	Cases reporting coronary IVL	1,505	2.7	$24,141
	All other cases	53,166	2.4	$16,017
248	All cases	555	5.9	$25,740
	Cases reporting coronary IVL	13	7.2	$34,492
	All other cases	542	5.9	$25,530
249	All cases	604	2.5	$14,909
	Cases reporting coronary IVL	11	2.8	$18,648
	All other cases	593	2.5	$14,840
250	All cases	3,483	4.8	$20,634
	Cases reporting coronary IVL	201	4.4	$25,628
	All other cases	3,282	4.8	$20,328
251	All cases	3,199	2.5	$14,273
	Cases reporting coronary IVL	185	2.4	$20,289
	All other cases	3,014	2.5	$13,904

As shown by the table, in MS–DRG 246, we identified a total of 40,647 cases, with an average length of stay of 5.2 days and average costs of $25,630. Of those 40,647 cases, there were 2,359 cases reporting percutaneous coronary IVL, with higher average costs as compared to all cases in MS–DRG 246 ($35,503 compared to $25,630), and a longer average length of stay (5.7 days compared to 5.2 days). In MS–DRG 247, we identified a total of 54,671 cases with an average length of stay of 2.4 days and average costs of $16,241. Of those 54,671 cases, there were 1,505 cases reporting percutaneous coronary IVL, with higher average costs as compared to all cases in MS–DRG 247 ($24,141 compared to $16,241), and a longer average length of stay (2.7 days compared to 2.4 days). In MS–DRG 248, we identified a total of 555 cases with an average length of stay of 5.9 days and average costs of $25,740. Of those 555 cases, there were 13 cases reporting percutaneous coronary IVL, with higher average costs as compared to all cases in MS–DRG 248 ($34,492 compared to $25,740), and a longer average length of stay (7.2 days compared to 5.9 days). In MS–DRG 249, we identified a total of 604 cases with an average length of stay of 2.5 days and average costs of $14,909. Of those 604 cases, there were 11 cases reporting percutaneous coronary IVL, with higher average costs as compared to all cases in MS–DRG 249 ($18,648 compared to $14,909), and a longer average length of stay (2.8 days compared to 2.5 days). In MS–DRG 250, we identified a total of 3,483 cases with an average length of stay of 4.8 days and average costs of $20,634. Of those 3,483 cases, there were 201 cases reporting percutaneous coronary IVL, with higher average costs as compared to all cases in MS–DRG 250 ($25,628 compared to $20,634), and a shorter average length of stay (4.4 days compared to 4.8 days). In MS–DRG 251, we identified a total of 3,199 cases with an average length of stay of 2.5 days and average costs of $14,273. Of those 3,199 cases, there were 185 cases reporting percutaneous coronary IVL, with higher average costs as compared to all cases in MS–DRG 251 ($20,289 compared to $14,273), and a shorter average length of stay (2.4 days compared to 2.5 days). We stated in the proposed rule that the data analysis shows that the average costs of cases reporting percutaneous coronary IVL, with or without involving the insertion of intraluminal device, are higher than for all cases in their respective MS–DRG.

We also stated that the data analysis also shows that when the insertion of an intraluminal device was reported with percutaneous coronary IVL, average costs are generally similar without regard as to whether a drug-eluting or a non-drug-eluting intraluminal device was placed. In MS–DRG 246, there were 2,359 cases reporting percutaneous coronary IVL involving the insertion of a drug-eluting intraluminal device with average costs of $35,503 compared to 13 cases reporting percutaneous coronary IVL involving the insertion of a non-drug-eluting intraluminal device with average costs of $34,492 in MS–DRG 248. In MS–DRG 247, there were 1,505 cases reporting percutaneous coronary IVL involving the insertion of a drug-eluting intraluminal device with average costs of $24,141 compared to 11 cases reporting percutaneous coronary IVL involving the insertion of a non-drug-eluting intraluminal device with average costs of $18,648 in MS–DRG 249.

In the proposed rule, we stated we reviewed this data analysis and agreed

that the performance of percutaneous coronary IVL contributes to increased resource consumption for these PCI procedures. We also stated that we agreed that clinically, the presence of severe calcification can increase the treatment difficulty and complexity of service. The data analysis clearly shows that cases reporting percutaneous coronary IVL, with or without involving the insertion of intraluminal device, have higher average costs and generally longer lengths of stay compared to all the cases in their assigned MS–DRG. For these reasons, we proposed to create new MS–DRGs for percutaneous coronary IVL involving the insertion of an intraluminal device. While there is not a large number of cases reporting percutaneous coronary IVL without the insertion of an intraluminal device represented in the Medicare data, and we generally prefer not to create a new MS–DRG unless it would include a substantial number of cases, we stated in the proposed rule that we believed creating a separate MS–DRG for these cases as well would appropriately address the differential in resource consumption. Therefore, we also proposed to create a new MS–DRG for cases describing percutaneous coronary IVL without the insertion of an intraluminal device.

To compare and analyze the impact of our suggested modifications, we noted that we ran a simulation using the most recent claims data from the December 2022 update of the FY 2022 MedPAR file. The following table illustrates our findings for all 4,238 cases reporting procedure codes describing percutaneous coronary IVL involving the insertion of an intraluminal device.

Proposed new MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed new MS-DRG XXX Coronary Intravascular Lithotripsy with Intraluminal Device	4,238	4.6	$31,115

We stated we applied the criteria to create subgroups in a base MS–DRG as discussed in section II.C.1.b. of the proposed rule and this FY 2024 IPPS/LTCH PPS final rule. As shown, a three-way split of the proposed new MS–DRG failed to meet the criterion that there be at least a 20% difference in average costs between the CC and NonCC subgroup and also failed to meet the criterion that there be at least a $2,000 difference in average costs between the CC and NonCC subgroup.

Proposed new MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
With MCC	2,079	6.3	$36,325
With CC	1,423	3.2	$26,707
Without CC/MCC	736	2.3	$24,924

We then applied the criteria for a two-way split for the ''with MCC'' and ''without MCC'' subgroups and found that all five criteria were met. The following table illustrates our findings.

Proposed new MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
With MCC	2,079	6.3	$36,325
Without MCC	2,159	2.9	$26,099

BILLING CODE 4120–01–C

As discussed in the proposed rule, for the proposed new MS–DRGs for cases reporting procedure codes describing percutaneous coronary IVL involving the insertion of an intraluminal device, there is at least (1) 500 cases in the MCC subgroup and 500 cases in the without MCC subgroup; (2) 5 percent of the cases in the MCC group and 5 percent in the without MCC subgroup; (3) a 20 percent difference in average costs between the MCC group and the without MCC group; (4) a $2,000 difference in average costs between the MCC group and the without MCC group; and (5) a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the proposed MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system.

For the cases describing coronary intravascular lithotripsy without the insertion of an intraluminal device, we identified a total of 404 cases using the most recent claims data from the December 2022 update of the FY 2022 MedPAR file, so the criterion that there are at least 500 or more cases in each subgroup could not be met. Therefore, for FY 2024, we did not propose to subdivide the proposed new MS–DRG for coronary intravascular lithotripsy

without an intraluminal device into severity levels.

In summary, for FY 2024, taking into consideration that it clinically requires greater resources to perform coronary intravascular lithotripsy, we proposed to create two new MS–DRGs with a two-way severity level split for cases describing coronary intravascular lithotripsy involving the insertion of an intraluminal device in MDC 05. We also proposed to create a new MS–DRG for cases describing coronary intravascular lithotripsy without an intraluminal device. These proposed new MS–DRGs are proposed new MS–DRG 323 (Coronary Intravascular Lithotripsy with Intraluminal Device with MCC), proposed new MS–DRG 324 (Coronary Intravascular Lithotripsy with Intraluminal Device without MCC) and proposed new MS–DRG 325 (Coronary Intravascular Lithotripsy without Intraluminal Device). We refer the reader to Table 6P.6a associated with the proposed rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index* for the list of procedure codes we proposed to define in the logic for each of the proposed new MS–DRGs. We refer the reader to section II.C.15. of the preamble of this final rule for the discussion of the surgical hierarchy and the complete list of our proposed modifications to the surgical hierarchy as well as our finalization of those proposals.

Comment: Many commenters expressed support for CMS' proposal to create new MS–DRGs for cases describing coronary intravascular lithotripsy. A commenter stated that CMS' proposal highlights the resources consumed when performing the procedure with or without the insertion of an intraluminal device. This commenter further stated the proposal also takes into consideration the challenges associated with coronary arteries that are severely calcified while simultaneously providing better outcomes with the optimal deployment of intraluminal devices, when necessary. A commenter stated they appreciate CMS' willingness to periodically review hospital resources associated with the MS–DRGs for percutaneous coronary intervention procedures. Another commenter applauded CMS' proposal and stated this adjustment should provide for greater access to this new technology and should contribute to better outcomes for Medicare patients with severely calcified arteries.

Response: We appreciate the commenters' support.

Comment: While supporting the proposal, some commenters suggested that proposed new MS–DRG 325 (Coronary Intravascular Lithotripsy without Intraluminal Device) be split into two severity levels (with and without MCC) to recognize the increased resource utilization when a secondary diagnosis designated as an MCC is present. Another commenter stated that CMS proposed to delay application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split for FY 2024 and questioned CMS' application of the methodology to the proposed new MS–DRGs. This commenter stated that the presence of a secondary diagnosis designated as CC and a MCC impacts the length of stay and costs and therefore distinct tiers within these proposed MS–DRGs are necessary to reflect the differences in resource utilization.

Response: We thank the commenters for their feedback.

In response to the suggestion that proposed new MS–DRG 325 for cases describing coronary intravascular lithotripsy without intraluminal device be subdivided with a two-way severity level split, as discussed in the proposed rule and earlier in this section, in the analysis of the cases describing coronary intravascular lithotripsy without the insertion of an intraluminal device, we note we identified a total of 404 cases using the most recent claims data from the December 2022 update of the FY 2022 MedPAR file. Therefore, the criterion that there are at least 500 or more cases in each subgroup could not be met so we did not propose to subdivide the proposed new MS–DRG for coronary intravascular lithotripsy without an intraluminal device into severity levels for FY 2024.

In response to the concern regarding the application of the NonCC subgroup criteria to the proposed new MS–DRGs, we note in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58448), we finalized our proposal to expand our existing criteria to create a new CC or MCC subgroup within a base MS–DRG. Specifically, we finalized the expansion of the criteria to include the NonCC subgroup for a three-way severity level split. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44798) and FY 2023 IPPS/LTCH PPS final rule (87 FR 48803), we finalized a delay in applying this technical criterion to existing MS–DRGs in light of the PHE. We note that this delay relates to applying this technical criterion to existing MS–DRGs with a three-way severity level split. As discussed in prior rulemaking, in general, once the decision has been made to propose to make further modifications to the MS–DRGs, such as creating a new base MS–DRG, all five criteria must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. We note that we have applied the criteria to create subgroups, including application of the NonCC subgroup criteria, in our annual analysis of the MS–DRG classification requests effective FY 2021 (85 FR 58446 through 58448). For example, we applied the criteria to create subgroups, including application of the NonCC subgroup criteria, for a proposed new base MS–DRG as discussed in our finalization of new base MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy), new base MS–DRG 019 (Simultaneous Pancreas and Kidney Transplant with Hemodialysis), new base MS–DRG 140 (Major Head and Neck Procedures), new base MS–DRG 143 (Other Ear, Nose, Mouth and Throat O.R. Procedures), new base MS–DRG 521 (Hip Replacement with Principal Diagnosis of Hip Fracture) and new base MS–DRG 650 (Kidney Transplant with Hemodialysis) for FY 2021. Similarly, we applied the criteria to create subgroups including application of the NonCC subgroup criteria for MS–DRG classification requests for FY 2022 that we received by November 1, 2020 (86 FR 44796 through 44798), for MS–DRG classification requests for FY 2023 that we received by November 1, 2021 (87 FR 48801 through 48804), and for MS–DRG classification requests for FY 2024 that we received by October 20, 2022 (88 FR 26673 through 26676), as well as any additional analyses that were conducted in connection with those requests. We refer the reader to section II.C.1.b. of the preamble of this final rule for related discussion regarding our finalization of the expansion of the criteria to include the NonCC subgroup in the FY 2021 final rule and our finalization of the proposal to continue to delay application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split for FY 2024.

Comment: Some commenters expressed concern with CMS' proposal and stated that the proposed MS–DRGs may not reflect the full range of treatment options for severely calcified coronary lesions that may demonstrate similar increased costs and acuity. These commenters stated that the presence of severe calcification can increase treatment difficulty and complexity of service, which lead to higher average costs and generally longer lengths of stay. These commenters stated that CMS should

consider other well-established advanced vessel preparation techniques, such as percutaneous coronary rotational and orbital atherectomy, that also use specialty devices to fully optimize PCI for severely calcified arteries. A commenter stated that they agreed that there is a subset of clinically complex PCI cases with higher average costs however, they do not believe it serves the integrity of the IPPS to create new MS–DRGs for a single technology serving a relatively low volume of patient cases and suggested that CMS refine the proposed new MS–DRGs 323, 324 and 325 to include coronary atherectomy procedures. Another commenter stated that its own analysis demonstrated that resource requirements for orbital atherectomy are virtually the same as those for coronary IVL. This commenter noted CMS proposed to create MS–DRG 325 for cases describing coronary intravascular lithotripsy without intraluminal device and stated that this is inconsistent with the labeled indications for use of these high-resource devices. The commenter stated that coronary IVL and other complex vessel preparation technologies focus on treating severe calcium to facilitate placement and technical success of intraluminal devices and expressed concern with the precedent of establishing a device-specific MS–DRG that is inconsistent with a technology's indications for use.

Other commenters opposed these recommendations and stated they believed that CMS' proposal correctly differentiates coronary IVL from other PCI procedures, given the significant resource variance when IVL is utilized, and the more clinically complex patients being treated. A commenter stated that atherectomy is distinct from coronary IVL in terms of mechanism of action and technique, and further noted that, the clinical utilization is different in that atherectomy is not a therapy that is exclusively utilized in heavily calcified lesions. This commenter stated that in its own analysis of the claims data, the costs of atherectomy cases are half the costs of coronary IVL cases.

These commenters all encouraged CMS to evaluate these and any other PCI-related procedures in future rulemaking to allow for all options to be considered appropriately.

Response: We thank the commenters for their feedback. Although we note that the initial request was to review the MS–DRG assignment of cases describing percutaneous coronary intravascular lithotripsy, and not cases describing other PCI techniques, the commenters are correct in that there are different types of treatment options available in the treatment of calcified coronary lesions. Under the ICD–10–PCS procedure classification system there are two root operations, Extirpation and Fragmentation, specifically defined as:

Extirpation: Taking or cutting out solid matter from a body part; and

Fragmentation: Breaking solid matter in a body part into pieces that are reported to describe the respective procedure that was performed.

In coronary IVL, emitters at the end of the catheter create acoustic pressure waves that are intended to break up the calcification that is restricting the blood flow in the vessels of the heart to help open the blood vessels when an angioplasty balloon is inflated. Because the technique fragments matter, procedures performed utilizing devices such as the Shockwave C2 Intravascular Lithotripsy System are identified and described by the root operation Fragmentation. In contrast, procedures such as rotational and orbital atherectomy are reported with the root operation Extirpation because both techniques cut up the calcified material into small particles that are removed from the blood stream by the normal hemofiltration process.

In response to the commenter's statement that both coronary IVL and coronary atherectomy are procedures intended to treat calcified coronary arteries, we agree, however, as shown, each of these procedures are defined by clinically distinct definitions and objectives, and there are separate and unique ICD–10–PCS procedure codes within the classification for reporting purposes. We do not believe it is appropriate to specifically compare the devices being utilized in the performance of these distinct procedures in consideration of MS–DRG assignment, rather, the emphasis is on the fragmentation and extirpation procedures performed and evaluating the treatment difficulty, resource utilization, and complexity of service.

In response to the commenter's statement regarding the labeled indications for coronary IVL, as discussed in the proposed rule, there may be instances where an intraluminal device is unable to be inserted after the application of the IVL pulses. Accordingly, we identified a total of 386 cases describing coronary intravascular lithotripsy without the insertion of an intraluminal device using the September 2022 update of the FY 2022 MedPAR file and 404 cases describing coronary intravascular lithotripsy without the insertion of an intraluminal device using the more recent claims data from the December 2022 update of the FY 2022 MedPAR file. We continue to we believe creating a MS–DRG for these cases as well would appropriately address the differential in resource consumption.

As discussed in the proposed rule, the data analysis clearly shows that cases reporting percutaneous coronary IVL, with or without involving the insertion of intraluminal device, have higher average costs and generally longer lengths of stay compared to all the cases in their assigned MS–DRG. We appreciate the commenters' feedback and suggestions, however, we believe that continued monitoring of the data and further analysis is needed prior to proposing any modifications to the proposed new MS–DRGs for percutaneous coronary IVL. We will continue to evaluate the claims data to determine if further modifications to the MS–DRG assignment of cases reporting percutaneous coronary intervention procedures are warranted and address any proposed modifications to the existing logic in future rulemaking.

Therefore, after consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal to create new MS–DRG 323 (Coronary Intravascular Lithotripsy with Intraluminal Device with MCC), new MS–DRG 324 (Coronary Intravascular Lithotripsy with Intraluminal Device without MCC) and new MS–DRG 325 (Coronary Intravascular Lithotripsy without Intraluminal Device) in MDC 05, without modification, effective October 1, 2023 for FY 2024. We are also finalizing the list of procedure codes to define the logic for each of the new MS–DRGs as displayed in Table 6P.6a associated with the proposed rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.*

In reviewing this issue, we noted in the FY 2024 proposed rule that we received a separate but related request in FY 2022 rulemaking. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44848 through 44850), we discussed a request to review the MS–DRG assignments of claims involving the insertion of coronary stents in PCIs. The requestor suggested that CMS eliminate the distinction between drug-eluting and bare-metal coronary stents in the MS–DRG classification. According to the requestor, coated stents have a clinical performance comparable to drug-eluting stents, however, they are grouped with bare-metal stents because they do not contain a drug. The requestor asserted that this comingling muddies the clinical coherence of the MS–DRG structure, as one cannot infer distinctions in clinical performance or

benefits among the groups and potentially creates a barrier (based on hospital decision-making) to patient access to modern coated stents. In response, we stated that based on a review of the procedure codes that are currently assigned to MS–DRGs 246, 247, 248, and 249, our clinical advisors agreed that further refinement of these MS–DRGs may be warranted. We noted that in the FY 2003 IPPS/LTCH PPS final rule (67 FR 50003 through 50005), although the FDA had not yet approved the technology for use, we created two new temporary CMS DRGs to reflect cases involving the insertion of a drug-eluting coronary artery stent as signified by the presence of ICD–9–CM procedure code 36.07 (Insertion of drug-eluting coronary artery stent) in recognition of the potentially significant impact this technology may conceivably have on the treatment of coronary artery blockages, the predictions of its rapid, widespread use, and that the higher costs of this technology could create undue financial hardships for hospitals due to the high volume of stent cases. In the FY 2022 final rule, we noted that the distinction between drug-eluting and non-drug-eluting stents is found elsewhere in the ICD–10–PCS procedure code classification and stated evaluating this request required a more extensive analysis to assess potential impacts across the MS–DRGs. We also stated that we believed it would be more appropriate to consider this request further in future rulemaking.

As discussed in the proposed rule and this section of the final rule, our analysis of claims data from the September 2022 update of the FY 2022 MedPAR file indicates that in cases reporting percutaneous coronary IVL involving the insertion of an intraluminal device, average costs are generally similar without regard as to whether a drug-eluting or non-drug-eluting intraluminal device was inserted. Therefore, in consideration of the prior request discussed in FY 2022 rulemaking and to further explore this current finding, we stated we examined claims data from the September 2022 update of the FY 2022 MedPAR file for MS–DRGs 246, 247, 248, and 249 for ''all other cases'' assigned to MS–DRGs 246, 247, 248, and 249 that did not report percutaneous coronary IVL as reflected in the previous table.

In the proposed rule, we again noted that the data analysis shows that in percutaneous cardiovascular procedures involving the insertion of an intraluminal device, the average costs are generally similar without regard as to whether a drug-eluting or non-drug-eluting intraluminal device(s) was inserted. In MS–DRG 246, there were 38,288 cases reporting percutaneous cardiovascular procedures involving the insertion of a drug-eluting intraluminal device with an MCC or procedures involving four or more arteries or intraluminal devices with average costs of $25,022 compared to 542 cases reporting percutaneous cardiovascular procedures involving the insertion of a non-drug-eluting intraluminal device with an MCC or procedures involving four or more arteries or intraluminal devices with average costs of $25,530 in MS–DRG 248. In MS–DRG 247, there were 53,166 cases reporting percutaneous cardiovascular procedures involving the insertion of a drug-eluting intraluminal device without an MCC with average costs of $16,017 compared to 593 cases reporting percutaneous coronary IVL involving the insertion of a non-drug-eluting intraluminal device without an MCC with average costs of $14,840 in MS–DRG 249.

We stated we reviewed these findings and believed that it may no longer be necessary to subdivide the MS–DRGs based on the type of coronary intraluminal device inserted. Drug-eluting intraluminal devices consist of a standard metallic stent, a polymer coating, and an anti-restenotic drug that is mixed within the polymer and released over time. In current practice, drug-eluting intraluminal devices are generally viewed as the default type of intraluminal device considered for patients undergoing PCI, although non-drug-eluting stents such as bare-metal coronary artery stents can also be used in PCI procedures for a range of indications, including stable and unstable angina, acute myocardial infarction (MI), and multiple-vessel disease. We noted the related data analysis clearly showed that in the years since the MS–DRGs for cases involving the insertion of a drug-eluting coronary artery stent were created, cases reporting percutaneous cardiovascular procedures involving the insertion of a drug-eluting intraluminal device now demonstrate average costs and lengths of stays comparable to cases reporting percutaneous cardiovascular procedures involving the insertion of a non-drug-eluting intraluminal device. For these reasons, we proposed the deletion of MS–DRGs 246, 247, 248, and 249, and the creation of new MS–DRGs.

We noted that in the FY 2008 IPPS/LTCH PPS final rule (72 FR 47259 through 47260) we stated we found that percutaneous transluminal coronary angioplasties (PTCAs) with four or more vessels or four or more stents were more comparable in average charges to the higher weighted DRG in the group and made changes to the GROUPER logic. Claims containing ICD–9–CM procedure code 00.66 for PTCA, and code 36.07 (Insertion of drug-eluting coronary artery stent(s)), and code 00.43 (Procedure on four or more vessels) or code 00.48 (Insertion of four or more vascular stents) were assigned to MS–DRG 246. In addition, claims containing ICD–9–CM procedure code 00.66 for PTCA, and code 36.06 (Insertion of non-drug-eluting coronary artery stent(s)), and code 00.43 or code 00.48 were assigned to MS–DRG 248. We also made conforming changes to the MS–DRG titles as follows: MS–DRG 246 was titled ''Percutaneous Cardiovascular Procedures with Drug-Eluting Stent(s) with MCC or 4 or more Vessels/Stents''. MS–DRG 248 was titled ''Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent(s) with MCC or 4 or more Vessels/Stents''. In FY 2018 IPPS/LTCH PPS final rule (82 FR 38024), we finalized our proposal to revise the title of MS–DRG 246 to ''Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Arteries or Stents'' and the title of MS–DRG 248 to ''Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent with MCC or 4+ Arteries or Stents'' to better reflect the ICD–10–PCS terminology of ''arteries'' versus ''vessels'' as used in the procedure code titles within the classification.

Recognizing that the current GROUPER logic for case assignment to MS–DRGs 246 or 248 continues to require at least one secondary diagnosis designated as an MCC or procedures involving four or more arteries or intraluminal devices, we examined claims data from the September 2022 update of the FY 2022 MedPAR file for cases reporting percutaneous cardiovascular procedures involving four or more arteries or intraluminal devices and compared these data to all cases in MS–DRGs 246 and 248.

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
246	All cases	40,647	5.2	$25,630
	Cases reporting percutaneous cardiovascular procedures involving four or more arteries or intraluminal devices	3,430	3.2	$27,397
248	All cases	555	5.9	$25,740
	Cases reporting percutaneous cardiovascular procedures involving four or more arteries or intraluminal devices	21	3.4	$28,251

As discussed in the proposed rule, in MS–DRG 246, we identified a total of 40,647 cases with an average length of stay of 5.2 days and average costs of $25,630. Of those 40,647 cases, there were 3,430 cases reporting percutaneous cardiovascular procedures involving four or more arteries or intraluminal devices, with higher average costs as compared to all cases in MS–DRG 246 ($27,397 compared to $25,630), and a shorter average length of stay (3.2 days compared to 5.2 days). In MS–DRG 248, we identified a total of 555 cases with an average length of stay of 5.9 days and average costs of $25,740. Of those 555 cases, there were 21 cases reporting percutaneous cardiovascular procedures involving four or more arteries or intraluminal devices, with higher average costs as compared to all cases in MS–DRG 248 ($28,251 compared to $25,740), and a shorter average length of stay (3.4 days compared to 5.9 days). We stated this analysis demonstrates that cases reporting percutaneous procedures involving four or more arteries or intraluminal devices continue to be more comparable in average costs and resource consumption to the cases in the higher weighted MS–DRG in the group and indicates that maintaining the logic that recognizes the performance of percutaneous cardiovascular procedures involving four or more arteries or intraluminal devices that exists currently in MS–DRGs 246 and 248 in the proposed new MS–DRGs was warranted.

We noted presently, MS–DRGs 246 and 248 are defined as base MS–DRGs, each of which is split by a two-way severity level subgroup. Our proposal includes the creation of one base MS–DRG split also by a two-way severity level subgroup. To compare and analyze the impact of our suggested modifications, we stated we ran a simulation using the most recent claims data from the December 2022 update of the FY 2022 MedPAR file. The following table illustrates our findings for all 97,338 cases reporting percutaneous cardiovascular procedures involving intraluminal devices.

Proposed new MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed new MS-DRG XXX Percutaneous Cardiovascular Procedures with Intraluminal Device	97,338	3.5	$19,766

We applied the criteria to create subgroups in a base MS–DRG as discussed in section II.C.1.b. of the proposed rule and this FY 2024 IPPS/LTCH PPS final rule. As shown in the table that follows, a three-way split of the proposed new MS–DRGs failed to meet the criterion that there be at least a 20% difference in average costs between the CC and NonCC subgroup and also failed to meet the criterion that there be at least a $2,000 difference in average costs between the CC and NonCC subgroup.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
With MCC	37,604	5.3	$24,871
With CC	33,088	2.7	$17,407
Without CC/MCC	26,646	2	$15,492

We then applied the criteria for a two-way split for the ''with MCC'' and ''without MCC'' subgroups for the proposed new MS–DRGs and found that all five criteria were met. The following table illustrates our findings.

Proposed new MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
With MCC or 4+ Arteries/Intraluminal Devices	37,604	5.3	$24,871
Without MCC	59,734	2.4	$16,553

For the proposed new MS–DRGs, there is (1) at least 500 cases in the MCC subgroup and in the without MCC subgroup; (2) at least 5 percent of the cases are in the MCC subgroup and in the without MCC subgroup; (3) at least a 20 percent difference in average costs between the MCC subgroup and the without MCC subgroup; (4) at least a $2,000 difference in average costs between the MCC subgroup and the without MCC subgroup; and (5) at least a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the proposed MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system.

We noted in that proposed rule that proposed refinements for cases reporting percutaneous cardiovascular procedures with intraluminal devices represented the first step in investigating how we may evaluate the distinctions between drug-eluting and non-drug-eluting intraluminal devices found elsewhere in the ICD–10–PCS procedure code classification. We stated we are making concerted efforts to continue refining the ICD–10 MS–DRGs and we believed the resulting MS–DRG assignments in our current proposal would be more clinically homogeneous, coherent and better reflect current trends and hospital resource use.

In summary, for FY 2024, taking into consideration it appears to no longer be necessary to subdivide the MS–DRGs for percutaneous cardiovascular procedures based on the type of coronary intraluminal device inserted, we proposed to delete MS–DRGs 246, 247, 248, and 249, and create a new base MS–DRG with a two-way severity level split for cases describing percutaneous cardiovascular procedures with intraluminal device in MDC 05. These proposed new MS–DRGs are proposed new MS–DRG 321 (Percutaneous Cardiovascular Procedures with Intraluminal Device with MCC or 4+ Arteries/Intraluminal Devices) and proposed new MS–DRG 322 (Percutaneous Cardiovascular Procedures with Intraluminal Device without MCC). We proposed to add the procedure codes from current MS–DRGs 246, 247, 248, and 249 to the proposed new MS–DRGs 321 and 322. We also proposed to revise the titles for MS–DRGs 250 and 251 from ''Percutaneous Cardiovascular Procedures without Coronary Artery Stent with MCC, and without MCC, respectively'' to ''Percutaneous Cardiovascular Procedures without Intraluminal Device with MCC, and without MCC, respectively'' to better reflect the ICD–10–PCS terminology of ''intraluminal devices'' versus ''stents'' as used in the procedure code titles within the classification.

We refer the reader to section II.C.15. of the preamble of this final rule for the discussion of the surgical hierarchy and the complete list of our proposed modifications to the surgical hierarchy as well as our finalization of those proposals.

Comment: Commenters supported CMS' proposals. These commenters stated that they agreed with CMS that the distinction between drug-eluting and bare metal stents is no longer required given the evolution of these technologies. A commenter stated they appreciated the simplification of MS–DRGs involving percutaneous intraluminal devices by omitting the distinction between drug-eluting versus non-drug-eluting devices with the proposed creation of MS–DRGs 321 and 322. Another commenter stated that they appreciate CMS periodically reviewing the MS–DRGs for percutaneous coronary interventions to ensure they appropriately reflect current clinical practice and appropriately reflect the hospital resources associated with these procedures. A commenter supported the proposal, but suggested that there be consideration to split the new base MS–DRG for cases describing percutaneous cardiovascular procedures with intraluminal device with a three-way severity level split, instead of a two-way severity level split as proposed.

Response: We appreciate the commenters' support. In response to the suggestion to split the new base MS–DRG for cases describing percutaneous cardiovascular procedures with intraluminal device with a three-way severity level split, as discussed in the proposed rule and earlier in this section, we note we applied the criteria to create subgroups in a base MS–DRG as discussed in section II.C.1.b. of the proposed rule and this FY 2024 IPPS/LTCH PPS final rule. We note that a three-way split of the proposed new MS–DRGs failed to meet the criterion that there be at least a 20% difference in average costs between the CC and NonCC subgroup and also failed to meet the criterion that there be at least a $2,000 difference in average costs between the CC and NonCC subgroup.

Comment: Other commenters stated that while they agreed with CMS' rationale that it is no longer necessary to subdivide the MS–DRGs based on the type of coronary intraluminal device inserted and supported the proposal to delete MS–DRGs 246, 247, 248, and 249 and create a new base MS–DRG with a two-way severity level split for cases describing percutaneous cardiovascular procedures with intraluminal device in MDC 05, they did not agree with the proposed relative weights for these new MS–DRGs and requested that CMS review the proposed weights for these MS–DRGs with the weight decline to ensure it adequately captures the resources for the complex treatment of these patients. These commenters stated a decrease in the relative weight for the proposed new MS–DRGs would cause inadequate payment for the medical care and treatment provided to the patient.

Response: We appreciate the commenters' feedback and concern. We note that each year, we calculate the relative weights by dividing the average cost for cases within each MS–DRG by the average cost for cases across all MS–DRGs. It is to be expected that when MS–DRGs are restructured, such as when procedure codes are reassigned or the hierarchy within an MDC is revised, resulting in a different case-mix within the MS–DRGs, the relative weights of the MS–DRGs will change as a result. As discussed in the FY 2024 IPPS/LTCH PPS proposed rule, and earlier in this section, upon application of the criteria to create subgroups, we proposed to create a base MS–DRG split by a two-way severity level subgroup for cases describing coronary intravascular lithotripsy involving the insertion of an intraluminal device in MDC 05 for FY

2024. Therefore, the data appear to reflect that the difference in the relative weights reflected in Table 5.—List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2024, associated with the proposed rule, can be attributed to the fact that these proposals resulted in a different case-mix within the MS–DRGs which is then being reflected in the relative weights. We refer the reader to section II.D. of the preamble of this FY 2024 IPPS/LTCH PPS final rule for a complete discussion of the relative weight calculations.

After consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal, without modification, to delete MS–DRGs 246, 247, 248, and 249 for FY 2024. We are also finalizing our proposal to create new MS–DRG 321 (Percutaneous Cardiovascular Procedures with Intraluminal Device with MCC or 4+ Arteries/Intraluminal Devices) and new MS–DRG 322 (Percutaneous Cardiovascular Procedures with Intraluminal Device without MCC). Accordingly, we are finalizing our proposal to reassign the procedure codes from current MS–DRGs 246, 247, 248, and 249 to the new MS–DRGs 321 and 322. Lastly, we are also finalizing our proposal to revise the titles of MS–DRGs 250 and 251 from ''Percutaneous Cardiovascular Procedures without Coronary Artery Stent with MCC, and without MCC, respectively'' to ''Percutaneous Cardiovascular Procedures without Intraluminal Device with MCC, and without MCC, respectively'' effective October 1, 2023 for FY 2024.

e. Shock

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44831 through 44833), we discussed a request we received to review the MS–DRG assignment of ICD–10–CM diagnosis code I21.A1 (Myocardial infarction type 2). The requestor stated that when a type 2 myocardial infarction is documented, per coding guidelines, it is to be coded as a secondary diagnosis since it is due to an underlying cause. This requestor also noted that when a type 2 myocardial infarction is coded with a principal diagnosis in MDC 05 (Diseases and Disorders of the Circulatory System), the GROUPER logic assigns MS–DRGs 280 through 282 (Acute Myocardial Infarction, Discharged Alive with MCC, with CC, and without CC/MCC, respectively). The requestor questioned if this GROUPER logic was correct or if the logic should be changed so that a type 2 myocardial infarction, coded as a secondary diagnosis, does not result in the assignment of a MS–DRG that describes an acute myocardial infarction. During our review of this issue, we also noted that ICD–10–CM diagnosis code I21.A1 (Myocardial infarction type 2) was one of the listed principal diagnoses in the GROUPER logic for MS–DRGs 222 and 223 (Cardiac Defibrillator Implant with Cardiac Catheterization with Acute Myocardial Infarction (AMI), Heart Failure (HF), or Shock with and without MCC, respectively). However, code I21.A1 was not recognized in these same MS–DRGs when coded as a secondary diagnosis. Acknowledging that coding guidelines instruct to code I21.A1 after the diagnosis code that describes the underlying cause, we indicated our clinical advisors recommended adding special logic in MS–DRGs 222 and 223 to have code I21.A1 also qualify when coded as a secondary diagnosis in combination with a principal diagnosis in MDC 05 since these diagnosis code combinations also describe acute myocardial infarctions. In the FY 2022 final rule, after consideration of the public comments, we finalized our proposal to maintain the structure of MS–DRGs 280 through 285, without modification, for FY 2022. We also finalized our proposal to modify the GROUPER logic to allow cases reporting diagnosis code I21.A1 (Myocardial infarction type 2) as a secondary diagnosis to group to MS–DRGs 222 and 223 when reported with qualifying procedures, effective October 1, 2021. Under this finalization, code I21.A1, as a secondary diagnosis, is used in the definition of the logic for assignment to MS–DRGs 222 and 223, and therefore does not act as an MCC in these MS–DRGs.

In response to this final policy, in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26712 through 26717), we discussed a related request we received to also add ICD–10–CM diagnosis code R57.0 (Cardiogenic shock) to the list of ''secondary diagnoses'' that group to MS–DRGs 222 and 223. Cardiogenic shock occurs when the heart cannot pump enough oxygen-rich blood to the brain and other vital organs resulting in inadequate tissue perfusion. The most common cause of cardiogenic shock is acute myocardial infarction. Other causes include myocarditis, endocarditis, papillary muscle rupture, left ventricular free wall rupture, acute ventricular septal defect, severe congestive heart failure, end-stage cardiomyopathy, severe valvular dysfunction, acute cardiac tamponade, cardiac contusion, massive pulmonary embolus, or the overdose of drugs such as beta blockers or calcium channel blockers.

As discussed in the proposed rule, since the MS–DRG titles contain the word ''shock'', the requestor indicated that it seemed reasonable for the GROUPER logic to recognize cardiogenic shock when coded as a secondary diagnosis because, according to the requestor, the specific underlying cardiac condition responsible for causing the cardiogenic shock must always be sequenced first. The requestor further asserted that ICD–10–CM coding guidelines require codes from Chapter 18 (Symptoms, Signs, and Abnormal Clinical and Laboratory Findings) to be sequenced first, therefore when coding guidelines are followed, this code can never be an appropriate principal diagnosis. The requestor acknowledged that if code R57.0 were to be added to the list of ''secondary diagnoses'' that group to MS–DRGs 222 and 223, and therefore used in the definition of the logic for assignment, the code would no longer act as an MCC in MS–DRGs 222 and 223.

To begin our analysis, we stated we reviewed the GROUPER logic. In the proposed rule, we noted that ICD–10–CM diagnosis code R57.0 (Cardiogenic shock) is currently one of the listed principal diagnoses in the GROUPER logic for MS–DRGs 222 and 223. We stated that requestor was correct that diagnosis code R57.0 is not currently recognized in these same MS–DRGs when coded as a secondary diagnosis. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 40.1, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for MS–DRGs 222 and 223.

We also stated that the requestor was also correct that the diagnosis code R57.0 is found in Chapter 18 (Symptoms, Signs and Abnormal Clinical and Laboratory Findings) of ICD–10–CM and that diagnosis code R57.0 has a current severity designation of MCC when reported as a secondary diagnosis. We disagreed, however, that this code can never be an appropriate principal diagnosis. We noted that according to the ICD–10–CM Official Guidelines for Coding and Reporting, diagnoses described by codes from Chapter 18 of ICD–10–CM, such as R57.0, are acceptable for reporting when a related definitive diagnosis has not been established (confirmed) by the provider. We also pointed out that a

''code first'' note appears at ICD–10–CM diagnosis code I21.A1 (Myocardial infarction type 2). The ''code first'' note is an etiology/manifestation coding convention (additional detail can be found in the ICD–10–CM Official Guidelines for Coding and Reporting), indicating that the condition has both an underlying etiology and manifestation due to the underlying etiology. No such ''code first'' notes appear at ICD–10–CM diagnosis code R57.0 (Cardiogenic shock). If providers have cases involving cardiogenic shock which they need ICD–10 coding assistance, we encourage them to submit their questions to the American Hospital Association's Central Office on ICD–10 at *https://www.codingclinicadvisor.com/.*

As discussed in the proposed rule, we then examined claims data from the September 2022 update of the FY 2022 MedPAR file for all cases in MS–DRGs 222 and 223 (Cardiac Defibrillator Implant with Cardiac Catheterization with AMI, HF or Shock, with and without MCC, respectively) and compared the results to cases that had a principal diagnosis or a secondary diagnosis of cardiogenic shock in these MS–DRGs. We also included MS–DRGs 224 and 225 (Cardiac Defibrillator Implant with Cardiac Catheterization without AMI, HF or Shock with and without MCC, respectively) and MS–DRGs 226 and 227 (Cardiac Defibrillator Implant without Cardiac Catheterization with and without MCC, respectively) in our analysis as the logic for these MS–DRGs is similar, differing only in the reporting of a diagnosis that describes acute myocardial infarction, heart failure or shock, or the performance of cardiac catheterization. The following table shows our findings:

MS-DRGs 222-227: All Cases and Cases with Principal or Secondary Diagnosis of Cardiogenic Shock

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
222	All cases	1,488	11	$64,794
	Cases with principal diagnosis of R57.0	6	13.5	$88,486
	Cases with secondary diagnosis of R57.0	322	15.1	$77,451
223	All cases	270	5.7	$43,500
	Cases with principal diagnosis of R57.0	0	0	$0
	Cases with secondary diagnosis of R57.0	0	0	$0
224	All cases	1,606	9.4	$60,583
	Cases with principal diagnosis of R57.0	0	0	$0
	Cases with secondary diagnosis of R57.0	268	12.9	$77,334
225	All cases	1,167	4.6	$42,442
	Cases with principal diagnosis of R57.0	0	0	$0
	Cases with secondary diagnosis of R57.0	0	0	$0
226	All cases	3,595	8.3	$53,706
	Cases with principal diagnosis of R57.0	4	14.3	$72,349
	Cases with secondary diagnosis of R57.0	325	12.5	$65,266
227	All cases	2,522	3.9	$41,636
	Cases with principal diagnosis of R57.0	0	0	$0
	Cases with secondary diagnosis of R57.0	0	0	$0

In MS–DRG 222, we identified a total of 1,488 cases with an average length of stay of 11 days and average costs of $64,794. Of those 1,488 cases, there were six cases reporting a principal diagnosis of R57.0, with higher average costs as compared to all cases in MS–DRG 222 ($88,486 compared to $64,794), and a longer average length of stay (13.5 days compared to 11 days). There were 322 cases reporting a secondary diagnosis of R57.0, with higher average costs as compared to all cases in MS–DRG 222 ($77,451 compared to $64,794), and a longer average length of stay (15.1 days compared to 11 days). In MS–DRG 224, we identified a total of 1,606 cases with an average length of stay of 9.4 days and average costs of $60,583. Of those 1,606 cases, there were zero cases reporting a principal diagnosis of R57.0. There were 268 cases reporting a secondary diagnosis of R57.0, with higher average costs as compared to all cases in MS–DRG 224 ($77,334 compared to $60,583), and a longer average length of stay (12.9 days compared to 9.4 days). In MS–DRG 226, we identified a total of 3,595 cases with an average length of stay of 8.3 days and average costs of $53,706. Of those 3,595 cases, there were four cases reporting a principal diagnosis of R57.0, with higher average costs as compared to all cases in MS–DRG 226 ($72,349 compared to $53,706), and a longer average length of stay (14.3 days compared to 8.3 days). There were 325 cases reporting a secondary diagnosis of R57.0, with higher average costs as compared to all cases in MS–DRG 226 ($65,266 compared to $53,706), and a longer average length of stay (12.5 days compared to 8.3 days). We found zero cases across MS–DRGs 223, 225, and 227 reporting R57.0 as principal or as a secondary diagnosis. Our analysis

clearly shows that the cases reporting a secondary diagnosis of cardiogenic shock in MS–DRGs 222, 224 and 226 had higher average costs and longer average length of stay compared to all cases in their respective MS–DRGs.

We stated in the proposed rule that we reviewed these data and did not recommend modifying the GROUPER logic to allow cases reporting diagnosis code R57.0 (Cardiogenic shock) as a secondary diagnosis to group to MS–DRGs 222 and 223 when reported with qualifying procedures. As noted by the requestor, and as discussed in FY 2022 IPPS/LTCH PPS final rule, (86 FR 44831 through 44833), a diagnosis code may define the logic for a specific MS–DRG assignment in three different ways. Whenever there is a secondary diagnosis component to the MS–DRG logic, the diagnosis code can either be used in the logic for assignment to the MS–DRG or to act as a CC/MCC.

We stated we believed that patients with cardiogenic shock as a secondary diagnosis tend to be more severely ill and these inpatient admissions are associated with greater resource utilization. Cardiogenic shock represents a life-threatening emergency that requires urgent treatment that focuses on getting blood flowing properly to prevent, and protect against, organ failure, brain injury or death. For clinical consistency, we stated it was more appropriate for ICD–10–CM diagnosis code R57.0 to act as an MCC when cardiogenic shock is documented in the medical record and coded as a secondary diagnosis. Therefore, we did not propose to modify the GROUPER logic to allow cases reporting diagnosis code R57.0 (Cardiogenic shock) as a secondary diagnosis to group to MS–DRGs 222 and 223 when reported with qualifying procedures.

Comment: Commenters expressed support for CMS' proposal to not modify the GROUPER logic to allow cases reporting diagnosis code R57.0 (Cardiogenic shock) as a secondary diagnosis to group to MS–DRGs 222 and 223 when reported with qualifying procedures.

Response: We thank the commenters for their support.

During our review of this issue, we noted in the proposed rule that the data analysis showed that in procedures involving a cardiac defibrillator implant, the average costs and length of stay are generally similar without regard to the presence of diagnosis codes describing AMI, HF or shock. In MS–DRG 222, there were 1,488 cases reporting cardiac defibrillator implant with cardiac catheterization with AMI, HF, or Shock with an MCC with average costs of $64,794 and an average length of stay of 11 days compared to 1,606 cases reporting cardiac defibrillator implant with cardiac catheterization without AMI, HF, or Shock with an MCC with average costs of $60,583 and an average length of stay of 9.4 days in MS–DRG 224. In MS–DRG 223, there were 270 cases reporting cardiac defibrillator implant with cardiac catheterization with AMI, HF or Shock without an MCC with average costs of $43,500 and an average length of stay of 5.7 days compared to 1,167 cases reporting cardiac defibrillator implant with cardiac catheterization without AMI, HF, or Shock without an MCC with average costs of $42,442 and an average length of stay of 4.6 days in MS–DRG 225.

We stated that the analysis of MS–DRGs 222, 223, 224, 225, 226, and 227 further demonstrated that the average length of stay and average costs for all cases are similar for each of the ''without MCC'' subgroups. As stated previously, for all of the cases in MS–DRG 223, we found that the average length of stay was 5.7 days with average costs of $43,500, and for all of the cases in MS–DRG 225, the average length of stay was 4.6 days with average costs of $42,442. Likewise, for all of the cases in MS–DRG 227, we found that the average length of stay was 3.9 days with average costs of $41,636.

We reviewed these findings and stated we believed that it may no longer be necessary to subdivide these MS–DRGs based on the diagnosis codes reported. We noted that in the FY 2004 IPPS/LTCH PPS final rule (68 FR 45356 through 45358) we stated we found that patients who are admitted with acute myocardial infarction, heart failure, or shock and have a cardiac catheterization are generally acute patients who require emergency implantation of the defibrillator. Thus, we stated there were very high costs associated with these patients. Therefore, we finalized the creation of new DRGs for patients receiving a cardiac defibrillator implant with cardiac catheterization and with a principal diagnosis of acute myocardial infarction, heart failure, or shock.

As discussed in the proposed rule, our analysis of claims data from the September 2022 update of the FY 2022 MedPAR file clearly shows that in the 20 years since the DRGs for cases involving a cardiac defibrillator implant with cardiac catheterization split based on the presence or absence of diagnosis codes describing acute myocardial infarction, heart failure, or shock were created, cases reporting a cardiac defibrillator implant with cardiac catheterization continue to demonstrate higher average costs and longer lengths of stays, however these increased costs appear to be more related to the procedures performed than to the diagnoses reported on the claim, and therefore we stated that we believed it was time to restructure these MS–DRGs accordingly.

In the proposed rule, we did note that when reviewing consumption of hospital resources for the cases reporting cardiac defibrillator implant with cardiac catheterization during a hospital stay, the claims data clearly shows that the cases reporting secondary diagnoses designated as MCCs are more resource intensive as compared to other cases reporting cardiac defibrillator implant. As noted previously, in MS–DRG 222, there were 1,488 cases reporting cardiac defibrillator implant with cardiac catheterization with AMI, HF, or Shock with an MCC with average costs of $64,794 and an average length of stay of 11 days. Similarly, in MS–DRG 224, there were 1,606 cases reporting cardiac defibrillator implant with cardiac catheterization without AMI, HF, or Shock with an MCC with average costs of $60,583 and an average length of stay of 9.4 days in MS–DRG 224. In comparison, there were 270 cases reporting cardiac defibrillator implant with cardiac catheterization with AMI, HF, or Shock without an MCC with average costs of $43,500 and an average length of stay of 5.7 days in MS–DRG 223, 1,167 cases reporting cardiac defibrillator implant with cardiac catheterization without AMI, HF, or Shock without an MCC with average costs of $42,442 and an average length of stay of 4.6 days in MS–DRG 225, 3,595 cases reporting cardiac defibrillator implant without cardiac catheterization with an MCC with average costs of $53,706 and an average length of stay of 8.3 days in MS–DRG 226, and 2,522 cases reporting cardiac defibrillator implant without cardiac catheterization without an MCC with average costs of $41,636 and an average length of stay of 3.9 days in MS–DRG 227.

Therefore, we stated we supported the removal of the special logic defined as ''Principal Diagnosis AMI/HF/SHOCK'' from the definition for assignment to any proposed modifications to the MS–DRGs, noting the cases can be appropriately grouped along with cases reporting any MDC 05 diagnosis when reported with qualifying procedures, in any restructured proposed MS–DRGs. For these reasons, we proposed the deletion of MS–DRGs 222, 223, 224, 225, 226, and 227, and the creation of three new MS–DRGs. Our proposal

included the creation of one new base MS–DRG for cases reporting a cardiac defibrillator implant with cardiac catheterization and a secondary diagnosis designated as an MCC and another new base MS–DRG split by a two-way severity level subgroup for cases reporting a cardiac defibrillator implant without cardiac catheterization.

We stated in the proposed rule that to compare and analyze the impact of our suggested modifications, we ran a simulation using the most recent claims data from the December 2022 update of the FY 2022 MedPAR file. The following table illustrates our findings for all 3,467 cases reporting a cardiac defibrillator implant with cardiac catheterization and a secondary diagnosis designated as an MCC. We note that as discussed in prior rulemaking (86 FR 44831 through 44833), a diagnosis code may define the logic for a specific MS–DRG assignment in three different ways. The diagnosis code may be listed as principal or as any one of the secondary diagnoses, as a secondary diagnosis, or only as a secondary diagnosis. For this specific scenario, we proposed that secondary diagnosis codes with a severity designation of MCC be used in the definition of the logic for assignment to the proposed base MS–DRG for cases reporting a cardiac defibrillator implant with cardiac catheterization and a secondary diagnosis designated as an MCC. Therefore, we did not apply the criteria to create further subgroups in a base MS–DRG for cases reporting a cardiac defibrillator implant with cardiac catheterization and a secondary diagnosis designated as an MCC as discussed in section II.C.1.b. of the FY 2024 IPPS/LTCH PPS proposed rule. We stated that we believed the resulting proposed MS–DRG assignment is more clinically homogeneous, coherent and better reflects hospital resource use.

Proposed new MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed new MS-DRG XXX Cardiac Defibrillator Implant with Cardiac Catheterization and MCC	3,467	10	$61,744

To further compare and analyze the impact of our suggested modifications, we stated we then ran a simulation using the most recent claims data from the December 2022 update of the FY 2022 MedPAR file for cases reporting a cardiac defibrillator implant without additionally reporting both a cardiac catheterization and a secondary diagnosis designated as an MCC. The following table illustrates our findings for all 7,935 cases.

Proposed new MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed new MS-DRG XXX Cardiac Defibrillator Implant	7,935	6.2	$47,822

We applied the criteria to create subgroups in a base MS–DRG as discussed in section II.C.1.b. of the FY 2024 IPPS/LTCH PPS proposed rule. As shown in the table that follows, a three-way split of the proposed new MS–DRGs failed the criterion that there be at least 500 cases for each subgroup due to low volume. Specifically, for the ''without CC/MCC'' (NonCC) split, there were only 452 cases in the subgroup. The criterion that there be at least a 20% difference in average costs between the CC and NonCC subgroup also failed to be met.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
With MCC	3,830	8.4	$53,924
With CC	3,653	4.3	$42,466
Without CC/MCC	452	3.2	$39,394

We then applied the criteria for a two-way split for the ''with MCC'' and ''without MCC'' subgroups for the proposed new MS–DRGs and found that all five criteria were met. The following table illustrates our findings.

Proposed new MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
With MCC	3,830	8.4	$53,924
Without MCC	4,105	4.2	$42,128

For the proposed new MS–DRGs, there is (1) at least 500 cases in the MCC subgroup and in the without MCC subgroup; (2) at least 5 percent of the cases are in the MCC subgroup and in the without MCC subgroup; (3) at least a 20 percent difference in average costs between the MCC subgroup and the without MCC subgroup; (4) at least a $2,000 difference in average costs between the MCC subgroup and the without MCC subgroup; and (5) at least a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory power of the base MS–DRG in capturing differences in expected cost between the proposed MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system.

In summary, for FY 2024, taking into consideration that it appears to no longer be necessary to subdivide the MS–DRGs for cases reporting a cardiac defibrillator implant based on the diagnosis code reported, we proposed to delete MS–DRGs 222, 223, 224, 225, 226, and 227, and create a new MS–DRG for cases reporting a cardiac defibrillator implant with cardiac catheterization and a secondary diagnosis designated as an MCC in MDC 05. We also proposed to create two new MS–DRGs with a two-way severity level split for cases reporting a cardiac defibrillator implant without additionally reporting both a cardiac catheterization and a secondary diagnosis designated as an MCC. These proposed new MS–DRGs are proposed new MS–DRG 275 (Cardiac Defibrillator Implant with Cardiac Catheterization and MCC), proposed new MS–DRG 276 (Cardiac Defibrillator Implant with MCC) and proposed new MS–DRG 277 (Cardiac Defibrillator Implant without MCC).

In the proposed rule, we noted that the procedure codes describing cardiac catheterization are designated as non-O.R. procedures, therefore, as part of the logic for MS–DRG 275, we also proposed to designate these codes as non-O.R. procedures affecting the MS–DRG. We referred the reader to Table 6P.7a and Table 6P.7b associated with the proposed rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*) for the list of procedure codes we proposed to define in the logic for each of the proposed new MS–DRGs. We refer the reader to section II.C.15. of the preamble of this final rule for the discussion of the surgical hierarchy and the complete list of our proposed modifications to the surgical hierarchy as well as our finalization of those proposals.

Comment: Most commenters supported the proposal to delete MS–DRGs 222, 223, 224, 225, 226, and 227, and to create three new MS–DRGs in MDC 05. These commenters stated that they agreed with CMS that it is no longer necessary to subdivide the MS–DRGs for cases reporting a cardiac defibrillator implant based on the diagnosis code reported. A few commenters stated that while they found the proposal reasonable based on the data and rationale provided, they urged CMS to monitor for any unintended consequences. However, a commenter opposed the proposal. This commenter stated that the proposed change will have a notable negative impact based on its own analysis of claims data at its organization. The commenter further noted claims at its organization demonstrate significant length of stay and cost variations across the current MS–DRGs which they asserted further supports that revising the MS–DRGs is not appropriate from a resource utilization perspective.

Response: We appreciate the commenters' support and appreciate the additional feedback. With regard to the commenter's concern that the proposal might have a negative impact based on its own analysis of claims data at its organization, the examination of claims data from the September 2022 update of the FY 2022 MedPAR file for MS–DRGs 222, 223, 224, 225, 226, and 227 showed that in procedures involving a cardiac defibrillator implant, the average costs and length of stay are generally similar without regard to the presence of diagnosis codes describing AMI, HF or shock. We note that the commenter did not provide any clinical rationale as to why the distinction based on the presence of diagnosis codes should be maintained in these MS–DRGs. As noted in prior rulemaking, the goals of reviewing the MS–DRG assignments of particular procedures are to better clinically represent the resources involved in caring for these patients and to enhance the overall accuracy of the system. Our analysis of the claims data demonstrated that for cases involving a cardiac defibrillator implant the increased costs appear to be more related to the procedures performed than to the diagnoses reported on the claim, and we continue to believe it is time to restructure these MS–DRGs accordingly, noting that cases reporting any MDC 05 diagnosis when reported with qualifying procedures will group to the proposed new MS–DRGs. CMS will continue to monitor the claims data for these procedures for unintended consequences as a result of the deletion of the six MS–DRGs from the GROUPER logic as we continue our comprehensive analysis in future rulemaking.

Comment: While supporting the proposal, other commenters noted that CMS proposed to create new MS–DRG 275 (Cardiac Defibrillator Implant with Cardiac Catheterization and MCC) for cases reporting a cardiac defibrillator implant with cardiac catheterization and a secondary diagnosis designated as an MCC in MDC 05. These commenters recommended that an additional MS–DRG be created for cardiac defibrillator implant with cardiac catheterization without MCC. A few commenters stated that it was not clear where cases reporting a cardiac defibrillator implant with a cardiac catheterization without MCC would be assigned. A commenter noted that the draft HTML version of the ICD–10 MS–DRG Definitions Manual for Version 41 available on the CMS website does not show ''MCC'' as part of the logic for MS–DRGs 275 and 276. Another commenter noted that CMS proposed to delay application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split for FY 2024 and questioned CMS' application of the methodology to the proposed new MS–DRGs.

Response: We thank the commenters for their feedback. We note to commenters that when reviewing consumption of hospital resources for the cases reporting cardiac defibrillator implant with cardiac catheterization during a hospital stay, as discussed earlier in this section, the claims data clearly showed that the cases reporting secondary diagnoses designated as MCCs are more resource intensive as compared to other cases reporting cardiac defibrillator implant. Accordingly, our proposal included the creation of one base MS–DRG for cases reporting a cardiac defibrillator implant with cardiac catheterization and a secondary diagnosis designated as an MCC and another base MS–DRG split by a two-way severity level subgroup for cases reporting a cardiac defibrillator implant without cardiac catheterization.

As discussed in the proposed rule, we examined claims data from the September 2022 update of the FY 2022 MedPAR file for all cases in MS–DRGs 222, 223, 224, 225, 226, and 227. In MS–DRGs 222 and 224, there were 3,094 cases reporting cardiac defibrillator implant with cardiac catheterization, with or without a diagnosis of AMI, HF, or Shock, and a secondary diagnosis designated as an MCC with average costs of $62,608 and an average length of stay of 10.2 days. In comparison, there were 3,959 cases reporting cardiac

defibrillator implant, with or without cardiac catheterization, with or without a diagnosis of AMI, HF, or Shock, without an MCC with average costs of $42,001 and an average length of stay of 4.2 days in MS–DRG 223, 225 and 227. We did not propose to subdivide the proposed new base MS–DRG 275 for cases reporting a cardiac defibrillator implant with cardiac catheterization and a secondary diagnosis designated as an MCC into severity levels as the cases reporting a cardiac defibrillator implant with cardiac catheterization without a secondary diagnosis designated as an MCC (that are currently assigned to MS–DRGs 223 and 225) have average costs and an average lengths of stay comparable to other cases reporting cardiac defibrillator implant, without cardiac catheterization, with or without a diagnosis of AMI, HF, or Shock, also without a secondary diagnosis designated as an MCC. Instead, for this specific scenario, we proposed that secondary diagnosis codes with a severity designation of MCC be used in the definition of the logic for assignment to the proposed base MS–DRG for cases reporting a cardiac defibrillator implant with cardiac catheterization and a secondary diagnosis designated as an MCC. We continue to believe the resulting proposed MS–DRG assignment is more clinically homogeneous, coherent and better reflects hospital resource use.

In response to commenters who stated that it was not clear where cases reporting a cardiac defibrillator implant with a cardiac catheterization without a secondary diagnosis designated as an MCC would be assigned, we note that these cases would be assigned to proposed new MS–DRG 277 (Cardiac Defibrillator Implant without MCC), as reflected in the test version of the ICD–10 MS–DRG GROUPER Software, Version 41.

In response to the comment regarding the draft version of the ICD–10 MS–DRG Definitions Manual, Version 41, available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*, we agree there was an inadvertent error in the logic table for MS–DRGs 275, 276 and 277. We are correcting the display as reflected in the following logic table:

Cardiac Catheterization	MCC	MS-DRG
Yes	Yes	275
No	Yes	276
No	No	277

This correction will also be reflected in the final ICD–10 MS–DRG Definitions Manual, Version 41.

In response to the concern regarding the application of the NonCC subgroup criteria to the proposed new MS–DRGs, we note that in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58448), we finalized our proposal to expand our existing criteria to create a new complication or comorbidity (CC) or major complication or comorbidity (MCC) subgroup within a base MS–DRG. Specifically, we finalized the expansion of the criteria to include the NonCC subgroup for a three-way severity level split. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44798) and FY 2023 IPPS/LTCH PPS final rule (87 FR 48803), we finalized a delay in applying this technical criterion to existing MS–DRGs in light of the PHE. We note that this delay relates to applying this technical criterion to existing MS–DRGs with a three-way severity level split. As discussed in prior rulemaking, in general, once the decision has been made to propose to make further modifications to the MS–DRGs, such as creating a new base MS–DRG, all five criteria must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. We note that we have applied the criteria to create subgroups, including application of the NonCC subgroup criteria, in our annual analysis of the MS–DRG classification requests effective FY 2021 (85 FR 58446 through 58448). For example, we applied the criteria to create subgroups, including application of the NonCC subgroup criteria, for a proposed new base MS–DRG as discussed in our finalization of new base MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell Immunotherapy), new base MS–DRG 019 (Simultaneous Pancreas and Kidney Transplant with Hemodialysis), new base MS–DRG 140 (Major Head and Neck Procedures), new base MS–DRG 143 (Other Ear, Nose, Mouth and Throat O.R. Procedures), new base MS–DRG 521 (Hip Replacement with Principal Diagnosis of Hip Fracture), and new base MS–DRG 650 (Kidney Transplant with Hemodialysis) for FY 2021. Similarly, we applied the criteria to create subgroups including application of the NonCC subgroup criteria for MS–DRG classification requests for FY 2022 that we received by November 1, 2020 (86 FR 44796 through 44798), for MS–DRG classification requests for FY 2023 (87 FR 48801 through 48804) that we received by November 1, 2021, and for MS–DRG classification requests for FY 2024 that we received by October 20, 2022 (88 FR 26673 through 26676), as well as any additional analyses that were conducted in connection with those requests. We refer the reader to section II.C.1.b. of the preamble of this final rule for related discussion regarding our finalization of the expansion of the criteria to include the NonCC subgroup in the FY 2021 final rule and our finalization of the proposal to continue to delay application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split for FY 2024.

Comment: A commenter stated that while they agreed that it appears to no longer be necessary to subdivide the MS–DRGs for cases reporting a cardiac defibrillator implant based on the diagnosis code reported, they did not think it was necessary to delete MS–DRGs 226 and 227 (Cardiac Defibrillator Implant without Cardiac Catheterization with and without MCC, respectively) and create new MS–DRGs 276 and 277 (Cardiac Defibrillator Implant with and without MCC, respectively). This commenter stated that the proposed new MS–DRG 276 has the same GROUPER logic as the existing MS–DRG 226 and therefore will capture the same cases. This commenter further stated they believed that the current title of MS–DRG 226 better identifies the cases assigned. This commenter also suggested keeping existing MS–DRG 227 and revising the title to ''Cardiac Defibrillator Implant with or without Cardiac Catheterization without MCC'' instead of creating new MS–DRG 277.

Response: We appreciate the commenter's feedback. The commenter is correct that proposed new MS–DRG 276 has the same GROUPER logic as current MS–DRG 226. In response to the

commenter's concern regarding why new MS–DRG numbers would be considered, as discussed in prior rulemaking (87 FR 48804), we note that new MS–DRG numbers are preferred because we anticipate that individuals, payers, and organizations conducting analysis would need to be aware if proposed changes to base DRG concepts are made to allow them time to adjust their programs, analyses, or queries that may have hard coded the DRG numbers. To minimize confusion for those who rely on MS–DRG concepts year to year and to avoid unintended consequences from maintaining the existing MS–DRG number, we believe it is appropriate to finalize the revision to both the MS–DRG number and corresponding description for cases reporting a cardiac defibrillator implant without cardiac catheterization with a secondary diagnosis designated as an MCC.

Therefore, after consideration of the public comments received, and for the reasons previously stated, we are finalizing our proposal to delete MS–DRGs 222, 223, 224, 225, 226, and 227. We are also finalizing our proposal to create new MS–DRG 275 (Cardiac Defibrillator Implant with Cardiac Catheterization and MCC), new MS–DRG 276 (Cardiac Defibrillator Implant with MCC), and new MS–DRG 277 (Cardiac Defibrillator Implant without MCC) in MDC 05, without modification, effective October 1, 2023, for FY 2024. Accordingly, we are also finalizing our proposal to designate the procedure codes describing cardiac catheterization as non-O.R. procedures affecting the MS–DRG.

Comment: Another commenter stated that a code proposal requesting new procedure codes to describe the implantation, removal and revision of extravascular implantable defibrillator (EV ICD) leads was presented and discussed at the March 7–8, 2023 ICD–10 Coordination and Maintenance Committee meeting. The commenter further stated that CMS has proposed to create new MS–DRGs 275, 276, and 277 for cases reporting cardiac defibrillator implant procedures, which includes procedures describing the insertion of implantable cardioverter-defibrillators (ICDs) for FY 2024, while cases reporting cardiac defibrillator lead removal and revision procedures are assigned to MS–DRG 265 (AICD Lead Procedures). This commenter suggested that any new procedure codes finalized after the March 7–8, 2023 ICD–10 Coordination and Maintenance Committee meeting that describe EV ICD procedures should be assigned to MS–DRG 265 and MS–DRGs 275–277 as well and stated that alignment of these new ICD–10–PCS codes with existing defibrillator procedure codes in terms of MS–DRG assignment will ensure clinical coherence and facilitate patient access and provider choice among ICD technologies.

Response: We thank the commenter for their feedback. We note that the proposal requesting new procedure codes to identify procedures involving extravascular implantable defibrillator leads that was discussed at the March 7–8, 2023 ICD–10 Coordination and Maintenance Committee meeting was approved and 11 new procedure codes to identify procedures involving EV ICD leads were finalized as reflected in the FY 2024 ICD–10–PCS Code Update files that were made publicly available on the CMS website at *https://www.cms.gov/Medicare/Coding/ICD10* on June 6, 2023. We also note that the new procedure codes are also reflected in Table 6B.—New Procedure Codes, in association with this final rule and available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*, including the MS–DRG assignments for these new codes for FY 2024. We refer the reader to section II.C.13. of the preamble of this final rule for further information regarding the table.

As we have noted in prior rulemaking (86 FR 44805), we used our established process to determine the most appropriate MS–DRG assignment for the new procedure codes approved after March 7–8, 2023 ICD–10 Coordination and Maintenance Committee meeting to identify procedures involving EV ICD leads. Specifically, we reviewed the predecessor codes and MS–DRG assignments most closely associated with the new procedure codes, and in the absence of claims data, we considered other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. The MS–DRG assignments for the predecessor codes that we utilized to inform this analysis and the new procedure codes to identify procedures involving extravascular implantable defibrillator leads under MDC 05 are identified as follows.

BILLING CODE 4120–01–P

ICD–10–PCS Code	Description	O.R.	Predecessor ICD–10–PCS Code	Description	MS-DRG
0WHC0GZ	Insertion of Defibrillator Lead into Mediastinum, Open Approach	Y	02HN0KZ	Insertion of defibrillator lead into pericardium, open approach	265 (AICD Lead Procedures)
0WHC3GZ	Insertion of Defibrillator Lead into Mediastinum, Percutaneous Approach	Y	02HN3KZ	Insertion of defibrillator lead into pericardium, percutaneous approach	265 (AICD Lead Procedures)
0WHC4GZ	Insertion of Defibrillator Lead into Mediastinum, Percutaneous Endoscopic Approach	Y	02HN4KZ	Insertion of defibrillator lead into pericardium, percutaneous endoscopic approach	265 (AICD Lead Procedures)
0WPC0GZ	Removal of Defibrillator Lead from Mediastinum, Open Approach	Y	0JPT0FZ	Removal of subcutaneous defibrillator lead from trunk subcutaneous tissue and fascia, open approach	265 (AICD Lead Procedures)
0WPC3GZ	Removal of Defibrillator Lead from Mediastinum, Percutaneous Approach	Y	0JPT3FZ	Removal of subcutaneous defibrillator lead from trunk subcutaneous tissue and fascia, percutaneous approach	265 (AICD Lead Procedures)
0WPC4GZ	Removal of Defibrillator Lead from Mediastinum, Percutaneous Endoscopic Approach	Y	0JPT0FZ	Removal of subcutaneous defibrillator lead from trunk subcutaneous tissue and fascia, open approach	265 (AICD Lead Procedures)
0WPCXGZ	Removal of Defibrillator Lead from Mediastinum, External Approach	N	0WPCXYZ	Removal of other device from mediastinum, external approach	
0WWC0GZ	Revision of Defibrillator Lead in Mediastinum, Open Approach	Y	0JWT0FZ	Revision of subcutaneous defibrillator lead in trunk subcutaneous tissue and fascia, open approach	265 (AICD Lead Procedures)
0WWC3GZ	Revision of Defibrillator Lead in Mediastinum, Percutaneous Approach	Y	0JWT3FZ	Revision of subcutaneous defibrillator lead in trunk subcutaneous tissue and fascia, percutaneous approach	265 (AICD Lead Procedures)
0WWC4GZ	Revision of Defibrillator Lead in Mediastinum, Percutaneous Endoscopic Approach	Y	0JWT0FZ	Revision of subcutaneous defibrillator lead in trunk subcutaneous tissue and fascia, open approach	265 (AICD Lead Procedures)
0WWCXGZ	Revision of Defibrillator Lead in Mediastinum, External Approach	N	0WWCXYZ	Revision of other device in mediastinum, external approach	

While the new procedure codes are being assigned to the same MS–DRG as the predecessor codes in this instance, as we have noted in prior rulemaking, and earlier in this section, this process does not automatically result in the new procedure code being assigned to the same MS–DRG or to have the same designation (O.R. versus Non-O.R.) as the predecessor code.

In addition to the MDC and MS–DRG assignments as reflected in Table 6B.—

New Procedure Codes, in association with this final rule, we note that the procedure code combinations describing the insertion of an EV ICD lead with the insertion of a defibrillator generator, are assigned to new MS–DRGs 275, 276, and 277 for FY 2024. This assignment is reflected in the final V41 GROUPER logic. The public may provide feedback on the MS–DRG assignments for FY 2024, which will then be taken into consideration for the following fiscal year.

6. MDC 06 (Diseases and Disorders of the Digestive System): Appendicitis

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28163 through 87 FR 28165) and final rule (87 FR 48849 through 87 FR 48850), we discussed a request related to the MS–DRG assignment of diagnosis codes describing acute appendicitis with generalized peritonitis, with and without perforation or abscess when reported with an appendectomy procedure. In that discussion, we stated that any future proposed changes to the MS–DRGs for appendectomy procedures would be dependent on the diagnosis code revisions that are finalized by the CDC/National Center for Health Statistics (NCHS) since the CDC/NCHS staff presented a proposal for further revisions to the diagnosis codes describing acute appendicitis with generalized peritonitis at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting. Specifically, the CDC/NCHS staff proposed to expand diagnosis codes K35.20 (Acute appendicitis with generalized peritonitis, without abscess) and K35.21 (Acute appendicitis with generalized peritonitis, with abscess), making them sub-categories and creating new diagnosis codes to identify and describe acute appendicitis with generalized peritonitis, with perforation and without perforation, and unspecified as to perforation. We noted that the deadline for submitting public comments on the diagnosis code proposals discussed at the March 8–9, 2022 ICD–10 Coordination and Maintenance Committee meeting was May 9, 2022, and according to the CDC/NCHS staff, the diagnosis code proposals were being considered for an October 1, 2023, implementation (FY 2024). We refer the reader to the CDC website at *https://www.cdc.gov/nchs/icd/icd10cm_maintenance.htm* for additional detailed information regarding the proposal, including a recording of the discussion and the related meeting materials.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26717), we stated that, as shown in Appendix B—Diagnosis Code/MDC/MS–DRG Index of the ICD–10 MS–DRG Definitions Manual V40.1 (available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software),* diagnosis codes K35.20 and K35.21 are currently assigned to medical MS–DRGs 371, 372, and 373 (Major Gastrointestinal Disorders and Peritoneal Infections with MCC, with CC, and without CC/MCC, respectively) in MDC 06. Diagnosis code K35.21 is also assigned to surgical MS–DRGs 338, 339, and 340 (Appendectomy with Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) in MDC 06 because diagnosis code K35.21 is defined as a complicated diagnosis in the GROUPER logic. Therefore, when a procedure code describing an appendectomy is reported with principal diagnosis code K35.21, the logic for case assignment to MS–DRGs 338, 339, or 340 is satisfied.

As discussed in section II.C.13. of the preamble of the proposed rule, Table 6C—Invalid Diagnosis Codes (available on the CMS website at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps*) lists the diagnosis codes that are no longer effective starting October 1, 2023. Included in this table are diagnosis codes K35.20 and K35.21. In addition, we noted that as shown in the following table and in Table 6A—New Diagnosis Codes associated with the proposed rule (and available on the CMS website at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps*), six new diagnosis codes describing acute appendicitis with generalized peritonitis, with and without perforation or abscess were finalized and are effective with discharges on and after October 1, 2023. We stated in the proposed rule that consistent with our established process for assigning new diagnosis and procedure codes, we reviewed the predecessor codes (K35.20 and K35.21) to determine the MS–DRG assignment most closely associated with the new diagnosis codes. In addition, we noted that the proposed severity level designations for the new diagnosis codes are set forth in Table 6A. As shown, the new codes are proposed for assignment to medical MS–DRGs 371, 372, and 373 (Major Gastrointestinal Disorders and Peritoneal Infections with MCC, with CC, and without CC/MCC, respectively), in accordance with the assignment of predecessor codes K35.20 and K35.21.

ICD-10-CM Code	Description	Proposed MS-DRGs
K35.200	Acute appendicitis with generalized peritonitis, without perforation or abscess	371, 372, 373
K35.201	Acute appendicitis with generalized peritonitis, with perforation, without abscess	371, 372, 373
K35.209	Acute appendicitis with generalized peritonitis, without abscess, unspecified as to perforation	371, 372, 373
K35.210	Acute appendicitis with generalized peritonitis, without perforation, with abscess	371, 372, 373
K35.211	Acute appendicitis with generalized peritonitis, with perforation and abscess	371, 372, 373
K35.219	Acute appendicitis with generalized peritonitis, with abscess, unspecified as to perforation	371, 372, 373

We stated in the proposed rule that because the acute appendicitis diagnosis code revisions have been finalized by the CDC/NCHS, we believed it is now appropriate to address the MS–DRG request for diagnosis code K35.20 describing acute appendicitis with generalized peritonitis when an appendectomy procedure is performed. We referred the reader to the ICD–10 MS-DRG Definitions Manual Version 40.1, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for MS–DRGs 338, 339, and 340 (Appendectomy with Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 341, 342, and 343 (Appendectomy without Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) that includes the procedure codes defined in the logic for an appendectomy.

As stated in the proposed rule, we first analyzed claims data from the September 2022 update of the FY 2022 MedPAR file for MS–DRGs 338, 339, and 340 and cases reporting any one of

the following diagnosis codes currently defined in the logic as a complicated principal diagnosis when reported as a principal diagnosis.

ICD-10-CM Code	Description
C18.1	Malignant neoplasm of appendix
C7A.020	Malignant carcinoid tumor of the appendix
K35.21	Acute appendicitis with generalized peritonitis, with abscess
K35.32	Acute appendicitis with perforation and localized peritonitis, without abscess
K35.33	Acute appendicitis with perforation and localized peritonitis, with abscess

Our findings are shown in the following table. We note that if a diagnosis is not listed it is because there were no cases found.

MS-DRG	ICD-10-CM Code	Number of Cases	Average Length of Stay	Average Costs
338	All Cases	579	7	$20,311
	C18.1	30	6.7	$20,285
	C7A.020	1	3	$20,984
	K35.21	20	8.5	$23,290
	K35.32	294	6.4	$19,743
	K35.33	234	7.7	$20,772
339	All Cases	2,018	4.7	$14,068
	C18.1	35	4	$13,855
	K35.21	47	6.4	$14,857
	K35.32	1,105	4.4	$13,370
	K35.33	831	5.1	$14,960
340	All Cases	1,437	2.7	$9,988
	C18.1	8	1.4	$11,529
	K35.21	26	4.1	$10,187
	K35.32	815	2.5	$9,670
	K35.33	588	2.9	$10,399

The data shows that overall, each of the ''complicated'' diagnoses appears to have a comparable average length of stay and similar average costs when compared to the average length of stay and average costs of all the cases in the respective MS–DRG, as well as, to each other.

Next, we analyzed claims data from the September 2022 update of the FY 2022 MedPAR file for MS–DRGs 341, 342, and 343 and cases reporting any one of the following diagnosis codes describing acute appendicitis.

ICD-10-CM Code	Description
K35.20	Acute appendicitis with generalized peritonitis, without abscess
K35.30	Acute appendicitis with localized peritonitis, without perforation or gangrene
K35.31	Acute appendicitis with localized peritonitis and gangrene, without perforation
K35.80	Unspecified acute appendicitis
K35.890	Other acute appendicitis without perforation or gangrene
K35.891	Other acute appendicitis without perforation, with gangrene

Our findings are shown in the following table.

MS-DRG	ICD-10-CM code	Number of cases	Average Length of Stay	Average Costs
341	All Cases	533	5.8	$19,080
	K35.20	30	6.6	$17,634
	K35.30	74	4.5	$16,483
	K35.31	21	4.7	$13,768
	K35.80	225	4.4	$16,427
	K35.890	9	5	$14,450
	K35.891	26	5.8	$20,554
342	All Cases	1,581	3.2	$12,309
	K35.20	82	4.5	$13,171
	K35.30	187	2.7	$10,540
	K35.31	64	2.7	$10,588
	K35.80	833	2.7	$11,678
	K35.890	33	2.6	$10,817
	K35.891	118	3.2	$11,896
343	All Cases	1,482	1.9	$9,596
	K35.20	61	2.4	$9,023
	K35.30	212	1.8	$8,433
	K35.31	59	2.1	$8,461
	K35.80	883	1.8	$9,651
	K35.890	39	1.5	$9,995
	K35.891	91	2.1	$9,587

Similar to the findings for the ''complicated'' diagnoses, the ''uncomplicated'' diagnoses also have a comparable average length of stay and similar average costs when compared to the average length of stay and average costs of all the cases in the respective MS–DRG.

We stated in the proposed rule that based on our analysis for both the ''complicated'' and ''uncomplicated'' diagnoses combined with our review of all the cases in the MS–DRGs, we believed the findings support a prior comment, as summarized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48849), that clinically, both localized and generalized peritonitis in association with an appendectomy require the same level of patient care, including extensive intraoperative irrigation at the surgical site, direct inspection or imaging of the abdomen to identify possible abscess, use of intravenous antibiotics, and prolonged monitoring. In addition, localized peritonitis progresses to generalized peritonitis. In our direct comparison of the ''complicated'' versus ''uncomplicated'' MS–DRGs, we believe the distinction is no longer meaningful with regard to resource consumption. As shown in the following table, we

found the ''with MCC'' MS–DRGs, the ''with CC'' MS–DRGs, and the ''without CC/MCC'' MS–DRGs all have a comparable average length of stay and similar average costs. For example, MS–DRG 338 has an average length of stay of 7 days with average costs of $20,311 and MS–DRG 341 has an average length of stay of 5.8 days and average costs of $19,080. The volume of cases for this MS–DRG pair is also similar with 579 cases in MS–DRG 338 and 533 cases in MS–DRG 341.

MS-DRG	Description	Number of cases	Average Length of Stay	Average costs
338	Appendectomy with Complicated Principal Diagnosis with MCC	579	7	$20,311
339	Appendectomy with Complicated Principal Diagnosis with CC	2,018	4.7	$14,068
340	Appendectomy with Complicated Principal Diagnosis without CC/ MCC	1,437	2.7	$9,988
341	Appendectomy without Complicated Principal Diagnosis with MCC	533	5.8	$19,080
342	Appendectomy without Complicated Principal Diagnosis with CC	1,581	3.2	$12,309
343	Appendectomy without Complicated Principal Diagnosis without CC/ MCC	1,482	1.9	$9,596

As a result of our analysis and review of this issue, we stated in the proposed rule that we believed the findings support eliminating the logic for ''complicated'' and ''uncomplicated'' diagnoses and restructuring the six MS–DRGs. We also noted that in our review of the logic for the appendectomy procedures, we identified procedures listed in the current logic that we did not agree reflect an actual appendectomy as suggested in the title of the current MS–DRGs, rather the logic describes various procedures performed on the appendix.

To compare and analyze the impact of our suggested modifications, we ran a simulation using the most recent claims data from the December 2022 update of the FY 2022 MedPAR file. The following table illustrates our findings for all 8,060 cases reporting procedure codes describing a procedure performed on the appendix.

Proposed new MS-DRG	Number of Cases	Average Length of Stay	Average Costs
Proposed new MS-DRG XXX	8,060	3.7	$12,838

Consistent with our established process as discussed in section II.C.1.b. of the preamble of the proposed rule, once the decision has been made to propose to make further modifications to the MS–DRGs, all five criteria to create subgroups must be met for the base MS–DRG to be split (or subdivided) by a CC subgroup. Therefore, we applied the criteria to create subgroups in a base MS–DRG. We noted that, as shown in the table that follows, a three-way split of this proposed new base MS–DRG was met. The following table illustrates our findings.

Proposed new MS-DRGs	Number of Cases	Average Length of Stay	Average Costs
With MCC	1,186	6.4	$19,584
With CC	3,813	4.0	$13,223
Without CC/MCC	3,061	2.3	$9,745

For the proposed new MS–DRGs, there is (1) at least 500 cases in the MCC subgroup, the CC subgroup, and the without CC/MCC subgroup; (2) at least 5 percent of the cases are in the MCC subgroup, the CC subgroup, and the without CC/MCC subgroup; (3) at least a 20 percent difference in average costs between the MCC subgroup and the CC subgroup and between the CC group and NonCC subgroup; (4) at least a $2,000 difference in average costs between the MCC subgroup and the CC subgroup and between the CC subgroup and NonCC subgroup; and (5) at least a 3-percent reduction in cost variance, indicating that the proposed severity level splits increase the explanatory

power of the base MS–DRG in capturing differences in expected cost between the proposed MS–DRG severity level splits by at least 3 percent and thus improve the overall accuracy of the IPPS payment system.

Therefore, we proposed to delete MS–DRGs 338, 339, 340, 341, 342, and 343 and proposed to create new MS–DRG 397 Appendix Procedures with MCC, MS–DRG 398 Appendix Procedures with CC, and MS–DRG 399 Appendix Procedures without CC/MCC for FY 2024. These proposed new MS–DRGs would no longer require a diagnosis in the definition of the logic for case assignment. We also proposed to include the current list of appendectomy procedures in the logic for case assignment of appendix procedures for the proposed new MS–DRGs.

Comment: Several commenters expressed support for the proposed changes to the MS–DRGs for appendectomy with and without a complicated principal diagnosis. A commenter who agreed with CMS that the average length of stay and average costs were comparable among the appendectomy MS–DRGs with and without a complicated principal diagnosis stated that the data for diagnosis code K35.21 (Acute appendicitis with generalized peritonitis, with abscess) specifically reflected a longer length of stay and higher average costs among all the MS–DRGs for appendectomy with complicated principal diagnosis (MS–DRGs 338, 339, and 340). The commenter requested that CMS continue to monitor this diagnosis code.

Response: We appreciate the commenters' support and feedback. CMS will continue to monitor and analyze the claims data for diagnosis code K35.21.

Comment: A commenter expressed concerns about the proposed new MS–DRGs 397, 398, and 399 no longer reflecting the differences in complexity and costs associated with treating appendicitis, including concerns about the potential decrease in case weight. The commenter stated tertiary care centers may have up to 30% of patients with complicated appendicitis and that the treatment of appendicitis with a complicated principal diagnosis utilizes substantially more resources. This commenter also stated specifically, patients with more complicated disease frequently have perforated disease which contaminates the peritoneal cavity and wounds. According to the commenter, as a result, these patients face significantly higher risk of surgical site infections and require longer hospitalizations in order to a receive longer duration IV antibiotics. Finally, the commenter stated that operations on complex patients take much longer and suggested there is little parity with regard to these populations between major referral centers and smaller centers of care.

Another commenter stated their belief that CMS failed to recognize clinical best practice for treatment of patients with complicated disease including perforation. The commenter stated that the proposed MS–DRG changes demonstrated a lack of understanding about the complexities of appendectomy procedures and urged CMS to maintain the existing MS–DRGs and reassign code K35.20 to MS–DRGs 338, 339, and 340, due to the risk of postoperative abscess formation and extended length of hospital stay, thereby warranting classification as a complicated diagnosis.

Another commenter who disagreed with CMS' proposal agreed that clinically, both localized and generalized peritonitis in association with an appendectomy requires increased levels of care, inclusive of extensive intraoperative irrigation at the surgical site, direct inspection or imaging of the abdomen, use of antibiotics and prolonged monitoring, however, the commenter stated both localized and general peritonitis are complicated appendicitis diagnoses and are clinically different than uncomplicated appendicitis, therefore, complicated appendicitis diagnoses should group to a complicated appendicitis MS–DRG. The commenter recommended retaining MS–DRGs 338, 339, and 340. Additionally, the commenter suggested CMS add four diagnoses currently considered uncomplicated principal diagnoses: K35.20 (Acute appendicitis with generalized peritonitis, without abscess); K35.30 (Acute appendicitis with localized peritonitis, without perforation or gangrene); K35.31 (Acute appendicitis with localized peritonitis and gangrene, without perforation); and K35.891 (Other acute appendicitis without perforation, with gangrene) to MS–DRGs 338, 339, and 340 to reflect the complicated appendectomy. The commenter further suggested that MS–DRGs 341, 342, and 343 (Appendectomy without Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) only reflect the principal diagnoses of K35.80 (Unspecified acute appendicitis), K35.890 (Other acute appendicitis without perforation or gangrene), and K36 (Other appendicitis) as they would clinically be considered an uncomplicated appendectomy.

Response: We thank the commenters for their feedback. In response to the commenter who expressed concerns about the potential decrease in case weight for the proposed new MS–DRGs, we note that the relative weights (RW) and geometric mean length of stay (GMLOS) for existing MS–DRGs 338, 339, 340, 341, 342, and 343 have been trending downward over the past few years as shown in the following table.

	FY 2020		FY 2021		FY 2022		FY 2023	
MS-DRG	RW	GMLOS	RW	GMLOS	RW	GMLOS	RW	GMLOS
338 Appendectomy with Complicated Principal Diagnosis with MCC	2.9101	6.6	2.7988	6.4	2.7973	6.4	2.6565	5.9
339 Appendectomy with Complicated Principal Diagnosis with CC	1.7161	4.2	1.6950	4.0	1.6974	4.0	1.6284	3.7
340 Appendectomy with Complicated Principal Diagnosis without CC/MCC	1.2375	2.3	1.2284	2.4	1.2283	2.4	1.1999	2.3
341 Appendectomy without Complicated Principal Diagnosis with MCC	2.5581	5.3	2.3162	4.3	2.3224	4.3	2.2590	4.4
342 Appendectomy without Complicated Principal Diagnosis with CC	1.6103	3.4	1.4331	2.7	1.4329	2.7	1.4532	2.5
343 Appendectomy without Complicated Principal Diagnosis without CC/MCC	1.1516	2.0	1.1094	1.7	1.1086	1.7	1.0927	1.6

In association with the proposed rule, we made available the proposed FY 2024 relative weights and GMLOS for proposed new MS–DRGs 397, 398, and 399 as reflected in Table 5—List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2024 Proposed Rule available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*.

Proposed new MS-DRGs	Proposed Relative Weight	Proposed GMLOS
397 - Appendix Procedures with MCC	2.2479	4.7
398 - Appendix Procedures with CC	1.5111	3.1
399 - Appendix Procedures without CC/MCC	1.1126	1.9

We believe the proposed relative weight and GMLOS for the proposed new MS–DRGs appear to be appropriately driven by the underlying data.

While we recognize the commenter's statement that tertiary care centers may provide treatment for up to 30% of patients with complicated appendicitis, we note that we do not propose MS–DRG modifications based on provider type. We also do not agree with the commenter's statement that complicated appendicitis utilizes substantially more resources since, as discussed in the proposed rule, our findings reflect that cases in the complicated appendectomy MS–DRGs are comparable to cases in the uncomplicated MS–DRGs with regard to volume, average length of stay, and average costs.

In response to the commenter who indicated that CMS failed to recognize clinical best practice for treatment of patients with complicated disease including perforation, we note that our proposed MS–DRG classification changes are not a reflection of, nor intended to define, how providers render care for patients diagnosed with acute appendicitis, rather, our proposals are based on a combination of data analysis and clinical judgement. With respect to the commenter's request that CMS reassign diagnosis code K35.20 (Acute appendicitis with generalized peritonitis, without abscess), we note that, as discussed in the preamble of the proposed rule and this final rule, diagnosis code K35.20 has been expanded and is no longer valid effective October 1, 2023, as reflected in Table 6C.—Invalid Diagnosis Codes.

In response to the commenter who disagreed with CMS' proposal but agreed that clinically, both localized and generalized peritonitis in association with an appendectomy are complicated appendicitis diagnoses and should group to a complicated appendicitis MS–DRG, we note that our proposal reflects that both localized and generalized peritonitis in association with an appendectomy are comparable, clinically coherent diagnoses and should be grouped together. The MS–DRGs are a classification system intended to group together those diagnoses and procedures with similar

clinical characteristics and utilization of resources. Our proposal also essentially reflects the commenter's suggestion to group the four diagnoses (K35.20, K35.30, K35.31, and K35.891) that are currently assigned to the appendectomy without complicated principal diagnosis MS–DRGs (MS–DRGs 341, 342, and 342) together with the diagnoses that are currently assigned to the appendectomy with complicated principal diagnosis MS–DRGs (MS–DRGs 338, 338, and 340). Additionally, as previously discussed, we believe our data findings and clinical review no longer support the distinction of complicated versus uncomplicated MS–DRGs with respect to resource utilization for acute appendicitis and therefore, disagree with the commenter's suggestion to retain the existing MS–DRGs and to only reflect diagnosis codes K35.80, K35.890, and K36 in an uncomplicated MS–DRG. We note that diagnosis code K36 (Other appendicitis) is currently assigned to MS–DRGs 393, 394, and 395 (Other Digestive System Diagnoses with MCC, with CC, and without CC/MCC, respectively), and was not specifically included or addressed in our analysis, nor our proposal.

After consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal to delete MS–DRGs 338, 339, 340, 341, 342, and 343 and to create MS–DRGs 397, 398, and 399 (Appendix Procedures with MCC, with CC, and without CC/MCCC, respectively), without modification, for FY 2024. These finalized new MS–DRGs no longer require a diagnosis in the definition of the logic for case assignment. We are also finalizing our proposal to include the current list of appendectomy procedures in the logic for case assignment of appendix procedures for the finalized new MS–DRGs.

7. MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas): Alcoholic Hepatitis

As stated in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26721 through 26726), we received a request to create new MS–DRGs with a two-way split (with MCC and without MCC) for cases reporting alcoholic hepatitis. Alcoholic hepatitis is identified with ICD–10–CM diagnosis codes K70.10 (Alcoholic hepatitis without ascites) and K70.11 (Alcoholic hepatitis with ascites) which are currently assigned to MS–DRGs 432, 433, and 434 (Cirrhosis and Alcoholic Hepatitis with MCC, with CC, and without CC/MCC, respectively) when reported as a principal diagnosis.

Alcoholic hepatitis is characterized as an inflammatory condition due to chronic, excessive alcohol use and is considered an acute form of alcohol-associated liver disease (ALD). Data suggests that ALD was responsible for over 100,000 hospitalizations in 2017 and admissions for ALD continued to increase during the COVID–19 public health emergency.[6] Data also suggest that ALD may be one of the leading causes of liver transplants in the U.S.

As discussed in the proposed rule, the requestor stated that currently there are no effective therapies available to treat alcoholic hepatitis and current treatment guidelines suggest corticosteroids, despite increased risk of infection and minimal impact on survival beyond 28 days. However, the requestor (manufacturer of Larsucosterol) also indicated that epigenetic therapy is currently being studied to address various types of acute and chronic organ injury and provided information related to its AHFIRM (*A*lcohol-associated *H*epatitis to evaluate sa*F*ety and eff*I*cacy of La*R*sucosterol (DUR–928) treat*M*ent) Phase 2b study for patients diagnosed with alcoholic hepatitis. The FDA granted Fast Track Designation to DUR–928 for the treatment of alcoholic hepatitis in 2020.

The requestor stated it performed its own analysis using 2 years of claims data, (calendar years 2018 and 2019), and its findings showed that the patients with alcoholic hepatitis are distinct from the typical Medicare beneficiary and that the condition disproportionately affects younger patients that represent a small proportion of the cases currently grouping to MS–DRGs 432, 433, and 434. According to the requestor, the low volume of cases reporting alcoholic hepatitis have little to no impact on the annual recalibration of the MS–DRG relative payment weights for MS–DRGs 432, 433, and 434, resulting in underpayments. The requestor stated its analysis of cases reporting alcoholic hepatitis showed higher resource utilization and a longer length of stay when compared to all cases in MS–DRGs 432, 433, and 434. The requestor stated it applied the criteria to create subgroups for the cases reporting alcoholic hepatitis currently grouping to MS–DRGs 432, 433, and 434 and found that the criteria for a two-way split (with MCC and without MCC) was met. The requestor further stated that splitting out the cases reporting alcoholic hepatitis from MS–DRGs 432, 433, and 434 would enable more accurate payment of these cases and support research that is specific to alcoholic hepatitis distinct from cirrhosis.

The logic for case assignment to MS–DRGs 432, 433, and 434 is comprised of the following diagnosis codes.

[6] Gonzalez HC, Zhou Y, Nimri FM, Rupp LB, Trudeau S, Gordon SC. Alcohol-related hepatitis admissions increased 50% in the first months of the COVID–19 pandemic in the USA. Liver Int. 2022 Apr;42(4):762–764.

ICD-10-CM Code	Description
K70.10	Alcoholic hepatitis without ascites
K70.11	Alcoholic hepatitis with ascites
K70.2	Alcoholic fibrosis and sclerosis of liver
K70.30	Alcoholic cirrhosis of liver without ascites
K70.31	Alcoholic cirrhosis of liver with ascites
K70.40	Alcoholic hepatic failure without coma
K70.41	Alcoholic hepatic failure with coma
K70.9	Alcoholic liver disease, unspecified
K74.00	Hepatic fibrosis, unspecified
K74.01	Hepatic fibrosis, early fibrosis
K74.02	Hepatic fibrosis, advanced fibrosis
K74.3	Primary biliary cirrhosis
K74.4	Secondary biliary cirrhosis
K74.5	Biliary cirrhosis, unspecified
K74.60	Unspecified cirrhosis of liver
K74.69	Other cirrhosis of liver

As stated in the proposed rule, we analyzed claims data from the September 2022 update of the FY 2022 MedPAR file for MS–DRGs 432, 433, and 434 and cases reporting any one of the listed diagnoses as a principal diagnosis. We noted that if a diagnosis code is not listed it is because there were no cases found reporting that code in the respective MS–DRG. The findings from our analysis are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
432 – All cases	16,836	6.8	$16,532
432 – Cases reporting a principal diagnosis of K70.10 (Alcoholic hepatitis without ascites)	269	7.4	$14,710
432 – Cases reporting a principal diagnosis of K70.11 (Alcoholic hepatitis with ascites)	244	9.1	$20,727

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
432 – Cases reporting a principal diagnosis of K70.30 (Alcoholic cirrhosis of liver without ascites)	1,241	5.4	$14,136
432 – Cases reporting a principal diagnosis of K70.31 (Alcoholic cirrhosis of liver with ascites)	5,687	7.5	$17,694
432 – Cases reporting a principal diagnosis of K70.40 (Alcoholic hepatic failure without coma)	1,179	8.1	$19,277
432 – Cases reporting a principal diagnosis of K70.41 (Alcoholic hepatic failure with coma)	33	8.7	$22,530
432 – Cases reporting a principal diagnosis of K70.9 (Alcoholic liver disease, unspecified)	28	4.8	$12,708
432 – Cases reporting a principal diagnosis of K74.3 (Primary biliary cirrhosis)	244	7.3	$18,020
432 – Cases reporting a principal diagnosis of K74.4 (Secondary biliary cirrhosis)	11	7.5	$15,324
432 – Cases reporting a principal diagnosis of K74.5 (Biliary cirrhosis, unspecified)	15	8.2	$16,569
432 – Cases reporting a principal diagnosis of K74.60 (Unspecified cirrhosis of liver)	5,501	6	$15,120
432 – Cases reporting a principal diagnosis of K74.69 (Other cirrhosis of liver)	2,384	6.9	$16,501
433 – All cases	8,436	4.3	$9,007
433 – Cases reporting a principal diagnosis of K70.10 (Alcoholic hepatitis without ascites)	309	4.8	$8,436
433 – Cases reporting a principal diagnosis of K70.11 (Alcoholic hepatitis with ascites)	173	5	$10,085
433 – Cases reporting a principal diagnosis of K70.30 (Alcoholic cirrhosis of liver without ascites)	433	4.5	$9,343
433 – Cases reporting a principal diagnosis of K70.31 (Alcoholic cirrhosis of liver with ascites)	2,825	4.4	$9,548
433 – Cases reporting a principal diagnosis of K70.40 (Alcoholic hepatic failure with coma)	815	4.6	$9,066
433 – Cases reporting a principal diagnosis of K70.41 (Alcoholic hepatic failure with coma)	6	3.2	$5,853
433 – Cases reporting a principal diagnosis of K70.9 (Alcoholic liver disease, unspecified)	24	4.8	$11,893
433 – Cases reporting a principal diagnosis of K74.3 (Primary biliary cirrhosis)	121	4	$7,757
433 – Cases reporting a principal diagnosis of K74.4 (Secondary biliary cirrhosis)	4	3.3	$5,687
433 – Cases reporting a principal diagnosis of K74.5 (Biliary cirrhosis, unspecified)	12	2.2	$4,784
433 – Cases reporting a principal diagnosis of K74.60 (Unspecified cirrhosis of liver)	2,679	3.9	$8,482
433 – Cases reporting a principal diagnosis of K74.69 (Other cirrhosis of liver)	1,035	4.3	$8,855
434 – All cases	358	2.8	$5,825
434 – Cases reporting a principal diagnosis of K70.10 (Alcoholic hepatitis without ascites)	41	2.4	$5,784

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
434 – Cases reporting a principal diagnosis of K70.11 (Alcoholic hepatitis with ascites)	8	2.1	$4,316
434 – Cases reporting a principal diagnosis of K70.30 (Alcoholic cirrhosis of liver without ascites)	27	2.3	$4,624
434 – Cases reporting a principal diagnosis of K70.31 (Alcoholic cirrhosis of liver with ascites)	179	3	$6,348
434 – Cases reporting a principal diagnosis of K70.40 (Alcoholic hepatic failure with coma)	54	2.6	$4,803
434 – Cases reporting a principal diagnosis of K70.9 (Alcoholic liver disease, unspecified)	2	2.5	$5,351
434 – Cases reporting a principal diagnosis of K74.3 (Primary biliary cirrhosis)	6	4.2	$8,485
434 – Cases reporting a principal diagnosis of K74.60 (Unspecified cirrhosis of liver)	36	2.6	$5,862
434 – Cases reporting a principal diagnosis of K74.69 (Other cirrhosis of liver)	5	3	$4,122

Based on our initial analysis for cases in MS–DRGs 432, 433, and 434, the data clearly demonstrate that there are several diagnoses, other than the two diagnoses identified by the requestor (codes K70.10 and K70.11) with increased resource utilization when compared to the average length of stay and average costs of all cases in MS–DRGs 432, 433, and 434.

We stated in the proposed rule that the data show cases in MS–DRG 432 reporting diagnosis codes K70.11, K70.31, K70.40, K70.41, K74.3, or K74.5 as a principal diagnosis have a longer average length of stay (9.1 days, 7.5 days, 8.1 days, 8.7 days, 7.3 days, and 8.2 days, respectively versus 6.8 days) and higher average costs ($20,727, $17,694, $19,277, $22,530, $18,020, and $16,569, respectively versus $16,532) compared to the average length of stay and the average costs for all the cases in MS–DRG 432. We noted that the cases reporting diagnosis codes K70.10, K74.4, or K74.69 as a principal diagnosis also have a longer average length of stay (7.4 days, 7.5 days, and 6.9 days, respectively versus 6.8 days) compared to all the cases in MS–DRG 432, however, the average costs of these cases are lower ($14,710, $15,324 and $16,501, respectively versus $16,532) compared to the average costs for all the cases.

For MS–DRG 433, the cases reporting diagnosis codes K70.11, K70.30, K70.31, K70.40, or K70.9 as a principal diagnosis have a longer average length of stay (5.0 days, 4.5 days, 4.4 days, 4.6 days, and 4.8 days, respectively versus 4.3 days) and comparable average costs ($10,085, $9,343, $9,548, $9,066, and $11,893, respectively versus $9,007) compared to the average length of stay and the average costs for all the cases in MS–DRG 433. We noted that the cases reporting diagnosis code K70.10 as a principal diagnosis also have a longer average length of stay (4.8 days versus 4.3 days) compared to all the cases in MS–DRG 433, however, the average costs of these cases are lower ($8,436 versus $9,007) compared to the average costs for all the cases in the MS–DRG.

Lastly, for MS–DRG 434, the cases reporting diagnosis codes K70.31, K74.3, or K74.60 as a principal diagnosis have a longer average length of stay (3 days, 4.2 days, and 2.6 days, respectively versus 2.8 days) and higher average costs ($6,348, $8,485, and $5,862, respectively versus $5,825) compared to the average length of stay and the average costs for all the cases in MS–DRG 434.

The data also show that there is significantly more case volume for several of the other diagnoses compared to the case volume of the two diagnoses (K70.10 and K70.11) associated with the request to create new MS–DRGs. We identified diagnosis code K70.31 (Alcoholic cirrhosis of liver with ascites) to be the most prevalent diagnosis with respect to case volume reported across MS–DRGs 432, 433, and 434. For example, as shown in the table, we found 5,687 cases in MS–DRG 432 reporting diagnosis code K70.31 as a principal diagnosis compared to 269 cases reporting diagnosis code K70.10 and 244 cases reporting diagnosis code K70.11. For MS–DRG 433, we found 2,825 cases reporting diagnosis code K70.31 as a principal diagnosis compared to 309 cases reporting diagnosis code K70.10 and 173 cases reporting diagnosis code K70.11. Lastly, for MS–DRG 434, we found 179 cases reporting diagnosis code K70.31 as a principal diagnosis compared to 41 cases reporting diagnosis code K70.10 and 8 cases reporting diagnosis code K70.11.

As discussed in the proposed rule, following our initial review of the claims data for the cases reporting any one of the listed diagnoses as a principal diagnosis that are included in the logic for case assignment to MS–DRGs 432, 433, and 434, we performed additional analyses to focus on the cases specifically reporting diagnosis code K70.10 or K70.11 as a principal diagnosis in response to the request to create new MS–DRGs with a two-way split (with and without MCC, respectively). The findings from our analysis are shown in the following table.

Summary Table for Cases Reporting Diagnosis Codes K70.10 or K70.11 in MS-DRGs 432, 433, and 434			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
432 – All cases	16,836	6.8	$16,532
432 – Cases reporting a principal diagnosis of alcoholic hepatitis without or with ascites (K70.10 or K70.11)	513	8.2	$17,572
433 – All cases	8,436	4.3	$9,007
433 – Cases reporting a principal diagnosis of alcoholic hepatitis without or with ascites (K70.10 or K70.11)	482	4.9	$9,028
434 – All cases	358	2.8	$5,825
434 – Cases reporting a principal diagnosis of alcoholic hepatitis without or with ascites (K70.10 or K70.11)	49	2.4	$5,544

The data show that the 513 cases reporting alcoholic hepatitis without or with ascites in MS–DRG 432 have a longer average length of stay (8.2 days versus 6.8 days) and higher average costs ($17,572 versus $16,532). For MS–DRG 433, the data show that the 482 cases reporting alcoholic hepatitis without or with ascites have a longer average length of stay (4.9 days versus 4.3 days) and a difference in average costs of $21 ($9,028 versus $9,007). For MS–DRG 434, the 49 cases reporting alcoholic hepatitis without or with ascites have a shorter length of stay (2.4 days versus 2.8 days) and lower average costs ($5,544 versus $5,825).

We stated in the proposed rule that, based on the results of our review and our analysis of the claims data for cases reporting a principal diagnosis of alcoholic hepatitis without or with ascites (codes K70.10 or K70.11), we believe the cases demonstrate similar patterns of resource intensity in comparison to the other cases in MS–DRGs 432, 433, and 434. We also stated we believed that these diagnoses are clinically coherent with the other diagnoses currently assigned to MS–DRGs 432, 433, and 434. In addition, we stated that while we recognize the concerns expressed by the requestor for this subset of patients with respect to the younger population and the lower volume of cases, we noted that the logic for case assignment to MS–DRGs 432, 433, and 434 includes clinically related diagnoses that differ in severity and resource intensity with alcoholic hepatitis being at the lowest end of the severity spectrum. Therefore, we proposed to maintain the structure of MS–DRGs 432, 433, and 434 for FY 2024.

Comment: The majority of commenters agreed with the proposal to maintain the structure of MS–DRGs 432, 433, and 434 for FY 2024 given the data and information provided.

Response: We thank the commenters for their support.

Comment: A commenter (the requestor) who disagreed with the proposal stated that alcoholic hepatitis (AH) is a distinct clinical pathological entity that is different from common forms of alcoholic-liver disease (ALD) and that liver failure in severe AH is driven by loss of hepatocyte nuclear factor 4 alpha (HNF4α) function and liver-specific changes distinct from those seen in other forms of ALD. The commenter expressed concerns regarding both the analysis conducted by CMS and the interpretation of the findings. Specifically, the commenter stated that analyses by principal diagnoses comparing average length of stay and average costs should not be used as the primary determinant in assessing resource use differences, although the commenter acknowledged some principal diagnoses findings will be above, and some will be below, when compared to an average. According to the commenter, the CMS analyses also did not account for the differences between AH and non-AH cases and masked resource use differences. Using data from calendar years 2018 through 2022, the commenter provided an updated analysis for MS–DRG 432 while combining its analyses for MS–DRGs 433 and 434, separating AH cases from non-AH and comparing average length of stay among the cases.

Response: The MS–DRGs were developed as a patient classification scheme consisting of patients who are similar clinically and with regard to their consumption of hospital resources. The concept of clinical coherence requires that the patient characteristics included in the definition of each MS–DRG relate to a common organ system or etiology and that a specific medical specialty should typically provide care to the patients in the MS–DRG. While all patients are unique, groups of patients have diagnostic and therapeutic attributes in common that determine their level of resource intensity. Similar resource intensity means that the resources used are relatively consistent across the patients in each MS–DRG. However, some variation in resource intensity will remain among the patients in each MS–DRG. In other words, the definition of a MS–DRG will not be so specific that every patient is identical, rather the level of variation is relatively understood and predictable. We continue to believe, as stated previously, that AH diagnoses are clinically coherent with the other diagnoses currently assigned to MS–DRGs 432, 433, and 434.

With respect to the updated analyses that was submitted, we appreciate the commenter's feedback. However, we note that the commenter did not uniquely identify and distinguish the AH cases from non-AH cases with specific ICD–10–CM codes that it was considering under its analyses, nor did the analysis include any case counts. As such, it was not clear specifically what diagnoses were included in the commenter's data analysis.

With respect to the commenter's assertion that the CMS analyses by principal diagnoses comparing average length of stay and average costs was used as the primary determinant in assessing resource use differences, we note that while the logic for case assignment to MS–DRGs 432, 433, and 434 is driven by the reporting of any one of the listed diagnoses as a principal diagnosis, we also consider other factors in deciding whether to propose to make further modifications to the MS–DRGs for particular circumstances brought to

our attention, as described in the preamble of the proposed rule (88 FR 26673) and discussed in prior rulemaking (for example, severity of illness, treatment difficulty, complexity of service, etc.).

In response to the commenter's statement that the CMS analyses did not account for the differences between AH and non-AH cases masking resource use differences, we note that the analysis we performed and made available in the proposed rule to address the MS–DRG request listed the number of cases (volume), average length of stay and average costs of all cases, as well as detailed data for each diagnosis code defined in the logic for case assignment to MS–DRGs 432, 433, and 434 when reported as the principal diagnosis. Therefore, the data findings for what we believe the commenter is referring to as non-AH cases were reflected and the ability to perform a comparison between AH and non-AH was made available. Specifically, in review of the findings for MS–DRG 432, as displayed in the proposed rule and this final rule, the number of non-AH cases (*e.g.,* cases reporting a principal diagnosis other than diagnosis code K70.10 or K70.11) can be calculated by subtracting the total number of cases reporting AH from the total number of all cases in the MS–DRG. For example, the total number of cases found in MS–DRG 432 is 16,836 and the total number of cases reporting AH is 513, therefore, the number of non-AH cases is 16,323 (16,836 − 513 = 16,323), with an average length of stay of 6.8 days and average costs of $16,499, resulting in a difference of 1.4 days for the average length of stay and a difference in average costs of $1,073 for AH and non-AH cases. For MS–DRG 433, the number of non-AH cases can be calculated as 7,954 (8,436 − 482 = 7,954) with an average length of stay of 4.3 days and average costs of $9,006, resulting in a difference of .6 days for the average length of stay and a difference in average costs of $22 for AH and non-AH cases. Lastly, for MS–DRG 434, the number of non-AH cases can be calculated as 309 (358 − 49 = 309) with an average length of stay of 2.9 days and average costs of $5,870, resulting in a difference of .5 days for the average length of stay and a difference in average costs of $326 for AH and non-AH cases. We illustrate these findings in the following table.

Summary Table for Cases Reporting Alcoholic Hepatitis and Non-Alcoholic Hepatitis

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
432 – All cases	16,836	6.8	$16,532
432 – Cases reporting a principal diagnosis of alcoholic hepatitis without or with ascites (K70.10 or K70.11)	513	8.2	$17,572
432 – All other cases	16,323	6.8	$16,499
433 – All cases	8,436	4.3	$9,007
433 – Cases reporting a principal diagnosis of alcoholic hepatitis without or with ascites (K70.10 or K70.11)	482	4.9	$9,028
433 – All other cases	7,954	4.3	$9,006
434 – All cases	358	2.8	$5,825
434 – Cases reporting a principal diagnosis of alcoholic hepatitis without or with ascites (K70.10 or K70.11)	49	2.4	$5,544
434 – All other cases	309	2.9	$5,870

After consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal to maintain the structure of MS–DRGs 432, 433, and 434, without modification, for FY 2024.

We also note, as discussed in section II.C.1.b. of the preamble of proposed rule, using the December 2022 update of the FY 2022 MedPAR file, we analyzed how applying the NonCC subgroup criteria to all MS–DRGs currently split into three severity levels would affect the MS–DRG structure beginning in FY 2024. Findings from our analysis indicated that MS–DRGs 432, 433, and 434, as well as approximately 44 other base MS–DRGs, would potentially be subject to change based on the three-way severity level split criterion finalized in FY 2021. We referred the reader to Table 6P.10b associated with the proposed rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for the list of the 135 MS–DRGs that would potentially be subject to deletion and the list of the 86 new MS–DRGs that would potentially be created under this policy if the NonCC subgroup criteria was applied.

Comment: A commenter expressed support for the analysis CMS performed to determine how applying the NonCC subgroup criteria would potentially impact MS–DRGs currently split into three severity levels. Specifically, the commenter stated application of the NonCC subgroup criteria for MS–DRGs 432, 433, and 434 is reflective of the MS–DRG structure that was requested for AH.

Response: We thank the commenter for their support. We refer the reader to section II.C.1.b. of the preamble of this final rule for related discussion regarding our finalization of the expansion of the criteria to include the NonCC subgroup and our finalization of the proposal to continue to delay application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split for FY 2024.

8. MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue): Spinal Fusion

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26726 through 26729), we received a request to

reassign cases reporting spinal fusion procedures utilizing an aprevo™ customized interbody fusion device from the lower severity MS–DRG 455 (Combined Anterior and Posterior Spinal Fusion without CC/MCC) to the higher severity MS–DRG 453 (Combined Anterior and Posterior Spinal Fusion with MCC), from the lower severity MS–DRG 458 (Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions without CC/MCC) to the higher severity level MS–DRG 456 (Spinal Fusion Except Cervical with Spinal Curvature, Malignancy, Infection or Extensive Fusions with MCC) when a diagnosis of malalignment is reported, and from MS–DRGs 459 and 460 (Spinal Fusion Except Cervical with MCC and without MCC, respectively) to MS–DRG 456.

We noted that the Aprevo™ Intervertebral Body Fusion Device technology was discussed in the FY 2022 IPPS/LTCH PPS proposed (86 FR 25361 through 25365) and final rules (86 FR 45127 through 45133) with respect to a new technology add-on payment application and was approved for add-on payments for FY 2022. We also noted that, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49468 through 49469), CMS finalized the continuation of the new technology add-on payments for this technology for FY 2023.

In support of the new technology add-on payment application that was submitted for FY 2022 consideration, we received a request and proposal to create new ICD–10–PCS codes to differentiate spinal fusion procedures that utilize an aprevo™ customized interbody fusion device, which was discussed at the March 9–10, 2021 ICD–10 Coordination and Maintenance Committee meeting. As a result, effective October 1, 2021 (FY 2022), we implemented 12 new ICD–10–PCS procedure codes to identify and describe spinal fusion procedures utilizing the aprevo™ customized interbody fusion device as shown in the following table.

ICD-10-PCS Code	Description
XRGA0R7	Fusion of thoracolumbar vertebral joint using customizable interbody fusion device, open approach, new technology group 7
XRGA3R7	Fusion of thoracolumbar vertebral joint using customizable interbody fusion device, percutaneous approach, new technology group 7
XRGA4R7	Fusion of thoracolumbar vertebral joint using customizable interbody fusion device, percutaneous endoscopic approach, new technology group 7
XRGB0R7	Fusion of lumbar vertebral joint using customizable interbody fusion device, open approach, new technology group 7
XRGB3R7	Fusion of lumbar vertebral joint using customizable interbody fusion device, percutaneous approach, new technology group 7
XRGB4R7	Fusion of lumbar vertebral joint using customizable interbody fusion device, percutaneous endoscopic approach, new technology group 7
XRGC0R7	Fusion of 2 or more lumbar vertebral joints using customizable interbody fusion device, open approach, new technology group 7
XRGC3R7	Fusion of 2 or more lumbar vertebral joints using customizable interbody fusion device, percutaneous approach, new technology group 7
XRGC4R7	Fusion of 2 or more lumbar vertebral joints using customizable interbody fusion device, percutaneous endoscopic approach, new technology group 7
XRGD0R7	Fusion of lumbosacral joint using customizable interbody fusion device, open approach, new technology group 7
XRGD3R7	Fusion of lumbosacral joint using customizable interbody fusion device, percutaneous approach, new technology group 7
XRGD4R7	Fusion of lumbosacral joint using customizable interbody fusion device, percutaneous endoscopic approach, new technology group 7

Each of the listed procedure codes are assigned to MDC 01 (Diseases and Disorders of the Nervous System) in MS–DRGs 028, 029, and 030 (Spinal Procedures with MCC, with CC or Spinal Neurostimulators, and without CC/MCC, respectively) and to MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue) in MS–DRGs 453, 454, and 455 (Combined Anterior and Posterior Spinal Fusion with MCC, with CC, and without CC/MCC, respectively), MS–DRGs 456, 457, and 458 (Spinal Fusion Except Cervical With Spinal Curvature, Malignancy, Infection or Extensive Fusions with MCC, with CC, and without CC/MCC, respectively), and MS–DRGs 459 and 460 (Spinal Fusion Except Cervical with MCC and without MCC, respectively).

As stated in the proposed rule, the requestor (the manufacturer of aprevo™ customized interbody spinal fusion devices) expressed concerns that findings from its analysis of claims data for spinal fusion MS–DRGs 453, 454, 455, 456, 457, 458, 459, and 460 from the first half of FY 2022 indicate there may be unintentional miscoded claims from providers with whom they do not have an explicit relationship. Specifically, the requestor stated that a subset of the facilities identified in its analysis are not customers to whom the aprevo™ custom-made device was provided. The volume of cases initially identified by the requestor in its analysis totaled 89 cases, however, upon

eliminating the provider claims from the facilities that are not a current client, the resulting volume was 14 cases. The requestor stated that subsequently, after another quarter's data became available from current clients for cases reporting the performance of a spinal fusion procedure utilizing an aprevo™ customized interbody spinal fusion device, they identified an additional 16 cases for a total of 30 cases, all of which were assigned to MS–DRGs 453, 454, and 455.

Upon further review of the data, the requestor stated it found that cases reporting the performance of a spinal fusion procedure utilizing an aprevo™ customized interbody spinal fusion device had higher average costs in comparison to the average costs of all the cases in the highest severity level ''with MCC'' MS–DRGs 453 and 456. According to the requestor, this finding suggested that the use of the device impacts intensity of resources such that the cases reporting the performance of a spinal fusion procedure utilizing an aprevo™ customized interbody spinal fusion device merit reassignment to the highest severity level ''with MCC'' MS–DRGs (MS–DRGs 453 and 456). The requestor asserted that while spinal disorders impact approximately 65 million patients in the U.S., the patients undergoing spine surgery with an aprevo™ customized interbody spinal fusion device are those with irreversible, debilitating conditions. In addition, the requestor stated that since the cases reporting the performance of a spinal fusion procedure utilizing an aprevo™ customized interbody spinal fusion device already appear to map to the most resource intensive MS–DRGs for spinal procedures, there is no other alternative assignment for these procedures, with the exception of a new MS–DRG. Lastly, the requestor maintained that reassigning cases reporting the performance of a spinal fusion procedure utilizing an aprevo™ customized interbody spinal fusion device to the ''with MCC'' level aligns with CMS's factors that are considered in review of MS–DRG classification change requests, including treatment difficulty, complexity of service, and utilization of resources.

As discussed in the proposed rule, we analyzed data from the September 2022 update of the FY 2022 MedPAR file for MS–DRGs 453, 454, 455, 456, 457, 458, 459, and 460 and cases reporting any one of the previously listed procedure codes describing utilization of an aprevo™ customized interbody spinal fusion device. Our findings are shown in the following table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 453 All cases	3,779	9.4	$77,856
MS-DRG 453 Cases reporting customized interbody spinal fusion	17	8.4	$79,080
MS-DRG 454 All cases	19,246	4.4	$54,227
MS-DRG 454 Cases reporting customized interbody spinal fusion	75	4.4	$75,294
MS-DRG 455 All cases	16,564	2.7	$40,683
MS-DRG 455 Cases reporting customized interbody spinal fusion	67	2.7	$54,287
MS-DRG 456 All cases	1,276	13.2	$73,399
MS-DRG 456 Cases reporting customized interbody spinal fusion	0	0	0
MS-DRG 457 All cases	2,973	6.4	$53,750
MS-DRG 457 Cases reporting customized interbody spinal fusion	2	3.5	$158,782
MS-DRG 458 All cases	777	3.5	$40,343
MS-DRG 458 Cases reporting customized interbody spinal fusion	1	12	$91,672
MS-DRG 459 All cases	3,128	9.8	$53,342
MS-DRG 459 Cases reporting customized interbody spinal fusion	2	5	$57,039
MS-DRG 460 All cases	30,310	3.5	$31,921
MS-DRG 460 Cases reporting customized interbody spinal fusion	30	4.5	$46,683

We found the majority of cases reporting the performance of a spinal fusion procedure utilizing an aprevo™ customized interbody spinal fusion device in MS–DRGs 453, 454, and 455 with a total of 159 cases (17 + 75 + 67 = 159) with an average length of stay of 4.1 days and average costs of $66,847. The 17 cases identified in MS–DRG 453 appear to have a comparable average length of stay and comparable average costs compared to all the cases in MS–DRG 453 with a difference of 1.0 day and a difference in average costs of $1,383 for the cases reporting the performance of a spinal fusion procedure utilizing an aprevo™ customized interbody spinal fusion device. The 75 cases found in MS–DRG 454 have an identical average length of stay of 4.4 days in comparison to all the cases in MS–DRG 454, however, the difference in average costs is $21,067 ($75,294 − $54,227 = $21,067) for the cases reporting the performance of a spinal fusion procedure utilizing an aprevo™ customized interbody spinal fusion device. The 67 cases found in MS–DRG 455 also have an identical average length of stay of 2.7 days in comparison to all the cases in MS–DRG 455, however, the difference in average costs is $13,604 ($54,287 − $40,683 = $13,604) for the cases reporting the performance of a spinal fusion procedure utilizing an aprevo™ customized interbody spinal fusion device. As shown in the table, there were no cases found to report utilization of an aprevo™ customized interbody spinal fusion device in MS–DRG 456. For MS–DRG 457, the 2 cases found to report utilization of an aprevo™ customized interbody spinal fusion device appear to be outliers with a difference in average costs of $105,032 ($158,782 − $53,750 = $105,032) and a shorter average length of stay (3.5 days versus 6.4 days) in comparison to all the cases in MS–DRG 457. For MS–DRG 458, we found 1 case reporting utilization of an aprevo™ customized interbody spinal fusion device with an average length of stay almost three times the average length of stay of all the cases in MS–DRG 458 (12 days versus 3.5 days) and average costs that are twice as

high ($91,672 versus $40,343) compared to the average costs of all the cases in MS–DRG 458. For MS–DRG 459, the 2 cases reporting utilization of an aprevo™ customized interbody spinal fusion device had a shorter average length of stay (5 days versus 9.8 days) compared to the average length of stay of all the cases in MS–DRG 459 with a difference in average costs of $3,697 ($57,039 − $53,342 = $3,697). For MS–DRG 460, the 30 cases reporting utilization of an aprevo™ customized interbody spinal fusion device had a longer average length of stay (4.5 days versus 3.5 days) compared to the average length of stay of all the cases in MS–DRG 460 with a difference in average costs of $14,762 ($46,683 − $31,921 = $14,762).

As discussed in the proposed rule, the requestor expressed concerns that there may be unintentional miscoded claims from providers with whom they do not have an explicit relationship. In the proposed rule, we noted that following the submission of the request for the FY 2024 MS–DRG classification change for cases reporting the performance of a spinal fusion procedure utilizing an aprevo™ customized interbody spinal fusion device, this same requestor (the manufacturer of aprevo™ customized interbody spinal fusion devices) submitted a code proposal requesting a revision to the title of the current procedure codes that identify and describe a spinal fusion procedure utilizing an aprevo™ customized interbody spinal fusion device for consideration as an agenda topic to be discussed at the March 7–8, 2023 ICD–10 Coordination and Maintenance Committee meeting. The requestor stated its belief that the term ''customizable'' as currently reflected in each of the 12 procedure code descriptions is potentially misunderstood by providers to encompass expandable interbody fusion cages that have been available for several years and which were not approved for new technology add-on payment as was the aprevo™ customized interbody spinal fusion device. According to the requestor, these other interbody fusion devices do not require the same patient specific surgical plan coordination as the aprevo™ customized interbody spinal fusion device and do not offer the personalized fit that matches the topography of a patient's bone. Therefore, in an effort to encourage appropriate reporting for cases where an aprevo™ customized interbody spinal fusion device has been utilized in the performance of a spinal fusion procedure, the requestor provided alternative terminology for consideration.

We stated in the proposed rule that the proposal to revise the code title was presented and discussed as an Addenda item at the March 7–8, 2023 ICD–10 Coordination and Maintenance Committee meeting. We referred the reader to the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials* for additional detailed information regarding the request, including a recording of the discussion and the related meeting materials. Public comments in response to the code proposal were due by April 7, 2023.

We noted in the proposed rule that the diagnosis and procedure code proposals that are presented at the March ICD–10–CM Coordination and Maintenance Committee meeting for an October 1 implementation (upcoming FY) are not finalized in time to include in Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, Table 6E.—Revised Diagnosis Code Titles or Table 6F.—Revised Procedure Code Titles in association with the proposed rule. Accordingly, we stated that any update to the title of the procedure codes describing utilization of an aprevo™ customized interbody spinal fusion device, if finalized following the March meeting, would be reflected in Table 6F.—Revised Procedure Code Titles associated with the final rule for FY 2024.

As discussed in the proposed rule, based on our review of this issue and our analysis of the claims data, we agreed that the findings appear to indicate that cases reporting the performance of a procedure utilizing an aprevo™ customized interbody spinal fusion device reflect a higher consumption of resources. However, due to the concerns expressed with respect to suspected inaccuracies of the coding and therefore, reliability of the claims data, we stated we believed further review is warranted. In addition, as previously discussed in the proposed rule and this final rule, the proposal to revise the current code descriptions was presented at the March 2023 ICD–10 Coordination and Maintenance Committee meeting and if finalized, the revised coding may improve the reporting of procedures where an aprevo™ customized interbody spinal fusion device is utilized. In the proposed rule, we also stated we believed that because this technology is currently receiving new technology add-on payments, it would be advantageous to allow for more claims data to be analyzed under the application of the policy in consideration of any future modifications to the MS–DRGs for which the technology is utilized in the performance of a spinal fusion procedure.

In the proposed rule, we noted that with regard to possible future action, we will continue to monitor the claims data for resolution of the potential coding issues identified by the requestor. We also noted that because the procedure codes that we analyzed and presented findings for in the FY 2024 IPPS/LTCH PPS proposed rule may be revised based on the proposal as discussed at the March 2023 ICD–10 Coordination and Maintenance Committee meeting, the claims data that we examine in the future may change. Additionally, we stated that we will continue to collaborate with the AHA as one of the four Cooperating Parties through the AHA's *Coding Clinic for ICD–10–CM/PCS* and provide further education on spinal fusion procedures utilizing an aprevo™ customized interbody spinal fusion device and the proper reporting of the ICD–10–PCS spinal fusion procedure codes. Until these potential coding inaccuracies are addressed and additional, future analysis of the procedures being reported in the claims data can occur, we stated we believed it would be premature to propose any MS–DRG modifications for spinal fusion procedures utilizing an aprevo™ customized interbody spinal fusion device at this time. For these reasons, we proposed to maintain the current structure of MS–DRGs 453, 454, 455, 456, 457, 458, 459, and 460 for FY 2024.

Comment: Commenters supported our proposal to maintain the current structure of MS–DRGs 453, 454, 455, 456, 457, 458, 459, and 460 for FY 2024.

Response: We thank the commenters for their support.

Comment: Several commenters (orthopedic surgeons) who expressed support for the requested reassignment of cases reporting the utilization of an aprevo™ customized interbody spinal fusion device stated how important these devices are for their patients because it optimizes patient alignment, is patient-specific, and therefore, beneficial for situations where a patient's normal anatomy does not allow for traditional implants. These commenters stated that without reassignment to the higher severity MS–DRGs their facilities would not allow use of the technology on the population of Medicare patients they serve.

Response: We appreciate the commenters' feedback. As discussed in the proposed rule, based on our review

and analysis of the claims data, we agreed that the findings appear to indicate that cases reporting the performance of a procedure utilizing an aprevo™ customized interbody spinal fusion device reflect a higher consumption of resources. We also note that the proposal to revise the current code descriptions that was presented at the March 2023 ICD–10 Coordination and Maintenance Committee meeting was finalized, as reflected in the FY 2024 ICD–10–PCS Code Update files available via the CMS website at: *https://www.cms.gov/medicare/icd-10/2024-icd-10-pcs* as well as in Table 6F.—Revised Procedure Code Titles—FY 2024 associated with this final rule and available via the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS.*

As also previously discussed, because of the concerns with respect to suspected inaccuracies of the current coding, we continue to believe additional review of claims data is warranted and would be informative as we continue to consider this technology for future rulemaking. Accurate and complete documentation within the medical record is important for patient management, outcome measurement, and quality improvement, as well as payment accuracy. We anticipate that the revisions to the code title for the aprevo™ customized interbody spinal fusion device will encourage more accurate reporting of procedures and improve the quality and reliability of the data. We also continue to believe that because this technology is currently receiving new technology add-on payments and will continue to receive new technology add-on payments, additional claims data analysis of the cases under the application of the policy in consideration of any future modifications to the MS–DRGs for which the technology is utilized in the performance of a spinal fusion procedure would be beneficial.

As we have stated in prior rulemaking, we rely on providers to assess the needs of their patients and provide the most appropriate treatment. It is not appropriate for facilities to deny treatment to beneficiaries needing a specific type of therapy or treatment that potentially involves increased costs (86 FR 44847). It would also not be appropriate to consider modifications to the MS–DRG assignment of cases reporting the performance of a procedure that identifies and describes a specific technology solely as an incentive for providers to purchase and utilize one technology over another.

After consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal to maintain the structure of MS–DRGs 453, 454, 455, 456, 457, 458, 459, and 460, without modification, for FY 2024.

9. MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract): Complications of Arteriovenous Fistulas and Shunts

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26729 through 26733), we discussed a request we received to add eight ICD–10–CM diagnosis codes to the list of principal diagnoses assigned to MS–DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively) in MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract) when reported with procedure codes describing the insertion of totally implantable vascular access devices (TIVADs) and tunneled vascular access devices. The list of eight ICD–10–CM diagnosis codes submitted by the requestor, as well as their current MDC assignments, are found in the table:

ICD-10-CM Code	Description	MDC
T82.510A	Breakdown (mechanical) of surgically created arteriovenous fistula, initial encounter	05
T82.511A	Breakdown (mechanical) of surgically created arteriovenous shunt, initial encounter	05
T82.520A	Displacement of surgically created arteriovenous fistula, initial encounter	05
T82.521A	Displacement of surgically created arteriovenous shunt, initial encounter	05
T82.530A	Leakage of surgically created arteriovenous fistula, initial encounter	05
T82.531A	Leakage of surgically created arteriovenous shunt, initial encounter	05
T82.590A	Other mechanical complication of surgically created arteriovenous fistula, initial encounter	05
T82.591A	Other mechanical complication of surgically created arteriovenous shunt, initial encounter	05

As noted in the proposed rule, in order to be treated with dialysis, a procedure that replaces kidney function when the organs fail, a connection must be established between the dialysis equipment and the patient's bloodstream. To establish long-term hemodialysis access, an arteriovenous (AV) fistula or an AV shunt can be surgically created. An AV fistula is created by suturing an artery directly to a vein, generally in the wrist, forearm, inner elbow or upper arm. AV fistulas usually require from 8 to 12 weeks for maturation prior to initial use. AV shunts, also called AV grafts, are created by connecting an artery and a vein using a graft made of synthetic material. AV shunts do not require maturation, as AV fistulas do, and they can be used for hemodialysis in as little as 24 hours after creation depending upon the type of graft that is used. The requestor noted that diagnosis codes that describe complications of dialysis catheters currently are in the list of qualifying principal diagnoses in MS–DRGs 673, 674, and 675 when reported with procedure codes describing the insertion of TIVADs or tunneled vascular access devices; therefore, according to the requestor, diagnosis codes that describe complications of arteriovenous fistulas and shunts should reasonably be added.

We stated in the proposed rule that to begin our analysis, we reviewed the GROUPER logic for MS–DRGs 673, 674, and 675 including the special logic in MS–DRGs 673, 674, and 675 for certain MDC 11 diagnoses reported with procedure codes for the insertion of tunneled or totally implantable vascular access devices. We refer the reader to the ICD–10 MS–DRG Definitions Manual Version 40.1, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* for complete documentation of the GROUPER logic for MS–DRGs 673, 674, and 675.

As discussed in the FY 2003 IPPS/LTCH PPS final rule (67 FR 49993 through 49994), the procedure code for the insertion of totally implantable

vascular access devices was added to the GROUPER logic of DRG 315 (Other Kidney and Urinary Tract O.R. Procedures), the predecessor DRG of MS–DRGs 673, 674, and 675, when combined with principal diagnoses specifically describing renal failure, recognizing that inserting these devices as an inpatient procedure for the purposes of hemodialysis can lead to higher average charges and longer lengths of stay for those cases. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58511 through 58517), we discussed a similar request to add 29 ICD–10–CM diagnosis codes to the list of principal diagnoses assigned to MS–DRGs 673, 674, and 675. In the FY 2021 IPPS/LTCH PPS final rule, we finalized the assignment of diagnosis codes that describe diabetes mellitus with diabetic chronic kidney disease, codes that describe complications of kidney transplant and codes that describe mechanical complications of vascular dialysis catheters to the list of qualifying principal diagnoses in MS–DRGs 673, 674, and 675 and stated that we believed the insertion of TIVADs or tunneled vascular access devices for the purposes of hemodialysis was clinically related to these diagnosis codes. We stated that for clinical coherence, the cases reporting these diagnoses should be grouped with the subset of cases that report the insertion of totally implantable vascular access devices or tunneled vascular access devices as an inpatient procedure for the purposes of hemodialysis for renal failure.

As discussed in the FY 2024 IPPS/LTCH proposed rule, we reviewed the eight diagnosis codes submitted by the requestor. Diagnosis codes T82.510A, T82.511A, T82.520A, T82.521A, T82.530A, T82.531A, T82.590A, and T82.591A describe mechanical complications of arteriovenous fistulas and shunts and are currently assigned to MDC 05 (Diseases and Disorders of the Circulatory System). The eight diagnosis codes would require reassignment to MDC 11 in MS–DRGs 673, 674, and 675 to group with the subset of cases that report the insertion of totally implantable vascular access devices or tunneled vascular access devices as an inpatient procedure for the purposes of hemodialysis for renal failure. We examined claims data from the September 2022 update of the FY 2022 MedPAR file for all cases reporting procedures describing the insertion of TIVADs or tunneled vascular access devices with a principal diagnosis describing mechanical complications of arteriovenous fistulas and shunts and compared these data to cases in MS–DRGs 673, 674 and 675. The following table shows our findings:

MS-DRGs 673, 674 and 675 Compared to Cases Reporting Procedures Describing the Insertion of TIVADs or Tunneled Vascular Access Devices with a Principal Diagnosis Code Describing Mechanical Complications of Complications of Arteriovenous Fistulas and Shunts

MS-DRG		Number of Cases	Average Length of Stay	Average Costs
673	All cases	13,904	12.1	$31,946
	Cases reporting procedures describing the insertion of TIVADs or tunneled vascular access devices with a principal diagnosis of T82.510A, T82.511A, T82.520A, T82.521A, T82.530A, T82.531A, T82.590A or T82.591A with secondary diagnosis designated as MCC	748	6	$24,467
674	All cases	5,532	7.8	$20,702
	Cases reporting procedures describing the insertion of TIVADs or tunneled vascular access devices with a principal diagnosis T82.510A, T82.511A, T82.520A, T82.521A, T82.530A, T82.531A, T82.590A or T82.591A with secondary diagnosis designated as CC	1	3	$6,418
675	All cases	303	3.6	$13,343
	Cases reporting procedures describing the insertion of TIVADs or tunneled vascular access devices with a principal diagnosis T82.510A, T82.511A, T82.520A, T82.521A, T82.530A, T82.531A, T82.590A or T82.591A without secondary diagnosis designated as CC or MCC	0	0	$0

As shown in the table, there were 13,904 cases in MS–DRG 673 with an average length of stay of 12.1 days and average costs of $31,946. There were 748 cases reporting a principal diagnosis describing mechanical complications of arteriovenous fistulas and shunts, with a secondary diagnosis of MCC, and a procedure code for the insertion of a TIVAD or tunneled vascular access device with an average length of stay of 6 days and average costs of $24,467. There were 5,532 cases in MS–DRG 674 with an average length of stay of 7.8 days and average costs of $20,702. There was one case reporting a principal diagnosis describing mechanical complications of arteriovenous fistulas and shunts, with a secondary diagnosis of CC, and a procedure code for the insertion of a TIVAD or tunneled vascular access device with a length of stay of 3 days and costs of $6,418. There were 303 cases in MS–DRG 675 with an average length of stay of 3.6 days and average costs of $13,343. There were zero cases reporting a principal diagnosis describing mechanical complications of arteriovenous fistulas and shunts, without a secondary diagnosis of CC or MCC, and a procedure code for the insertion of a TIVAD or tunneled vascular access device. We note that the average length of stay and average costs of cases reporting a principal diagnosis describing mechanical complications of arteriovenous fistulas and shunts and the insertion of a TIVAD or a tunneled

vascular access device are lower than for all cases in MS–DRGs 673 and 674, respectively.

To further examine the impact of moving the eight MDC 05 diagnoses into MDC 11, in the proposed rule, we stated we analyzed claims data for cases reporting an O.R. procedure assigned to MDC 05 and a principal diagnosis describing mechanical complications of arteriovenous fistulas and shunts. Our findings are reflected in the following table:

Cases Reporting Circulatory System O.R. Procedures with a Principal Diagnosis Describing Mechanical Complications of Arteriovenous Fistulas and Shunts				
MS-DRG	Description	Number of Cases	Average Length of Stay	Average Costs
215	Other Heart Assist System Implant	1	1	$68,682
219	Cardiac Valve and Other Major Cardiothoracic Procedures without Cardiac Catheterization with MCC	1	13	$207,909
228	Other Cardiothoracic Procedures with MCC	3	5	$61,681
233	Coronary Bypass with Cardiac Catheterization or Open Ablation with MCC	1	13	$143,481
239	Amputation for Circulatory System Disorders Except Upper Limb and Toe with MCC	6	19.5	$71,860
242	Permanent Cardiac Pacemaker Implant with MCC	2	16.5	$94,850
246	Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Arteries or Stents	7	12.7	$56,048
252	Other Vascular Procedures with MCC	1,323	5.2	$22,734
253	Other Vascular Procedures with CC	42	4	$13,092
254	Other Vascular Procedures without CC/MCC	4	2.5	$9,344
255	Upper Limb and Toe Amputation for Circulatory System Disorders with MCC	2	6	$21,212
263	Vein Ligation and Stripping	9	4.6	$19,576
264	Other Circulatory System O.R. Procedures	102	6	$23,393
268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC	1	8	$49,865
270	Other Major Cardiovascular Procedures with MCC	75	4.9	$26,697
271	Other Major Cardiovascular Procedures with CC	2	3	$37,375
	Total Cases	**1,581**	**5.3**	**$23,643**

We noted in the proposed rule that whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in an MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''. As shown in the table, if we were to move the eight diagnosis codes describing mechanical complications of arteriovenous fistulas and shunts from MDC 05 to MDC 11, 1,581 cases would be assigned to the surgical class referred to as ''unrelated operating room procedures'' as an unintended consequence. We stated that the data also indicates that there were more cases that reported an O.R. procedure assigned to MDC 05 with a principal diagnosis describing mechanical complications of arteriovenous fistulas and shunts than there were cases reporting a principal diagnosis describing mechanical complications of arteriovenous fistulas and shunts and a procedure code for the insertion of a TIVAD or tunneled vascular access device (1,581 cases versus 749 cases) demonstrating that inpatient admissions for mechanical complications of arteriovenous fistulas and shunts more typically have an O.R. procedure assigned to MDC 05 performed.

We further stated we also reviewed the cases reporting an O.R. procedure assigned to MDC 05 and a principal diagnosis describing mechanical complications of arteriovenous fistulas and shunts to identify the top 10 O.R. procedures assigned to MDC 05 that were reported within the claims data for these cases. Our findings are shown in the following table:

Top 10 Procedures Assigned to MDC 05 Reported with a Principal Diagnosis Describing Mechanical Complications of Arteriovenous Fistulas and Shunts				
ICD-10-PCS Code	Description	Number of Times Reported	Average Length of Stay	Average Costs
03WY0JZ	Revision of synthetic substitute in upper artery, open approach	91	5.6	$23,543
037Y3ZZ	Dilation of upper artery, percutaneous approach	66	4.6	$24,564
05WY0JZ	Revision of synthetic substitute in upper vein, open approach	58	5.1	$20,969
05763ZZ	Dilation of left subclavian vein, percutaneous approach	56	4.8	$18,662
057Y3ZZ	Dilation of upper vein, percutaneous approach	53	5.8	$27,740
057F3ZZ	Dilation of left cephalic vein, percutaneous approach	49	6.8	$29,862
05CY3ZZ	Extirpation of matter from upper vein, percutaneous approach	45	4.4	$28,177
03CY0ZZ	Extirpation of matter from upper artery, open approach	44	5.1	$23,969
03B80ZZ	Excision of left brachial artery, open approach	43	5.6	$20,718

As noted previously, if we were to move the eight diagnosis codes describing mechanical complications of arteriovenous fistulas and shunts to MDC 11, cases reporting one of the O.R. procedures assigned to MDC 05 shown in the table would be assigned to the surgical class referred to as ''unrelated operating room procedures'' as an unintended consequence.

Based on the results of our analysis, we stated we did not support adding the eight diagnosis codes that describe mechanical complications of arteriovenous fistulas and shunts to the special logic in MS–DRGs 673, 674, and 675. As discussed previously, these diagnosis codes are assigned to MDC 05 (Diseases and Disorders of the Circulatory System). In the proposed rule, we noted that patients can sometimes require the insertion of tunneled or totally implantable vascular access devices for hemodialysis while surgically created AV fistulas or AV shunts are unable to be accessed due to mechanical complications, however more often these mechanical complications related to AV fistulas or AV shunts require inpatient admission for vascular surgery to be effectively treated. We stated we believed that the eight diagnosis codes describing mechanical complications of arteriovenous fistulas and shunts are most clinically aligned with the diagnosis codes assigned to MDC 05 (where they are currently assigned). We also stated we believed it would not be appropriate to move these diagnoses into MDC 11 because it would inadvertently cause cases reporting the eight diagnosis codes that describe mechanical complications of arteriovenous fistulas and shunts with O.R. procedures assigned to MDC 05 to be assigned to an unrelated MS–DRG.

Therefore, for the reasons discussed, we did not propose to add the following eight ICD–10–CM codes to the list of principal diagnosis codes for MS–DRGs 673, 674, and 675 when reported with a procedure code describing the insertion of a TIVAD or a tunneled vascular access device: T82.510A, T82.511A, T82.520A, T82.521A, T82.530A, T82.531A, T82.590A, and T82.591A.

Comment: Commenters supported the proposal to maintain the current assignment of the eight diagnosis codes in MDC 05 and expressed appreciation for CMS' analysis of clinical best practice and claims data. A commenter stated that while they recognize that the insertion of TIVADS and tunneled vascular access devices may be performed to treat renal failure, the resources used for such treatment—including surgical equipment, interventional radiology services, clinical staff, among others—are more consistent with vascular disease than the primary diagnosis (that is, kidney disease) that led to the procedure.

Response: We thank the commenters for their support and appreciate the feedback. After consideration of the public comments we received, we are finalizing for FY 2024, without modification, our proposal to not add the following eight ICD–10–CM codes to the list of principal diagnosis codes for MS–DRGs 673, 674, and 675 when reported with a procedure code describing the insertion of a TIVAD or a tunneled vascular access device: T82.510A, T82.511A, T82.520A, T82.521A, T82.530A, T82.531A, T82.590A, and T82.591A.

10. Review of Procedure Codes in MS–DRGs 981 Through 983 and 987 Through 989

We annually conduct a review of procedures producing assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987 through 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move cases reporting these procedure codes out of these MS–DRGs into one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls. The data are arrayed in two ways for comparison purposes. We look at a frequency count of each major operative procedure code. We also compare procedures across MDCs by volume of procedure codes within each MDC. We use this information to determine which procedure codes and diagnosis codes to examine.

We identify those procedures occurring in conjunction with certain principal diagnoses with sufficient frequency to justify adding them to one of the surgical MS–DRGs for the MDC in which the diagnosis falls. We also consider whether it would be more appropriate to move the principal diagnosis codes into the MDC to which the procedure is currently assigned.

Based on the results of our review of the claims data from the September 2022 update of the FY 2022 MedPAR file of cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989, we proposed to move the cases reporting the procedures and/or principal diagnosis codes described in

this section of this rule from MS–DRGs 981 through 983 or MS–DRGs 987 through 989 into one of the surgical MS–DRGs for the MDC into which the principal diagnosis or procedure is assigned.

a. Percutaneous Endoscopic Resection of Colon

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26733 through 26735), during our review of the cases that group to MS–DRGs 981 through 983, we noted that when ICD–10–PCS procedure code 0DTN4ZZ (Resection of sigmoid colon, percutaneous endoscopic approach) is reported with a principal diagnosis in MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract), the cases group to MS–DRGs 981 through 983. We stated in the proposed rule that the principal diagnosis most frequently reported with ICD–10–PCS procedure code 0DTN4ZZ in MDC 11 is ICD–10–CM code N32.1 (Vesicointestinal fistula). ICD–10–PCS procedure code 0DTN4ZZ currently groups to several MDCs, which are listed in the following table.

MS-DRG Assignments for ICD-10-PCS Procedure Code 0DTN4ZZ		
MDC	**MS-DRG**	**Description**
06	329-331	Major Small and Large Bowel Procedures
17	820-822	Lymphoma and Leukemia with Major Procedure
17	826-828	Myeloproliferative Disorders or Poorly Differentiated Neoplasms with Major Procedure
21	907-909	Other O.R. Procedures for Injuries
24	957-959	Other Procedures for Multiple Significant Trauma

As noted in the proposed rule, we examined claims data from the September 2022 update of the FY 2022 MedPAR file to identify the average length of stay and average costs for cases reporting procedure code 0DTN4ZZ with a principal diagnosis in MDC 11, which are currently grouping to MS–DRGs 981 through 983, as well as all cases in MS–DRGs 981 through 983. Our findings are shown in the following table.

MS-DRGs 981-983: All Cases and Cases with Principal Diagnosis in MDC 11 and Procedure Code 0DTN4ZZ			
MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
MS-DRG 981--All cases	21,139	12.6	$37,872
MS-DRG 981--Cases reporting procedure code 0DTN4ZZ and a principal diagnosis in MDC 11	12	11.5	$36,596
MS-DRG 982--All cases	9,386	5.9	$20,819
MS-DRG 982--Cases reporting procedure code 0DTN4ZZ and a principal diagnosis in MDC 11	38	5.2	$23,624
MS-DRG 983--All cases	1,782	2.6	$14,541
MS-DRG 983--Cases reporting procedure code 0DTN4ZZ and a principal diagnosis in MDC 11	12	2.8	$25,172

We then examined the MS–DRGs within MDC 11 and determined that the cases reporting procedure code 0DTN4ZZ with a principal diagnosis in MDC 11 would most suitably group to MS–DRGs 673, 674, and 675 (Other Kidney and Urinary Tract Procedures with MCC, with CC, and without CC/MCC, respectively), which contain procedures performed on structures other than kidney and urinary tract anatomy.

To determine how the resources for this subset of cases compared to cases in MS–DRGs 673, 674, and 675 as a whole, we stated in the proposed rule we examined the average costs and length of stay for cases in MS–DRGs 673, 674, and 675. Our findings are shown in this table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 673--All cases	13,904	12.1	$31,946
MS-DRG 674--All cases	5,532	7.8	$20,702
MS-DRG 675--All cases	303	3.6	$13,343

We reviewed the data and noted in the proposed rule that for this subset of cases, the average costs are higher and the average length of stays are shorter than for cases in MS–DRGs 673, 674, and 675. However, we stated we believed that when ICD–10–PCS procedure code 0DTN4ZZ is reported with a principal diagnosis in MDC 11 (typically vesicointestinal fistula), the procedure is related to the principal diagnosis. Because vesicointestinal fistulas involve both the bladder and the bowel, we stated some procedures in both MDC 06 (Diseases and Disorders of the Digestive System) and MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract) would be expected to be related to a principal diagnosis of vesicointestinal fistula (ICD–10–CM code N32.1). Therefore, we proposed to add ICD–10–PCS procedure code 0DTN4ZZ to MDC 11. Under this proposal, cases reporting procedure code 0DTN4ZZ with a principal diagnosis of vesicointestinal fistula (diagnosis code N32.1) in MDC 11 would group to MS–DRGs 673, 674, and 675.

Comment: Commenters supported the proposal to add ICD–10–PCS procedure code 0DTN4ZZ (Resection of sigmoid colon, percutaneous endoscopic approach) to MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract).

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add ICD–10–PCS procedure code 0DTN4ZZ to MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract), without modification, effective October 1, 2023 for FY 2024.

b. Open Excision of Muscle

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26735 through 26737), during the review of the cases that group to MS–DRGs 981 through 983, we noted that when ICD–10–PCS procedure codes describing the open excision of muscle are reported in conjunction with ICD–10–CM diagnosis codes in MDC 05 (Diseases and Disorders of the Circulatory System), the cases group to MS–DRGs 981 through 983. The list of 28 ICD–10–CM procedure codes reviewed, as well as their current MDC assignments, are found in the table:

ICD-10-PCS Code	Description	MDC
0KB00ZZ	Excision of head muscle, open approach	01; 08; 09; 21; 24
0KB10ZZ	Excision of facial muscle, open approach	01; 08; 09; 21; 24
0KB20ZZ	Excision of right neck muscle, open approach	01; 08; 09; 21; 24
0KB30ZZ	Excision of left neck muscle, open approach	01; 08; 09; 21; 24
0KB40ZZ	Excision of tongue, palate, pharynx muscle, open approach	01; 08; 09; 21; 24
0KB50ZZ	Excision of right shoulder muscle, open approach	01; 08; 09; 21; 24
0KB60ZZ	Excision of left shoulder muscle, open approach	01; 08; 09; 21; 24
0KB70ZZ	Excision of right upper arm muscle, open approach	01; 08; 09; 21; 24
0KB80ZZ	Excision of left upper arm muscle, open approach	01; 08; 09; 21; 24
0KB90ZZ	Excision of right lower arm and wrist muscle, open approach	01; 08; 09; 21; 24
0KBB0ZZ	Excision of left lower arm and wrist muscle, open approach	01; 08; 09; 21; 24
0KBC0ZZ	Excision of right hand muscle, open approach	08; 21; 24
0KBD0ZZ	Excision of left hand muscle, open approach	08; 21; 24
0KBF0ZZ	Excision of right trunk muscle, open approach	01; 08; 09; 21; 24
0KBG0ZZ	Excision of left trunk muscle, open approach	01; 08; 09; 21; 24
0KBH0ZZ	Excision of right thorax muscle, open approach	01; 08; 09; 21; 24
0KBJ0ZZ	Excision of left thorax muscle, open approach	01; 08; 09; 21; 24
0KBK0ZZ	Excision of right abdomen muscle, open approach	01; 08; 09; 21; 24
0KBL0ZZ	Excision of left abdomen muscle, open approach	01; 08; 09; 21; 24
0KBM0ZZ	Excision of perineum muscle, open approach	01; 08; 09; 21; 24
0KBN0ZZ	Excision of right hip muscle, open approach	01; 08; 09; 10; 21; 24
0KBP0ZZ	Excision of left hip muscle, open approach	01; 08; 09; 10; 21; 24
0KBQ0ZZ	Excision of right upper leg muscle, open approach	01; 08; 09; 21; 24
0KBR0ZZ	Excision of left upper leg muscle, open approach	01; 08; 09; 21; 24
0KBS0ZZ	Excision of right lower leg muscle, open approach	01; 08; 09; 10; 21; 24
0KBT0ZZ	Excision of left lower leg muscle, open approach	01; 08; 09; 10; 21; 24
0KBV0ZZ	Excision of right foot muscle, open approach	01; 08; 09; 10; 21; 24
0KBW0ZZ	Excision of left foot muscle, open approach	01; 08; 09; 10; 21; 24

We refer the reader to Appendix E of the ICD–10 MS–DRG Version 40.1 Definitions Manual (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/AcuteInpatientPPS/MS-DRGClassifications-and-Software*) for the MS–DRG assignment for each procedure code listed and further discussion of how each procedure code may be assigned to multiple MDCs and MS–DRGs under the IPPS.

As discussed in the proposed rule, the principal diagnosis most frequently reported with the 28 ICD–10–PCS procedure codes describing the open excision of muscle in MDC 05 is ICD–10–CM code I96 (Gangrene, not elsewhere classified). Gangrene is a condition in which body tissue dies from not getting enough blood. It can cause changes in skin color, numbness or pain, swelling, and other symptoms. The combination of a procedure code describing the open excision of muscle and ICD–10–CM diagnosis code I96 indicates open debridement of muscle for gangrene was performed.

We stated we examined claims data from the September 2022 update of the FY 2022 MedPAR file to identify the average length of stay and average costs for cases reporting a procedure code describing the open excision of muscle with a principal diagnosis in MDC 05, which are currently grouping to MS–DRGs 981 through 983, as well as all cases in MS–DRGs 981 through 983. Our findings are shown in the following table.

MS-DRGs 981-983: All Cases and Cases Reporting a Procedure Code Describing the Open Excision of Muscle and a Principal Diagnosis in MDC 05			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 981--All cases	21,139	12.6	$37,872
MS-DRG 981--Cases reporting procedure code describing the open excision of muscle and a principal diagnosis in MDC 05	362	11.7	$27,392
MS-DRG 982--All cases	9,386	5.9	$20,819
MS-DRG 982--Cases reporting procedure code describing the open excision of muscle and a principal diagnosis in MDC 05	121	7.9	$16,989
MS-DRG 983--All cases	1,782	2.6	$14,541
MS-DRG 983--Cases reporting procedure code describing the open excision of muscle and a principal diagnosis in MDC 05	6	4.7	$7,140

We then examined the MS–DRGs within MDC 05 and stated we determined that the cases reporting procedure codes describing the open excision of muscle with a principal diagnosis in MDC 05 would most suitably group to MS–DRG 264 (Other Circulatory System O.R. Procedures), which contains procedures performed on structures other than circulatory anatomy.

To determine how the resources for this subset of cases compared to cases in MS–DRG 264 as a whole, we examined the average costs and length of stay for cases in MS–DRG 264. Our findings are shown in this table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 264--All cases	6,774	9.9	$27,237

As discussed in the proposed rule, we reviewed the data and noted for this subset of cases, in the ''with MCC'' subgroup the average costs of the cases reporting procedure codes describing the open excision of muscle with a principal diagnosis in MDC 05 are slightly higher ($27,392 compared to $27,237) and the average length of stay is longer (11.7 days compared to 9.9 days) than for all cases in MS–DRGs 264, while the cases in the ''with CC'' and the ''without CC/MCC'' subgroups have lower average costs ($16,989 and $7,140 respectively compared to $27,237) and a shorter average length of stay (7.9 days and 4.7 days respectively compared to 9.9 days) than for cases in MS–DRG 264. However, we stated we believed that when a procedure code describing the open excision of muscle is reported with a principal diagnosis in MDC 05 (typically gangrene, not elsewhere classified), the procedure is related to the principal diagnosis. Because debridement, or the cutting away of dead and dying tissue, can be performed to keep gangrene from spreading, we stated a procedure code describing the open excision of muscle would be expected to be related to a principal diagnosis of gangrene, not elsewhere classified (diagnosis code I96), and it would be clinically appropriate for the procedures to group to the same MS–DRGs as the principal diagnoses. Therefore, we proposed to add the 28 procedure codes listed previously to MDC 05. Under this proposal, cases reporting a procedure code describing the open excision of muscle with a principal diagnosis of gangrene, not elsewhere classified (diagnosis code I96) in MDC 05 would group to MS–DRG 264.

Comment: Commenters supported the proposal to add the 28 ICD–10–PCS codes that describe the open excision of muscle to MDC 05 (Diseases and Disorders of the Circulatory System).

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the 28 ICD–10–PCS codes that describe the open excision of muscle listed previously to MDC 05 (Diseases and Disorders of the Circulatory System), without modification, effective October 1, 2023, for FY 2024.

c. Open Replacement of Skull With Synthetic Substitute

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26737 through 26739), during our review of the cases that group to MS–DRGs 981 through 983, we noted that when ICD–10–PCS procedure code 0NR00JZ (Replacement of skull with synthetic substitute, open approach) is reported with a principal diagnosis in MDC 09 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast), the cases group to MS–DRGs 981 through 983. The principal diagnosis most frequently reported with ICD–10–PCS procedure code 0NR00JZ in MDC 09 is ICD–10–CM code Z42.8 (Encounter for other plastic and reconstructive surgery

following medical procedure or healed injury).

ICD–10–PCS procedure code 0NR00JZ currently groups to several MDCs, which are listed in the following table.

MS-DRG Assignments for ICD-10-PCS Procedure Code 0NR00JZ		
MDC	**MS-DRG**	**Description**
01	023-024	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis
	025-027	Craniotomy and Endovascular Intracranial Procedures
03	143-145	Other Ear, Nose, Mouth and Throat O.R. Procedures
08	515-517	Other Musculoskeletal System and Connective Tissue O.R. Procedures
21	907-909	Other O.R. Procedures for Injuries
24	955	Craniotomy for Multiple Significant Trauma

As discussed in the proposed rule, we examined claims data from the September 2022 update of the FY 2022 MedPAR file to identify the average length of stay and average costs for cases reporting procedure code 0NR00JZ with a principal diagnosis in MDC 09, which are currently grouping to MS–DRGs 981 through 983, as well as all cases in MS–DRGs 981 through 983. Our findings are shown in the following table.

MS-DRGs 981-983: All Cases and Cases with Principal Diagnosis in MDC 09 and Procedure Code 0NR00JZ			
MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
MS-DRG 981--All cases	21,139	12.6	$37,872
MS-DRG 981--Cases reporting procedure code 0NR00JZ and a principal diagnosis in MDC 09	10	5.4	$34,627
MS-DRG 982--All cases	9,386	5.9	$20,819
MS-DRG 982--Cases reporting procedure code 0NR00JZ and a principal diagnosis in MDC 09	28	3.3	$21,776
MS-DRG 983--All cases	1,782	2.6	$14,541
MS-DRG 983--Cases reporting procedure code 0NR00JZ and a principal diagnosis in MDC 09	21	2.1	$23,709

We then examined the MS–DRGs within MDC 09 and determined that the cases reporting procedure code 0NR00JZ with a principal diagnosis in MDC 09 would most suitably group to MS–DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC, and without CC/MCC, respectively) given the nature of the procedure. MS–DRGs 579, 580, and 581 contain procedures assigned to MDC 09 that do not fit within the specific surgical MS–DRGs in MDC 09, which are: skin graft; skin debridement; mastectomy for malignancy; and breast biopsy, local excision, and other breast procedures.

To determine how the resources for this subset of cases compared to cases in MS–DRGs 579, 580, and 581 as a whole, we stated we examined the average costs and length of stay for cases in MS–DRGs 579, 580, and 581. Our findings are shown in this table.

MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
MS-DRG 579--All cases	3,391	11	$26,423
MS-DRG 580--All cases	5,896	5.7	$14,628
MS-DRG 581--All cases	1,831	2.6	$11,784

We reviewed the data and noted for this subset of cases, the average costs are higher and the average length of stays are shorter than for cases in MS–DRGs 579, 580, and 581. However, we stated we believed that when ICD–10–PCS procedure code 0NR00JZ is reported with a principal diagnosis in MDC 09 (typically encounter for other plastic and reconstructive surgery following medical procedure or healed injury), the

procedure is related to the principal diagnosis.

We noted in the proposed rule that open brain surgeries that require removing a portion of the skull, for indications such as brain tumor resection, hydrocephalus shunt implantation, cerebral aneurysm clipping, evacuation of a brain hemorrhage, microvascular decompression, and lobectomy, can sometimes result in a residual cranial defect. We stated we believed that would be clinically appropriate for the procedure to group to the same MS–DRGs as the principal diagnosis as procedure code 0NR00JZ can be used to describe cranial reconstruction procedures that involve applying a cranial prosthetic device to address the residual bony void and/or defect to restore the natural contours of the skull.

Therefore, we proposed to add ICD–10–PCS procedure code 0NR00JZ to MDC 09. Under this proposal, cases reporting procedure code 0NR00JZ with a principal diagnosis in MDC 09 (such as encounter for other plastic and reconstructive surgery following medical procedure or healed injury) would group to MS–DRGs 579, 580, and 581.

Comment: Most commenters supported the proposal to add ICD–10–PCS procedure code 0NR00JZ to MDC 09 (Diseases and Disorders of the Skin, Subcutaneous Tissue and Breast). However, a commenter opposed CMS' proposal. The commenter stated they did not agree and stated MS–DRGs 579, 580, and 581 are not reflective of the clinical nature of skull procedures which are more in line with cranial procedures in MDC 01 (Diseases and Disorders of the Nervous System). This commenter further requested the creation of new MS–DRGs in MDC 01 to reflect the resources utilized in the performance of these procedures.

Response: We thank the commenters for their support and feedback.

In response to the commenter that opposed the proposal, we note that ICD–10–PCS procedure code 0NR00JZ currently groups to several MDCs, which are listed in the previous table. In MDC 01 specifically, ICD–10–PCS procedure code 0NR00JZ is assigned to MS–DRG 023 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator), MS–DRG 024 (Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC), and MS–DRGs 025, 026, and 027 (Craniotomy and Endovascular Intracranial Procedures with MCC, with CC, and without CC/MCC, respectively). When ICD–10–PCS procedure code 0NR00JZ is reported with an ICD–10–CM diagnosis code assigned to MDC 01, the cases group MS–DRGs 023 through 027 depending on the circumstances of the admission. ICD–10–CM diagnosis code Z42.8 (Encounter for other plastic and reconstructive surgery following medical procedure or healed injury), however, is currently assigned to MDC 09 and would require reassignment to MDC 01 in order for these cases to group to MS–DRGs in MDC 01 as suggested by the commenter. We believe that diagnosis code Z42.8 is appropriately assigned to MDC 09 (Diseases and Disorders of the Circulatory System) as it describes encounters for other plastic and reconstructive surgery following medical procedure or healed injury. In reviewing the commenter's concerns, we note that diagnosis code Z42.8 does not describe a diagnosis or circumstance limited to affecting the nervous system. It would not be appropriate to move this diagnosis code into another MDC because it could inadvertently cause cases reporting this MDC 09 diagnosis with reconstructive procedures to be assigned to an unrelated MS–DRG. We note that whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in a MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

As discussed in the proposed rule, we note that MS–DRGs 579, 580, and 581 contain procedures assigned to MDC 09 that do not fit within the specific surgical MS–DRGs in MDC 09. We continue to believe that when ICD–10–PCS procedure code 0NR00JZ is reported with a principal diagnosis in MDC 09 (typically encounter for other plastic and reconstructive surgery following medical procedure or healed injury), the procedure is related to the principal diagnosis and that it would be clinically appropriate for the procedure to group to the same MS–DRGs as the principal diagnosis. We also continue to believe that cases reporting procedure code 0NR00JZ with a principal diagnosis in MDC 09 would most suitably group to MS–DRGs 579, 580, and 581 (Other Skin, Subcutaneous Tissue and Breast Procedures with MCC, with CC, and without CC/MCC, respectively) given the nature of the procedure.

Therefore, after consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal to add ICD–10–PCS procedure code 0NR00JZ to MDC 09 (Diseases and Disorders of the Circulatory System), without modification, effective October 1, 2023 for FY 2024.

d. Endoscopic Dilation of Ureters With Intraluminal Device

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26739 through 26740), during the review of the cases that group to MS–DRGs 987 through 989, we noted that when ICD–10–PCS procedure codes describing the endoscopic dilation of ureters with an intraluminal device are reported in conjunction with ICD–10–CM diagnosis codes in MDC 05 (Diseases and Disorders of the Circulatory System), the cases group to MS–DRGs 987 through 989. The principal diagnosis most frequently reported with ICD–10–PCS procedure codes describing the endoscopic dilation of ureters with an intraluminal device in MDC 05 is ICD–10–CM code I13.0 (Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease).

In the following tables, the ICD–10–PCS procedure codes describing the endoscopic dilation of ureters with an intraluminal device are listed, as well as their MDC and MS–DRG assignments.

ICD-10-PCS Code	Description
0T768DZ	Dilation of right ureter with intraluminal device, via natural or artificial opening endoscopic
0T778DZ	Dilation of left ureter with intraluminal device, via natural or artificial opening endoscopic
0T788DZ	Dilation of bilateral ureters with intraluminal device, via natural or artificial opening endoscopic

MS-DRG Assignments for ICD-10-PCS Codes 0T768DZ, 0T778DZ and 0T788DZ		
MDC	**MS-DRG**	**Description**
11	656-658	Kidney and Ureter Procedures for Neoplasm
	659-661	Kidney and Ureter Procedures for Non-Neoplasm
21	907-909	Other O.R. Procedures for Injuries
24	957-959	Other Procedures for Multiple Significant Trauma

As discussed in the proposed rule, we examined claims data from the September 2022 update of the FY 2022 MedPAR file to identify the average length of stay and average costs for cases reporting procedure code 0T768DZ, 0T778DZ, or 0T788DZ with a principal diagnosis in MDC 05, which are currently grouping to MS–DRGs 987 through 989, as well as all cases in MS–DRGs 987 through 989. Our findings are shown in the following table.

MS-DRGs 987-989: All Cases and Cases with Principal Diagnosis in MDC 05 and Procedure Code 0T768DZ, 0T778DZ or 0T788DZ			
MS-DRG	**Number of Cases**	**Average Length of Stay**	**Average Costs**
MS-DRG 987--All cases	7,305	11.2	$28,127
MS-DRG 987--Cases reporting procedure code 0T768DZ, 0T778DZ or 0T788DZ and a principal diagnosis in MDC 05	358	10.3	$24,657
MS-DRG 988--All cases	5,001	5.7	$14,402
MS-DRG 988--Cases reporting procedure code 0T768DZ, 0T778DZ or 0T788DZ and a principal diagnosis in MDC 05	134	4.6	$13,704
MS-DRG 989--All cases	681	3.0	$9,570
MS-DRG 989--Cases reporting procedure code 0T768DZ, 0T778DZ or 0T788DZ and a principal diagnosis in MDC 05	7	1.4	$8,729

We stated we then examined the MS–DRGs within MDC 05 and determined that the cases reporting procedure codes describing the endoscopic dilation of ureters with an intraluminal device with a principal diagnosis in MDC 05 would most suitably group to MS–DRG 264 (Other Circulatory System O.R. Procedures), which contains procedures performed on structures other than circulatory anatomy.

To determine how the resources for this subset of cases compared to cases in MS–DRG 264 as a whole, we stated we examined the average costs and length of stay for cases in MS–DRG 264. Our findings are shown in this table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 264--All cases	6,774	9.9	$27,237

As discussed in the proposed rule, we reviewed these data and noted that the average costs for this subset of cases, most of which group to MS–DRG 987, are lower than the average costs than for cases in MS–DRG 264. However, we stated we believed that when a procedure code describing the endoscopic dilation of ureters with an intraluminal device is reported with a principal diagnosis in MDC 05 (typically hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease), the procedure is related to the principal diagnosis. We noted in the proposed rule that ureteral intraluminal devices are used to relieve ureteral obstruction by passively dilating the ureter to allow urine to drain through the center of the hollow intraluminal device as well as around the device. Indications for endoscopic

ureteral intraluminal device placement include the uncomplicated ureteral obstruction due to causes such as nephrolithiasis, tumor, or retroperitoneal fibrosis, or obstruction complicated by urinary tract infection, renal insufficiency, or renal failure. As the endoscopic dilation of ureters with an intraluminal device would be expected to be related to a principal diagnosis of hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease, not elsewhere classified (diagnosis code I13.0), we stated it would be clinically appropriate for the procedures to group to the same MS–DRGs as the principal diagnoses.

Therefore, we proposed to add ICD–10–PCS procedure codes 0T768DZ, 0T778DZ, and 0T788DZ to MDC 05. Under this proposal, cases reporting procedure code 0T768DZ, 0T778DZ, or 0T788DZ with a principal diagnosis of hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease (I13.0) in MDC 05 would group to MS–DRG 264.

Comment: Most commenters supported the proposal to add ICD–10–PCS procedure codes 0T768DZ, 0T778DZ and 0T788DZ to MDC 05 (Diseases and Disorders of the Circulatory System). However, a commenter opposed CMS' proposal. The commenter stated they did not agree and stated these cases would most appropriately group to MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract).

Response: We thank the commenters for their support and feedback. In response to the commenter that opposed the proposal, we note that ICD–10–CM diagnosis code I13.0 (Hypertensive heart and chronic kidney disease with heart failure and stage 1 through stage 4 chronic kidney disease, or unspecified chronic kidney disease) is currently assigned to MDC 05 and would require reassignment to MDC 11 in order for these cases to group to MDC 11 as suggested by the commenter. As discussed in prior rulemaking (85 FR 58504), we believe that this diagnosis code is appropriately assigned to MDC 05 (Diseases and Disorders of the Circulatory System) as it describes heart failure. We continue to believe it would not be appropriate to move this diagnosis into another MDC because it could inadvertently cause cases reporting this MDC 05 diagnosis with a circulatory system procedure to be assigned to an unrelated MS–DRG. We note that whenever there is a surgical procedure reported on the claim that is unrelated to the MDC to which the case was assigned based on the principal diagnosis, it results in a MS–DRG assignment to a surgical class referred to as ''unrelated operating room procedures''.

Therefore, after consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal to add ICD–10–PCS procedure codes 0T768DZ, 0T778DZ, and 0T788DZ to MDC 05 (Diseases and Disorders of the Circulatory System), without modification, effective October 1, 2023, for FY 2024.

e. Occlusion of Splenic Artery

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26740 through 26742), during our review of the cases currently grouping to MS–DRGs 987 through 989, we noted that when ICD–10–PCS procedure codes describing the occlusion of the splenic artery are reported in conjunction with ICD–10–CM diagnosis codes in MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs and Immunologic Disorders), the cases group to MS–DRGs 987 through 989. The principal diagnosis most frequently reported with ICD–10–PCS procedure codes describing the occlusion of the splenic artery in MDC 16 is ICD–10–CM code S36.032A (Major laceration of spleen, initial encounter).

In the following tables, the ICD–10–PCS procedure codes describing the occlusion of the splenic artery are listed, as well as their MDC and MS–DRG assignments.

ICD-10-PCS Code	Description
04L40CZ	Occlusion of splenic artery with extraluminal device, open approach
04L40DZ	Occlusion of splenic artery with intraluminal device, open approach
04L40ZZ	Occlusion of splenic artery, open approach
04L43CZ	Occlusion of splenic artery with extraluminal device, percutaneous approach
04L43DZ	Occlusion of splenic artery with intraluminal device, percutaneous approach
04L43ZZ	Occlusion of splenic artery, percutaneous approach
04L44CZ	Occlusion of splenic artery with extraluminal device, percutaneous endoscopic approach
04L44DZ	Occlusion of splenic artery with intraluminal device, percutaneous endoscopic approach
04L44ZZ	Occlusion of splenic artery, percutaneous endoscopic approach

MS-DRG Assignments of the ICD-10-PCS Procedure Codes Describing the Occlusion of the Splenic Artery		
MDC	MS-DRG	Description
05	270-272	Other Major Cardiovascular Procedures
06	515-517	Other Digestive System O.R. Procedures
21	907-909	Other O.R. Procedures for Injuries
24	957-959	Other O.R. Procedures for Multiple Significant Trauma

As discussed in the proposed rule, we examined claims data from the September 2022 update of the FY 2022 MedPAR file to identify the average length of stay and average costs for cases reporting procedure codes describing the occlusion of the splenic artery with a principal diagnosis in MDC 16, which are currently grouping to MS–DRGs 987 through 989, as well as all cases in MS–DRGs 987 through 989. Our findings are shown in the following table.

MS-DRGs 987-989: All Cases and Cases with Principal Diagnosis in MDC 16 and Procedure Code Describing the Occlusion of the Splenic Artery			
MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 987--All cases	7,305	11.2	$28,127
MS-DRG 987--Cases reporting procedure code describing the occlusion of the splenic artery and a principal diagnosis in MDC 16	118	9.1	$36,334
MS-DRG 988--All cases	5,001	5.7	$14,402
MS-DRG 988--Cases reporting procedure code describing the occlusion of the splenic artery and a principal diagnosis in MDC 16	76	4.8	$21,845
MS-DRG 989--All cases	681	3.0	$9,570
MS-DRG 989--Cases reporting procedure code describing the occlusion of the splenic artery and a principal diagnosis in MDC 16	4	3.3	$25,768

We stated we then examined the MS–DRGs within MDC 16 and determined that the cases reporting a procedure code describing the occlusion of the splenic artery with a principal diagnosis in MDC 16 would most suitably group to MS–DRGs 799, 800, and 801 (Splenectomy with MCC, with CC, and without CC/MCC, respectively) given the nature of the procedure.

We note, as discussed in section II.C.1.b of the proposed rule and this final rule, using the December 2022 update of the FY 2022 MedPAR file, we analyzed how applying the NonCC subgroup criteria to all MS–DRGs currently split into three severity levels would affect the MS–DRG structure beginning in FY 2024. Findings from our analysis indicate that MS–DRGs 799, 800, and 801 as well as approximately 44 other base MS–DRGs would be subject to change based on the three-way severity level split criterion finalized in FY 2021. We refer the reader to Table 6P.10b associated with the proposed rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for the list of the 135 MS–DRGs that would potentially be subject to deletion and the list of the 86 new MS–DRGs that would potentially be created if the NonCC subgroup criteria was applied.

To determine how the resources for this subset of cases compared to cases in MS–DRGs 799, 800, and 801 as a whole, we stated we examined the average costs and length of stay for cases in MS–DRGs 799, 800, and 801. Our findings are shown in this table.

MS-DRG	Number of Cases	Average Length of Stay	Average Costs
MS-DRG 799--All cases	286	10.6	$43,368
MS-DRG 800--All cases	168	6.2	$26,498
MS-DRG 801--All cases	62	2.6	$15,248

BILLING CODE 4120–01–C

We reviewed these data and noted that the average length of stay and average costs of the subset of cases reporting a procedure code describing the occlusion of the splenic artery with a principal diagnosis in MDC 16 are more similar to those of cases in MS–DRGs 799, 800, and 801. In the proposed rule, we also noted that in cases of splenic injury, the diagnosis and prompt management of potentially life-threatening hemorrhage is the primary goal. Procedures to occlude the splenic artery, such as splenic embolization, can be performed for spleen injuries, such as lacerations, in order to manage bleeding prior to or instead of more invasive splenic procedures. We stated a procedure code describing the occlusion of the splenic artery would be expected to be related to a principal diagnosis of a major laceration of spleen, initial encounter

(diagnosis code S36.032A) and would be clinically appropriate for the procedures to group to the same MS–DRGs as the principal diagnoses.

Given the similarity in resource use between this subset of cases and cases in MS–DRGs 799, 800, and 801, and that we believed that procedure codes describing the occlusion of the splenic artery are related to principal diagnoses in MDC 16 (typically major laceration of spleen, initial encounter), we stated these cases would be more appropriately assigned to MS–DRGs 799, 800, and 801 in MDC 16 than their current assignment in MS–DRGs 987 through 989. Therefore, we proposed to add the nine procedure codes listed in the previous table that describe the occlusion of the splenic artery to MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs and Immunologic Disorders) in MS–DRGs 799, 800, and 801. Under this proposal, cases reporting a principal diagnosis of a major laceration of spleen, initial encounter (S36.032A) with a procedure describing the occlusion of the splenic artery would group to MS–DRGs 799, 800, and 801.

As discussed in the proposed rule, during the review of this issue, we noted that a splenectomy is a surgical operation involving removal of the spleen, however the GROUPER logic list for MS–DRGs 799, 800, and 801 does not exclusively contain procedure codes that describe the removal of the spleen. We refer the reader to the ICD–10 MS–DRG Version 40.1 Definitions Manual (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/AcuteInpatientPPS/MS-DRGClassifications-and-Software*) for complete documentation of the GROUPER logic for MS–DRGs 799, 800, and 801. Therefore, we also proposed to revise the titles of MDC 16 MS–DRGs 799, 800, and 801 from ''Splenectomy with MCC, with CC, and without CC/MCC, respectively'' to ''Splenic Procedures with MCC, with CC, and without CC/MCC, respectively'' to better reflect the assigned procedures.

Comment: Commenters supported the proposal to add the nine ICD–10–PCS codes that describe the occlusion of the splenic artery to MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs and Immunologic Disorders) and to revise the titles of MDC 16 MS–DRGs 799, 800, and 801. A commenter stated they appreciated CMS' analysis and requested that CMS provide ongoing analysis of other splenic diseases and disorders that group to MS–DRGs 987, 988, and 989 when reported with ICD–10–PCS procedure codes.

Response: We appreciate the commenters' support. We note that consistent with our process as described previously in this section, we do conduct an annual review of procedures producing assignment to MS–DRGs 981 through 983 (Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) or MS–DRGs 987 through 989 (Non-Extensive O.R. Procedure Unrelated to Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) on the basis of volume, by procedure, to see if it would be appropriate to move cases reporting these procedure codes out of these MS–DRGs into one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls.

After consideration of the public comments we received, we are finalizing our proposal to add the nine procedure codes listed in the previous table that describe the occlusion of the splenic artery to MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs and Immunologic Disorders) in MS–DRGs 799, 800, and 801, without modification, effective October 1, 2023, for FY 2024. We are also finalizing our proposal to revise the titles of MDC 16 MS–DRGs 799, 800, and 801 from ''Splenectomy with MCC, with CC, and without CC/MCC, respectively'' to ''Splenic Procedures with MCC, with CC, and without CC/MCC, respectively'' to better reflect the assigned procedures for FY 2024.

In addition to the internal review of procedures producing assignment to MS–DRGs 981 through 983 or MS–DRGs 987 through 989, as discussed in the proposed rule, we also consider requests that we receive to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989 to determine if it would be appropriate to add procedure codes to one of the surgical MS–DRGs for the MDC into which the principal diagnosis falls or to move the principal diagnosis to the surgical MS–DRGs to which the procedure codes are assigned. We stated we did not receive any requests suggesting reassignment.

We also review the list of ICD–10–PCS procedures that, when in combination with their principal diagnosis code, result in assignment to MS–DRGs 981 through 983, or 987 through 989, to ascertain whether any of those procedures should be reassigned from one of those two groups of MS–DRGs to the other group of MS–DRGs based on average costs and the length of stay. We look at the data for trends such as shifts in treatment practice or reporting practice that would make the resulting MS–DRG assignment illogical. If we find these shifts, we would propose to move cases to keep the MS–DRGs clinically similar or to provide payment for the cases in a similar manner.

Additionally, we also consider requests that we receive to examine cases found to group to MS–DRGs 981 through 983 or MS–DRGs 987 through 989 to determine if it would be appropriate for the cases to be reassigned from one of the MS–DRG groups to the other. In the proposed rule, we stated that based on the results of our review of the claims data from the September 2022 update of the FY 2022 MedPAR file we did not identify any cases for reassignment. We also stated we did not receive any requests suggesting reassignment. Therefore, for FY 2024 we did not propose to move any cases reporting procedure codes from MS–DRGs 981 through 983 to MS–DRGs 987 through 989 or vice versa.

Comment: Commenters expressed support for CMS' proposal to not move any cases reporting procedure codes from MS–DRGs 981 through 983 to MS–DRGs 987 through 989 or vice versa.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing, without modification, our proposal to not move any cases reporting procedure codes from MS–DRGs 981 through 983 to MS–DRGs 987 through 989 or vice versa.

11. Operating Room (O.R.) and Non-O.R. Procedures

a. Background

Under the IPPS MS–DRGs (and former CMS DRGs), we have a list of procedure codes that are considered operating room (O.R.) procedures. Historically, we developed this list using physician panels that classified each procedure code based on the procedure and its effect on consumption of hospital resources. For example, generally the presence of a surgical procedure which required the use of the operating room would be expected to have a significant effect on the type of hospital resources (for example, operating room, recovery room, and anesthesia) used by a patient, and therefore, these patients were considered surgical. Because the claims data generally available do not precisely indicate whether a patient was taken to the operating room, surgical patients were identified based on the procedures that were performed. Generally, if the procedure was not expected to require the use of the operating room, the

patient would be considered medical (non-O.R.).

Currently, each ICD–10–PCS procedure code has designations that determine whether and in what way the presence of that procedure on a claim impacts the MS–DRG assignment. First, each ICD–10–PCS procedure code is either designated as an O.R. procedure for purposes of MS–DRG assignment (''O.R. procedures'') or is not designated as an O.R. procedure for purposes of MS–DRG assignment (''non-O.R. procedures''). Second, for each procedure that is designated as an O.R. procedure, that O.R. procedure is further classified as either extensive or non-extensive. Third, for each procedure that is designated as a non-O.R. procedure, that non-O.R. procedure is further classified as either affecting the MS–DRG assignment or not affecting the MS–DRG assignment. We refer to these designations that do affect MS–DRG assignment as ''non O.R. affecting the MS–DRG.'' For new procedure codes that have been finalized through the ICD–10 Coordination and Maintenance Committee meeting process and are proposed to be classified as O.R. procedures or non-O.R. procedures affecting the MS–DRG, we recommend the MS–DRG assignment which is then made available in association with the proposed rule (Table 6B.—New Procedure Codes) and subject to public comment. These proposed assignments are generally based on the assignment of predecessor codes or the assignment of similar codes. For example, we generally examine the MS–DRG assignment for similar procedures, such as the other approaches for that procedure, to determine the most appropriate MS–DRG assignment for procedures proposed to be newly designated as O.R. procedures. As discussed in section II.C.13 of the preamble of this final rule, we are making Table 6B.—New Procedure Codes—FY 2024 available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.* We also refer readers to the ICD–10 MS–DRG Version 40.1 Definitions Manual at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html* for detailed information regarding the designation of procedures as O.R. or non-O.R. (affecting the MS–DRG) in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index.

In the FY 2020 IPPS/LTCH PPS proposed rule, we stated that, given the long period of time that has elapsed since the original O.R. (extensive and non-extensive) and non-O.R. designations were established, the incremental changes that have occurred to these O.R. and non-O.R. procedure code lists, and changes in the way inpatient care is delivered, we plan to conduct a comprehensive, systematic review of the ICD–10–PCS procedure codes. This will be a multiyear project during which we will also review the process for determining when a procedure is considered an operating room procedure. For example, we may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is now available in the ICD–10 claims data. We refer readers to the discussion regarding the designation of procedure codes in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38066) where we stated that the determination of when a procedure code should be designated as an O.R. procedure has become a much more complex task. This is, in part, due to the number of various approaches available in the ICD–10–PCS classification, as well as changes in medical practice. While we have typically evaluated procedures on the basis of whether or not they would be performed in an operating room, we believe that there may be other factors to consider with regard to resource utilization, particularly with the implementation of ICD–10.

We discussed in the FY 2020 IPPS/LTCH PPS proposed rule that as a result of this planned review and potential restructuring, procedures that are currently designated as O.R. procedures may no longer warrant that designation, and conversely, procedures that are currently designated as non-O.R. procedures may warrant an O.R. type of designation. We intend to consider the resources used and how a procedure should affect the MS–DRG assignment. We may also consider the effect of specific surgical approaches to evaluate whether to subdivide specific MS–DRGs based on a specific surgical approach. We stated we plan to utilize our available MedPAR claims data as a basis for this review and the input of our clinical advisors. As part of this comprehensive review of the procedure codes, we also intend to evaluate the MS–DRG assignment of the procedures and the current surgical hierarchy because both of these factor into the process of refining the ICD–10 MS–DRGs to better recognize complexity of service and resource utilization.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58540 through 58541), we provided a summary of the comments we had received in response to our request for feedback on what factors or criteria to consider in determining whether a procedure is designated as an O.R. procedure in the ICD–10–PCS classification system for future consideration. In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25158) and final rule (86 FR 44891), and FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28174) and final rule (87 FR 48862), we stated that in consideration of the ongoing PHE, we believed it may be appropriate to allow additional time for the claims data to stabilize prior to selecting the timeframe to analyze for this review.

We stated in the FY 2024 IPPS/LTCH PPS proposed rule, we continue to believe additional time is necessary as we continue to develop our process and methodology. Therefore, we stated we will provide more detail on this analysis and the methodology for conducting this review in future rulemaking.

Comment: Commenters supported CMS' plan to continue to conduct the comprehensive, systematic review of the ICD–10–PCS codes and to evaluate their current O.R. and non-O.R. designations. These commenters expressed that they were supportive of CMS' decision to continue to develop the processes and methodology over the upcoming years and to allow the claims data to become more stable. Other commenters stated they agreed that a restructuring of these designations may be warranted as a result of the expanded detail in the ICD–10–PCS classification and changes in medical practice and that they look forward to commenting on CMS' data analysis and methodology in the future.

Response: We thank the commenters for their support.

Comment: Other commenters stated that designation of O.R. versus non-O.R. may no longer be the most critical differentiator between resource-intensive procedures for MS–DRG purposes. These commenters stated presently, there are increasingly complex and resource-intensive procedures performed by hospitals that do not involve the use of an operating room. A commenter stated that the administration of certain complex biologics or radiotherapies are not surgical procedures at all, yet these procedures represent significant resource utilization by hospitals. Another commenter stated that biplane radiology interventional suites and cardiac catheterization labs used for procedures such as mechanical thrombectomy or endovascular coiling for aneurysms can utilize more advanced equipment and supplies than a basic operating room with minimal installed equipment. This commenter

encouraged CMS to recognize that the revolution in medical procedures in recent years may render O.R. vs. non-O.R. a less critical distinction in driving payment policy.

As part of the broader and continuing conversation about future MS–DRG assignments and designations for these procedures and therapies, a commenter encouraged CMS to consider how other factors influence resource utilization, and recommended CMS consider questions such as whether:

- Certain types of procedures and therapies make up a substantial percentage of the costs within a particular MS–DRG?
- There is an average amount of cost within the relative weight of a MS–DRG that represents significant resource utilization and complexity?
- Certain types of interventions, such as the administration of certain complex drugs/biologics or therapies (for example, radiation therapy), that demonstrate higher costs and resource utilization, warrant consideration of a designation as an O.R. procedure or another equivalent designation? Should these therapies be considered for another type of distinction apart from medical and surgical MS–DRGs—for example, a third category, or be treated like CCs/MCCs?
- What percentage of cases within an MS–DRG receive outlier payment?

Response: CMS appreciates the commenters' feedback and recommendations as to what factors to consider in evaluating O.R. versus non-O.R. designations. As stated previously, we have typically evaluated procedures on the basis of whether or not they would be performed in an operating room. We agree with commenters and believe that there may be other factors to consider with regard to resource utilization, particularly with the implementation of ICD–10. As discussed in the proposed rule, we are exploring alternatives on how we may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is available in the ICD–10 claims data. As we continue to consider the feedback we have received to help inform the development of our process and methodology, we will provide more detail in future rulemaking. We encourage the public to continue to submit comments on any other factors to consider in our refinement efforts to recognize and differentiate consumption of resources for the ICD–10 MS–DRGs for consideration.

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26744 through 26746), we received the following requests regarding changing the designation of specific ICD–10–PCS procedure codes from non-O.R. to O.R. procedures. In this section of this rule, as we did in the proposed rule, we summarize these requests and address why we are not considering a change to the designation of these codes at this time and, further, respond to the public comments we received regarding these requests.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 48863), we discussed a request we received to change the designation of all ICD–10–PCS codes that describe diagnostic and therapeutic percutaneous endoscopic procedures performed on thoracic and abdominal organs, from non-O.R. to O.R. In the FY 2023 final rule, we stated that we believed additional time was needed to fully examine the numerous ICD–10–PCS codes in the classification that describe diagnostic and therapeutic percutaneous endoscopic procedures performed on thoracic and abdominal organs. We stated that rather than evaluating the procedure codes describing diagnostic and therapeutic percutaneous endoscopic procedures performed on thoracic and abdominal organs in isolation, analysis should be performed for this subset of procedure codes across the MS–DRGs, as part of the comprehensive procedure code review. We also stated that as a component of our broader comprehensive procedure code review, we are also reviewing the process for determining when a procedure is considered an operating room procedure.

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule, we again received a request to change the designation of all ICD–10–PCS procedure codes that describe diagnostic and therapeutic percutaneous endoscopic procedures performed on thoracic and abdominal organs, from non-O.R. to O.R from the same requestor. According to the requestor, diagnostic and therapeutic thoracoscopic and laparoscopic procedures on thoracic and abdominal organs are always performed in the operating room under complex general anesthesia. The requestor did not provide a specific list of the procedure codes that describe diagnostic and therapeutic percutaneous endoscopic procedures performed on thoracic and abdominal organs and are currently designated as non-O.R. for CMS for review, to narrow the scope of this repeat request.

As we have signaled in prior rulemaking, the designation of an O.R. procedure encompasses more than the physical location of the hospital in which the procedure may be performed; in other words, the performance of a procedure in an operating room is not the sole determining factor we consider as we examine the designation of a procedure in the ICD–10–PCS classification system. We also examine if, and in what way, the performance of the procedure affects the resource expenditure in those admissions in the inpatient setting, in addition to examining other clinical factors such as procedure complexity, and need for anesthesia administration as well as other types of sedation. As also stated in prior rulemaking, we plan to conduct a comprehensive, systematic review of the ICD–10–PCS procedure codes. We stated in the proposed rule that rather than evaluating this subset of procedure codes in isolation, as any potential change to the designation of these codes requires significant review, we continue to believe that analysis of the designation of the procedure codes describing diagnostic and therapeutic percutaneous endoscopic procedures performed on thoracic and abdominal organs should be performed across the MS–DRGs, as part of the comprehensive procedure code review. Therefore, for the reasons discussed, we did not propose any changes to the designation of all ICD–10–PCS procedure codes that describe diagnostic and therapeutic percutaneous endoscopic procedures performed on thoracic and abdominal organs, from non-O.R. to O.R. for FY 2024. As diagnostic and therapeutic percutaneous endoscopic procedures performed on thoracic and abdominal organs differ greatly in terms of clinical factors such as procedure complexity and resource utilization, we invited feedback on what factors or criteria to consider in determining whether a procedure should be designated as an O.R. procedure in the ICD–10–PCS classification system when evaluating this subset of procedure codes as part of the comprehensive procedure code review. Feedback and other suggestions may be submitted by October 20, 2023, and directed to the new electronic intake system, Medicare Electronic Application Request Information System™ (MEARIS™), discussed in section II.C.1.b of the preamble of the proposed rule at: *https://mearis.cms.gov/public/home.*

We will provide more detail on the comprehensive procedure code review and the methodology for conducting this review in future rulemaking.

Comment: Most commenters agreed with CMS' proposal to maintain the designation of all ICD–10–PCS procedure codes that describe

diagnostic and therapeutic percutaneous endoscopic procedures performed on thoracic and abdominal organs for FY 2024.

Response: We appreciate the commenters' support.

Comment: A commenter stated that while they did not dispute that there may be numerous ICD–10–PCS codes that describe procedures performed using a percutaneous endoscopic approach, they believed that this list could be narrowed down substantially by considering only codes describing procedures performed on thoracic and abdominal organs. This commenter stated that even with a smaller list utilizing the criteria they suggested, they were unable to envision a thoracoscopic or laparoscopic procedure that would not require general anesthesia and be performed in an operating room and urged CMS to designate any ICD–10–PCS procedure code that describes a thoracic or abdominal procedure using a percutaneous endoscopic approach as an operating room procedure.

Response: We thank the commenter for their feedback. We also appreciate the commenter's suggestion, however, as stated in the proposed rule, and in prior rulemaking, we plan to conduct a comprehensive, systematic review of the ICD–10–PCS procedure codes. We continue to believe that rather than evaluating the procedure codes describing diagnostic and therapeutic percutaneous endoscopic procedures performed on thoracic and abdominal organs in isolation, analysis should be performed for this subset of procedure codes across the MS–DRGs, as part of the comprehensive procedure code review. As a component of our broader comprehensive procedure code review, we are also reviewing the process for determining when a procedure is considered an operating room procedure. For example, we may restructure the current O.R. and non-O.R. designations for procedures by leveraging the detail that is available in the ICD–10 claims data. Therefore, after consideration of the public comments we received, and for the reasons discussed, we are not making changes in this final rule to the designation of all ICD–10–PCS procedure codes that describe diagnostic and therapeutic percutaneous endoscopic procedures performed on thoracic and abdominal organs, from non-O.R. to O.R.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44892 through 44895), CMS finalized the proposal to remove the 22 codes that describe the open drainage of subcutaneous tissue and fascia listed in the following table from the ICD–10 MS–DRGs Version 39 Definitions Manual in Appendix E—Operating Room Procedures and Procedure Code/MS–DRG Index as O.R. procedures. Under this finalization, these procedures no longer impact MS–DRG assignment.

ICD-10-PCS Code	Description
0J900ZZ	Drainage of scalp subcutaneous tissue and fascia, open approach
0J910ZZ	Drainage of face subcutaneous tissue and fascia, open approach
0J940ZZ	Drainage of right neck subcutaneous tissue and fascia, open approach
0J950ZZ	Drainage of left neck subcutaneous tissue and fascia, open approach
0J960ZZ	Drainage of chest subcutaneous tissue and fascia, open approach
0J970ZZ	Drainage of back subcutaneous tissue and fascia, open approach
0J980ZZ	Drainage of abdomen subcutaneous tissue and fascia, open approach
0J990ZZ	Drainage of buttock subcutaneous tissue and fascia, open approach
0J9B0ZZ	Drainage of perineum subcutaneous tissue and fascia, open approach
0J9C0ZZ	Drainage of pelvic region subcutaneous tissue and fascia, open approach
0J9D0ZZ	Drainage of right upper arm subcutaneous tissue and fascia, open approach
0J9F0ZZ	Drainage of left upper arm subcutaneous tissue and fascia, open approach
0J9G0ZZ	Drainage of right lower arm subcutaneous tissue and fascia, open approach
0J9H0ZZ	Drainage of left lower arm subcutaneous tissue and fascia, open approach
0J9J0ZZ	Drainage of right hand subcutaneous tissue and fascia, open approach
0J9K0ZZ	Drainage of left hand subcutaneous tissue and fascia, open approach
0J9L0ZZ	Drainage of right upper leg subcutaneous tissue and fascia, open approach
0J9M0ZZ	Drainage of left upper leg subcutaneous tissue and fascia, open approach
0J9N0ZZ	Drainage of right lower leg subcutaneous tissue and fascia, open approach
0J9P0ZZ	Drainage of left lower leg subcutaneous tissue and fascia, open approach
0J9Q0ZZ	Drainage of right foot subcutaneous tissue and fascia, open approach
0J9R0ZZ	Drainage of left foot subcutaneous tissue and fascia, open approach

In the FY 2022 final rule, we noted that the designation of the 22 procedure codes that describe the open drainage of subcutaneous tissue and fascia as O.R. procedures was a result of a replication error in transitioning to ICD–10. This replication error led to ICD–10–PCS procedure codes that describe the open drainage of subcutaneous tissue and fascia being listed as comparable translations for ICD–9–CM code 83.09 (Other incision of soft tissue), which was designated as a non-extensive O.R. procedure under the ICD–9–CM MS–DRGs Version 32, as opposed to being listed as comparable translations for ICD–9–CM code 86.04 (Other incision with drainage of skin and subcutaneous tissue), which was designated as a non-O.R. procedure under the ICD–9–CM MS–DRGs Version 32. We stated in the FY 2022 final rule that designating the 22 procedure codes that describe the open drainage of subcutaneous tissue

and fascia as non-O.R. procedures would result in a more accurate replication of the comparable procedure, under the ICD–9–CM MS–DRGs Version 32 which was 86.04, not 83.09 and is more aligned with current shifts in treatment practices.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 48863 through 48865), we discussed a request we received to re-examine this change in designation. In the FY 2023 final rule, we did not make changes to the designation of these codes and stated that procedure codes that describe the open drainage of subcutaneous tissue and fascia do not reflect the technical complexity or resource intensity in comparison to other procedures that are designated as O.R. procedures. We stated that our analysis of the September 2021 update of the FY 2021 MedPAR file reflected that when the procedure codes that describe the open drainage of the subcutaneous tissue and fascia are reported, approximately 70% of the MS–DRGs assigned are classified as surgical MS–DRGs which indicated at least one procedure code designated as an O.R. procedure was also reported in these cases. We also stated that the non-O.R. designation of the 22 procedure codes that describe the open drainage of subcutaneous tissue and fascia as finalized in the FY 2022 final rule better reflects the associated technical complexity and hospital resource use of these procedures.

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule, we again received a request to re-examine the designation of the 22 procedure codes that describe the open drainage of subcutaneous tissue and fascia as non-O.R. procedures from the same requestor. The requestor stated that CMS should return the designation of these procedure codes to O.R. procedures to reflect the operating room resources utilized in the performance of these procedures and suggested that CMS analyze claims containing the 22 ICD–10–PCS codes to determine the percentage that contained timed O.R. charges billed under revenue code 360. The requestor also indicated there was confusion about the coded claims data as presented in the FY 2023 final rule. The requestor noted that the 22 procedure codes that describe the open drainage of subcutaneous tissue and fascia were designated as O.R. procedures in FY 2021 so it was unclear to the requestor why the table displayed by CMS associated with the FY 2023 final rule contained assignment to medical MS–DRGs.

First, in response to the question about the coded claims data as presented in the FY 2023 final rule, in the proposed rule we noted as generally stated in the preamble of the proposed rule each year, the diagnosis and procedure codes from the specified FY MedPAR claims data are grouped through the applicable version of the proposed FY GROUPER. The FY 2021 MedPAR claims data presented in the FY 2023 final rule were regrouped using the proposed FY 2023 MS–DRG classifications. In the proposed FY 2023 GROUPER, the procedure codes that describe the open drainage of subcutaneous tissue and fascia no longer impacted MS–DRG assignment and that is the reason why assignments to medical DRGs were displayed in Table 6P.1f associated with the FY 2023 final rule.

Next, we referred the reader to Table 6P.8a associated with the proposed rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for the data analysis of cases reporting the 22 procedure codes that describe the open drainage of subcutaneous tissue and fascia in the September 2022 update of the FY 2022 MedPAR file. We noted that within each MDC, the MS–DRGs are divided into medical and surgical categories. In general, surgical MS–DRGs are further defined based on the precise surgical procedure performed while the medical MS–DRGs are further defined based on the precise principal diagnosis for which a patient was admitted to the hospital. In Table 6P.8a associated with the proposed rule, column B displays the category of each MS–DRG in MS–DRG GROUPER Version 40.1. The letter M is used to designate a medical MS–DRG and the letter P is used to designate a surgical MS–DRG. In the proposed rule, we stated that overall, the data continues to indicate that the open drainage of subcutaneous tissue and fascia was not the underlying reason for, or main driver of, resource utilization for those cases. As shown in the table, when the procedure codes that describe the open drainage of the subcutaneous tissue and fascia are reported, approximately 55% of the MS–DRGs assigned are classified as surgical MS–DRGs, which indicates at least one procedure code designated as an O.R. procedure was also reported in these cases. We referred the reader to the ICD–10 MS–DRG Version 40.1 Definitions Manual (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRGClassifications-and-Software*) for complete documentation of the GROUPER logic for the listed MS–DRGs.

We stated we reviewed these data and continued to believe that procedure codes that describe the open drainage of subcutaneous tissue and fascia do not reflect the technical complexity or resource intensity in comparison to other procedures that are designated as O.R. procedures. As stated in prior rulemaking, procedures describing the open drainage of subcutaneous tissue and fascia can now be safely performed in the outpatient setting and when performed during a hospitalization, it is typically in conjunction with another O.R. procedure. In cases where procedures describing open drainage of subcutaneous tissue and fascia are the only procedures performed in an admission, the admission is quite likely due to need for IV antibiotics as opposed to the need for operating room resources in an inpatient setting.

We also noted that, as stated in prior rulemaking (84 FR 42069), in deciding whether to propose to make further modifications to the MS–DRGs for particular circumstances brought to our attention, we do not consider the reported revenue codes. Rather, as stated previously, we consider whether the resource consumption and clinical characteristics of the patients with a given set of conditions are significantly different than the remaining patients represented in the MS–DRG. We stated we do this by evaluating the ICD–10–CM diagnosis and/or ICD–10–PCS procedure codes that identify the patient conditions, procedures, and the relevant MS–DRG(s) that are the subject of a request. Specifically, for this request, we analyzed the cases reporting the ICD–10–PCS procedure codes that describe the open drainage of subcutaneous tissue and fascia. We then evaluated patient care costs using average costs and average lengths of stay (based on the MedPAR data) to detect if, and in what way, the performance of these procedures affects the resource expenditure in those admissions in the inpatient setting, in addition to examining other clinical factors such as procedure complexity and need for anesthesia administration as well as other types of sedation.

We stated in the proposed rule, we continue to believe that the non-O.R. designation of the 22 procedure codes that describe the open drainage of subcutaneous tissue and fascia as finalized in the FY 2022 final rule better reflects the associated technical complexity and hospital resource use of these procedures. Therefore, for the reasons discussed, we did not propose changes to the designation of the 22

codes that describe the open drainage of subcutaneous tissue and fascia listed in the previous table for FY 2024.

Comment: Most commenters agreed with CMS' proposal to maintain the designation of the 22 codes that describe the open drainage of subcutaneous tissue and fascia for FY 2024.

Response: We appreciate the commenters' support.

Comment: A commenter opposed the non-O.R. designation of the 22 procedure codes that describe the open drainage of subcutaneous tissue and fascia as finalized in the FY 2022 final rule. This commenter stated that they disagree that these 22 ICD–10–PCS procedures do not typically require the resources of an O.R. when occurring in the inpatient setting and stated they do not believe these procedures can be safely performed in a non-O.R. setting. The commenter stated in the FY 2018 IPPS proposed rule, these same 22 ICD–10–PCS codes were identified, and a commenter opposed the proposal to re-designate these codes at that time. In response to the issues raised by this commenter, CMS determined in the FY 2018 IPPS final rule that it was appropriate to maintain the designation of the 22 procedure codes. This commenter further stated they find CMS' rulemaking on this issue between FY 2018 and FY 2024 to be contradictory and believe that the rationale to maintain these 22 codes as O.R. procedures remains the same and that there is no safe way to effectively drain an infection involving the subfascial plane without the resources of an operating room.

Response: We thank the commenter for their feedback. We reviewed the commenters' concerns and continue to state that treatment practices have continued to shift since FY 2018 rulemaking. As stated in the proposed rule, and in prior rulemaking, in response to similar comments, we believe procedures describing the open drainage of subcutaneous tissue and fascia can now be safely performed in the outpatient setting and when performed during a hospitalization, it is typically in conjunction with another O.R. procedure. In cases where procedures describing open drainage of subcutaneous tissue and fascia are the only procedures performed in an admission, the admission is quite likely due to need for IV antibiotics as opposed to the need for operating room resources in an inpatient setting. As shown in Table 6P.8a associated with the proposed rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*), when the procedure codes that describe the open drainage of the subcutaneous tissue and fascia are reported, approximately 55% of the MS–DRGs assigned are classified as surgical MS–DRGs which indicates at least one procedure code designated as an O.R. procedure was also reported in these cases.

As discussed in the proposed rule and earlier in this section, we have signaled in prior rulemaking that the designation of an O.R. procedure encompasses more than the physical location of the hospital room in which the procedure may be performed; in other words, the performance of a procedure in an operating room is not the sole determining factor we consider as we examine the designation of a procedure in the ICD–10–PCS classification system. We continue to believe that procedure codes that describe the open drainage of subcutaneous tissue and fascia do not reflect the technical complexity or resource intensity in comparison to other procedures that are designated as O.R. procedures. The non-O.R. designation of the 22 procedure codes that describe the open drainage of subcutaneous tissue and fascia as finalized in the FY 2022 final rule better reflects the associated technical complexity and hospital resource use of these procedures.

Therefore, after consideration of the public comments we received, and for the reasons discussed, we are not making changes in this final rule to the designation of the 22 codes that describe the open drainage of subcutaneous tissue and fascia listed in the previous table for FY 2024.

12. Changes to the MS–DRG Diagnosis Codes for FY 2024

a. Background of the CC List and the CC Exclusions List

Under the IPPS MS–DRG classification system, we have developed a standard list of diagnoses that are considered CCs. Historically, we developed this list using physician panels that classified each diagnosis code based on whether the diagnosis, when present as a secondary condition, would be considered a substantial complication or comorbidity. A substantial complication or comorbidity was defined as a condition that, because of its presence with a specific principal diagnosis, would cause an increase in the length-of-stay by at least 1 day in at least 75 percent of the patients. However, depending on the principal diagnosis of the patient, some diagnoses on the basic list of complications and comorbidities may be excluded if they are closely related to the principal diagnosis. In FY 2008, we evaluated each diagnosis code to determine its impact on resource use and to determine the most appropriate CC subclassification (NonCC, CC, or MCC) assignment. We refer readers to sections II.D.2. and 3. of the preamble of the FY 2008 IPPS final rule with comment period for a discussion of the refinement of CCs in relation to the MS–DRGs we adopted for FY 2008 (72 FR 47152 through 47171).

b. Overview of Comprehensive CC/MCC Analysis

In the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159), we described our process for establishing three different levels of CC severity into which we would subdivide the diagnosis codes. The categorization of diagnoses as a MCC, a CC, or a NonCC was accomplished using an iterative approach in which each diagnosis was evaluated to determine the extent to which its presence as a secondary diagnosis resulted in increased hospital resource use. We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of our approach. Since the comprehensive analysis was completed for FY 2008, we have evaluated diagnosis codes individually when assigning severity levels to new codes and when receiving requests to change the severity level of specific diagnosis codes.

We noted in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235 through 19246) that with the transition to ICD–10–CM and the significant changes that have occurred to diagnosis codes since the FY 2008 review, we believed it was necessary to conduct a comprehensive analysis once again. Based on this analysis, we proposed changes to the severity level designations for 1,492 ICD–10–CM diagnosis codes and invited public comments on those proposals. As summarized in the FY 2020 IPPS/LTCH PPS final rule, many commenters expressed concern with the proposed severity level designation changes overall and recommended that CMS conduct further analysis prior to finalizing any proposals. After careful consideration of the public comments we received, as discussed further in the FY 2020 final rule, we generally did not finalize our proposed changes to the severity designations for the ICD–10–CM diagnosis codes, other than the changes to the severity level designations for the diagnosis codes in category Z16 (Resistance to antimicrobial drugs) from a NonCC to a CC. We stated that postponing adoption

of the proposed comprehensive changes in the severity level designations would allow further opportunity to provide additional background to the public on the methodology utilized and clinical rationale applied across diagnostic categories to assist the public in its review. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42150 through 42152) for a complete discussion of our response to public comments regarding the proposed severity level designation changes for FY 2020.

As discussed in the FY 2021 IPPS/LTCH PPS proposed rule (85 FR 32550), to provide the public with more information on the CC/MCC comprehensive analysis discussed in the FY 2020 IPPS/LTCH PPS proposed and final rules, CMS hosted a listening session on October 8, 2019. The listening session included a review of this methodology utilized to mathematically measure the impact on resource use. We refer readers to *https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums/Downloads/10082019ListingSessionTrasncriptandQandAsandAudioFile.zip* for the transcript and audio file of the listening session. We also refer readers to *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html* for the supplementary file containing the mathematical data generated using claims from the FY 2018 MedPAR file describing the impact on resource use of specific ICD–10–CM diagnosis codes when reported as a secondary diagnosis that was made available for the listening session.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58550 through 58554), we discussed our plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data as discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235) and the application of nine guiding principles and plan to present the findings and proposals in future rulemaking. The nine guiding principles are as follows:

- Represents end of life/near death or has reached an advanced stage associated with systemic physiologic decompensation and debility.
- Denotes organ system instability or failure.
- Involves a chronic illness with susceptibility to exacerbations or abrupt decline.
- Serves as a marker for advanced disease states across multiple different comorbid conditions.
- Reflects systemic impact.
- Post-operative/post-procedure condition/complication impacting recovery.
- Typically requires higher level of care (that is, intensive monitoring, greater number of caregivers, additional testing, intensive care unit care, extended length of stay).
- Impedes patient cooperation or management of care or both.
- Recent (last 10 years) change in best practice, or in practice guidelines and review of the extent to which these changes have led to concomitant changes in expected resource use.

We refer readers to the FY 2021 IPPS/LTCH PPS final rule for a complete discussion of our response to public comments regarding the nine guiding principles.

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25175 through 25180), as another interval step in our comprehensive review of the severity designations of ICD–10–CM diagnosis codes, we requested public comments on a potential change to the severity level designations for ''unspecified'' ICD–10–CM diagnosis codes that we were considering adopting for FY 2022. Specifically, we noted we were considering changing the severity level designation of ''unspecified'' diagnosis codes to a NonCC where there are other codes available in that code subcategory that further specify the anatomic site. As summarized in the FY 2022 IPPS/LTCH PPS final rule, many commenters expressed concern with the potential severity level designation changes overall and recommended that CMS delay any possible change to the designation of these codes to give hospitals and their physicians time to prepare. After careful consideration of the public comments we received, we maintained the severity level designation of the ''unspecified'' diagnosis codes currently designated as a CC or MCC where there are other codes available in that code subcategory that further specify the anatomic site for FY 2022. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 44916 through 44926) for a complete discussion of our response to public comments regarding the potential severity level designation changes. Instead, for FY 2022, we finalized a new Medicare Code Editor (MCE) code edit for ''unspecified'' codes, effective with discharges on and after April 1, 2022. We stated we believe finalizing this new edit would provide additional time for providers to be educated while not affecting the payment the provider is eligible to receive. We refer the reader to section II.D.14.e. of the FY 2022 IPPS/LTCH PPS final rule (86 FR 44940 through 44943) for the complete discussion.

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48866), we stated that as the new unspecified code edit became effective beginning with discharges on and after April 1, 2022, we believed it was appropriate to not propose to change the designation of any ICD–10–CM diagnosis codes, including the unspecified codes that are subject to the ''Unspecified Code'' edit, as we continue our comprehensive CC/MCC analysis to allow interested parties the time needed to become acclimated to the new edit.

In the FY 2023 IPPS/LTCH proposed rule (87 FR 28177 through 28181), we also requested public comments on how the reporting of diagnosis codes in categories Z55–Z65 might improve our ability to recognize severity of illness, complexity of illness, and/or utilization of resources under the MS–DRGs. Consistent with the Administration's goal of advancing health equity for all, including members of historically underserved and under-resourced communities, as described in the President's January 20, 2021 Executive Order 13985 on ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' [7] we stated we were also interested in receiving feedback on how we might otherwise foster the documentation and reporting of the diagnosis codes describing social and economic circumstances to more accurately reflect each health care encounter and improve the reliability and validity of the coded data including in support of efforts to advance health equity.

We noted that social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.[8] The subset of Z codes that describe the social determinants of health are found in categories Z55–Z65 (Persons with potential health hazards related to socioeconomic and psychosocial circumstances). These codes describe a range of issues related—but not limited—to education and literacy, employment, housing, ability to obtain adequate amounts of food or safe drinking water, and occupational

[7] *Available at: https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[8] *Available at: https://health.gov/healthypeople/objectives-and-data/social-determinants-health.*

exposure to toxic agents, dust, or radiation.

We received numerous public comments that expressed a variety of views on our comment solicitation, including many comments that were supportive, and others that offered specific suggestions for our consideration in future rulemaking. Many commenters applauded CMS' efforts to encourage documentation and reporting of SDOH diagnosis codes given the impact that social risks can have on health outcomes. These commenters stated that it is critical that physicians, other health care professionals, and facilities recognize the impact SDOH have on the health of their patients. Many commenters also stated that the most immediate and important action CMS could take to increase the use of SDOH Z codes is to finalize the evidence-based ''Screening for Social Drivers of Health'' and ''Screen Positive Rate for Social Drivers of Health'' measures proposed to be adopted in the Hospital Inpatient Quality Reporting (IQR) Program. In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49202 through 49220), CMS finalized the ''Screening for Social Drivers of Health'' and ''Screen Positive Rate for Social Drivers of Health'' measures in the Hospital Inpatient Quality Reporting (IQR) Program. We refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 48867 through 48872) for the complete discussion of the public comments received regarding the request for information on SDOH diagnosis codes as well as the following section of this final rule for our proposed changes to the severity level designation for certain diagnosis codes that describe homelessness for FY 2024, as well as our finalization of that proposal.

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule, we continue to solicit feedback regarding the guiding principles, as well as other possible ways we can incorporate meaningful indicators of clinical severity. We have made available on the CMS website updated impact on resource use files so that the public can review the mathematical data for the impact on resource use generated using claims from the FY 2019 through the FY 2022 MedPAR files. The link to these files is posted on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.* When providing additional feedback or comments, we encourage the public to provide a detailed explanation of how applying a suggested concept or principle would ensure that the severity designation appropriately reflects resource use for any diagnosis code. We also continue to be interested in receiving feedback on how we might otherwise foster the documentation and reporting of the most specific diagnosis codes supported by the available medical record documentation and clinical knowledge of the patient's health condition to more accurately reflect each health care encounter and improve the reliability and validity of the coded data.

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26748), for new diagnosis codes approved for FY 2024, consistent with our annual process for designating a severity level (MCC, CC, or NonCC) for new diagnosis codes, we first review the predecessor code designation, followed by review and consideration of other factors that may be relevant to the severity level designation, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis or treatment of the condition. We noted that this process does not automatically result in the new diagnosis code having the same designation as the predecessor code. We refer the reader to section II.C.13 of this final rule for the discussion of the finalized changes to the ICD–10–CM and ICD–10–PCS coding systems for FY 2024.

c. Changes to Severity Levels

As discussed earlier in this section, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28177 through 28181), we requested public comments on how the reporting of diagnosis codes in categories Z55–Z65 might improve our ability to recognize severity of illness, complexity of illness, and/or utilization of resources under the MS–DRGs. We sought comment on which specific SDOH Z codes were most likely to influence (that is, increase) hospital resource utilization related to inpatient care, including any supporting information that correlates inpatient hospital resource use to specific SDOH Z codes. In the FY 2023 proposed rule, we stated CMS believed a potential starting point for discussion was consideration of the SDOH Z diagnosis codes describing homelessness as homelessness can be reasonably expected to have an impact on hospital utilization.

To further examine the diagnosis codes that describe SDOH, in the FY 2023 proposed rule, we stated we reviewed the data on the impact on resource use for diagnosis code Z59.0 (Homelessness) when reported as a secondary diagnosis to facilitate discussion for the purposes of the comment solicitation. We noted that prior to FY 2022, homelessness was one of the more frequently reported codes that describe social determinants of health. We also noted that effective FY 2022, the subcategory was expanded and now included codes Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), and code Z59.02 (Unsheltered homelessness).

We also displayed the impact on resource use data generated using claims from the FY 2019 MedPAR file, FY 2020 MedPAR file and the FY 2021 MedPAR file, respectively, for the diagnosis code that describes homelessness as a NonCC. We noted there was no data for codes Z59.01 (Sheltered homelessness) and code Z59.02 (Unsheltered homelessness) as these codes became effective on October 1, 2021. We stated that when examining diagnosis code Z59.0 (Homelessness) in FY 2019 and FY 2020, the data suggested that when homelessness is reported as a secondary diagnosis, the resources involved in caring for these patients are more aligned with a CC than a NonCC or an MCC. However, in FY 2021, the data suggested that the resources involved in caring for patients experiencing homelessness are more aligned with a NonCC severity level than a CC or an MCC severity level. We stated we were uncertain if the data from FY 2021, in particular, reflected fluctuations that may be a result of the public health emergency or even reduced hospitalizations of certain conditions. We also stated we were uncertain if homelessness may be underreported when there is not an available field on the claim when other diagnoses are reported instead.

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule, we again reviewed the data on the impact on resource use for the ICD–10–CM SDOH Z codes that describe homelessness, currently designated as NonCC, when reported as a secondary diagnosis. The following table reflects the impact on resource use data generated using claims from the September 2022 update of the FY 2022 MedPAR file. We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47159) for a complete discussion of our historical approach to mathematically evaluate the extent to which the presence of an ICD–10–CM code as a secondary diagnosis resulted in increased hospital resource use, and the explanation of the columns in the table.

ICD-10-CM Code[a]	Description[b]	Tota1 Count[c]	Cnt1[d]	C1[e]	Cnt2[f]	C2[g]	Cnt3[h]	C3[i]
Z59.00	Homelessness, unspecified	27,148	3,485	1.75	12,608	2.19	11,055	3.10
Z59.01	Sheltered homelessness	6,862	821	2.00	3,027	2.24	3,014	3.08
Z59.02	Unsheltered homelessness	4,394	453	2.12	1,948	2.35	1,993	3.10

[a] This column is the secondary diagnosis code (SDX).
[b] This column is the title of the SDX.
[c] The total count of discharge claims with the SDX.
[d] Count of discharge claims with the SDX but with no other SDX or with all other SDX a NonCC.
[e] "C1" impact on resource use of the SDX for discharge claims in "Cnt1".
[f] Count of discharge claims with the SDX and with at least one other SDX that is a CC but none that is an MCC.
[g] "C2" impact on resource use of the SDX for discharge claims in "Cnt2".
[h] Count of discharge claims with the SDX and with at least one other SDX that is a MCC.
[i] "C3" impact on resource use of the SDX for discharge claims in "Cnt3".

The table shows that the C1 is 1.75 for ICD–10–CM diagnosis code Z59.00, 2.00 for ICD–10–CM diagnosis code Z59.01, and 2.12 for ICD–10–CM diagnosis code Z59.02. A value close to 2.0 in column C1 suggests that the secondary diagnosis is more aligned with a CC than a NonCC. Because the C1 values in the table are generally close to 2, the data suggest that when these three SDOH Z codes are reported as a secondary diagnosis, the resources involved in caring for a patient experiencing homelessness support increasing the severity level from a NonCC to a CC. In the proposed rule, we noted the table also shows that the C2 finding was 2.19 for ICD–10–CM diagnosis code Z59.00, 2.24 for ICD–10–CM diagnosis code Z59.01, and 2.35 for ICD–10–CM diagnosis code Z59.02. A C2 value close to 2.0 suggests the condition is more like a CC than a NonCC, but not as significant in resource usage as an MCC when there is at least one other secondary diagnosis that is a CC but none that is an MCC. Because the C2 values in the table are generally close to 2, we stated that the data again suggested that when these three SDOH Z codes are reported as a secondary diagnosis, the resources involved in caring for a patient experiencing homelessness support increasing the severity level from a NonCC to a CC.

As discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58550 through 58554), following the listening session on October 8, 2019, we reconvened an internal workgroup comprised of clinicians, consultants, coding specialists and other policy analysts to identify guiding principles to apply in evaluating whether changes to the severity level designations of diagnoses are needed and to ensure the severity designations appropriately reflect resource use based on review of the claims data, as well as consideration of relevant clinical factors (for example, the clinical nature of each of the secondary diagnoses and the severity level of clinically similar diagnoses) and improve the overall accuracy of the IPPS payments. In considering the nine guiding principles identified by the workgroup, as summarized previously, to illustrate how they might be applied in evaluating changes to the severity designations of diagnosis codes, in the FY 2024 IPPS/LTCH PPS proposed rule we noted that homelessness is a circumstance that can impede patient cooperation or management of care or both. In addition, patients experiencing homelessness can require a higher level of care by needing an extended length of stay. As discussed in the FY 2023 proposed rule, healthcare needs for patients experiencing homelessness (sheltered,[9] unsheltered,[10] or unspecified) may be associated with increased resource utilization.[11] Healthcare needs for patients experiencing homelessness may be associated with increased resource utilization compared to other patients due to difficulty finding discharge destinations to meet the patient's multifaceted needs which can result in longer inpatient stays and can have financial impacts for hospitals.[12] Longer hospital stays for these patients [13] can also be associated with increased costs because patients experiencing homelessness are less able to access care at early stages of illness, and also may be exposed to communicable disease and harsh climate conditions, resulting in more severe and complex symptoms by the time they are admitted to hospitals, potentially leading to worse health outcomes. Patients experiencing homelessness can also be disproportionately affected by mental health diagnoses and issues with substance use disorders. In addition, patients experiencing homelessness may have limited or no access to prescription medicines or over-the-counter medicines, including adequate locations to store medications away from the heat or cold,[14] and studies have shown difficulties adhering to medication regimens among persons experiencing homelessness.[15]

Therefore, after considering the C1 and C2 ratings of the three ICD–10–CM diagnosis codes that describe

[9] "Sheltered homelessness" refers to people experiencing homelessness who were found in emergency shelters, safe havens, transitional housing, or other temporary settings. Department of Housing and Urban Development (HUD) Press Release No. 22–022, *https://www.hud.gov/press/press_releases_media_advisories/hud_no_22_022#:~:text=HUD%20Releases%202021%20Annual%20Homeless%20Assessment%20Report%20Part%201,-Report%20Suggests%20that&text=%E2%80%9CSheltered%20homelessness%E2%80%9D%20refers%20to%20people,housing%2C%20or%20other%20temporary%20settings* (accessed October 2022).

[10] Unsheltered homelessness refers to "a primary nighttime residence that is a public or private place not designed for or ordinarily used as a regularly sleeping accommodation for human beings, including a car, park, abandoned building, bus or train station, airport, or camping ground." HUD. 2011. HEARTH Homeless Definition Final Rule, 24 CFR 578.3, *https://www.govinfo.gov/content/pkg/FR-2011-12-05/pdf/2011-30942.pdf* (accessed October 2022).

[11] Koh HK, O'Connell JJ. Improving Health Care for Homeless People. JAMA. 2016;316(24):2586–2587. doi:10.1001/jama.2016.18760.

[12] Canham SL, Custodio K, Mauboules C, Good C, Bosma H. Health and Psychosocial Needs of Older Adults Who Are Experiencing Homelessness Following Hospital Discharge. Gerontologist. 2020 May 15;60(4):715–724. doi: 10.1093/geront/gnz078. PMID: 31228238. *https://pubmed.ncbi.nlm.nih.gov/31228238/.*

[13] Hwang SW, Weaver J, Aubry T. Hospital costs and length of stay among homeless patients admitted to medical, surgical, and psychiatric services. Med Care. 2011;49:350–354. *https://journals.lww.com/lww-medicalcare/Fulltext/2019/01000/Trends,_Causes,_and_Outcomes_of_Hospitalizations.4.aspx.*

[14] Sun R (Agency for Healthcare Research and Quality (AHRQ)), Karaca Z (AHRQ), Wong HS (AHRQ). Characteristics of Homeless Individuals Using Emergency Department Services in 2014. Healthcare Cost and Utilization Project (HCUP) Statistical Brief #229. October 2017. Agency for Healthcare Research and Quality, Rockville, MD. *www.hcup-us.ahrq.gov/reports/statbriefs/sb229-Homeless-ED-Visits-2014.pdf.*

[15] Coe, Antoinette B. Coe et al. "Medication Adherence Challenges Among Patients Experiencing Homelessness in a Behavioral Health Clinic. *https://journals.lww.com/lww-medicalcare/Fulltext/2019/01000/Trends,_Causes,_and_Outcomes_of_Hospitalizations.4.aspx.*

homelessness and consideration of the nine guiding principles, we proposed to change the severity level designation for diagnosis codes Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), and Z59.02 (Unsheltered homelessness) from NonCC to CC for FY 2024. As discussed in the FY 2023 IPPS/LTCH PPS final rule, if SDOH Z codes are not consistently reported in inpatient claims data, our methodology utilized to mathematically measure the impact on resource use, as described previously, may not adequately reflect what additional resources were expended by the hospital to address these SDOH circumstances in terms of requiring clinical evaluation, extended length of hospital stay, increased nursing care or monitoring or both, and comprehensive discharge planning. In the proposed rule, we stated we also expect that SDOH Z code reporting may continue to increase for a number of reasons, for example, newer SDOH screening performed as a result of new quality measures in the Hospital Inpatient Quality Reporting program. We may consider proposed changes for other SDOH codes in the future based on our analysis of the impact on resource use, per our methodology, as previously described, and consideration of the guiding principles. We further stated we also continue to be interested in receiving feedback on how we might otherwise foster the documentation and reporting of the diagnosis codes describing social and economic circumstances to more accurately reflect each health care encounter and improve the reliability and validity of the coded data including in support of efforts to advance health equity.

Feedback and other suggestions may be submitted by October 20, 2023 and directed to the electronic intake system, Medicare Electronic Application Request Information System™ (MEARIS™) at: *https://mearis.cms.gov/public/home*.

Comment: Commenters expressed overwhelming support for our proposal to change the severity level designation for diagnosis codes Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), and Z59.02 (Unsheltered homelessness) from NonCC to CC for FY 2024. These commenters stated this proposal acknowledges the impact of homelessness as a social determinant of health, its implications for resource utilization, and its costs to healthcare providers in effectively addressing the healthcare needs of Medicare beneficiaries experiencing homelessness. A commenter stated they especially appreciate thoughtful policies that are data-driven and intended to bridge the gap of compensation for providers who have been tirelessly caring for underserved populations. Another commenter stated that this change will confer enhanced financial resources to safety net hospitals, which care for a disproportionate number of patients impacted by health-related social risk factors. A commenter specifically stated that they see this proposal as a watershed moment as it is the first time CMS will be linking social determinants of health to payment in traditional Medicare. Commenters stated that a change to the severity level designation of the three diagnosis codes that describe homelessness from NonCC to CC may increase voluntary reporting of these circumstances, incentivize treating the whole patient, while enabling CMS to assess homelessness-related impacts on illness severity, care complexity, and hospital utilization to drive meaningful evaluation of the association between these Z codes and outcomes. A few commenters stated that based on their own analysis, homelessness has an effect on resource utilization on par with other diagnoses currently designated as MCCs but stated changing the designation to a CC is a logical and necessary step.

Response: We thank the commenters for their support.

Comment: While commending CMS' efforts, many commenters noted an operational concern in that currently only 25 diagnoses are captured on the institutional claim form. Commenters stated that documenting and reporting the social and economic circumstances patients may be experiencing may require a substantial number of SDOH Z codes and stated that this could lead to the crowding out of other diagnosis codes that also need to be captured on the institutional claim form for both payment and quality measures. A commenter stated that the ''Screening for Social Drivers of Health'' and ''Screen Positive Rate for Social Drivers of Health'' measures in the Hospital Inpatient Quality Reporting (IQR) Program, finalized in the FY 2023 IPPS/LTCH final rule, will result in the need to include additional Z codes on the claim to represent the findings of the SDOH screenings, further limiting the space available. Commenters stated that given the number of fields available to report diagnosis codes, it would be helpful if CMS would instruct hospitals on how to prioritize the use of SDOH diagnosis codes to ensure that all the medical diagnoses that govern mortality and readmission rates are also captured. A few commenters suggested that CMS evaluate the potential to expand the number of diagnosis codes that can be submitted, or alternatively, design a separate way to report the Z codes on the claim form, separate and distinct from the fields for the diagnosis codes.

Response: We thank the commenters for their feedback. We note that any proposed changes to the institutional claim form would need to be submitted to the National Uniform Billing Committee (NUBC) for consideration as the NUBC develops and maintains the Uniform Billing (UB) 04 data set and form. The NUBC is a Data Content Committee named in the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and is composed of a diverse group of interested parties representing providers, health plans, designated standards maintenance organizations, public health organizations, and vendors.

Comment: Some commenters requested that CMS further explore other SDOH diagnosis codes that could impact hospital resource use. These commenters encouraged CMS to examine other SDOH Z codes that describe circumstances such as food insecurity, lack of adequate food and drinking water, extreme poverty, lack of transportation, inadequate housing environmental temperature, and problems related to employment, physical environment, social environment, upbringing, primary support group, literacy, economic circumstances, and psychosocial circumstances to determine the hospital resource utilization related to addressing these factors and to analyze whether these SDOH Z codes should be considered for severity designation changes in future rulemaking as well. Other commenters also pointed to conditions outside of the SDOH Z codes in categories Z55–Z65 such as: medical debt, malnutrition, delirium due to a known physiological condition, elder abuse and neglect, contact with and (suspected) exposure to hazards in the physical environment, personal history of falling, personal history of adult physical and sexual abuse, awaiting organ transplant status, and underdosing of medication regimens as examples of other areas where fostering better documentation and reporting, and considering severity designation changes in future rulemaking, could improve health outcomes.

Response: We appreciate the feedback. We will examine these suggestions and determine if there are other diagnoses codes, including diagnosis codes that describe SDOH, that should also be considered further. We will consider these diagnosis codes

for changes to severity level designations, using a combination of mathematical analysis of claims data and the application of nine guiding principles, as we continue our comprehensive CC/MCC analysis and will provide more detail in future rulemaking.

Comment: While supporting the proposal to designate the three ICD–10–CM diagnosis codes describing homelessness as CCs, some commenters expressed concern with the perceived diminished value that designating homelessness as a CC when reported as a secondary diagnosis may have, due to the expansion of the criteria for subdividing a base MS–DRG into a three-way split. These commenters stated the application of the NonCC subgroup criteria as demonstrated by the MS–DRG changes associated with Table 6P.10—Potential MS–DRG Changes with Application of the NonCC Subgroup Criteria and Detailed Data Analysis—FY 2024, associated with the proposed rule, appears to frequently not recognize the need for a severity level of CC by eliminating many ''with CC'' and ''without CC/MCC'' MS–DRGs, meaning there is a potential for fewer MS–DRGs to be impacted by the presence of homelessness as a CC. The commenters further stated that if there are a limited number of MS–DRGs impacted by the presence of a CC, the change of the severity designation of these three diagnosis codes will not accomplish the desired documentation and reporting goals.

Response: We appreciate the commenters' feedback and concern. We concur with commenters that the application of the NonCC subgroup criteria to existing MS–DRGs currently subdivided by a three-way severity level split going forward may result in modifications to certain MS–DRGs that are currently split into three severity levels and potentially result in MS–DRGs that are proposed to be split into two severity levels. As discussed in section II.C.1.b of the proposed rule, we identified four base MS–DRGs currently subdivided with a three-way severity level split that result in the potential creation of a single, base MS–DRG. We refer the reader to Table 6P.10b associated with the proposed rule (which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*) for the list of the 135 MS–DRGs that would be subject to deletion and the list of the 86 new MS–DRGs that would potentially be created if the NonCC subgroup criteria were applied.

In response to the commenters who expressed concern that changes to the underlying MS–DRG structure would have the greatest impacts with respect to particular MS–DRGs, as noted in prior rulemaking, we note that generally, changes to the MS–DRG classifications and related policies under the IPPS that are implemented on an annual basis, including any potential MS–DRG updates to be considered for a future proposal in connection with application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split, would also involve a redistribution of cases, which would impact the relative weights, and, thus, the payment rates proposed for particular types of cases. As discussed in the FY 2021 final rule (85 FR 58446), we believe that applying these criteria to the NonCC subgroup of existing MS–DRGs with a three-way severity level split would better reflect resource stratification and also promote stability in the relative weights by avoiding low volume counts for the NonCC level MS–DRGs. We refer the reader to section II.C.1.b. of the preamble of this final rule for related discussion regarding our finalization of the expansion of the criteria to include the NonCC subgroup and our finalization of the proposal to continue to delay application of the NonCC subgroup criteria to existing MS–DRGs with a three-way severity level split.

Comment: A commenter stated that even though they applaud CMS' efforts to recognize the underreporting of SDOH, they recommended only changing the designation of diagnosis codes Z59.01 (Sheltered homelessness) and Z59.02 (Unsheltered homelessness) from NonCC to CC. This commenter stated that if the proposed change to the severity designation of diagnosis code Z59.00 (Homelessness, unspecified) is finalized, they envisioned payment oversight agencies would question its significance and effect on resource utilization due to the ''unspecified'' code description, especially if code Z59.00 is the only secondary diagnosis code designated as a CC on the claim.

Response: We thank the commenter for their feedback. We reviewed the commenter's concern and note that whether the patient is experiencing sheltered, unsheltered, or unspecified homelessness, the patient may still have limited or no access to prescription medicines or over-the-counter medicines, including adequate locations to store medications away from the heat or cold, and have difficulties adhering to medication regimens. We continue to believe that patients experiencing homelessness (regardless of type) may be less able to access care at early stages of illness, and also may be exposed to communicable disease and harsh climate conditions, resulting in more severe and complex symptoms by the time they are admitted to hospitals, potentially leading to worse health outcomes. If SDOH Z codes are consistently reported in inpatient claims data, our methodology utilized to mathematically measure the impact on resource use may more adequately reflect what additional resources were expended by the hospital to address these SDOH circumstances in terms of requiring clinical evaluation, extended length of hospital stay, increased nursing care or monitoring or both, and comprehensive discharge planning and we can reexamine these severity designations in future rulemaking.

Comment: Some commenters thanked CMS for its continued interest in receiving feedback on documentation and reporting of the ICD–10–CM diagnosis SDOH Z codes, yet stated there continue to be many challenges for clinicians in documenting SDOH, such as the lack of knowledge surrounding these codes, the time and burden associated with adding them to a patient's problem list, and the perceived inability to do anything with the information. Other commenters stated assigning codes for SDOH can be a time-consuming and labor-intensive process, as many electronic health records (EHRs) do not have pathways to add a Z code to the problem or diagnosis list. These commenters stated prioritizing provider education on the reporting of Z codes and offering support mechanisms, including the use of incentives, would significantly improve the acquisition of SDOH data, as such data is essential in helping health systems better anticipate needs and help vulnerable patients receive support at both the individual and population levels. Another commenter stated that given the administrative and operational challenges for providers associated with capturing SDOH data, they recommended CMS delay implementation of the change in severity level designation of diagnosis codes Z59.00, Z59.01, and Z59.02 by one year so that providers may continue to adapt their processes and workflows to properly capture the homelessness Z codes. This commenter stated that although the proposed change would not require additional work for providers beyond reporting the codes, the act of reporting itself is still a broad change to hospital coding practices and electronic health record (EHR) use that

they believe deserves additional time for provider adoption.

Response: We appreciate the feedback. We note that the ICD–10–CM Official Guidelines for Coding and Reporting have been regularly revised to provide additional guidance as it relates to diagnosis codes describing social determinants of health diagnosis. Specifically, Section I.C.21.c.17 of the ICD–10–CM Official Guidelines for Coding and Reporting were updated:

- Effective October 1, 2021, to clarify that code assignment may be based on medical record documentation from clinicians involved in the care of the patient who are not the patient's provider and that patient self-reported documentation may be used to assign codes for social determinants of health, as long as the patient self-reported information is signed-off by and incorporated into the medical record by either a clinician or provider;
- Effective October 1, 2022, to clarify that SDOH codes should be assigned only when the documentation specifies that the patient has an associated problem or risk factor; and
- Effective April 1, 2023, to provide more guidance on reporting SDOH and to provide more examples to facilitate the capture of these data.

We encourage the commenters to review the Official ICD–10–CM Coding Guidelines, which can be found on the CDC website at: *https://www.cdc.gov/nchs/icd/icd10.htm*. The American Hospital Association (AHA)'s *Coding Clinic for ICD–10–CM/PCS* publication has provided further clarification on the appropriate documentation and use of Z codes to enable hospitals to incorporate them into their processes. The AHA also offers a range of tools and resources for hospitals, health systems and clinicians to address the social needs of their patients. We believe these updates and resources will help alleviate the concerns expressed by these commenters. As one of the four Cooperating Parties for ICD–10, we will continue to collaborate with the AHA to provide guidance for coding problems or risk factors related to SDOH through the AHA's *Coding Clinic for ICD–10–CM/PCS* publication and to review the ICD–10–CM Coding Guidelines to determine where further clarifications may be made.

In response to commenters that state there continue to be many challenges for clinicians in documenting SDOH, such as the time and burden associated with adding them to a patient's problem list, and state that many electronic health records (EHRs) do not have pathways to add a Z code to the problem or diagnosis list, the Office of the Assistant Secretary for Planning and Evaluation (ASPE), the principal advisor to the Secretary of the U.S. Department of Health and Human Services, conducted interviews with six electronic health records (EHRs) vendors with large market shares in both ambulatory and inpatient settings to investigate the development of software products that allow health care providers to identify and address patients SDOH in health care settings. The findings of the study indicate commercial vendors appear to be ready to collaboratively discuss policy solutions, such as standards or guidelines with each other, health care systems, and government agencies in order to further promote integration of SDOH data into the standard of care for all health systems.[16] We further note that on April 18, 2023, the Office of the National Coordinator proposed updated certification standards (USCDI v3) that would, if finalized, require certified EHR vendors to include four SDOH data elements: SDOH Assessment, Goals, Interventions, Problems/Health Concerns.[17]

In response to the suggestion that CMS delay implementation of the change to the severity level designation of diagnosis codes Z59.00, Z59.01, and Z59.02 by one year so that providers may continue to adapt their processes and workflows to properly capture the diagnosis codes describing homelessness, we reviewed the commenters' concern and do not agree that a delay is necessary or appropriate. As discussed in the proposed rule, and previously in this section, when examining the data on the impact on resource use for the ICD–10–CM SDOH Z codes that describe homelessness from the FY 2019, FY 2020, and FY 2022 MedPAR files, the data suggested that when homelessness is reported as a secondary diagnosis, the resources involved in caring for these patients are more aligned with a CC than a NonCC. After considering the C1 and C2 ratings of the three ICD–10–CM diagnosis codes that describe homelessness and consideration of the nine guiding principles, we believe changing the severity level designation for diagnosis codes Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), and Z59.02 (Unsheltered homelessness) from NonCC to CC at this time to be prudent, without the need for further delay.

Therefore, after consideration of the public comments received, we are finalizing changes to the severity levels for diagnosis codes Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), and Z59.02 (Unsheltered homelessness), from NonCC to CC for FY 2024, without modification. In addition, these diagnosis codes are reflected in Table 6J.1—Additions to the CC List—FY 2024 associated with this final rule and available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*. We refer the reader to section II.C.13 of the preamble of the proposed rule and this final rule for further information regarding Table 6J.1.

We again thank commenters for sharing their views and their willingness to support CMS in these efforts. We will take the commenters' feedback into consideration in future policy development. We hope and expect that this finalization will foster the increased documentation and reporting of the diagnosis codes describing social and economic circumstances and serve as an example for providers that when they document and report Z codes, CMS can further examine the claims data and consider future changes to the designation of these codes when reported as a secondary diagnoses. CMS will continue to monitor and evaluate the reporting of the diagnosis codes describing social and economic circumstances, including diagnosis codes Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness), and Z59.02 (Unsheltered homelessness).

Additionally, as discussed in the FY 2024 IPPS/LTCH PPS proposed rule, we received a request to change the severity level designations of three ICD–10–CM diagnosis codes. The requestor suggested the severity level of ICD–10–CM diagnosis code K76.72 (Hepatic encephalopathy) be changed from NonCC to CC or MCC; N14.11 (Contrast-induced nephropathy) be changed from NonCC to CC; and S06.2XAA (Diffuse traumatic brain injury with loss of consciousness status unknown, initial encounter) be changed from CC to MCC.

In the proposed rule, we noted that these three diagnosis codes became effective with discharges on and after October 1, 2022 (FY 2023), and the current claims data from the September 2022 update of the FY 2022 MedPAR file did not yet reflect these new diagnosis codes. The proposed and finalized severity level designations for

[16] Freij M, Dullabh P, Lewis S, Smith SR, Hovey L, Dhopeshwarkar R. Incorporating Social Determinants of Health in Electronic Health Records: Qualitative Study of Current Practices Among Top Vendors. JMIR Med Inform. 2019 Jun 7;7(2):e13849. doi: 10.2196/13849. PMID: 31199345; PMCID: PMC6592390. *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/185561/NORCSDH.pdf.*

[17] 88 FR 23746 (*https://www.federalregister.gov/d/2023-07229/p-318*).

these ICD–10–CM diagnosis codes were displayed in Table 6A- New Diagnosis Codes (associated with the FY 2023 proposed rule and final rule and are available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*). As discussed earlier in this section, for new diagnosis codes approved for each fiscal year, consistent with our annual process for designating a severity level (MCC, CC, or NonCC) for new diagnosis codes, in establishing the severity level of these codes, we first reviewed the predecessor code designation, followed by review and consideration of other factors that may be relevant to the severity level designation, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis or treatment of the condition.

Specifically, the predecessor code for K76.72 (Hepatic encephalopathy) was diagnosis code K72.90 (Hepatic failure, unspecified without coma), which is designated as a NonCC. We stated when we reviewed and considered the factors as described previously, we did not believe that the resources required for hepatic encephalopathy exceeded the resources required for patients with hepatic failure, unspecified without coma as both conditions require treatment to rid the body of toxins. Therefore, our proposed and finalized severity level designation for hepatic encephalopathy was also a NonCC for FY 2023. Similarly, the predecessor code for N14.11 (Contrast-induced nephropathy) was diagnosis code N14.1 (Nephropathy induced by other drugs, medicaments and biological substances), which was designated as a NonCC. After review and consideration of the factors as described previously, we did not believe that the resources required for contrast-induced nephropathy exceeded the resources required for patients with nephropathy induced by other drugs, medicaments and biological substances, as code N14.11 was created as an expansion of the subcategory to identify contrast dyes as the substance causing nephropathy. Before the implementation of N14.11, the diagnosis was identified with code N14.1. Therefore, our proposed and finalized severity level designation for contrast-induced nephropathy was also a NonCC. Lastly, the predecessor code for S06.2XAA (Diffuse traumatic brain injury with loss of consciousness status unknown, initial encounter) was diagnosis code S06.2X9A (Diffuse traumatic brain injury with loss of consciousness of unspecified duration, initial encounter), which is designated as a CC. When we reviewed and considered the factors as described previously, we did not believe that the resources required for diffuse traumatic brain injury with loss of consciousness status unknown, initial encounter exceeded the resources required for diffuse traumatic brain injury with loss of consciousness of unspecified duration, initial encounter, therefore our proposed and finalized severity level designation for diffuse traumatic brain injury with loss of consciousness status unknown, initial encounter was also a CC.

As stated in prior rulemaking (85 FR 58560), generally, the proposed severity level ultimately depends on clinical judgement and, where the data is available, the empirical analysis of the additional resources associated with the secondary diagnosis. The impact of the secondary diagnosis is dependent on the principal diagnosis reported, with which it is associated. If the secondary diagnosis is reported primarily with a principal diagnosis that reflects serious illness with treatment complexity, then the marginal contribution of the secondary diagnosis to the overall resource use may actually be relatively small. We stated in the proposed rule we continue to believe that in the absence of claims data, the severity designation of these three codes as established in FY 2023 rulemaking is appropriate.

We further stated we believed that claims data reflecting the reporting of these new diagnosis codes are needed for analysis prior to proposing changes to these three diagnosis codes. As stated earlier in this section, we plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data and the application of nine guiding principles. We stated we believed it was appropriate to consider these requests in connection with our continued comprehensive CC/MCC analysis in future rulemaking, using the available claims data, rather than proposing to change the designation of these individual ICD–10–CM diagnosis codes in the absence of such data at this time. We will consider these individual requests received for changes to severity level designations as we continue our comprehensive CC/MCC analysis and will provide more detail in future rulemaking.

Comment: Commenters stated that they support CMS' decision not to propose to change the severity level designation of diagnosis codes K76.72 (Hepatic encephalopathy), N14.11 (Contrast-induced nephropathy) and S06.2XAA (Diffuse traumatic brain injury with loss of consciousness status unknown, initial encounter) at this time and to consider these requests in connection with our continued comprehensive CC/MCC analysis in future rulemaking. A commenter specifically stated they appreciate CMS moving cautiously with changes that could cause considerable upheaval during this time of unprecedented stress on hospitals and encouraged CMS to continue careful assessment of significant changes in the future. However, another commenter expressed concern that CMS continues to not be able to undertake a comprehensive analysis of the severity designation of the diagnosis codes in the ICD–10–CM classification. The commenter stated they believed that the nation is being negatively impacted since, in their opinion, some diagnoses currently designated as an MCC (for example severe malnutrition) do not require the resources inherent to a MCC whereas others that do (for example cardiac tamponade) are not designated as such. This commenter further stated it would be helpful if CMS made a proposed list of severity level designation changes available along with the impact on resource use files generated using claims from the FY 2019 through the FY 2022 MedPAR files that have been made publicly available on the CMS website.

Response: We thank the commenters for their support and appreciate the feedback. With respect to CMS not being able to undertake a comprehensive analysis, we note that in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19235 through 19246) we stated that with the transition to ICD–10–CM and the significant changes that have occurred to diagnosis codes since the FY 2008 review, we believed it was necessary to conduct a comprehensive analysis once again and therefore proposed changes to the severity level designations for 1,492 ICD–10–CM diagnosis codes. As summarized in the FY 2020 IPPS/LTCH PPS final rule, after careful consideration of the public comments we received in response, we generally did not finalize our proposed changes to the severity designations for the ICD–10–CM diagnosis codes, other than the changes to the severity level designations for the diagnosis codes in category Z16- (Resistance to antimicrobial drugs) from a NonCC to a CC. We stated that postponing adoption of the proposed comprehensive changes in the severity level designations would allow further opportunity to provide additional background to the public on the methodology utilized and clinical

rationale applied across diagnostic categories to assist the public in its review.

Since that time, CMS has taken interval steps to continue a comprehensive CC/MCC analysis. First, CMS hosted a listening session on October 8, 2019, to review the methodology utilized to mathematically measure the impact on resource use. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58550 through 58554), we discussed our plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data and the application of nine guiding principles. In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25175 through 25180), as another interval step in our comprehensive review of the severity designations of ICD–10–CM diagnosis codes, we requested public comments on a potential change to the severity level designations for ''unspecified'' ICD–10–CM diagnosis codes that we were considering adopting for FY 2022. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44940 through 44943), instead of changing the severity level designations of the ''unspecified'' ICD–10–CM diagnosis codes identified, we finalized a new Medicare Code Editor (MCE) code edit for ''unspecified'' codes, effective with discharges on and after April 1, 2022. We stated we believed finalizing this new edit would provide additional time for providers to be educated while not affecting the payment the provider is eligible to receive. As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48866), as the new unspecified edit became effective beginning with discharges on and after April 1, 2022, we believed it was appropriate to not propose to change the designation of any ICD–10–CM diagnosis codes, including the unspecified codes that are subject to the ''Unspecified Code'' edit, to allow interested parties the time needed to become acclimated to the new edit.

In the FY 2023 IPPS/LTCH proposed rule (87 FR 28177 through 28181), we requested public comments on how the reporting of diagnosis codes in categories Z55–Z65 might improve our ability to recognize severity of illness, complexity of illness, and/or utilization of resources under the MS–DRGs. In addition, we have provided updated impact on resource use files so that the public can review the mathematical data for the impact on resource use generated using claims from the FY 2018, FY 2019, FY 2020, FY 2021 and the FY 2022 MedPAR files, respectively at *https://www.cms.gov/Medicare/MedicareFee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software.html*.

Considering the potential impact of implementing a significant number of severity designation changes, and in light of the public health emergency (PHE) that was occurring concurrently during much of this timeframe, we believe these interval steps were appropriate as we plan to continue a comprehensive CC/MCC analysis, using a combination of mathematical analysis of claims data and the application of nine guiding principles. We continue to solicit comments regarding the nine guiding principles, as well as other possible ways we can incorporate meaningful indicators of clinical severity. We encourage commenters to provide a detailed explanation of how applying a suggested concept or principle would ensure that the severity designation appropriately reflects resource use for ICD–10–CM codes when reported as secondary diagnoses. Commenters should submit their recommendations by October 20, 2023 via the electronic intake system, Medicare Electronic Application Request Information System™ (MEARIS™) at: *https://mearis.cms.gov/public/home*. With respect to the suggestion that CMS make a proposed list of severity level designation changes available along with the impact on resource use files generated using claims from the fiscal year MedPAR files, we appreciate the feedback and will take this suggestion under consideration.

After consideration of the public comments we received, and for the reasons discussed, we are finalizing our proposal, without modification, to maintain the current severity level designation of diagnosis codes K76.72 (Hepatic encephalopathy), N14.11 (Contrast-induced nephropathy), and S06.2XAA (Diffuse traumatic brain injury with loss of consciousness status unknown, initial encounter) for FY 2024.

d. Additions and Deletions to the Diagnosis Code Severity Levels for FY 2024

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26750), we noted the following tables identify the proposed additions and deletions to the diagnosis code MCC severity levels list and the proposed additions and deletions to the diagnosis code CC severity levels list for FY 2024 and are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*:

Table 6I.1—Proposed Additions to the MCC List FY 2024;

Table 6I.2—Proposed Deletions to the MCC List FY 2024;

Table 6J.1—Proposed Additions to the CC List FY 2024; and

Table 6J.2—Proposed Deletions to the CC List FY 2024.

Comment: Commenters agreed with the proposed additions and deletions to the MCC and CC lists as shown in tables 6I.1, 6I.2, 6J.1, and 6J.2 associated with the proposed rule.

Response: We appreciate the commenters' support.

The following tables associated with this final rule reflect the finalized severity levels under Version 41 of the ICD–10 MS–DRGs for FY 2024 and are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*; Table 6I. —Complete MCC List—FY 2024; Table 6I.1—Additions to the MCC List—FY 2024; Table 6I.2—Deletions to the MCC List—FY 2024; Table 6J.—Complete CC List—FY 2024; Table 6J.1—Additions to the CC List—FY 2024; and Table 6J.2—Deletions to the CC List—FY 2024.

e. CC Exclusions List for FY 2024

In the September 1, 1987 final notice (52 FR 33143) concerning changes to the DRG classification system, we modified the GROUPER logic so that certain diagnoses included on the standard list of CCs would not be considered valid CCs in combination with a particular principal diagnosis. We created the CC Exclusions List for the following reasons: (1) to preclude coding of CCs for closely related conditions; (2) to preclude duplicative or inconsistent coding from being treated as CCs; and (3) to ensure that cases are appropriately classified between the complicated and uncomplicated DRGs in a pair.

In the May 19, 1987 proposed notice (52 FR 18877) and the September 1, 1987 final notice (52 FR 33154), we explained that the excluded secondary diagnoses were established using the following five principles:

- Chronic and acute manifestations of the same condition should not be considered CCs for one another;
- Specific and nonspecific (that is, not otherwise specified (NOS)) diagnosis codes for the same condition should not be considered CCs for one another;
- Codes for the same condition that cannot coexist, such as partial/total, unilateral/bilateral, obstructed/unobstructed, and benign/malignant, should not be considered CCs for one another;

• Codes for the same condition in anatomically proximal sites should not be considered CCs for one another; and

• Closely related conditions should not be considered CCs for one another.

The creation of the CC Exclusions List was a major project involving hundreds of codes. We have continued to review the remaining CCs to identify additional exclusions and to remove diagnoses from the master list that have been shown not to meet the definition of a CC. We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50541 through 50544) for detailed information regarding revisions that were made to the CC and CC Exclusion Lists under the ICD–9–CM MS–DRGs.

The ICD–10 MS–DRGs Version 40.1 CC Exclusion List is included as Appendix C in the ICD–10 MS–DRG Definitions Manual, which is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*, and includes two lists identified as Part 1 and Part 2. Part 1 is the list of all diagnosis codes that are defined as a CC or MCC when reported as a secondary diagnosis. For all diagnosis codes on the list, a link is provided to a collection of diagnosis codes which, when reported as the principal diagnosis, would cause the CC or MCC diagnosis to be considered as a NonCC. Part 2 is the list of diagnosis codes designated as an MCC only for patients discharged alive; otherwise, they are assigned as a NonCC.

In the FY 2024 IPPS/LTCH PPS proposed rule, we proposed additional changes to the ICD–10 MS–DRGs Version 41 CC Exclusion List based on the diagnosis and procedure code updates as discussed in section II.C.13. of the proposed rule and set forth in Tables 6G.1, 6G.2, 6H.1, and 6H.2 associated with the proposed rule and available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*.

As discussed in section II.C.13 of the preamble of this final rule, we are finalizing, without modification, the proposed assignments and designations for the diagnosis codes after consideration of the public comments received. Therefore, the finalized CC Exclusions List as displayed in Tables 6G.1, 6G.2, 6H.1, 6H.2, and 6K, associated with this final rule reflect the severity levels under V41 of the ICD–10 MS–DRGs. We have developed Table 6G.1.—Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2024; Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusions List—FY 2024; Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2024; and Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2024; and Table 6K. Complete List of CC Exclusions—FY 2024.

For Table 6G.1, each secondary diagnosis code finalized for addition to the CC Exclusion List is shown with an asterisk and the principal diagnoses finalized to exclude the secondary diagnosis code are provided in the indented column immediately following it. For Table 6G.2, each of the principal diagnosis codes for which there is a CC exclusion is shown with an asterisk and the conditions finalized for addition to the CC Exclusion List that will not count as a CC are provided in an indented column immediately following the affected principal diagnosis. For Table 6H.1, each secondary diagnosis code finalized for deletion from the CC Exclusion List is shown with an asterisk followed by the principal diagnosis codes that currently exclude it. For Table 6H.2, each of the principal diagnosis codes is shown with an asterisk and the finalized deletions to the CC Exclusions List are provided in an indented column immediately following the affected principal diagnosis. Tables 6G.1., 6G.2., 6H.1., and 6H.2. associated with this final rule are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

As discussed in the proposed rule, we also noted that in our review of the CC Exclusion List that we identified a total of 668 diagnosis codes currently listed on various principal diagnosis collection lists that are not able to be reported as a principal diagnosis based on the ICD–10–CM Official Guidelines for Coding and Reporting. In addition, these codes are listed on the Medicare Code Editor (MCE) code edit lists for Unacceptable Principal Diagnosis or Manifestations not allowed as Principal Diagnosis. Therefore, we stated we believed it was appropriate to remove these codes from the affected principal diagnosis collection lists for V41 of the GROUPER. Because we were unable to reflect these changes in Table 6G.1., 6G.2., 6H.1., or 6H.2 at the time of the development of the proposed rule, we provided a supplementary table, Table 6H.3—Principal Diagnosis Codes for Removal from CC Exclusion List—FY 2024 listing each of these 668 diagnosis codes, including the code descriptions, the applicable MCE edit, and the current principal diagnosis collection list(s) where each code is currently listed and from which the code would be removed for the final FY 2024 V41 GROUPER. Table 6H.3 associated with the proposed rule is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

The ICD–10 MS–DRGs Version 41 CC Exclusion List is included as Appendix C of the Definitions Manual (available in two formats; text and HTML). The manuals are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software* and each format includes two lists identified as Part 1 and Part 2. Part 1 is the list of all diagnosis codes that are defined as a CC or MCC when reported as a secondary diagnosis. For all diagnosis codes on the list, a link (HTML version) is provided to a collection of diagnosis codes which, when used as the principal diagnosis, would cause the CC or MCC diagnosis to be considered as a NonCC. Part 2 is the list of diagnosis codes designated as a MCC only for patients discharged alive; otherwise, they are assigned as a NonCC.

13. Changes to the ICD–10–CM and ICD–10–PCS Coding Systems

To identify new, revised and deleted diagnosis and procedure codes, for FY 2024, we have developed Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, Table 6E.—Revised Diagnosis Code Titles and Table 6F.—Revised Procedure Code Titles for this final rule.

These tables are not published in the Addendum to the proposed rule or final rule, but are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* as described in section VI. of the Addendum to this final rule. As discussed in section II.C.16. of the preamble of the proposed rule and this final rule, the code titles are adopted as part of the ICD–10 Coordination and Maintenance Committee meeting process. Therefore, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26752), we proposed the MDC and MS–DRG assignments for the new diagnosis codes and procedure codes as set forth in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes. We also stated that the proposed severity level designations for the new diagnosis codes are set forth in Table 6A. and the proposed O.R. status for the new

procedure codes are set forth in Table 6B. Consistent with our established process, we examined the MS–DRG assignment and the attributes (severity level and O.R. status) of the predecessor diagnosis or procedure code, as applicable, to inform our proposed assignments and designations.

Specifically, we reviewed the predecessor code and MS–DRG assignment most closely associated with the new diagnosis or procedure code, and in the absence of claims data, we considered other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, complexity of service and the resources utilized in the diagnosis and/or treatment of the condition. We noted that this process does not automatically result in the new diagnosis or procedure code being proposed for assignment to the same MS–DRG or to have the same designation as the predecessor code.

In this section of this rule, we summarize the public comments received for Table 6A and Table 6B and provide our responses.

Comment: A commenter applauded the addition of diagnosis code Z29.81 (Encounter for HIV pre-exposure prophylaxis) (PrEP) and encouraged ongoing monitoring of the code to ensure appropriate billing. The commenter stated a diagnostic code for PrEP has the opportunity to improve HIV prevention efforts for patients at the point of care. According to the commenter, HIV remains an issue in every region of the United States (U.S.) and significant gaps persist in ongoing HIV preventive care in clinical practice, including early detection of HIV and linking patients to appropriate prevention services, such as PrEP.

Response: We thank the commenter for their feedback.

Comment: A commenter stated that CMS proposed the severity level designation for diagnosis code O90.41 (Hepatorenal syndrome following labor and delivery) to the MCC list, proposed the removal of diagnosis code O90.4 (Postpartum acute kidney failure) from the MCC list (since the code will no longer be valid), and proposed to add several diagnosis codes describing osteoporosis and intrahepatic cholestasis of pregnancy codes to the CC list. However, according to the commenter, CMS did not include a proposal to add diagnosis code O26.649 (Intrahepatic cholestasis of pregnancy, unspecified trimester) to the CC list. The commenter stated that in FY 2022, CMS finalized maintaining the severity level designation of ''unspecified'' diagnosis codes as CC or MCC where there are other codes available in the code subcategory that further specify the anatomic site for purposes of a new Medicare Code Editor (MCE) ''Unspecified code edit'' effective with discharges on or after April 1, 2022. As such, the commenter requested consideration for the addition of diagnosis code O26.649 (Intrahepatic cholestasis of pregnancy, unspecified trimester) to the CC list to be in alignment with the other diagnosis codes describing intrahepatic cholestasis of pregnancy first trimester, second trimester, and third trimester (codes O26.641, O26.642, and O26.643, respectively) or to consider adding as a diagnosis subject to the ''unspecified'' code edit.

Response: We appreciate the commenters' feedback. We are providing clarification that the Unspecified code edit is only applicable to diagnosis codes that are (1) defined as an unspecified code in the classification by the title description, (2) currently designated as a CC or MCC, and (3) able to be further specified by laterality (right, left, or bilateral) for the anatomic site by other codes in the code subcategory. Because the other intrahepatic cholestasis of pregnancy codes do not include laterality in their code title descriptions, and code O26.649 is not a CC or MCC, the intrahepatic cholestasis of pregnancy, unspecified trimester code (O26.649) is unable to be considered for addition to the Unspecified code edit. We also note that consistent with our established process, we examined the severity level for the predecessor code to determine the most appropriate severity level designation. The predecessor code for code O26.649 is diagnosis code O26.619 (Liver and biliary tract disorders in pregnancy, unspecified trimester), as reflected in the FY 2024 ICD–10–CM Conversion Table (available on the CMS web page at: *https://www.cms.gov/medicare/icd-10/2024-icd-10-cm*) and is designated as a NonCC. Therefore, consistent with the designation of that predecessor code, we proposed to designate code O26.649 as a NonCC.

Comment: A couple commenters requested that CMS change the MS–DRG assignment for new procedure codes X2H03R9 (Insertion of intraluminal device, bioprosthetic valve into inferior vena cava, percutaneous approach, new technology group (9) and X2H13R9 (Insertion of intraluminal device, bioprosthetic valve into superior vena cava, percutaneous approach, new technology group 9) that describe insertion of the TricValve® Bicaval Valve System from MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) to MS–DRGs 266 and 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures with and without MCC, respectively). According to the commenters, these procedures describe bioprostheses that replace the function of the diseased tricuspid valve while leaving the native valve in place. A commenter stated that while the ICD–10–PCS codes are new and do not yet have cost data associated with them, cases reporting use of the devices will require resources and work similar to other endovascular cardiac valve replacement procedures, such as placement within the major vessels and heart to treat valve disease. The commenter urged CMS to consider moving procedure codes X2H03R9 and X2H13R9 to MS–DRGs 266 and 267 and to monitor the costs of these procedures going forward to ensure appropriate assignment. Another commenter stated the TricValve® replaces the function of the tricuspid valve and should be described as a replacement procedure with assignment to MS–DRGs 266 and 267.

Response: We appreciate the commenters' feedback. We note that as reflected in Table 6B.—New Procedure Codes, associated with the FY 2024 IPPS/LTCH PPS proposed rule, we finalized the two procedure codes (X2H03R9 and X2H13R9) after consideration of public comments from the September 13, 2022 ICD–10 Coordination and Maintenance (C&M) Committee meeting. We note that under the ICD–10–PCS classification, the root operation Replacement is defined as: Putting in or on biological or synthetic material that physically takes the place and/or function of all or a portion of a body part. As such, the TricValve® technology is not literally replacing the tricuspid valve as defined under ICD–10–PCS and the body part is not the tricuspid valve, rather, the site of the procedure is the superior vena cava (SVC) and inferior vena cava (IVC). Therefore, while the *intent* of the technology is to replace the function of the tricuspid valve, the procedure to place the bicaval valve system is not literally doing that and the native tricuspid valve is left in place. Using our established process, we proposed the Operating Room (O.R.) designations, MDC and MS–DRG assignments based on the predecessor code assignments. The predecessor code for procedure code X2H03R9 is procedure code 06H03DZ (Insertion of intraluminal device into inferior vena cava, percutaneous approach) and the

predecessor code for procedure code X2H13R9 is procedure code 02HV3DZ (Insertion of intraluminal device into superior vena cava, percutaneous approach), as reflected in the FY 2024 ICD–10–PCS Conversion Table (available on the CMS web page at: *https://www.cms.gov/medicare/icd-10/2024-icd-10-pcs*). The predecessor code 06H03DZ is designated as non-O.R. while the predecessor code 02HV3DZ is designated as an O.R. procedure and is assigned to MS–DRGs 252, 253, and 254. Therefore, we proposed that code X2H03R9 also be designated as non-O.R. and code 02HV3DZ be designated as O.R. and assigned to MS–DRGs 252, 253, and 254. Because the TricValve® technology requires the reporting of both procedure codes (X2H03R9 and X2H13R9) as a ''pair'', cases reporting the procedure were proposed for assignment to MS–DRGs 252, 253, and 254.

For the reasons discussed, we are maintaining the severity level assignment for diagnosis code O26.649 as NonCC and finalizing the MS–DRG assignment for procedure codes X2H03R9 and X2H13R9 to MS–DRGs 252, 253, and 254. We will continue to monitor the claims data when it becomes available to determine if additional modifications are warranted.

After consideration of the public comments received, we are finalizing the MDC and MS–DRG assignments for the new diagnosis codes and procedure codes as set forth in Table 6A.—New Diagnosis Codes and Table 6B.—New Procedure Codes associated with this final rule. In addition, the finalized severity level designations for the new diagnosis codes are set forth in Table 6A. and the finalized O.R. status for the new procedure codes are set forth in Table 6B associated with this final rule.

We are making available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* the following tables associated with this final rule:

- Table 6A.—New Diagnosis Codes—FY 2024.
- Table 6B.—New Procedure Codes—FY 2024.
- Table 6C.—Invalid Diagnosis Codes—FY 2024.
- Table 6D.—Invalid Procedure Codes—FY 2024;
- Table 6E.—Revised Diagnosis Code Titles—FY 2024.
- Table 6F.—Revised Procedure Code Titles—FY 2024.
- Table 6G.1.—Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2024.
- Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusions List—FY 2024.
- Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2024.
- Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2024.
- Table 6 I. —Complete MCC List—FY 2024.
- Table 6I.1.—Additions to the MCC List—FY 2024.
- Table 6I.2.–Deletions to the MCC List—FY 2024.
- Table 6J.—Complete CC List—FY 2024.
- Table 6J.1.—Additions to the CC List—FY 2024.
- Table 6J.2.—Deletions to the CC List—FY 2024.
- Table 6K.—Complete List of CC Exclusions—FY 2024.

14. Changes to the Medicare Code Editor (MCE)

The Medicare Code Editor (MCE) is a software program that detects and reports errors in the coding of Medicare claims data. Patient diagnoses, procedure(s), and demographic information are entered into the Medicare claims processing systems and are subjected to a series of automated screens. The MCE screens are designed to identify cases that require further review before classification into an MS–DRG.

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48874), we made available the FY 2023 ICD–10 MCE Version 40 manual file. The manual contains the definitions of the Medicare code edits, including a description of each coding edit with the corresponding diagnosis and procedure code edit lists. The link to this MCE manual file, along with the link to the mainframe and computer software for the MCE Version 40 (and ICD–10 MS–DRGs) are posted on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26755), we discussed an MCE request we received related to the Sex Conflict edit by the October 20, 2022, deadline, as discussed further in this section of the preamble of this final rule. Additionally, we discussed the proposals we were making based on our internal review and analysis. In this FY 2024 IPPS/LTCH PPS final rule, we present a summation of the comments we received in response to the MCE proposals presented based on internal review and analyses in the proposed rule, our responses to those comments, and our finalized policies.

In addition, as a result of new and modified code updates approved after the annual spring ICD–10 Coordination and Maintenance Committee meeting, we routinely make changes to the MCE. In the past, in both the IPPS proposed and final rules, we have only provided the list of changes to the MCE that were brought to our attention after the prior year's final rule. We historically have not listed the changes we have made to the MCE as a result of the new and modified codes approved after the annual spring ICD–10 Coordination and Maintenance Committee meeting. These changes are approved too late in the rulemaking schedule for inclusion in the proposed rule. Furthermore, although our MCE policies have been described in our proposed and final rules, we have not provided the detail of each new or modified diagnosis and procedure code edit in the final rule. However, we make available the finalized Definitions of Medicare Code Edits (MCE) file. Therefore, we are making available the FY 2024 ICD–10 MCE Version 41 Manual file, along with the link to the mainframe and computer software for the MCE Version 41 (and ICD–10 MS–DRGs), on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

We also note that, as discussed in the CY 2024 Outpatient Prospective Payment System and Ambulatory Surgical Center (OPPS/ASC) proposed rule (CY 2024 OPPS/ASC proposed rule) (88 FR 49552, July 31, 2023), consistent with the process that is used for updates to the ''Integrated'' Outpatient Code Editor (I/OCE) and other Medicare claims editing systems, we proposed to address any future revisions to the IPPS MCE, including any additions or deletions of claims edits, as well as the addition or deletion of ICD–10 diagnosis and procedure codes to the applicable MCE edit code lists, outside of the annual IPPS rulemakings. As discussed in the CY 2024 OPPS/ASC proposed rule, we proposed to remove discussion of the IPPS MCE from the annual IPPS rulemakings, beginning with the FY 2025 rulemaking, and to generally address future changes or updates to the MCE through instruction to the Medicare administrative contractors (MACs). We encourage readers to review the discussion in the CY 2024 OPPS/ASC proposed rule and submit comments in response to the proposal by the applicable deadline by following

the instructions provided in that proposed rule.

a. External Causes of Morbidity Codes as Principal Diagnosis

In the MCE, the external cause codes (V, W, X, or Y codes) describe the circumstance causing an injury, not the nature of the injury, and therefore should not be used as a principal diagnosis.

As discussed in section II.C.13. of the preamble of the proposed rule and this final rule, Table 6A.—New Diagnosis Codes, lists the diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2023. We proposed to add the ICD–10–CM diagnosis codes shown in Table 6P.9a associated with the proposed rule and available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* to the edit code list for the External causes of morbidity codes as principal diagnosis edit.

Comment: Commenters agreed with CMS' proposal to add the diagnosis codes listed in Table 6P.9a to the External causes of morbidity codes as principal diagnosis edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the diagnosis codes listed in Table 6P.9a associated with the proposed rule to the External causes of morbidity codes as principal diagnosis edit code list under the ICD–10 MCE Version 41, effective October 1, 2023.

b. Age Conflict Edit

In the MCE, the Age conflict edit exists to detect inconsistencies between a patient's age and any diagnosis on the patient's record; for example, a 5-year-old patient with benign prostatic hypertrophy or a 78-year-old patient coded with a delivery. In these cases, the diagnosis is clinically and virtually impossible for a patient of the stated age. Therefore, either the diagnosis or the age is presumed to be incorrect. Currently, in the MCE, the following four age diagnosis categories appear under the Age conflict edit and are listed in the manual and written in the software program:

- Perinatal/Newborn—Age 0 years only; a subset of diagnoses which will only occur during the perinatal or newborn period of age 0 (for example, tetanus neonatorum, health examination for newborn under 8 days old).
- Pediatric—Age is 0–17 years inclusive (for example, Reye's syndrome, routine child health exam).
- Maternity—Age range is 9–64 years inclusive (for example, diabetes in pregnancy, antepartum pulmonary complication).
- Adult—Age range is 15–124 years inclusive (for example, senile delirium, mature cataract).

Comment: A commenter requested that we provide clarification regarding the overlapping age ranges (0 to 17 years and 15 to 124 years) in the Pediatric and Adult categories under the Age Conflict edit.

Response: As stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38045), the age ranges defined within the Age Conflict edits were established with the implementation of the IPPS. The adult age range includes the minimum age of 15 years to account for those patients who are declared emancipated minors.

(1) Perinatal/Newborn Diagnosis Category

Under the ICD–10 MCE, the Perinatal/Newborn diagnoses category for the Age conflict edit considers the age range of 0 years only. For that reason, the diagnosis codes on this Age conflict edit list would be expected to apply to conditions or disorders which will only occur during the perinatal or newborn period of age 0.

As discussed in section II.C.13. of the preamble of the proposed rule and this final rule, Table 6A.—New Diagnosis Codes, lists the diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2023. We proposed to add new ICD–10–CM diagnosis codes Z05.81 (Observation and evaluation of newborn for suspected condition related to home physiologic monitoring device ruled out) and Z05.89 (Observation and evaluation of newborn for other specified suspected condition ruled out) to the edit code list for the Perinatal/Newborn diagnoses category under the Age conflict edit.

Comment: Commenters agreed with CMS' proposal to add diagnosis codes Z05.81and Z05.89 to the edit code list for the Perinatal/Newborn diagnoses category under the Age conflict edit.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add diagnosis codes Z05.81and Z05.89 to the edit code list for the Perinatal/Newborn diagnoses category under the Age conflict edit for the ICD–10 MCE Version 41, effective October 1, 2023.

In addition, as discussed in section II.C.13. of the preamble of the proposed rule and this final rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective October 1, 2023. Included in this table is ICD–10–CM diagnosis code Z05.8 (Observation and evaluation of newborn for other specified suspected condition ruled out) that is currently listed on the edit code list for the Perinatal/Newborn diagnoses category under the Age conflict edit. We proposed to delete this code from the Perinatal/Newborn diagnoses edit code list.

Comment: Commenters agreed with CMS' proposal to delete diagnosis code Z05.8 from the edit code list for the Perinatal/Newborn diagnoses category since it is no longer valid.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to delete diagnosis code Z05.8 from the edit code list for the Perinatal/Newborn diagnoses category under the Age conflict edit for the ICD–10 MCE Version 41, effective October 1, 2023.

(2) Maternity Diagnoses

Under the ICD–10 MCE, the Maternity diagnoses category for the Age conflict edit considers the age range of 9 to 64 years inclusive. For that reason, the diagnosis codes on this Age conflict edit list would be expected to apply to conditions or disorders specific to that age group only.

As discussed in section II.C.13. of the preamble of the proposed rule, Table 6A.—New Diagnosis Codes, lists the diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2023. We proposed to add new ICD–10–CM diagnosis codes to the edit code list for the Maternity diagnoses category under the Age conflict edit.

BILLING CODE 4120–01–P

ICD-10-CM Code	Code Description
O26.641	Intrahepatic cholestasis of pregnancy, first trimester
O26.642	Intrahepatic cholestasis of pregnancy, second trimester
O26.643	Intrahepatic cholestasis of pregnancy, third trimester
O26.649	Intrahepatic cholestasis of pregnancy, unspecified trimester
O90.41	Hepatorenal syndrome following labor and delivery
O90.49	Other postpartum acute kidney failure

Comment: Commenters agreed with CMS' proposal to add the diagnosis codes listed in the previous table to the Maternity diagnoses edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the diagnosis codes listed in the previous table to the Maternity diagnoses edit code list under the Age conflict edit for the ICD–10 MCE Version 41, effective October 1, 2023.

In addition, as discussed in section II.C.13. of the preamble of the proposed rule and this final rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective October 1, 2023. Included in this table is ICD–10–CM diagnosis code O90.4 (Postpartum acute kidney failure) that is currently listed on the edit code list for the Maternity diagnoses category under the Age conflict edit. We proposed to delete this code from the Maternity diagnoses edit code list.

Comment: Commenters agreed with CMS' proposal to remove diagnosis code O90.4 from the Maternity diagnoses edit code list since it is no longer valid.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to remove diagnosis code O90.4 from the Maternity diagnoses edit code list under the Age conflict edit for the ICD–10 MCE Version 41, effective October 1, 2023.

(3) Adult Diagnoses

Under the ICD–10 MCE, the Adult diagnoses category for the Age conflict edit considers the age range of 15 to 124 years inclusive. For that reason, the diagnosis codes on this Age conflict edit list would be expected to apply to conditions or disorders specific to that age group only.

As discussed in section II.C.13. of the preamble of the proposed rule and this final rule, Table 6A.—New Diagnosis Codes, lists the diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2023. We proposed to add the following new ICD–10–CM diagnosis codes to the edit code list for the Adult diagnoses category under the Age conflict edit.

ICD-10-CM Code	Code Description
G93.44	Adult-onset leukodystrophy with axonal spheroids
M80.0B1A	Age-related osteoporosis with current pathological fracture, right pelvis, initial encounter for fracture
M80.0B1D	Age-related osteoporosis with current pathological fracture, right pelvis, subsequent encounter for fracture with routine healing
M80.0B1G	Age-related osteoporosis with current pathological fracture, right pelvis, subsequent encounter for fracture with delayed healing
M80.0B1K	Age-related osteoporosis with current pathological fracture, right pelvis, subsequent encounter for fracture with nonunion
M80.0B1P	Age-related osteoporosis with current pathological fracture, right pelvis, subsequent encounter for fracture with malunion
M80.0B1S	Age-related osteoporosis with current pathological fracture, right pelvis, sequela
M80.0B2A	Age-related osteoporosis with current pathological fracture, left pelvis, initial encounter for fracture
M80.0B2D	Age-related osteoporosis with current pathological fracture, left pelvis, subsequent encounter for fracture with routine healing
M80.0B2G	Age-related osteoporosis with current pathological fracture, left pelvis, subsequent encounter for fracture with delayed healing
M80.0B2K	Age-related osteoporosis with current pathological fracture, left pelvis, subsequent encounter for fracture with nonunion
M80.0B2P	Age-related osteoporosis with current pathological fracture, left pelvis, subsequent encounter for fracture with malunion
M80.0B2S	Age-related osteoporosis with current pathological fracture, left pelvis, sequela
M80.0B9A	Age-related osteoporosis with current pathological fracture, unspecified pelvis, initial encounter for fracture
M80.0B9D	Age-related osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with routine healing
M80.0B9G	Age-related osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with delayed healing
M80.0B9K	Age-related osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with nonunion
M80.0B9P	Age-related osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with malunion
M80.0B9S	Age-related osteoporosis with current pathological fracture, unspecified pelvis, sequela

Comment: Commenters agreed with CMS' proposal to add the diagnosis codes listed in the previous table to the Adult diagnoses edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the diagnosis codes listed in the previous table to the Adult diagnoses edit code list under the ICD–10 MCE Version 41, effective October 1, 2023.

c. Sex Conflict Edit

As discussed in the proposed rule, we received a request to reconsider sex conflict edits in connection with concerns related to claims processing for transgender individuals. The requestor raised concerns that the current edit is not clinically accurate and is inconsistent with equitable documentation of gender at the time of service. The requestor expressed concerns that automated systems are contributing to administrative burden for obstetrician-gynecologists because the sex conflict edit requires physicians to choose the sex assigned at birth only and that hospitals must include condition code 45 to override the edit for appropriate payment for certain

surgeries or procedures. The requestor described that claims are inappropriately denied due to the edit singling out transgender individuals, contributing to continued alienation of transgender patients. The requestor further shared that obstetrician-gynecologists have indicated that to provide high-quality, patient-centered care, they need to be able to document a patient's gender identity along with their sex.[18] We note that the requestor raises a number of issues that are related to multiple prospective payment systems and broader aspects of health care, such as the electronic health record.

We share the requestor's concern that the original design of the sex conflict edits is descriptive of a patient's sex assigned at birth as submitted on a claim, which may not be fully reflective of the practice of medicine and patient-doctor interactions, as well as that CMS policy and communications about the use of condition code 45 for institutional claims has not been re-examined in some time. As we state in the CMS Framework for Health Equity, 2022–2032,[19] we strive to identify and remedy systemic barriers to equity so that every one of the people we serve has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes. CMS is committed to looking holistically at the concerns raised by the commenter across settings of care and will consider how to address for future rulemaking or guidance, and we thank the commenter for continuing to share firsthand experiences.

Comment: Commenters expressed their appreciation that CMS stated it is committed to looking holistically at the concerns raised with respect to the sex conflict edit and claims processing of transgender individuals across settings of care. A commenter who expressed support for the continued application of the sex conflict edit stated that while the edit plays an important role in coding error detection and condition code 45 is intended to ensure claims submission accuracy, coding and MS–DRG assignment remain challenging as a result of the edit.

Response: We appreciate the commenters' feedback. We also note that following publication of the FY 2024 IPPS/LTCH PPS proposed rule, in further consideration of the concerns expressed by the requestor and recognizing that communication about the use of condition code 45 for institutional claims had not been re-examined in some time, we issued guidance via a Medicare Learning Network® (MLN Connects) article on June 8, 2023 that is intended to provide clarification on the proper billing and usage of condition code 45 and modifier KX. This guidance also informed providers that effective July 1, 2023, the National Uniform Billing Committee (NUBC) revised the terminology and definition for Condition Code 45 to Gender Incongruence, defined as ''characterized by a marked and persistent incongruence between an individual's experienced gender and sex at birth.'' We refer the reader to the CMS website at: *https://www.cms.gov/outreach-and-education/outreach/ffsprovpartprog/provider-partnership-email-archive/2023-06-08-mlnc* for additional information regarding this guidance.

d. Manifestation Code as Principal Diagnosis Edit

In the ICD–10–CM classification system, manifestation codes describe the manifestation of an underlying disease, not the disease itself, and therefore should not be used as a principal diagnosis.

As discussed in section II.C.13. of the preamble of the proposed rule and this final rule, Table 6A.—New Diagnosis Codes, lists the new diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2023. Included in this table are the following new ICD–10–CM diagnosis codes that we proposed to add to the edit code list for the Manifestation code as principal diagnosis edit, because the disease itself would be required to be reported first.

ICD-10-CM Code	Code Description
E20.811	Secondary hypoparathyroidism in diseases classified elsewhere
H36.89	Other retinal disorders in diseases classified elsewhere

Comment: Commenters agreed with CMS' proposal to add the diagnosis codes listed in the previous table to the Manifestation code as principal diagnosis edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the diagnosis codes listed in the previous table to the Manifestation code as principal diagnosis edit code list under the ICD–10 MCE Version 41, effective October 1, 2023.

In addition, as discussed in section II.C.13. of the preamble of the proposed rule and this final rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective October 1, 2023. Included in this table is ICD–10–CM diagnosis code H36 (Retinal disorders in diseases classified elsewhere) that is currently listed on the edit code list for the Manifestation code as principal diagnosis edit. We proposed to delete this code from the Manifestation code as principal diagnosis edit code list.

Comment: Commenters agreed with CMS' proposal to remove diagnosis code H36 from the Manifestation code as principal diagnosis edit code list since it is no longer valid.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to remove diagnosis code H36 from the Manifestation code as principal diagnosis edit code list under the ICD–10 MCE Version 41, effective October 1, 2023.

e. Unacceptable Principal Diagnosis Edit

In the MCE, there are select codes that describe a circumstance which influences an individual's health status but does not actually describe a current illness or injury. There also are codes that are not specific manifestations but may be due to an underlying cause. These codes are considered

[18] We note that the requester used the phrase ''gender identity along with their sex''. We believe the requester was referring to ''sex assigned at birth'' in this context.

[19] *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.*

unacceptable as a principal diagnosis. In limited situations, there are a few codes on the MCE Unacceptable Principal Diagnosis edit code list that are considered ''acceptable'' when a specified secondary diagnosis is also coded and reported on the claim.

As discussed in section II.C.13. of the preamble of the proposed rule and this final rule, Table 6A.—New Diagnosis Codes, lists the new diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2023. We proposed to add the following new ICD–10–CM diagnosis codes to the Unacceptable Principal Diagnosis edit code list.

ICD-10-CM Code	Code Description
B96.83	Acinetobacter baumannii as the cause of diseases classified elsewhere
E88.A	Wasting disease (syndrome) due to underlying condition
H36.811	Nonproliferative sickle-cell retinopathy, right eye
H36.812	Nonproliferative sickle-cell retinopathy, left eye
H36.813	Nonproliferative sickle-cell retinopathy, bilateral
H36.819	Nonproliferative sickle-cell retinopathy, unspecified eye
H36.821	Proliferative sickle-cell retinopathy, right eye
H36.822	Proliferative sickle-cell retinopathy, left eye
H36.823	Proliferative sickle-cell retinopathy, bilateral
H36.829	Proliferative sickle-cell retinopathy, unspecified eye
R40.2A	Nontraumatic coma due to underlying condition
Z02.84	Encounter for child welfare exam
Z16.13	Resistance to carbapenem
Z22.340	Carrier of carbapenem-resistant Acinetobacter baumannii
Z22.341	Carrier of carbapenem-sensitive Acinetobacter baumannii
Z22.349	Carrier of Acinetobacter baumannii, unspecified
Z22.350	Carrier of carbapenem-resistant Enterobacterales
Z22.358	Carrier of other Enterobacterales
Z22.359	Carrier of Enterobacterales, unspecified
Z29.81	Encounter for HIV pre-exposure prophylaxis
Z29.89	Encounter for other specified prophylactic measures
Z62.23	Child in custody of non-parental relative
Z62.24	Child in custody of non-relative guardian
Z62.823	Parent-step child conflict
Z62.831	Non-parental relative-child conflict
Z62.832	Non-relative guardian-child conflict
Z62.833	Group home staff-child conflict
Z62.892	Runaway [from current living environment]
Z83.710	Family history of adenomatous and serrated polyps
Z83.711	Family history of hyperplastic colon polyps
Z83.718	Other family history of colon polyps
Z83.719	Family history of colon polyps, unspecified
Z91.A41	Caregiver's other noncompliance with patient's medication regimen due to financial hardship
Z91.A48	Caregiver's other noncompliance with patient's medication regimen for other reason
Z91.A51	Caregiver's noncompliance with patient's renal dialysis due to financial hardship
Z91.A58	Caregiver's noncompliance with patient's renal dialysis for other reason
Z91.A91	Caregiver's noncompliance with patient's other medical treatment and regimen due to financial hardship
Z91.A98	Caregiver's noncompliance with patient's other medical treatment and regimen for other reason
Z91.85	Personal history of military service

Comment: Commenters agreed with our proposal to add the diagnosis codes listed in the previous table to the Unacceptable Principal Diagnosis edit code list.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to add the diagnosis codes listed in the previous table to the Unacceptable Principal Diagnosis edit code list under the ICD–10 MCE Version 41, effective October 1, 2023.

In addition, as discussed in section II.C.13. of the preamble of the proposed rule and this final rule, Table 6C.—Invalid Diagnosis Codes, lists the diagnosis codes that are no longer effective October 1, 2023. Included in this table are the following ICD–10–CM diagnosis codes that are currently listed on the Unacceptable Principal Diagnosis edit code list. We proposed to delete these codes from the Unacceptable Principal Diagnosis edit code list.

ICD-10-CM Code	Code Description
Z29.8	Encounter for other specified prophylactic measures
Z83.71	Family history of colonic polyps
Z91.A4	Caregiver's other noncompliance with patient's medication regimen
Z91.A5	Caregiver's noncompliance with patient's renal dialysis
Z91.A9	Caregiver's noncompliance with patient's other medical treatment and regimen

Comment: Commenters agreed with CMS' proposal to remove the diagnosis codes listed in the previous table from the Unacceptable principal diagnosis edit code list since they are no longer valid.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposal to remove the diagnosis codes listed in the previous table from the Unacceptable Principal Diagnosis edit code list under the ICD–10 MCE Version 41, effective October 1, 2023.

f. Unspecified Code

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 44940 through 44943), we finalized the implementation of a new Unspecified code edit, effective with discharges on and after April 1, 2022. Unspecified codes exist in the ICD–10–CM classification for circumstances when documentation in the medical record does not provide the level of detail needed to support reporting a more specific code. However, in the inpatient setting, there should generally be very limited and rare circumstances for which the laterality (right, left, bilateral) of a condition is unable to be documented and reported.

As discussed in section II.C.13. of the preamble of the proposed rule and this final rule, Table 6A.—New Diagnosis Codes, lists the new diagnosis codes that have been approved to date which will be effective with discharges on and after October 1, 2023. We proposed to add the following new ICD–10–CM diagnosis codes to the Unspecified code edit list.

ICD-10-CM Code	Code Description
M80.0B9A	Age-related osteoporosis with current pathological fracture, unspecified pelvis, initial encounter for fracture
M80.0B9D	Age-related osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with routine healing
M80.0B9G	Age-related osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with delayed healing
M80.0B9K	Age-related osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with nonunion
M80.0B9P	Age-related osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with malunion
M80.0B9S	Age-related osteoporosis with current pathological fracture, unspecified pelvis, sequela
M80.8B9A	Other osteoporosis with current pathological fracture, unspecified pelvis, initial encounter for fracture
M80.8B9D	Other osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with routine healing
M80.8B9G	Other osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with delayed healing
M80.8B9K	Other osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with nonunion
M80.8B9P	Other osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with malunion
M80.8B9S	Other osteoporosis with current pathological fracture, unspecified pelvis, sequela

Comment: Commenters agreed with our proposal to add the diagnosis codes listed in the previous table to the Unspecified code edit code list.

Response: We thank the commenters for their support. We also note that we erroneously included the following diagnosis codes in our proposal that are not designated as a CC or MCC, and are therefore excluded from being subject to the Unspecified code edit. Specifically, Table 6A. associated with the proposed rule and this final rule lists the severity level designation for these six new diagnosis codes as NonCC.

ICD-10-CM Code	Code Description
M80.0B9D	Age-related osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with routine healing
M80.0B9G	Age-related osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with delayed healing
M80.0B9S	Age-related osteoporosis with current pathological fracture, unspecified pelvis, sequela
M80.8B9D	Other osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with routine healing
M80.8B9G	Other osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with delayed healing
M80.8B9S	Other osteoporosis with current pathological fracture, unspecified pelvis, sequela

After consideration of the public comments we received, we are finalizing our proposal to add the following diagnosis codes that are designated as CC to the Unspecified code edit code list under the ICD–10 MCE Version 41, effective October 1, 2023.

ICD-10-CM Code	Code Description
M80.0B9A	Age-related osteoporosis with current pathological fracture, unspecified pelvis, initial encounter for fracture
M80.0B9K	Age-related osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with nonunion
M80.0B9P	Age-related osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with malunion
M80.8B9A	Other osteoporosis with current pathological fracture, unspecified pelvis, initial encounter for fracture
M80.8B9K	Other osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with nonunion
M80.8B9P	Other osteoporosis with current pathological fracture, unspecified pelvis, subsequent encounter for fracture with malunion

In addition, as stated in the proposed rule, we identified four diagnosis codes that were inadvertently omitted from the Unspecified code edit list effective with discharges on and after April 1, 2022. We therefore proposed to also add the following ICD–10–CM diagnosis codes to the Unspecified code edit list effective with discharges on and after October 1, 2023.

ICD-10-CM Code	Code Description
L89.103	Pressure ulcer of unspecified part of back, stage 3
L89.104	Pressure ulcer of unspecified part of back, stage 4
L89.93	Pressure ulcer of unspecified site, stage 3
L89.94	Pressure ulcer of unspecified site, stage 4

Comment: Commenters agreed with our proposal to add the diagnosis codes listed in the previous table to the Unspecified code edit code list.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to add the previously listed diagnosis codes that are designated as MCC to the Unspecified code edit code list under the ICD–10 MCE Version 41, effective October 1, 2023.

g. Future Enhancement

As discussed previously in this section of this final rule, we have continued to evaluate the purpose and function of the MCE with respect to ICD–10, and encouraged public input for future discussion. As we have also discussed in prior rulemaking, we recognize a need to further examine the current list of edits and the definitions of those edits. We refer the reader to our discussion in the CY 2024 Outpatient Prospective Payment System and Ambulatory Surgical Center (OPPS/ASC) proposed rule (88 FR 49552, July 31, 2023), where we proposed to address any future revisions to the IPPS MCE, including any additions or deletions of claims edits, as well as the addition or deletion of ICD–10 diagnosis and procedure codes to the applicable MCE edit code lists, outside of the annual IPPS rulemakings.

We continue to encourage public comments on whether there are additional concerns with the current edits, including specific edits or language that should be removed or revised, edits that should be combined, or new edits that should be added to assist in detecting errors or inaccuracies in the coded data. Comments should be directed to the new electronic intake system, Medicare Electronic Application Request Information System (MEARIS™), discussed in section II.C.1.b. of the preamble of the proposed rule and this final rule, at: *https://mearis.cms.gov/public/home* by October 20, 2023.

15. Changes to Surgical Hierarchies

Some inpatient stays entail multiple surgical procedures, each one of which, occurring by itself, could result in assignment of the case to a different MS–DRG within the MDC to which the principal diagnosis is assigned. Therefore, it is necessary to have a decision rule within the GROUPER by which these cases are assigned to a single MS–DRG. The surgical hierarchy, an ordering of surgical classes from most resource-intensive to least resource-intensive, performs that function. Application of this hierarchy ensures that cases involving multiple surgical procedures are assigned to the MS–DRG associated with the most resource-intensive surgical class.

A surgical class can be composed of one or more MS–DRGs. For example, in MDC 11, the surgical class ''kidney transplant'' consists of a single MS–DRG (MS–DRG 652) and the class ''major bladder procedures'' consists of three MS–DRGs (MS–DRGs 653, 654, and 655).

Consequently, in many cases, the surgical hierarchy has an impact on more than one MS–DRG. The methodology for determining the most resource-intensive surgical class involves weighting the average resources for each MS–DRG by frequency to determine the weighted average resources for each surgical class. For example, assume surgical class A includes MS–DRGs 001 and 002 and surgical class B includes MS–DRGs 003, 004, and 005. Assume also that the average costs of MS–DRG 001 are higher than that of MS–DRG 003, but the average costs of MS–DRGs 004 and 005 are higher than the average costs of MS–DRG 002. To determine whether surgical class A should be higher or lower than surgical class B in the surgical hierarchy, we would weigh the average costs of each MS–DRG in the class by frequency (that is, by the number of cases in the MS–DRG) to determine average resource consumption for the surgical class. The surgical classes would then be ordered from the class with the highest average resource utilization to that with the lowest, with the exception of ''other O.R. procedures'' as discussed in this final rule.

This methodology may occasionally result in assignment of a case involving multiple procedures to the lower-weighted MS–DRG (in the highest, most resource-intensive surgical class) of the available alternatives. However, given that the logic underlying the surgical hierarchy provides that the GROUPER search for the procedure in the most resource-intensive surgical class, in cases involving multiple procedures, this result is sometimes unavoidable.

We note that, notwithstanding the foregoing discussion, there are a few instances when a surgical class with a lower average cost is ordered above a surgical class with a higher average cost. For example, the ''other O.R. procedures'' surgical class is uniformly ordered last in the surgical hierarchy of each MDC in which it occurs, regardless of the fact that the average costs for the MS–DRG or MS–DRGs in that surgical class may be higher than those for other surgical classes in the MDC. The ''other O.R. procedures'' class is a group of procedures that are only infrequently related to the diagnoses in the MDC but are still occasionally performed on patients with cases assigned to the MDC with these diagnoses. Therefore, assignment to these surgical classes should only occur if no other surgical class more closely related to the diagnoses in the MDC is appropriate.

A second example occurs when the difference between the average costs for two surgical classes is very small. We have found that small differences generally do not warrant reordering of the hierarchy because, as a result of reassigning cases on the basis of the hierarchy change, the average costs are likely to shift such that the higher-ordered surgical class has lower average costs than the class ordered below it.

Based on the changes that we proposed to make for FY 2024, as discussed in section II.C. of the preamble of the proposed rule and this final rule, we proposed to modify the existing surgical hierarchy for FY 2024 as follows.

We proposed to revise the surgical hierarchy for the MDC 04 (Diseases and Disorders of the Respiratory System) MS–DRGs as follows: In the MDC 04 MS–DRGs, we proposed to sequence proposed new MS–DRG 173 (Ultrasound Accelerated and Other Thrombolysis with Principal Diagnosis Pulmonary Embolism) above MDC 04 MS–DRGs 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) and below MS–DRGs 163, 164, and 165 (Major Chest Procedures with MCC, with CC, and without CC/MCC, respectively).

As discussed in section II.C.2.b. of the preamble of the proposed rule and this final rule, we proposed to revise the surgical hierarchy for the MDC 05 (Diseases and Disorders of the Circulatory System) MS–DRGs as follows: In the MDC 05 MS–DRGs, we proposed to sequence proposed new MS–DRG 212 (Concomitant Aortic and Mitral Valve Procedures) above MS–DRGs 216, 217, 218, 219, 220, and 221 (Cardiac Valve & Other Major Cardiothoracic Procedure with and without Cardiac Catheterization, with MCC, with CC, without CC/MCC, respectively) and below MS–DRG 215 (Other Heart Assist System Implant). As discussed in section II.C.4. of the preamble of the proposed rule and this final rule, we proposed to delete MS–DRGs 222, 223, 224, 225, 226, and 227 (Cardiac Defibrillator Implant with and without Cardiac Catheterization with and without AMI/HF/Shock with and without MCC, respectively). Based on the changes we proposed to make for those MS–DRGs in MDC 05, we proposed to sequence proposed new MS–DRG 275 (Cardiac Defibrillator Implant with Cardiac Catheterization and MCC) above proposed new MS–DRG 276 (Cardiac Defibrillator Implant with MCC) and below MS–DRGs 231, 232, 233, 234, 235, and 236 (Coronary Bypass with or without PTCA, with or without Cardiac Catheterization or Open Ablation, with and without MCC, respectively). We proposed to sequence proposed new MS–DRG 276 (Cardiac Defibrillator Implant with MCC) above proposed new MS–DRG 277 (Cardiac Defibrillator Implant without MCC) and below proposed new MS–DRG 275 (Cardiac Defibrillator Implant with Cardiac Catheterization and MCC). We proposed to sequence proposed new MS–DRG 277 (Cardiac Defibrillator Implant without MCC) above MS–DRGs 266 and 267 (Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC and without MCC, respectively) and below proposed new MS–DRG 276 (Cardiac Defibrillator Implant with MCC).

As discussed in section II.C.4. of the preamble of the proposed rule and this final rule, we proposed to delete MDC 05 MS–DRGs 246 and 247 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Arteries or Stents and without MCC, respectively). We also proposed to delete MDC 05 MS–DRGs 248 and 249 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent with MCC or 4+ Arteries or Stents and without MCC, respectively). We proposed to revise the titles for MS–DRGs 250 and 251 from ''Percutaneous Cardiovascular Procedures without Coronary Artery Stent with MCC and without MCC, respectively'' to ''Percutaneous Cardiovascular Procedures without Intraluminal Device with MCC and without MCC, respectively.'' Based on the changes we proposed to make for those MS–DRGs in MDC 05, we proposed to sequence proposed new MS–DRGs 323 and 324 (Coronary Intravascular Lithotripsy with Intraluminal Device with MCC and without MCC, respectively) above proposed new MS–DRG 325 (Coronary Intravascular Lithotripsy without Intraluminal Device) and below MS–DRGs 273 and 274 (Percutaneous and Other Intracardiac Procedures with MCC and without MCC, respectively). We proposed to sequence proposed new MS–DRG 325 (Coronary Intravascular Lithotripsy without Intraluminal Device) above proposed new MS–DRGs 321 and 322 (Percutaneous Cardiovascular Procedures with Intraluminal Device, with MCC or 4+ Arteries/Intraluminal Devices and

without MCC, respectively) and below proposed new MS–DRGs 323 and 324 (Coronary Intravascular Lithotripsy with Intraluminal Device with MCC and without MCC, respectively). We proposed to sequence proposed new MS–DRGs 321 and 322 (Percutaneous Cardiovascular Procedures with Intraluminal Device with MCC or 4+ Arteries/Intraluminal Devices and without MCC, respectively), above MS–DRGs 250 and 251 (Percutaneous Cardiovascular Procedures without Intraluminal Device with MCC and without MCC, respectively) and below proposed new MS–DRG 325 (Coronary Intravascular Lithotripsy without Intraluminal Device).

In addition, based on the changes that we proposed to make as discussed in section II.C.8.a. of the preamble of the proposed rule and this final rule, we also proposed to sequence proposed new MDC 05 MS–DRGs 278 and 279 (Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures with MCC and without MCC, respectively) above MDC 05 MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) and below MS–DRGs 250 and 251 (Percutaneous Cardiovascular Procedures without Intraluminal Device with and without MCC, respectively).

As discussed in section II.C.4. of the preamble of the proposed rule and this final rule, we proposed to delete MS–DRGs 338, 339, and 340 (Appendectomy with Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 341, 342, and 343 (Appendectomy without Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively). Based on the changes we proposed to make for those MS–DRGs in MDC 06 (Diseases and Disorders of the Digestive System), we proposed to revise the surgical hierarchy for MDC 06 as follows: In MDC 06, we proposed to sequence proposed new MS–DRGs 397, 398, and 399 (Appendix Procedures with MCC, with CC, and without CC/MCC, respectively) above MS–DRGs 344, 345, and 346 (Minor Small and Large Bowel Procedures with MCC, with CC, and without CC/MCC, respectively) and below MS–DRGs 335, 336, and 337 (Peritoneal Adhesiolysis with MCC, with CC, and without CC/MCC, respectively).

Lastly, as discussed in section II.C.2.b. of the preamble of the proposed rule and this final rule, we proposed to revise the title for MDC 16 (Diseases and Disorders of Blood, Blood Forming Organs and Immunologic Disorders) MS–DRGs 799, 800, and 801 from ''Splenectomy with MCC, with CC, and without CC/MCC, respectively'' to ''Splenic Procedures with MCC, with CC, and without CC/MCC, respectively.''

Our proposal for Appendix D MS–DRG Surgical Hierarchy by MDC and MS–DRG of the ICD–10 MS–DRG Definitions Manual Version 41 is illustrated in the following tables.

Proposed Surgical Hierarchy: MDC 04	
MS-DRGs 163-165	Major Chest Procedures
Proposed New MS-DRG 173	Ultrasound Accelerated and Other Thrombolysis with Principal Diagnosis Pulmonary Embolism
MS-DRGs 166-168	Other Respiratory System O.R. Procedures

Proposed Surgical Hierarchy: MDC 05	
MS-DRG 215	Other Heart Assist System Implant
Proposed New MS-DRG 212	Concomitant Aortic and Mitral Valve Procedures
MS-DRGs 216-221	Cardiac Valve and Other Major Cardiothoracic Procedures

Proposed Surgical Hierarchy: MDC 05	
MS-DRGs 231-236	Coronary Bypass
Delete MS-DRGs 222-227	Cardiac Defibrillator Implant
Proposed New MS-DRG 275	Cardiac Defibrillator Implant with Cardiac Catheterization and MCC
Proposed New MS-DRG 276	Cardiac Defibrillator Implant with MCC
Proposed New MS-DRG 277	Cardiac Defibrillator Implant without MCC
MS-DRGs 266-267	Endovascular Cardiac Valve Replacement and Supplement Procedures
MS-DRGs 268-269	Aortic and Heart Assist Procedures
MS-DRGs 228-229	Other Cardiothoracic Procedures
MS-DRGs 319-320	Other Endovascular Cardiac Valve Procedures
MS-DRGs 270-272	Other Major Cardiovascular Procedures
MS-DRGs 239-241	Amputation for Circulatory System Disorders Except Upper Limb and Toe
MS-DRGs 242-244	Permanent Cardiac Pacemaker Implant
MS-DRG 245	AICD Generator Procedures
MS-DRG 265	AICD Lead Procedures
MS-DRGs 273-274	Percutaneous and Other Intracardiac Procedures
Delete MS-DRGs 246-249	Percutaneous Cardiovascular Procedures with Coronary Artery Stent
Proposed New MS-DRGs 323-324	Coronary Intravascular Lithotripsy with Intraluminal Device
Proposed New MS-DRG 325	Coronary Intravascular Lithotripsy without Intraluminal Device
Proposed New MS-DRGs 321-322	Percutaneous Cardiovascular Procedures with Intraluminal Device
MS-DRGs 250-251	Percutaneous Cardiovascular Procedures without Intraluminal Device
Proposed New MS-DRGs 278-279	Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures
MS-DRGs 252-254	Other Vascular Procedures
MS-DRGs 255-257	Upper Limb and Toe Amputation for Circulatory System Disorders
MS-DRGs 258-259	Cardiac Pacemaker Device Replacement
MS-DRGs 260-262	Cardiac Pacemaker Revision Except Device Replacement
MS-DRG 263	Vein Ligation and Stripping
MS-DRG 264	Other Circulatory O.R Procedures

Proposed Surgical Hierarchy: MDC 06	
MS-DRGs 335-337	Peritoneal Adhesiolysis
Delete MS-DRGs 338-343	Appendectomy
Proposed New MS-DRGs 397-399	Appendix Procedures
MS-DRGs 344-346	Minor Small and Large Bowel Procedures

Proposed Surgical Hierarchy: MDC 16	
Proposed New Title MS-DRGs 799-801	Splenic Procedures
MS-DRGs 802-804	Other O.R. Procedures of the Blood and Blood Forming Organs

Comment: Commenters supported the proposed additions, deletions, and sequencing for the surgical hierarchy under MDCs 04, 05, 06, and 16. In response to the changes we proposed to make for MS–DRGs in MDC 05, a commenter stated this hierarchy is the most logical order given the clinical complexity associated with cases

requiring coronary intravascular lithotripsy followed by the MS–DRGs for percutaneous cardiovascular procedures with or without intraluminal device.

We received a few public comments recommending that CMS consider an alternate option for the surgical hierarchy in MDC 05. Specifically, these commenters requested CMS consider switching—

- MS–DRGs 270, 271, and 272 and MS–DRG 319 and 320 in the surgical hierarchy so that MS–DRGs 270, 271, and 272 are sequenced before MS–DRGs 319 and 320;
- MS–DRG 245 with MS–DRGs 266 and 267 so that MS–DRG 245 is sequenced before MS–DRGs 266 and 267; and
- MS–DRGs 323, 324, and 325 to be sequenced after MS–DRGs 319 and 320 after these MS–DRGs are sequenced after MS–DRGs 270, 271, and 272 as shown in the following table.

MS-DRGs 270-272	Other Major Cardiovascular Procedures
MS-DRGs 319-320	Other Endovascular Cardiac Valve Procedures
Proposed New MS-DRGs 323-324	Coronary Intravascular Lithotripsy with Intraluminal Device
Proposed New MS-DRG 325	Coronary Intravascular Lithotripsy without Intraluminal Device

A commenter displayed the proposed relative weights of MS–DRGs 245, MS–DRGs 266–267, MS–DRGs 270–272, MS–DRGs 319–320, proposed new MS–DRGs 323–324 and proposed new MS–DRG 325 from Table 5.—List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2024, associated with the proposed rule, in listing this alternative option. However, these commenters did not provide any rationale for their alternate recommendations.

Response: We appreciate the commenters' support of our proposal. We also thank the commenters for their feedback. In response to the commenters that provided an alternate recommendation for the surgical hierarchy for MDC 05, we reviewed the suggestions from the commenters. In the absence of additional information to support the suggested modifications to our proposal, we continue to believe our proposed revisions to the surgical hierarchy account for the resources expended to address these complex procedures and do not believe any modifications are warranted at this time. We believe sequencing as discussed in the proposed rule more appropriately reflects resource utilization when the assigned cardiac procedures are performed and will result in the most suitable MS–DRG assignments. We will continue to review the surgical hierarchy, consistent with our annual rulemaking, to determine if other modifications are warranted in the future.

Therefore, after consideration of the public comments we received, and based on the changes that we are finalizing for FY 2024, as discussed in section II.C. of the preamble of the proposed rule and this final rule, we are finalizing our proposals to modify the existing surgical hierarchy, effective with the ICD–10 MS–DRGs Version 41, without modification.

For issues pertaining to the surgical hierarchy, as with other MS–DRG related requests, we encourage interested parties to submit comments no later than October 20, 2023 via the new electronic intake system, Medicare Electronic Application Request Information System™ (MEARIS™) at *https://mearis.cms.gov/public/home* so that they can be considered for possible inclusion in the annual proposed rule. We will consider these public comments for possible proposals in future rulemaking as part of our annual review process.

16. Maintenance of the ICD–10–CM and ICD–10–PCS Coding Systems

In September 1985, the ICD–9–CM Coordination and Maintenance Committee was formed. This is a Federal interdepartmental committee, co-chaired by the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) and CMS, charged with maintaining and updating the ICD–9–CM system. The final update to ICD–9–CM codes was made on October 1, 2013. Thereafter, the name of the Committee was changed to the ICD–10 Coordination and Maintenance Committee, effective with the March 19–20, 2014, meeting. The ICD–10 Coordination and Maintenance Committee addresses updates to the ICD–10–CM and ICD–10–PCS coding systems. The Committee is jointly responsible for approving coding changes, and developing errata, addenda, and other modifications to the coding systems to reflect newly developed procedures and technologies and newly identified diseases. The Committee is also responsible for promoting the use of Federal and non-Federal educational programs and other communication techniques with a view toward standardizing coding applications and upgrading the quality of the classification system.

The official list of ICD–9–CM diagnosis and procedure codes by fiscal year can be found on the CMS website at: *https://cms.hhs.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/codes.html*. The official list of ICD–10–CM and ICD–10–PCS codes can be found on the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/index.html*.

The NCHS has lead responsibility for the ICD–10–CM and ICD–9–CM diagnosis codes included in the Tabular List and Alphabetic Index for Diseases, while CMS has lead responsibility for the ICD–10–PCS and ICD–9–CM procedure codes included in the Tabular List and Alphabetic Index for Procedures.

The ICD–10 Coordination and Maintenance Committee holds its meetings in the spring and fall to update the codes and the applicable payment and reporting systems by October 1 or April 1 of each year. Items are placed on the agenda for the Committee meeting if the request is received at least 3 months prior to the meeting. This requirement allows time for staff to review and research the coding issues and prepare material for discussion at the meeting. It also allows time for the topic to be publicized in meeting announcements in the **Federal Register** as well as on the CMS website.

The Committee encourages participation in the previously mentioned process by health-related organizations and other interested parties. In this regard, the Committee holds public meetings for discussion of educational issues and proposed coding changes. These meetings provide an opportunity for representatives of recognized organizations in the coding field, such as the American Health Information Management Association (AHIMA), the American Hospital Association (AHA), and various

physician specialty groups, as well as individual physicians, health information management professionals, and other members of the public, to contribute ideas on coding matters. After considering the opinions expressed during the public meetings and in writing, the Committee formulates recommendations, which then must be approved by the agencies. A complete addendum describing details of all diagnosis and procedure coding changes, both tabular and index, is published on the CMS and NCHS websites in June of each year. Publishers of coding books and software use this information to modify their products that are used by health care providers.

The Committee presented proposals for coding changes for implementation in FY 2024 at a public meeting held on September 13–14, 2022, and finalized the coding changes after consideration of comments received at the meetings and in writing by November 14, 2022.

The Committee held its 2023 meeting on March 7–8, 2023. The deadline for submitting comments on these code proposals was April 7, 2023. It was announced at this meeting that any new diagnosis and procedure codes for which there was consensus of public support and for which complete tabular and indexing changes would be made by June 2023 would be included in the October 1, 2023, update to the ICD–10–CM diagnosis and ICD–10–PCS procedure code sets.

As discussed in earlier sections of the preamble of this final rule, there are new, revised, and deleted ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes that are captured in Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, Table 6E.—Revised Diagnosis Code Titles and Table 6F.–Revised Procedure Code Titles for this final rule, which are available on the CMS website at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps*. The code titles are adopted as part of the ICD–10 Coordination and Maintenance Committee process. Therefore, although we make the code titles available in these tables for the IPPS proposed and final rules, they are not subject to comment in the proposed or final rule. Because of the length of these tables, they are not published in the Addendum to the proposed or final rule. Rather, they are available via the CMS website as discussed in section VI. of the Addendum to the proposed rule and this final rule.

Recordings for the virtual meeting discussions of the procedure codes at the Committee's September 13–14, 2022, meeting and the March 7–8, 2023, meeting can be obtained from the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10/C-and-M-Meeting-Materials*. The materials for the discussions relating to diagnosis codes at the September 13–14, 2022, meeting and March 7–8, 2023, meeting can be found at: *http://www.cdc.gov/nchs/icd/icd10cm_maintenance.html*. These websites also provide detailed information about the Committee, including information on requesting a new code, participating in a Committee meeting, timeline requirements and meeting dates.

We encourage commenters to submit questions and comments on coding issues involving diagnosis codes via Email to: *nchsicd10cm@cdc.gov*.

Questions and comments concerning the procedure codes should be submitted via Email to: *ICDProcedureCodeRequest@cms.hhs.gov*.

We stated in the proposed rule that in an effort to better enable the collection of health-related social needs (HRSNs), defined as individual-level, adverse social conditions that negatively impact a person's health or healthcare, are significant risk factors associated with worse health outcomes as well as increased healthcare utilization, the Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics (NCHS) implemented 42 new diagnosis codes into the ICD–10–CM classification, for reporting effective April 1, 2023. The diagnosis codes are as follows:

ICD-10-CM Code	Description
T74.A1XA	Adult financial abuse, confirmed, initial encounter
T74.A1XD	Adult financial abuse, confirmed, subsequent encounter
T74.A1XS	Adult financial abuse, confirmed, sequela
T74.A2XA	Child financial abuse, confirmed, initial encounter
T74.A2XD	Child financial abuse, confirmed, subsequent encounter
T74.A2XS	Child financial abuse, confirmed, sequela
T76.A1XA	Adult financial abuse, suspected, initial encounter
T76.A1XD	Adult financial abuse, suspected, subsequent encounter
T76.A1XS	Adult financial abuse, suspected, sequela
T76.A2XA	Child financial abuse, suspected, initial encounter
T76.A2XD	Child financial abuse, suspected, subsequent encounter
T76.A2XS	Child financial abuse, suspected, sequela
Y07.010	Husband, current, perpetrator of maltreatment and neglect
Y07.011	Husband, former, perpetrator of maltreatment and neglect
Y07.020	Wife, current, perpetrator of maltreatment and neglect
Y07.021	Wife, former, perpetrator of maltreatment and neglect
Y07.030	Male partner, current, perpetrator of maltreatment and neglect
Y07.031	Male partner, former, perpetrator of maltreatment and neglect
Y07.040	Female partner, current, perpetrator of maltreatment and neglect
Y07.041	Female partner, former, perpetrator of maltreatment and neglect
Y07.050	Non-binary partner, current, perpetrator of maltreatment and neglect
Y07.051	Non-binary partner, former, perpetrator of maltreatment and neglect
Y07.44	Child, perpetrator of maltreatment and neglect
Y07.45	Grandchild, perpetrator of maltreatment and neglect
Y07.46	Grandparent, perpetrator of maltreatment and neglect
Y07.47	Parental sibling, perpetrator of maltreatment and neglect
Y07.54	Acquaintance or friend, perpetrator of maltreatment and neglect
Z55.6	Problems related to health literacy
Z58.81	Basic services unavailable in physical environment
Z58.89	Other problems related to physical environment
Z59.10	Inadequate housing, unspecified
Z59.11	Inadequate housing environmental temperature
Z59.12	Inadequate housing utilities
Z59.19	Other inadequate housing
Z62.814	Personal history of child financial abuse
Z62.815	Personal history of intimate partner abuse in childhood
Z91.141	Patient's other noncompliance with medication regimen due to financial hardship
Z91.148	Patient's other noncompliance with medication regimen for other reason
Z91.151	Patient's noncompliance with renal dialysis due to financial hardship
Z91.158	Patient's noncompliance with renal dialysis for other reason
Z91.413	Personal history of adult financial abuse
Z91.414	Personal history of adult intimate partner abuse

We refer the reader to the CDC web page at *https://www.cdc.gov/nchs/icd/Comprehensive-Listing-of-ICD-10-CM-Files.htm* for additional details regarding the implementation of these new diagnosis codes.

As discussed in the proposed rule, we provided the MS–DRG assignments for the 42 diagnosis codes effective with

discharges on and after April 1, 2023, consistent with our established process for assigning new diagnosis codes. Specifically, we review the predecessor diagnosis code and MS–DRG assignment most closely associated with the new diagnosis code and consider other factors that may be relevant to the MS–DRG assignment, including the severity of illness, treatment difficulty, and the resources utilized for the specific condition/diagnosis. We note that this process does not automatically result in the new diagnosis code being assigned to the same MS–DRG as the predecessor code. The assignments for the previously listed diagnosis codes are reflected in Table 6A.—New Diagnosis Codes associated with the proposed rule and available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*. As with the other new diagnosis codes and MS–DRG assignments included in Table 6A in association with the proposed rule, we solicited public comments on the most appropriate MDC, MS–DRG, and severity level assignments for these codes for FY 2024, as well as any other options for the GROUPER logic.

We did not receive any comments opposing the MDC, MS–DRG, and severity level assignments for the listed codes and are therefore, finalizing, without modification, the assignments as reflected in Table 6A.—New Diagnosis Codes in association with this final rule.

In addition, we noted in the proposed rule that CMS implemented 34 new procedure codes including laser interstitial thermal therapy (LITT) of various vertebral body sites, bone marrow transfusions, and the introduction or infusion of therapeutics, into the ICD–10–PCS classification effective with discharges on and after April 1, 2023. The procedure codes are as follows:

Procedure Code	Description	O.R.	MDC	MS-DRG
02LW0DJ	Occlusion of thoracic aorta, descending with intraluminal device, temporary, open approach	Y	05 21	270-272 907-909
04L00DJ	Occlusion of abdominal aorta with intraluminal device, temporary, open approach	Y	05 06 21 24	268-269 356-358 907-909 957-959
0P530Z3	Destruction of cervical vertebra using laser interstitial thermal therapy, open approach	Y	03 21 24	143-145 907-909 957-959
0P533Z3	Destruction of cervical vertebra using laser interstitial thermal therapy, percutaneous approach	Y	03 21 24	143-145 907-909 957-959
0P534Z3	Destruction of cervical vertebra using laser interstitial thermal therapy, percutaneous endoscopic approach	Y	03 21 24	143-145 907-909 957-959
0P540Z3	Destruction of thoracic vertebra using laser interstitial thermal therapy, open approach	Y	08 21 24	495-497 907-909 957-959
0P543Z3	Destruction of thoracic vertebra using laser interstitial thermal therapy, percutaneous approach	Y	08 21 24	495-497 907-909 957-959
0P544Z3	Destruction of thoracic vertebra using laser interstitial thermal therapy, percutaneous endoscopic approach	Y	08 21 24	495-497 907-909 957-959
0Q500Z3	Destruction of lumbar vertebra using laser interstitial thermal therapy, open approach	Y	08 21 24	495-497 907-909 957-959
0Q503Z3	Destruction of lumbar vertebra using laser interstitial thermal therapy, percutaneous approach	Y	08 21 24	495-497 907-909 957-959
0Q504Z3	Destruction of lumbar vertebra using laser interstitial thermal therapy, percutaneous endoscopic approach	Y	08 21 24	495-497 907-909 957-959
0Q510Z3	Destruction of sacrum using laser interstitial thermal therapy, open approach	Y	08 21 24	495-497 907-909 957-959
0Q513Z3	Destruction of sacrum using laser interstitial thermal therapy, percutaneous approach	Y	08 21 24	495-497 907-909 957-959
0Q514Z3	Destruction of sacrum using laser interstitial thermal therapy, percutaneous endoscopic approach	Y	08 21 24	495-497 907-909 957-959
302A3H0*	Transfusion of autologous whole blood into bone marrow, percutaneous approach	N		
302A3H1*	Transfusion of nonautologous whole blood into bone marrow, percutaneous approach	N		
302A3J0*	Transfusion of autologous serum albumin into bone marrow, percutaneous approach	N		

Procedure Code	Description	O.R.	MDC	MS-DRG
302A3J1*	Transfusion of nonautologous serum albumin into bone marrow, percutaneous approach	N		
302A3K0*	Transfusion of autologous frozen plasma into bone marrow, percutaneous approach	N		
302A3K1*	Transfusion of nonautologous frozen plasma into bone marrow, percutaneous approach	N		
302A3L0*	Transfusion of autologous fresh plasma into bone marrow, percutaneous approach	N		
302A3L1*	Transfusion of nonautologous fresh plasma into bone marrow, percutaneous approach	N		
302A3N0*	Transfusion of autologous red blood cells into bone marrow, percutaneous approach	N		
302A3N1*	Transfusion of nonautologous red blood cells into bone marrow, percutaneous approach	N		
302A3P0*	Transfusion of autologous frozen red cells into bone marrow, percutaneous approach	N		
302A3P1*	Transfusion of nonautologous frozen red cells into bone marrow, percutaneous approach	N		
302A3R0*	Transfusion of autologous platelets into bone marrow, percutaneous approach	N		
302A3R1*	Transfusion of nonautologous platelets into bone marrow, percutaneous approach	N		
XW013G6*	Introduction of regn-cov2 monoclonal antibody into subcutaneous tissue, percutaneous approach, new technology group 6	N		
XW0DXK8*	Introduction of sabizabulin into mouth and pharynx, external approach, new technology group 8	N		
XW0G7K8*	Introduction of sabizabulin into upper GI, via natural or artificial opening, new technology group 8	N		
XW0H7K8*	Introduction of sabizabulin into lower GI, via natural or artificial opening, new technology group 8	N		
XW133J8	Transfusion of exagamglogene autotemcel into peripheral vein, percutaneous approach, new technology group 8	N**	Pre-MDC	016-017
XW143J8	Transfusion of exagamglogene autotemcel into central vein, percutaneous approach, new technology group 8	N**	Pre-MDC	016-017

* As the procedure codes are designated as non-O.R. procedures, there is no assigned MDC or MS-DRG. The ICD-10 MS-DRG assignment is dependent on the reported principal diagnosis, any secondary diagnoses defined as a complication or comorbidity (CC) or major complication or comorbidity (MCC), procedures or services performed, age, sex, and discharge status.

** NonOR affecting MS-DRG assignment.

The 34 procedure codes are also reflected in Table 6B—New Procedure Codes in association with the proposed rule and available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/*

AcuteInpatientPPS. As with the other new procedure codes and MS–DRG assignments included in Table 6B in association with the proposed rule, we solicited public comments on the most appropriate MDC, MS–DRG, and operating room status assignments for these codes for FY 2024, as well as any other options for the GROUPER logic.

We did not receive any comments opposing the MDC, MS–DRG, and operating room status assignments for the listed codes and are therefore, finalizing, without modification, the assignments as reflected in Table 6B.—New Procedure Codes in association with this final rule.

In the proposed rule, we also noted that Change Request (CR) 13034, Transmittal 11746, titled ''April 2023 Update to the Medicare Severity—Diagnosis Related Group (MS–DRG) Grouper and Medicare Code Editor (MCE) Version 40.1 for the International Classification of Diseases, Tenth Revision (ICD–10) Diagnosis Codes for Collection of Health-Related Social Needs (HRSNs) and New ICD–10 Procedure Coding System (PCS) Codes'', was issued on December 15, 2022 (available on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r11746cp*), regarding the release of an updated version of the ICD–10 MS–DRG GROUPER and Medicare Code Editor software, Version 40.1, effective with discharges on and after April 1, 2023, reflecting the new diagnosis and procedure codes. The updated software, along with the updated ICD–10 MS–DRG V40.1 Definitions Manual and the Definitions of Medicare Code Edits V40.1 manual is available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

In the September 7, 2001 final rule implementing the IPPS new technology add-on payments (66 FR 46906), we indicated we would attempt to include proposals for procedure codes that would describe new technology discussed and approved at the Spring meeting as part of the code revisions effective the following October.

Section 503(a) of Public Law 108–173 included a requirement for updating diagnosis and procedure codes twice a year instead of a single update on October 1 of each year. This requirement was included as part of the amendments to the Act relating to recognition of new technology under the IPPS. Section 503(a) of Public Law 108–173 amended section 1886(d)(5)(K) of the Act by adding a clause (vii) which states that the Secretary shall provide for the addition of new diagnosis and procedure codes on April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) until the fiscal year that begins after such date. This requirement improves the recognition of new technologies under the IPPS by providing information on these new technologies at an earlier date. Data will be available 6 months earlier than would be possible with updates occurring only once a year on October 1.

In the FY 2005 IPPS final rule, we implemented section 1886(d)(5)(K)(vii) of the Act, as added by section 503(a) of Public Law 108–173, by developing a mechanism for approving, in time for the April update, diagnosis and procedure code revisions needed to describe new technologies and medical services for purposes of the new technology add-on payment process. We also established the following process for making these determinations. Topics considered during the Fall ICD–10 (previously ICD–9–CM) Coordination and Maintenance Committee meeting were considered for an April 1 update if a strong and convincing case was made by the requestor during the Committee's public meeting. The request needed to identify the reason why a new code was needed in April for purposes of the new technology process. Meeting participants and those reviewing the Committee meeting materials were provided the opportunity to comment on the expedited request. We refer the reader to the FY 2022 IPPS/LTCH PPS final rule (86 FR 44950) for further discussion of the implementation of this prior April 1 update for purposes of the new technology add-on payment process.

However, as discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 44950 through 44956), we adopted an April 1 implementation date, in addition to the annual October 1 update, beginning with April 1, 2022. We noted that the intent of this April 1 implementation date is to allow flexibility in the ICD–10 code update process. With this new April 1 update, CMS now uses the same process for consideration of all requests for an April 1 implementation date, including for purposes of the new technology add-on payment process (that is, the prior process for consideration of an April 1 implementation date only if a strong and convincing case was made by the requestor during the meeting no longer applies). We are continuing to use several aspects of our existing established process to implement new codes through the April 1 code update, which includes presenting proposals for April 1 consideration at the September ICD–10 Coordination and Maintenance Committee meeting, requesting public comments, reviewing the public comments, finalizing codes, and announcing the new codes with their assignments consistent with the new GROUPER release information. We note that under our established process, requestors indicate whether they are submitting their code request for consideration for an April 1 implementation date or an October 1 implementation date. The ICD–10 Coordination and Maintenance Committee makes efforts to accommodate the requested implementation date for each request submitted. However, the Committee determines which requests are to be presented for consideration for an April 1 implementation date or an October 1 implementation date. As discussed earlier in this section of the preamble of this final rule, there were code proposals presented for an April 1, 2023, implementation at the September 13–14, 2022, Committee meetings. Following the receipt of public comments, the code proposals were approved and finalized, therefore, there were new codes implemented April 1, 2023.

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule, consistent with the process we outlined for the April 1 implementation date, we announced the new codes in November 2022 and provided the updated code files and ICD–10–CM Official Guidelines for Coding and Reporting in January 2023. On January 30, 2023, the **Federal Register** (88 FR 5882) notice for the March 7–8, 2023 ICD–10 Coordination and Maintenance Committee Meeting was published that includes the tentative agenda and identifies which topics are related to a new technology add-on payment application. By February 1, 2023, we made available the updated V40.1 ICD–10 MS–DRG Grouper software and related materials on the CMS web page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/MS-DRG-Classifications-and-Software*.

ICD–9–CM addendum and code title information is published on the CMS website at *https://www.cms.gov/Medicare/Coding/ICD9ProviderDiagnosticCodes/addendum*. ICD–10–CM and ICD–10–PCS addendum and code title information is published on the CMS website at *https://www.cms.gov/Medicare/Coding/ICD10*. CMS also sends electronic files

containing all ICD–10–CM and ICD–10–PCS coding changes to its Medicare contractors for use in updating their systems and providing education to providers. Information on ICD–10–CM diagnosis codes, along with the Official ICD–10–CM Coding Guidelines, can be found on the CDC website at *https://www.cdc.gov/nchs/icd/Comprehensive-Listing-of-ICD-10-CM-Files.htm*. Additionally, information on new, revised, and deleted ICD–10–CM diagnosis and ICD–10–PCS procedure codes is provided to the AHA for publication in the Coding Clinic for ICD–10. The AHA also distributes coding update information to publishers and software vendors.

In the proposed rule, we noted that for FY 2023, there are currently 73,674 diagnosis codes and 78,530 procedure codes. We also noted that as displayed in Table 6A.—New Diagnosis Codes and in Table 6B.—New Procedure Codes associated with the proposed rule (and available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*), there are 395 new diagnosis codes and 10 new procedure codes that had been finalized for FY 2024 at the time of the development of the proposed rule. As discussed in section II.C.13 of the preamble of this final rule, we are making Table 6A.—New Diagnosis Codes, Table 6B.—New Procedure Codes, Table 6C.—Invalid Diagnosis Codes, Table 6D.—Invalid Procedure Codes, Table 6E.—Revised Diagnosis Code Titles and Table 6F.—Revised Procedure Code Titles available on the CMS website at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps* in association with this final rule. As shown in Table 6B.—New Procedure Codes, there were procedure codes discussed at the March 7–8, 2023 ICD–10 Coordination and Maintenance Committee meeting that were not finalized in time to include in the proposed rule and are identified with an asterisk. We refer the reader to Table 6B.—New Procedure Codes associated with this final rule and available on the CMS website at: *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps* for the detailed list of these additional 68 new procedure codes. The addition of these 68 new procedure codes to the 10 procedure codes that had been finalized at the time of the development of the proposed rule results in a total of 78 (10 + 68 = 78) new procedure codes for FY 2024.

We also note, as reflected in Table 6C.—Invalid Diagnosis Codes and in Table 6D.—Invalid Procedure Codes, there are a total of 25 diagnosis codes and 5 procedure codes that will become invalid effective October 1, 2023. Based on these code updates, effective October 1, 2023, there are a total of 74,044 ICD–10–CM diagnosis codes and 78,603 ICD–10–PCS procedure codes for FY 2024 as shown in the following table.

FY 2023 ICD-10-CM	73,674 total codes	FY 2023 ICD-10-PCS	78,530 total codes
FY 2024 ICD-10-CM	395 additions	FY 2024 ICD-10-PCS	78 additions
FY 2024 ICD-10-CM	25 deletions	FY 2024 ICD-10-PCS	5 deletions
FY 2024 ICD-10-CM	**74,044 total codes**	**FY 2024 ICD-10-PCS**	**78,603 total codes**

As stated previously, the public is provided the opportunity to comment on any requests for new diagnosis or procedure codes discussed at the ICD–10 Coordination and Maintenance Committee meeting. The code titles are adopted as part of the ICD–10 Coordination and Maintenance Committee process. Thus, although we publish the code titles in the IPPS proposed and final rules, they are not subject to comment in the proposed or final rules.

17. Replaced Devices Offered Without Cost or With a Credit

a. Background

In the FY 2008 IPPS final rule with comment period (72 FR 47246 through 47251), we discussed the topic of Medicare payment for devices that are replaced without cost or where credit for a replaced device is furnished to the hospital. We implemented a policy to reduce a hospital's IPPS payment for certain MS–DRGs where the implantation of a device that subsequently failed or was recalled determined the base MS–DRG assignment. At that time, we specified that we will reduce a hospital's IPPS payment for those MS–DRGs where the hospital received a credit for a replaced device equal to 50 percent or more of the cost of the device.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51556 through 51557), we clarified this policy to state that the policy applies if the hospital received a credit equal to 50 percent or more of the cost of the replacement device and issued instructions to hospitals accordingly.

b. Changes for FY 2024

As discussed in section II.C.5. of the preamble of the proposed rule and this final rule, for FY 2024, we proposed to delete MS–DRGs 222, 223, 224, 225, 226, and 227, add new MS–DRG 275 (Cardiac Defibrillator Implant with Cardiac Catheterization and MCC) and new MS–DRGs 276 and 277 (Cardiac Defibrillator Implant with MCC, and without MCC, respectively), and to reassign a subset of the procedures currently assigned to MS–DRGs 222 through 227 to proposed new MS–DRGs 275, 276, and 277.

As stated in the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24409), we generally map new MS–DRGs onto the list when they are formed from procedures previously assigned to MS–DRGs that are already on the list. Currently, MS–DRGs 222 through 227 are on the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit as shown in the following table. A subset of the procedures currently assigned to MS–DRGs 222 through 227 was proposed for assignment to proposed new MS–DRGs 275, 276, and 277. Therefore, we proposed that if the applicable proposed MS–DRG changes are finalized, we also would add proposed new MS–DRGs 275, 276, and 277 to the list of MS–DRGs subject to the policy for payment under the IPPS for replaced devices offered without cost or with a credit and make conforming changes to delete MS–DRGs 222 through 227 from the list of MS–DRGs subject to the policy. We also proposed to continue to include the existing MS–DRGs currently subject to the policy.

As discussed in section II.C.5. of the preamble of this final rule, we are finalizing our proposal to delete MS–DRGs 222, 223, 224, 225, 226, and 227. Additionally, we are finalizing our proposal to create new MS–DRG 275 (Cardiac Defibrillator Implant with Cardiac Catheterization and MCC) and new MS–DRGs 276 and 277 (Cardiac Defibrillator Implant with MCC, and without MCC, respectively), and to reassign a subset of the procedures currently assigned to MS–DRGs 222

through 227 to proposed new MS–DRGs 275, 276, and 277. We did not receive any public comments opposing our proposal to delete MS–DRGs 222, 223, 224, 225, 226, and 227 from the list of MS–DRGs that will be subject to the replaced devices offered without cost or with a credit policy effective October 1, 2023. Additionally, we did not receive any public comments opposing our proposal to add MS–DRGs 275, 276, and 277 to the list of MS–DRGs that will be subject to the policy for replaced devices offered without cost or with credit or to continue to include the existing MS–DRGs currently subject to the policy. Therefore, we are finalizing the list of MS–DRGs in the following table that will be subject to the replaced devices offered without cost or with a credit policy effective October 1, 2023.

MDC	MS-DRG	MS-DRG Title
Pre-MDC	001	Heart Transplant or Implant of Heart Assist System with MCC
Pre-MDC	002	Heart Transplant or Implant of Heart Assist System without MCC
01	023	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis with MCC or Chemotherapy Implant or Epilepsy with Neurostimulator
01	024	Craniotomy with Major Device Implant or Acute Complex CNS Principal Diagnosis without MCC
01	025	Craniotomy and Endovascular Intracranial Procedures with MCC
01	026	Craniotomy and Endovascular Intracranial Procedures with CC
01	027	Craniotomy and Endovascular Intracranial Procedures without CC/MCC
01	040	Peripheral, Cranial Nerve and Other Nervous System Procedures with MCC
01	041	Peripheral, Cranial Nerve and Other Nervous System Procedures with CC or Peripheral Neurostimulator
01	042	Peripheral, Cranial Nerve and Other Nervous System Procedures without CC/MCC
03	140	Major Head and Neck Procedures with MCC
03	141	Major Head and Neck Procedures with CC
03	142	Major Head and Neck Procedures without CC/MCC
05	215	Other Heart Assist System Implant

MDC	MS-DRG	MS-DRG Title
05	216	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with MCC
05	217	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization with CC
05	218	Cardiac Valve and Other Major Cardiothoracic Procedure with Cardiac Catheterization without CC/MCC
05	219	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with MCC
05	220	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization with CC
05	221	Cardiac Valve and Other Major Cardiothoracic Procedure without Cardiac Catheterization without CC/MCC
05	242	Permanent Cardiac Pacemaker Implant with MCC
05	243	Permanent Cardiac Pacemaker Implant with CC
05	244	Permanent Cardiac Pacemaker Implant without CC/MCC
05	245	AICD Generator Procedures
05	258	Cardiac Pacemaker Device Replacement with MCC
05	259	Cardiac Pacemaker Device Replacement without MCC
05	260	Cardiac Pacemaker Revision Except Device Replacement with MCC
05	261	Cardiac Pacemaker Revision Except Device Replacement with CC
05	262	Cardiac Pacemaker Revision Except Device Replacement without CC/MCC
05	265	AICD Lead Procedures
05	266	Endovascular Cardiac Valve Replacement and Supplement Procedures with MCC
05	267	Endovascular Cardiac Valve Replacement and Supplement Procedures without MCC
05	268	Aortic and Heart Assist Procedures Except Pulsation Balloon with MCC
05	269	Aortic and Heart Assist Procedures Except Pulsation Balloon without MCC
05	270	Other Major Cardiovascular Procedures with MCC
05	271	Other Major Cardiovascular Procedures with CC
05	272	Other Major Cardiovascular Procedures without CC/MCC
05	275	Cardiac Defibrillator Implant with Cardiac Catheterization and MCC
05	276	Cardiac Defibrillator Implant with MCC
05	277	Cardiac Defibrillator Implant without MCC
05	319	Other Endovascular Cardiac Valve Procedures with MCC
05	320	Other Endovascular Cardiac Valve Procedures without MCC
08	461	Bilateral or Multiple Major Joint Procedures of Lower Extremity with MCC
08	462	Bilateral or Multiple Major Joint Procedures of Lower Extremity without MCC
08	466	Revision of Hip or Knee Replacement with MCC
08	467	Revision of Hip or Knee Replacement with CC
08	468	Revision of Hip or Knee Replacement without CC/MCC
08	469	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or Total Ankle Replacement
08	470	Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity without MCC
08	521	Hip Replacement with Principal Diagnosis of Hip Fracture with MCC
08	522	Hip Replacement with Principal Diagnosis of Hip Fracture without MCC

BILLING CODE 4120–01–C

The final list of MS–DRGs subject to the IPPS policy for replaced devices offered without cost or with a credit will be issued to providers in the form of a Change Request (CR).

18. Out of Scope Public Comments Received

We received public comments on MS–DRG related issues that were outside the scope of the proposals included in the FY 2024 IPPS/LTCH PPS proposed rule.

Because we consider these public comments to be outside the scope of the proposed rule, we are not addressing them in this final rule. As stated in

section II.D.1.b. of the preamble of this final rule, we encourage individuals with comments about MS–DRG classifications to submit these comments no later than October 20, 2023, via the new electronic intake system, Medicare Electronic Application Request Information System™ (MEARIS™) at: *https://mearis.cms.gov/public/home*, so that they can be considered for possible inclusion in the annual proposed rule. We will consider these public comments for possible proposals in future rulemaking as part of our annual review process.

D. Recalibration of the FY 2024 MS–DRG Relative Weights

1. Data Sources for Developing the Relative Weights

Consistent with our established policy, in developing the MS–DRG relative weights for FY 2024, we proposed to use two data sources: claims data and cost report data. The claims data source is the MedPAR file, which includes fully coded diagnostic and procedure data for all Medicare inpatient hospital bills. The FY 2022 MedPAR data used in this final rule include discharges occurring on October 1, 2021, through September 30, 2022, based on bills received by CMS through March 31, 2023, from all hospitals subject to the IPPS and short-term, acute care hospitals in Maryland (which at that time were under a waiver from the IPPS).

The FY 2022 MedPAR file used in calculating the relative weights includes data for approximately 6,991,373 Medicare discharges from IPPS providers. Discharges for Medicare beneficiaries enrolled in a Medicare Advantage managed care plan are excluded from this analysis. These discharges are excluded when the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field, indicating that the claim was an ''IME only'' claim submitted by a teaching hospital on behalf of a beneficiary enrolled in a Medicare Advantage managed care plan. In addition, the December 2022 update of the FY 2022 MedPAR file complies with version 5010 of the X12 HIPAA Transaction and Code Set Standards, and includes a variable called ''claim type.'' Claim type ''60'' indicates that the claim was an inpatient claim paid as fee-for-service. Claim types ''61,'' ''62,'' ''63,'' and ''64'' relate to encounter claims, Medicare Advantage IME claims, and HMO no-pay claims. Therefore, the calculation of the relative weights for FY 2024 also excludes claims with claim type values not equal to ''60.'' The data exclude CAHs, including hospitals that subsequently became CAHs after the period from which the data were taken. We note that the FY 2024 relative weights are based on the ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes from the FY 2022 MedPAR claims data, grouped through the ICD–10 version of the FY 2024 GROUPER (Version 41).

The second data source used in the cost-based relative weighting methodology is the Medicare cost report data files from the HCRIS. In general, we use the HCRIS dataset that is 3 years prior to the IPPS fiscal year. Specifically, for this final rule, we used the March 2023 update of the FY 2021 HCRIS for calculating the FY 2024 cost-based relative weights. Consistent with our historical practice, for this FY 2024 final rule, we are providing the version of the HCRIS from which we calculated these 19 CCRs on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*. Click on the link on the left side of the screen titled ''FY 2024 IPPS Proposed Rule Home Page'' or ''Acute Inpatient Files for Download.''

2. Methodology for Calculation of the Relative Weights

a. General

We calculated the FY 2024 relative weights based on 19 CCRs. The methodology we proposed to use to calculate the FY 2024 MS–DRG cost-based relative weights based on claims data in the FY 2022 MedPAR file and data from the FY 2021 Medicare cost reports is as follows:

- To the extent possible, all the claims were regrouped using the FY 2024 MS–DRG classifications discussed in sections II.B. and II.C. of the preamble of this final rule.
- The transplant cases that were used to establish the relative weights for heart and heart-lung, liver and/or intestinal, and lung transplants (MS–DRGs 001, 002, 005, 006, and 007, respectively) were limited to those Medicare-approved transplant centers that have cases in the FY 2022 MedPAR file. (Medicare coverage for heart, heart-lung, liver and/or intestinal, and lung transplants is limited to those facilities that have received approval from CMS as transplant centers.)
- Organ acquisition costs for kidney, heart, heart-lung, liver, lung, pancreas, and intestinal (or multivisceral organs) transplants continue to be paid on a reasonable cost basis.

Because these acquisition costs are paid separately from the prospective payment rate, it is necessary to subtract the acquisition charges from the total charges on each transplant bill that showed acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.

Section 108 of the Further Consolidated Appropriations Act, 2020 provides that, for cost reporting periods beginning on or after October 1, 2020, costs related to hematopoietic stem cell acquisition for the purpose of an allogeneic hematopoietic stem cell transplant shall be paid on a reasonable cost basis. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule for further discussion of the reasonable cost basis payment for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 through 58842). For FY 2022 and subsequent years, we subtract the hematopoietic stem cell acquisition charges from the total charges on each transplant bill that showed hematopoietic stem cell acquisition charges before computing the average cost for each MS–DRG and before eliminating statistical outliers.

- Claims with total charges or total lengths of stay less than or equal to zero were deleted. Claims that had an amount in the total charge field that differed by more than $30.00 from the sum of the routine day charges, intensive care charges, pharmacy charges, implantable devices charges, supplies and equipment charges, therapy services charges, operating room charges, cardiology charges, laboratory charges, radiology charges, other service charges, labor and delivery charges, inhalation therapy charges, emergency room charges, blood and blood products charges, anesthesia charges, cardiac catheterization charges, computed tomography (CT) scan charges, and magnetic resonance imaging (MRI) charges were also deleted.
- At least 92.6 percent of the providers in the MedPAR file had charges for 14 of the 19 cost centers. All claims of providers that did not have charges greater than zero for at least 14 of the 19 cost centers were deleted. In other words, a provider must have no more than five blank cost centers. If a provider did not have charges greater than zero in more than five cost centers, the claims for the provider were deleted.
- Statistical outliers were eliminated by removing all cases that were beyond 3.0 standard deviations from the

geometric mean of the log distribution of both the total charges per case and the total charges per day for each MS–DRG.

• Effective October 1, 2008, because hospital inpatient claims include a POA indicator field for each diagnosis present on the claim, only for purposes of relative weight-setting, the POA indicator field was reset to ''Y'' for ''Yes'' for all claims that otherwise have an ''N'' (No) or a ''U'' (documentation insufficient to determine if the condition was present at the time of inpatient admission) in the POA field.

Under current payment policy, the presence of specific HAC codes, as indicated by the POA field values, can generate a lower payment for the claim. Specifically, if the particular condition is present on admission (that is, a ''Y'' indicator is associated with the diagnosis on the claim), it is not a HAC, and the hospital is paid for the higher severity (and, therefore, the higher weighted MS–DRG). If the particular condition is not present on admission (that is, an ''N'' indicator is associated with the diagnosis on the claim) and there are no other complicating conditions, the DRG GROUPER assigns the claim to a lower severity (and, therefore, the lower weighted MS–DRG) as a penalty for allowing a Medicare inpatient to contract a HAC. While the POA reporting meets policy goals of encouraging quality care and generates program savings, it presents an issue for the relative weight-setting process. Because cases identified as HACs are likely to be more complex than similar cases that are not identified as HACs, the charges associated with HAC cases are likely to be higher as well. Therefore, if the higher charges of these HAC claims are grouped into lower severity MS–DRGs prior to the relative weight-setting process, the relative weights of these particular MS–DRGs would become artificially inflated, potentially skewing the relative weights. In addition, we want to protect the integrity of the budget neutrality process by ensuring that, in estimating payments, no increase to the standardized amount occurs as a result of lower overall payments in a previous year that stem from using weights and case-mix that are based on lower severity MS–DRG assignments. If this would occur, the anticipated cost savings from the HAC policy would be lost.

To avoid these problems, we reset the POA indicator field to ''Y'' only for relative weight-setting purposes for all claims that otherwise have an ''N'' or a ''U'' in the POA field. This resetting ''forced'' the more costly HAC claims into the higher severity MS–DRGs as appropriate, and the relative weights calculated for each MS–DRG more closely reflect the true costs of those cases.

In addition, in the FY 2013 IPPS/LTCH PPS final rule, for FY 2013 and subsequent fiscal years, we finalized a policy to treat hospitals that participate in the Bundled Payments for Care Improvement (BPCI) initiative the same as prior fiscal years for the IPPS payment modeling and ratesetting process without regard to hospitals' participation within these bundled payment models (77 FR 53341 through 53343). Specifically, because acute care hospitals participating in the BPCI initiative still receive IPPS payments under section 1886(d) of the Act, we include all applicable data from these subsection (d) hospitals in our IPPS payment modeling and ratesetting calculations as if the hospitals were not participating in those models under the BPCI initiative. We refer readers to the FY 2013 IPPS/LTCH PPS final rule for a complete discussion on our final policy for the treatment of hospitals participating in the BPCI initiative in our ratesetting process. For additional information on the BPCI initiative, we refer readers to the CMS' Center for Medicare and Medicaid Innovation's website at *https://innovation.cms.gov/initiatives/Bundled-Payments/index.html* and to section IV.H.4. of the preamble of the FY 2013 IPPS/LTCH PPS final rule (77 FR 53341 through 53343).

The participation of hospitals in the BPCI initiative concluded on September 30, 2018. The participation of hospitals in the BPCI Advanced model started on October 1, 2018. The BPCI Advanced model, tested under the authority of section 1115A of the Act, is comprised of a single payment and risk track, which bundles payments for multiple services beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in BPCI Advanced in one of two capacities: as a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced model, participating acute care hospitals will continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are Participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at *https://innovation.cms.gov/initiatives/bpci-advanced/*. Consistent with our policy for FY 2023, and consistent with how we have treated hospitals that participated in the BPCI Initiative, for FY 2024, we continue to believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations because, as noted previously, these hospitals are still receiving IPPS payments under section 1886(d) of the Act. Consistent with the FY 2023 IPPS/LTCH PPS final rule, we also proposed to include all applicable data from subsection (d) hospitals participating in the Comprehensive Care for Joint Replacement (CJR) Model in our IPPS payment modeling and ratesetting calculations.

The charges for each of the 19 cost groups for each claim were standardized to remove the effects of differences in area wage levels, IME, and DSH payments, and for hospitals located in Alaska and Hawaii, the applicable cost-of-living adjustment. Because hospital charges include charges for both operating and capital costs, we standardized total charges to remove the effects of differences in geographic adjustment factors, cost-of-living adjustments, and DSH payments under the capital IPPS as well. Charges were then summed by MS–DRG for each of the 19 cost groups so that each MS–DRG had 19 standardized charge totals. Statistical outliers were then removed. These charges were then adjusted to cost by applying the proposed national average CCRs developed from the FY 2021 cost report data.

The 19 cost centers that we used in the relative weight calculation are shown in a supplemental data file, Cost Center HCRIS Lines Supplemental Data File, posted via the internet on the CMS website for this final rule and available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS.* The supplemental data file shows the lines on the cost report and the corresponding revenue codes that we used to create the 19 national cost center CCRs. We stated in the proposed rule that if we receive comments about the groupings in this supplemental data file, we may consider these comments as we finalize our policy. However, we did not receive any comments on the groupings in this table, and therefore, we are finalizing the groupings as proposed.

Consistent with historical practice, we account for rare situations of non-monotonicity in a base MS–DRG and its severity levels, where the mean cost in the higher severity level is less than the

mean cost in the lower severity level, in determining the relative weights for the different severity levels. If there are initially non-monotonic relative weights in the same base DRG and its severity levels, then we combine the cases that group to the specific non-monotonic MS–DRGs for purposes of relative weight calculations. For example, if there are two non-monotonic MS–DRGs, combining the cases across those two MS–DRGs results in the same relative weight for both MS–DRGs. The relative weight calculated using the combined cases for those severity levels is monotonic, effectively removing any non-monotonicity with the base DRG and its severity levels. For the FY 2024 proposed rule, this calculation was applied to address non-monotonicity for cases that grouped to MS–DRG 016 and MS–DRG 017. In the supplemental file titled AOR/BOR File associated with the proposed rule, we included statistics for the affected MS–DRGs both separately and with cases combined.

We invited public comments on our proposals related to recalibration of the proposed FY 2024 relative weights and the changes in relative weights from FY 2023.

Comment: A commenter stated that CMS erred in calculating the relative weights for MS–DRG 016 and MS–DRG 017. The commenter stated that if the relative weight is going to be kept the same, the MS–DRGs should be combined, as they are for allogenic bone marrow transplants.

Response: As discussed in the proposed rule, we intentionally combined the cases across the two MS–DRGs because the mean cost in the higher severity level is less than the mean cost in the lower severity level, consistent with our historical practice for accounting for situations of non-monotonicity in a base MS–DRG and its severity levels. We may consider the suggestion to combine these two MS–DRGs for future rulemaking.

Accordingly, for this FY 2024 final rule, this calculation was applied to address non-monotonicity for cases that grouped to MS–DRG 016 and MS–DRG 017. In the supplemental file titled AOR/BOR File associated with this final rule, we include statistics for the affected MS–DRGs both separately and with cases combined.

Comment: A commenter requested that CMS implement an edit for claims that group to MS–DRG 014, that would reject claims when an inpatient type of bill 11X claim is received without charges mapped to revenue code 0815. The commenter stated that this edit would help ensure accurate claims reporting, ensure the accuracy of CMS' budget neutrality calculations, and help ensure that CMS does not inappropriately generate outlier payment on MS–DRG 014 claims (given that CMS removes costs associated with revenue code 0815 from its outlier calculation).

Response: We expect providers to appropriately report charges associated with revenue code 0815 and do not believe that a novel claims processing edit such as this is necessary at this time. We may consider provider education materials regarding reporting Allogeneic Stem Cell Acquisition/Donor Services in the future.

After consideration of the comments received, we are finalizing our proposals related to the recalibration of the FY 2024 relative weights. We summarize and respond to comments relating to the methodology for calculating the relative weight for MS–DRG 018 in the next section of this final rule.

b. Relative Weight Calculation for MS–DRG 018

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58451 through 58453), we created MS–DRG 018 for cases that include procedures describing Chimeric Antigen Receptor (CAR) T-cell therapies. We also finalized our proposal to modify our existing relative weight methodology to ensure that the relative weight for MS–DRG 018 appropriately reflects the relative resources required for providing CAR T-cell therapy outside of a clinical trial, while still accounting for the clinical trial cases in the overall average cost for all MS–DRGs (85 FR 58599 through 58600). Specifically, we stated that clinical trial claims that group to new MS–DRG 018 will not be included when calculating the average cost for MS–DRG 018 that is used to calculate the relative weight for this MS–DRG, so that the relative weight reflects the costs of the CAR T-cell therapy drug. We stated that we identified clinical trial claims as claims that contain ICD–10–CM diagnosis code Z00.6 or contain standardized drug charges of less than $373,000, which was the average sales price of KYMRIAH and YESCARTA, the two CAR T-cell biological products licensed to treat relapsed/refractory large B-cell lymphoma as of the time of the development of the FY 2021 final rule. In addition, we stated that: (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for new MS–DRG 018 to the extent such cases can be identified in the historical data, and (b) when there is expanded access use of immunotherapy, these cases will not be included when calculating the average cost for new MS–DRG 018 to the extent such cases can be identified in the historical data.

We also finalized our proposal to calculate an adjustment to account for the CAR T-cell therapy cases identified as clinical trial cases in calculating the national average standardized cost per case that is used to calculate the relative weights for all MS–DRGs and for purposes of budget neutrality and outlier simulations. We calculate this adjustor by dividing the average cost for cases that we identify as clinical trial cases by the average cost for cases that we identify as non-clinical trial cases, with the additional refinements that (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for cases not determined to be clinical trial cases to the extent such cases can be identified in the historical data, and (b) when there is expanded access use of immunotherapy, these cases will be included when calculating the average cost for cases determined to be clinical trial cases to the extent such cases can be identified in the historical data. We stated that to the best of our knowledge, there were no claims in the historical data used in the calculation of this adjustment for cases involving a clinical trial of a different product, and to the extent the historical data contain claims for cases involving expanded access use of immunotherapy we believe those claims would have drug charges less than $373,000.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58842), we also finalized an adjustment to the payment amount for applicable clinical trial and expanded access use immunotherapy cases that group to MS–DRG 018, and indicated that we would provide instructions for identifying these claims in separate guidance. Following the issuance of the FY 2021 IPPS/LTCH PPS final rule, we issued guidance [20] stating that providers may enter a Billing Note NTE02 ''Expand Acc Use'' on the electronic claim 837I or a remark ''Expand Acc Use'' on a paper claim to notify the Medicare administrative contractor (MAC) of expanded access use of CAR T-cell therapy. In this case, the MAC would add payer-only condition code ''ZB'' so that Pricer will apply the payment adjustment in calculating payment for the case. In cases when the CAR T-cell therapy product is

[20] *https://www.cms.gov/files/document/r10571cp.pdf.*

purchased in the usual manner, but the case involves a clinical trial of a different product, the provider may enter a Billing Note NTE02 ''Diff Prod Clin Trial'' on the electronic claim 837I or a remark ''Diff Prod Clin Trial'' on a paper claim. In this case, the MAC would add payer-only condition code ''ZC'' so that the Pricer will not apply the payment adjustment in calculating payment for the case.

In the FY 2022 IPPS/LTCH PPS final rule, we revised MS–DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 44806). We also finalized our proposal to continue to use the proxy of standardized drug charges of less than $373,000 (86 FR 44965) to identify clinical trial claims.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 48894), we once again finalized our policy to use a proxy of standardized drug charges of less than $373,000. We also stated that we will continue to monitor the data with respect to the clinical trial threshold. As in prior years, we stated that we continue to believe to the best of our knowledge there were no claims in the historical data (FY 2021 MedPAR) used in the calculation of the adjustment for cases involving a clinical trial of a different product, and to the extent the historical data contain claims for cases involving expanded access use of immunotherapy we believe those claims would have drug charges less than $373,000. We also stated, in response to comments, that we agreed that the availability of condition code 90 obviates the need for the use of the remarks field to identify expanded access claims that group to MS–DRG 018 for the purposes of applying the clinical trial adjustment. We stated that effective October 1, 2022, providers should submit condition code 90 to identify expanded access claims that group to MS–DRG 018, rather than the remarks field, and that the MACs will no longer flag cases as expanded access claims based on information submitted in the remarks field for claims submitted on or after October 1, 2022 (87 FR 48896). We also noted that we were in the process of making modifications to the MedPAR files to include information for claims with the payer-only condition code ''ZC'' in the future, which is used by the IPPS Pricer to identify a case where the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product so that the payment adjustment is not applied in calculating the payment for the case (87 FR 49080).

Following the issuance of the FY 2023 IPPS/LTCH PPS final rule, we issued guidance [21] stating where there is expanded access use of immunotherapy, the provider may submit condition code ''90'' on the claim so that Pricer will apply the payment adjustment in calculating payment for the case. We stated that MACs would no longer append Condition Code 'ZB' to inpatient claims reporting Billing Note NTE02 ''Expand Acc Use'' on the electronic claim 837I or a remark ''Expand Acc Use'' on a paper claim, effective for claims for discharges that occur on or after October 1, 2022.

We stated in the proposed rule that while we have applied a proxy of standardized drug charges of less than $373,000 to identify clinical trial claims and expanded access use cases under our special methodology for the calculation of the relative weight for MS–DRG 018 to date, we believe that because of changes that have occurred since CMS initially adopted this policy, it may no longer be necessary to apply this proxy to identify these claims. In the FY 2021 IPPS/LTCH PPS final rule, we stated that because ICD–10–CM diagnosis code Z00.6 is required to be included with clinical trial cases, we expect hospitals to include this code for such cases grouping to MS–DRG 018 for FY 2021 and all subsequent years, and we believe that providers have continued to gain experience with the use of ICD–10–CM diagnosis code Z00.6 to report cases involving a clinical trial of CAR T-cell therapy. This is supported by our observation that the percentage of claims reporting standardized drug charges of less than $373,000 that do not report ICD–10–CM code Z00.6 relative to all claims that group to MS–DRG 018 fell significantly from the FY 2019 data (used in the FY 2021 ratesetting) to the FY 2022 data (used in the FY 2024 ratesetting). For example, in the FY 2019 MedPAR data used for the FY 2021 IPPS/LTCH PPS final rule, cases that we identified as clinical trial cases (using our proxy of standardized drug charges of less than $373,000) that did not contain ICD–10–CM diagnosis code Z00.6 comprised 18 percent of all cases that grouped to MS–DRG 018. In the FY 2022 MedPAR data used for the FY 2024 IPPS/LTCH PPS proposed rule, cases that we identified as clinical trial cases using our proxy that did not contain ICD–10–CM diagnosis code Z00.6 comprised 4 percent of all cases that grouped to MS–DRG 018. In addition, prior to FY 2022, we were unable to identify cases in the MedPAR claims data that were provided as part of expanded access use in developing the relative weights. The December update of the FY 2022 MedPAR claims data now includes a field that identifies whether or not the claim includes expanded access use of immunotherapy. For the FY 2022 MedPAR claims data, this field identifies whether or not the claim includes condition code ZB. For the FY 2023 MedPAR data and for subsequent years, this field will identify whether or not the claim includes condition code 90. This allows us to exclude these claims, similar to our methodology for clinical trial cases, in the calculation of the relative weight for MS–DRG 018, without relying on a proxy. (We noted that because the expanded access indicator was not available prior to the FY 2022 MedPAR, the comparison of cases identified using the proxy, as described previously, did not include the cases in the FY 2022 MedPAR data used for the FY 2024 IPPS/LTCH PPS proposed rule with an expanded access indicator on the claim, as including these cases would mean we were not comparing the same group of cases). We further note that the MedPAR files now also include a variable that indicates whether the claim includes the payer-only condition code ''ZC'', which identifies a case involving the clinical trial of a different product where the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner.

Therefore, in the FY 2024 IPPS/LTCH PPS proposed rule, we proposed two changes to our methodology for identifying clinical trial claims and expanded access use claims in MS–DRG 018. First, we proposed to exclude claims with the presence of condition code ''90'' (or, for FY 2024 ratesetting, which is based on the FY 2022 MedPAR data, the presence of condition code ''ZB'') and claims that contain ICD–10–CM diagnosis code Z00.6 without payer-only code ''ZC'' that group to MS–DRG 018 when calculating the average cost for MS–DRG 018. Second, for the reasons described previously, we proposed to no longer use the proxy of standardized drug charges of less than $373,000 to identify clinical trial claims and expanded access use cases when calculating the average cost for MS–DRG 018. Accordingly, we proposed that in calculating the relative weight for MS–DRG 018 for FY 2024, only those claims that group to MS–DRG 018 that (1) contain ICD–10–CM diagnosis code Z00.6 and do not include payer-only code ''ZC'' or (2) contain condition code

[21] *https://www.cms.gov/files/document/r11727cp.pdf.*

''ZB'' (or, for subsequent fiscal years, condition code ''90'') would be excluded from the calculation of the average cost for MS–DRG 018.

Consistent with this proposal, we also proposed to modify our calculation of the adjustment to account for the CAR T-cell therapy cases identified as clinical trial cases in calculating the national average standardized cost per case that is used to calculate the relative weights for all MS–DRGs:

- Calculate the average cost for cases assigned to MS–DRG 018 that either—(a) contain ICD–10–CM diagnosis code Z00.6 and do not contain condition code ''ZC'' or (b) contain condition code 90 (or, for FY 2024 ratesetting, condition code ''ZB'').
- Calculate the average cost for all other cases assigned to MS–DRG 018.
- Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.
- Apply the adjustor calculated in step 3 to the cases identified in step 1 as applicable clinical trial or expanded access use cases, then add this adjusted case count to the non-clinical trial case count prior to calculating the average cost across all MS–DRGs.

Applying this proposed methodology, based on the December 2022 update of the FY 2022 MedPAR file used for the proposed rule, we estimated that the average costs of cases assigned to MS–DRG 018 that are identified as clinical trial cases ($89,379) were 28 percent of the average costs of the cases assigned to MS–DRG 018 that are identified as nonclinical trial cases ($323,903). Accordingly, as we did for FY 2023, we proposed to adjust the transfer-adjusted case count for MS–DRG 018 by applying the proposed adjustor of 0.28 to the applicable clinical trial and expanded access use immunotherapy cases, and to use this adjusted case count for MS–DRG 018 in calculating the national average cost per case, which is used in the calculation of the relative weights. Therefore, in calculating the national average cost per case for purposes of the proposed rule, each case identified as an applicable clinical trial or expanded access use immunotherapy case was adjusted by 0.28. As we did for FY 2023, we are applied this same adjustor for the applicable cases that group to MS–DRG 018 for purposes of budget neutrality and outlier simulations. We also proposed to update the value of the adjustor based on more recent data for the final rule.

Comment: Some commenters supported our proposal to remove the use of the proxy of excluding cases with standardized drug charges of less than $373,000, stating that it is consistent with existing hospital billing practices and would simplify the reimbursement for chimeric antigen receptor therapy (CAR–T) services. Many commenters opposed our proposal, stating that it was premature to remove this trim. While these commenters stated that provider charging practices are improving, they expressed concern that some providers have limited experience properly reporting claims for clinical trial and expanded access use cases and some providers do not appear to have fully complied with CMS guidance. A commenter requested that CMS maintain this trim for at least one additional fiscal year.

A commenter also requested that CMS publish information on cases included in the rate-setting methodology that are below the $373,000 threshold in the interest of transparency given the likely impact of those cases on the base DRG payment. A commenter expressed concern that 4 percent of cases are still reporting standardized drug charges of less than $373,000, given the relatively low volume of cases assigned to MS–DRG 018. A commenter stated that the inclusion of the 4 percent of cases would result in a potentially meaningful reduction in the base DRG payment for CAR–T cases. Another commenter modeled the inclusion of the 4 percent of cases and indicated that excluding them resulted in a $3,100 reduction in the base payment for MS–DRG 018. Commenters recommended that CMS monitor the impact of including these cases in ratesetting to ensure base payments for DRG 018 remain stable prior to removing the $373,000 low-cost threshold.

Response: We agree that removing the trim of excluding cases with standardized drug charges of less than $373,000 would be consistent with existing hospital billing practices. As discussed in the proposed rule, we believe providers have continued to gain experience with the use of ICD–10–CM diagnosis code Z00.6 to report cases involving a clinical trial of CAR T-cell therapy, as well as coding of expanded access use immunotherapy cases. This is supported by our observation that the percentage of claims reporting standardized drug charges of less than $373,000 that do not report ICD–10–CM code Z00.6 relative to all claims that group to MS–DRG 018 fell significantly from the FY 2019 data (used in the FY 2021 ratesetting) to the FY 2022 data (used in the FY 2024 ratesetting). While there continue to be a small percentage of claims that report standardized drug charges of less than $373,000 and do not report ICD–10–CM code Z00.6, we do not believe it is necessary to continue to use the proxy until the number of these claims reaches zero. We note that there is now only a very small percentage variation in the relative weight with and without this proxy, unlike in prior years. The $3,100 reduction referenced by the commenter in the range of 1 percent of the base DRG payment. With respect to the commenter who requested that CMS publish the details regarding specific cases, we note that information on obtaining the MedPAR Limited Data Set is available on the CMS website, at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Files-for-Order/LimitedDataSets/MEDPARLDSHospitalNational*.

After consideration of the public comments we received, we are finalizing our proposals regarding the calculation of the relative weight for MS–DRG 018. Applying this finalized methodology, based on the March 2023 update of the FY 2022 MedPAR file used for this final rule, we estimated that the average costs of cases assigned to MS–DRG 018 that are identified as clinical trial cases ($84,883) were 27 percent of the average costs of the cases assigned to MS–DRG 018 that are identified as non-clinical trial cases ($314,862). Accordingly, as we did for FY 2023, we are finalizing our proposal to adjust the transfer-adjusted case count for MS–DRG 018 by applying the adjustor of 0.27 to the applicable clinical trial and expanded access use immunotherapy cases, and to use this adjusted case count for MS–DRG 018 in calculating the national average cost per case, which is used in the calculation of the relative weights. Therefore, in calculating the national average cost per case for purposes of this final rule, each case identified as an applicable clinical trial or expanded access use immunotherapy case was adjusted by 0.27. As we did for FY 2023, we are applying this same adjustor for the applicable cases that group to MS–DRG 018 for purposes of budget neutrality and outlier simulations.

c. Cap for Relative Weight Reductions

In the FY 2023 IPPS/LTCH PPS final rule, we finalized a permanent 10-percent cap on the reduction in an MS–DRG's relative weight in a given fiscal year, beginning in FY 2023. We also finalized a budget neutrality adjustment to the standardized amount for all hospitals to ensure that application of the permanent 10-percent cap does not result in an increase or decrease of estimated aggregate payments. We refer the reader to the FY 2023 IPPS/LTCH PPS final rule for further discussion of this policy. In the Addendum to this IPPS/LTCH PPS final rule, we present

the budget neutrality adjustment for reclassification and recalibration of the FY 2024 MS–DRG relative weights with application of this cap. Table 5 contains the FY 2024 MS–DRG relative weights with and without the application of this cap. For a further discussion of the budget neutrality adjustment for FY 2024, we refer readers to the Addendum of this final rule.

3. Development of National Average CCRs

We developed the national average CCRs as follows:

Using the FY 2021 cost report data, we removed CAHs, Indian Health Service hospitals, all-inclusive rate hospitals, and cost reports that represented time periods of less than 1 year (365 days). We included hospitals located in Maryland because we include their charges in our claims database. Then we created CCRs for each provider for each cost center (see the supplemental data file for line items used in the calculations) and removed any CCRs that were greater than 10 or less than 0.01. We normalized the departmental CCRs by dividing the CCR for each department by the total CCR for the hospital for the purpose of trimming the data. Then we took the logs of the normalized cost center CCRs and removed any cost center CCRs where the log of the cost center CCR was greater or less than the mean log plus/minus 3 times the standard deviation for the log of that cost center CCR. Once the cost report data were trimmed, we calculated a Medicare-specific CCR. The Medicare-specific CCR was determined by taking the Medicare charges for each line item from Worksheet D–3 and deriving the Medicare-specific costs by applying the hospital-specific departmental CCRs to the Medicare-specific charges for each line item from Worksheet D–3. Once each hospital's Medicare-specific costs were established, we summed the total Medicare-specific costs and divided by the sum of the total Medicare-specific charges to produce national average, charge-weighted CCRs.

After we multiplied the total charges for each MS–DRG in each of the 19 cost centers by the corresponding national average CCR, we summed the 19 ''costs'' across each MS–DRG to produce a total standardized cost for the MS–DRG. The average standardized cost for each MS–DRG was then computed as the total standardized cost for the MS–DRG divided by the transfer-adjusted case count for the MS–DRG. The average cost for each MS–DRG was then divided by the national average standardized cost per case to determine the relative weight. The FY 2024 cost-based relative weights were then normalized by an adjustment factor of 1.941198 so that the average case weight after recalibration was equal to the average case weight before recalibration. The normalization adjustment is intended to ensure that recalibration by itself neither increases nor decreases total payments under the IPPS, as required by section 1886(d)(4)(C)(iii) of the Act. We then applied the permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year; specifically for those MS–DRGs for which the relative weight otherwise would have declined by more than 10 percent from the FY 2023 relative weight, we set the FY 2024 relative weight equal to 90 percent of the FY 2023 relative weight. The relative weights for FY 2024 as set forth in Table 5 associated with this final rule and available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS* reflect the application of this cap.

The 19 national average CCRs for FY 2024 are as follows:

BILLING CODE 4120–01–P

Group	CCR
Routine Days	0.417
Intensive Days	0.351
Drugs	0.18
Supplies & Equipment	0.303
Implantable Devices	0.269
Inhalation Therapy	0.153
Therapy Services	0.268
Anesthesia	0.072
Labor & Delivery	0.416
Operating Room	0.16
Cardiology	0.086
Cardiac Catheterization	0.102
Laboratory	0.102
Radiology	0.128
MRIs	0.067
CT Scans	0.033
Emergency Room	0.153
Blood and Blood Products	0.245
Other Services	0.34

Since FY 2009, the relative weights have been based on 100 percent cost weights based on our MS–DRG grouping system.

When we recalibrated the DRG weights for previous years, we set a

threshold of 10 cases as the minimum number of cases required to compute a reasonable weight. We proposed to use that same case threshold in recalibrating the proposed MS–DRG relative weights for FY 2024. Using data from the FY 2022 MedPAR file, there were 7 MS–DRGs that contain fewer than 10 cases. For FY 2024, because we do not have sufficient MedPAR data to set accurate and stable cost relative weights for these low-volume MS–DRGs, we proposed to compute relative weights for the low-volume MS–DRGs by adjusting their final FY 2023 relative weights by the percentage change in the average weight of the cases in other MS–DRGs from FY 2023 to FY 2024. The crosswalk table is as follows.

Low-Volume MS-DRG	MS-DRG Title	Crosswalk to MS-DRG
789	Neonates, Died or Transferred to Another Acute Care Facility	Final FY 2023 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
790	Extreme Immaturity or Respiratory Distress Syndrome, Neonate	Final FY 2023 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
791	Prematurity with Major Problems	Final FY 2023 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
792	Prematurity without Major Problems	Final FY 2023 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
793	Full-Term Neonate with Major Problems	Final FY 2023 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
794	Neonate with Other Significant Problems	Final FY 2023 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)
795	Normal Newborn	Final FY 2023 relative weight (adjusted by percent change in average weight of the cases in other MS-DRGs)

BILLING CODE 4120–01–C

Comment: A commenter requested that CMS utilize the ''other'' CCR for CAR–T product charges associated with revenue code 0891 to mitigate charge compression problems until CMS data is available for cost center 0078. The commenter stated that this would result in a more appropriate case cost and a higher relative weight for MS–DRG 018.

Response: We do not believe it would be appropriate to utilize the ''other'' CCR for CART product charges associated with revenue code 0891. The categories assigned to the ''other'' cost center are categorically not described by another cost center. This is not the case for CAR–T product charges, as the drug cost center describes the same type of product. Therefore, we do not believe it is necessary to make changes to the CCR used for CAR T-cell product charges.

After consideration of the public comments we received, we are finalizing our proposals without modification.

E. Add-On Payments for New Services and Technologies for FY 2024

1. Background

Sections 1886(d)(5)(K) and (L) of the Act establish a process of identifying and ensuring adequate payment for new medical services and technologies (sometimes collectively referred to in this section as ''new technologies'') under the IPPS. Section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered new if it meets criteria established by the Secretary after notice and opportunity for public comment. Section 1886(d)(5)(K)(ii)(I) of the Act specifies that a new medical service or technology may be considered for new technology add-on payment if, based on the estimated costs incurred with respect to discharges involving such service or technology, the DRG prospective payment rate otherwise applicable to such discharges under this subsection is inadequate. The regulations at 42 CFR 412.87 implement these provisions and § 412.87(b) specifies three criteria for a new medical service or technology to receive the additional payment: (1) The medical service or technology must be new; (2) the medical service or technology must be costly such that the DRG rate otherwise applicable to discharges involving the medical service or technology is determined to be inadequate; and (3) the service or technology must demonstrate a substantial clinical improvement over existing services or technologies. In addition, certain transformative new devices and antimicrobial products may qualify under an alternative inpatient new technology add-on payment pathway, as set forth in the regulations at § 412.87(c) and (d).

We note that section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services and technologies under the payment system established under that subsection, which establishes the system for paying for the operating costs of inpatient hospital services. The system of payment for capital costs is established under section 1886(g) of the Act. Therefore, as discussed in prior rulemaking (72 FR 47307 through 47308), we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs.

In this rule, we highlight some of the major statutory and regulatory provisions relevant to the new technology add-on payment criteria, as well as other information. For further discussion on the new technology add-on payment criteria, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51572 through 51574), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42300), and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58736 through 58742).

a. New Technology Add-on Payment Criteria

(1) Newness Criterion

Under the first criterion, as reflected in § 412.87(b)(2), a specific medical service or technology will no longer be considered ''new'' for purposes of new medical service or technology add-on payments after CMS has recalibrated the MS–DRGs, based on available data, to

reflect the cost of the technology. We note that we do not consider a service or technology to be new if it is substantially similar to one or more existing technologies. That is, even if a medical product receives a new FDA approval or clearance, it may not necessarily be considered ''new'' for purposes of new technology add-on payments if it is ''substantially similar'' to another medical product that was approved or cleared by FDA and has been on the market for more than 2 to 3 years. In the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43813 through 43814), we established criteria for evaluating whether a new technology is substantially similar to an existing technology, specifically whether: (1) a product uses the same or a similar mechanism of action to achieve a therapeutic outcome; (2) a product is assigned to the same or a different MS–DRG; and (3) the new use of the technology involves the treatment of the same or similar type of disease and the same or similar patient population. If a technology meets all three of these criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments. For a detailed discussion of the criteria for substantial similarity, we refer readers to the FY 2006 IPPS final rule (70 FR 47351 through 47352) and the FY 2010 IPPS/LTCH PPS final rule (74 FR 43813 through 43814).

(2) Cost Criterion

Under the second criterion, § 412.87(b)(3) further provides that, to be eligible for the add-on payment for new medical services or technologies, the MS–DRG prospective payment rate otherwise applicable to discharges involving the new medical service or technology must be assessed for adequacy. Under the cost criterion, consistent with the formula specified in section 1886(d)(5)(K)(ii)(I) of the Act, to assess the adequacy of payment for a new technology paid under the applicable MS–DRG prospective payment rate, we evaluate whether the charges of the cases involving a new medical service or technology will exceed a threshold amount that is the lesser of 75 percent of the standardized amount (increased to reflect the difference between cost and charges) or 75 percent of one standard deviation beyond the geometric mean standardized charge for all cases in the MS–DRG to which the new medical service or technology is assigned (or the case-weighted average of all relevant MS–DRGs if the new medical service or technology occurs in many different MS–DRGs). The MS–DRG threshold amounts generally used in evaluating new technology add-on payment applications for FY 2024 are presented in a data file that is available, along with the other data files associated with the FY 2023 IPPS/LTCH PPS final rule and correction notification, on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*.

We note that, under the policy finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58603 through 58605), beginning with FY 2022, we use the proposed threshold values associated with the proposed rule for that fiscal year to evaluate the cost criterion for all applications for new technology add-on payments and previously approved technologies that may continue to receive new technology add-on payments, if those technologies would be assigned to a proposed new MS–DRG for that same fiscal year.

As finalized in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41275), beginning with FY 2020, we include the thresholds applicable to the next fiscal year (previously included in Table 10 of the annual IPPS/LTCH PPS proposed and final rules) in the data files associated with the prior fiscal year. Accordingly, the proposed thresholds for applications for new technology add-on payments for FY 2025 were presented in a data file that is available on the CMS website, along with the other data files associated with the FY 2024 proposed rule, by clicking on the FY 2024 IPPS Proposed Rule Home Page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*. We noted that, for the reasons discussed in section I.F. of the preamble of the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26777) and this final rule, we proposed to use the FY 2022 MedPAR claims data for FY 2024 ratesetting. Consistent with this proposal, for the FY 2025 proposed threshold values, we proposed to use the FY 2022 claims data to set the proposed thresholds for applications for new technology add-on payments for FY 2025.

As discussed in section I.E. of the preamble of this final rule, we are finalizing our proposal to use the FY 2022 MedPAR claims data for FY 2024 ratesetting. Accordingly, in this final rule, we are finalizing that we will use FY 2022 claims data to set the thresholds for applications for new technology add-on payments for FY 2025. The finalized thresholds for applications for new technology add-on payments for FY 2025 are presented in a data file that is available on the CMS website, along with the other data files associated with this FY 2024 final rule, by clicking on the FY 2024 IPPS Final Rule Home Page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index*.

In the September 7, 2001 final rule that established the new technology add-on payment regulations (66 FR 46917), we discussed that applicants should submit a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. Specifically, applicants should submit a sample of sufficient size to enable us to undertake an initial validation and analysis of the data. We also discussed in the September 7, 2001 final rule (66 FR 46917) the issue of whether the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule at 45 CFR parts 160 and 164 applies to claims information that providers submit with applications for new medical service or technology add-on payments. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51573) for further information on this issue.

(3) Substantial Clinical Improvement Criterion

Under the third criterion at § 412.87(b)(1), a medical service or technology must represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42292), we prospectively codified in our regulations at § 412.87(b) the following aspects of how we evaluate substantial clinical improvement for purposes of new technology add-on payments under the IPPS:

- The totality of the circumstances is considered when making a determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries.
- A determination that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries means—

++ The new medical service or technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments;

++ The new medical service or technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable, or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods, and there must also be evidence that use of the new medical service or technology to make a diagnosis affects the management of the patient;

++ The use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available as demonstrated by one or more of the following: a reduction in at least one clinically significant adverse event, including a reduction in mortality or a clinically significant complication; a decreased rate of at least one subsequent diagnostic or therapeutic intervention; a decreased number of future hospitalizations or physician visits; a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time; an improvement in one or more activities of daily living; an improved quality of life; or, a demonstrated greater medication adherence or compliance; or

++ The totality of the circumstances otherwise demonstrates that the new medical service or technology substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries.

• Evidence from the following published or unpublished information sources from within the United States or elsewhere may be sufficient to establish that a new medical service or technology represents an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of Medicare beneficiaries: clinical trials, peer reviewed journal articles; study results; meta-analyses; consensus statements; white papers; patient surveys; case studies; reports; systematic literature reviews; letters from major healthcare associations; editorials and letters to the editor; and public comments. Other appropriate information sources may be considered.

• The medical condition diagnosed or treated by the new medical service or technology may have a low prevalence among Medicare beneficiaries.

• The new medical service or technology may represent an advance that substantially improves, relative to services or technologies previously available, the diagnosis or treatment of a subpopulation of patients with the medical condition diagnosed or treated by the new medical service or technology.

We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42288 through 42292) for additional discussion of the evaluation of substantial clinical improvement for purposes of new technology add-on payments under the IPPS.

We note, consistent with the discussion in the FY 2003 IPPS final rule (67 FR 50015), that while FDA has regulatory responsibility for decisions related to marketing authorization (for example, approval, clearance, etc.), we do not rely upon FDA criteria in our evaluation of substantial clinical improvement for purposes of determining what services and technologies qualify for new technology add-on payments under Medicare. This criterion does not depend on the standard of safety and effectiveness on which FDA relies but on a demonstration of substantial clinical improvement in the Medicare population.

b. Alternative Inpatient New Technology Add-on Payment Pathway

Beginning with applications for FY 2021 new technology add-on payments, under the regulations at § 412.87(c), a medical device that is part of FDA's Breakthrough Devices Program may qualify for the new technology add-on payment under an alternative pathway. Additionally, under the regulations at § 412.87(d) for certain antimicrobial products, beginning with FY 2021, a drug that is designated by FDA as a Qualified Infectious Disease Product (QIDP), and, beginning with FY 2022, a drug that is approved by FDA under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD), may also qualify for the new technology add-on payment under an alternative pathway. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739) for further discussion on this policy. We note that a technology is not required to have the specified FDA designation at the time the new technology add-on payment application is submitted. CMS reviews the application based on the information provided by the applicant only under the alternative pathway specified by the applicant at the time of application submission. However, to receive approval for the new technology add-on payment under that alternative pathway, the technology must have the applicable FDA designation and meet all other requirements in the regulations in § 412.87(c) and (d), as applicable.

(1) Alternative Pathway for Certain Transformative New Devices

For applications received for new technology add-on payments for FY 2021 and subsequent fiscal years, a medical device designated under FDA's Breakthrough Devices Program that has received FDA marketing authorization will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to meet the requirement under § 412.87(b)(1) that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under this alternative pathway, a medical device that has received FDA marketing authorization (that is, has been approved or cleared by, or had a De Novo classification request granted by, FDA) as a Breakthrough Device, for the indication covered by the Breakthrough Device designation, will need to meet the requirements of § 412.87(c). We note that in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58734 through 58736), we clarified our policy that a new medical device under this alternative pathway must receive marketing authorization for the indication covered by the Breakthrough Devices Program designation. We refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58734 through 58736) for further discussion regarding this clarification.

(2) Alternative Pathway for Certain Antimicrobial Products

For applications received for new technology add-on payments for certain antimicrobial products, beginning with FY 2021, if a technology is designated by FDA as a QIDP and received FDA marketing authorization, and, beginning with FY 2022, if a drug is approved under FDA's LPAD pathway and used for the indication approved under the LPAD pathway, it will be considered not substantially similar to an existing technology for purposes of new technology add-on payments and will not need to meet the requirement that it represent an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. Under this alternative pathway for QIDPs and LPADs, a medical product that has received FDA marketing authorization and is designated by FDA as a QIDP or approved under the LPAD pathway will need to meet the requirements of § 412.87(d). We refer

the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739) for further discussion on this policy.

We note that, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58737 through 58739), we clarified that a new medical product seeking approval for the new technology add-on payment under the alternative pathway for QIDPs must receive FDA marketing authorization for the indication covered by the QIDP designation. We also finalized our policy to expand our alternative new technology add-on payment pathway for certain antimicrobial products to include products approved under the LPAD pathway and used for the indication approved under the LPAD pathway.

c. Additional Payment for New Medical Service or Technology

The new medical service or technology add-on payment policy under the IPPS provides additional payments for cases with relatively high costs involving eligible new medical services or technologies, while preserving some of the incentives inherent under an average-based prospective payment system. The payment mechanism is based on the cost to hospitals for the new medical service or technology. As noted previously, we do not include capital costs in the add-on payments for a new medical service or technology or make new technology add-on payments under the IPPS for capital-related costs (72 FR 47307 through 47308).

For discharges occurring before October 1, 2019, under § 412.88, if the costs of the discharge (determined by applying operating cost-to-charge ratios (CCRs) as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), CMS made an add-on payment equal to the lesser of: (1) 50 percent of the costs of the new medical service or technology; or (2) 50 percent of the amount by which the costs of the case exceed the standard DRG payment.

Beginning with discharges on or after October 1, 2019, for the reasons discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300), we finalized an increase in the new technology add-on payment percentage, as reflected at § 412.88(a)(2)(ii). Specifically, for a new technology other than a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 65 percent of the costs of the new medical service or technology; or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment. For a new technology that is a medical product designated by FDA as a QIDP, beginning with discharges on or after October 1, 2019, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. For a new technology that is a medical product approved under FDA's LPAD pathway, beginning with discharges on or after October 1, 2020, if the costs of a discharge involving a new technology (determined by applying CCRs as described in § 412.84(h)) exceed the full DRG payment (including payments for IME and DSH, but excluding outlier payments), Medicare will make an add-on payment equal to the lesser of: (1) 75 percent of the costs of the new medical service or technology; or (2) 75 percent of the amount by which the costs of the case exceed the standard DRG payment. As set forth in § 412.88(b)(2), unless the discharge qualifies for an outlier payment, the additional Medicare payment will be limited to the full MS–DRG payment plus 65 percent (or 75 percent for certain antimicrobial products (QIDPs and LPADs)) of the estimated costs of the new technology or medical service. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42297 through 42300) for further discussion on the increase in the new technology add-on payment beginning with discharges on or after October 1, 2019.

We note that, consistent with the prospective nature of the IPPS, we finalize the new technology add on payment amount for technologies approved or conditionally approved for new technology add-on payments in the final rule for each fiscal year and do not make mid-year changes to new technology add-on payment amounts. Updated cost information may be submitted and included in rulemaking for the following fiscal year.

Section 503(d)(2) of Public Law 108–173 provides that there shall be no reduction or adjustment in aggregate payments under the IPPS due to add-on payments for new medical services and technologies. Therefore, in accordance with section 503(d)(2) of Public Law 108–173, add-on payments for new medical services or technologies for FY 2005 and subsequent years have not been subjected to budget neutrality.

d. Evaluation of Eligibility Criteria for New Medical Service or Technology Applications

In the FY 2009 IPPS final rule (73 FR 48561 through 48563), we modified our regulation at § 412.87 to codify our longstanding practice of how CMS evaluates the eligibility criteria for new medical service or technology add-on payment applications. That is, we first determine whether a medical service or technology meets the newness criterion, and only if so, do we then make a determination as to whether the technology meets the cost threshold and represents a substantial clinical improvement over existing medical services or technologies. We specified that all applicants for new technology add-on payments must have FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. In the FY 2021 IPPS/LTCH PPS final rule, to more precisely describe the various types of FDA approvals, clearances and classifications that we consider under our new technology add-on payment policy, we finalized a technical clarification to the regulation to indicate that new technologies must receive FDA marketing authorization (such as pre-market approval (PMA); 510(k) clearance; the granting of a De Novo classification request, or approval of a New Drug Application (NDA)) by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. Consistent with our longstanding policy, we consider FDA marketing authorization as representing that a product has received FDA approval or clearance when considering eligibility for the new technology add-on payment under § 412.87(e)(2) (85 FR 58742).

Additionally, in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58739 through 58742), we finalized our proposal to provide conditional approval for new technology add-on payment for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products at § 412.87(d) that does not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that

the technology otherwise meets the applicable add-on payment criteria. Under this policy, cases involving eligible antimicrobial products would begin receiving the new technology add-on payment sooner, effective for discharges the quarter after the date of FDA marketing authorization provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments.

As discussed in more detail in section II.E.9. of the preamble of this final rule, in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26779 through 26780), beginning with the new technology add-on payment applications for FY 2025, we proposed, for technologies that are not already FDA market authorized, to require applicants to have a complete and active FDA market authorization request at the time of new technology add-on payment application submission, and to provide documentation of FDA acceptance or filing to CMS at the time of application submission. We also proposed that, beginning with FY 2025 applications, in order to be eligible for consideration for the new technology add-on payment for the upcoming fiscal year, an applicant for new technology add-on payments must have received FDA approval or clearance by May 1 rather than July 1 of the year prior to the beginning of the fiscal year for which the application is being considered (except for an application that is submitted under the alternative pathway for certain antimicrobial products). Please refer to section II.E.9. of the preamble of this final rule for a full discussion of these proposals, the comments we received on these proposals, and our final policies.

e. New Technology Liaisons

Many interested parties (including device/biologic/drug developers or manufacturers, industry consultants, others) engage CMS for coverage, coding, and payment questions or concerns. In order to streamline engagement by centralizing the different innovation pathways within CMS including new technology add-on payments, CMS has established a team of new technology liaisons that can serve as an initial resource for interested parties. This team is available to assist with all of the following:

- Help to point interested parties to or provide information and resources where possible regarding process, requirements, and timelines.
- Coordinate and facilitate opportunities for interested parties to engage with various CMS components.
- Serve as a primary point of contact for interested parties and provide updates on developments where possible or appropriate.

We receive many questions from parties interested in pursuing new technology add-on payments who may not be entirely familiar with working with CMS. While we encourage interested parties to first review our resources available at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech*, we know that there may be additional questions about the application process. Interested parties with further questions about Medicare's coverage, coding, and payment processes, and about how they can navigate these processes, whether for new technology add-on payments or otherwise, can contact the new technology liaison team at *MedicareInnovation@cms.hhs.gov*.

f. Application Information for New Medical Services or Technologies

Applicants for add-on payments for new medical services or technologies for FY 2025 must submit a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement (unless the application is under one of the alternative pathways as previously described), along with a significant sample of data to demonstrate that the medical service or technology meets the high-cost threshold. CMS will review the application based on the information provided by the applicant under the pathway specified by the applicant at the time of application submission. Complete application information, along with final deadlines for submitting a full application, will be posted as it becomes available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html*.

To allow interested parties to identify the new medical services or technologies under review before the publication of the proposed rule for FY 2025, once the application deadline has closed, CMS will post on its website a list of the applications submitted, along with a brief description of each technology as provided by the applicant.

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48986 through 48990), we finalized our proposal to publicly post online new technology add-on payment. applications, including the completed application forms, certain related materials, and any additional updated application information submitted subsequent to the initial application submission (except certain volume, cost and other information identified by the applicant as confidential), beginning with the application cycle for FY 2024, at the time the proposed rule is published. We also finalized that with the exception of information included in a confidential information section of the application, cost and volume information, and materials identified by the applicant as copyrighted and/or not otherwise releasable to the public, the contents of the application and related materials may be posted publicly, and that we will not post applications that are withdrawn prior to publication of the proposed rule. We refer the reader to the FY 2023 IPPS/LTCH PPS final rule (87 FR 48986 through 48990) for further information regarding this policy.

We note that the burden associated with this information collection requirement is the time and effort required to collect and submit the data in the formal request for add-on payments for new medical services and technologies to CMS. The aforementioned burden is subject to the PRA and approved under OMB control number 0938–1347, and has an expiration date of November 30, 2023.

2. Public Input Before Publication of a Notice of Proposed Rulemaking on Add-On Payments

Section 1886(d)(5)(K)(viii) of the Act, as amended by section 503(b)(2) of Public Law 108–173, provides for a mechanism for public input before publication of a notice of proposed rulemaking regarding whether a medical service or technology represents a substantial clinical improvement. The process for evaluating new medical service and technology applications requires the Secretary to do all of the following:

- Provide, before publication of a proposed rule, for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries.
- Make public and periodically update a list of the services and technologies for which applications for add-on payments are pending.
- Accept comments, recommendations, and data from the public regarding whether a service or

technology represents a substantial clinical improvement.

• Provide, before publication of a proposed rule, for a meeting at which organizations representing hospitals, physicians, manufacturers, and any other interested party may present comments, recommendations, and data regarding whether a new medical service or technology represents a substantial clinical improvement to the clinical staff of CMS.

In order to provide an opportunity for public input regarding add-on payments for new medical services and technologies for FY 2024 prior to publication of the FY 2024 IPPS/LTCH PPS proposed rule, we published a notice in the **Federal Register** on October 3, 2022 (87 FR 59793), and held a virtual town hall meeting on December 14, 2022. In the announcement notice for the meeting, we stated that the opinions and presentations provided during the meeting would assist us in our evaluations of applications by allowing public discussion of the substantial clinical improvement criterion for the FY 2024 new medical service and technology add-on payment applications before the publication of the FY 2024 IPPS/LTCH IPPS proposed rule.

Approximately 180 individuals registered to attend the virtual town hall meeting. We posted the recordings of the virtual town hall on the CMS web page at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech*.

We considered each applicant's presentation made at the town hall meeting, as well as written comments received by the December 22, 2022, deadline, in our evaluation of the new technology add-on payment applications for FY 2024 in the development of the FY 2024 IPPS/LTCH PPS proposed rule. In response to the published notice and the December 14, 2022 New Technology Town Hall meeting, we received written comments regarding the applications for FY 2024 new technology add on payments. As explained earlier and in the **Federal Register** notice announcing the New Technology Town Hall meeting (87 FR 59793 through 59795), the purpose of the meeting was specifically to discuss the substantial clinical improvement criterion with regard to pending new technology add-on payment applications for FY 2024. Therefore, we did not summarize any written comments in the proposed rule that were unrelated to the substantial clinical improvement criterion. In section II.E.6. of the preamble of the proposed rule, we summarized comments regarding individual applications, or, if applicable, indicating that there were no comments received in response to the New Technology Town Hall meeting notice or New Technology Town Hall meeting, at the end of each discussion of the individual applications.

3. ICD–10–PCS Section ''X'' Codes for Certain New Medical Services and Technologies

As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49434), the ICD–10–PCS includes a new section containing the new Section ''X'' codes, which began being used with discharges occurring on or after October 1, 2015. Decisions regarding changes to ICD–10–PCS Section ''X'' codes will be handled in the same manner as the decisions for all of the other ICD–10–PCS code changes. That is, proposals to create, delete, or revise Section ''X'' codes under the ICD–10–PCS structure will be referred to the ICD–10 Coordination and Maintenance Committee. In addition, several of the new medical services and technologies that have been, or may be, approved for new technology add-on payments may now, and in the future, be assigned a Section ''X'' code within the structure of the ICD–10–PCS. We posted ICD–10–PCS Guidelines on the CMS website at: *https://www.cms.gov/Medicare/Coding/ICD10*, including guidelines for ICD–10–PCS Section ''X'' codes. We encourage providers to view the material provided on ICD–10–PCS Section ''X'' codes.

4. New COVID–19 Treatments Add-On Payment (NCTAP)

In response to the COVID–19 public health emergency (PHE), we established the New COVID–19 Treatments Add-on Payment (NCTAP) under the IPPS for COVID–19 cases that meet certain criteria (85 FR 71157 through 71158). We believe that as drugs and biological products are authorized for emergency use or approved by FDA for the treatment of COVID–19 in the inpatient setting, it is appropriate to increase the current IPPS payment amounts to mitigate any potential financial disincentives for hospitals to provide new COVID–19 treatments during the PHE. Therefore, effective for discharges occurring on or after November 2, 2020 and until the end of the PHE for COVID–19, we established the NCTAP to pay hospitals the lesser of (1) 65 percent of the operating outlier threshold for the claim or (2) 65 percent of the amount by which the costs of the case exceed the standard DRG payment, including the adjustment to the relative weight under section 3710 of the Coronavirus Aid, Relief, and Economic Security (CARES) Act, for certain cases that include the use of a drug or biological product currently authorized for emergency use or approved for treating COVID–19.

In the FY 2022 IPPS/LTCH PPS final rule, we finalized a change to our policy to extend NCTAP through the end of the FY in which the PHE ends for all eligible products in order to continue to mitigate potential financial disincentives for hospitals to provide these new treatments, and to minimize any potential payment disruption immediately following the end of the PHE. We also finalized that, for a drug or biological product eligible for NCTAP that is also approved for new technology add-on payments, we will reduce the NCTAP for an eligible case by the amount of any new technology add-on payments so that we do not create a financial disincentive between technologies eligible for both the new technology add-on payment and NCTAP compared to technologies eligible for NCTAP only (86 FR 45162). As the PHE ended on May 11, 2023, as planned by the Department of Health and Human Services (HHS),[22] discharges involving eligible products will continue to be eligible for the NCTAP through September 30, 2023 (that is, through the end of FY 2023). The NCTAP will expire at the end of FY 2023 and no NCTAP will be made beginning in FY 2024 (that is, for discharges on or after October 1, 2023).

Further information about NCTAP, including updates and a list of currently eligible drugs and biologicals, is available on the CMS website at *https://www.cms.gov/medicare/covid-19/new-covid-19-treatments-add-payment-nctap*.

Comment: We received public comments related to NCTAP. A commenter expressed appreciation for continued NCTAP through Sept. 30, 2023. A few commenters recommended that CMS continue NCTAP, including a commenter who recommended that CMS continue NCTAP through December 31, 2023, in order to provide financial assistance for COVID–19 treatments as hospitals navigate the public health emergency (PHE) unwinding. A commenter also recommended that when NCTAP does end, that CMS automatically add any newly developed COVID–19 treatments to the new technology add-on payment list without application. Some

[22] *https://www.hhs.gov/about/news/2023/05/11/hhs-secretary-xavier-becerra-statement-on-end-of-the-covid-19-public-health-emergency.html.*

commenters recommended that CMS monitor Medicare beneficiaries' access to COVID–19 treatments in the hospital inpatient setting after NCTAP expires to determine whether there is a reduction in beneficiaries' access to treatment, with a commenter further recommending that CMS take steps to minimize any barriers that could restrict the ability of Medicare beneficiaries to receive lifesaving treatments after the sunsetting of the NCTAP and other COVID–19 payment adjustments.

Response: We thank the commenters for their input. In the FY 2022 IPPS/LTCH PPS final rule, we finalized a change to our policy to extend NCTAP through the end of the FY in which the PHE ends for all eligible products in order to continue to mitigate potential financial disincentives for hospitals to provide these new treatments, and to minimize any potential payment disruption immediately following the end of the PHE. We did not make any proposals to extend or modify NCTAP in this year's proposed rule, and NCTAP will end on September 30, 2023, as previously finalized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45160 through 45162). Further information about NCTAP, including updates and a list of currently eligible drugs and biologicals, is available on the CMS website at *https://www.cms.gov/medicare/covid-19/new-covid-19-treatments-add-payment-nctap*.

5. FY 2024 Status of Technologies Receiving New Technology Add-On Payments for FY 2023

In this section of the final rule, we discuss the FY 2024 status of 24 technologies approved for FY 2023 new technology add-on payments, as set forth in the tables that follow. In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26781 through 26785) we presented our proposals to continue the new technology add-on payments for FY 2024 for those technologies that were approved for the new technology add-on payment for FY 2023 and which would still be considered ''new'' for purposes of new technology add-on payments for FY 2024. We also presented our proposals to discontinue new technology add-on payments for FY 2024 for those technologies that were approved for the new technology add-on payment for FY 2023 and which would no longer be considered ''new'' for purposes of new technology add-on payments for FY 2024.

Additionally, we noted that we conditionally approved DefenCath™ (a formulation of taurolidine/heparin) for FY 2023 new technology add-on payments under the alternative pathway for certain antimicrobial products (87 FR 26955 through 26957), subject to the technology receiving FDA marketing authorization by July 1, 2023. In the FY 2024 IPPS/LTCH PPS proposed rule, we proposed that if DefenCath™ receives FDA marketing authorization before July 1, 2023, we would continue making new technology add-on payments for DefenCath™ for FY 2024. We proposed that if DefenCath™ does not receive FDA marketing authorization by July 1, 2023, then it would not be eligible for new technology add-on payments for FY 2023, and therefore would not be eligible for the continuation of new technology add-on payments for FY 2024. Because DefenCath™ did not receive FDA approval by July 1, 2023, no new technology add-on payments will be made for cases involving the use of DefenCath™ for FY 2023, and DefenCath™ is therefore not eligible for the continuation of new technology add-on payments for FY 2024. We note that the applicant for DefenCath™ also submitted an application for new technology add-on payments for FY 2024 under the name taurolidine/heparin, and we refer the reader to section II.E.7.b.(1). of the preamble of this final rule for discussion of our conditional approval of the FY 2024 application for new technology add on payments for taurolidine/heparin.

Our policy is that a medical service or technology may continue to be considered ''new'' for purposes of new technology add-on payments within 2 or 3 years after the point at which data begin to become available reflecting the inpatient hospital code assigned to the new service or technology. Our practice has been to begin and end new technology add-on payments on the basis of a fiscal year, and we have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the new technology add-on payment for an additional fiscal year. In general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the fiscal year (70 FR 47362).

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26783), we provided a table listing the technologies for which we proposed to continue making new technology add-on payments for FY 2024 because they are still considered ''new'' for purposes of new technology add-on payments. This table also presented the newness start date, new technology add-on payment start date, 3-year anniversary date of the product's entry onto the U.S. market, relevant final rule citations from prior fiscal years, proposed maximum add-on payment amount, and coding assignments for each technology. We referred readers to the cited final rules in the following table for a complete discussion of the new technology add-on payment application, coding and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

We invited public comments on our proposals to continue new technology add-on payments for FY 2024 for the technologies listed in the table in the proposed rule.

Comment: We received multiple comments in support of our proposed continuation of new technology add-on payments for FY 2024 for those technologies that were approved for the new technology add-on payment for FY 2023 and which would still be considered ''new'' for purposes of new technology add-on payments for FY 2024.

Response: We appreciate the commenters' support.

After consideration of the public comments we received, we are finalizing our proposals to continue new technology add-on payments for FY 2024 for the technologies that were approved for new technology add-on payment for FY 2023 and would still be considered ''new'' for purposes of new technology add-on payments for FY 2024, as listed in the proposed rule and in the following Table II.F.-01 in this section of this final rule.

Table II.F.-01 in this final rule presents the newness start date, new technology add-on payment start date, 3-year anniversary date of the product's entry onto the U.S. market, relevant final rule citations from prior fiscal years, maximum add-on payment amount, and coding assignments. We refer readers to the final rules cited in the following table for a complete discussion of the new technology add-on payment application, coding and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

BILLING CODE 4120–01–P

TABLE II.F.-01: CONTINUATION OF TECHNOLOGIES APPROVED FOR FY 2023 NEW TECHNOLOGY ADD-ON PAYMENTS STILL CONSIDERED NEW FOR FY 2024 BECAUSE 3-YEAR ANNIVERSARY DATE WILL OCCUR ON OR AFTER APRIL 1, 2024

	Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto U.S. Market	Previous Final Rule Citations	Maximum NTAP Amount for FY 2024	Coding Used to Identify Cases Eligible for NTAP
1	*Intercept® (PRCFC)*	*05/05/2021*	*10/1/2021*	*5/05/2024*	86 FR 45149 through 45150 86 FR 67875 87 FR 48913	$2,535.00	30233D1 or 30243D1 in combination with one of the following D62, D65, D68.2, D68.4 or D68.9
2	*Rybrevant™*	*05/21/2021*	*10/1/2021*	*05/21/2024*	86 FR 44988 through 44996 87 FR 48913	$6,405.89	XW033B7 or XW043B7
3	*StrataGraft®*	*06/15/2021*	*10/1/2021*	*06/15/2024*	86 FR 45079 through 45090 87 FR 48913	$44,200.00	XHRPXF7
4	*aprevo® Intervertebral Body Fusion Device*	*6/30/2021 (TLIF)*	*10/1/2021*	*6/30/2024 (TLIF)*	86 FR 45127 through 45133 86 FR 67874 through 67876 87 FR 48913	$40,950.00	XRGA0R7 or XRGA3R7 orXRGA4R7 or XRGB0R7 or XRGB3R7 or XRGB4R7 or XRGC0R7 or XRGC3R7 or XRGC4R7 or XRGD0R7 or XRGD3R7 or XRGD4R7
5	*Hemolung Respiratory Assist System (RAS)*	*11/15/2021 (other)*	*10/1/2022*	*11/15/2024 (other)*	87 FR 48937 through 48948	$6,500.00	5A0920Z without U07.1*
6	*Livtencity™*	*12/2/2021*	*10/1/2022*	*12/2/2024*	87 FR 48948 through 48954	$32,500.00	XW0DX38 or XW0G738 or XW0H738
7	*Thoraflex Hybrid Device*	*04/19/2022*	*10/1/2022*	*04/19/2025*	87 FR 48974 through 48975	$22,750.00	X2RX0N7 in combination with X2VW0N7
8	*ViviStim*	*04/29/2022*	*10/1/2022*	*04/29/2025*	87 FR 48975 through 48977	$23,400.00	X0HQ3R8
9	*GORE TAG Thoracic Branch Endoprosthesis*	*05/13/2022*	*10/1/2022*	*05/13/2025*	87 FR 48966 through 48969	$27,807.00	02VW3DZ in combination with 02VX3EZ
10	*Cerament® G*	*05/17/2022*	*10/1/2022*	*05/17/2025*	87 FR 48961 through 48966	$4,918.55	XW0V0P7
11	*iFuse Bedrock Granite Implant System*	*05/26/2022*	*10/1/2022*	*05/26/2025*	87 FR 48969 through 48974	$9,828.00	XNH6058 or XNH6358 or XNH7058 or XNH7358 or XRGE058 or XRGE358 or XRGF058 or XRGF358

*As discussed in the following section, we are finalizing our proposal to discontinue new technology add-on payments for COVID-19 Hemolung RAS cases.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26785), we provided Table II.P.-02 listing the technologies for which we proposed to discontinue making new technology add-on payments for FY 2024 because

they are no longer ''new'' for purposes of new technology add-on payments. This table also presented the newness start date, new technology add-on payment start date, the 3-year anniversary date of the product's entry onto the U.S. market, and relevant final rule citations from prior fiscal years. We referred readers to the cited final rules in the table for a complete discussion of each new technology add-on payment application and the coding and payment amount for these technologies, including the applicable indications and discussion of the newness start date.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26784), we noted, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48939) and in previous rulemaking, the intent of section 1886(d)(5)(K) of the Act and regulations under § 412.87(b)(2) is to pay for new medical services and technologies for the first 2 to 3 years that a product comes on the market, during the period when the costs of the new technology are not yet fully reflected in the MS–DRG weights (69 FR 49002). While our policy is, generally, to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market, as discussed in prior rulemaking (77 FR 53348), we have noted that data reflecting the costs of products that have received an emergency use authorization (EUA) could become available as soon as the date of the EUA issuance and prior to receiving FDA approval or clearance (86 FR 45159). With respect to the Hemolung RAS, which received an EUA on April 22, 2020, when used for patients with COVID–19, we discussed whether the newness period for the use of the Hemolung RAS for patients with COVID–19 should begin on the date of its EUA (April 22, 2020), when the product became available on the market for this indication. We described a public comment submitted by the applicant for Hemolung RAS which stated that the newness period for COVID–19 Hemolung RAS cases should begin on November 15, 2021 (the date of commercial availability of the De Novo classified device), instead of April 22, 2020 (the date of the Hemolung RAS EUA). The applicant indicated that it provided the Hemolung RAS to hospitals free or at cost to swiftly respond to the global pandemic, and that it did not profit from EUA therapies. The applicant stated that additionally, during the EUA period, hospitals were not seeking payment for Hemolung RAS therapy. The applicant stated that, therefore, cost data collected during the EUA period and prior to FDA clearance do not accurately reflect the added cost of Hemolung RAS therapy. In our response, we noted that, while the commenter stated that it provided the Hemolung RAS to hospitals free or at cost, and that hospitals were not seeking payment for the Hemolung RAS therapy during the EUA period, additional information regarding whether hospitals charged for use of the Hemolung RAS therapy between the date of its EUA and the date of commercial availability of the De Novo classified device, and how it impacts whether use of the technology may be reflected in the data, would be helpful in determining that data reflecting the cost of the product did not become available until the date of commercial availability of the De Novo classified device.

We stated in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26784), that in the absence of additional information to support a conclusion that data reflecting the cost of the Hemolung RAS when used for patients with COVID–19 did not begin to become available as of the issuance of the EUA on April 22, 2020, we were proposing to discontinue new technology add-on payments for FY 2024 for Hemolung RAS patients with hypercapnic respiratory failure related to COVID–19, as the technology will no longer be considered new for this indication. We further stated that, as discussed in the FY 2023 IPPS/LTCH PPS final rule, we continued to welcome additional information regarding whether hospitals charged for use of the Hemolung RAS therapy between the date of its EUA and the date of commercial availability of the De Novo classified device, and how it impacts whether use of the technology may be reflected in the data. We further noted, as set forth in Table II.P.-01 of the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26783), that we were proposing to continue the new technology add-on payment in FY 2024 for the use of the Hemolung RAS for patients with other causes of hypercapnic respiratory failure unrelated to COVID–19, for which we considered the beginning of the newness period to commence on the date of commercial availability of the De Novo classified device (November 15, 2021), as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48939). In order to identify use of Hemolung RAS unrelated to COVID–19, we proposed to identify cases eligible for new technology add-on payment with ICD–10–PCS code 5A0920Z without ICD–10–CM diagnosis code U07.1 (COVID–19).

We invited public comments on our proposals to discontinue new technology add-on payments for FY 2024 for the technologies listed in Table II.P.-02 in the proposed rule.

Comment: A commenter disagreed with defining the newness start date as the date of commercial availability/FDA approval date for cell and gene therapies, and requested that CMS extend new technology add-on payments into FY 2024 for both ABECMA® and CARVYKTI™ as the newness start date being utilized is extremely close to the mid-year benchmark and also likely to be functionally inaccurate. The commenter stated that while it does not have sales or ordering information for ABECMA® and CARVYKTI™, it believes that it is likely that the first commercial shipment of ABECMA® took place weeks after FDA approval (which occurred March 26, 2021) and would have crossed the April 1 threshold date, enabling these technologies to be eligible for a third year of add-on payments. The commenter explained that this delay is due to the fact that CAR T-cell products take weeks to manufacture, in addition to the certification of treatment sites as required under a product's REMS. The commenter stated that it is far more logical to use the definition of ''market date'' described in the May 2023 Medicaid proposed rule with regard to covered outpatient drugs, which is the date on which the drug was first sold (88 FR 34257), for cell and gene therapies due to their unique manufacturing parameters. The commenter also requested that CMS consider a standard third-year extension of new technology add-on payments for cell and gene therapies in general, due to the unique manufacturing process and low volume nature of the diseases treated.

Response: We thank the commenter for its input. We note that the timeframe that a new technology can be eligible to receive new technology add-on payments begins when data become available (69 FR 49003, 85 FR 58610). Consistent with the statute, a technology no longer qualifies as ''new'' once it is more than 2 to 3 years old, irrespective of how frequently it has been used in the Medicare population. Therefore, if a product is more than 2 to 3 years old, we consider its costs to be included in the MS–DRG relative weights whether its use in the Medicare population has been frequent or infrequent. In addition, while CMS may consider a documented delay in the technology's market availability in our determination of newness, our policy for determining

whether to extend new technology add-on payments for an additional year generally applies regardless of the volume of claims for the technology after the beginning of the newness period (83 FR 41280). We do not consider the date of first sale of a product, or first shipment of a product, as an indicator of the entry of a product onto the U.S. market; neither of these dates indicate when a technology in fact became available for sale. Similarly, our policy for determining whether to extend new technology add-on payments for a third year generally applies regardless of the claims volume for the technology after the start of the newness period (85 FR 58610). We further note that, as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48911), in response to a comment from the applicant for Abecma® stating that the date of first sale for this technology was May 10, 2021, and that add-on payments for Abecma® should therefore extend past FY 2023, we requested additional information from the applicant for Abecma® on when the technology first became *available* for sale. We stated that, absent such additional information from the applicant, we cannot determine a newness date based on a documented delay in the technology's availability on the U.S. market. The applicant did not submit further information related to the availability of Abecma® for this final rule, nor did the commenter provide such information. Accordingly, we are finalizing that we consider March 26, 2021, to be the date the technology became available on the market and the beginning of its newness period. As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48925), because we determined that CARVYKTI™ is substantially similar to ABECMA®, we consider the beginning of the newness period for CARVYKTI™ to be March 26, 2021 as well.

Comment: A commenter requested that CMS consider at least another year of new technology add-on payments for aprevo™, which has a newness start date of December 3, 2020 for its ALIF and LLIF indications, as many surgeries were not performed in 2020 due to the COVID–19 pandemic. The commenter stated that with hospital revenue trending negatively, this is an opportunity for hospitals to provide exceptional care with appropriate reimbursement due to the clinical benefits of this technology.

Response: We thank the commenter for its input. Consistent with the statute and our implementing regulations, a technology is no longer considered as ''new'' once it is more than 2 to 3 years old, irrespective of how frequently the medical service or technology has been used in the Medicare population (70 FR 47349, 85 FR 58610). As such, once a technology has been available on the U.S. market for more than 2 to 3 years, we consider the costs to be included in the MS–DRG relative weights regardless of whether the technology's use in the Medicare population has been frequent or infrequent. We further note that we are renewing the TLIF indication for aprevo™, which has a newness start date of June 30, 2021, for FY 2024 as noted in the previous table, as this indication will still be considered ''new''.

After consideration of the public comments we received, we are finalizing our proposal to discontinue new technology add-on payments for the technologies as listed in the proposed rule and in the following Table II.F.-02 of this final rule for FY 2024 because they are no longer ''new'' for purposes of new technology add-on payments. This table also presents the newness start date, new technology add-on payment start date, the 3-year anniversary date of the product's entry onto the U.S. market, and relevant final rule citations from prior fiscal years. We also refer readers to the final rules cited in the following table for a complete discussion of the new technology add-on payment application, coding and payment amount for these technologies, including the applicable indications and discussion of the newness start dates.

TABLE II.F.-02: PROPOSED DISCONTINUATION OF TECHNOLOGIES APPROVED FOR FY 2023 NEW TECHNOLOGY ADD-ON PAYMENTS NO LONGER CONSIDERED NEW FOR FY 2024 BECAUSE 3-YEAR ANNIVERSARY DATE WILL OCCUR PRIOR TO APRIL 1, 2024

	Technology	Newness Start Date	NTAP Start Date	3-year Anniversary Date of Entry onto U.S. Market	Previous Final Rule Citations
1	*TECARTUS®*	*7/4/2020*	*10/1/2021*	*7/4/2023*	86 FR 45090 through 45104 87 FR 48913
2	*VEKLURY®**	*7/1/2020**	*10/1/2021*	*7/1/2023**	86 FR 45104 through 45116 87 FR 48909 through 48914
3	*Zepzelca™*	*6/15/2020*	*10/1/2021*	*6/15/2023*	86 FR 45116 through 45126 87 FR 48912 through 48913
4	*aScope® Duodeno*	*7/17/2020*	*10/1/2021*	*7/17/2023*	86 FR 45133 through 45135 87 FR 48912 through 48916
5	*Caption Guidance™*	*9/15/2020*	*10/1/2021*	*9/15/2023*	86 FR 45135 through 45138 87 FR 48911 through 48913
6	*aprevo® Intervertebral Body Fusion Device*	*12/3/2020 (ALIF and LLIF)*	*10/1/2021*	*12/3/2023 (ALIF and LLIF)*	86 FR 45127 through 45133 86 FR 67874 through 67876 87 FR 48913
7	*Cosela™*	*2/12/2021*	*10/1/2021*	*2/12/2024*	86 FR 45008 through 45017 87 FR 48912 through 48913
8	*ShockWave C2 Intravascular Lithotripsy (IVL) System*	*2/12/2021*	*10/1/2021*	*2/12/2024*	86 FR 45151 through 45153 87 FR 48913
9	*ABECMA®*	*3/26/2021*	*10/1/2021*	*3/26/2024*	86 FR 45028 through 45035 87 FR 48911 through 48925
10	*Harmony™ Transcatheter Pulmonary Valve (TPV) System*	*03/26/2021*	*10/1/2021*	*3/26/2024*	86 FR 45146 through 45149 87 FR 48913
11	*Recarbrio™ (HABP/VABP)*	*6/4/2020*	*10/1/2021*	*6/4/2023*	86 FR 45157 through 45158 86 FR 67874 87 FR 48914
12	*Fetroja® (HABP/VABP)*	*9/25/2020*	*10/1/2021*	*9/25/2023*	86 FR 45156 through 45157 86 FR 67876 87 FR 48913
13	*DARZALEX FASPRO®*	*01/15/2021*	*10/1/2022*	*01/15/2024*	87 FR 48925 through 48937
14	*CARVYKTI™*	*03/26/2021***	*10/1/2022*	*03/26/2024*	87 FR 48920 through 48925
15	*Hemolung Respiratory Assist System (RAS)*	*04/22/2020 (COVID-19)*	*10/1/2022*	*04/22/2023 (COVID-19)*	87 FR 48937 through 48948

*See discussion in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48909 through 48914).

** As discussed in the FY 2023 IPPS/LTCH PPS final rule, because we determined that CARVYKTI™ is substantially similar to ABECMA®, we consider the beginning of the newness period for CARVYKTI™ to be March 26, 2021, which is the date that ABECMA® received FDA marketing authorization (87 FR 48925)

6. FY 2024 Applications for New Technology Add-On Payments (Traditional Pathway)

As discussed previously, in the FY 2023 IPPS/LTCH PPS final rule, we finalized our policy to publicly post online applications for new technology add-on payment beginning with FY 2024 applications (87 FR 48986 through 48990). As noted in the FY 2023 IPPS/LTCH PPS final rule, we stated in the proposed rule that we are continuing to summarize each application in the proposed rule. However, we stated that while we are continuing to provide discussion of the concerns or issues we identified with respect to applications submitted under the traditional pathway, we are providing more succinct information as part of the summaries in the proposed and final rules regarding the applicant's assertions as to how the medical service or technology meets the newness, cost, and substantial clinical improvement criteria. We refer readers to *https://mearis.cms.gov/public/publications/ntap* for the publicly posted FY 2024 new technology add-on payment applications and supporting information (with the exception of certain cost and volume information, and information or materials identified by the applicant as confidential or copyrighted). In addition, we noted that we made available separate tables listing the ICD–10–CM codes, ICD–10–PCS codes, and/or MS–DRGs related to the analyses of the cost criterion for certain technologies for the FY 2024 new technology add-on payment applications in Table 10 associated with the FY 2024 IPPS/LTCH PPS proposed rule, available via the internet on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps.* Click on the link on the left side of the screen titled ''FY 2024 IPPS Proposed Rule Home Page'' or ''Acute Inpatient—Files for Download.'' Please see section VI of the Addendum of the proposed rule for additional information regarding tables associated with the proposed rule.

We received 27 applications for new technology add-on payments for FY 2024 under the traditional new technology add-on payment pathway. In accordance with the regulations under § 412.87(e), applicants for new technology add-on payments must have received FDA approval or clearance by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. Eight applicants withdrew their applications prior to the issuance of the proposed rule. Subsequently, four applicants withdrew their respective applications for sabizabulin, DuraGraft, VEST, and omidubicel prior to the issuance of this FY 2024 IPPS/LTCH PPS final rule. In addition, two applicants, Daiichi Sankyo and Pfizer, for Vanflyta and elranatamab respectively, did not receive FDA approval for their technologies by July 1, 2023. Therefore, Vanflyta and elranatamab are not eligible for consideration for new technology add-on payments for FY 2024. Consistent with our standard approach, we are not including in this final rule the description and discussion of applications that were withdrawn or that are ineligible for consideration for FY 2024 due to not meeting the July 1 deadline, described previously, which were included in the FY 2024 IPPS/LTCH PPS proposed rule. We are also not summarizing nor responding to public comments received regarding these withdrawn or ineligible applications in this final rule. Of the remaining 13 applications, we are not approving the applications for NexoBrid™, SeptiCyte® RAPID, and XENOVIEW™ for the reasons discussed in the following sections. We are approving the remaining 10 applications, with 4 of the applications considered as 2 technologies due to substantial similarity, for a total of 8 new approvals for new technology add-on payments for FY 2024. A discussion of these 13 applications is presented in the following sections.

a. CYTALUX® (Pafolacianine), First Indication

On Target Laboratories submitted an application for new technology add-on payments for CYTALUX® for use in ovarian cancer for FY 2024. The applicant stated that CYTALUX® is the first targeted intraoperative molecular imaging agent that illuminates ovarian cancer in real time, enabling the detection of more cancer for resection. CYTALUX® is an optical imaging agent comprised of a folic acid analog conjugated with a fluorescent dye which binds to folate receptor positive cancer cells and illuminates malignant lesions during surgery. Per the applicant, CYTALUX® is used in adult patients with ovarian cancer as an adjunct for intraoperative identification of malignant lesions. CYTALUX® is to be used with a near-infrared imaging system (NIR) cleared by the FDA for specific use with CYTALUX®. We note that On Target Laboratories also submitted a second application for new technology add-on payments for CYTALUX® for FY 2024 for use in lung cancer, as discussed separately in this section.

Please refer to the online application posting for CYTALUX®, available at *https://mearis.cms.gov/public/publications/ntap/NTP221017X8NAN*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, the applicant stated that a new drug application (NDA) for CYTALUX® was approved by FDA on November 29, 2021, as an optical imaging agent indicated in adult patients with ovarian cancer as an adjunct for intraoperative identification of malignant lesions. According to the applicant, CYTALUX® had market availability delayed until April 15, 2022, due to supply/product availability. The recommended dose of CYTALUX® is a single intravenous infusion of 0.025 mg/kg diluted in 250 mL of 5% Dextrose Injection, administered prior to surgery over 60 minutes using a dedicated infusion line.

The applicant submitted a request for a unique ICD–10–PCS procedure codes for CYTALUX® and was granted approval to use the following procedure codes effective October 1, 2023: 8E0U0EN (Fluorescence guided procedure of female reproductive system using pafolacianine, open approach), 8E0U3EN (Fluorescence guided procedure of female reproductive system using pafolacianine, percutaneous approach), 8E0U4EN (Fluorescence guided procedure of female reproductive system using pafolacianine, percutaneous endoscopic approach), 8E0U7EN (Fluorescence guided procedure of female reproductive system using pafolacianine, via natural or artificial opening), and 8E0U8EN (Fluorescence guided procedure of female reproductive system using pafolacianine, via natural or artificial opening endoscopic). The applicant provided a list of diagnosis codes that may be used to currently identify this indication for CYTALUX®, and differentiate it from the lung cancer indication, under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant believed that CYTALUX® is not substantially similar to other currently

available technologies because there are no other optical imaging agents with the same active ingredient, nor the same mechanism of action for the same indication of ovarian cancer, and that therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for CYTALUX® for the applicant's complete statements in support of its assertion that CYTALUX® is not substantially similar to other currently available technologies.

Substantial Similarity Criteria	Applicant Response	Applicant Assertions Regarding this Criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	There are no existing drugs/biological products that are used as an adjunct for intraoperative identification of malignant lesions in adults with ovarian cancer other than CYTALUX®. Furthermore, there is no other drug marketed under the same active ingredient category or generic name, nor which have the same mechanism of action to target the folate receptor to illuminate cancerous lesions.
Is the technology assigned to the same MS-DRG as existing technologies?	No	There are no existing drugs/biological products that are used as an adjunct for intraoperative identification of malignant lesions in adult ovarian cancer other than CYTALUX®. Furthermore, there is no other drug marketed under the same active ingredient category or generic name.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	There are no existing drugs/biological products that are used as an adjunct for intraoperative identification of malignant lesions in adults with ovarian cancer other than CYTALUX®. Furthermore, there is no other drug marketed under the same active ingredient category or generic name.

We invited public comments on whether CYTALUX® is substantially similar to existing technologies and whether CYTALUX® meets the newness criterion.

Comment: The applicant reiterated that there are no existing FDA-approved drugs/biological products that are used as an adjunct for intraoperative identification of malignant lesions in adults with ovarian cancer other than CYTALUX®. The applicant also reiterated that there is no other drug marketed under the same active ingredient category or generic name, nor which has the same mechanism of action to target the folate receptor to illuminate cancerous lesions. In terms of newness, the applicant asserted that the appropriate newness date for CYTALUX® for ovarian cancer is April 15, 2022, the date on which a supply of CYTALUX® was first made available for sale. The applicant stated that CYTALUX® experienced a documented and verifiable delay in market entry, as CYTALUX® was approved for ovarian cancer in November 2021 but experienced a delay in commercialization primarily due to external circumstances. The applicant further explained that as CYTALUX® was not available before April 15, 2022, and there were no clinical uses of CYTALUX® between the date of FDA approval and its market entry, the newness period for the technology should begin on April 15, 2022.

In addition, the applicant noted that initial clinical use of CYTALUX® involved 20 cases that were performed at only three select centers between May and June 2022 during a small commercial pilot with remaining product lots manufactured specifically to support planned clinical development. The applicant explained that the batch of CYTALUX® expired at the end of June 2022, thereby rendering it impossible to perform additional cases. The applicant further explained that due to the removal of the FDA cleared imaging system for use with CYTALUX® from the market, a commercial lot was not initiated again until there was strong confidence that the FDA would approve CYTALUX® for lung cancer, and that therefore, the first full commercial lot was released in June 2023, coinciding with the newness date for CYTALUX® for lung cancer, as discussed separately in this section.

Response: We thank the applicant for its comment. Based on our review of comments received and information submitted by the applicant as part of its FY 2024 new technology add-on payment application for CYTALUX®, we agree with the applicant that CYTALUX® is the only adjunct for intraoperative identification of malignant lesions in adults with ovarian cancer with a mechanism of action to target the folate receptor to illuminate cancerous lesions. Therefore, we believe that CYTALUX® is not substantially similar to existing treatment options and meets the newness criterion. We consider the beginning of the newness period to commence when CYTALUX® became commercially available on April 15, 2022.

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for CYTALUX®, the applicant searched the FY 2021 Inpatient Standard Analytic File (IPSAF) for cases reporting a combination of ICD–10–CM/PCS codes for ovarian cancer that may require an adjunct for intraoperative identification of malignant lesions. Using the inclusion/exclusion criteria described in the following table, the applicant identified 3,281 claims mapping to five MS–DRGs. The applicant noted that it limited its search to these five MS–DRGs as 99 percent of cases map to these MS–DRGs. Please see Table 10.8.A.—CYTALUX® (ovarian) Codes—FY 2024 associated with the proposed rule for the complete list of codes that the applicant indicated were included in its cost analysis. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $133,657, which exceeded the average case-weighted threshold amount of $93,649. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the

applicant asserted that CYTALUX® meets the cost criterion.

CYTALUX® COST ANALYSIS	
Data Source and Time Period	FY 2021 Inpatient Standard Analytic Files
List of ICD-10-CM codes	Please see Table 10.8.A. – CYTALUX® (ovarian) Codes – FY 2024 associated with the proposed rule for the complete list of ICD-10-CM codes included in the cost analysis.
List of ICD-10-PCS codes	Please see Table 10.8.A. – CYTALUX® (ovarian) Codes – FY 2024 associated with the proposed rule for the complete list of ICD-10-PCS codes included in the cost analysis.
List of MS-DRGs	736 (Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy with MCC) 737 (Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy with CC) 738 (Uterine and Adnexa Procedures for Ovarian or Adnexal Malignancy without CC/MCC) 739 (Uterine, Adnexa Procedures for Non-Ovarian and Non-Adnexal Malignancy with MCC) 740 (Uterine, Adnexa Procedures for Non-Ovarian and Non-Adnexal Malignancy with CC)
Inclusion/exclusion criteria	The applicant searched for cases reporting a combination of ICD-10-CM/PCS codes for ovarian cancer that may require an adjunct for intraoperative identification of malignant lesions as listed in Table 10.8.A. – CYTALUX® (ovarian) Codes – FY 2024 associated with the proposed rule that mapped to MS-DRG 736-740. The applicant limited its search to these five MS-DRGs as 99% of cases map to these MS-DRGs. The applicant calculated the average unstandardized charge per case for each MS-DRG. Hospitals with less than 11 admissions had their volume data hidden.
Charges removed for prior technology	Per the applicant, CYTALUX® does not completely replace any current technology so no direct or indirect charges were removed.
Standardized charges	The applicant used the standardization formula provided in Technical Appendix A of the FY 2024 application. The applicant used all relevant values reported in the impact file and the standardization file posted with the FY 2023 IPPS/LTCH PPS final rule. Hospitals were removed from this calculation if they were not present within the FY 2023 Standardizing File provided by CMS.
Inflation factor	The applicant applied an inflation factor of 20.47% to the standardized charges, which is based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule.
Charges added for the new technology	CYTALUX® is supplied as a single dose vial for IV administration and one vial is used per patient. The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.184 for drugs from the FY 2023 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

We invited public comments on whether CYTALUX® meets the cost criterion.

Comment: The applicant submitted a public comment reiterating that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, CYTALUX® meets the cost criterion.

Response: We thank the applicant for its comment. We agree that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. Therefore, CYTALUX® meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that CYTALUX® represents a substantial clinical improvement over existing technologies because CYTALUX® enables the surgeon to identify cancer intraoperatively in real time that otherwise would have been missed, enabling the surgeon to achieve more complete resection in cytoreductive surgery for ovarian cancer. Per the applicant, the results of the Phase 3 study confirm that CYTALUX® serves as an adjunct to the surgeon, helping them to identify additional cancer which otherwise would not have been identified, enabling the surgeon to achieve more complete resection, which is the goal of cytoreductive surgery. The applicant provided two studies to support these claims as well as 11 background articles. The background articles included studies to demonstrate the importance of removing all residual disease (lesions) to improve patients' survival; studies that showed that lesions can be diffuse and numerous, of various sizes, and often not readily visible in the surgical field; a study that showed, when CYTALUX® was used in a murine tumor model and in early clinical studies, that it enabled identifying occult tumor nodules and showed potential to eliminate positive tumor margins; a study demonstrating that the folate receptor was expressed in most ovarian cancers; and a study and a review supporting the use of fluorescence in real-time to improve cancer surgery.[23] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for CYTALUX® for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

[23] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Substantial Clinical Improvement Assertion #1: This technology significantly improves clinical outcomes relative to services or technologies previously available.		
Applicant Statements in Support	**Supporting Evidence Provided by the Applicant**	**Outcome(s) or Findings Cited by the Applicant from Supporting Evidence to Support its Statements**
CYTALUX® Substantial Clinical Improvement supportive ovarian cancer data: The goal of cytoreductive surgery for ovarian cancer is to safely remove all cancer, to minimize recurrence, and improve survival rates	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.	
CYTALUX® Substantial Clinical Improvement supportive ovarian cancer data: Optimal or complete cytoreduction relies on accurate detection and successful surgical resection of all lesions.	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.	
CYTALUX® aided the surgeon by identifying additional cancer intraoperatively, in real time, enabling the surgeon to achieve a more complete resection in cytoreductive surgery for ovarian cancer.	Tanyi JL, Randall LM, Chambers SK, Butler KA, Winer IS, Langstraat CL, Han ES, Vahrmeijer AL, Chon HS, Morgan MA, Powell MA, Tseng JH, Lopez A, Wenham RM. A Randomized Phase 3 Study of Pafolacianine Injection (OTL38) for Intraoperative Imaging of Folate Receptor Positive Ovarian Cancer. J Clin Oncol. 2022. doi:10.1200/JCO.22.00291. Brief study description: A phase III, randomized, multicenter, single dose, open-label study to examine the use of pafolacianine injection as a tool for real-time detection of folate receptor-positive ovarian cancer.	In 33.0% of patients (95% CI, 24.3 to 42.7; P < .001), pafolacianine with near-infrared imaging identified additional cancer on tissue not planned for resection and not detected by white light assessment and palpation, exceeding the prespecified threshold of 10%. Pafolacianine, to the authors' knowledge, is the first of a new class of intraoperative fluorescent imaging agents to improve detection of malignant lesions during surgery. The accumulation of evidence through the clinical development supports the introduction of targeted fluorescent imaging into the surgical theater to enhance completeness of surgical resection with the goal of improving survival.
CYTALUX® Substantial Clinical Improvement supportive ovarian cancer data: Targeted fluorescent	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.	

Substantial Clinical Improvement Assertion #1: This technology significantly improves clinical outcomes relative to services or technologies previously available.		
Applicant Statements in Support	**Supporting Evidence Provided by the Applicant**	**Outcome(s) or Findings Cited by the Applicant from Supporting Evidence to Support its Statements**
imaging agents have potential to enable surgeons to identify malignant lesions intraoperatively		
During interval debulking surgery after chemotherapy, CYTALUX® aided the surgeon by identifying additional cancer intraoperatively, in real time, enabling the surgeon to achieve more complete resection.	Randall LM, Wenham RM, Low PS, Dowdy SC, Tanyi JL. A phase II, multicenter, open-label trial of OTL38 injection for the intra-operative imaging of folate receptor-alpha positive ovarian cancer. Gynecol Oncol. 2019 Oct;155(1):63-68. doi: 10.1016/j.ygyno.2019.07.010. Epub 2019 Jul 27. PMID: 31362825. Brief study description: A phase II, multicenter, open-label trial of OTL38 (a folate-indole-cyanine green-like conjugate to folate receptor alpha (FRa)) injection to assess the safety and efficacy (sensitivity and positive predictive value (PPV)) of OTL38 for intraoperative imaging during epithelial ovarian cancer surgery.	The proportion of women receiving neoadjuvant chemotherapy (NACT) prior to surgery has significantly increased from 8.6% to 22.6% between the years of 2004 and 2013 ($p < 0.001$), and adoption of this treatment modality occurred primarily after 2007 (95%CI 2006–2009; $p = 0.001$).
	Tanyi JL, Randall LM, Chambers SK, Butler KA, Winer IS, Langstraat CL, Han ES, Vahrmeijer AL, Chon HS, Morgan MA, Powell MA, Tseng JH, Lopez A, Wenham RM. A Randomized Phase 3 Study of Pafolacianine Injection (OTL38) for Intraoperative Imaging of Folate Receptor Positive Ovarian Cancer. J Clin Oncol. 2022. doi:10.1200/JCO.22.00291. See prior study description	Among patients who underwent interval debulking surgery, the rate was 39.7% (95% CI, 27.0 to 53.4; $P < .001$). Pafolacianine, to the authors' knowledge, is the first of a new class of intraoperative fluorescent imaging agents for improving detection of malignant lesions during surgery. The accumulation of evidence through the clinical development supports the introduction of targeted fluorescent imaging into the surgical theater to enhance completeness of surgical resection with the goal of improving survival.

BILLING CODE 4120–01–C

In the FY 2024 IPPS/LTCH proposed rule (88 FR 26789 through 26790), after review of the information provided by the applicant, we stated we had the following concerns regarding whether CYTALUX® meets the substantial clinical improvement criterion. We noted that CYTALUX® showed a false positive rate of 24.8 percent that led to resections in the Phase 3, randomized, multicenter, single-dose, open-label study of this technology.[24] While the applicant submitted a separate comment stating there was no worsening in the safety profile for patients with false positive results, we continued to question the impact on patient outcomes when taking additional tissues that were false positives. In addition, while the applicant provided background citations to support the assertion that optimal or improved cytoreduction of tumor results in improved survival in ovarian adenocarcinoma, we noted that the Phase 3 study of CYTALUX® appears to have been designed to assess the efficacy of the technology rather than clinical outcomes such as survival, recurrence, or rate of additional procedures. We noted that we would be interested in additional or longer-term data demonstrating that CYTALUX® results in improved outcomes such as improved survival or a reduced rate of recurrence to support an assessment of whether CYTALUX® represents a substantial clinical improvement.

We invited public comments on whether CYTALUX® meets the substantial clinical improvement criterion.

Comment: Several commenters supported the application for CYTALUX®. A commenter explained that ovarian cancer remains the most lethal gynecologic cancer, and that complete surgical cytoreduction is the single most important prognostic indicator for survival. The commenter explained that although bulky disease can be easily recognized, sub-centimeter implants are often difficult to discriminate from adjacent normal tissue and may not be recognized and

[24] Tanyi JL, Randall LM, Chambers SK, Butler KA, Winer IS, Langstraat CL, Han ES, Vahrmeijer AL, Chon HS, Morgan MA, Powell MA, Tseng JH, Lopez A, Wenham RM. A Randomized Phase 3 Study of Pafolacianine Injection (OTL38) for Intraoperative Imaging of Folate Receptor Positive Ovarian Cancer. J Clin Oncol. 2022. doi:10.1200/JCO.22.00291.

resected. The commenter further noted that intraoperatively, a surgeon has only two tools to improve the outcome of the tumor resections: visual inspection and palpation, and thus, surgeons need tools to augment these approaches. The commenter explained that the Phase 3 study of CYTALUX® demonstrates that the technology provides an important real-time adjunct to current surgical approaches for ovarian cancer, identifying malignant lesions that would not have been resected without CYTALUX®.

Another commenter stated that CYTALUX® allowed discovery of more lesions which were not seen with the naked eye and these lesions were removed safely to achieve the surgical goal of removal of all visible tumor. The commenter asserted that during interval debulking surgery after chemotherapy, as CYTALUX® improved detection of viable tumor from scar tissue, lesions were removed and sent for quick pathology evaluation, leading to efficiency of the surgical procedure, reducing operative time and less surgical morbidity. The commenter stated that additional removal of lesions discovered by CYTALUX® use did not lead to an increase of surgical morbidities.

Response: We thank the commenters for their input and have taken it into consideration in determining whether CYTALUX® meets the substantial clinical improvement criterion, discussed later in this section.

Comment: The applicant submitted a public comment regarding the substantial clinical improvement criterion, and provided responses to concerns raised by CMS in the proposed rule. In response to concerns on how CYTALUX® improves health outcomes and changes patient management, the applicant asserted that CYTALUX® helps surgeons detect ovarian cancer that is currently undetectable during surgery, allowing them to diagnose and treat additional cancer lesions earlier. The applicant stated that in the CYTALUX® Phase 3 trial, the use of CYTALUX® identified additional ovarian cancer on tissue that was not part of the preoperative surgical plan and not otherwise planned for resection in 27 percent of imaged patients.[25] The applicant stated that the surgeons involved in the Phase 3 study responded that use of CYTALUX® led to a revision in their surgical plan for 56 percent of patients and more complete debulking was achieved in 51 percent of patients.[26] The applicant stated that identifying additional cancer on tissue not planned for resection in the preoperative plan led to a change in the management of the patient, allowing the surgeon to treat additional cancer which otherwise would have been left behind and may not have been discovered and treated until the patient presented with a recurrence. Therefore, the applicant believes that CYTALUX® not only allowed identification of cancerous lesions that would have otherwise remained undetected, but that it also may potentially shorten the amount of treatment time for a given patient by potentially reducing the risk of recurrence of ovarian cancer. The applicant asserted that CYTALUX® improves health outcomes through the more complete resection of residual disease. The applicant added that, consistent with the goal of achieving R0 (no remaining visible disease after surgery), following what surgeons deemed to be complete (R0) resection with conventional methods of identifying cancer during surgery, the surgeons indicated that intraoperative imaging with CYTALUX® enabled them to achieve ''R(-1),'' having found additional disease that they otherwise would not have found.

In addition, the applicant asserted that CYTALUX® improves health outcomes through the more complete resections of residual disease, which is supported by a wealth of peer-reviewed literature and longstanding bedrock principles relating to the treatment of cancer. The applicant stated that in the CYTALUX® Phase 3 trial, in 70 percent of patients in which additional ovarian cancer was detected by CYTALUX® and not by white light palpation, the specimen size of malignant lesions plus the tissue margin was greater than 1cm. The applicant stated that in its Phase 3 trial, CYTALUX® demonstrated the ability to aid surgeons by identifying additional cancer intraoperatively otherwise unknown to the surgeon and on tissue not planned for resection, in real time, enabling the surgeon to achieve a more complete resection in cytoreductive surgery for ovarian cancer and therefore improving clinical outcomes for these patients. According to the applicant, substantial clinical literature demonstrates that complete resections are associated with improved survival in ovarian cancer, with a steep drop in survival with residual tumors greater than 1 cm remaining following cytoreductive surgery. The applicant asserted that CYTALUX® is not a therapeutic agent, and stated that it therefore believes that long-term survival studies are not necessary to prove the clinical improvement CYTALUX® can add to help surgeons identify and diagnose additional cancer they may have otherwise missed, thus supporting them in achieving the surgical goal.

With regard to the false positive rates, the applicant asserted that CYTALUX®'s false positive rates do not meaningfully alter CYTALUX®'s significant clinical improvement analysis. The applicant conducted an analysis to compare false positives under white light palpation and CYTALUX® with NIR imaging. The applicant stated that rates and specimen size of false positives are comparable between those identified and removed by the surgeon under standard methods of white light and palpation and those identified and removed by the surgeon under NIR imaging with CYTALUX®. The applicant stated that, for CYTALUX® the presence of false positive results did not cause negative patient outcomes or additional unnecessary treatments as the removal of benign tissue is often a consequence of standard surgical resection. Additionally, the applicant stated that the false positive results after use of CYTALUX® were comparable to those following standard treatment; and the false positive results from use of CYTALUX® led to only a small amount of noncancerous tissue being removed.

Response: We thank the applicant for its comment and the additional information provided regarding the substantial clinical improvement criterion.

Based on the additional information received, we agree with the applicant and commenters that CYTALUX® represents a substantial clinical improvement over existing technology because CYTALUX® can detect ovarian cancer that is currently undetectable during surgery, which enables the surgeon to diagnose and treat additional cancer earlier, and affects the management of the patient by identifying additional ovarian cancer not otherwise planned for resection, leading to revisions in the surgical plan that result in more complete resection of the cancer.

After consideration of the information included in the applicant's new technology add-on payment application

[25] Tanyi JL, Randall LM, Chambers SK, Butler KA, Winer IS, Langstraat CL, Han ES, Vahrmeijer AL, Chon HS, Morgan MA, Powell MA, Tseng JH, Lopez A, Wenham RM. A Randomized Phase 3 Study of Pafolacianine Injection (OTL38) for Intraoperative Imaging of Folate Receptor Positive Ovarian Cancer. J Clin Oncol. 2022. doi:10.1200/JCO.22.00291.

[26] Tanyi JL, Randall LM, Chambers SK, Butler KA, Winer IS, Langstraat CL, Han ES, Vahrmeijer AL, Chon HS, Morgan MA, Powell MA, Tseng JH, Lopez A, Wenham RM. A Randomized Phase 3 Study of Pafolacianine Injection (OTL38) for Intraoperative Imaging of Folate Receptor Positive Ovarian Cancer. J Clin Oncol. 2022. doi:10.1200/JCO.22.00291.

and the comments received, we have determined that CYTALUX® meets the criteria for approval for new technology add-on payment. Therefore, we are approving new technology add-on payments for this technology for FY 2024. Cases involving the use of CYTALUX® that are eligible for new technology add-on payments will be identified by ICD–10–PCS codes: 8E0U0EN (Fluorescence guided procedure of female reproductive system using pafolacianine, open approach), 8E0U3EN (Fluorescence guided procedure of female reproductive system using pafolacianine, percutaneous approach), 8E0U4EN (Fluorescence guided procedure of female reproductive system using pafolacianine, percutaneous endoscopic approach), 8E0U7EN (Fluorescence guided procedure of female reproductive system using pafolacianine, via natural or artificial opening), or 8E0U8EN (Fluorescence guided procedure of female reproductive system using pafolacianine, via natural or artificial opening endoscopic).

In its application, the applicant estimated that the cost of CYTALUX® is $4,250 per single-use vial (one vial is used per patient). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of CYTALUX® is $2,762.50 for FY 2024.

b. CYTALUX® (Pafolacianine), Second Indication

On Target Laboratories submitted an application for new technology add-on payments for CYTALUX® for use in lung cancer for FY 2024. The applicant stated that CYTALUX® is the first targeted intraoperative molecular imaging agent that illuminates lung cancer in real time, enabling the detection of more cancer for resection. CYTALUX® is an optical imaging agent comprised of a folic acid analog conjugated with a fluorescent dye which binds to folate receptor positive cancer cells and illuminates malignant lesions during surgery. Per the applicant, CYTALUX® is used in adult patients with known or suspected cancer in the lung as an adjunct for intraoperative identification of pulmonary lesions. CYTALUX® is to be used with a NIR cleared by the FDA for specific use with CYTALUX®. CYTALUX® is used by surgeons to illuminate cancer in real time during surgery. We note that On Target Laboratories also submitted a separate application for new technology add-on payments for CYTALUX® for FY 2024 for use in ovarian cancer, as discussed previously in this section.

Please refer to the online application posting for CYTALUX®, available at *https://mearis.cms.gov/public/publications/ntap/NTP221017ED6BY*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, the applicant stated that CYTALUX® received FDA approval in a supplemental new drug application (sNDA), effective December 16, 2022, to include an additional indication for lung cancer, following approval of the original NDA for use in ovarian cancer. CYTALUX® is indicated as an adjunct for intraoperative identification of malignant and non-malignant pulmonary lesions in adult patients with known or suspected cancer in the lung. According to the applicant, CYTALUX® will have market availability delayed until approximately the middle of 2023 due to supply/product availability. The recommended dose of CYTALUX® is a single intravenous infusion of 0.025 mg/kg diluted in 250 mL of 5% Dextrose Injection, administered prior to surgery over 60 minutes using a dedicated infusion line. We noted that, as discussed previously, the applicant stated that CYTALUX® for ovarian cancer became commercially available on April 15, 2022. We were interested in additional information regarding whether the versions or formulations for CYTALUX® for use in lung cancer and ovarian cancer are different, or further explanation regarding the longer delay for the market availability for CYTALUX® for lung cancer.

The applicant submitted a request for unique ICD–10–PCS procedure codes for CYTALUX® and was granted approval to use the following procedure codes effective October 1, 2023: 8E0W0EN (Fluorescence guided procedure of trunk region using pafolacianine, open approach), 8E0W3EN (Fluorescence guided procedure of trunk region using pafolacianine, percutaneous approach), 8E0W4EN (Fluorescence guided procedure of trunk region using pafolacianine, percutaneous endoscopic approach), 8E0W7EN (Fluorescence guided procedure of trunk region using pafolacianine, via natural or artificial opening), and 8E0W8EN (Fluorescence guided procedure of trunk region using pafolacianine, via natural or artificial opening endoscopic). The applicant provided a list of diagnosis codes that may be used to currently identify this indication for CYTALUX®, and differentiate it from the ovarian cancer indication, under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant believed that CYTALUX® is not substantially similar to other currently available technologies because there are no other optical imaging agents with the same active ingredient, nor same mechanism of action, for the same indication, and that therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for CYTALUX® for the applicant's complete statements in support of its assertion that CYTALUX® is not substantially similar to other currently available technologies.

BILLING CODE 4120–01–P

Substantial Similarity Criteria	Applicant Response	Applicant Assertions Regarding this Criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	There are no existing drugs/biological products that are used as an adjunct for intraoperative identification of malignant lesions in adults with lung cancer other than CYTALUX®. Furthermore, there is no other drug marketed under the same active ingredient category or generic name, nor which have the same mechanism of action to target the folate receptor to illuminate cancerous lesions.
Is the technology assigned to the same MS-DRG as existing technologies?	No	There are no existing drugs/biological products that are used as an adjunct for intraoperative identification of malignant lesions in adult lung cancer other than CYTALUX®. Furthermore, there is no other drug marketed under the same active ingredient category or generic name.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	There are no existing drugs/biological products that are used as an adjunct for intraoperative identification of malignant lesions in adults with lung cancer other than CYTALUX®. Furthermore, there is no other drug marketed under the same active ingredient category or generic name.

We invited public comments on whether CYTALUX® is substantially similar to existing technologies and whether CYTALUX® meets the newness criterion.

Comment: The applicant submitted a public comment regarding the newness criterion. The applicant reiterated that there are no existing FDA approved drugs/biological products that are used as an adjunct for intraoperative identification of malignant and non-malignant pulmonary lesions in adult patients with known or suspected cancer in the lung other than CYTALUX®. The applicant also reiterated that there is no other drug marketed under the same active ingredient category or generic name, nor which has the same mechanism of action to target the folate receptor to illuminate cancerous lesions in the lung. In terms of newness, the applicant asserted that the appropriate newness date for CYTALUX® for lung cancer is June 5, 2023, the date CYTALUX® became available for purchase. The applicant explained that while CYTALUX® was approved in December 2022 to assist surgeons in identifying lung lesions in adult patients with known or suspected lung cancer, the product has never been sold or made available to the market after its approval for use in lung cancer. As discussed previously in this section, the applicant explained that although the use of CYTALUX® for ovarian cancer was briefly available on the market for a small limited pilot of 20 cases from April through June 2022 at three select centers, the technology was subsequently taken off the market due to the market withdrawal of the necessary imaging system, and therefore a commercial lot of CYTALUX® was not initiated again until there was strong confidence that the FDA would approve CYTALUX® for use in lung cancer. The applicant further stated that on June 5, 2023, the first commercial lot of CYTALUX® became available for use in lung cancer. The applicant asserted that therefore, because CYTALUX® was not available on the market following FDA approval of CYTALUX® for lung cancer, the appropriate newness date for CYTALUX® for lung cancer would be June 5, 2023, the market availability of the product.

Response: We thank the applicant for its comments. Based on our review of comments received and information submitted by the applicant as part of its FY 2024 new technology add-on payment application for CYTALUX®, we agree with the applicant that CYTALUX® is the only adjunct for intraoperative identification of malignant and non-malignant pulmonary lesions in adult patients with known or suspected cancer in the lung with a mechanism of action to target the folate receptor to illuminate cancerous lesions in the lung. Therefore, we believe that CYTALUX® is not substantially similar to existing treatment options and meets the newness criterion. We consider the beginning of the newness period to commence when CYTALUX® became commercially available on June 5, 2023.

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for CYTALUX®, the applicant searched the FY 2021 IPSAF for cases reporting a combination of ICD–10–CM/PCS codes for malignant or suspected lung lesions. Using the inclusion/exclusion criteria described in the following table, the applicant identified 15,033 claims mapping to three MS–DRGs. The applicant noted that it limited its search to these three MS–DRGs as 99 percent of cases map to these MS–DRGs. Please see Table 10.9.A.—CYTALUX® (lung) Codes—FY 2024 associated with the proposed rule for the complete list of codes that the applicant included in its cost analysis. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $122,700, which exceeded the average case-weighted threshold amount of $101,584. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that CYTALUX® meets the cost criterion.

CYTALUX® COST ANALYSIS	
Data Source and Time Period	FY 2021 Inpatient Standard Analytic Files
List of ICD-10-CM codes	Please see Table 10.9.A. – CYTALUX® (lung) Codes – FY 2024 associated with the proposed rule for the complete list of ICD-10-CM codes included in the cost analysis.
List of ICD-10-PCS codes	Please see Table 10.9.A. – CYTALUX® (lung) Codes – FY 2024 associated with the proposed rule for the complete list of ICD-10-PCS codes included in the cost analysis.
List of MS-DRGs	163 (Major Chest Procedures with MCC) 164 (Major Chest Procedures with CC) 165 (Major Chest Procedures without CC MCC)
Inclusion/exclusion criteria	The applicant searched for cases reporting a combination of ICD-10-CM/PCS codes for malignant or suspected lung lesions as listed in Table 10.9.A. – CYTALUX® (lung) Codes – FY 2024 associated with the proposed rule that mapped to MS-DRG 163-165. The applicant limited its search to these three MS-DRGs as 99% of cases map to these MS-DRGs. The applicant calculated the average unstandardized charge per case for each MS-DRG. Hospitals with less than 11 admissions had their volume data hidden.
Charges removed for prior technology	Per the applicant, CYTALUX® does not replace any current technology so no direct or indirect charges were removed.
Standardized charges	The applicant used the standardization formula provided in Technical Appendix A of the FY 2024 application. The applicant used all relevant values reported in the impact file and the standardization file posted with the FY 2023 IPPS/LTCH PPS final rule. Hospitals were removed from this calculation if they were not present within the FY 2023 Standardizing File provided by CMS.
Inflation factor	The applicant applied an inflation factor of 20.47% to the standardized charges, which is based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule.
Charges added for the new technology	CYTALUX® is supplied as a single dose vial for IV administration and one vial is used per patient. The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.184 for drugs from the FY 2023 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

We invited public comments on whether CYTALUX® meets the cost criterion.

Comment: The applicant submitted a comment reiterating that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, CYTALUX® meets the cost criterion.

Response: We thank the applicant for its comment. We agree that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. Therefore, CYTALUX® meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that CYTALUX® represents a substantial clinical improvement over existing technologies because CYTALUX® enables the surgeon to visualize cancer intraoperatively, in real time, that otherwise may have gone undetected. Per the applicant, the use of the CYTALUX® during pulmonary resection for lung cancer represents a significant potential advancement over current standards of surgery by enhancing the intraoperative localization of pulmonary nodules, improving the ability to remove them with clean margins, and reducing the probability of leaving otherwise undetected malignant synchronous lesions behind. The applicant provided six studies to support these claims and nine background articles. The background articles included studies about the importance of complete cancer tissue resection to overall survival, the limitations of thoracoscopic surgery by localizing the exact location of a pulmonary nodule for resection, the low 5-year survival for lung cancer patients, and the high rates of local recurrence after lung cancer surgery; one study demonstrating that contrasted chest computed tomography (CT) scan is not sufficient to identify pulmonary nodules that need resection; one study supporting the need for cleaner margins during resection to reduce local recurrence of lung cancer; one study supporting the use of the folate receptor as an appropriate tumor specific marker; one study indicating that folate-targeted agents may have a place in cancer treatment before, as well as, after chemotherapy; and a study showing that the folate receptor is expressed in the majority of lung cancers and that CYTALUX® targets and binds to folate receptors and thus the mechanism of action is a viable target for lung cancer.[27] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for CYTALUX® for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

[27] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Substantial Clinical Improvement Assertion #1: This technology significantly improves clinical outcomes relative to services or technologies previously available.		
Applicant Statements in Support	**Supporting Evidence Provided by the Applicant**	**Outcome(s) or Findings Cited by the Applicant from Supporting Evidence to Support its Statements**
In 29% of subjects, CYTALUX® impacted the overall scope of the surgical procedure.	Singhal S, Martin L, Rice D, Blackmon S, Murthy S, Gangadharan S, Reddy R, Sarkaria I. Randomized, Multi Center Phase 3 Trial of Pafolacianine during Intraoperative Molecular Imaging of Cancer in the Lung: Results of the ELUCIDATE Trial. AATS 102nd Annual Meeting. Boston MA. May 2022. Brief study description: A prospective study with 112 patients to evaluate the efficacy and safety of CYTALUX®.	The investigators indicated a change in scope in the surgical procedure based on IMI with pafolacianine for 29% (22% increase, 7% decrease) of the patients. In the group randomized to IMI pafolacianine, there were 8/78 (10%) NSCLC patients whose stage was changed due to the CSE. Study CSEs were counted as: IMI with pafolacianine (i) localized the index lung nodule that could not be located by white light, (ii) identified a synchronous malignant lesion, or (iii) identified a close surgical margin (<= 10mm).
CYTALUX® Substantial Clinical Improvement supportive lung cancer data: High rates of recurrence/poor survival in part due to incomplete resection of disease	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.	
Clinically Significant Events (CSE) occurred in 54% of	Manuscript in preparation on the ELUCIDATE trial. Brief study description:	One or more clinically significant events (CSE) occurred in 53% of evaluated participants compared to a prespecified

patients with the use of CYTALUX®.	A Phase III, 12-center trial with 112 patients to determine the clinical utility of pafolacianine, a folate receptor (FR)-targeted fluorescent agent, in revealing by intraoperative molecular imaging (IMI) FRa positive cancers in the lung and narrow surgical margins that may otherwise be undetected with conventional visualization.	limit of 10% ($p < 0.0001$). In 38 participants, at least one was a margin <=10 mm from the resected primary nodule (38%, 95% CI 28.5 – 48.3), 32 being confirmed by histopathology. In 19 subjects (19%, 95% CI 11.8 – 28.1), IMI located the primary nodule that the surgeon could not locate with white light and palpation. IMI revealed 10 occult synchronous malignant lesions in 8 subjects (8%, 95% CI 3.5 – 15.2) undetected using white light. Most (73%) IMI-discovered synchronous malignant lesions were outside the planned resection field. A change in the overall scope of surgical procedure occurred for 29 of the subjects (22 increase, 7 decrease).
CYTALUX® Substantial Clinical Improvement supportive lung cancer data: The Folate Receptor (FR) is an appropriate tumor specific marker for Non-Small Cell Lung Cancer (NSCLC)	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.	
In 9% of subjects, surgeons identified a synchronous lesion with CYTALUX® that was not identified with conventional methods.	Singhal S, Martin L, Rice D, Blackmon S, Murthy S, Gangadharan S, Reddy R, Sarkaria I. Randomized, Multi Center Phase 3 Trial of Pafolacianine during Intraoperative Molecular Imaging of Cancer in the Lung: Results of the ELUCIDATE Trial. AATS 102nd Annual Meeting. Boston MA. May 2022. See prior study description	IMI with pafolacianine identified occult synchronous malignant lesions in nine patients (9%, 95% CI 4.2 – 16.4). Most (73%) IMI-identified synchronous malignant lesions were outside the planned field of resection.
	Predina JD, Newton AD, Keating J, Barbosa EM Jr, Okusanya O, Xia L, Dunbar A, Connolly C, Baldassari MP, Mizelle J, Delikatny EJ, Kucharczuk JC, Deshpande C, Kularatne SA, Low P, Drebin J, Singhal S. Intraoperative Molecular Imaging Combined With Positron Emission Tomography Improves Surgical Management of Peripheral Malignant Pulmonary Nodules. Ann Surg. 2017 Sep;266(3):479-488. doi: 10.1097/SLA.0000000000002382. PMID: 28746152. Brief study description: A study with 50 patients with pulmonary nodules to examine whether IMI with a folate receptor targeted near-infrared contrast agent (OTL38) can improve malignant pulmonary nodule identification when combined with PET.	In this study, CYTALUX® identified 56 of 59 (94.9%) malignant pulmonary nodules identified by preoperative imaging. CYTALUX® located an additional 9 malignant lesions not identified preoperatively. Nodules only detected by CYTALUX® were smaller than nodules detected preoperatively (0.5 vs 2.4 cm; P < 0.01) but displayed similar fluorescence (tumor-to-background ratio 3.3 and 3.1; P = 0.50). Sensitivity of IMI and PET were 95.6% and 73.5% (P ¼ 0.001), respectively; and positive predictive values were 94.2% and 89.3%, respectively (P > 0.05). Additionally, utilization of IMI clinically upstaged 6 (12%) subjects and improved management of 15 (30%) subjects. These data suggest that combining CYTALUX® with PET may provide superior oncologic outcomes for patients with resectable lung cancer.
In 38% of the subjects, a close surgical resection margin was detected with CYTALUX®.	Singhal S, Martin L, Rice D, Blackmon S, Murthy S, Gangadharan S, Reddy R, Sarkaria I. Randomized, Multi Center Phase 3 Trial of Pafolacianine during Intraoperative Molecular Imaging of Cancer in the Lung: Results of the ELUCIDATE Trial. AATS 102nd Annual Meeting. Boston MA. May 2022. See prior study description	Per the applicant, IMI with CYTALUX® found 38 patients with close margins <=10 mm (38%, 95% CI 28.5 – 48.3).

	Kennedy GT, Azari, FS, Bernstein E, Marfatia I, Din A, Kucharczuk JC, Low PS, Singhal S. Targeted Intraoperative Molecular Imaging for Localizing Nonpalpable Tumors and Quantifying Resection Margin Distances. JAMA Surg . 2021 Nov 1;156(11):1043-1050. doi: 10.1001/jamasurg.2021.3757. PMID: 34431971. PMCID: PMC8387952. Brief study description: A nonrandomized, open-label, single-center trial with 40 patients to assess the capability of IMI, a novel technology using a fluorescent tracer targeted to malignant cells, to localize visually occult, nonpalpable tumors and quantify margin distances during resection.	The results of this study demonstrated that CYTALUX® is reliable for intraoperative lesion localization and margin identification. In 40 patients, conventional surgical methods localized 22 of 40 lesions (55%), while CYTALUX® localized 36 of 40 (90%). Of 18 nonpalpable lesions, CYTALUX® identified 15 (83.3%). Both palpable and nonpalpable lesions demonstrated mean signal-to-background ratio more than 2. A CYTALUX® margin was able to be calculated for 39 of 40 patients (95%). CYTALUX® margins were nearly identical to margins reported on final pathology (R2 = 0.9593), with median (interquartile range) difference of 1.3 (0.7-2.0) mm. CYTALUX® detected 2 margins in nonpalpable tumors that were clinically unacceptable and would have had a high probability of recurrence.
In 19% of subjects, surgeons localized primary lesions with CYTALUX® that otherwise were undetected by conventional methods.	Singhal S, Martin L, Rice D, Blackmon S, Murthy S, Gangadharan S, Reddy R, Sarkaria I. Randomized, Multi Center Phase 3 Trial of Pafolacianine during Intraoperative Molecular Imaging of Cancer in the Lung: Results of the ELUCIDATE Trial. AATS 102nd Annual Meeting. Boston MA. May 2022. See prior study description	Per the applicant, CYTALUX® located the primary lesion in 19 patients (19%, 95% CI 11.8 – 28.1) whose lesions could not be found under white light and palpation.
	Predina JD, Newton A, Corbett C, Xia L, Sulyok LF, Shin M, Deshpande C, Litzky L, Barbosa E, Low PS, Kucharczuk JC, Singhal S. Localization of Pulmonary Ground-Glass Opacities with Folate Receptor-Targeted Intraoperative Molecular Imaging. J Thorac Oncol. 2018 Jul;13(7):1028-1036. Doi: 10.1016/j.jtho.2018.03.023. Epub 2018 Apr 4. PMID: 29626619. PMCID: PMC6015787. Brief study description: A clinical trial exploring an alternative method involving near-infrared molecular imaging with a folate receptor–targeted agent, OTL38, to improve localization of GGOs and confirmation of resection margins.	The study demonstrated that of the 21 GGOs, 20 accumulated CYTALUX® and displayed fluorescence upon in situ or back table evaluation. Intraoperatively, near-infrared imaging localized 15 of 21 lesions whereas standard methods localized 10 of 21 (p = 0.05). The addition of molecular imaging affected care of nine (9) of 21 subjects by improving intraoperative localization (n = 6) and identifying close margins (n = 3).
	Kennedy GT, Azari FS, Bernstein E, Marfatia I, Din A, Deshpande C, Galvis N, Sorger J, Kucharczuk JC, Singhal S. First-in-human results of targeted intraoperative molecular imaging for visualization of ground glass opacities during robotic pulmonary resection. Transl Lung Cancer Res. 2022 Aug;11(8):1567-1577. doi: 10.21037/tlcr-21-1004. PMID: 36090642. PMCID: PMC9459620. Brief study description: A pilot study to determine whether IMI during RATS (RIMI) can localize GGOs.	As lung cancer screening rates rise, GGOs are becoming increasingly common. These types of lesions are particularly challenging to localize during surgery because they are not fully solid, and thus difficult to palpate. This paper demonstrated that CYTALUX® identified tumor-specific fluorescence in 100% (10/10) subjects in the study, whereas traditional methods identified the nodule in 70% (7/10) subjects.

BILLING CODE 4120–01–C

In the FY 2024 IPPS/LTCH proposed rule (88 FR 26795), after review of the information provided by the applicant, we stated we had the following concerns regarding whether CYTALUX® meets the substantial clinical improvement criterion. We noted that CYTALUX® showed a false positive rate

of 25.8 percent that led to resections in the Phase 3, multicenter study of this technology.[28] While the applicant submitted a separate comment stating there was no worsening in the safety profile for patients with false positive results, we continued to question the impact on patient outcomes when taking additional tissues that were false positive. We noted that the authors discussed in the results of the Phase 3 trial that there was a decreased rate of subsequent diagnostic intervention. We questioned if they were referring to fewer resections in future surgical procedure, and/or if this also implied a subsequent positive outcome of reduced mortality. While the studies provided in support of CYTALUX® measure identification of lesions and changes in the scope of the surgical procedure, we noted that the applicant did not provide data indicating that these endpoints directly lead to improved clinical outcomes (for example, reduction in mortality, hospitalizations, subsequent procedures, and/or rate of recurrence) based on use of CYTALUX®. Rather, we stated that improved outcomes were inferred by relying on the assumption that increased or decreased scope of resection results in better outcomes. We noted that we were interested in additional information or long-term data measuring the impact of the technology on treatment outcomes or the management of the patient to support that CYTALUX® results in an improvement over the standard of care.

We invited public comments on whether CYTALUX® meets the substantial clinical improvement criterion.

Comment: The applicant submitted a public comment regarding the substantial clinical improvement criterion and provided responses to CMS's concerns from the proposed rule. With regard to improvement of patient management, the applicant asserted that CYTALUX® objectively improves surgeons' management of the patient through enabling use of tissue-sparing procedures and by helping surgeons to identify and more completely resect undetected cancerous lesions during surgery. The applicant stated that as demonstrated in the Phase 3 ELUCIDATE trial, use of CYTALUX® allowed surgeons to localize the primary lesion in 19 percent of patients whose lesion could not be seen by white light and otherwise localized by the surgeon using standard techniques and a positive/close margin (<10mm from the resection line) in 38 percent of patients.[29]

In addition, the applicant asserted that the surgeon was able to identify the lesion more quickly with CYTALUX® as compared to preoperative localization techniques, thus improving the management of the patient through reducing the amount of time the patient is under anesthesia. The applicant stated that in the Phase 3 ELUCIDATE trial, the median time to localize the primary nodule was 1 minute (range <1–23), compared with another study showing that the mean procedural time for robotic navigational bronchoscopy, which is a preferred method for preoperative localization, was 67 minutes (range 37–97).[30]

Moreover, the applicant asserted that CYTALUX® aids surgeons' ability to perform tissue-sparing procedures by providing visualization of the precise location and borders of the tumor, which helps surgeons determine where to resect tissue while ensuring a proper margin. The applicant stated that results from the Phase 3 ELUCIDATE trial indicated the maximum depth of lesions detected by CYTALUX® alone was 27.9mm increasing to 37.7mm with both CYTALUX® and white light while the minimum size of lesions identified by CYTALUX® and not by standard white light was as small as 2mm for synchronous lesions and 5mm for primary lesions.[31] The applicant stated that Phase 2 and Phase 2 clinical trial date showed CYTALUX® increased the surgeon's ability to detect the primary lesion intraoperatively from 72 percent to 94 percent of patients. The applicant stated that across all lesions in the Phase 2 and Phase 3 trials, 94 percent were folate receptor alpha or beta positive, demonstrating the efficacy of CYTALUX®'s mechanism of action across a multitude of cancer histologies in both primary lung cancer and metastatic disease.

Additionally, the applicant asserted that appropriate staging is a critical area to guide long-term treatment plans adjuvant to surgery, since correct staging ensures improved patient care, enabling earlier notification of the extent of disease and faster time to optimal treatment. According to the applicant, in clinical trials, CYTALUX® detected additional synchronous malignant lesions which were not identified on preoperative imaging. The applicant stated that one trial, the detection of 9 synchronous lesions in 8 percent of patients (n = 7 out of 92) resulted in each of the 7 patients being upstaged, enabling alterations to adjuvant treatment plans to reflect the greater extent of disease.[32] The applicant stated that in the Phase 3 ELUCIDATE trial, CYTALUX® allowed the surgeon to identify one more or additional synchronous malignant lesions that were previously unidentified on preoperative scans nor intraoperatively in 8 percent of patients, with the majority outside the planned field of resection.[33]

In response to concerns on improvement of patient outcomes, the applicant claimed that CYTALUX® improves health outcomes through the more complete resection of otherwise undetected cancer, which is supported by substantial peer-reviewed literature and longstanding bedrock principles relating to the treatment of cancer. According to the applicant, CYTALUX® improves surgeons' ability to treat the disease more completely via resection, which thereby may reduce the risk of recurrence and has the potential to increase the likelihood of patient survival by assisting the surgeon to overcome each of these established surgical challenges. The applicant stated that among the Phase 3 ELUCIDATE participants, 53 percent had a clinically significant event from use of CYTALUX®: in 19 percent of patients, CYTALUX® was able to localize the primary lesion otherwise not found by the surgeon using standard techniques; in 8 percent of patients, CYTALUX® identified an unknown occult synchronous lesions; and in 38 percent

[28] Singhal S, Sarkaria I., Martin L, Rice D, Blackmon S, Slade H. Pafolacianine for Intraoperative Molecular Imaging for Cancer in the Lung—The ELUCIDATE Trial (Manuscript in preparation). 2022.

[29] Sarkaria IS, Martin LW, Rice DC, Blackmon SH, Slade HB, Singhal S; ELUCIDATE Study Group. Pafolacianine for intraoperative molecular imaging of cancer in the lung: The ELUCIDATE trial. J Thorac Cardiovasc Surg. 2023 Mar 3:S0022–5223(23)00185–X. doi: 10.1016/j.jtcvs.2023.02.025. Epub ahead of print. PMID: 37019717.

[30] Value of Robotic Navigational Bronchoscopy to Enhance Diagnostic Yield and Guide Oncological Strategy in Treatment of Pulmonary Nodules. Abstract presented at the 2023 American Association of Thoracic Surgeons Annual Meeting.

[31] Abbas A, Kadakia S, Ambur V, Muro K, Kaiser L. Intraoperative electromagnetic navigational bronchoscopic localization of small, deep, or subsolid pulmonary nodules. J Thorac Cardiovasc Surg. 2017 Jun;153(6):1581–1590. doi: 10.1016/j.jtcvs.2016.12.044. Epub 2017 Feb 7. PMID: 28314525.

[32] Gangadharan S, Sarkaria IN, Rice D, Murthy S, Braun J, Kucharczuk J, Predina J, Singhal S. Multiinstitutional Phase 2 Clinical Trial of Intraoperative Molecular Imaging of Lung Cancer. Ann Thorac Surg. 2021 Oct;112(4):1150–1159. doi: 10.1016/j.athoracsur.2020.09.037. Epub 2020 Nov 19. PMID: 33221195.

[33] Sarkaria IS, Martin LW, Rice DC, Blackmon SH, Slade HB, Singhal S; ELUCIDATE Study Group. Pafolacianine for intraoperative molecular imaging of cancer in the lung: The ELUCIDATE trial. J Thorac Cardiovasc Surg. 2023 Mar 3:S0022–5223(23)00185–X. doi: 10.1016/j.jtcvs.2023.02.025. Epub ahead of print. PMID: 37019717.

of patients, CYTALUX® was able to identify a close resection margin less than or equal to 10 mm.[34] The applicant stated that use of CYTALUX® led to a change in the overall scope of surgical procedure for 29 percent of patients.[35]

In response to CMS's questioning if the noted CYTALUX® ''decreased rate of subsequent diagnostic intervention'' refers to ''fewer resections in future surgical procedure, and/or if this also implies a subsequent positive outcome of reduced mortality'', the applicant stated that the ELUCIDATE trial was not designed to follow patients long term to determine reduction in additional procedures, oncologic outcomes, nor mortality rates. According to the applicant, considering existing preoperative procedures commonly utilized today to provide localization aides to surgeons, CYTALUX® has the potential to reduce preoperative localization procedures, including endobrochial dye marking, microcoil placement, fiducial marker placement, and transthoracic percutaneous hook wire placement. The applicant stated that the ELUCIDATE phase 3 trial demonstrated that, without the use of CYTALUX, synchronous malignant lesions would have been left behind in 8 percent of patients, confirming similar findings from the phase 2 trial. The applicant stated that as the synchronous lesions increased in size, they would have been identified on follow up scans, and additional surgeries are likely to have been required to remove these lesions increasing the risk of complications and mortality in these patients. The applicant stated that the ability to perform a more complete resection during the initial procedure using a targeted imaging agent has the potential to reduce the need for future intervention (for example, additional surgery) and the associated morbidity risks thus addressing the goal of the surgeon and patients.[36]

[34] Singhal S, Martin L, Rice D, Blackmon S, Murthy S, Gangadharan S, Reddy R, Sarkaria I. Randomized, Multi Center Phase 3 Trial of Pafolacianine during Intraoperative Molecular Imaging of Cancer in the Lung: Results of the ELUCIDATE Trial. AATS 102nd Annual Meeting. Boston MA. May 2022.

[35] Singhal S, Martin L, Rice D, Blackmon S, Murthy S, Gangadharan S, Reddy R, Sarkaria I. Randomized, Multi Center Phase 3 Trial of Pafolacianine during Intraoperative Molecular Imaging of Cancer in the Lung: Results of the ELUCIDATE Trial. AATS 102nd Annual Meeting. Boston MA. May 2022.

[36] Mohiuddin K, Haneuse S, Sofer T, et al. Relationship between margin distance and local recurrence among patients undergoing wedge resection for small (≤2 cm) non-small cell lung cancer. J Thorac Cardiovasc Surg. 2014 Apr;147(4):1169–75; discussion 1175–7. doi: 10.1016/j.jtcvs.2013.11.056. Epub 2014 Jan 2. PMID: 24507406.

With regards to CMS's concerns about false positives, the applicant stated that false positive rates for CYTALUX® do not meaningfully alter the substantial clinical improvement analysis presented in the application. The applicant stated that in the Phase 3 trial, the false positive rate for primary lesions in patients with confirmed cancer was low, at 1.4 percent, demonstrating the ability of CYTALUX® to correctly identify malignant lesions with multiple histologies in the lung, and that in patients with suspected or confirmed cancer in the lung, the false positive rate was 12.7 percent. Per the applicant, the difference between 1.4 percent and the 12.7 percent accounts for situations in which the patient did not have a confirmed diagnosis prior to surgery. Additionally, the applicant stated that clinical trial results across 769 patients from multiple clinical trials with CYTALUX® showed there were no drug-related serious adverse events among participants. The applicant stated that patients who had false positive lesions removed showed no associated increase in respiratory or pulmonary adverse events as compared to events occurring during standard of care resections. The applicant also asserted that the presence of false positive results did not cause negative patient outcomes. The applicant stated that additionally, the false-positive results after use of CYTALUX® were comparable to those following standard treatment without CYTALUX®.

We also received several additional comments in support of the application for CYTALUX®, stating that the technology represents a substantial clinical improvement over existing technologies. These commenters stated that the Phase 3 trial presented in the application for CYTALUX® highlighted key challenges in the operative landscape namely localization of lesions, margin control and occult synchronous lesions. Commenters stated that CYTALUX® facilitates minimally invasive lung cancer surgery, improves the ability to detect smaller than 1 cm tumors and otherwise undetectable lesions without unreliable procedurally placed surrogates (for example, percutaneous wires, dye-marking, or coils) or larger procedures to locate lesions. Commenters asserted that CYTALUX® is easy for patients because they just undergo intravenous safe infusion of a medication preoperatively. Commenters asserted that CYTALUX® demonstrated a better option to visualize occult disease compared to advanced imaging or standard visualization techniques that fail to reveal occult lesions during initial operative intervention. Commenters stated that CYTALUX® allowed the discovery of synchronous adenocarcinomas that were not identified by standard CT scan procedures, aided in confirming the location of a metastatic renal cell carcinoma lesion in the lung of a patient and allowed more precise detection and localization of lesions both for primary lung cancer and metastatic disease to the lung (pancreatic adenocarcinoma and pleomorphic liposarcoma). Commenters stated that CYTALUX® provided surgeons the ability to visually assess margin distance to ensure an adequate margin was obtained in real time. A commenter asserted that CYTALUX® allows the surgeon to see the tumor during stapler firing to visualize the margin prior to a point that could leave an inadequate margin or require moving to a full lobectomy procedure. Commenters believed that CYTALUX® can transform surgical techniques, increase operative efficiency, and decrease risk for local recurrence or inaccurate staging. Commenters believed that CYTALUX® offers the possibility to improve cancer surgery outcomes by enabling surgeons to better identify primary tumors, detect occult synchronous lesions, ensure adequate margins of resection, and ensure resection of a related lesion that will upstage the cancer and likely necessitate adjuvant systemic therapy. A commenter stated that CYTALUX® will impact patient outcomes now that more sublobar resections are occurring as a result of earlier diagnosis of lung lesions. Another commenter encouraged CMS to assign new technology add-on payment status for new technologies like CYTALUX® supporting personalized medicine; stating this will remove barriers to accessing innovative tools that advance this approach to care. Another commenter believed that false positives are not significantly impactful, as very little tissue is removed to determine histology, and added that as more experience is gained with CYTALUX®, surgeons will learn how to better interpret the intraoperative imaging.

Response: We thank the applicant and other commenters for their comments regarding the substantial clinical improvement criterion.

Based on the additional information received, we agree with the applicant that CYTALUX® represents a substantial clinical improvement over existing technology because CYTALUX® can identify lung cancer that is otherwise undetectable using standard methods, which enables more precise removal of

the cancer by the surgeon and affects patient management, as the detection of synchronous lesions using CYTALUX® results in the upstaging of patient care, enabling alterations to adjuvant treatment plans to reflect the greater extent of disease.

After consideration of the information included in the applicant's new technology add-on payment application, we have determined that CYTALUX® meets the criteria for approval for new technology add-on payment. Therefore, we are approving new technology add-on payments for this technology for FY 2024. Cases involving the use of CYTALUX® that are eligible for new technology add-on payments will be identified by ICD–10–PCS codes: 8E0W0EN (Fluorescence guided procedure of trunk region using pafolacianine, open approach), 8E0W3EN (Fluorescence guided procedure of trunk region using pafolacianine, percutaneous approach), 8E0W4EN (Fluorescence guided procedure of trunk region using pafolacianine, percutaneous endoscopic approach), 8E0W7EN (Fluorescence guided procedure of trunk region using pafolacianine, via natural or artificial opening), or 8E0W8EN (Fluorescence guided procedure of trunk region using pafolacianine, via natural or artificial opening endoscopic).

In its application, the applicant estimated that the cost of CYTALUX® is $4,250 per single-use vial (one vial is used per patient). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of CYTALUX® is $2,762.50 for FY 2024.

c. EPKINLY™ (Epcoritamab-bysp) and COLUMVI™ (Glofitamab-gxbm)

Two manufacturers, Genmab US and Genentech, Inc., submitted separate applications for new technology add-on payments for FY 2024 for EPKINLY™ (epcoritamab-bysp) and COLUMVI™ (glofitamab-gxbm), respectively. We note that we discussed both of these technologies in the proposed rule at 88 FR 26809 and 26816 using their generic names, epcoritamab and glofitamab, respectively, which received FDA Marketing Authorization after the proposed rule and are updated to EPKINLY™ (epcoritamab-bysp) and COLUMVI™ (glofitamab-gxbm), respectively in this final rule. Both of these technologies are bispecific antibodies used for the treatment of patients with relapsed/refractory (R/R) large B-cell lymphoma (LBCL) after two or more prior therapies, with COLUMVI™ specifically targeting the largest subset of LBCL, diffuse LBCL (DLBCL). The bispecific antibodies directly bind two types of clusters of differentiation CD simultaneously, CD20 expressing B-cells and CD3 expressing T-cells, to induce activation, proliferation and cytotoxic activity of the T-cells against the malignant B-cells. In the FY 2024 IPPS/LTCH PPS proposed rule we discussed these applications as two separate technologies. After further consideration and as discussed later in this section, we believe EPKINLY™ and COLUMVI™ are substantially similar to each other and that it is appropriate to evaluate both technologies as one application for new technology add-on payments under the IPPS. We refer the reader below for a complete discussion regarding our analysis of the substantial similarity of EPKINLY™ and COLUMVI™.

Please refer to the online application postings for EPKINLY™ available at *https://mearis.cms.gov/public/publications/ntap/NTP221012JQM0G*, and for COLUMVI™ available at *https://mearis.cms.gov/public/publications/ntap/NTP221017RK2RD*, for additional detail describing the technologies and the disease treated by the technologies.

With respect to the newness criterion, the applicant for EPKINLY™ stated that it was seeking Biologic License Application (BLA) approval from FDA for the indication of treatment of adult patients with R/R LBCL after two or more lines of systemic therapy. The applicant for EPKINLY™ stated that EPKINLY™ is intended for subcutaneous administration with patients receiving 0.16 milligram (mg) priming and 0.87 mg intermediate dose before the first full dose of 48 mg. This is administered weekly in cycles one through three, every 2 weeks in cycles four through nine, and every 4 weeks in cycles 10 and onward until disease progression. According to the applicant, in the EPCORE NHL–1 study, all patients were required per protocol to be hospitalized for 24 hours on the third dose, which was the first full dose of 48 mg. According to the applicant, the mean per patient dose, including when provided during or related to inpatient stays across all 28 injection visits, is 44.61 mg. The applicant subsequently received BLA approval from FDA for EPKINLY™ on May 19, 2023, for the indication of treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from indolent lymphoma, and high-grade B-cell lymphoma after two or more lines of systemic therapy.

With regard to COLUMVI™, the applicant received BLA approval from FDA on June 15, 2023, for the indication of treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, including DLBCL arising from follicular lymphoma after two or more lines of systemic therapy. The applicant for COLUMVI™ stated that COLUMVI™ is administered as an intravenous infusion through a dedicated infusion line according to a dose step-up schedule leading to the recommended dosage of 30 mg, after completion of pre-treatment with obinutuzumab on cycle day 1, where each cycle is 21 days. The applicant recommends treatment for a maximum of 12 cycles or until the disease progresses to unmanageable toxicity. According to the applicant, the administration of COLUMVI™ will be treated as part of an inpatient stay and reimbursed through the DRG when a patient is admitted within 72 hours of the outpatient administration to treat a condition that results from the administration such as developing grade two or higher cytokine release syndrome (CRS). The applicant stated that, in clinical trials, when Grade 2, 3, or 4 CRS developed, 69 percent of the time it occurred after a 2.5 mg dose, 27 percent of the time it developed after a 10 mg dose, and 4 percent after a 30 mg dose. Therefore, according to the applicant, the expected average dose of COLUMVI™ associated with an inpatient hospital stay is ((2.5 mg * 0.69) + (10 mg * 0.27) + (30mg * 0.04)) = 5.625 mg.

The applicant for EPKINLY™ submitted a request for a unique ICD–10–PCS code for EPKINLY™ beginning in FY 2024 and was granted approval for the following procedure code effective October 1, 2023: XW013S9 (Introduction of epcoritamab monoclonal antibody into subcutaneous tissue, percutaneous approach, new technology group 9). The applicant for COLUMVI™ submitted a request for a unique ICD–10–PCS code for COLUMVI™ beginning in FY 2024 and was granted approval for the following procedure codes effective October 1, 2023: XW033P9 (Introduction of glofitamab antineoplastic into peripheral vein, percutaneous approach, new technology group 9 and XW043P9 (Introduction of glofitamab antineoplastic into central vein, percutaneous approach, new technology group 9). The applicants provided lists of diagnosis codes that may be used to

currently identify the indication for EPKINLY™ and COLUMVI™ under the ICD–10–CM coding system. Please refer to the online application postings for the complete list of ICD–10–CM codes provided by each applicant.

As stated earlier and for the reasons discussed further later in this section, we believe that EPKINLY™ and COLUMVI™ are substantially similar to each other such that it is appropriate to analyze these two applications as one technology for purposes of new technology add-on payments, in accordance with our policy. We discuss the information provided by the applicants, as summarized in the proposed rule, regarding whether EPKINLY™ and COLUMVI™ are substantially similar to existing technologies prior to their approval by the FDA and their release onto the U.S. market. As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With respect to the substantial similarity criteria, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, the applicant for EPKINLY™ asserted that the mechanism of action of EPKINLY™ is not the same as or similar to an existing technology. The applicant described EPKINLY™ as an anti-CD3xCD20 bispecific antibody with a unique mechanism of action that will be the first of its kind for the treatment of R/R LBCL. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for EPKINLY™ for the applicant's complete statements in support of its assertion that EPKINLY™ is not substantially similar to other currently available technologies.

BILLING CODE 4120–01–P

Substantial Similarity Criteria	Applicant Response	Applicant's assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	EPKINLY™ has a novel mechanism of action compared to any approved therapy for R/R LBCL. Currently, there are no approved anti-CD3xCD20 bispecific antibodies. In the non-immune activating class of LBCL therapies, EPKINLY™ shares the mechanism of targeting lymphoma cells through binding of antibodies with the monoclonal antibodies (mAbs). POLIVY® and ZYNLONTA® are both antibody drug conjugates (ADC), relying on the internalization and release of a cytotoxic agent to induce cell death. Moreover, POLIVY® targets CD79b and ZYNLONTA® targets CD19. Small molecule chemotherapies are the largest class of therapies for LBCL. While being non-immune activating therapies, they are defined as small molecules compared to the biologic, EPKINLY™. 1. Non-Immune Activating Therapies 1.A. Small molecule chemotherapies include REVLIMID®, XPOVIO®, cyclophosphamide, doxorubicin, vincristine, prednisone, gemcitabine, bendamustine, oxaliplatin, and etoposide. Small molecule chemotherapies inhibit critical cellular functions associated with cell division, inducing cell death. 1.B. mAbs 1.B.i. POLIVY® is an anti-CD79b antibody conjugated to the cytotoxic agent MMAE. Upon binding CD79b, POLIVY® releases MMAE and induces cell death. 1.B. ii. ZYNLONTA® is an anti-CD19 antibody conjugated to the cytotoxic agent PBD. After binding CD19, ZYNLONTA® releases PBD and induces cell death. EPKINLY™ is an immune activating LBCL therapy within the class of CD19 and CD20 therapies. CD19 therapies include CAR T-cell therapy and Monjuvi®, both of which have a wholly different mechanism of action compared to epcoritamab. Within the immune

Substantial Similarity Criteria	Applicant Response	Applicant's assertions regarding this criterion
		activating CD20, only rituximab is approved for LBCL. Rituximab is a mAb, while epcoritamab is a CD3xCD20 bispecific antibody. 2. Immune Activating Therapies 2.A. CD-19 Therapies 2.A.i. CAR T-cell Therapies: YESCARTA®, KYMRIAH®, and Breyanzi® are genetically modified autologous T-cell therapies that express an anti-CD19 exocellular domain to enable the targeting and binding of cytotoxic T-cells to the surface of CD19 expressing B-cells, killing CD19 expressing B-cells. 2.A. ii. Anti-CD19 Antibodies: Monjuvi® is an anti-CD19 mAb that binds to CD19, which is highly expressed in malignant B-cells. After binding CD19, Monjuvi® stimulates cytotoxicity of CD19 expressing cells. 2.B. CD-20 Therapies 2.B.i. Rituximab is an anti-CD20 mAb that binds to CD20, which is expressed on mature B-cells, including malignant B-cells. After binding, rituximab stimulates cytotoxicity through direct binding and CD20 inhibition and through Natural Killer (NK) cells and T-cell mediated cytotoxicity or macrophage phagocytosis. 2.B. ii. EPKINLY™ is an anti-CD3xCD20 bispecific antibody enabling the simultaneous binding of a CD3 T-cell and a CD20 B-cell, thereby inducing T-cell activation and cytotoxic activity. Only National Comprehensive Cancer Network (NCCN) recommended therapies were included.
Is the technology assigned to the same MS-DRG as existing technologies?	Yes	Potential cases of patients who may be eligible for EPKINLY™ treatment would be assigned to the same MS-DRGs as cases representing patients who currently receive FDA-approved therapies.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	Yes	EPKINLY™ will be for the treatment of R/R LBCL patients, including diffuse large B-cell lymphoma (DLBCL), HGBCL, PMBCL, and G3B FL who have failed at least two previous treatments. Standard of care (SOC) for the treatment of these patients is chemoimmunotherapy regimen, however, 20-50% of patients are refractory or will relapse, and these patients consistently have poor clinical outcomes. While there are existing therapies approved for 3L+ LBCL patients (summarized in Substantial Clinical Improvement section), the unmet need for this population is quite high as a significant number of patients are unresponsive to currently available treatments. EPKINLY™ is posed to address this high unmet need by providing a safe and effective treatment option for a highly refractory patient population. See Substantial Clinical Improvement section for more info. Only NCCN recommended therapies are included here. Three FDA approved CAR T therapies are currently indicated for the treatment of 3L+ R/R LBCL: 1) Breyanzi® – Indicated for adults with LBCL, including DLBCL not otherwise specified (NOS) & DLBCL arising from indolent lymphoma, HGBCL, PMBCL, and G3b FL, refractory to 1L chemotherapy or that relapses within 12 months of chemotherapy 2) KYMRIAH® – Indicated for adult patients with R/R LBCL after two or more lines of systemic therapies, including DLBCL NOS, HGBCL, and DLBCL arising from FL 3) YESCARTA® – Indicated for adults with LBCL refractory to 1L chemotherapy or relapse within 12 months of chemotherapy; R/R LBCL after two or more systemic therapies, including DLBCL NOS, PMBCL, HGBCL, and DLBCL arising from FL Other currently approved drugs for patients who have failed at least two therapies (that is, 3L+ therapies) are POLIVY®, XPOVIO®, and ZYNLONTA®: 1) POLIVY® – Indicated for adults with R/R DLBCL NOS, including DLBCL arising from FL after at least two lines of systemic therapies 2) XPOVIO®– Indicated for adults with R/R DLBCL NOS, including DLBCL arising from FL after at least two lines of systemic therapies

Substantial Similarity Criteria	Applicant Response	Applicant's assertions regarding this criterion
		3) ZYNLONTA® – Indicated for adult patients with R/R DLBCL after two or more lines of systemic therapy, including DLBCL NOS, DLBCL arising from low-grade lymphoma, and HGBCL

The applicant for COLUMVI™ asserted that COLUMVI™ offers a novel mechanism of action for the treatment of R/R DLBCL with two or more prior lines of therapy patients and is not substantially similar to other currently available technologies because the mechanism of action of COLUMVI™ is distinct from other available DLBCL therapies because COLUMVI™ does not treat the same or similar type of disease or patient population, and that therefore, the technology meets the newness criterion. The applicant's assertions regarding substantial similarity are summarized briefly in the following table. Please see the online application posting for COLUMVI™ for the applicant's complete statements in support of its assertion that COLUMVI™ is not substantially similar to other currently available technologies.

Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	COLUMVI™ has a mechanism of action that involves binding simultaneously to the target B-cell (via CD20 which are expressed on the cell surface of B-cells) and an effector T-cell (via CD3, expressed on the surface of T-cells). Upon binding to both cells, the T-cell is activated to kill the bound B-cell. At least two other investigational bispecific antibodies have similar mechanisms of action. However, to date, there have been no other bispecific antibody approved for the treatment of DLBCL. So, to date, COLUMVI™ mechanism of action does not resemble that of any approved therapy in the treatment of DLBCL. COLUMVI™ is the only anti-CD20/CD3 bispecific antibody that has a 2:1 structural configuration. This means that there are two CD20 binding domains on the COLUMVI™ Fab region and one CD3 binding domain and its binding to CD20 is bivalent. This is in contrast to traditional bispecific antibodies which have a 1:1 configuration. The unique structure of COLUMVI™ and its high avidity to CD20 contribute to its activity in vitro (up to 40x potency in cell killing compared to traditional bispecific antibodies with 1:1 configuration) and the structure may also contribute to its clinical characteristics in terms of efficacy, safety and combinability with other anti-CD20 molecules. COLUMVI™ is distinct from the BiTE molecules (such as blinatumomab) because, unlike the BiTEs (which are protein fragments), COLUMVI™ is a full-length antibody molecule, which contributes to the stability of the COLUMVI™ molecule in vivo and allows for a once-every-21-day dosing schedule. Blinatumomab (anti-CD19, CD3 bispecific BiTE) requires continuous dosing. To date, there have been no BiTE molecules that are indicated for the treatment of patients with DLBCL. Chimeric antigen receptor (CAR)-T therapies are live-cell therapies that also engage T-cells in their mechanism of action. In contrast to CAR T-cell therapy, COLUMVI™ does not entail a weeks-long manufacturing turn-around time, and physicians can readily access COLUMVI™ for their patients "off-the-shelf," which is particularly beneficial for patients with aggressive disease who need treatment immediately. In addition, because COLUMVI™ is not manufactured for an individual patient, product manufacture and supply can be consistent.

Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Is the technology assigned to the same MS-DRG as existing technologies?	Yes	COLUMVI™ and existing therapies for 3L+ DLBCL could be assigned to the same MS-DRGs.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	COLUMVI™ will fill an unmet need left by other 3L+ DLBCL approved therapies. Therefore, the use of COLUMVI™ in 3L+ R/R DLBCL does not involve the treatment of the same or a similar type of disease or the same or similar patient population when compared to an existing technology. Although there are approved therapies for treatment of R/R DLBCL, there is no standard of care. The prognosis of patients with R/R disease is poor, with overall survival being less than 10-12 months. The median age at diagnosis of DLBCL is 66 years, an age in which a significant number of patients have a history of other malignancies and comorbidities. In general, this is a difficult to treat patient population. Additionally, by the time patients reach 3L+, they have had multiple prior therapies, are frequently relapsed after or are refractory to chemoimmunotherapy (CIT), anti-CD20s, ASCT, and CAR T-cell therapy. The patient population in the pivotal NCT03075696 study demonstrated the efficacy of COLUMVI™ in heavily pretreated and highly refractory patients, a cohort that reflects patients requiring 3L+ treatment in the real world. The median age of patients enrolled in the NCT03075696 study was 66 years (range 21-90); 54% were aged ≥65 years. All patients had prior anti-CD20 therapy (100%), 96.8% had anthracycline (CIT), 33% had CAR T-cell therapy, and 18.2% had a prior autologous stem cell transplantation (ASCT). Most patients were refractory to the last prior therapy (85.7%), with 29.9% refractory to prior CAR T-cell therapy. Furthermore 58.4% were refractory to 1L therapy, a historically hard-to-treat patient population with poor outcomes. Responses to COLUMVI™ treatment were achieved across all patient subpopulations.

BILLING CODE 4120–01–C

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26811 and 88 FR 26817), we noted that EPKINLY™ and COLUMVI™ may have a similar mechanism of action, for the treatment of adult patients with R/R LBCL/DLBCL after three or more prior lines of therapy. We noted that COLUMVI™'s mechanism of action is described as bivalent binding of CD20 on malignant B-cells and CD3 on T-cells, bringing them into close proximity inducing proliferation and targeted killing of B-cells. According to COLUMVI™'s application, the 2:1 structure of COLUMVI™ enables high-avidity, bivalent binding to CD20 that can result in activity against malignant B-cells even under low effector-to-target cells. Because of the potential similarity with the mechanism of binding of the CD3xCD20 bispecific antibody and other actions, we stated our belief that the mechanism of action for EPKINLY™ may be the same or similar to that of COLUMVI™. While the applicant for COLUMVI™ stated that the use of COLUMVI™ does not involve treatment of the same or similar patient population when compared to existing technology, there are existing therapies approved for LBCL/DLBCL patients with three or more lines of therapy including CAR–T-cell therapies and others such as POLIVY®, XPOVIO®, and ZYNLONTA®. We therefore stated our belief that COLUMVI™ may treat the same or similar patient population as these existing FDA-approved treatments.

We further stated our belief that EPKINLY™ and COLUMVI™ may treat the same or similar disease (LBCL/DLBCL) in the same or similar patient population (R/R patients who have previously received two or more lines of therapy), which is also the same disease and population as existing treatments for R/R LBCL. Accordingly, we stated that as it appears that EPKINLY™ and COLUMVI™ are purposed to achieve the same therapeutic outcome using the same or similar mechanism of action and would be assigned to the same MS–DRG, we believed that these technologies may be substantially similar to each other such that they should be considered as a single application for purposes of new technology add-on payments. We were interested in information on how these two technologies may differ from each other with respect to the substantial similarity criteria and newness criterion, to inform our analysis of whether EPKINLY™ and COLUMVI™ are substantially similar to each other and therefore should be considered as a single application for purposes of new technology add-on payments.

We invited public comment on whether EPKINLY™ and COLUMVI™ meet the newness criterion, including whether EPKINLY™ and COLUMVI™ are substantially similar to each other and therefore should be evaluated as a single technology for purposes of new technology add-on payments.

Comment: The applicant for EPKINLY™ submitted a letter maintaining that EPKINLY™ meets the newness criterion. The applicant stated that EPKINLY™ is an IgG1-bispecific antibody created using Genmab's proprietary DuoBody® technology platform and is administered subcutaneously, designed to simultaneously bind to CD3 on T-cells and CD20 on B-cells to induce T-cell mediated killing of CD20+ B-cells. The applicant stated that the DuoBody® platform enables controlled Fab-arm exchange to generate whole IgG1 monoclonal antibodies employing specific point mutations while preserving the natural architecture. The applicant stated that EPKINLY™'s mechanism of action differs from CAR T-cell therapy as well as chemotherapy or conventional CD20-targeting monoclonal antibodies as these

therapies primarily affect either cellular processes or functions of rapidly dividing cells through interference with DNA, RNA, or protein synthesis. We note that the applicant did not discuss whether it believed EPKINLY™ is substantially similar to COLUMVI™ in its comment.

The applicant for COLUMVI™ submitted a letter maintaining that COLUMVI™ meets the newness criterion. With respect to whether COLUMVI™ uses the same or a similar mechanism or action when compared to an existing technology, the applicant commented that COLUMVI™ is a novel bispecific antibody that binds to the target B-cell antigen CD20 bivalently, eliciting a complete response in heavily pre-treated patients with R/R DLBCL in the third line setting.

With respect to the request for comment on whether COLUMVI™ is substantially similar to EPKINLY™ and whether these technologies should be evaluated as a single technology for the purposes of new technology add-on payments, the applicant for COLUMVI™, while recognizing the COLUMVI™ and EPKINLY™ have similarities, stated that there are key distinctions between the two bispecific antibodies and compared the two CD20 binding domains in COLUMVI™ as substantially different than a single CD20 binding domain in EPKINLY™. Specifically, the applicant for COLUMVI™ stated that COLUMVI™ is a bispecific antibody with a unique 2:1 configuration, which enables bivalent binding of CD20 on B cells and monovalent binding of CD3 on T cells, making COLUMVI™ the only bivalent bispecific antibody available for patients with R/R DLBCL, whereas EPKINLY™ includes a 1:1 configuration with monovalent binding of CD20 and CD3, a configuration common to other bispecific antibodies. Furthermore, the applicant for COLUMVI™ stated that COLUMVI™ elicits complete responses (CRs) faster than EPKINLY™ (citing a median of 1.4 months to CR versus 2.7 months) and is administered with a dosing schedule that requires fewer total treatment visits for patients compared with EPKINLY™. The applicant for COLUMVI™ also stated that COLUMVI™ is administered as a fixed-duration treatment, allowing patients the benefit of time off therapy while EPKINLY™ requires continuous administration until disease progression or intolerability.

With respect to CMS's concern regarding existing FDA-approved therapies that are used to treat R/R DLBCL patients with 3 or more lines of therapy including CAR T-cell therapies, POLIVY®, XPOVIO®, and ZYNLONTA®, the applicant stated that there are significant limitations that render patients ineligible for or unable to benefit from these therapies. For CAR T-cell therapy, the applicant stated that despite promising response rates, they have adverse effect profiles that may not be manageable for some patients with R/R DLBCL, especially those with comorbidities and who are older. For POLIVY®, the applicant stated that limitations include serious adverse effects, such as peripheral neuropathy (40% all grades and 2.3% grades 3 or higher), which is reflected in the 31 percent discontinuation rate reported in the U.S. prescribing information. For XPOVIO®, the applicant stated that XPOVIO® has shown low responses (29% ORR and 13% CR) and high toxicity rates, including 80 percent patients that experienced any-grade gastrointestinal events (13% grade 3 or higher). Lastly, for ZYNLONTA®, the applicant stated that challenges with ZYNLONTA® include a low CR rate in patients (24%) and limited durability in responses (median duration of response was 10.3 months). Additionally, the applicant stated that the CD19-targeting MOA of ZYNLONTA® may impact how the treatment is sequenced for patients considering CAR T-cell therapy or who have relapsed after treatment. Lastly, the applicant stated that ZYNLONTA® has adverse effects of edema and skin reactions (including grade 3 or higher).

Response: We thank the applicants for their comments. After consideration of the public comments we received, although we recognize that there may be slight molecular differences, we believe EPKINLY™ and COLUMVI™ both fall into the same class of IG1 bispecific antibodies and are therefore substantially similar to one another. While COLUMVI™ has bivalent binding domains as opposed to monovalent binding domains for EPKINLY™, we do not believe number of domains meaningfully differentiate the mechanism of action, as discussed in prior rulemaking (87 FR 48924), and we instead believe that the technologies are purposed to achieve the same therapeutic outcome using the same or similar mechanism of action using bispecific CD20 and CD3 binding antibodies. Further, while COLUMVI™ may have a different administration schedule, we do not believe the administration schedule affects or substantiates a new mechanism of action. In addition, while COLUMVI™ may elicit a faster time to CR in comparison to EPKINLY™, we believe that these differences relate to an assessment of whether the technologies meet the substantial clinical improvement criterion, rather than the newness criterion. For these reasons, while the applicant for COLUMVI™ highlighted differences between COLUMVI™ and EPKINLY™, we are not convinced that these differences result in the use of a different mechanism of action, therefore, we believe that the two technologies' mechanisms of action are the same. Furthermore, we believe that EPKINLY™ and COLUMVI™ are substantially similar to one another because the technologies are intended to treat the same or similar disease in the same or similar patient population—patients with R/R LBCL/DLBCL with two or more prior lines of therapy, and that potential cases representing patients who may be eligible for treatment would be assigned to the same MS–DRGs.

We also believe EPKINLY™ and COLUMVI™ are not substantially similar to any other existing technologies because, as both applicants asserted in their FY 2024 new technology add-on payment applications and in their comments that they are anti-CD3xCD20 bispecific antibodies with a unique mechanism of action that will be the first of its kind for the treatment of R/R DLBCL after two or more lines of prior therapy, the technologies do not use the same or similar mechanism of action to achieve a therapeutic outcome as any other existing drug or therapy assigned to the same or different MS–DRG. Based on the information described in this section, we believe EPKINLY™ and COLUMVI™ meet the newness criterion.

Based on the previous discussion, we are making one determination regarding approval for new technology add-on payments that will apply to both applications, and in accordance with our policy, we use the earliest market availability date submitted as the beginning of the newness period for both EPKINLY™ and COLUMVI™.

We believe our current policy for evaluating new technology payment applications for two technologies that are substantially similar to each other is consistent with the authority and criteria in section 1886(d)(5)(K) of the Act. We note that CMS is authorized by the Act to develop criteria for the purposes of evaluating new technology add-on payment applications. For the purposes of new technology add-on payments, when technologies are substantially similar to each other, we believe it is appropriate to evaluate both technologies as one application for new

technology add-on payments under the IPPS, for the reasons we discussed earlier and consistent with our evaluation of substantially similar technologies in prior rulemaking (82 FR 38120).

With respect to the newness criterion, as previously stated, EPKINLY™ received FDA approval on May 19, 2023, and COLUMVI™ received FDA approval on June 15, 2023. In accordance with our policy, because these technologies are substantially similar to each other, we use the earliest market availability date submitted as the beginning of the newness period for both technologies. Therefore, based on our policy, with regard to both technologies, if the technologies are approved for new technology add-on payments, we believe that the beginning of the newness period would be the date on which EPKINLY™ received FDA approval, which is May 19, 2023.

The applicants submitted separate cost and clinical data, and in the proposed rule, we reviewed and discussed each set of data separately. However, as stated previously, for this final rule, we will make one determination regarding new technology add-on payments that will apply to both applications. We believe that this is consistent with our policy statements in the past regarding substantial similarity (85 FR 58679).

If substantially similar technologies are submitted for review in different (and subsequent) years, rather than the same year, we evaluate and make a determination on the first application and apply that same determination to the second application. However, because the technologies have been submitted for review in the same year, and because we believe they are substantially similar to each other, we consider both sets of cost data and clinical data in making a determination, and we do not believe that it is possible to choose one set of data over another set of data in an objective manner.

As we discussed in the proposed rule and as stated previously, each applicant submitted separate analyses regarding the cost criterion for each of their products, and both applicants maintained that their product meets the cost criterion. We summarize each analysis in this section.

With respect to the cost criterion, the applicant for EPKINLY™ provided multiple analyses to demonstrate that it meets the cost criterion. For each analysis, the applicant searched the FY 2021 MedPAR file using different ICD–10–CM codes to identify potential cases representing patients who may be eligible for EPKINLY™. Each analysis followed the order of operations described in the following table.

For the first analysis, the applicant searched for cases that represent potential patients who are being treated for CRS arising from the administration of EPKINLY™ with a diagnosis code for DLBCL. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 33 claims mapping to two MS–DRGs. The applicant calculated a final inflated average case-weighted standardized charge per case of $114,027, which exceeded the average case-weighted threshold amount of $59,550.

For the second analysis, the applicant searched for cases reporting diagnosis codes for CRS. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 101 claims mapping to three MS–DRGs. The applicant calculated a final inflated average case-weighted standardized charge per case of $88,482, which exceeded the average case-weighted threshold amount of $56,682. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in both scenarios, the applicant maintained that EPKINLY™ meets the cost criterion.

BILLING CODE 4120–01–P

EPKINLY™ COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of ICD-10-CM codes	Scenario 1 and 2 T80.89XA Other complications following infusion, transfusion, and therapeutic injection Scenario 1 C83.30 Diffuse large B-cell lymphoma, unspecified site C83.31 Diffuse large B-cell lymphoma, lymph nodes of head, face, and neck C83.32 Diffuse large B-cell lymphoma, intrathoracic lymph nodes C83.33 Diffuse large B-cell lymphoma, intra-abdominal lymph noes C83.34 Diffuse large B-cell lymphoma, lymph nodes of axilla and upper limb C83.35 Diffuse large B-cell lymphoma, lymph nodes of inguinal region and lower limb C83.36 Diffuse large B-cell lymphoma, intrapelvic lymph nodes C83.37 Diffuse large B-cell lymphoma, spleen C83.38 Diffuse large B-cell lymphoma, lymph nodes of multiple sites C83.39 Diffuse large B-cell lymphoma, extranodal and solid organ sites Scenario 2 D89.831 Cytokine release syndrome, grade 1 D89.832 Cytokine release syndrome, grade 2 D89.833 Cytokine release syndrome, grade 3 D89.834 Cytokine release syndrome, grade 4 D89.835 Cytokine release syndrome, grade 5 D89.839 Cytokine release syndrome, grade unspecified
List of MS-DRGs	Scenario 1: 814 (Reticuloendothelial and Immunity Disorders with MCC) 815 (Reticuloendothelial and Immunity Disorders with CC) Scenario 2: 814 (Reticuloendothelial and Immunity Disorders with MCC), 815 (Reticuloendothelial and Immunity Disorders with CC) 816 (Reticuloendothelial and Immunity disorders without CC/MCC)
Inclusion/exclusion criteria	Scenario 1: The applicant selected claims with an ICD-10-CM principal diagnosis code of T80.89XA in combination with one of the remaining ICD-10-CM diagnosis codes listed for scenario 1. The applicant believes that cases reporting this combination of codes represent potential patients who are being treated for CRS arising from the administration of EPKINLY™ with a diagnosis code for DLBCL. The applicant included 100% of the cases identified. The applicant then trimmed cases that were mapped to low volume MS-DRGs (<11 cases). The applicant calculated the average unstandardized charge per case for each MS-DRG. Scenario 2: The applicant selected claims with an ICD-10-CM principal diagnosis code of T80.89XA in combination with one of the remaining ICD-10-CM diagnosis codes listed for scenario 2 for Cytokine Release Syndrome. The applicant included 100% of the cases identified. The applicant then trimmed cases that were mapped to low volume MS-DRGs (<11 cases). The applicant calculated the average unstandardized charge per case for each MS-DRG.
Charges removed for prior technology	Per the applicant, use of EPKINLY™ would not replace any current therapies. The applicant did not remove any direct or indirect charges from the identified cases.
Standardized charges	The applicant used the standardization formula provided in Technical Appendix A of the FY 2024 application. The applicant used all relevant values reported in the Standardizing File posted with the FY 2021 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 13.2% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule.
Charges added for the new technology	Per the applicant they have not yet established the price of EPKINLY™. The applicant stated that it will provide CMS with EPKINLY™ pricing information by June 30, 2023, subject to FDA approval. Therefore, the applicant stated charges for EPKINLY™ were not incorporated because the price has not yet been finalized. However, once the price is finalized, the applicant stated that this analysis will be updated to incorporate those charges.

With respect to the cost criterion, the COLUMVI™ applicant searched the FY 2021 MedPAR file for potential cases representing patients who may be eligible for COLUMVI™, defining two cohorts of patients who may be eligible for treatment and merging the cases for the cost criterion analysis.

For the first cohort, the applicant searched for cases representing potential patients who, as a result of developing CRS following outpatient administration of COLUMVI™, require an inpatient admission within the 3-day payment window following the outpatient

administration. Using the inclusion/exclusion criteria described in the following table, the applicant identified 101 claims mapping to 3 MS–DRGs.

For the second cohort, the applicant searched for cases representing a potential subset of patients who are admitted as inpatients for the purposes of being administered COLUMVI™ based on the clinical judgment of their provider. Using the inclusion/exclusion criteria described in the following table, the applicant identified 4,705 claims mapping to 9 MS–DRGs.

The applicant combined these two cohorts as there was no overlap between the MS–DRGs of the two cohorts (see the table that follows for a list of MS–DRGs for each cohort). The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $134,690 which exceeded the average case-weighted threshold amount of $96,417. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that COLUMVI™ meets the cost criterion.

COLUMVI™ COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of ICD-10-CM codes	Cohort 1 T80.89XA (Other complications following infusion, transfusion and therapeutic injection, initial encounter) as principal diagnosis and D89.31 (Cytokine Release Syndrome, grade 1), as secondary or additional diagnosis, or D89.32 (Cytokine Release Syndrome, Grade 2), as secondary or additional diagnosis, or D89.833 (Cytokine Release Syndrome, Grade 3), as secondary or additional diagnosis, or D89.834 (Cytokine Release Syndrome, Grade 4), as secondary or additional diagnosis, or D89.835 (Cytokine Release Syndrome, Grade 5), as secondary or additional diagnosis, or D89.839 (Cytokine Release Syndrome, Grade unspecified), as secondary or additional diagnosis. Cohort 2 C83.38 (Diffuse Large B-cell Lymphoma, Lymph Nodes of Multiple Sites) as principal diagnosis code
List of MS-DRGs	Cohort 1 814 (Reticuloendothelial and Immunity Disorders with MCC), 815 (Reticuloendothelial and Immunity Disorders with CC) 816 (Reticuloendothelial and Immunity Disorders without CC/MCC) Cohort 2 820 (Lymphoma and Leukemia with Major O.R. Procedures with MCC) 823 (Lymphoma and Non-Acute Leukemia with Other Procedures with MCC) 824 (Lymphoma and Non-Acute Leukemia with Other Procedures with CC) 840 (Lymphoma and Non-Acute Leukemia with MCC) 841 (Lymphoma and Non-Acute Leukemia with CC)
Inclusion/exclusion criteria	Cohort 1: The applicant searched for cases representing potential patients who, as a result of developing CRS following outpatient administration of COLUMVI™, require an inpatient admission within the three-day payment window following the outpatient administration. The applicant identified these cases by searching for claims reporting an ICD-10-CM principal diagnosis code of T80.89XA in combination with one of the remaining ICD-10-CM diagnosis codes listed previously in this table for Cohort 1. Cohort 2: The applicant searched for cases representing a potential subset of patients who are admitted as inpatients for the purposes of being administered COLUMVI™ based on the clinical judgment of their provider. The applicant identified these cases by searching for claims reporting an ICD-10-CM diagnosis code of C83.38 as listed previously in this table. The applicant combined the results of both cohorts. The applicant then trimmed cases that were mapped to low volume MS-DRGs (<11 cases). The applicant calculated the average unstandardized charge per case for each MS-DRG.
Charges removed for prior technology	Per the applicant, use of COLUMVI™ would not replace any other treatments. The applicant did not remove any direct or indirect charges from the identified cases.
Standardized charges	The applicant used the standardization formula provided in Technical Appendix A of the FY 2024 application. The applicant used all relevant values reported in the IPPS impact file posted with the FY 2023 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 13.2% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant stated that the average sales price of the technology has yet to be determined, and that when the price is available, a revised cost analysis will be provided that includes estimated hospital charges for the technology.

We invited public comment on whether EPKINLY™ or COLUMVI™ meet the cost criterion.

Comment: The applicant for EPKINLY™ submitted a comment referring to the two cost analyses submitted with the application; one scenario using DLBCL diagnosis codes for patients who are being treated for cytokine release syndrome arising from the outpatient administration of EPKINLY™ that would require inpatient admission within the 3-day payment window and the other scenario of cases reporting diagnosis codes for cytokine release syndrome. Given the availability of the wholesale acquisition cost (WAC) of EPINKLY, the applicant re-calculated the cost threshold analyses using the cost of $11,463.61 ($317.20/mg * 36.14 mg) for EPKINLY™ per patient to the hospital. The applicant reiterated that EPKINLY™ meets the cost criterion under both scenarios where the final inflated case weighted standardized charge per case of $176,329 exceeds the case weighted threshold of $59,550 by $116,779 in the first scenario and where the final inflated case weighted standardized charge per case of $150,780 exceeds the case weighted threshold of $56,682 by $94,103 in the second scenario.

The applicant for COLUMVI™ submitted a comment reiterating that COLUMVI™ meets the cost criterion because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in the cost criterion analysis submitted in its new technology add-on payment application.

Response: We thank the applicants for their comments. We agree that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount for both technologies. Therefore, both EPKINLY™ and COLUMVI™ meet the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that EPKINLY™ represents a substantial clinical improvement over existing technologies because it offers a treatment option with improved efficacy and safety for R/R LBCL patients unresponsive to currently available treatments (for example, CAR T-cell therapies such as KYMRIAH®, YESCARTA®, and Breyanzi®, and non-CAR T-cell therapies such as POLIVY®, ADCETRIS®, XPOVIO®, and ZYNLONTA®); and it significantly improves clinical outcomes among R/R LBCL patients as they progress through lines of therapy. The applicant provided two studies to support these claims, and nine background articles about other treatments available for R/R DLBCL patients and clinical outcomes for patients treated with other therapies such as Breyanzi®, ZYNLONTA®, YESCARTA®, XPOVIO®, KYMRIAH®, and POLIVY®.[37] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion.

[37] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Outcome(s) or findings cited by the applicant from supporting evidence to support its statements**
R/R LBCL patients have increasingly worse prognosis as they progress through lines of therapy	Susanibar-Adaniya, S., & Barta, S. K. (2021). 2021 Update on Diffuse large B cell lymphoma: A review of current data and potential applications on risk stratification and management. American journal of hematology, 96(5), 617–629. https://doi.org/10.1002/ajh.26151. Brief study description: Clinical review that described recent data and discussed ongoing efforts to improve DLBCL treatment in the frontline and relapsed refractory settings.	DLCBL is a highly heterogeneous disease with variable clinical presentation, therapies available, and outcomes. Although there are numerous therapy options available for R/R DLBCL patients, appropriate sequencing and prioritization of treatments both on and off clinical trials is required. Results and treatment options for R/R DLBCL disease are described (page 5-9): • Salvage chemotherapy and ASCT: Salvage chemotherapy with ASCT is the current SOC for transplant-eligible patients who have chemotherapy-sensitive disease - 3-year PFS of patients previously treated with rituximab: 21% • CAR T therapies: Currently, there are three FDA- approved autologous CAR T therapies for the treatment of R/R LBCL after ≥2 lines of systemic therapy – Breyanzi®, KYMRIAH®, and YESCARTA®. Real-world results show effective results in only 30-40% of patients receiving CAR T therapies. ~49% of patients receiving CAR T therapies experience relapse within the first month of treatment. - Breyanzi® (TRANSCED trial): ORR = 73%, CR = 53% - KYMRIAH® (JULIET trial): ORR = 52%, CR = 40% - YESCARTA® (ZUMA-1 trial): ORR = 83%, CR = 54% • Antibody-drug conjugates (ADC): Currently there are two FDA-approved ADCs for the treatment of R/R DLBCL after ≥2 lines of systemic therapy – POLIVY® and ZYNLONTA®. - POLIVY®: ORR = 45%, CR = 40%, mDoR = 12.6 months - ZYNLONTA®: ORR = 42.3%, mDoR = 4.5 months • Anti-CD19 antibody – Monjuvi® is a Fc-enhanced mAb with direct cytotoxic and enhanced antibody-dependent cell-mediated toxicity and phagocytosis approved for treatment of R/R DLBCL. - ORR = 60%, mDoR = 21.7 months
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Outcome(s) or findings cited by the applicant from supporting evidence to support its statements**
Epcoritamab has the potential to substantially improve both the efficacy and safety outcomes of 3L+ R/R LBCL patients compared to non-CAR T-cell therapies	Thieblemont, C., Phillips, T., Ghesquieres, H., Cheah, C.Y, Clausen, M.R., Cunningham, D., Do, Y.R, Feldman, T., Gasiorowski, R., Jurczak, W., et al. (2022, June). Subcutaneous Epcoritamab in Patients with Relapsed or Refractory Large B-Cell Lymphoma (EPCORE NHL-1): Pivotal Results from a Phase 2 Study. 2022 European Hematology Association Brief study description: Safety, anti-tumor activity, and dosing of epcoritamab was evaluated in a multi-center, open-label, phase 1/2 trial consisting of dose-escalation and dose-expansion in adult patients aged	The median number of prior therapies was 3 with 71% having more than three previous therapies. 39% had prior CAR T and 20% had prior ASCT. 83% were refractory to the last systemic therapy and 76% were refractory to two or more prior lines of therapy. Treatment responses of epcoritamab • Overall Response Rate (ORR) = 63% (95% CI) • Complete Response (CR) = 39 (95% CI) • Partial Response (PR) = 24% • Median Duration of Response (mDoR) (estimated) 12 months Treatment Emergent Adverse Events grade ≥3 (page 5) • Neutropenia (21%) • Anemia (10%) • Cytokine release syndrome (CRS; 2.5%) • Fatigue (2%) • Nausea (1%)

	18 or older with R/R CD20+ B-cell NHL, including patients with de novo or transformed DLBCL, HGBCL, PMBCL, FL, MCL, small lymphocytic lymphoma, and marginal zone lymphoma.	• Neurologic event (<1%) 7% of patients discontinued treatment due to AEs.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Epcoritamab has the potential to substantially improve the safety outcomes of 3L+ R/R LBCL patients compared to CAR T-cell therapies	Thieblemont, C., Phillips, T., Ghesquieres, H., et al. (2022, June). Subcutaneous Epcoritamab in Patients with Relapsed or Refractory Large B-Cell Lymphoma (EPCORE NHL-1): Pivotal Results from a Phase 2 Study. 2022 European Hematology Association See prior study description	The median number of prior therapies was 3 with 71% having more than three previous therapies. 39% had prior CAR T, of which 75% progressed within 6-months of CAR T therapy. 20% had prior ASCT. 83% were refractory to the last systemic therapy and 76% were refractory to two or more prior lines of therapy. Treatment responses of epcoritamab (page 7&10) Adverse Events grade ≥3 • Neutropenia (21%) • Anemia (10%) • Cytokine release syndrome (CRS; 2.5%) • Fatigue (2%) • Nausea (1%) • Neurologic Event (<1%) Only 7% of patients discontinued treatment due to AEs.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26816), after review of the information provided by the applicant, we had the following concerns regarding whether EPKINLY™ meets the substantial clinical improvement criterion. With respect to whether the technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, the applicant described EPKINLY™ as having stronger efficacy data in comparison to other 3L+ treatment options available. We noted that the applicant provided many background studies regarding R/R DLBCL treatment options. However, they were unable to provide the complete study of EPKINLY™ (EPCORE NHL–1) in support of its claim of EPKINLY™'s stronger efficacy data in comparison to other 3L+ treatment options, providing only the presentation of partial results used for the European Hematology Association meeting of 2022. Therefore, we stated we were limited in our ability to fully evaluate and assess the supporting evidence for this claim. Furthermore, we noted that there may be other available treatments for this specific population, including CAR T-cell therapies. We also noted that it is unclear which patient population is ineligible for these available treatment options. With respect to whether the technology improves clinical outcomes relative to services or technologies previously available, the applicant described EPKINLY™ as having better safety profiles and efficacy than existing treatments. However, the comparisons are not matched cases within a comparative study, and we questioned whether there are differences between the trials, such as differences in the patient populations included and the way outcomes are defined, that should be considered in assessing the comparison of clinical outcomes across these studies. We were interested in additional information to demonstrate that EPKINLY™ has significantly better efficacy and safety profiles than other available treatments.

With regard to the substantial clinical improvement criterion, the applicant asserted that COLUMVI™ represents a substantial clinical improvement over existing technologies because it offers a treatment option for R/R DLBCL patients who have progressed after three or more lines of therapy that engages T-cells in its mechanism of action with off-the-shelf access and a fixed-treatment duration; and it significantly improves clinical outcomes among R/R DLBCL patients with three or more lines of therapy as compared to placebo. The applicant provided two studies to support these claims, as well as 41 background articles about current therapies for R/R DLBCL patients including access and clinical outcomes for this patient population.[38] The following table summarizes the applicant's assertions regarding the substantial clinical improvement. Please see the online posting for COLUMVI™ for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

[38] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Outcome(s) or findings cited by the applicant from supporting evidence to support its statements**
COLUMVI™ expands treatment options for R/R DLBCL patients who have progressed after other 2L or 3L+ therapies	Dickinson M, et al. N Engl J Med 2022; 387:2220-2231. Brief study description: a phase I/II, multicenter, open-label, dose escalation and dose expansion study of COLUMVI™.	ORR n (%): 80 (51.6%); CR rate, n (%): 61 (39.4). Median PFS, months (95% CI): 4.9 (3.4, 8.1), Median OS, months (95% CI): 11.5 (7.9, 15.7).
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
COLUMVI™ reduced mortality of patients who had progressed after ASCT or CAR T-cell therapy — a population for whom there are few successful treatment options	Dickinson M, et al. N Engl J Med 2022; 387:2220-2231. See prior study description	The median overall survival months: (95% CI): 11.5 (7.9, 15.7)
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
COLUMVI™ is an off-the-shelf therapy without any delay due to personalized manufacturing	Hutchings M, et al. J Clin Oncol. 2021; 39(18):1959-1970) Brief study description: Phase I, multicenter, open-label, dose escalation, and dose-expansion study to evaluate safety and efficacy of COLUMVI™ in R/R B-cell NHL with obinutuzumab pretreatment (Gpt).	7 days before the first dose of COLUMVI™, all patients received 1,000 mg Gpt, to deplete peripheral and tissue-based B-cells and mitigate serious CRS. Obinutuzumab was chosen as pretreatment because of its deeper clearance of peripheral and tissue-based B-cells compared with rituximab. COLUMVI™ was given as an initial 4 hour IV infusion, reduced to 2 hours once a prior infusion had occurred without complications. COLUMVI™ was given in 14- or 21-day cycles. Details of premedication, infusion time, and scheduling are provided in the supplementary material. A Bayesian-modified continuous reassessment method with overdose control based on emerging toxicity data guided the dose escalation.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
COLUMVI™ is a therapy that can be made available across various geographies for patients with DLBCL	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.	
COLUMVI™ is expected to be an efficacious option for patients who are ineligible for ASCT or CAR T-cell therapies,	Dickinson M, et al. N Engl J Med 2022; 387:2220-2231. See prior study description	Median OS, months (95% CI): 11.5 (7.9, 15.7)

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Outcome(s) or findings cited by the applicant from supporting evidence to support its statements**
expanding access to treatment for these patients	Hutchings M, et al. J Clin Oncol. 2021; 39(18):1959-1970). See prior study description	Key inclusion criteria were patients age ≥18 years with histologically confirmed B-NHL expected to express CD20; ≥1 prior lymphoma treatment, with no available life-extending treatment options; and who had >1 measurable target lesion >1.5 cm. Key exclusion criteria were a history of CNS lymphoma or other CNS pathology, anticancer therapy within 4 weeks or five half-lives of the drug or ASCT within 100 days before Gpt, or prior allogeneic stem-cell transplantation. Phase I study enrolling patients to be treated with COLUMVI™ based on age ≥18 years, histologically confirmed disease, and expression of CD20. No exclusions for chemosensitivity, T-cell number, or disease progression.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available		
Applicant statements in support	**Supporting evidence that the applicant provided**	**Outcome(s) or findings cited by the applicant from supporting evidence to support its statements**
COLUMVI™ demonstrated efficacy, durable remissions, and a manageable safety profile with a fixed treatment duration	Dickinson M, et al. N Engl J Med 2022; 387:2220-2231. See prior study description	Baseline characteristics: Median no of prior lines, n (range): 3 (2-7) -≥3 prior lines 92 (59.7%). ORR n (%): 80 (51.6%) -CR rate, n (%): 61 (39.4). Median duration of response (DoR): 18.4 mo (95% CI: 13.7, NE). Adverse events (AE) leading to treatment discontinuation, n (%): 14 (9.1)
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
COLUMVI™ has a manageable safety profile and had a low rate of treatment discontinuation in heavily pretreated and refractory patient populations.	Dickinson M, et al. N Engl J Med 2022; 387:2220-2231. See prior study description	Median no of prior lines, n (range): -2 prior lines 62 (40.3) -≥3 prior lines 92 (59.7) -Refractory to any prior lines 139 (90.3). Complete response rates by IRC in pre-specified group, Table: Prior CAR-T therapy CR (95% CI): -Yes 35% (22%, 49%) -No 42% (32%, 52%). Other adverse events of interest, AE leading to treatment discontinuation, n (%): 14 (9.1). Infections (all grade), n (%): 59 (38.3)
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
COLUMVI™ has a durable response and low rates of peripheral neuropathy	Dickinson M, et al. N Engl J Med 2022; 387:2220-2231. See prior study description	Median DoR: 18.4 months (95% CI: 13.7, NE). AE leading to treatment discontinuation, n (%): 14 (9.1) -Peripheral neuropathy was not noted in any of the tables
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
COLUMVI™ demonstrated efficacy with a manageable safety profile in heavily pretreated and refractory populations	Dickinson M, et al. N Engl J Med 2022; 387:2220-2231. See prior study description	Median no of prior lines, n (range): 3 (2-7) -≥3 prior lines 92 (59.7). ORR n (%): 80 (51.6%) CR rate, n (%): 61 (39.4). Median DoR: 18.4 month (95% CI: 13.7, NE). Median OS, months (95% CI): 11.5 (7.9, 15.7). AE leading to treatment discontinuation, n (%): 14 (9.1)

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Outcome(s) or findings cited by the applicant from supporting evidence to support its statements**
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
COLUMVI™ is associated with a manageable safety profile.	Dickinson M, et al. N Engl J Med 2022; 387:2220-2231. See prior study description	CRS (any grade), n (%): 97 (63.0); CRS (Grade 3): 4 (2.6); CRS (Grade 4): 2 (1.3). Neurologic AEs (all grade), n (%): 59 (38.3), Grade ≥3: 5 (3.2); ICANS (all grade), n (%): 12 (7.8); Grade ≥3: 4 (2.6); Infections (all grade), n (%): 59 (38.3); Grade ≥3: 23 (14.9).
COLUMVI™ is a fixed-treatment duration therapy, providing patients with time off treatment and the potential to improve patient quality of life	Dickinson M, et al. N Engl J Med 2022; 387:2220-2231. See prior study description	Median 5 cycles (range, 1-13)

BILLING CODE 4120–01–C

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26823), after review of the information provided by the applicant, we stated we had the following concerns regarding whether COLUMVI™ meets the substantial clinical improvement criterion. To support its assertion that COLUMVI™ offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, the applicant asserted that COLUMVI™ expands treatment options for R/R DLBCL patients who have progressed after other 2L or 3L+ therapies. However, we noted that there are other technologies and treatments approved for this specific population, as mentioned earlier, such that it is not clear that this would represent a patient population unresponsive to, or ineligible for, currently available treatments. With respect to the applicant's claim that COLUMVI™ reduces mortality of patients who had progressed after ASCT or CAR T-cell therapy, we noted that the applicant provided several background studies [39] [40] [41] [42] regarding other existing treatments for R/R DLBCL as well as the main COLUMVI™ study, however, as this conclusion was based on the comparison of results across these independent studies, we stated we would be interested in additional information regarding the comparability of these findings regarding mortality reduction for each respective technology. With respect to the applicant's claims that COLUMVI™ is an off-the-shelf therapy without any delay due to personalized manufacturing, such as CAR T-cell therapy, and that COLUMVI™ can be made available across various geographies for patients with DLBCL, we questioned whether other available therapies, such as POLIVY®, XPOVIO®, and ZYNLONTA®, that may be used to treat patients with multiple relapses or who are refractory to other therapies, also would not have those limitations.

With respect to the applicant's claims that COLUMVI™ improves outcomes as compared to existing treatments, including safety and rate of treatment discontinuations, we noted that only one single arm trial with no comparators was provided in support of this claim. We further noted that the comparisons of the supporting evidence [43] [44] provided for other existing technologies to the main COLUMVI™ study are not matched cases; for example, the studies do not adjust for type and severity of AEs. Therefore, we questioned whether these comparisons can be used to demonstrate a significant difference in safety or efficacy.

With respect to the applicant's claim that COLUMVI™ is a fixed-treatment duration therapy, providing patients with time off treatment and the potential to improve patient quality of life, we noted that this appears to be an inference, as the applicant did not provide any evidence that a fixed-treatment improves quality of life. According to the applicant, during the first cycle (each cycle is 21 days), the patient is required to receive the drug infusion once a week. After cycle 1, the frequency of infusion is reduced to once a month. While COLUMVI™ provides a fixed-treatment, it requires weekly up to monthly infusions in comparison to CAR–T cell therapy, which is a one-time treatment. We were interested in additional information regarding the association between treatment type and duration and quality of life, particularly how COLUMVI™'s treatment type and duration results in higher quality of life as compared to the treatment type and duration of existing technologies.

We invited public comments on whether EPKINLY™ or COLUMVI™ meet the substantial clinical improvement criterion.

Comment: The applicant for EPKINLY™ submitted a comment regarding the substantial improvement criterion and provided responses to concerns raised by CMS in the proposed rule. In response to CMS's request for additional support of the claim that EPKINLY™ has stronger efficacy in comparison to other 3L+ treatment options available, the applicant for EPKINLY™ stated EPKINLY™ was shown to have significantly better clinical outcomes compared to chemoimmunotherapy in two indirect treatment comparisons. The applicant stated that R/R DLBCL patients face significant disease burden and poor clinical outcomes. The applicant further stated that for patients who have failed two or more prior lines of therapy (LOT), there is no standard of care; although chemoimmunotherapy (CIT) regimens are commonly used, they do not provide optimal outcomes. The applicant also stated that while direct

[39] Gisselbrecht C, et al. J Clin Oncol 2010; 28(27):4184–90.

[40] Schuster SJ, et al. Lancet Oncol 2021;21:1403–15.

[41] Abramson JS, et al. The Lancet. 2020;396(10254):839–52.

[42] Locke FL, et al. Lancet Oncol 2019;20:31–42.

[43] Salles G, et al. Lancet Oncol 2020;21(7):978–88.

[44] MONJUVI® (tafasitamab) [prescribing information]. Boston, MA: Morphosys US Inc.; June 2021.

treatment comparisons have not yet been made, real world indirect comparisons have shown that compared to chemoimmunotherapy, EPKINLY™ offers a substantially higher chance of response and significantly lower risks of progression and mortality.[45] [46] The applicant also stated that EPKINLY™ demonstrated clinically meaningful outcomes compared to polatuzumab vedotin and tafasitamab plus lenalidomide in a matched cohort comparative analysis. Furthermore, the applicant stated that two indirect treatment comparison studies have been conducted comparing EPKINLY™ and CAR T-cell therapy in patients with R/R LBCL, and that in both studies, EPKINLY™ was shown to have no statistically significant difference in efficacy compared to CAR T-cell therapy. The applicant stated that EPKINLY™ is an off-the-shelf therapy that may be effective for patients who cannot easily access CAR T-cell therapy, who are ineligible for CAR T-cell therapy, or who have progressed from CAR T-cell therapy. The applicant indicated that access to CAR T-cell therapy is limited due to its availability only at approximately 200 centers in specialized medical centers to which older adults may be unable to travel to. In addition, the applicant indicated that an estimated 35 percent to 50 percent of patients would not be eligible for second line CAR T-cell therapy and that this number likely increases in third and subsequent lines of therapy.[47] The applicant stated that in a real-world analysis of patients who received CAR T-cell therapy, ~60 percent of patients never respond to treatment with a median failure at only 49 days. For these patients, who relapse or who are refractory to CAR T-cell therapy, a standard of care has not been established.[48] The applicant concluded that EPKINLY™ would be effective for those patients who are either ineligible or have progressed from CAR T-cell therapy, and that because EPKINLY is an off-the-shelf therapy, it is not constrained by the same individualized manufacturing timelines and associated challenges that can delay patient starts on CAR T-cell therapy.

Another commenter submitted a comment in support of the approval of the new technology add-on payment application for EPKINLY™, citing its efficacy in the third line setting in patients with R/R LBCL with an overall response rate of 63.1 percent and a complete response rate of 39 percent based on Lugano criteria and a manageable safety profile.[49] Furthermore, the commenter stated that despite recent approval and expanded utilization of CAR T-cell therapy, there remains no clear standard of care for treatment of many patients with R/R LBCL due to issues surrounding access. The commenter stated that CAR T-cell therapy is offered at only ~210 centers in the U.S, often concentrated in major metropolitan areas, creating significant barriers for patients living in remote or rural areas.[50] The commenter further stated that even when CAR T-cell therapy is accessible, CAR T-cell therapy poses several challenges for patients, starting with the potentially lengthy manufacturing process that includes pre-treatment procedures like leukapheresis, to collect T-cells, and then genetically modifying T-cells to express CARs, which can take up to several weeks.[51] Lastly, the commenter stated that approximately 40 percent of DLBCL patients were ineligible for CAR T-cell therapy due to factors such as organ dysfunction, active infections or prior stem cell transplantation, while around 18–20 percent of those that were eligible underwent leukapheresis but did not receive CAR T-cells due to disease progression, adverse events, or clinical deterioration.[52] [53] The commenter concluded that, in summary, the significant challenges associated with CAR T-cell therapy including limited access, lengthy manufacturing processes, eligibility restrictions, and risk of treatment failure, underscore the need for effective treatments with comparable clinical benefits and broader patient reach.

The applicant for COLUMVI™ submitted comments in response to CMS's concerns in the FY 2024 IPPS/LTCH PPS proposed rule regarding whether COLUMVI™ meets the substantial clinical improvement criterion. The applicant reiterated its support for COLUMVI™ stating that COLUMVI™ significantly improves clinical outcomes of patients with R/R DLBCL after at least two prior systemic therapies.

With respect to CMS's concern that the existence of other technologies and treatments approved for the R/R DLBCL patients with two or more lines of therapy made it unclear that this would represent a patient population unresponsive to or ineligible for currently available treatments, the applicant stated that COLUMVI™ expands treatment options for three key subsets of patients in the R/R/DLBCL setting receiving and inadequately treated by existing therapies, including: patients who are ineligible for or who cannot access ASCT or CAR T-cell therapy, patients who have progressed after ASCT or CAR T-cell therapy, and patients who have progressed after two or more other lines of approved therapies. The applicant stated that COLUMVI™ is a treatment option for patients who are ineligible for or cannot access ASCT or CAR T-cell therapy, indicating that about half of patients with R/R DLBCL with three or more lines of therapies are ineligible for ASCT or CAR T-cell therapies because of treatment-related toxicities. The applicant stated that this patient population is further vulnerable to accessing ASCT or CAR T-cell therapy as there are limited treatment sites and manufacturing delays. The applicant cited a retrospective study which showed that in patients with R/R DLBCL receiving three or more lines of treatment (3L) post CAR T-cell therapy approval, less than 20 percent of patients received CAR T-cell therapy in 3L between October 2017 and March 2020.[54] The applicant further stated COLUMVI™ is a new option for patients who have progressed after ASCT or CAR T-cell therapy, stating that about two-thirds of patients with R/R DLBCL relapse after ASCT, and about half of patients receiving CAR T-cell therapies experience disease

[45] Ip, A., et al. Comparison of Real-World Clinical Outcomes in Patients With Relapsed/Refractory Large B-cell Lymphoma Treated With Epcoritamab vs Chemoimmunotherapy. The European Hematology Association Abstract Library. 2023.

[46] Ip, A., et al. Comparison of Real-World Clinical Outcomes in Patients With Relapsed/Refractory Large B-cell Lymphoma Treated With Epcoritamab vs Chemoimmunotherapy. The European Hematology Association Abstract Library. 2023.

[47] Puckrin R., et al. Real-World Eligibility for Second-Line Chimeric Antigen Receptor T Cell Therapy in Large B Cell Lymphoma: A Population-Based Analysis. Transplant Cell Ther. 2022 Apr;28(4):218.e1–218.

[48] Dodero, A., et al. Patients Outcome after Chimeric Antigen Receptor (CAR) T-Cells Failure in Aggressive B-Cell Lymphomas: Role of Immunotherapy and Prognostic Factors. Blood 2022; 140 (Supplement 1): 9468–9469.

[49] Thieblemont C., et al. Epcoritamab, a Novel, Subcutaneous CD3xCD20 Bispecific T-Cell-Engaging Antibody, in Relapsed or Refractory Large B-Cell Lymphoma: Dose Expansion in a Phase I/II Trial. J Clin Oncol. 2023 Apr 20;41(12):2238–2247.

[50] Snyder S., et al. Access to Chimeric Antigen Receptor T Cell Therapy for Diffuse Large B Cell Lymphoma. Adv Ther. 2021 Sep;38(9):4659–4674.

[51] Bishop M., et al. Second-Line Tisagenlecleucel or Standard Care in Aggressive B-Cell Lymphoma. N Engl J Med. 2022; 386: 629–39.

[52] Schuster S., et al. Tisagenlecleucel in Adult Relapsed or Refractory Diffuse Large B-Cell Lymphoma. N Engl J Med. 2019;380(1):45–5.

[53] Jacobson C., et al. Axicabtagene Ciloleucel in the Non-Trial Setting: Outcomes and Correlates of Response, Resistance, and Toxicity. J Clin Oncol. 2020;38(27):3095–3106.

[54] Xie, J., et al. 2021. ''Characteristics and Treatment Patterns of Relapsed/Refractory Diffuse Large B-Cell Lymphoma in Patients Receiving ≥3 Therapy Lines in Post-CAR–T Era.'' *Curr Med Res Opin* 37, no. 10 (Oct): 1789–1798.

progression.[55] [56] The applicant stated that many patients in the 3L+ setting have low response rates to available therapies, and that tolerability of approved treatments can be poor with a range of potential adverse events (AEs) associated with these therapies. The applicant stated that tolerability of COLUMVI™ was demonstrated by low rates of treatment discontinuation and an overall favorable safety profile with AEs that are more tolerable than those associated with other treatment options in the 3L+ setting.

With respect to CMS's concern that the applicant provided several background studies regarding other existing treatments for R/R DLBCL as well as the main COLUMVI™ study to support the applicant's claim that COLUMVI™ reduces mortality of patients who had progressed after ASCT or CAR T-cell therapy, the applicant for COLUMVI™ stated that while ASCT can produce long-term remissions in about one-third of patients who undergo the procedure, the remaining patients who experience disease progression have poor outcomes. The applicant stated that effective treatments for patients who progress after ASCT is an unmet need in R/R DLBCL and cited the CORAL [57] study where patients who relapsed after ASCT had a median overall survival (OS) of 10 months and an estimated 1-year OS of 39 percent whereas for patients who relapse within 6 months the median OS was 5.7 months. The applicant further stated that about half of patients receiving CAR T-cell therapy experience disease progression with 48 percent of patients who receive CAR T-cell therapy in 3L began a 4L treatment within 4 months. The applicant stated there is limited data on how patients progress after CAR T-cell therapy progression and patient response to salvage treatment given the recent introduction of commercial CAR T-cell therapy. The applicant indicated the outcomes from limited data are poor and cited a recent analysis of 298 patients who received CAR T-cells in the United Kingdom, 54 percent experienced disease with a median of 2.4 months to progression and had a median OS of 4.4 months.[58] The applicant further stated that patients who went on to additional therapies had a median OS of 8.8 months with only 22 percent achieving a CR whereas patients who did not receive further treatment had a median OS of 1.7 months.[59] The applicant stated that among currently approved 3L+ options, there is either no data or a lack of efficacy for patients after CAR T-cell therapy, indicating that in a trial of one therapy, enrolled patients with prior ASCT and CAR T-cell therapy 29 percent and 15 percent respectively achieved CRs.[60] The applicant indicated that COLUMVI™ study patients with prior ASCT and CAR T-cell therapy achieved CRs at rates of 67 percent and 35 percent respectively indicating that this is a substantial clinical improvement for a patient population with an unmet need.

With respect to CMS's concerns as to whether other available therapies, such as POLIVY®, XPOVIO®, and ZYNLONTA®, may be used to treat patients with multiple relapses and do not require personalized manufacturing such as CAR T-cell therapy, the applicant for COLUMVI™ stated that although these therapies are available off the shelf, COLUMVI™ is an off-the-shelf therapy that provides a substantial clinical improvement via efficacy, durability, and low toxicity in a heavily pretreated, highly refractory patient population.

With respect to CMS's concerns as to whether COLUMVI™ improves outcomes as compared to existing treatments, including safety and rate of treatment discontinuations, the applicant for COLUMVI™ stated that head-to-head data of therapies in 3L+ are not available and that while direct comparisons across different trials are subject to confounding and bias because of systematic differences, consideration of outcomes in clinical trials for currently approved therapies indicate the outcomes are in line with historical rates of response in the 3L+ setting where typically less than half of patients respond to conventional 3L therapies and the median OS of patients in the 3L setting is 4–10 months.[61] [62] [63] The applicant further stated that single-arm studies are an important mechanism to facilitate faster access to novel therapies, particularly for patients who have exhausted other approved options.

With respect to our request for additional information regarding the association between treatment type and the applicant for COLUMVI™'s claim that COLUMVI™ is a fixed-treatment duration therapy that provides patients with time off treatment and the potential to improve patient quality of life, the applicant responded that while there is no data available on this subject in 3L+ DLBCLs yet, fixed-duration versus continuous therapy have been studied in other therapeutic areas and a range of benefits have been associated with fixed-duration therapies. The applicant indicated that the time off treatment may be associated with improvement in quality of life based on a nonrandomized study of patients with chronic myeloid leukemia whose patient-reported outcomes included improvement in treatment-related adverse effects when discontinuing a tyrosine kinase inhibitor treatment.[64] The applicant indicated that patients prefer fixed-duration therapies to continuous therapies citing surveys of patients with chronic lymphocytic leukemia and Waldenstrom's macroglobulinemia identified fixed duration therapy as a positive attribute when compared to continuous therapy.[65] [66] The applicant for COLUMVI™ further stated that fixed-duration therapy can reduce costs as compared to continuous treatment options.

Response: We thank the commenters for their comments regarding the

[55] Dickinson, M. J., et al. 2022. ''Glofitamab for Relapsed or Refractory Diffuse Large B-Cell Lymphoma.'' *N Engl J Med* 387, no. 24 (Dec 15): 2220–2231.

[56] Sehn, L. H., et al. 2021. ''Diffuse Large B-Cell Lymphoma.'' *N Engl J Med* 384, no. 9 (Mar 4): 842–858.

[57] Van Den Neste, E., et al. 2016. ''Outcome of Patients with Relapsed Diffuse Large B-Cell Lymphoma Who Fail Second-Line Salvage Regimens in the International CORAL Study.'' Bone Marrow Transplant 51, no. 1 (Jan): 51–7.

[58] Xie, J., et al. 2021. ''Characteristics and Treatment Patterns of Relapsed/Refractory Diffuse Large B-Cell Lymphoma in Patients Receiving >/=3 Therapy Lines in Post-CAR–T Era.'' *Curr Med Res Opin* 37, no. 10 (Oct): 1789–1798.

[59] Kuhnl, A., et al. 2021. ''Outcome of Large B-Cell Lymphoma Patients Failing CD19 Targeted CAR T Therapy.'' *ICML* Oral 087.

[60] Caimi, P. F., et al. 2021. ''Loncastuximab Tesirine in Relapsed or Refractory Diffuse Large B-Cell Lymphoma (LOTIS–2): A Multicentre, Open-Label, Single-Arm, Phase 2 Trial.'' *The Lancet Oncol* 22, no. 6: 790–800.

[61] Gisselbrecht, C., et al. 2010. ''Salvage Regimens with Autologous Transplantation for Relapsed Large B-Cell Lymphoma in the Rituximab Era.'' *J Clin Oncol* 28, no. 27 (Sep 20): 4184–90.

[62] Van Den Neste, E., et al. 2017. ''Outcomes of Diffuse Large B-Cell Lymphoma Patients Relapsing after Autologous Stem Cell Transplantation: An Analysis of Patients Included in the CORAL Study.'' *Bone Marrow Transplant* 52, no. 2 (Feb): 216–221.

[63] Crump, M., et al. 2017. ''Outcomes in Refractory Diffuse Large B=Cell Lymphoma: Results from the International SCHOLAR–1 Study.'' *Blood* 130: 1800–1809.

[64] Atallah, E., et al. 2021. ''Assessment of Outcomes after Stopping Tyrosine Kinase Inhibitors among Patients with Chronic Myeloid Leukemia: A Nonrandomized Clinical Trial.'' *JAMA Oncol* 7, no. 1 (Jan 1): 42–50.

[65] Ravelo, A, et al. 2022. ''Understanding Patient Preferences for Chronic Lymphocytic Leukemia Treatments.'' *Blood* 140, no. Supplement 1: 10803–10805.

[66] Amaador, K., et al. 2023. ''Patient Preferences Regarding Treatment Options for Waldenstrom's Macroglobulinemia: A Discrete Choice Experiment.'' *Cancer Med* 12, no. 3 (Feb): 3376–3386.

substantial clinical improvement criterion. Based on the additional information received, we agree that EPKINLY™ and COLUMVI™ represent a substantial clinical improvement over existing technologies because these technologies offer treatment options for patients with R/R DLBCL after two or more prior therapies who are unresponsive to, or ineligible for, currently available treatments, who are ineligible due to factors such as organ dysfunction, active infection, or prior stem cell transplantation, or for whom CAR T-cell therapy is not an available treatment option.

After consideration of the public comments we received, and the information included in both the applicants' new technology add-on payment applications, we have determined that EPKINLY™ and COLUMVI™ meet all of the criteria for approval of new technology add-on payments. Therefore, we are approving new technology add-on payments for EPKINLY™ and COLUMVI™ for FY 2024. As previously stated, cases involving EPKINLY™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code XW013S9 (Introduction of epcoritamab monoclonal antibody into subcutaneous tissue, percutaneous approach, new technology group 9). Cases involving COLUMVI™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code XW033P9 (Introduction of glofitamab antineoplastic into peripheral vein, percutaneous approach, new technology group 9) or XW043P9 (Introduction of glofitamab antineoplastic into central vein, percutaneous approach, new technology group 9).

Each of the applicants submitted cost information for its application. The manufacturer of EPKINLY™ stated that the cost of its technology is $11,463.61 per patient. The applicant projected that 117 cases will involve the use of EPKINLY™ in FY 2024. The manufacturer of COLUMVI™ stated that the cost of its technology is $5,748.53. The applicant projected that 40 cases will involve the use of COLUMVI™ in FY 2024. Because the technologies are substantially similar to each other, we believe using a single cost for purposes of determining the new technology add-on payment amount is appropriate for EPKINLY™ and COLUMVI™ even though each applicant has its own set of codes. We also believe using a single cost provides predictability regarding the add on payment when using EPKINLY™ or COLUMVI™ for the treatment of patients with R/R DLBCL. As such, consistent with prior rulemaking (85 FR 58684), we believe that the use of a weighted average of the cost of EPKINLY™ and COLUMVI™ based on the projected number of cases involving each technology to determine the maximum new technology add-on payment would be most appropriate. To compute the weighted cost average, we summed the total number of projected cases for each of the applicants, which equaled 157 cases (117 plus 40). We then divided the number of projected cases for each of the applicants by the total number of cases, which resulted in the following case-weighted percentages: 74.5 percent for EPKINLY™ and 25.5 percent for COLUMVI™. We then multiplied the cost per case for the manufacturer specific drug by the case-weighted percentage (0.745 * $11,463.61 = $8,540.39 for EPKINLY™ and 0.255 * $5,748.53 = $1,465.87 for COLUMVI™). This resulted in a case-weighted average cost of $10,006.26 for the technology. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of EPKINLY™ or COLUMVI™ is $6,504.07 for FY 2024.

d. Lunsumio™ (Mosunetuzumab)

Genentech, Inc. submitted an application for new technology add-on payments for Lunsumio™ for FY 2024. Per the applicant, Lunsumio™ is a novel, full-length, humanized, immunoglobulin G1 (IgG1) bispecific antibody that is designed to concomitantly bind CD3 on T cells and CD20 on B cells, in the treatment of adults with relapsed/refractory (R/R) follicular lymphoma (FL) who have received at least 2 (≥2) prior systemic therapies (also referred to herein as 3L+FL). The applicant further stated that target B cell killing occurs only upon simultaneous binding to both targets, as it is a conditional agonist. We note that Genentech, Inc submitted an application for new technology add-on payments for Lunsumio™ for FY 2023 under the name mosunetuzumab, as summarized in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28261 through 28274), that it withdrew prior to the issuance of the FY 2023 IPPS/LTCH PPS final rule (87 FR 48920).

Please refer to the online application posting for Lunsumio™, available at *https://mearis.cms.gov/public/publications/ntap/NTP221017LJLDM*, for additional detail describing the drug and the disease treated by the technology.

With respect to the newness criterion, Lunsumio™ was granted accelerated approval of its BLA from FDA on December 22, 2022, for the treatment of adult patients with relapsed or refractory follicular lymphoma after two or more lines of systemic therapy. According to the applicant, Lunsumio™ was not commercially available immediately after FDA approval. The applicant stated that Lunsumio™ was made available for sale after the new year with the first order occurring on January 6, 2023, due to a companywide holiday shutdown and to provide manufacturing time. We noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26824), for the purposes of new technology add-on payments, we do not consider the date of first sale as an indicator of the entry of a product onto the U.S. market. According to the applicant, Lunsumio™ is sold in a 1 mg and 30 mg single dose vial and is administered for eight cycles according to the dosage schedule in the following table unless patients experience unacceptable toxicity or disease progression. Per the applicant, most of the inpatient usage of Lunsumio™ will occur as the result of adverse events, mainly CRS, that develop after outpatient administration of the drug. The applicant stated that clinical protocols require that inpatient hospitalization occur for most Grade 2 CRS patients, and for all patients with Grade 3 or 4 CRS. In clinical trials, when Grade 2, 3, or 4 CRS developed, 75 percent of the time it occurred after a 60 mg dose, 20 percent of the time it developed after a 1 mg dose, and 5 percent after a 2 mg dose. Based on this information, it seems that the weighted average inpatient dose would be 45.3 mg.

BILLING CODE 4120–01–P

Day of Treatment		Dosage	Rate of Infusion
Cycle 1	Day 1	1 mg	Administer over a minimum of 4 hours
	Day 8	2 mg	
	Day 15	60 mg	
Cycle 3	Day 1	60 mg	Administer over 2 hours if infusion from cycle 1 were well-tolerated
Cycle 3 +	Day 1	30 mg	

According to the applicant, effective October 1, 2022, the following ICD–10–PCS procedure codes may be used to distinctly identify administration of Lunsumio™: XW03358 (Introduction of mosunetuzumab antineoplastic into peripheral vein, percutaneous approach, new technology group 8) or XW04358 (Introduction of mosunetuzumab antineoplastic into central vein, percutaneous approach, new technology group 8). The applicant stated that diagnosis code C82 (Follicular lymphoma) may be used to currently identify the indication for Lunsumio™ under the ICD–10–CM coding system.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that Lunsumio™ is not substantially similar to other currently available technologies because it does not use the same or a similar mechanism of action compared to any existing technology approved for treatment of 3L+ FL and because the use of Lunsumio™ in 3L+ FL does not involve the treatment of the same or a similar type of disease or the same or similar patient population when compared to an existing technology. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for Lunsumio™ for the applicant's complete statements in support of its assertion that Lunsumio™ is not substantially similar to other currently available technologies.

Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	Lunsumio™ does not use the same or a similar mechanism of action compared to any existing technology approved for treatment of 3L+ R/R FL. As the first and only CD20xCD3 bispecific monoclonal antibody for the treatment of 3L+ FL, Lunsumio™ has a mechanism of action that is unique and different from that of existing technologies in this indication. Lunsumio™ binds CD20 on the surface of B cells and CD3 on T cells, allowing T cells to attack cancerous B cells. CD20 has been previously validated as a therapeutic target for the treatment of B-cell cancers such as FL, but Lunsumio™ is the only treatment for 3L+ FL that concomitantly targets both CD20 and CD3 at the same time. None of the available treatments for 3L+ FL uses the same mechanism of action; none are CD20xCD3 bispecific antibodies.
Is the technology assigned to the same MS-DRG as existing technologies?	Yes	Lunsumio™ might be assigned to the same MS-DRG as existing technologies.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	Genentech Inc is seeking approval for Lunsumio™ as a 3L+ therapy for a heavily pretreated and highly refractory patient population. There is no standard of care for 3L+FL patients who have received two or more prior therapies. The heterogeneity of FL and transformation of disease over time are challenges for later lines of treatment. Additionally, there is continued unmet need, even with currently available 3L+ therapies due to high-risk features such as refractoriness to prior therapy, double refractoriness to prior alkylator and anti-CD20 monoclonal antibody therapy, POD24, FLIPI score of 3-5, or older age. The prognosis for patients with R/R FL who have received two or more prior therapies is poor and OS diminishes with each subsequent line of therapy. Lunsumio™'s clinical trial program is inclusive of patients reflecting a real-world FL patient population seeking 3L+ therapy. The patient population in the pivotal GO29781 study demonstrated the efficacy of Lunsumio™ in heavily pretreated, highly refractory, and older (>65) patients. These patients have characteristics that reflect those in the real world requiring 3L+ FL treatment. The median age of patients enrolled in the study was 60 (range 53-67); 33.3% were aged ≥65 years. Most patients (71%) had FLIPI scores of ≥2, and 52% were POD24. All patients had prior alkylator therapy (100%) and anti-CD20 therapy (100%); 98% had anti-CD20 plus alkylator or anthracycline; 82% had anthracyclines; 19% had phosphoinositide 3-kinase (PI3K) inhibitors; 14% had immunomodulatory drugs; and 3% had chimeric antigen receptor (CAR) T-cell therapy. Most patients were refractory to the last prior therapy (69%). Responses to Lunsumio™ treatment were achieved across all patient subpopulations. Lunsumio™ is a fixed-treatment duration therapy that will be widely accessible to patients with R/R FL who have received two or more prior therapies. Currently, there is no approved fixed-treatment duration option for patients with 3L+ FL that is widely accessible across multiple treatment settings. Copanlisib and tazemetostat are indicated for continuous treatment until disease progression or unacceptable toxicity. Accessibility of axicabtagene ciloleucel and tisagenlecleucel are limited due to eligibility requirements, manufacturing slots, and geographic isolation. Finally, all currently approved therapies have limitations, including high toxicity or increased risk of high toxicity with ongoing exposures, limited utility in patients without cytogenetic mutation, and lower rates of CR. Lunsumio™ is a novel agent with a fixed-treatment duration that has shown efficacy (80% overall response rates and 60% CR.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26825), we stated that while the applicant indicated that the technology does not involve the treatment of the same or similar patient population as compared to existing technology, we noted that FL in 3L+ settings is not a new population because there are FDA approved therapies indicated in the treatment of patients with r/r FL after two or more lines of systemic therapy. We stated our belief that Lunsumio™ would be used for the same disease and patient population when compared to other therapies approved to treat FL in 3L+ settings.

We invited public comments on whether Lunsumio™ is substantially similar to existing technologies and whether Lunsumio™ meets the newness criterion.

Comment: The applicant submitted a public comment regarding the newness criterion. In response to CMS's questions related to newness, the applicant stated that although several treatment regimens have been developed and approved for R/R FL in the U.S., there are no preferred treatment options for patients in the 3L+ setting. The applicant further stated that although currently available therapies for patients with R/R FL who have had two or more prior therapies may be appropriate for certain patients, substantial clinical factors impact whether a patient can benefit from these 3L+ treatment options (for example, copanlisib, tazemetostat, axicabtagene ciloleucel, and tisagenlecleucel). The applicant noted these include high-risk features such as refractoriness to prior therapy, double refractoriness to prior alkylator and anti-CD20 monoclonal antibody therapy, POD24 of 1L chemoimmunotherapy, FLIPI score of 3–5, or older age. The applicant further stated that certain treatment options for patients with R/R FL who have had two or more prior therapies have their own limitations that may restrict the eligible patient population. The applicant used copanlisib, tazemetosib, and CAR T-cell therapy as examples. According to the applicant, copanlisib is associated with severe toxicities and suboptimal responses that limit its use in patients with R/R FL who have received 2+ prior systemic therapies. With regard to tazemetostat, the applicant stated that it offers limited efficacy to patients with R/R FL who have received ≥2 prior systemic therapies and do not have an EZH2 mutation. The applicant stated that while tazemetostat is still approved for patients with wildtype EZH2, the label includes language that tazemetostat is indicated for the treatment of ''Adult patients with relapsed or refractory follicular lymphoma who have no satisfactory alternative treatment options,'' and that because EZH2 mutations are found in less than 30 percent of FL cases, 70 percent of the patients who progress after 2+ prior systemic treatments can benefit from additional options. With regard to CAR T-cell therapy, the applicant maintained that benefits of this treatment in patients with R/R FL who have received 2+ prior systemic therapies are limited by tolerability and accessibility. The applicant stated that patients aged 65 years or older make up about 35 percent of CAR T-cell recipients (25%–41%) and may experience higher rates of CRS and neurological AEs than patients under 65 years of age, and that unlike treatment-emergent AEs with other therapies, CAR T cells cannot be dose-reduced or delayed managing these AEs, nor can treatment be discontinued once administered.

According to the applicant, additional treatment options are needed for patients who may not be candidates for CAR T-cell therapies or who cannot access the therapy. The applicant argued that even for patients who are fit enough to tolerate CAR T-cell therapy toxicities, access to treatment remains a significant barrier. The applicant noted that twelve states currently have no available CAR T-cell therapy sites. The applicant stated that even for those with access to a treatment center, additional barriers limit the number of patients who can receive CAR T-cell therapy, such as with ensuring that a manufacturing slot is available when a patient's cells are collected (if frozen cells are not an option), or obtaining necessary reagents.

The applicant asserted that Lunsumio™ is efficacious in patients with R/R FL who have received 2+ lines of systemic therapy. According to the applicant, Lunsumio™ is efficacious across all subgroups, including those who are heavily pretreated and highly refractory, and those who aged 65 years or older, and has a generally manageable safety profile. In addition, the applicant maintained that the tolerability of Lunsumio™ compared with currently approved 3L+ treatment options is a substantial clinical improvement. Per the applicant, Lunsumio™ is anticipated to be a reasonable treatment option for patients who have progressed after CAR T-cell therapy, substantially improving access to 3L+ treatment for these patients. According to the applicant, as an off-the-shelf therapy that does not require patient-specific manufacturing, Lunsumio™ will be widely available at hospitals and clinics across the country, substantially improving access to treatment compared with CAR T-cell therapies. The applicant expected that Lunsumio™ will fill an unmet need left by other approved 3L+ therapies and therefore does not treat the same or similar type of disease in the same or similar patient population when compared with existing technologies.

Another commenter submitted a public comment supporting the newness of Lunsumio™ in the treatment of multiply relapsed FL, as the first approved CD20xCD3 bispecific antibody. According to the commenter, while there are other agents approved for the treatment of multiply relapsed FL, they have clinical limitations that significantly constrain their utility, such as lower response rates, inferior durability of response, treatment schedules that limit routine use, and key toxicities. The commenter also explained that the use of CAR–T cell therapies for FL are limited by toxicity and by access to centers of excellence with the resources to administer such treatment. The commenter asserted that Lunsumio™ represents a critical innovation for patients with multiply relapsed FL, offers a potent immunotherapy appropriate for outpatient and community-based use, and has a new and unique mechanism of action.

Response: We thank the applicant and commenter for their comments. We disagree with the commenter and continue to believe that Lunsumio™ would be used for the same disease in a similar patient population when compared to other therapies approved to treat FL in 3L+ settings. We note that according to the applicant, treatment options are available for R/R FL patients, though limitations impact which patients can benefit from these available 3L+ treatment options. However, we believe that these limitations relate to an assessment of whether the technology meets the substantial clinical improvement criterion rather than the newness criterion. As a result, we believe that Lunsumio™ treats the same or similar disease in the same or similar patient population when compared to existing treatments for FL in 3L+ settings. Based on our review of the comments received and information submitted by the applicant as part of its FY 2024 new technology add-on payment application for Lunsumio™, we agree with the applicant that Lunsumio™ has a unique mechanism of action as a CD20xCD3 bispecific monoclonal antibody for the treatment of 3L+ FL. Therefore, we believe that Lunsumio™ is not substantially similar to existing treatment options and meets the newness criterion. As we have discussed in prior rulemaking (77 FR 53348), generally, our policy is to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market. The applicant stated that Lunsumio™ was FDA approved for 3L+ treatment of adult patients with R/R FL on December 22, 2022, and became available for sale after the new year with a date of first sale on January 6, 2023. However, it is unclear from the information provided whether the technology would have been available for sale prior to January 6, 2023. Nonetheless, we note that using either

the FDA approval date of December 22, 2022, or the date suggested by manufacturer of January 6, 2023, Lunsumio™ is still new for FY 2024 because the 3-year anniversary date (December 22, 2025, or January 6, 2026, respectively) would occur after FY 2024. Because we did not receive any additional information about whether the technology was available for sale before January 6, 2023, we therefore consider the beginning of the newness period to commence on December 22, 2022.

With respect to the cost criterion, the applicant provided multiple analyses to demonstrate that it meets the cost criterion. For each analysis, the applicant searched the FY 2021 MedPAR file using different ICD–10–CM codes to identify potential cases representing patients who may be eligible for Lunsumio™. The applicant explained that it used different codes to identify different cohorts that may be eligible for the technology. Each analysis followed the order of operations described in the following table.

For the first analysis, the applicant searched for cases reporting ICD–10–CM diagnosis codes for follicular lymphoma without a corresponding chemotherapy administration code. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 704 claims mapping to 12 MS–DRGs. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $104,824, which exceeded the average case-weighted threshold amount of $96,820.

For the second analysis, the applicant searched for cases reporting ICD–10–CM diagnosis codes for follicular lymphoma excluding follicular lymphoma grade 3B (FL3B) without a corresponding chemotherapy administration code. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 687 claims mapping to 12 MS–DRGs. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $103,171, which exceeded the average case-weighted threshold amount of $96,578.

For the third analysis, the applicant searched for cases reporting ICD–10–CM diagnosis codes for follicular lymphoma with accompanying chemotherapy administration codes. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 844 claims mapping to 13 MS–DRGs. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $101,992, which exceeded the average case-weighted threshold amount of $98,198.

For the fourth analysis, the applicant searched for cases reporting ICD–10–CM diagnosis codes for follicular lymphoma excluding FL3B with accompanying chemotherapy administration codes. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 813 claims mapping to 13 MS–DRGs. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $99,322, which exceeded the average case-weighted threshold amount of $97,505.

LUNSUMIO™ COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of ICD-10-CM codes	Scenarios 1-4: Please see Table 10.14.A - Lunsumio™ Codes - FY 2024 associated with the proposed rule for the complete list of ICD-10-CM codes included in the cost analysis.
List of ICD-10-PCS codes	Scenarios 1-4: Please see Table 10.14.A - Lunsumio™ Codes - FY 2024 associated with the proposed rule for the complete list of ICD-10-PCS codes included in the cost analysis.
List of MS-DRGs	Scenarios 1-4: Please see Table 10.14.A - Lunsumio™ Codes - FY 2024 associated with the proposed rule for the complete list of MS-DRGs included in the cost analysis.
Inclusion/exclusion criteria	Scenario 1: The applicant required the presence of a follicular lymphoma ICD-10-CM code from C82.00 to C82.99 as listed in Table 10.14.A - Lunsumio™ Codes - FY 2024 associated with the proposed rule as it believes these codes represent indications for Lunsumio™. As a potential patient would need to fail an established prior therapy and not be engaged in active treatment, the applicant then removed all claims with a diagnosis code listed in Table 10.14.A - Lunsumio™ Codes - FY 2024 associated with the proposed rule that suggested the patient was still actively in the bone marrow transplant process and would not receive Lunsumio™. Additionally, cases that had at least one chemotherapy administration-related ICD-10-PCS code from Table 10.14.A. - Lunsumio™ Codes - FY 2024 associated with the proposed rule were removed. Scenario 2: The applicant selected claims based on scenario 1, except that cases with ICD-10-CM codes listed in Table 10.14.A - Lunsumio™ Codes - FY 2024 associated with the proposed rule for FL3B patients were excluded to align with one portion of the clinical trial. Scenario 3: The applicant selected claims based on scenario 1, except that cases with ICD-10-CM codes listed in Table 10.14.A. - Lunsumio™ Codes - FY 2024 associated with the proposed rule with chemotherapy administration-related codes were included in the analysis. Scenario 4: The applicant selected claims based on scenario 3, except cases that had at least one chemotherapy administration-related ICD-10-PCS code listed in Table 10.14.A. - Lunsumio™ Codes - FY 2024 associated with the proposed rule for FL3B patients were removed. Only claims that would be used for Medicare IPPS rate setting were included (fee-for-service IPPS discharges, plus Maryland hospital discharges). All case counts less than 11 were imputed to have 11 cases. The applicant excluded all cases from PPS-exempt hospitals in its cost criterion analysis and calculated the average unstandardized charge per case for each MS-DRG.
Charges removed for prior technology	No charges were removed because the applicant stated that patients receiving Lunsumio™ would benefit from pain and inflammation relief included in the charges on the claim. The applicant did not remove indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Technical Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 13.2% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant did not include charges for Lunsumio™.

We invited public comments on whether Lunsumio™ meets the cost criterion.

Comment: The applicant submitted a comment that summarized the results of the four analyses discussed in the proposed rule, and reiterated that regardless of the criteria for selecting the cases for the analysis, the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount.

Response: We thank the applicant for their comment. We agree that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. Therefore, Lunsumio™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that Lunsumio™ represents a substantial clinical improvement over existing technologies because it will expand access to patients for whom existing therapies are not adequate and because it offers patients with 3L+ FL multiple substantial clinical benefits, including high efficacy with significant tolerability; broad efficacy across patients with 3L+; and the opportunity to achieve sustained remission without continuous treatment. The applicant provided 13 studies to support these claims as well as 34 background articles. The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for Lunsumio™ for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Outcome(s) or findings cited by the applicant from supporting evidence to support its statements**
Increases treatment options for patients who do not have an EZH2 mutation and provides an additional option for patients who do have the mutation	Budde LE, et al. Lancet Oncol. 2022; Safety and efficacy of mosunetuzumab, a bispecific antibody, in patients with relapsed or refractory follicular lymphoma: a single-arm, multicenter, phase 2 study. 23(8):P1055-P1065, https://doi.org/10.1016/.	EZH2 mutation was not a consideration in the inclusion or exclusion criteria for Lunsumio™. Forest plot of overall response rate (ORR) and complete response (CR) rate by independent review committee (IRC) in pre-specified patient subgroups showed EZH2 mutation (n=8) (IRC assessed) CR: 38% ORR: 75% WT EZH2 (n=43) (IRC assessed) CR: 60% ORR: 79%.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Efficacy in patients with prior CAR T-cell treatment (100% ORR, 33% CR)	Budde LE, et al. (2022) *op.cit.* See prior study description	The baseline patient and disease characteristics of all enrolled patients (n=90) who had previous lymphoma therapy, 3 (3%) had Chimeric antigen receptor T-cell therapy: 3 (3%). Forest plot of ORR and CR rate by IRC in pre-specified patient subgroups showed Prior CAR T-cell therapy: Yes (N=3) CR (95% CI): 33% (1%, 91%) ORR (95% CI): 100% (29%, 100%).
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Low frequency and severity of CRS	Budde, LE, et al. (2022) *op.cit.* See prior study description	Among the 40 patients who developed cytokine release syndrome, six (15%) were managed with corticosteroids alone, 6.6% of all patients; three (8%) received tocilizumab alone, 3.3% of all patients; and four (10%) received both corticosteroids and tocilizumab, 4.4% of all patients. Ninety Lunsumio™ developed CRS Any grade: 44.4% (n=40); Grade 1/2: 42% (n=38); Grade ≥3: 2.2% (n=2) The median duration of CRS was 3 days (IQR 2-4). All events resolved.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Is an off-the-shelf therapy that does not require personalized manufacturing	Budde LE, et al. (2022) *op.cit.*, See prior study description	Lunsumio™ is a full-length, IgG1-based CD20 × CD3 T-cell engaging bispecific monoclonal antibody that engages and redirects T cells to eliminate malignant B cells.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Will increase treatment options for patients who	Budde LE, et al. (2022). *op.cit.*	Neurological adverse events observed by investigator assessment as related to Lunsumio™ and consistent with immune effector cell-associated neurotoxicity syndrome were confusional state (three

have a higher risk of TEAEs and neurological AEs.	See prior study description	[3%] of 90; grade 1–2), disturbance in attention (one [1%]; grade 1), and cognitive disorder (one [1%]; grade 1). All events resolved. Neurological events consistent with ICANS: 5 events All events resolved. Any treatment-emergent adverse events (TEAE): 92.2% Grade 3/4 TEAE: 51.1%.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Will be widely available to patients, substantially improving access to 3L treatment as an off-the-shelf therapy	Budde LE, et al. (2022) *op.cit.* See prior study description	A single-arm, multicenter, phase II study was conducted at 49 centers in seven countries (Australia, Canada, Germany, South Korea, Spain, UK, and USA).
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Substantial Clinical Improvement Assertion 2: Use of the new medical service or technology significantly improves clinical outcomes relative to services or technologies previously available.		
Fixed-treatment duration allows patients to have time off treatment without exhausting the drug class and the potential for retreatment with Lunsumio™	Budde LE, et al. (2022) *op.cit.* See prior study description	Patients who reached a complete response completed treatment after cycle 8. Patients who reached a partial response or had stable disease after cycle 8 continued treatment for up to 17 cycles. Re-treatment was allowed in complete responders who progressed after completion of initial treatment.
	Cheah, Y.C., M.L. Bartlett, S. Assouline, et al. (2022) Mosunetuzumab treatment is effective and well-tolerated in patients with relapsed or refractory B-cell non-Hodgkin lymphoma. 2022 European Hematology Association Annual Meeting, poster 1124. Brief study description: Poster presentation of single arm trial of Lunsumio	Patients with relapsed or refractory follicular lymphoma (FL) (n=9) Observed response: 6 (66.7); median duration of response (mDOR), months: 5.4-20.7. Complete response (CR): 4 (44.4); mDOR, months: 8.3-20.7. Of 9 patients with FL who were retreated with Lunsumio™, 6 had second responses (4 CR and 2 Partial response (PR). Any grade AE related to Lunsumio™: Initial treatment phase (N=15) 100%; Retreatment phase (N=15) 86.7% -Grade 3/4 AE related to Lunsumio™: Initial treatment phase (N=15) 60%; Retreatment phase (N=15) 46.7% -CRS any grade: Initial treatment phase (N=15) 26.7%; Retreatment phase (N=15) 33.3%. Our results show that IV Lunsumio™ monotherapy retreatment was efficacious in heavily pretreated patients with R/R NHL who initially achieved a CR with Lunsumio™ treatment, but subsequently developed progressive disease (PD), indicating treatment activity through multiple lines of therapy. Lunsumio™ retreatment had a manageable safety profile, consistent with that observed with initial treatment.
Fixed-treatment duration therapy provides patients with time off treatment and the potential to increase patient quality of life (QOL)	Budde LE, et al. (2022) *op.cit.* See prior study description	The proportion of patients who achieved an objective response according to IRC assessment was 80.0% (95% CI 70.3–87.7; 72 of 90 patients) and the proportion with a complete response was 60.0% (49.1–70.2; 54 of 90 patients). The median number of cycles of Lunsumio™ received was eight (IQR 8–8). Median duration of response per IRC was 22·8 months (95% CI 9.7–not reached). mDOR: 22.8 months. Notably, adverse events leading to Lunsumio™ discontinuation were rare and occurred in only four patients (4 of 90 patients = 4.4%).
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Lunsumio™ is efficacious in all subgroups investigated including heavily pretreated, highly refractory patients and those aged ≥65 years	Budde LE, et al. (2022) *op.cit.* See prior study description	The proportion of patients who achieved an objective response according to IRC assessment was 80.0% (95% CI 70.3–87.7; 72 of 90 patients) and the proportion with a complete response was 60.0% (49.1–70.2); 54 of 90 patients. Forest plot of ORR and CR rate by IRC in pre-specified patient subgroups. Lunsumio™ (N=90) 2 therapies (N=34) CR: 74% ORR: 85% ≥3 therapies (N=56) CR: 52% ORR: 77% POD24 Yes (N=47) CR: 57% ORR: 85% POD24 No (N=43) CR: 63% ORR: 74% Refractory to last prior therapy Yes (N=62) CR: 52% ORR: 77% Refractory to last prior therapy No (N=28) CR: 79% ORR: 86% Refractory to any prior anti-CD20 and an alkylating agent (double refractory) Yes (N=48) CR: 50% ORR: 71% Refractory to any prior anti-CD20 and an alkylating agent (double refractory) No (N=42) CR: 71% ORR: 90% <65 years (N=60) CR: 55% ORR: 77% ≥65 years (N=30) CR: 70% ORR: 87%.

	Matasar M, et al. EHA 2022. Abstract P1126, poster of subgroup analysis from the pivotal phase II Lunsumio™ trial.	Response rates and duration of response for patients ≥65 years (N=30) CR rate, % (95% CI): 70.0 (50.6-85.3) ORR, % (95% CI): 86.7 (69.3-96.2) DOR Median, months (95% CI): 18.7 (9.4-NE).
Lunsumio™ is associated with high response rates	Budde LE, et al. (2022) *op.cit.* See prior study description	The proportion of patients who achieved an objective response according to IRC assessment was 80.0% (95% CI 70/3–87.7; 72 of 90 patients) and the proportion with a complete response was 60.0% (49.1–70.2; 54 of 90 patients). Median duration of response per IRC was 22.8 months (95% CI 9·7–not reached). Lunsumio™ (N=90) -CR: 60% -ORR: 80%. mDOR: 22.8 months.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Lunsumio™ has a manageable safety profile	Budde LE, et al. (2022) *op.cit.* See prior study description	Treatment-emergent adverse events Lunsumio™ (N=90) CRS Any grade: 44.4% (n=40) Grade 1/2: 42% (n=38) Grade ≥3: 2.2% (n=2). Neurological adverse events observed by investigator assessment as related to Lunsumio™ and consistent with immune effector cell-associated neurotoxicity syndrome were confusional state (three [3%] of 90; grade 1–2), disturbance in attention (one [1%]; grade 1), and cognitive disorder (one [1%]; grade 1). All events resolved. Neurological events consistent with ICANS: 5 events, all events resolved. The most common AEs occurring in 10% or more of patients with ≥1 AE are Hyperglycemia: <10% Hypertension: <10% Adverse events leading to Lunsumio™ discontinuation were rare and occurred in only four patients" 4 of 90 patients = 4.4%.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	

BILLING CODE 4120–01–C

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26830), after review of the information provided by the applicant, we stated that we had the following concerns regarding whether Lunsumio™ meets the substantial clinical improvement criterion. We noted that the applicant provided a single-arm, phase II trial of 90 patients, sub-study analysis, and another single-arm phase I/II trial of 15 patients to support its claims of substantial clinical improvement. As noted in the previous table, the studies evaluated complete response rates or indicators of safety, but did not evaluate survival as a primary outcome. They were also single-arm, without comparison to other existing treatments for the patient population. The applicant compared outcomes of the phase II trial with Lunsumio™ to outcomes, including QOL and AE from background studies of other technologies.[67] [68] [69] However, we noted limitations in comparing to rates found in other clinical trials that were conducted in earlier time periods and under different circumstances of patient enrollment and treatment options. Additionally, the historical rates were compared directly to those from Lunsumio™ without more detailed adjustment for patient characteristics. Without a direct comparison of outcomes between these therapies, we were concerned as to whether the differences in outcomes identified by the applicant translate to clinically meaningful differences or improvements for patients treated with Lunsumio™ as compared to historical rates for other treatments.

We invited public comments on whether Lunsumio™ meets the substantial clinical improvement criterion.

Comment: The applicant submitted a public comment in response to CMS's concerns regarding substantial clinical improvement. In response to the issue of study design, the applicant responded that there are benefits and limitations to single-arm studies in the 3L+ FL setting. The applicant noted that single-arm studies are an important mechanism to facilitate faster access to novel therapies, especially for patients who have exhausted other approved options. According to the applicant, investigating Lunsumio™ for patients in the 3L+ FL setting is an example of using a single-arm clinical trial strategy to bring a novel treatment to patients who have an unmet need. Other benefits of single-arm trials are smaller sample size requirements, shorter completion time, and the ability to identify signs of efficacy early in drug development.[70] [71] At the same time, the applicant acknowledged that single-arm studies are most appropriate for assessing response rates and since they lack a comparator arm, time-to-event endpoints, such as progression-free survival and overall survival, can only be understood in the context of a historical control. The applicant also noted that evaluation of safety outcomes is likewise limited by a lack of a comparator arm.[72] [73] Nonetheless, the applicant maintained that despite these limitations, single-arm trials are a valuable tool for drug discovery.

With regard to the use of historical control without adjusting for potential confounders, the applicant stated that

[67] Cheah, Y.C. et al. (2022), *op.cit.*

[68] Morschhauser, F., H. Tilly, A. Chaidos, et al. (2020) Tazemetostat for patients with relapsed or refractory follicular lymphoma: an open-label, single-arm, multicenter, phase 2 trial. *Lancet Oncology.* 21(11):1433–1442. doi:10.1016/S1470–2045(20)30441–1.

[69] Budde, L. et al. (2022), *op.cit.*

[70] Nierengarten, M.B. 2023. ''Single-Arm Trials for US Food and Drug Administration Cancer Drug Approvals.'' *Cancer* 129, no. 11 (Jun 1): 1626.

[71] Agrawal, S., et al. 2023. ''Use of Single-Arm Trials for US Food and Drug Administration Drug Approval in Oncology, 2002–2021.'' *JAMA Oncol* 9, no. 2 (Feb 1): 266–272.

[72] Budde, L.E., et al. 2022. ''Safety and Efficacy of Mosunetuzumab, a Bispecific Antibody, in Patients with Relapsed or Refractory Follicular Lymphoma: A Single-Arm, Multicentre, Phase 2 Study.'' *Lancet Oncol* 23, no. 8: 1055–1065.

[73] Salles, G.A., et al. 2022. ''Efficacy Comparison of Tisagenlecleucel vs Usual Care in Patients with Relapsed or Refractory Follicular Lymphoma.'' *Blood Adv* (Aug 16).

head-to-head data comparing Lunsumio™ to other approved 3L+ treatments are not available. The applicant acknowledged that direct comparisons across different trials are subject to confounding and bias because of systematic differences including study population, comparators, and outcomes between or among trials being compared. Nonetheless, the applicant argued that information regarding how pivotal studies of other therapies were carried out may still be useful when considering clinical trial outcomes.

With regard to the absence of endpoints related to survival, the applicant asserted that the response criteria used to assess responses in Lunsumio™ were similar to those in pivotal clinical trials for other currently available therapies. The applicant noted that for instance, the response rates for Lunsumio™ in patients with R/R FL who have received 2+ prior therapies were assessed using the International Working Group Revised Response Criteria for Malignant Lymphoma, for which a response was defined as a CR (that is, positron emission tomography [PET]-negative response) even if a mass of any size is persistent, and a PR was defined as a regression of measurable disease via at least a 50 percent decrease in sum of the product of the diameters (SPD) of up to six of the largest dominant nodes or nodal masses and no new sites.[74] The applicant also argued that the response rates for copanlisib and tazemetostat in patients with R/R indolent lymphoma and patients with mutated or wild type *EZH2* R/R FL, respectively, were assessed using the same International Working Group Revised Response Criteria for Malignant Lymphoma. The applicant added that the response rates for axicabtagene ciloleucel in adult patients with indolent NHL after 2+ lines of prior therapy and tisagenlecleucel in adult patients with R/R FL after 2+ lines of prior therapy were assessed using the 2014 Lugano classification, which defines CR as a complete metabolic response even with a persistent mass, and defines PR as a decrease by more than 50 percent in the SPD of up to six representative nodes or extranodal lesions, which are consistent with the definitions from the International Working Group Revised Response Criteria for Malignant Lymphoma.[75] [76]

The applicant asserted that therefore, the criteria used to assess response in patients with R/R FL who had 2+ prior systemic therapies across all pivotal trials reflects a similar approach to assessing antitumor activity for each therapeutic option.

In addition, the applicant included results of an updated analysis of the pivotal Lunsumio™ study (that is, Budde et al. 2022) in their comments. According to the applicant, the median duration of complete response (DOCR) was not reached (median time on study was 28.6 months). The 24-month DOCR rate after first CR was 65 percent (95% CI, 39–90). Also, the applicant stated that median Physician Fee Schedule (PFS) was not reached; 24-month PFS rate was 77 percent (95% CI, 63–91). Per the applicant, two years after the end of fixed-duration treatment, 67 percent of these 49 patients remained free of progressive disease or death.[77] The applicant maintained that these outcomes approached the best ORRs and CRs reported with axicabtagene ciloleucel and tisagenlecleucel (ORRs of 91% and 86% and CRs of 60% and 68%, respectively)[78] [79] and were substantially better than the best outcomes with copanlisib (ORR of 59% and CR 14%) and tazemetostat (mutant EZH2 was 69% ORR and 12% CR; wild-type EZH2 was 34% ORR and 4% CR).[80] [81] The applicant stated that in addition, at 22.8 months, the median DOR with Lunsumio™ was longer than both copanlisib (DOR: 12.2 months) and tazemetostat (mutant EZH2 DOR of 10.9 months, wild-type EZH2 was 10.9 months).[82] [83] [84]

Response: We thank the applicant for their comment regarding the substantial clinical improvement criterion. Based on the additional information received, we agree that Lunsumio™ represents a substantial clinical improvement over existing technologies for the treatment of patients with 3L+FL because Lunsumio™ offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, in particular: R/R FL patients who have undergone 2+ prior treatments, but cannot access any of the four PI3K inhibitors or EZH2 inhibitor approved by FDA for 3L+ treatment of R/R FL; patients with EZH2 mutation, who are contra-indicated for tazemetostat, an EZH2 inhibitor approved for R/R FL; and patients who were unable to tolerate CAR T-cell therapy.

After consideration of the public comments received and the information included in the applicant's new technology add-on payment application, we have determined that Lunsumio™ meets the criteria for approval for new technology add-on payment. Therefore, we are approving new technology add-on payments for this technology for FY 2024. Cases involving the use of Lunsumio™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS codes: XW03358 (Introduction of mosunetuzumab antineoplastic into peripheral vein, percutaneous approach, new technology group 8), or XW04358 (Introduction of mosunetuzumab antineoplastic into central vein, percutaneous approach, new technology group 8).

Per the applicant, the WAC of Lunsumio™ is $594.06 for a 1 mg single dose vial. As stated previously, according to the applicant, Lunsumio™ is sold in a 1 mg and 30 mg single dose vial (we note, a 30 mg single dose vial is priced at the 1 mg single dose vial × 30 = $17,821.80). According to the applicant, most of the inpatient usage would occur as the result of adverse events, mainly CRS, that develop after outpatient administration of the drug, and that in clinical trials, when Grade 2, 3, or 4 CRS developed, 75 percent of the time it occurred after a 60 mg dose, 20 percent of the time it developed after a 1 mg dose, and 5 percent after a 2 mg dose. Based on this information, we determined a weighted average inpatient dose of 45.3 mg. Therefore, the average cost per patient for Lunsumio™ is $26,910.92 (45.3 mg * $594.06 per 1 mg vial). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a

[74] Cheson, B.D., et al. 2007. ''Revised Response Criteria for Malignant Lymphoma.'' *J Clin Oncol* 25, no. 5 (Feb 10): 579–86.

[75] Cheson, B.D., et al. 2014. ''Recommendations for Initial Evaluation, Staging, and Response Assessment of Hodgkin and Non-Hodgkin Lymphoma: The Lugano Classification.'' *J Clin Oncol* 32, no. 27 (Sep 20): 3059–68.

[76] Cheson et al., 2007, *op.cit.*

[77] Sehn, L., et al. 2023. ''Mosunetuzumab Demonstrates Durable Responses in Patients with Relapsed and/or Refractory Follicular Lymphoma Who Have Received ≥2 Prior Therapies: Updated Analysis of a Pivotal Phase II Study.'' *EHA Annual Meeting* Abstract P1078.

[78] Kymriah (Tisagenlecleucel) [Prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; 2022.

[79] Yescarta (Axicabtagene Ciloleucel) [Prescribing information]. Santa Monica, CA: Kite Pharma Inc.; 2017.

[80] Aliqopa (Copanlisib) [Prescribing information]. Whippany, NJ: Bayer Healthcare Pharmaceuticals In; 2017.

[81] Tazverik (Tazemetostat) [Prescribing information]. Cambridge, MA: Epizyme, Inc.; 2020.

[82] Lunsumio™ (mosunetuzumab-axgb). 1 DNA Way South San Francisco, CA. Genentech, Inc.; 2022.

[83] Tazverik (Tazemetostat) [Prescribing information]. Cambridge, MA: Epizyme, Inc.; 2020.

[84] Aliqopa (Copanlisib) [Prescribing information]. Whippany, NJ: Bayer Healthcare Pharmaceuticals Inc.; 2017.

case involving the use of Lunsumio™ is $17,492.10 for FY 2024.

e. NexoBrid™ (Anacaulase-bcdb)

Vericel Corporation submitted an application for new technology add-on payments for NexoBrid™ for FY 2024. According to the applicant, NexoBrid™ is a novel, non-surgical option for eschar removal (debridement) in adult patients with deep partial thickness (DPT) and/or full thickness (FT) thermal burns. Per the applicant, NexoBrid™ is a botanical and biologic product for topical use consisting of a concentrate of proteolytic enzymes enriched in bromelain extracted from pineapple stems. We note that Vericel Corporation submitted an application for new technology add-on payments for NexoBrid™ for FY 2022, as summarized in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25286 through 25291), that it withdrew prior to the issuance of the FY 2022 IPPS/LTCH PPS final rule (86 FR 44774).

Please refer to the online application posting for NexoBrid™, available at *https://mearis.cms.gov/public/publications/ntap/NTP221017WGWTP*, for additional detail describing the technology and the condition treated by the technology.

With respect to the newness criterion, according to the applicant, NexoBrid™ was granted BLA approval from FDA on December 28, 2022, for eschar removal (debridement) in adults with DPT and/or FT thermal burns. According to the applicant, NexoBrid™ is expected to be commercially available the end of June or beginning of July 2023 in the U.S. market as manufacturing preparations are currently underway. NexoBrid™ is applied topically to the wound at 2-gram lyophilized powder with 20-gram gel vehicle per 1% total body surface area (TBSA), or 5-gram lyophilized powder with 50-gram gel vehicle per 2.5% TBSA, up to an area of up to 15% TBSA in one application. The applicant estimated that the average U.S. patient will receive approximately 2.8 5-gram packs of NexoBrid™ per inpatient stay, based upon the average NexoBrid™-treated area of 6.28% TBSA in the DETECT clinical trial with an expected wastage assumption of approximately 10 percent, as well as commercial use of the technology in Europe.

The applicant stated that effective October 1, 2021, the following ICD–10–PCS codes may be used to uniquely describe procedures involving the use of NexoBrid™: XW00X27 (Introduction of bromelain-enriched proteolytic enzyme into skin, external approach, new technology group 7) and XW01X27 (Introduction of bromelain-enriched proteolytic enzyme into subcutaneous tissue, external approach, new technology group 7).

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that NexoBrid™ is not substantially similar to other currently available technologies because NexoBrid™ has a novel mechanism of action and is the first enzymatic technology to achieve rapid, consistent eschar removal; the applicant further asserted that the active ingredient in NexoBrid™ has never been approved in any application under section 505(b)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) of 1938 or section 351(a) of the Public Health Service (PHS) Act; and no existing technology under the existing burn DRGs is similar to NexoBrid™, and that therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for NexoBrid™ for the applicant's complete statements in support of its assertion that NexoBrid™ is not substantially similar to other currently available technologies.

BILLING CODE 4120–01–P

Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	Collagenase-based technologies (that is, C.O), the comparator products presently on the market for burns, are generally considered inefficient, can result in a lengthy sloughing period, and have the potential for development of granulation tissue and increased infection and scarring. These products are all based on Clostridial collagenase, a bacterial enzyme that breaks down collagen in damaged tissue and helps healthy tissue to grow. Such products only have one major mode of action: proteolysis of a single substrate, resulting in cleavage of necrotic tissue at seven specific sites along the denatured collagen strand. In contrast, NexoBrid™ has a novel mechanism of action and is the first enzymatic technology to achieve rapid, consistent eschar removal. NexoBrid™ contains a concentrate of proteolytic enzymes enriched in bromelain extracted from pineapple stems (Ananas comosus L Merr.) These pineapple stems are obtained from distinct pineapple cultivars, and they are processed using Bromelain Special Production (BSP), a proprietary method, from which the NexoBrid™ drug substance and drug product are produced. By design, NexoBrid™ is a combination of different thiol endopeptidases and other components such as phosphatases, glucosidases, peroxidases, cellulases and escharase. Because it is a natural product with a mixture of components, it has complex and varied modes of action, and thus it is an improvement on a single mode of action product such as a collagenase. The major mechanism of action of NexoBrid™ on wound healing is mediated by the proteolytic activity of its enzymes. It is associated selective degradation of eschar and denatured collagen while sparing healthy tissue.
Is the technology assigned to the same MS-DRG as existing technologies?	No	No existing technology used now (or previously) to treat patients under the existing burn DRGs (for example, 927, 928, 929, 933, 934, 935) is similar to NexoBrid™. As described previously, existing technologies for eschar removal are either surgical in nature or, if enzymatic, rely on collagenase (and not bromelain).
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	Yes	NexoBrid™ does treat the same patient population as existing approaches to eschar removal.

BILLING CODE 4120–01–C

However, we had the following concerns with regard to the newness criterion. We noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26831) that as discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25288), while the applicant discussed the differences between NexoBrid™ and collagenase-based products, we did not receive enough information regarding the specific composition of the proteolytic enzymes used within the NexoBrid™ active pharmaceutical ingredient and its mechanism of action. Specifically, it was unclear whether the proteolytic enzymes act similarly to existing collagenase-based enzymatic debridement products since the applicant claimed that NexoBrid™ debrides denatured collagen in the wound. We also noted that the applicant asserted that NexoBrid™ is not assigned to the same MS–DRGs as existing technologies used for burns, although it seemed that NexoBrid™ would be assigned to the same burn MS–DRGs as other enzymatic and surgical debridement technologies.

We invited public comments on whether NexoBrid™ is substantially similar to existing technologies and whether NexoBrid™ meets the newness criterion.

Comment: A commenter stated that NexoBrid™ does not meet the newness criterion because it has been commercially available in the European Union for a decade. Additionally, the commenter noted fruit-based enzymatic debridement products have been utilized for decades and marketed under various trade names, including Accuzyme®, Allanzyme, Ethezyme, Gladase™, Kovia, and Panafil. The commenter explained that these enzymatic debridement products utilize papain extract from papaya fruit (*Carica papaya*) and exhibit identical activation catalytic mechanisms as NexoBrid™'s pineapple-derived enzymes. The commenter further explained that papain and bromelain are fruit-derived cysteine proteases, also known as thiol proteases, with non-specific degradation profiles and proteolytic mechanisms of action. The commenter added that in addition to the fruit-based enzymatic debridement products mentioned, SANTYL® Collagenase Ointment is an enzymatic debridement product that has been commercially available since its approval in 1965 and is utilized to treat chronic dermal ulcers and severe burns.

Response: We thank the commenter and have taken it into consideration in determining whether NexoBrid™ meets the newness criterion, discussed later in this section.

Comment: The applicant submitted a comment reiterating its assertion that NexoBrid™ has a novel mechanism of action that satisfies the newness criterion. The applicant stated that the active pharmaceutical ingredient in NexoBrid™, anacaulase-bcbd, is a mixture of proteolytic enzymes extracted from the stems of pineapple plants and is composed mainly (80% to 95% weight by weight [w/w]) of stem bromelain, ananain, jacalin-like lectin, bromelain inhibitors, phytocystatin inhibitor, small molecule metabolites, and saccharides, as both free monosaccharides and the N-linked glycan of stem bromelain.[85] The applicant further explained that bromelain is a combination of thiol endopeptidases and other components, such as phosphatases, glucosidases, peroxidases, cellulases, glycoproteins, carbohydrates, and several protease inhibitors.[86]

In response to CMS's concern regarding NexoBrid™'s mechanism of action, the applicant stated that NexoBrid™ degrades collagen by bromelain via a combination of endopeptidases and other enzymes. The applicant further explained that this degradation by bromelain results in a wide range of reactions beyond hydrolysis, such as peroxidases catalyze oxidation reactions,[87] and acts on a group of substrates, including gelatin, chromogenic tripeptides, and casein.[88] Additionally, the applicant noted, in the context of eschar removal, it has been hypothesized that the presence of multiple proteolytic enzymes likely results in the degradation of multiple substrates contained within the eschar in addition to denatured collagen.[89] The applicant stated that NexoBrid™'s combination of enzymes is unique and distinct from collagenase-based debridement agents, which are primarily composed of collagenase derived from *Clostridium histolyticum* in petrolatum USP.[90] The applicant explained that clostridial collagenase-based debridement agents are based on proteolysis of a collagen substrate through hydrolysis reactions [91] and result in cleavage of necrotic tissue at seven specific sites along the denatured collagen strand.[92]

The applicant also asserted that since the mechanism of action of NexoBrid™ differs significantly from collagenase-based debridement agents, the dosage and administration, as well as resulting clinical outcome, is also different. The applicant explained that NexoBrid™ is applied to the burn wound once (in some cases twice, for a four-hour period) and was shown in clinical studies to achieve complete eschar removal (≥95% eschar removal) in 93 percent of patients, while on the other hand, collagenase-based debridement agents are typically used daily, as a continuous application for multiple days with varying results.

In response to CMS's concern regarding the MS–DRG assignment for procedures in which NexoBrid™ is administered, the applicant stated that it may be appropriate for NexoBrid™ administration to be assigned to existing burn MS–DRGs (for example, 927, 928, 929, 933, 934, 935); however, the payment associated with these MS–DRGs would not adequately account for NexoBrid™'s cost.

Response: We appreciate the additional information from the applicant and commenters with respect to whether NexoBrid™ is substantially similar to existing technologies.

As stated in the preamble of this section, a specific medical service or technology will no longer be considered ''new'' for purposes of new medical service or technology add-on payments after CMS has recalibrated the MS–DRGs, based on available data, to reflect the cost of the technology. Therefore, we disagree with the commenter that NexoBrid™ would not be considered new because it was launched a decade ago in the European Union, as the available data to reflect the cost of the technology would not have been available for CMS to recalibrate the MS–DRGs for those administrations.

We also disagree with the commenter that fruit-based enzymatic debridement products that have not received FDA marketing authorization are appropriate existing technology comparators for evaluating whether a new technology is substantially similar to an existing technology. As stated in the preamble of this section, even if a medical product receives a new FDA approval or clearance, it may not necessarily be considered ''new'' for purposes of new technology add-on payments if it is ''substantially similar'' to another medical product that was approved or cleared by FDA and has been on the market for more than 2 to 3 years. We believe that technologies that receive FDA marketing authorization have met regulatory standards that provide a reasonable assurance of safety and efficacy. We maintain that our intent in requiring applicants to receive FDA marketing authorization was to exclude technologies that lack FDA marketing authorization. Therefore, we do not believe that medical products that have not received FDA marketing authorization are appropriate comparators for evaluating if a new technology is ''substantially similar'' to another medical product that was approved or cleared by FDA and has been on the market for more than 2 to 3 years.

In regard to the first criterion, whether a technology uses the same or similar mechanism of action to achieve a therapeutic outcome, we agree with the commenter that there is an existing enzymatic debrider, the SANTYL Collagenase Ointment, that is commercially available for the treatment of burn and chronic wounds. We note that the applicant asserted that NexoBrid™ has a novel composition because it contains a unique pharmaceutical ingredient derived from pineapple and therefore has a unique combination of proteolytic enzymes as compared to collagenase-based debridement agents that are derived from *Clostridium histolyticum.* However, we note that the composition/ingredients of a technology does not represent the mechanism of action. Further, while the applicant asserted that NexoBrid™ degrades collagen via multiple reactions beyond hydrolysis, while clostridial collagenase degradation is based on hydrolysis reactions, we note that the applicant hypothesizes, but does not demonstrate that the presence of multiple proteolytic

[85] NexoBrid® Prescribing Information. Vericel Corporation. Cambridge, MA. 20222. Page 9.

[86] Pavan R, Jain S, Kumar A. Properties and therapeutic application of bromelain: a review. *Biotechnology research international.* 2012. Page 2

[87] Pavan R, Jain S, Kumar A. Properties and therapeutic application of bromelain: a review. Biotechnology research international. 2012. Page 2.

[88] Chakraborty AJ, Mitra S, Tallei TE, Tareq AM, Nainu F, Cicia D, Dhama K, Emran TB, Simal-Gandara J, Capasso R. Bromelain a Potential Bioactive Compound: A Comprehensive Overview from a Pharmacological Perspective. *Life.* 2021; 11(4):317.

[89] Singer AJ, Goradia EN, Grandfield S, Zhang N, Shah K, McClain SA, et al. A Comparison of Topical Agents for Eschar Removal in a Porcine Model: Bromelain-enriched vs Traditional Collagenase Agents. Journal of Burn Care & Research. 2023;44(2):408–13. Page 408, ''The bromelain-enriched enzymatic debridement agent is derived from the stems of pineapples and contains a mixture of other proteolytic enzymes including at least four distinct cysteine proteinases: ananain1, ananain2, stem bromelain, and comosain. The presence of multiple proteolytic enzymes likely results in the degradation of multiple substrates contained within the eschar in addition to denatured collagen.''

[90] SANTYL® Prescribing Information. Smith & Nephew, Inc. Fort Worth, TX. 2016. Page 1.

[91] Eckhard U, Schönauer E, Brandstetter H. Structural Basis for Activity Regulation and Substrate Preference of Clostridial Collagenases G, H, and T*. Journal of Biological Chemistry. 2013; 288(28): 20184.

[92] Shi L, Ermis R, Garcia A, Telgenhoff D, Aust D. Degradation of human collagen isoforms by Clostridium collagenase and the effects of degradation products on cell migration. International Wound Journal. 2010;7(2): 94.

enzymes by NexoBrid™ results in the degradation of multiple substrates contained within the eschar in addition to denatured collagen. In addition, although we recognize that NexoBrid™ has a different use case than collagenase-based debridement agents with respect to the dosage and administration, these differences do not result in a substantially different therapeutic mechanism of action, and in our view, any differences in the resulting clinical outcome relate to an assessment of whether NexoBrid™ meets the substantial clinical improvement criterion. Therefore, even though there may be differences in composition between bromelain and clostridial collagenase, resulting in collagen degradation through hydrolysis and other reactions, these two technologies use a similar mechanism of action to achieve the same therapeutic outcome: the enzymatic degradation of collagen to debride eschar for the treatment of burns.

In regard to the second criterion, whether a technology is assigned to the same or a different MS–DRG, we note that the applicant acknowledged that the use of NexoBrid™ may be assigned under the existing MS–DRGs (for example, 927, 928, 929, 933, 934, 935), but stated the payment associated with these MS–DRGs does not adequately account for the cost of NexoBrid™. We agree with the applicant that NexoBrid™ would be assigned to these same burn MS–DRGs as other enzymatic and surgical debridement technologies used in the treatment of burns. However, we believe that inadequate payment for the technology associated with these MS–DRGs relates to an assessment of whether NexoBrid™ meets the cost criterion, rather than an assessment of substantial similarity.

In regard to the third criterion, whether a technology treats the same or similar type of disease and patient populations, we agree with the applicant's assertion in its application that use of the technology would involve the treatment of a similar type of disease and a similar patient population when compared to existing approaches for eschar removal.

Because NexoBrid™ meets all three of the substantial similarity criteria, we believe the NexoBrid™ is substantially similar to an existing collagenase-based debridement agent, SANTYL Collagenase Ointment. Therefore, we consider the beginning of the newness period for NexoBrid™ to begin on the date on which SANTYL Collagenase Ointment received FDA approval for the treatment of burns. Since SANTYL Collagenase Ointment has been on the U.S. market for many years, the 3-year anniversary date of its entry onto the market occurred prior to FY 2024,[93] and therefore, NexoBrid™ does not meet the newness criterion and is not eligible for new technology add-on payments for FY 2024. We note that we received public comments with regard to the cost and substantial clinical improvement criteria for this technology, but because we have determined that the technology does not meet the newness criterion and therefore is not eligible for approval for new technology add-on payments for FY 2024, we are not summarizing comments received or making a determination on those criteria in this final rule.

f. REBYOTA™ (Fecal Microbiota, Live-jslm) and VOWST™ (Fecal Microbiota Spores, Live-brpk)

Two manufacturers, Ferring Pharmaceuticals, Inc., an affiliate of the manufacturer, Rebiotix Inc., and Seres Therapeutics, Inc., submitted separate applications for new technology add-on payments for FY 2024 for REBYOTA™ (fecal microbiota, live-jslm, referred to as 'RBX2660' in the proposed rule) and VOWST™ (fecal microbiota spores, live-brpk, referred to as 'SER–109' in the proposed rule), respectively. Both of these technologies are microbiota-based treatments indicated for the reduction or prevention of recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older, following antibiotic treatment for recurrent CDI (rCDI). In the FY 2024 IPPS/LTCH PPS proposed rule, we discussed these applications as two separate technologies. After further consideration, and as discussed elsewhere, we believe REBYOTA™ and VOWST™ are substantially similar to each other and that it is appropriate to evaluate both technologies as one application for new technology add-on payments under the IPPS. We refer the reader elsewhere for a complete discussion regarding our analysis of the substantial similarly of REBYOTA™ and VOWST™.

Please refer to the online application posting for REBYOTA™, available at *https://mearis.cms.gov/public/publications/ntap/NTP221017WUDXM*, and the online application posting for VOWST™, available at *https://mearis.cms.gov/public/publications/ntap/NTP221016VHL8B*, for additional detail describing the technologies and the disease treated by the technologies.

With respect to the newness criterion, the applicant for REBYOTA™ received BLA approval from FDA on November 30, 2022, for the prevention of rCDI in individuals 18 years of age and older, following antibiotic treatment for rCDI. According to the applicant, REBYOTA™ is a broad consortium microbiota-based live biotherapeutic suspension indicated for the prevention of recurrence of CDI in individuals 18 years of age and older, following antibiotic treatment for rCDI. Per the applicant, REBYOTA™ is administered rectally, 24 to approximately 72 hours after the last dose of antibiotics for CDI. The applicant stated that each 150mL dose of REBYOTA™ contains between $1x10^8$ and $5x10^{10}$ colony forming units (CFU) per mL of fecal microbes including more than $1x10^5$ CFU/mL of Bacteroides and contains not greater than 5.97 grams of PEG3350 in saline. Per the applicant, REBYOTA™ first became commercially available on January 23, 2023, as the process to create packaging components and then start the packaging process could not start until FDA approval was received.

The applicant for VOWST™ stated that it received BLA approval from FDA on April 26, 2023, for the prevention of the recurrence of CDI in individuals 18 years of age and older following antibacterial treatment for rCDI. The applicant stated that the dose is four capsules taken orally once daily on an empty stomach before the first meal of the day for 3 consecutive days. The applicant stated that VOWST™ is an oral microbiome therapeutic administered to reduce CDI recurrence as part of a two-pronged treatment approach of (1) antibiotics to kill vegetative C. diff bacteria, followed by (2) VOWST™ to repair the microbiome to manage CDI and prevent its recurrence. According to the applicant, VOWST™ is a consortium of purified Firmicutes bacteria spores collected from healthy stool donors. The applicant stated that engraftment of spore producing Firmicutes bacteria is a necessary first step in microbiome repair, as Firmicutes bacteria produce metabolites, such as secondary bile acids, which inhibit C. diff spore germination and vegetative growth.

The applicant for REBYOTA™ stated that, effective October 1, 2022, the following ICD–10–PCS code may be used to uniquely describe procedures involving the use of REBYOTA™: XW0H7X8 (Introduction of broad consortium microbiota-based live biotherapeutic suspension into lower GI, via natural or artificial opening, new tech. group 8). The applicant for VOWST™ submitted a request for approval for a unique ICD–10–PCS code for VOWST™ beginning in FY 2024 and

[93] CDER Therapeutic Biologic Products, *https://www.fda.gov/media/76650/download.*

was granted approval for the following ICD–10–PCS procedure code, effective October 1, 2023: XW0DXN9 (Introduction of SER–109 into mouth and pharynx, external approach, new technology group 9). Both applicants stated that diagnosis codes A04.71 (Enterocolitis due to Clostridium difficile, recurrent) and A04.72 (Enterocolitis due to Clostridium difficile, not otherwise specified as recurrent) may be used to currently identify the indication for their technologies under the ICD–10–CM coding system.

As stated earlier and for the reasons discussed later in this section, we believe that REBYOTA™ and VOWST™ are substantially similar to each other such that it is appropriate to analyze these two applications as one technology for the purposes of new technology add-on payments, in accordance with our policy. We discuss the information provided by the applicants, as summarized in the FY 2024 IPPS/LTCH PPS proposed rule, regarding whether REBYOTA™ and VOWST™ are substantially similar to existing technologies. As discussed earlier, if a technology meets all three of the substantial similarity criteria, it would be considered substantially similar to an existing technology and would not be considered ''new'' for purposes of new technology add-on payments.

With respect to the substantial similarity criteria, whether a product uses the same or a similar mechanism of action to achieve a therapeutic outcome, in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26853 through 26854), the applicant for REBYOTA™ stated that REBYOTA™ is not substantially similar to other currently available technologies to reduce rCDI because REBYOTA™ has a new mechanism of action and is approved to treat a broader patient population than existing therapies (including standard of care antibiotics (for example, DIFICID®, FIRVANQ®), Fecal Microbiota Transplantation (FMT), and ZINPLAVA™), and that therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for REBYOTA™ for the applicant's complete statements in support of its assertion that REBYOTA™ is not substantially similar to other currently available technologies.

BILLING CODE 4120–01–P

REBYOTA™ Substantial Similarity Criteria Table		
Substantial Similarity Criteria	**Applicant Response**	**Applicant assertions regarding this criterion**
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	There are no existing technologies with the same or similar mechanism of action as REBYOTA™ currently approved by the FDA to achieve a therapeutic outcome. While the exact mechanism of action for REBYOTA™ has not been established, in studies, REBYOTA™-treated responders experienced clinically significant change in their gut microbiome, with a shift in gut bile acid predominance, which has been associated with suppression of *C.difficile* outgrowth. DIFICID™ (fidaxomicin) is a macrolide antibacterial that is bactericidal against C. difficile in vitro, inhibiting ribonucleic acid (RNA) synthesis by RNA polymerases. FIRVANQ™ (vancomycin hydrochloride) is a glycopeptide antibacterial whose bactericidal action results primarily from inhibition of cell-wall biosynthesis. ZINPLAVA™ (bezlotoxumab) is a human monoclonal antibody that binds C. difficile toxin B. FMT is an investigational and non-standardized treatment that has not been approved by the FDA and its mechanism of action and the extent to which it may affect dysbiosis are not fully understood.
Is the technology assigned to the same MS-DRG as existing technologies?	Yes	Patients who may be eligible for treatment with REBYOTA™ could have their hospital stays assigned to the same MS-DRGs as patients who receive antibiotics, ZINPLAVA™, or FMT to reduce rCDI.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	There are differences in the type of disease and potential patient population for REBYOTA™ compared to existing technologies. Antibiotic treatments are currently recommended as standard-of-care therapy for CDI, an initial rCDI episode, and sometimes for later rCDI episodes. However, CDI-targeted antibiotics maintain and exacerbate a low-diversity microbiome (that is dysbiosis), while microbiome recovery is essential for durable clinical resolution of rCDI. REBYOTA™ is a treatment option that may help patients in reducing rCDI where standard-of-care antibiotics have fallen short. ZINPLAVA™ is indicated to reduce recurrence of CDI in adults who are receiving antibacterial drug treatment of CDI and who are at a high risk for CDI recurrence. The FDA has advised that ZINPLAVA™ should be used with caution—when the benefits outweigh the risks—in patients with a history of congestive heart failure (CHF). REBYOTA™'s use is not restricted to high-risk patients nor is there evidence of increased safety concerns in patients with a history of congestive heart failure CHF. FMT is a non-standardized therapy with limited clinical data that include considerable heterogeneity and variability. The lack of robust clinical data and serious safety concerns make understanding the exact patient population for FMT difficult to identify. REBYOTA™ is an FDA approved treatment alternative that addresses the safety and standardization concerns of FMT for rCDI patients. REBYOTA™ is a readily available, pathogen-tested, pharmaceutical-grade product that, unlike FMT, would not require healthcare providers to perform independent screening of donors or donor specimens.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26854), we noted the following concern with regard to the newness criterion for REBYOTA™. We noted that the applicant stated that ZINPLAVA™ is restricted to high-risk patients, and we questioned whether these high-risk patients were the same or a similar patient population as that treated with REBYOTA™, which is indicated for patients who have already had at least one recurrence of rCDI. In addition, we noted that the indication for ZINPLAVA™ does not exclude patients with a history of CHF and the labeling has no listed contraindications. Therefore, we sought clarification from the applicant regarding the differences in patient populations for ZINPLAVA™ and REBYOTA™.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26874 through 26875), according to the applicant for VOWST™, VOWST™ is not substantially similar to other currently available technologies because VOWST™ does not have the same or a similar mechanism of action as any currently FDA-approved CDI treatment and does not involve treatment of the same or similar type of disease or patient population as there are currently no approved therapies indicated to repair a disrupted microbiome as a treatment intervention to prevent recurrence in patients with rCDI. Therefore, the applicant asserted that VOWST™ meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for

VOWST™ for the applicant's complete statements in support of its assertion that VOWST™ is not substantially similar to other currently available technologies.

VOWST™ Substantial Similarity Criteria Table		
Substantial Similarity Criteria	**Applicant Response**	**Applicant assertions regarding this criterion**
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	VOWST™ does not have the same or similar mechanism of action as any currently approved treatment for CDI. The two categories of approved therapies for CDI include antibiotics and ZINPLAVA™. Antibiotics function by killing the toxin-producing C. diff bacteria. However, antibiotics also kill beneficial flora, including Firmicutes bacteria, and do not kill dormant C. diff spores. After treatment discontinuation, these spores germinate into toxin-producing vegetative bacteria, which thrive in an environment depleted of Firmicutes bacteria, thereby causing recurrent infections. The symptoms caused by C. diff are caused primarily by the production of an enterotoxin (Toxin A) and/or a cytotoxin (Toxin B), which bind to the surface of endothelial cell receptors in the large intestine and damage the cells lining the intestinal wall. ZINPLAVA™ is used concomitantly with standard of care antibiotics and neutralizes Toxin B sites, preventing Toxin B from binding to the host cell. This provides passive immunity against Toxin B; however, ZINPLAVA™ does not act to restore the patient's native gastrointestinal flora. Unlike antibiotics and ZINPLAVA™, VOWST™ prevents rCDI by repairing the microbiome. While the specific mechanism of action of VOWST™ is still under investigation, findings from the ECOSPOR III clinical trial indicate that VOWST™ results in more rapid and durable engraftment of the Firmicute bacteria relative to placebo, producing bile-acid profiles that are known to inhibit C.diff spore germination, and thus reduce rates of recurrent infection.
Is the technology assigned to the same MS-DRG as existing technologies?	Yes	The MS-DRGs to which cases for VOWST™ administration will be assigned will be the same as compared to the MS-DRGs assigned to an existing technology.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	There are currently no approved therapies indicated to treat a disrupted microbiome in patients with rCDI. Antibacterial drug treatment to kill vegetative C. diff remains a cornerstone of CDI treatment. However, antibiotics alone are often not adequate for patients diagnosed with rCDI. Even when treatment with an antibacterial drug is successful in treating the initial occurrence of CDI, recurrence of CDI occurs in 40% to 60% of patients who had prior infections, with most occurrences after 3 weeks of antibiotic discontinuation. This recurrence stems from the microbiome disturbance often caused by the antibiotic treatment itself or prior exposure to broad-spectrum antibiotics, combined with persistence of C. diff spores not killed by antibiotic treatment. When germination of these C. diff spores overtakes the re-establishment of intestinal microbiota, CDI reemerges together with the need for subsequent treatment. VOWST™ treats rCDI using a two-pronged approach: when followed by antibiotics, which kill the active C. diff infection, VOWST™ prevents the infection from recurring by repairing the microbiome. Thus, unlike antibiotics and ZINPLAVA™, VOWST™ is intended to treat rCDI specifically by reestablishing the microbiome necessary to prevent reinfection. VOWST™ also provides treatment options for patients who cannot currently access other therapies that might be used to treat CDI. In particular, VOWST™ can be administered to patients with a history of congestive heart failure (CHF) where use of ZINPLAVA™ should be reserved per the product prescribing information.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26875 through 26876), we noted the following concern with regard to the newness criterion for VOWST™. The applicant asserted that VOWST™ can be administered to patients with CHF and stated that the use of ZINPLAVA™ (bezlotoxumab) should be reserved in this patient population. We noted that the indication for ZINPLAVA™ does not exclude patients with a history of CHF

and the labeling has no listed contraindications. We sought clarification from the applicant regarding the differences in patient populations for ZINPLAVA™ and VOWST™.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26854 through 26855 and 26875 through 26876), we noted that REBYOTA™ and VOWST™ may have similar mechanism of actions, and both are microbiome therapeutic agents for which we received an application for new technology add-on payments for FY 2024 to reduce the recurrence of rCDI in adults following antibiotic treatment for rCDI, inclusive of the first recurrence. We stated that notably, the exact mechanism of action for each biological product was not yet known; however, both appeared to act on the gut microbiome to suppress C.diff. and thereby prevent rCDI. Both REBYOTA™ and VOWST™ appeared to lead to compositional changes in the gastrointestinal microbiome that restore the diversity of gut flora which enabled each of these therapeutics to suppress outgrowth of C.diff. and rCDI, following standard-of-care treatment with antibiotics for rCDI. Further, we stated that both technologies appeared to map to the same MS–DRGs as each other and as existing technologies, and to treat the same or similar disease (rCDI) in the same or similar patient population (patients who have previously received standard-of-care antibiotics for CDI or rCDI). Accordingly, since it appeared that REBYOTA™ and VOWST™ were purposed to achieve the same therapeutic outcome using a similar mechanism of action and would be assigned to the same MS–DRG, we stated we believed that these technologies may be substantially similar to each other such that they should be considered as a single application for purposes of new technology add-on payments.

We stated that we believe that if these technologies are substantially similar to each other, it is appropriate to use the earliest market availability date submitted as the beginning of the newness period for both technologies (83 FR 41286 through 41287). Therefore, with regard to both technologies, we believed that the beginning of the newness period would be the date on which REBYOTA™ became commercially available, January 23, 2023. We noted that although our policy is generally to begin the newness period on the date of FDA approval or clearance, we may consider a documented delay in the technology's market availability in our determination of newness (87 FR 48977 and 77 FR 53348).

We invited public comment on whether REBYOTA™ or VOWST™ is substantially similar to existing technologies and whether it meets the newness criterion, including whether REBYOTA™ and VOWST™ are substantially similar to each other and therefore should be evaluated as a single technology for purposes of new technology add-on payments.

Comment: The applicant for REBYOTA™ submitted a comment in response to our question as to whether REBYOTA™ is substantially similar to VOWST™. The applicant stated that VOWST™ is an oral microbiome therapeutic consisting of gram-positive Firmicutes, and that administration of VOWST™ cannot begin until at least 8 hours after bowel prep and after 2 to 4 days of completing antibacterial treatment for rCDI. The applicant also noted that administration requirements may be burdensome on both patients and hospitals since patients must take 4 capsules daily on an empty stomach prior to the first meal of the day for 3 consecutive days, and that oral administration issues should be a consideration in older patients. The applicant stated that in comparison, REBYOTA™ is a microbiota suspension that is delivered via rectal administration, contains both gram-positive and gram-negative bacteria, can be administered 24 to 72 hours following the last dose of antibiotics for recurrent CDI, and does not have pretreatment requirements. The applicant also noted that REBYOTA™ studies reported safety and efficacy in older adult (age ≥65 years) patients with comorbid conditions, such as CHF, and that therefore, REBYOTA™ is safe and effective for a broader population of patients.

The applicant for REBYOTA™ also stated that REBYOTA™ is not substantially similar to ZINPLAVA™ because it is available to a broader patient population than those considered high risk for recurrence of CDI, as unlike ZINPLAVA™, REBYOTA™ use is not restricted to high-risk patients and can be administered after the first recurrence of CDI. The applicant noted the different mechanism of action of ZINPLAVA™, which is a human monoclonal antibody that is administered through intravenous infusion and that neutralizes the effect of the *C.diff* toxin by binding to it. The applicant also acknowledged that although the mechanism of action of REBYOTA™ has not been established, in comparison, REBYOTA™ consists of live fecal microbes, including *Bacteroidia* and *Clostridia* classes, which in studies, results in clinically significant changes in patients' gut microbiome associated with restorative microbiome changes that may help resist *C. diff* colonization and recurrence.

The applicant for VOWST™ also submitted a comment maintaining that CMS should not evaluate VOWST™ and REBYOTA™ as a single applicant because the technologies are not substantially similar, arguing that since the mechanism of action for both therapies is unknown, it is not possible to state that the mechanism for both products is the same. The applicant for VOWST™ argued that there is reason to believe its mechanism of action differs from REBYOTA™'s in terms of therapeutic composition, manufacturing process, route of administration, dosage, and storage, stating that in contrast to REBYOTA™, VOWST™ has a low pill burden, containing ~1 percent residual mass comprised of defined consortia of Firmicutes bacterial spores recovered from healthy donor stool. The applicant further stated that the manufacturing process mitigates risk of transmission of agents of infection by including ethanolic inactivation of potential pathogens and removal of non-spore biomass. The applicant also provided an overview of the clinical and scientific evidence for VOWST™, noting differences in effectiveness, safety, and patient care in contrast to REBYOTA™.

The applicant for VOWST™ also stated that VOWST™ is not substantially similar to ZINPLAVA™ because the FDA labeling for VOWST™ does not include a warning or precaution for heart failure, nor a contraindication for any patient population; and that in contrast, the FDA-approved labeling for ZINPLAVA™ concludes that, in patients with a history of CHF, ZINPLAVA™ ''should be reserved for use when the benefit outweighs the risk.''

Response: We appreciate the additional information from both applicants with respect to whether their products are substantially similar to one another or to existing technologies. After consideration of the public comments we received, although we recognize that the exact mechanism of action for each technology is not fully defined, and that the technologies may not be completely the same in terms of their manufacturing process, route of administration, dosage, and storage, we are not convinced that these differences result in a substantially different therapeutic mechanism of action. Both applicants provide sufficient data to

suggest that their mechanisms of action relate to repopulation of the gastrointestinal microbiome. We believe that differences in the clinical and scientific evidence on effectiveness, safety, tolerability, and patient care between REBYOTA™ and VOWST™ relate to an assessment of whether the technologies meet the substantial clinical improvement criterion rather than the newness criterion.

With regard to the commenters noting differences in therapeutic composition, as both technologies are derived from donor human stool, where REBYOTA™ contains both gram-positive and gram-negative bacteria including *Bacteroidia* and *Clostridia* classes, and VOWST™ consists of a defined consortia of gram-positive *Firmicutes* bacteria, we also believe that there is, in fact, an overlap, and that the *Firmicutes* contained in VOWST™ would also exist in the broad consortium of microorganisms contained in the REBYOTA™ suspension. Although there might be slight differences in their proportional contributions to specific downstream molecular pathways, we believe that these two technologies achieve the same therapeutic outcome and overall clinical mechanism of action, as each restores the gut microbiome and resolves dysbiosis to prevent the recurrence of CDI in patients following antibacterial treatment for rCDI by restoring the diversity and composition to one that resembles a healthy microbiome. Furthermore, we believe REBYOTA™ and VOWST™ are substantially similar to one another because the technologies are intended to treat the same or similar disease in the same or similar patient population—indicated for individuals 18 years of age and older, for the prevention of recurrence of CDI, following antibiotic treatment for rCDI, and that potential cases representing patients who may be eligible for treatment would be assigned to the same MS–DRGs.

We also believe REBYOTA™ and VOWST™ are not substantially similar to any other existing technologies because, as both applicants asserted in their FY 2024 new technology add-on payment applications and in their comments, the technologies do not use the same or similar mechanism of action to achieve a therapeutic outcome as any other existing drug or therapy assigned to the same or different MS–DRG. Based on the information described in this section, we believe REBYOTA™ and VOWST™ meet the newness criterion.

Based on the previous discussion, we are making one determination regarding approval for new technology add-on payments that will apply to both applications, and in accordance with our policy, we use the earliest market availability date submitted as the beginning of the newness period for both REBYOTA™ and VOWST™.

We believe our current policy for evaluating new technology payment applications for two technologies that are substantially similar to each other is consistent with the authority and criteria in section 1886(d)(5)(K) of the Act. We note that CMS is authorized by the Act to develop criteria for the purposes of evaluating new technology add-on payment applications. For the purposes of new technology add-on payments, when technologies are substantially similar to each other, we believe it is appropriate to evaluate both technologies as one application for new technology add-on payments under the IPPS, for the reasons we discussed previously and consistent with our evaluation of substantially similar technologies in prior rulemaking (85 FR 58679 and 82 FR 38120).

With respect to the newness criterion, as previously stated, REBYOTA™ received BLA approval from FDA on November 30, 2022, and became commercially available on January 23, 2023. VOWST™ received BLA approval from FDA on April 26, 2023. In accordance with our policy, because these technologies are substantially similar to each other, we use the earliest market availability date submitted as the beginning of the newness period for both technologies. Therefore, with regard to both technologies, we believe that the beginning of the newness period would be the date on which REBYOTA™ became commercially available: January 23, 2023. We note that although our policy is generally to begin the newness period on the date of FDA approval or clearance, we may consider a documented delay in the technology's market availability in our determination of newness (87 FR 48977 and 77 FR 53348).

The applicants submitted separate cost and clinical data, and in the proposed rule, we reviewed and discussed each set of data separately. However, as stated previously, for this final rule, we will make one determination regarding new technology add-on payments that will apply to both applications. We believe that this is consistent with our policy statements in the past regarding substantial similarity (85 FR 58679).

If substantially similar technologies are submitted for review in different (and subsequent) years, rather than the same year, we evaluate and make a determination on the first application and apply that same determination to the second application. However, because these technologies have been submitted for review in the same year, and because we believe they are substantially similar to each other, we consider both sets of cost data and clinical data in making a determination, and we do not believe that it is possible to choose one set of data over another set of data in an objective manner. As we discussed in the proposed rule and as stated previously, each applicant submitted separate analyses regarding the cost criterion for each of their products, and both applicants maintained that their product meets the cost criterion.

With respect to the cost criterion, to identify cases that may be eligible for REBYOTA™, the applicant searched the FY 2021 MedPAR file for claims using ICD–10–CM code A04.71 (Enterocolitis due to Clostridium difficile, recurrent). Using the inclusion/exclusion criteria described in the following table, the applicant identified 14,653 claims mapping to 398 MS–DRGs. Please see Table 10.17.A.—REBYOTA™ Codes—FY 2024 associated with the proposed rule for the complete list of MS–DRGs that the applicant indicated were included in its cost analysis. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $156,292, which exceeded the average case-weighted threshold amount of $71,397. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that REBYOTA™ meets the cost criterion.

REBYOTA™ COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of ICD-10-CM codes	A04.71 (Enterocolitis due to Clostridium difficile, recurrent)
List of MS-DRGs	Please see Table 10.17.A. - REBYOTA™ Codes - FY 2024 associated with the proposed rule for the complete list of MS-DRGs included in the cost analysis.
Inclusion/exclusion criteria	The applicant identified cases with the ICD-10-CM diagnosis code listed in this table. The applicant included only inpatient discharges paid as fee-for-service - claim type ''60.'' Medicare Advantage discharges were excluded. These discharges are excluded when the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field. The applicant used claims from the FY 2021 MedPAR with MS-DRG assignments based on ICD–10 MS–DRG GROUPER Software, Version 40. The applicant calculated the average unstandardized charge per case for each MS-DRG. Cases were excluded if a standardized charge could not be calculated. Any MS-DRG with a total discharge count less than 11 was imputed with a count of 11.
Charges removed for prior technology	The applicant did not remove direct or indirect charges related to the prior technology as REBYOTA™ does not replace prior technologies.
Standardized charges	The applicant used the standardization formula provided in Technical Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2021 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 20.4686% to the standardized charges based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.184 for drugs from the FY 2023 IPPS/LTCH PPS final rule. The cost of the technology per patient is for a single-use dose bag and is based on its wholesale acquisition cost (WAC). The applicant did not add indirect charges related to the new technology.

With respect to the cost criterion, the applicant for VOWST™ conducted the following analysis to demonstrate that VOWST™ meets the cost criterion. To identify cases that may be eligible for the use of VOWST™, the applicant searched the FY 2021 MedPAR file for cases reporting ICD–10–CM code A04.71 (Enterocolitis due to Clostridium difficile, recurrent). Using the inclusion/exclusion criteria described in the following table, the applicant identified 14,497 claims mapping to 392 MS–DRGs. Please see Table 10.22.A.—SER–109 Codes—FY 2024 associated with the proposed rule for the complete list of MS–DRGs the applicant indicated were included in its cost analysis. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $175,157, which exceeded the average case-weighted threshold amount of $69,830. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained that VOWST™ meets the cost criterion.

VOWST™ COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of ICD-10-CM codes	A04.71 (Enterocolitis due to Clostridium difficile, recurrent)
List of MS-DRGs	Please see Table 10.22.A. - SER-109 Codes - FY 2024 associated with the proposed rule for the complete list of MS-DRGs included in the cost analysis.
Inclusion/exclusion criteria	The applicant identified cases reporting ICD-10-CM code A04.71 (Enterocolitis due to Clostridium difficile, recurrent). Only claims that are used for Medicare IPPS rate setting were included: fee-for-service IPPS discharges, plus Maryland hospital discharges. Any MS-DRG with a total discharge count less than 11 was imputed with a count of 11. The applicant calculated the average unstandardized charge per case for each MS-DRG.
Charges removed for prior technology	No charges were removed because VOWST™ would not replace other treatments.
Standardized charges	The applicant used the standardization formula provided in the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 13.2% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant has not yet established the price of VOWST™ or the per-patient cost of the technology to hospitals. However, for the purposes of this analysis, the applicant approximated the per-patient cost related to the technology. The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.184 for drugs from the FY 2023 IPPS/LTCH PPS final rule

We invited public comment on whether VOWST™ or REBYOTA™ meet the cost criterion.

Comment: The applicant for REBYOTA™ submitted a comment regarding an updated cost analysis utilizing its updated final wholesale acquisition cost (WAC). The applicant stated that in the new cost analysis, the final inflated case-weighted average standardized charge per case of $153,574 exceeded the case-weighted threshold of $71,397, demonstrating that the applicant continued to meet the cost criterion.

The applicant for VOWST™ submitted a comment regarding an updated cost analysis utilizing its updated final WAC to confirm their belief that VOWST™ meets the cost criterion because cost threshold analysis demonstrated the final inflated case-weighted standardized charge per case of $329,947 exceeded the case weighted threshold of $95,859, therefore the applicant met the cost criterion.

Response: We thank the applicants for their comments and appreciate the updated cost analyses. We agree that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount for both REBYOTA™ and VOWST™. Therefore, both REBYOTA™ and VOWST™ meet the cost criterion.

With respect to the substantial clinical improvement criterion, the applicant for REBYOTA™ asserted that REBYOTA™ represents a substantial clinical improvement over existing technologies because it offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, and because the use of REBYOTA™ significantly improves clinical outcomes relative to the treatment options previously available. The applicant provided eight studies to support these claims, as well as background articles about occurrence and treatment of CDI and rCDI.[94] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for REBYOTA™ for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

[94] Background articles are not included in the table in this section but can be accessed via the online posting for the technology.

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Outcome(s) or findings cited by the applicant from supporting evidence to support its statements**
REBYOTA™ is an FDA-approved treatment option that addresses the inconsistent safety and efficacy results for FMT.	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.	
REBYOTA™ provides an FDA-approved intervention for the prevention of rCDI in patients following standard-of-care antibiotic therapy for rCDI	Blount KF, Shannon WD, Deych E, Jones C. Restoration of bacterial microbiome composition and diversity among treatment responders in a phase 2 trial of REBYOTA™: an investigational microbiome restoration therapeutic. Open Forum Infect Dis. 2019;6(4):ofz095. Brief study description: A randomized, double-blinded placebo-controlled phase 2B trial.	60% (50/83) of patients who received ≥1 dose of REBYOTA™ achieved treatment success vs 43% (19/44) of patients who received placebo. The overall gut composition was significantly different between placebo responders and REBYOTA™ responders 60 days after treatment (P=0.02; Wald-type test), confirming that REBYOTA™ treatment is more effective at shifting the microbiome composition.
	Blount K, Walsh D, Gonzalez C, et al. Treatment success in reducing recurrent Clostridioides difficile infection with investigational live biotherapeutic REBYOTA™ is associated with microbiota restoration: consistent evidence from a phase 3 clinical trial. Abstract presented at: 10th Annual ID Week; September29, 2021. Brief study description: Results from the PUNCH CD3 study, a Phase 3 randomized, double-blinded, placebo controlled (2:1) study of REBYOTA™ versus placebo to reduce rCDI.	REBYOTA™ induced significant shifts to the intestinal microbiota of treatment-responsive participants. Changes among REBYOTA™-treated responders were significantly different than among placebo-treated responders (P<0.001). REBYOTA™-treated responders demonstrated more rapid and more extensive recovery of Bacteroidia and decreased Gammaproteobacteria relative to placebo-treated responders. Among PUNCH CD3 clinical responders, REBYOTA™ significantly increased taxa associated with health and decreased taxa associated with C. difficile pathology, and these shifts were durable to at least 6 months.
	Papazyan R, Ferdyan N, Gonzalez C, et al. Rapid restoration of bile acid compositions after treatment with REBYOTA™ for recurrent Clostridioides difficile infection—results from the PUNCH CD3 phase 3 trial. Abstract presented at: 10th Annual IDWeek; September 29, 2021. Brief study description: See PUNCH CD3 study description as previously detailed. This analysis included 487 longitudinal stool samples from 192 participants.	Commensals (for example, Clostridia and Bacteroidia) in the colon convert primary Bile Acids (BAs) into secondary BAs, contributing to suppression of C. difficile outgrowth in a healthy gut, measured by a high secondary-BA-to-primary-BA (S:P) fecal concentration ratio. Treatment responders (both those treated with REBYOTA™ and placebo) had a higher S:P ratio; treatment failure was associated with a lower S:P ratio. The S:P ratio in responders (REBYOTA™-treated and placebo) was significantly different than in non-responders (REBYOTA™-treated and placebo) (P=0.00033).
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
REBYOTA™ is an FDA-approved intervention with potential earlier use than FMT in reducing rCDI	Bancke L, Su X. Efficacy of investigational microbiota-based live biotherapeutic REBYOTA™ in individuals with recurrent Clostridioides difficile infection: data from five prospective clinical studies. Abstract presented at: 10th Annual IDWeek; September 29, 2021. Abstract 167. Brief study description: A summary of REBYOTA™ efficacy in treating rCDI using data from five prospective clinical studies, two phase 3 RCTs (PUNCH CD3, PUNCH CD3-OLS *ad hoc* analysis), and three phase 2 open label studies (PUNCH CD, PUNCH CD2, PUNCH CD Open Label).	Across 5 trials with consistent investigational product and clinical endpoints, REBYOTA™ consistently reduced rCDI within 8 weeks after treatment.

	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
REBYOTA™ is an FDA-approved therapeutic option for some patients who may not be eligible for treatment with ZINPLAVA™	Feuerstadt P, Harvey A, Bancke L. REBYOTA™, an investigational live microbiota-based biotherapeutic, improves outcomes of Clostridioides difficile infection in a real-world population: a retrospective study of use under an FDA enforcement discretion. Abstract for ACG2021. Brief study description: A retrospective analysis of a primary safety set (PSS) population who had not previously been treated with REBYOTA™.	REBYOTA™ has been studied in a broad patient population, with no significant differences in safety and efficacy outcomes among subgroups including age, gender, race, number of previous cases of rCDI, or presence of certain common comorbid conditions, such as IBS.
	Braun T, Guthmueller B, Harvey A. Safety of investigational microbiota-based live biotherapeutic REBYOTA™ in individuals with recurrent Clostridioides difficile infection: data from five prospective clinical studies. Abstract presented at: 10th Annual IDWeek; September 29, 2021 Brief study description: Poster presentation pooling the safety data from five prospective studies (three Phase 2 and two Phase 3).	Among 832 clinical trial participants who received ≥1 treatment with REBYOTA™ or placebo, 571 (68.6%) experienced ≥1 treatment emergent adverse events (TEAEs). In all treatment groups, most TEAEs were mild or moderate in severity, with most being GI-related. No potentially life-threatening TEAEs were considered related to REBYOTA™. REBYOTA™ was well-tolerated, with low incidence of discontinuation in REBYOTA™-treated participants: <1% (7/749) vs 0% (0/83) for placebo. Overall, study participants treated with REBYOTA™ were older and had more previous CDI recurrences than placebo-treated patients.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available.		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Outcome(s) or findings cited by the applicant from supporting evidence to support its statements**
REBYOTA™ offers a sustained clinical response	Orenstein R, Mische S, Blount D, et al. A long-time coming: final 2-year analysis of efficacy, durability, and microbiome changes in a controlled open-label trial of investigational microbiota-based drug REBYOTA™ for recurrent Clostridioides difficile infections. IDWeek 2019 late breaker oral abstract LB5. Open Forum InfectDis. 2019;6(Suppl 2):S994-S995. Brief study description: A 2-year analysis that studied the clinical safety, efficacy, and durability of REBYOTA™ in a Phase 2 open-label trial.	Among REBYOTA™-treated participants, 79% (112/142) were recurrence-free at 8 weeks after treatment. At 6 months, 97% of evaluable primary REBYOTA™ responders (104/107) remained infection-free. At 12 months, 95% of evaluable primary REBYOTA™ responders (98/103) remained infection-free. At 24 months, 91% of evaluable primary REBYOTA™ responders (87/95) remained infection-free.
Fewer serious adverse events related to the administration and use of REBYOTA™ than FMT	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.	

Fewer serious adverse events with REBYOTA™ than with ZINPLAVA™	Braun T, Guthmueller B, Harvey A. Safety of investigational microbiota-based live biotherapeutic REBYOTA™ in individuals with recurrent Clostridioides difficile infection: data from five prospective clinical studies. Abstract presented at: 10th Annual IDWeek; September 29, 2021. See prior study description.	Among 832 clinical trial participants who received ≥1 treatment with REBYOTA™ or placebo, 571 (68.6%) experienced ≥1 treatment emergent adverse events (TEAEs). In all treatment groups, most TEAEs were mild or moderate in severity, with most being GI-related. No potentially life-threatening treatment-emergent AEs were considered related to REBYOTA™. REBYOTA™ was well-tolerated, with low incidence of discontinuation in REBYOTA™-treated participants: <1% (7/749) vs 0% (0/83) for placebo. One TEAE-related death occurred within 30 days of treatment. This death was assessed as possibly related to REBYOTA™ or its administration procedure and related to CDI and a preexisting condition. Overall, study participants treated with REBYOTA™ were older and had more previous CDI recurrences than placebo-treated patients.
REBYOTA™ is indicated for a broader patient population than either FMT or ZINPLAVA™	Feuerstadt P, Harvey A, Bancke L. REBYOTA™, an investigational live microbiota-based biotherapeutic, improves outcomes of Clostridioides difficile infection in a real-world population: a retrospective study of use under an FDA enforcement discretion. Abstract for ACG2021. Brief study description: See prior study description.	REBYOTA™ has been studied in a broad patient population, with no significant differences in safety and efficacy outcomes among subgroups including age, gender, race, number of previous cases of rCDI, or presence of certain common comorbid conditions, such as IBS.
REBYOTA™ is the only FDA-approved therapy indicated for reduction of rCDI that addresses dysbiosis	Papazyan R, Ferdyan N, Gonzalez C, et al. Rapid restoration of bile acid compositions after treatment with REBYOTA™ for recurrent Clostridioides difficile infection—results from the PUNCH CD3 phase 3 trial. Abstract presented at: 10th Annual IDWeek; September 29, 2021. See prior study description.	In clinical responders, REBYOTA™ significantly restored bile acids (BA) toward healthier compositions. Significant and durable BA changes occur as early as 1-week post-treatment with REBYOTA™. These clinically correlated BA shifts are highly consistent with results from a prior trial of REBYOTA™.
	Garcia-Diaz J, Jones C, Karathia H, Fanelli B, Hasan NA, Blount K. Response to microbiota-based drug REBYOTA™ is associated with reduction in antimicrobial resistance genes in patients with recurrent Clostridioides difficile infections. Presented at: ASM Microbe 2019; June 20-24, 2019; San Francisco, CA. Brief study description: PUNCH Open Label: a prospective, multicenter, open label Phase 2 study assessing the efficacy and safety of REBYOTA™ treatment of rCDI in patients with multi rCDI (≥2 recurrent episodes at enrollment).	Participants were dysbiotic at study entry, with decreased Bacteroidia and Clostridia and overabundance of Gammaproteobacteria and Bacilli. Bacteroidia and Clostridia increased, while Gammaproteobacteria and Bacilli decreased after treatment. Changes were durable to 6 months after treatment.

	Blount KF, Shannon WD, Deych E, Jones C. Restoration of bacterial microbiome composition and diversity among treatment responders in a phase 2 trial of REBYOTA™: an investigational microbiome restoration therapeutic. Open Forum Infect Dis. 2019;6(4):ofz095. See prior study description.	Exposure to broad-spectrum antibiotics is an important risk factor for primary CDI and rCDI. In a randomized double-blinded placebo-controlled phase 2B trial, participants who received ≥1 dose of REBYOTA™ had fewer CDI recurrences than placebo-treated participants 8 weeks after treatment. The overall composition was significantly different between placebo responders and REBYOTA™ responders 60 days after treatment (P=0.02; Wald-type test), confirming that REBYOTA™ treatment is more effective at shifting the microbiome composition.
	Blount K, Walsh D, Gonzalez C, et al. Treatment success in reducing recurrent Clostridioides difficile infection with investigational live biotherapeutic REBYOTA™ is associated with microbiota restoration: consistent evidence from a phase 3 clinical trial. Abstract presented at: 10th Annual IDWeek; September 29, 2021. See prior study description.	REBYOTA™ induced significant shifts to the intestinal microbiota of treatment-responsive participants. Changes among REBYOTA™-treated responders were significantly different than among placebo-treated responders (P<0.001). REBYOTA™-treated responders demonstrated more rapid and more extensive recovery of Bacteroidia and decreased Gammaproteobacteria relative to placebo-treated responders. Among PUNCH CD3 clinical responders, REBYOTA™ significantly increased taxa associated with health and decreased taxa associated with C. difficile REBYOTA™-treated subjects showed more rapid and extensive recovery of Bacteroidia and decreased Gammaproteobacteria relative to placebo-treated subjects, and the effects lasted for at least 6 months post-treatment.
	Orenstein R, Mische S, Blount D, et al. A long-time coming: final 2-year analysis of efficacy, durability, and microbiome changes in a controlled open-label trial of investigational microbiota-based drug REBYOTA™ for recurrent Clostridioides difficile infections. IDWeek 2019 late breaker oral abstract LB5. Open Forum InfectDis. 2019;6(Suppl 2):S994-S995. See prior study description.	At 6 months, 97% of the evaluable primary REBYOTA™ responders (104/107) remained infection-free, while 95% of evaluable primary REBYOTA™ responders (98/103) were infection-free at 12 months.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Efficacy of REBYOTA™	Blount KF, Shannon WD, Deych E, Jones C. Restoration of bacterial microbiome composition and diversity among treatment responders in a phase 2 trial of REBYOTA™: an investigational microbiome restoration therapeutic. Open Forum Infect Dis. 2019;6(4):ofz095. See prior study description.	In a phase 2 RCT, 60% (50/83) of patients who received ≥1 dose of REBYOTA™ achieved treatment success vs 43% (19/44) of patients who received placebo. REBYOTA™ is manufactured through a consistent quality-controlled process to minimize variation.
	Bancke L, Su X. Efficacy of investigational microbiota-based live biotherapeutic REBYOTA™ in individuals with recurrent Clostridioides difficile infection: data from five prospective clinical studies. Abstract presented at: 10th Annual IDWeek; September 29, 2021. Abstract 167 See prior study description.	Overall, the majority of primary REBYOTA™ responders remained CDI-free to 6 months and up to 24 months post-treatment, with success rates in the phase 3 program ranging from 82.0% to 92.1%. Separation in treatment success between REBYOTA™ and placebo was durable through 6 months. There was a higher recurrence rate in the placebo-treated patients. Across 5 trials with consistent investigational product and clinical endpoints, REBYOTA™ consistently reduced rCDI within 8 weeks after treatment.

	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26859 through 26860), we stated that we had the following concerns regarding whether REBYOTA™ meets the substantial clinical improvement criterion. Regarding the assertion that REBYOTA™ is an FDA-approved therapeutic option for some patients who may not be eligible for treatment with ZINPLAVA™ due to patient population restrictions (for example, high-risk patients) or contraindications (for example, history of congestive heart failure [CHF]), and that there is no evidence that REBYOTA™ poses an increased risk of serious AEs in patients with a history of CHF, the applicant cited a retrospective study of REBYOTA™ reported by Feuerstadt et al.[95] in which 94 participants with comorbid conditions commonly found in people with rCDI were treated with REBYOTA™. The analysis showed a treatment success rate of 82.8 percent, with no observable difference between participants who received one dose (83.3%) vs. two doses (82.5%). We noted that the comorbid conditions represented in this population included: gastroesophageal reflux disease (47.9%); irritable bowel syndrome (17%); gastritis (11.7%); constipation (8.5%); microscopic colitis (7.4%); diverticulitis (6.4%); Crohn's disease (5.3%); and ulcerative colitis (4.3%) but did not include patients with CHF as a comorbidity. We believed additional information regarding whether REBYOTA™ was tested in patients with CHF to determine clinical outcomes would be helpful to evaluate the applicant's assertion. The applicant also referenced a poster presentation by Braun et al.[96] that presents the safety data from five prospective studies in which 749 pooled participants received at least one dose of REBYOTA™, and 83 participants received placebo only to support its assertion. We stated that additional information demonstrating whether REBYOTA™ is safe for the patient population with CHF would help inform our assessment of whether REBYOTA™ demonstrates substantial clinical improvement over existing technologies.

Regarding the claim of sustained clinical response, the applicant referenced an abstract of an open-label trial of REBYOTA™ by Orenstein et al. This trial was a Phase 2 open-label trial where participants with multiple rCDI received two doses of REBYOTA™ administered 7 + 2 days apart. Researchers conducted a 2-year analysis of the clinical safety, efficacy, and durability of REBYOTA™. The absence of rCDI was compared between the REBYOTA™ and a historical control cohort that received standard-of-care antibiotic therapy. Durability was defined as continued absence of CDI episodes beyond 8 weeks, and was assessed at 3, 6, 12, and 24 months by assessing changes in stool samples. While the applicant submitted results from both a phase 2 trial of REBYOTA™,[97] and the PUNCH CD3 phase 3 trial [98] to demonstrate the superiority of REBYOTA™ over placebo, we questioned whether other treatment options indicated to prevent rCDI, such as ZINPLAVA™, would be a more appropriate comparator. We noted that additional information regarding clinical outcomes as a result of treatment with REBYOTA™ compared to ZINPLAVA™ would be helpful to assess the substantial clinical improvement criterion. In summary, while we understood that there were no head-to-head trials comparing REBYOTA™ to ZINPLAVA™, we indicated that additional information would help inform our assessment of whether REBYOTA™ demonstrated a substantial clinical improvement over existing technologies.

With regard to the substantial clinical improvement criterion, the applicant for VOWST™ asserted that VOWST™ represents a substantial clinical improvement over existing technologies because VOWST™ treats patients unresponsive to antibiotic treatment for rCDI and can be used in patients ineligible for ZINPLAVA™ due to CHF. The applicant also asserted that it improves clinical outcomes by reducing rCDI, increasing resolution of the disease process by expediting microbiome repair, and reducing carriage of antimicrobial resistance genes. The applicant provided five studies to support these claims, as well as 11 background articles about CDI recurrence and risks of increased exposure to antibiotic therapies in a hospital setting for rCDI and cardiac risk of prescribing existing treatments, such as ZINPLAVA™, to patients with pre-existing heart failure.[99] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for VOWST™ for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

[95] Feuerstadt P, Harvey A, Bancke L. REBYOTA™, an investigational live microbiota-based biotherapeutic, improves outcomes of Clostridioides difficile infection in a real-world population: a retrospective study of use under an FDA enforcement discretion. Abstract for ACG2021.

[96] Braun T, Guthmueller B, Harvey A. Safety of investigational microbiota-based live biotherapeutic REBYOTA™ in individuals with recurrent Clostridioides difficile infection: data from five prospective clinical studies. Abstract presented at: 10th Annual IDWeek; September 29, 2021.

[97] Blount KF, Shannon WD, Deych E, Jones C. Restoration of bacterial microbiome composition and diversity among treatment responders in a phase 2 trial of REBYOTA™: an investigational microbiome restoration therapeutic. Open Forum Infect Dis. 2019;6(4):ofz095.

[98] Blount K, Walsh D, Gonzalez C, et al. Treatment success in reducing recurrent Clostridioides difficile infection with investigational live biotherapeutic REBYOTA™ is associated with microbiota restoration: consistent evidence from a phase 3 clinical trial. Abstract presented at: 10th Annual IDWeek; September 29, 2021.

[99] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Substantial Clinical Improvement Criterion: Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Outcome(s) or findings cited by the applicant from supporting evidence to support its statements**
VOWST™ (SER-109) can be used in patients ineligible for ZINPLAVA™ due to diagnosis of congestive heart failure (CHF).	McGovern et al., SER-109 an Investigational Microbiome Drug to Reduce Recurrence After Clostridioides difficile Infection: Lessons Learned From a Phase 2 Trial. Clin Infect Dis 2021;72(12):2132–2140, https://doi.org/10.1093/cid/ciaa387. Brief study description: Multi-center, randomized, double-blind placebo-controlled phase 2 clinical trial that evaluated the safety and efficacy of VOWST™ (SER-109) versus placebo to reduce rCDI.	VOWST™ (SER-109) was generally well tolerated among subjects. Adverse events (Aes) occurred in 76.7% (46/60) subjects given VOWST™ (SER-109) and 20 of 29 (69.0%) subjects on the placebo. Aes were generally mild to moderate in severity. Six subjects (10.0%) on VOWST™ (SER-109) experienced a severe AE; none of these severe Aes were considered related to the study drug. These did not differ by treatment arm (55.0% VOWST™ (SER-109) vs 44.8% placebo; P = .44). Overall, 16.9% of subjects experienced an AE that the investigator considered to be related or possibly related to the study drug, including 18.3% on VOWST™ (SER-109) and 13.8% on placebo. 13.5% (12/89) subjects experienced a serious AE: 15.0% (9/60) subjects who received VOWST™ (SER-109) and 10.3% (3/29) who received placebo. None of the serious Aes were considered treatment-related.
	Khanna S, Feuerstadt P, Huang E, et al. An open-label study (ECOSPOR IV) to evaluate the safety, efficacy, and durability of SER-109 in adults with recurrent Clostridioides difficile infection (rCDI). Am College Gastroenterol 2022 Annual Scientific Meeting. Charlotte, NC. Abstract 63. Brief study description: Phase 3, open label, single-arm study. Following standard-of-care antibiotics with vancomycin or fidaxomicin.	VOWST™ (SER-109) was well-tolerated. Overall, 137 subjects (52.1%) experienced treatment-emergent adverse events (TEAEs) through week 8; the majority were mild to moderate in intensity and gastrointestinal. There were 6 deaths (2.3%) and 20 subjects (7.6%) had serious TEAEs, none of which were deemed treatment-related.
	Supplement to: Feuerstadt P, Louie TJ, Lashner B, et al. SER-109, an oral microbiome therapy for recurrent Clostridioides difficile infection. N Engl J Med 2022;386:220-9. DOI: 10.1056/NEJMoa2106516 Brief study description: Double-blind, placebo-controlled trial to show superiority of VOWST™ (SER-109) as compared to placebo in reducing the risk of C. diff infection recurrence up to 8 weeks after treatment.	The only reported SAE for worsening of CHF was among the placebo group; no such SAEs were reported among the VOWST™ (SER-109) test group.
	Cohen, Stuart H., Louie, Thomas J., et al. Extended Follow-up of Microbiome Therapeutic SER-109 Through 24 Weeks for Recurrent Clostridioides difficile Infection in a Randomized Clinical Trial. JAMA. Published Online: October 19, 2022. Doi:10.1001/jama.2022.16476 Brief study description:	This study provides 24-week follow-up data for the Phase III study (VOWST™ (SER-109), an Oral Microbiome Therapy for Recurrent Clostridioides difficile Infection ("ECOSPOR III")) and supplement. Benefit from VOWST™ (SER-109) was evident at week 2 and durable through 24 weeks. ECOSPOR III included 182 participants (89 given VOWST™ (SER-109) and 93 given placebo); this October 2022 study assessed prespecified secondary

	ECOSPOR III was a double-blind, randomized, multicenter trial with patients randomized to receive VOWST™ (SER-109) or matching placebo administered as 4 capsules daily for 3 days	endpoints of adverse events (Aes) and durability of response through 24 weeks and time to recurrence. After 24 weeks, 63 of 182 participants had recurring CDI (19 in the VOWST™ (SER-109) group, compared to 44 in placebo). At 4, 8, 12, and 24 weeks, a significantly lower proportion of patients given VOWST™ (SER-109) experienced recurrence, compared to placebo. Serious Aes occurred in 15 patients given VOWST™ (SER-109) and 19 in placebo; none were considered drug-related. Overall, VOWST™ (SER-109) durably reduced rates of recurring CDI and was well-tolerated through 24 weeks in patients with prevalent comorbidities.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
VOWST™ (SER-109) treats patients who have been unresponsive to antibiotics, as evidenced by their rCDI, by reducing rates of CDI recurrence.	Khanna S, Feuerstadt P, Huang E, et al. An open-label study (ECOSPOR IV) to evaluate the safety, efficacy, and durability of SER-109 in adults with recurrent Clostridioides difficile infection (rCDI). Am College Gastroenterol 2022 Annual Scientific Meeting. Charlotte, NC. Abstract 63. See prior study description	Among patients treated with VOWST™ (SER-109), the rate of CDI recurrence was low through week 8, which is consistent with results in the Phase 3 randomized controlled trial (ECOSPOR III). At week 8, 23 of 263 (8.7%) participants had recurring CDI: the rate of recurrence among patients with one recurring CDI episode was 6.5% (5/77), and 9.7% (18/186) among those with at least two recurrent episodes. CDI rates remained low through 24 weeks: 13.7% (36/263 participants).
	McGovern, et al., SER-109, an Investigational Microbiome Drug to Reduce Recurrence After Clostridioides difficile Infection: Lessons Learned From a Phase 2 Trial. Clin Infect Dis 2021;72(12):2132–2140, https://doi.org/10.1093/cid/ciaa387. See prior study description	In the overall population, there was no significant difference in CDI recurrence rates between VOWST™ (SER-109) or placebo subjects (44.1% vs 53.3%; RR, 1.2; 95% CI, .8–1.9). However, the primary endpoint by age stratum showed that VOWST™ (SER-109) significantly reduced recurrence, compared with placebo, among those aged 65 years or older (45.2% vs 80%, respectively; RR, 1.8; 95% CI, 1.1–2.8).
	Feuerstadt P, Louie TJ, Lashner B, et al., SER-109, an oral microbiome therapy for recurrent Clostridioides difficile infection. N Engl J Med 2022;386:220-9. DOI: 10.1056/NEJMoa2106516 See prior study description	VOWST™ (SER-109) was found to be superior to the placebo in reducing risk of CDI recurrence: The percentage of patients with recurrence was significantly lower in the VOWST™ (SER-109) group than in the placebo group (12% and 40%, respectively; relative risk, 0.32; 95% confidence interval [CI], 0.18 to 0.58; P<0.001 for both hypotheses tested). In the analysis of the alternative metric of sustained clinical response, 88% of the VOWST™ (SER-109) recipients were found to have a sustained clinical response, as compared with 60% of the placebo recipients VOWST™ (SER-109) also led to lower percentages of patients with C. difficile infection recurrence than did placebo in the age-stratified analysis (relative risk, 0.24 [95% CI, 0.07 to 0.78] among patients <65 years of age and 0.36 [95% CI, 0.18 to 0.72] among those ≥65 years of age) and in the antibiotic-stratified analysis (relative risk, 0.41 [95% CI, 0.22 to 0.79] among patients who took vancomycin and 0.09 [95% CI, 0.01 to 0.63] among those who took fidaxomicin). However, more patients were treated with vancomycin than with fidaxomicin." (Efficacy pg. 224, para 1-2) Further, study results showed the benefit of VOWST™ (SER-109) as compared with placebo (that is, antibiotics alone) in patients with recurrent disease was also observed among age- and antibiotic. . . -stratified groups. Additionally, [a]lthough fidaxomicin is

		viewed as less disruptive than vancomycin to microbial communities, the higher percentages of recurrence in the fidaxomicin–placebo subgroup highlight the paradox of treating an antibiotic-associated disease, rooted in microbiome disruption, with antibiotics alone.
	Cohen, Stuart H., Louie, Thomas J., et al. Extended Follow-up of Microbiome Therapeutic SER-109 Through 24 Weeks for Recurrent Clostridioides difficile Infection in a Randomized Clinical Trial. JAMA. Published Online: October 19, 2022. doi:10.1001/jama.2022.16476 See prior study description	This study provides 24-week follow-up data for the Phase III study, "ECOSPOR III" and supplement. Benefit from VOWST™ (SER-109) was evident at week 2 and durable through 24 weeks. After 24 weeks, 63 of 182 participants had recurring CDI (19 in the VOWST™ (SER-109) group, compared to 44 in placebo). At 4, 8, 12, and 24 weeks, a significantly lower proportion of patients given VOWST™ (SER-109) experienced recurrence, compared to placebo. Serious AEs occurred in 15 patients given VOWST™ (SER-109) and 19 in placebo; none were considered drug-related. Overall, VOWST™ (SER-109) durably reduced rates of recurring CDI and was well-tolerated through 24 weeks in patients with prevalent comorbidities.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Substantial Clinical Improvement Criterion Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available.		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Outcome(s) or findings cited by the applicant from supporting evidence to support its statements**
There is an increased resolution of the disease process because of the use of the VOWST™ (SER-109) technology.	Feuerstadt P, Louie TJ, Lashner B, et al., SER-109, an oral microbiome therapy for recurrent Clostridioides difficile infection. N Engl J Med 2022;386:220-9. DOI: 10.1056/NEJMoa2106516 See prior study description	See study outcomes previously described
	McGovern et al., SER-109, an Investigational Microbiome Drug to Reduce Recurrence After Clostridioides difficile Infection: Lessons Learned From a Phase 2 Trial. Clin Infect Dis 2021;72(12):2132–2140, https://doi.org/10.1093/cid/ciaa387. See prior study description	The study assessed engraftment by comparing the number of dose-species in stool samples at 3 time points. Minimal VOWST™ (SER-109) dose-species were detected at baseline (that is, following cessation of antibiotic) in either treatment arm. As early as week 1 following dosing, subjects receiving VOWST™ (SER-109) had significantly more dose-species than those on placebo; this response was durable through 8 weeks (P <0.001 for all comparisons; MannWhitney U test)" (P 2135, par 4) The study evaluated whether the degree of engraftment differed by clinical outcome. Since 50% of recurrences were observed by day 11, the study compared dose-species diversity at baseline and week 1 by clinical outcome. Before VOWST™ (SER-109) treatment, dose-species diversity was not associated with outcome in either treatment group (Mann-Whitney U test). At week 1, VOWST™ (SER-109)–treated subjects with non-recurrence had significantly more dose-species than those who did experience a recurrence (P <0.05, Mann-Whitney U test). This association was not observed in placebo recipients at week 1. Although VOWST™ (SER-109) was associated with a significant reduction in recurrence among

		subjects aged 65 years or older, age had no impact on the magnitude of engraftment. (P 2136, par 1) To understand the association of VOWST™ (SER-109) engraftment with non-recurrence, study evaluated the relationship between engraftment and the abundance of secondary bile acids (BAs), previously shown to inhibit C. difficile germination. At week 1, there was a significant positive correlation between the number of VOWST™ (SER-109) species and the abundance of secondary BAs lithocholic acid (LCA) and deoxycholic acid (DCA), as shown in Fig. 5 (Spearman correlation, P <0.0001 for both comparisons). In subjects receiving VOWST™ (SER-109), DCA and LCA levels were higher in subjects with nonrecurrent CDI compared with subjects who experienced recurrence before week 8; however, these observations were not significant (P = 0.08 and 0.10, respectively; MannWhitney U test).
	Khanna S, Feuerstadt P, Huang E, et al. An open-label study (ECOSPOR IV) to evaluate the safety, efficacy, and durability of SER-109 in adults with recurrent Clostridioides difficile infection (rCDI). Am College Gastroenterol 2022 Annual Scientific Meeting. Charlotte, NC. Abstract 63. See prior study description	Earlier intervention with VOWST™ (SER-109) in first recurrence may reduce morbidity associated with rCDI. In study participants evaluated following first recurrence of C. difficile infection, 5/77 (6.5%) had a recurrent event compared with 18/186 (9.7%) of participants who entered the study with two or more prior recurrences. This reduction in recurrent infections eliminates the need for subsequent treatment interventions in those individuals who respond to VOWST™ (SER-109) after a first recurrence. Such earlier intervention (that is., after the first recurrence) with VOWST™ (SER-109) may reduce the healthcare burden of further CDI episodes.
	Cohen, Stuart H., Louie, Thomas J., et al. Extended Follow-up of Microbiome Therapeutic SER-109 Through 24 Weeks for Recurrent Clostridioides difficile Infection in a Randomized Clinical Trial. JAMA. Published Online: October 19, 2022. doi:10.1001/jama.2022.16476 See prior study description	This study provides 24-week follow-up data for the Phase III study, "ECOSPOR III" and supplement. Benefit from VOWST™ (SER-109) was evident at week 2 and durable through 24 weeks. After 24 weeks, 63 of 182 participants had recurring CDI (19 in the VOWST™ (SER-109) group, compared to 44 in placebo). At 4, 8, 12, and 24 weeks, a significantly lower proportion of patients given VOWST™ (SER-109) experienced recurrence, compared to placebo. Serious AEs occurred in 15 patients given VOWST™ (SER-109) and 19 in placebo; none were considered drug-related. Overall, VOWST™ (SER-109) durably reduced rates of recurring CDI and was well-tolerated through 24 weeks in patients with prevalent comorbidities.
VOWST™ (SER-109) may reduce the number of future hospitalizations or physician visits for patients diagnosed with rCDI.	Feuerstadt P, Stong L, Dahdal D, et al., Healthcare resource utilization and direct medical costs associated with index and recurrent Clostridioides difficile infection: a real-world data analysis, J Med Econ 2020;23:603–609, DOI: 10.1080/13696998.2020.1724117 Brief study description: Retrospective analysis of commercial claims data from the IQVIA PharMetrics Plus database for patients ages 18–64 with CDI episodes requiring inpatient stay with CDI diagnosis code or an	The mean time from one CDI episode to another recurrence was approximately 1 month regardless of number of prior recurrences. In the 12-month follow-up period, those with no recurrence had 1.4 inpatient visits per person and those with 3 or more recurrences had 5.8 inpatient visits per person. Most patients who had 3 or more recurrences had 2 or more hospital admissions. The mean annual, total all-cause direct medical costs per patient were $71,980 for those with no recurrence and rose (by $59,973) to a total of $131,953 for first recurrence, a total of $180,574 from the first to second recurrence, and a total of $207,733 for those with three or more

	outpatient medical claim for CDI plus a CDI treatment. Index CDI episodes occurred between Jan. 1, 2010–June 30, 2017.	recurrences. The study found that inpatient costs were the key cost driver, accounting for 61–70% of the total costs across the study cohorts. Furthermore, HRU was high for all patients with an index CDI, with the highest utilization for those with 3 or more CDI recurrences.
	Feuerstadt P, Louie TJ, Lashner B, et al., SER-109, an oral microbiome therapy for recurrent Clostridioides difficile infection. N Engl J Med 2022;386:220-9. DOI: 10.1056/NEJMoa2106516 See prior study description	The benefit of VOWST™ (SER-109) as compared with placebo (that is, antibiotics alone) in patients with recurrent disease was also observed among age- . . . -stratified groups. As demonstrated in the ECOSPOR III study, VOWST™ (SER-109) reduced CDI reinfection among Medicare-eligible patients (those ≥65 years of age), compared to those taking a placebo, 17% vs 46% (absolute difference, –29%), respectively, [relative risk, 0.36; 95% CI, 0.18 to 0.72]. A reduction in the risk of recurrence among patients 65 years of age or older is clinically important, since patients in this age group are at increased risk for recurrent disease and hospital readmission.
	Cohen, Stuart H., Louie, Thomas J., et al. Extended Follow-up of Microbiome Therapeutic SER-109 Through 24 Weeks for Recurrent Clostridioides difficile Infection in a Randomized Clinical Trial. JAMA. Published Online: October 19, 2022. doi:10.1001/jama.2022.16476 See prior study description	This study provides 24-week follow-up data for the Phase III study, "ECOSPOR III" and supplement. Benefit from VOWST™ (SER-109) was evident at week 2 and durable through 24 weeks. After 24 weeks, 63 of 182 participants had recurring CDI (19 in the VOWST™ (SER-109) group, compared to 44 in placebo). At 4, 8, 12, and 24 weeks, a significantly lower proportion of patients given VOWST™ (SER-109) experienced recurrence, compared to placebo. Serious AEs occurred in 15 patients given VOWST™ (SER-109) and 19 in placebo; none were considered drug-related. Overall, VOWST™ (SER-109) durably reduced rates of recurring CDI and was well-tolerated through 24 weeks in patients with prevalent comorbidities.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
VOWST™ (SER-109) is well-tolerated and mitigates the safety concerns of other alternative therapies.	Feuerstadt P, Louie TJ, Lashner B, et al., SER-109, an oral microbiome therapy for recurrent Clostridioides difficile infection. N Engl J Med 2022;386:220-9. DOI: 10.1056/NEJMoa2106516Study 3 See prior study description	No serious adverse events that were assessed by the site investigator as being related to VOWST™ (SER-109) were observed through week 8. Adverse events that were related or possibly related to VOWST™ (SER-109) or placebo occurred in slightly more than half of the patients in each group. The most common adverse events were gastrointestinal disorders, the majority of which were mild to moderate in nature. Three deaths occurred in the VOWST™ (SER-109) group, none of which were deemed by the investigators, who were unaware of the trial-group assignments, to be drug-related.
	Khanna S, Feuerstadt P, Huang E, et al. An open-label study (ECOSPOR IV) to evaluate the safety, efficacy, and durability of SER-109 in adults with recurrent Clostridioides difficile infection (rCDI). Am College Gastroenterol 2022 Annual Scientific Meeting. Charlotte, NC. Abstract 63. See prior study description	See study outcomes previously described
	McGovern et al., SER-109, an Investigational Microbiome Drug to Reduce Recurrence After Clostridioides	See study outcomes previously described

	difficile Infection: Lessons Learned From a Phase 2 Trial. Clin Infect Dis 2021;72(12):2132–2140, https://doi.org/10.1093/cid/ciaa387. See prior study description	
	Cohen, Stuart H., Louie, Thomas J., et al. Extended Follow-up of Microbiome Therapeutic SER-109 Through 24 Weeks for Recurrent Clostridioides difficile Infection in a Randomized Clinical Trial. JAMA. Published Online: October 19, 2022. doi:10.1001/jama.2022.16476 See prior study description	This study provides 24-week follow-up data for the Phase III study, "ECOSPOR III" and supplement. Benefit from VOWST™ (SER-109) was evident at week 2 and durable through 24 weeks. After 24 weeks, 63 of 182 participants had recurring CDI (19 in the VOWST™ (SER-109) group, compared to 44 in placebo). At 4, 8, 12, and 24 weeks, a significantly lower proportion of patients given VOWST™ (SER-109) experienced recurrence, compared to placebo. Serious AEs occurred in 15 patients given VOWST™ (SER-109) and 19 in placebo; none were considered drug-related. Overall, VOWST™ (SER-109) durably reduced rates of recurring CDI and was well-tolerated through 24 weeks in patients with prevalent comorbidities.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Unlike antibiotics, VOWST™ (SER-109) reduces carriage of antimicrobial resistance genes (ARGs) along with associated antibiotic resistance bacteria	Straub T, Diao L, Ford C, et al. SER-109, an investigational microbiome therapeutic, reduces abundance of antimicrobial resistance genes in patients with recurrent Clostridioides difficile infection (rCDI) after standard-of-care antibiotics. IDWeek 2021, OFID 2021:8, S812-S813 (Suppl 1), Late Breaking Abstract #LB15. Brief study description: Double-blind Phase 3 trial of rCDI patients (ECOSPOR III), VOWST™ (SER-109), an orally formulated consortia of purified Firmicutes spores.	rCDI patients in the ECOSPOR-III study had an abundance of ARGs providing resistance against multiple drug classes after completion of standard of care antibiotics, which is not surprising since patients with CDI usually have a history of antibiotic exposure prior to clinical onset of CDI. Treatment with VOWST™ (SER-109) led to a significant decrease in ARG abundance vs. placebo, which was both rapid and sustained through week 8. Further studies will be needed to determine if the significant reduction of ARGs is associated with prevention of subsequent infections with drug resistant bacteria in patients with CDI. For recurrent CDI patients (ECOSPOR III), VOWST™ (SER-109), was superior to placebo in reducing CDI recurrence at week 8 post clinical resolution on standard-of-care (SoC) antibiotics. Overall, recurrence rates were lower in VOWST™ (SER-109) (n=89) vs placebo (n=93) (12.4% vs 39.8%, respectively) relative risk, 0.32 [95% CI, 0.18-0.58; p<0.001 for RR<1.0; p<0.001 for RR<0.833]. This is a post-hoc analysis examining the impact of VOWST™ (SER-109) on antimicrobial resistance genes (ARGs) abundance in the intestinal microbiota compared to placebo at weeks 1, 2, and 8.

In the FY 2024 IPPS/LTCH proposed rule (88 FR 26881 through 26882), after reviewing the information provided by the applicant, we noted that we had the following concerns regarding whether VOWST™ meets the substantial clinical improvement criterion. We stated that to demonstrate that VOWST™ reduces rates of CDI recurrence compared to standard of care therapies, the application primarily cited to the ECOSPOR phase II trial and ECOSPOR III phase III trial. The application also cited an abstract of the open-label single-arm ECOSPOR IV trial which did not appear to provide a comparison against currently available therapies. We stated that the major limitation of these data was that patients who received ZINPLAVA™ in the prior 3 months were excluded. We stated that while the study provided data comparing the effectiveness of VOWST™ to antibiotics alone, no data comparing the treatment of rCDI utilizing antibiotics plus ZINPLAVA™, as was recommended for rCDI, against antibiotics plus VOWST™ (with or without ZINPLAVA™) was provided. Without a comparison against such currently available therapies, we

questioned whether the information provided by the applicant was sufficient to support the applicant's statements that VOWST™ is well-tolerated and mitigates the safety concerns of other alternative therapies, and that VOWST™ can be used in patients ineligible for ZINPLAVA™ due to diagnosis of CHF.

With regard to the claim that VOWST™ can be used safely in patients with CHF, the cited trials either did not identify or document effects on participants with comorbid CHF to support this conclusion. The ECOSPOR trial specifically excluded patients with poor concurrent medical risks or clinically significant co-morbid disease such that, in the opinion of the investigator, the subject should not be enrolled. We stated that it was not clear whether this criterion necessarily excluded individuals with known pre-existing CHF from the study group and that it was also not clear how many individuals diagnosed with CHF prior to or during the study were identified in the study populations. We considered whether a lack of participants with CHF could potentially account for the low incidence of adverse effects, rather than being attributable to the safety of VOWST™ relative to ZINPLAVA™ for patients with CHF. Absent additional information, we stated that it was difficult to confirm that VOWST™ offers a treatment option for patients ineligible for ZINPLAVA™ due to CHF.

The applicant stated that there is an increased resolution of the disease process because VOWST™ expedites microbiome repair during the window of vulnerability, identified as 1–4 weeks after antibiotic discontinuation, by ensuring more rapid engraftment of beneficial Firmicutes bacteria needed to decrease germination of C. diff. spores and prevent recurrence. For this claim, the applicant cited three articles: two randomized controlled trials and one unpublished abstract. While the results of the Phase III randomized controlled trial [100] demonstrated the superiority of VOWST™ over placebo, we questioned whether other treatment options indicated to prevent rCDI, such as ZINPLAVA™, would have been a more appropriate comparator. We stated that additional information regarding clinical outcomes as a result of treatment with VOWST™ compared to such treatment options, instead of placebo, would have been helpful in our assessment of the substantial clinical improvement criterion. With respect to the applicant's claim that VOWST™ may reduce the number of future hospitalizations or physician visits for patients diagnosed with rCDI, the applicant cited the Feuerstadt study to suggest that reduced rates of rCDI shown in Phase III clinical trials would likely lead to fewer days in hospital. However, we stated that the study did not address this measure directly; rather, this was an inference by the applicant. We welcomed additional data to support the claim VOWST™ may reduce the number of future hospitalizations or physician visits for patients with rCDI.

With respect to the claim that VOWST™ reduces the abundance of antimicrobial resistance genes (ARGs) and associated taxa compared to placebo, which accelerates microbiome recovery from antibiotics, we stated that the applicant cited one unpublished study showing treatment with VOWST™ led to a significant decrease in ARG abundance versus placebo, which was both rapid and sustained through week eight. However, the authors stated that further studies were needed to determine if the significant reduction of ARGs is associated with prevention of subsequent infections with drug resistant bacteria in CDI patients.

We invited public comments on whether REBYOTA™ or VOWST™ meet the substantial clinical improvement criterion.

Comment: The applicants for REBYOTA™ and VOWST™ each submitted comments in response to CMS's concerns in the FY 2024 IPPS/LTCH PPS proposed rule regarding whether REBYOTA™ and VOWST™ meet the substantial clinical improvement criterion.

In the applicant for VOWST™'s comment regarding substantial clinical improvement, it asserted that VOWST™ significantly improves clinical outcomes relative to services or technologies previously available as most CDI recurrences occur within 2 weeks of antibiotic discontinuation, and VOWST™ expedites microbiome repair during the ''window of vulnerability.'' The applicant further stated that reduction of CDI recurrence as a result of VOWST™ may potentially lessen future healthcare costs, morbidity, and rCDI-related hospitalizations. The applicant also asserted that VOWST™ offers a therapeutic option to a patient population with a suboptimal response to, or ineligible for, currently available treatments, specifically, patients who developed rCDI following antibiotic treatment due to continued disruption of the gut microbiome by antibiotics themselves. The applicant noted that ZINPLAVA™ does not address the underlying gut microbiome dysbiosis, and that no data suggest that VOWST™ cannot be used in patients diagnosed with CHF, who may be at an increased risk of heart failure associated with treatment with ZINPLAVA™. The applicant noted that its oral administration process may enhance the patient experience, in part, because the product can be taken at home compared to REBYOTA™.

The applicant for VOWST™ further stated, with regard to the concerns whether the information provided by the applicant is sufficient to support the applicant's statements that VOWST™ is well-tolerated and mitigates the safety concerns of other alternative therapies, and whether VOWST™ can be used in patients ineligible for ZINPLAVA™ due to CHF, that treatment with VOWST™ did not result in adverse events, nor deaths, in patients with CHF. The applicant noted that in the ECOSPOR III (SERES–012) and IV (SERES–013) Phase 3 clinical trials, 109 of 349 (31%) participants had cardiac disease as a concomitant illness, and 24 subjects with CHF who received VOWST™. The applicant stated that adverse event profile of VOWST in subjects with cardiac disease was consistent with that observed in the overall subject population.

With regard to our question about whether other treatment options indicated to prevent rCDI, such as ZINPLAVA™, would have been a more appropriate comparator for VOWST™, rather than a placebo, the applicant for VOWST™ stated that it consulted with the FDA on the design of the Phase 3 studies and was required to evaluate VOWST™ against placebo. The applicant anticipated capability of collecting real world evidence of VOWST™ against other preventative modalities as VOWST™ becomes standard of care.

With regard to CMS's concern that one unpublished study was used as evidence to show treatment with VOWST™ led to a significant decrease in ARG abundance versus placebo, the applicant for VOWST™ stated that a manuscript is in final redaction with the authors with an anticipated June 30 submission to an infectious diseases journal for publication.

In the applicant for REBYOTA™'s comment regarding substantial clinical improvement, with regard to the request for additional information demonstrating the safety of REBYOTA™ in the patient population with CHF, the applicant presented

[100] Feuerstadt P, Louie TJ, Lashner B, et al., VOWST™ (SER–109), an oral microbiome therapy for recurrent Clostridioides difficile infection. N Engl J Med 2022;386:220–9. DOI: 10.1056/NEJMoa2106516.

results from a post hoc subgroup analysis of the PUNCH CD3 trial by Tillotson et al.[101] that was published in January 2023. The applicant stated that the subgroup of patients with cardiac disorders included patients with CHF, described as ''Cardiac failure congestive.'' Per the applicant, results from the Tillotson et al. subgroup analysis showed that REBYOTA™ treatment success was better than placebo in older adults with cardiac disorders (69% [n = 25/36]), and that overall treatment success of older adults with comorbidities was similar to the total REBYOTA™-treated population (70.6%). The applicant also stated that the subgroup analysis of adverse events further supports REBYOTA™ is safe for CHF patients, and that, unlike the CHF warning included with ZINPLAVA®, the FDA did not issue a warning about CHF on the approved label for REBYOTA™.

The applicant for REBYOTA™ also provided additional details regarding the absence of comparative data using ZINPLAVA™. The applicant stated that due to the limited use of ZINPLAVA™ in real-world practice, it was not considered in a recent cost-effective analysis comparing REBYOTA™ with standard-of-care. The applicant also noted that the different routes of administration for each of ZINPLAVA™ (given by IV infusion) and REBYOTA™ (via rectal administration) would make it difficult to blind the study and would require that the study sites be equipped to accommodate infusion administration, in addition to being overly burdensome to the study participants.

Response: We thank the applicants for their comments regarding the substantial clinical improvement criterion. After consideration of the information previously submitted in the applications for REBYOTA™ and VOWST™ and summarized in this final rule, and after review of the comments we received, we agree that both REBYOTA™ and VOWST™ represent a substantial clinical improvement over existing technologies because the technologies improve clinical outcomes by increasing resolution of the disease process over placebo without serious adverse effects for patients who have previously received standard of care antibiotics for rCDI. We believe that these two technologies restore the gut microbiome and resolve dysbiosis to prevent the recurrence of CDI in patients following antibacterial treatment for rCDI. In summary, we have determined that REBYOTA™ and VOWST™ meet all of the criteria for approval of new technology add-on payments. Therefore, we are approving new technology add-on payments for REBYOTA™ and VOWST™ for FY 2024. As previously stated, cases involving REBYOTA™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code XW0H7X8 (Introduction of broad consortium microbiota-based live biotherapeutic suspension into lower GI, via natural or artificial opening, new technology group 8). Cases involving VOWST™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code XW0DXN9 (Introduction of SER–109 into mouth and pharynx, external approach, new technology group 9).

Each of the applicants submitted cost information for its technology. The applicant for REBYOTA™ stated that the cost of its technology is $9,000.00 per patient, and projected that 2,180 cases will involve the use of REBYOTA™ in FY 2024. The manufacturer of VOWST™ stated that the cost of its technology is $17,500.00 and projected that 448 cases will involve the use of VOWST™ in FY 2024. Because the technologies are substantially similar to each other, we believe using a single cost for purposes of determining the new technology add-on payment amount is appropriate for REBYOTA™ and VOWST™ even though each applicant has its own set of codes. We also believe using a single cost provides predictability regarding the add-on payment when using REBYOTA™ or VOWST™ for the prevention of recurrence of CDI following antibiotic treatment for rCDI. As such, consistent with prior rulemaking (85 FR 58684), we believe that the use of a weighted average of the cost of REBYOTA™ and VOWST™ based on the projected number of cases involving each technology to determine the maximum new technology add-on payment would be most appropriate. To compute the weighted cost average, we summed the total number of projected cases for each of the applicants, which equaled 2,628 cases (2,180 plus 448). We then divided the number of projected cases for each of the applicants by the total number of cases, which resulted in the following case-weighted percentages: 83 percent for REBYOTA™ and 17 percent for VOWST™. We then multiplied the cost per case for the specific drug by the case-weighted percentage (0.83 * $9,000 = $7,470 for REBYOTA™ and 0.17 * $17,500 = $2,975 for VOWST™). This resulted in a case-weighted average cost of $10,445 for the technology. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of REBYOTA™ or VOWST™ is $6,789.25 for FY 2024.

g. SeptiCyte® RAPID

Immunexpress, Inc. submitted an application for new technology add-on payments for SeptiCyte® RAPID for FY 2024. Per the applicant, SeptiCyte® RAPID is a gene expression assay used in conjunction with clinical assessments and other laboratory findings as an aid to differentiate infection-positive (sepsis) from infection-negative systemic inflammatory response syndrome (SIRS) in patients suspected of sepsis on their first day of intensive care unit (ICU) admission. According to the applicant, the test is performed in a fully integrated cartridge, which runs on the Biocartis Idylla system, with sample to answer turnaround time of approximately 60 minutes. The applicant stated that SeptiCyte® RAPID generates a score (SeptiScore®) ranging from 0 to 15 that falls within one of four discrete Interpretation Bands based on the increasing likelihood of infection-positive systemic inflammation, also known as sepsis.

Please refer to the online application posting for SeptiCyte® RAPID, available at *https://mearis.cms.gov/public/publications/ntap/NTP2210170WWBT*, for additional detail describing the technology and diagnostic indications.

With respect to the newness criterion, according to the applicant, SeptiCyte® RAPID received 510(k) clearance (K203748) from FDA on November 29, 2021, for the following indication: SeptiCyte® RAPID is indicated as a gene expression assay using reverse transcription polymerase chain reaction to quantify the relative expression levels of host response genes isolated from whole blood collected in the PAXgene® Blood RNA Tube. The SeptiCyte® RAPID test is used in conjunction with clinical assessments and other laboratory findings as an aid to differentiate infection-positive (sepsis) from infection-negative systemic inflammation in patients suspected of sepsis on their first day of ICU admission. The SeptiCyte® RAPID test

[101] Glenn Tillotson et. al.; Microbiota-Based Live Biotherapeutic RBX2660 for the Reduction of Recurrent Clostridioides difficile Infection in Older Adults With Underlying Comorbidities, Open Forum Infectious Diseases, Volume 10, Issue 1, January 2023, ofac703, *https://doi.org/10.1093/ofid/ofac703*.

generates a score (SeptiScore®) that falls within one of four discrete Interpretation Bands based on the increasing likelihood of infection-positive systematic inflammation. SeptiCyte® RAPID is intended for in-vitro diagnostic use on the Biocartis Idylla™ System. The applicant stated the SeptiCyte® RAPID was commercially available immediately after FDA clearance. Per the applicant, Septicyte® RAPID was cleared based on substantial equivalency to the predicate device SeptiCyte® LAB (K163260), which received 510(k) clearance [102] from the FDA on April 6, 2017. The applicant described differences between the two versions of the technology including: the automatic extraction of material from SeptiCyte® RAPID versus the manual extraction for SeptiCyte® LAB; reverse transcription polymerase chain reaction (RT–PCR) and dry format for SeptiCyte® RAPID versus reverse transcription-quantitative polymerase chain reaction (RT-qPCR) and wet format for SeptiCyte® LAB; use of the Biocartis Idylla™ System for SeptiCyte® RAPID versus ABI 7500 Fast Dx for SeptiCyte® LAB; different fluorescent probes and quenchers between SeptiCyte® RAPID and SeptiCyte® LAB; and use of MS2 phage internal sample processing control for SeptiCyte® RAPID versus three external controls for SeptiCyte® LAB.

The applicant stated that effective October 1, 2022, the following ICD–10–PCS code may be used to uniquely describe procedures involving the use of SeptiCyte® RAPID: XXE5X38 (Measurement of infection, whole blood nucleic acid-base microbial detection, new technology group 5). We note that the correct descriptor for this code appears to be (Measurement of infection, whole blood reverse transcription and quantitative real-time polymerase chain reaction, new technology group 8).

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that SeptiCyte® RAPID is not substantially similar to other currently available technologies because SeptiCyte® RAPID differs in mechanism, performance, and turnaround time from all current sepsis diagnostic tools by leveraging the host's immune response to systemic inflammation of infectious origin via measurement of the gene expression ratio between upregulated and downregulated genes, and therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for SeptiCyte® RAPID for the applicant's complete statements in support of its assertion that SeptiCyte® RAPID is not substantially similar to other currently available technologies.

Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	SeptiCyte® RAPID uses a unique and novel technology which detects the host's immune response to systemic inflammation of infectious origin via measurement of gene expression. It is the ratio between the upregulated gene PLAC8 and down regulated gene PLA2G7, that is measured and translated into a sepsis probability score, or SeptiScore®, ranging between 0 – 15 with a higher score correlating with higher likelihood of sepsis. Although many biomarkers are used in sepsis diagnosis, none have sufficient specificity or sensitivity to accurately differentiate sepsis versus SIRS. Consequently, they have limited value in assessing if the systemic inflammation has pathogenic origin, requiring antibiotics, or if there is some other etiology. A major factor limiting their use is the complex and heterogeneity of the immune response to sepsis. SeptiCyte® RAPID is the first and only host response gene expression assay to be clinically validated and FDA-cleared for use in conjunction with clinical assessments, vital signs, and laboratory findings to differentiate infection-positive (sepsis) from infection-negative systemic inflammation in patients suspected of sepsis on their first day of ICU admission.
Is the technology assigned to the same MS-DRG as existing technologies?	Yes	SeptiCyte® RAPID would most likely be grouped into the same MS-DRG for sepsis.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	This technology is unique to aid in the early diagnosis of sepsis and guide treatment decisions for suspected sepsis patients. It accomplishes this primarily by providing a sepsis probability with high accuracy, differentiating sepsis versus non-infectious systemic inflammation, generating results in one hour to aid in guiding prompt and appropriate intervention. There is no other technology that can accomplish this with such a high level of accuracy and in such a timely manner. It can be used on any adult patient population where a patient is suspected of sepsis with SIRS criteria, such as critically ill patients, patient's post-operative, trauma, or burn patients etc.

[102] *https://www.accessdata.fda.gov/cdrh_docs/reviews/K163260.pdf.*

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26867 through 26868), after reviewing of the information provided by the applicant, we stated that we had the following concerns with regard to the newness criterion. We noted that the applicant did not include SeptiCyte® LAB, the predicate device for SeptiCyte® RAPID which was cleared by FDA on April 6, 2017, in its discussion of existing technologies. While the applicant described differences between the two versions of the technology, we explained that it does not appear that these differences materially affect the mechanism of action of the technology. We noted that both devices utilize a gene expression assay using reverse transcription polymerase chain reaction to quantify the relative expression levels of host response genes.[103] We further noted that the applicant also appears to consider the devices as similar, as they rely on studies conducted using the SeptiCyte® LAB to demonstrate substantial clinical improvement.

We also noted that the applicant did not explain how SeptiCyte® RAPID targets a different disease or patient population compared to existing sepsis diagnostic testing. Instead, the applicant stated that SeptiCyte® RAPID does not diagnose the same patient population compared to existing technology, because it allows for early diagnosis, guides treatment decisions, and has high accuracy. While this may be relevant to the assessment of substantial clinical improvement, it did not appear to be related to newness, and it was unclear how the patient population tested with Septicyte® RAPID differs from other patients tested for sepsis, including those tested with Septicyte® LAB. As the applicant stated that Septicyte® RAPID maps to the same MS–DRG as existing technologies, and it appears to have a similar mechanism of action and is used in the same patient population as SeptiCyte® LAB, we stated our belief these technologies may be substantially similar to each other. We noted that if Septicyte® RAPID is substantially similar to SeptiCyte® LAB, we believe the newness period for this technology would begin on April 6, 2017, with the 510(k) clearance date for SeptiCyte® LAB and, therefore, because the 3-year anniversary date of the technology's entry onto the U.S. market (April 6, 2020) occurred in FY 2020, the technology would no longer be considered new and would not be eligible for new technology add-on payments for FY 2024.

[103] *https://www.accessdata.fda.gov/cdrh_docs/reviews/K163260.pdf.*

We invited public comments on whether SeptiCyte® RAPID is substantially similar to existing technologies and whether SeptiCyte® RAPID meets the newness criterion.

Comment: The applicant submitted a comment in response to CMS's concerns pertaining to the newness criterion. Regarding our concern whether SeptiCyte® RAPID uses the same or similar mechanism of action as existing technology, the applicant clarified that SeptiCyte® LAB, the predicate device to SeptiCyte® RAPID, was never manufactured, commercialized, or sold in the U.S. The applicant stated that it does not believe SeptiCyte® RAPID is substantially similar to SeptiCyte® LAB, because SeptiCyte® RAPID applies the technology to an improved, streamlined methodology consisting of fewer steps that result in a 1-hour turnaround time. However, the applicant also noted that SeptiCyte® RAPID demonstrates a high correlation ($r^2 = 0.94$) to SeptiCyte® LAB, which were developed and validated using the same underlying polymerase chain reaction technology.

The applicant stated its belief that even if CMS considers SeptiCyte® RAPID to be substantially similar to SeptiCyte® LAB, SeptiCyte® RAPID should be considered new because SeptiCyte® LAB was never commercially available in the U.S. The applicant explained that FDA cleared SeptiCyte® LAB on April 6, 2017, but Immunexpress Inc. never manufactured or sold the device in the U.S. due to the market access impediment of a 6-hour test turnaround time, when clinical management of sepsis needs to meet a 3-hour sepsis bundle of care, according to the CMS Severe Sepsis and Septic Shock Management Bundle core measure. The applicant stated that while FDA subsequently granted 510(k) clearance to SeptiCyte® RAPID on November 29, 2021, it believes the newness date for SeptiCyte® RAPID should begin on the date of the device's first sale, which was April 20, 2022. The applicant noted that it provided SeptiCyte® RAPID free of charge for evaluations and quality improvement initiatives between its FDA clearance on November 29, 2021, and April 20, 2022, the date of first sale. The applicant stated its belief because the date of first sale occurred after a substantial delay from the date of FDA clearance on November 29, 2021, it should therefore be the newness date for the purposes of new technology add-on payments.

Regarding our concern that SeptiCyte® RAPID targets the same disease or patient population as existing sepsis diagnostic testing, the applicant stated that all sepsis diagnostic tools target the same population. The applicant stated that no existing diagnostic technology can accurately or rapidly differentiate sepsis from non-infectious systemic inflammation as SeptiCyte® RAPID does.

Response: We thank the applicant for its comment and the additional information provided.

Based on our review of comments received and information submitted by the applicant as part of its FY 2024 new technology add-on payment application for SeptiCyte® RAPID, we agree with the applicant that SeptiCyte® RAPID has a unique mechanism of action as the first commercially available gene expression assay using reverse transcription polymerase chain reaction to aid in differentiating infection-positive (sepsis) from infection-negative systemic inflammation. Therefore, we believe that SeptiCyte® RAPID is not substantially similar to existing diagnostic options and meets the newness criterion.

In regard to the first criterion, whether a technology uses the same or similar mechanism of action to achieve a therapeutic outcome, we continue to believe that SeptiCyte® RAPID uses the same or similar mechanism of action as the predicate device, SeptiCyte® LAB, as gene expression assays using reverse transcription polymerase chain reaction to aid in differentiating infection-positive (sepsis) from infection-negative systemic inflammation. Although the applicant states that SeptiCyte® RAPID applies the technology to an improved methodology, which impacts clinical utility for rapid results to aid the clinician in suspected sepsis, we believe that improvements in clinical utility do not result in a substantially different mechanism of action, and these differences instead relate to an assessment of whether SeptiCyte® RAPID meets the substantial clinical improvement criterion. We also believe that regardless of whether the procedural steps have changed, the manner in which SeptiCyte® RAPID functions is unchanged from SeptiCyte® LAB. For example, we note that the applicant stated that SeptiCyte® RAPID was developed and validated using the same underlying PCR technology as SeptiCyte® LAB (RT–PCR). In addition, we note that the analytes assessed by SeptiCyte® RAPID (PLAC8; PLA2G7) are a subset of those assessed by SeptiCyte® LAB (PLAC8; PLA2G7; LAMP1; CEACAM4); and as noted previously, studies conducted using SeptiCyte® LAB were used to demonstrate substantial clinical improvement for SeptiCyte® RAPID. Therefore, we believe that the SeptiScore® results

obtained by SeptiCyte® RAPID are the same or similar as to those that would have been obtained with SeptiCyte® LAB, and that differences in methodology between the two technologies do not represent a new mechanism of action.

Furthermore, we agree with the applicant that the two versions of the technology map to the same MS–DRGs and are intended to treat the same or similar disease in the same or similar patient population—patients tested for sepsis to differentiate sepsis from infection-negative systemic inflammation. Because SeptiCyte® RAPID meets all three of the substantial similarity criteria, we believe SeptiCyte® RAPID is substantially similar to the predicate technology, SeptiCyte® LAB.

In accordance with our policy, because these technologies are substantially similar to each other, we use the earliest market availability date submitted as the beginning of the newness period for both technologies. However, we note that the applicant stated that SeptiCyte® LAB, although FDA cleared, was never manufactured, commercialized or sold in the U.S. market due to the market access impediment of a 6-hour test turnaround time. As we have discussed in prior rulemaking, generally, our policy is to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market, and we may consider a documented delay in the technology's market availability in our determination of newness (77 FR 53348 and 70 FR 47341). Since SeptiCyte® LAB has not been available for sale on the U.S. market, we are unable to establish the beginning of the newness period for SeptiCyte® LAB. Therefore, we believe it is appropriate to use the earliest market availability date submitted for SeptiCyte® RAPID as the beginning of the newness period for both technologies.

We note that, as stated previously, while CMS may consider a documented delay in the technology's market availability in our determination of newness, our policy for determining whether to extend new technology add-on payments for an additional year generally applies regardless of the volume of claims for the technology after the beginning of the newness period (83 FR 41280). We do not consider the date of first sale of a product as an indicator of its entry onto the U.S. market. The applicant stated that the date of first sale of SeptiCyte® RAPID was April 20, 2022, but it is unclear from the information provided when the technology first became available for sale and, absent additional information from the applicant, we cannot determine a newness date based on a documented delay in the technology's availability on the U.S. market. Therefore, we consider the beginning of the newness period for SeptiCyte® RAPID to commence on November 29, 2021, when SeptiCyte® RAPID received FDA marketing authorization.

With respect to the cost criterion, the applicant searched the FY 2021 MedPAR file for potential cases representing patients who may be eligible for SeptiCyte® RAPID. The applicant identified three different types of patient cases where SeptiCyte® RAPID could be used: patients with sepsis as an admission diagnosis; patients who develop sepsis after hospital admission; and patients with symptoms similar to sepsis patients. To identify these patients, the applicant used MS–DRGs and ICD–10–CM codes. These three groups were combined into one analysis with no overlap in cases between the three groups. Please see Table 10.21.A.—SeptiCyte® RAPID Codes—FY 2024 associated with the proposed rule for the complete list of MS–DRGs and codes provided by the applicant. Using the inclusion/exclusion criteria described in the following table, the applicant identified 3,460,256 claims mapping to 691 MS–DRGs. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $88,326, which exceeded the average case-weighted threshold amount of $72,992. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant maintained that SeptiCyte® RAPID meets the cost criterion.

SeptiCyte® RAPID COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of ICD-10-CM codes	Please see Table 10.21.A. - SeptiCyte® RAPID Codes - FY 2024 associated with the proposed rule for the complete list of ICD-10-CM codes provided by the applicant.
List of MS-DRGs	Please see Table 10.21.A. - SeptiCyte® RAPID Codes - FY 2024 associated with the proposed rule for the complete list of MS-DRGs provided by the applicant.
Inclusion/exclusion criteria	The applicant identified and included three types of patients in its analysis: • Group 1- Patients with sepsis as an admission diagnosis: The applicant identified three MS-DRGs (870-872) related to sepsis or septicemia and included all the cases in these MS-DRGs in its analysis. • Group 2- Patients who develop sepsis after hospital admission: The applicant identified cases using ICD-10-CM diagnosis codes related to sepsis or septicemia. • Group 3- Patients with symptoms similar to sepsis patients: A clinical expert identified ICD-10-CM diagnosis codes where symptoms would potentially be similar to sepsis patients and MS-DRGs for the treatment of conditions that could present similarly to sepsis. For this group, the applicant also required the presence of emergency department charges, to signify that the patient presented initially in the emergency department, where SeptiCyte® RAPID would be used to aid in diagnosis and treatment planning. Note: These three groups were combined into one analysis with no overlap in cases between the three groups. Any MS-DRG with a total discharge count less than 11 was imputed with a count of 11. The applicant excluded claims that would not be used for Medicare IPPS rate setting. The applicant calculated the average unstandardized charge per case for each MS-DRG.
Charges removed for prior technology	The applicant did not remove any direct or indirect charges related to the prior technology, because SeptiCyte® RAPID would not replace any prior technology.
Standardized charges	The applicant used the standardization formula provided in the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied an inflation factor of 13.2% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant stated that it is expected the hospital would use one SeptiCyte® RAPID test per patient, per hospitalization. The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.107 for laboratories from the FY 2023 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

We invited public comments on whether SeptiCyte® RAPID meets the cost criterion.

Comment: The applicant submitted a comment reiterating that SeptiCyte® RAPID meets the cost criterion because the inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount.

Response: We thank the applicant for its comment. We agree the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. Therefore, SeptiCyte® RAPID meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that SeptiCyte® RAPID represents a substantial clinical improvement over existing technologies because SeptiCyte® RAPID is the only technology to accurately differentiate sepsis versus non-infectious systemic inflammation in 1 hour, allowing for early, appropriate intervention in suspected sepsis patients and driving prompt source control investigation, while outperforming currently used sepsis diagnostic tools. The applicant asserted that for these reasons, SeptiCyte® RAPID offers the ability to diagnose sepsis earlier than allowed by currently available diagnostic methods and significantly improves clinical outcomes relative to current technologies. The applicant provided eight studies to support these claims, as well as 12 background articles about sepsis clinical guidelines, screening criteria, and treatment.[104] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for SeptiCyte® RAPID for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

[104] Background articles are not included in the following table but can be accessed via the online posting for the technology.

Substantial Clinical Improvement Assertion #1: The technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods.		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Outcomes or findings cited by the applicant from supporting evidence to support its statements**
SeptiCyte® RAPID is the Only Technology to Provide Early Differentiation Between Sepsis from Non-Infectious Systemic Inflammation (SIRS).	Hassan, E., David, R., Sampson, D., & Miller, R. (2021). Comparison of lactate, procalcitonin and a gene signature assay alone or in combination to differentiate sepsis from non-infectious systemic inflammation in ICU patients. Infectious Disease Society of America IDWeek, A 994. Brief study description: Evaluate the use of lactate, PCT or SeptiCyte® either alone or in combination in differentiating sepsis from SIRS.	AUROC (area under the receiving operator curve) to Differentiate Sepsis from SIRS Lactate Alone: 0.56 PCT Alone: 0.76 PCT + Lactate: 0.76 SeptiCyte® Alone: 0.85 SeptiCyte® + Lactate 0.85 SeptiCyte® + PCT 0.86 SeptiCyte® + PCT + Lactate 0.86
	Balk, R., Esper, A.M., Martin, G.S., Miller III, R.R., Lopansri, B.K., et al. (2022). Validation of SeptiCyte RAPIDSeptiCyte® RAPID to discriminate sepsis from non-infectious systemic inflammation. Submitted for review and publication September 2022. https://doi.org/10.1101/2022.07.20.22277648. Brief study description: Validation and clinical performance of SeptiCyte® RAPID, 2 biomarker assay to distinguish between sepsis and non-infectious systemic inflammation (SIRS).	Correlation between SeptiCyte® Lab (4 biometric assay) to SeptiCyte® RAPID (2 biometric assay): R = 0.88, P <0.001. Page 14, Figure 5 Probability of Sepsis SeptiCyte® Band 1: 9.4% SeptiCyte® Band 2: 20.7% SeptiCyte® Band 3: 42.3% SeptiCyte® Band 4: 80.7%
	Miller lll, R.R., Lopansri, B.K., Burke, J.P., Levy, M., Opal, S., et al. (2018). Validation of a Host Response Assay, SeptiCyte LAB, for Discriminating Sepsis from Systemic Inflammatory Response Syndrome in the ICU. American Journal of Respiratory and Critical Care Medicine, 198(7), 903-913. https://doi.org/10.1164/rccm.201712-2472oc. Brief study description: Can SeptiCyte® distinguish between sepsis and non-infectious systemic inflammation (SIRS). Combination of 3) separate prospective, observational studies on the clinical performance of SeptiCyte®. Adult pts with two (2) or more SIRS findings upon ICU admission. SeptiCyte® sample obtained within 24 hours of ICU admission.	In the absence of a gold standard, a panel of experts (RPD) reached unanimous decision on sepsis vs SIRS to generate these results: Page 907, Table 2 Sepsis (n=180) SIRS (n=230) SeptiCyte® Band 1, n (%) 10 (5.6) 79 (34.3) SeptiCyte® Band 2, n (%) 20 (11.1) 82 (35.6) SeptiCyte® Band 3, n (%) 45 (25.0) 49 (21.3) SeptiCyte® Band 4, n (%) 105 (58.3) 20 (8.7) Page 909, Table 3 Unanimous expert panel agreement: AUROC = 0.89 Sensitivity = 0.97 Specificity = 0.34 NPV = 0.94 PPV = 0.51 NB. Table 3 per Erratum (Erratum: Validation of a Host Response Assay, SeptiCyte® LAB, for Discriminating Sepsis from Systemic Inflammatory Response Syndrome in the ICU. [No authors listed] Am J Respir Crit Care Med. 2020 Jul 1;202(1):155. doi: 10.1164/rccm.v202erratum2. PMID: 32609017) Unanimous expert panel agreement: AUROC = 0.89 Sensitivity = 0.97 Specificity = 0.33 NPV = 0.93 PPV = 0.50.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	

SeptiCyte® RAPID Outperforms Current Sepsis Diagnostic Tools When Used Alone or in Combination	Balk, R., Esper, A.M., Martin, G.S., Miller III, R.R., Lopansri, B.K., et al. (2022). Validation of SeptiCyte® RAPID to discriminate sepsis from non-infectious systemic inflammation. Submitted for review and publication September 2022. https://doi.org/10.1101/2022.07.20.22277648. See prior study description	AUROC of 32,767 possible logistic combinations of 14 variables (SeptiCyte®, PCT, Lactate, various laboratories, minimum and maximum vital signs, demographics. For discrimination between sepsis and SIRS. Approximate AUROC: Clinical Variables Only (without SeptiCyte® or PCT): 0.68 PCT alone: 0.77 PCT with Clinical Variables, without SeptiCyte®: 0.80 SeptiCyte® Alone: 0.84 SeptiCyte® with PCT and Clinical Variables: 0.87.
	Miller III, R.R., et al. (2018). Validation of a Host Response Assay, SeptiCyte® LAB, for Discriminating Sepsis from Systemic Inflammatory Response Syndrome in the ICU. American Journal of Respiratory and Critical Care Medicine, 198(7), 903-913. https://doi.org/10.1164/rccm.201712-2472oc. See prior study description	AUROC of 16,383 possible logistic combinations of 14 variables SeptiCyte®, PCT, Lactate, various laboratories, minimum and maximum vital signs, demographics. Approximate AUROC: Clinical Variables Only (without SeptiCyte® or PCT): 0.70 PCT without SeptiCyte®: 0.84 Models containing SeptiCyte®: 0.91.
SeptiCyte® RAPID Results Can Aid in Improving Diagnostic Stewardship Practices.	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology	
SeptiCyte® RAPID Allows for Early Appropriate Antibiotic Decisions in Patients with Suspected Sepsis Cases.	Balk, R., et al. (2022). Validation of SeptiCyte® RAPID to discriminate sepsis from non-infectious systemic inflammation. Submitted for review and publication September 2022. https://doi.org/10.1101/2022.07.20.22277648. See prior study description	Correlation between SeptiCyte® Lab (4 biometric assay) to SeptiCyte® RAPID (2 biometric assay): R = 0.88, P <0.001. Page 14, Figure 5 Probability of Sepsis SeptiCyte® Band 1: 9.4% SeptiCyte® Band 2: 20.7% SeptiCyte® Band 3: 42.3% SeptiCyte® Band 4: 80.7%
	Miller III, et al. (2018). Validation of a Host Response Assay, SeptiCyte® LAB, for Discriminating Sepsis from Systemic Inflammatory Response Syndrome in the ICU. American Journal of Respiratory and Critical Care Medicine, 198(7), 903-913. https://doi.org/10.1164/rccm.201712-2472oc. See prior study description	In the absence of a gold standard a panel of experts RPD reached unanimous decision on sepsis vs SIRS to generate these results: Page 907, Table 2 Sepsis (n=180) SIRS (n=230) SeptiCyte® Band 1, n (%) 10 (5.6) 79 (34.3) SeptiCyte® Band 2, n (%) 20 (11.1) 82 (35.6) SeptiCyte® Band 3, n (%) 45 (25.0) 49 (21.3) SeptiCyte® Band 4, n (%) 105 (58.3) 20 (8.7) Page 909, Table 3 Unanimous expert panel agreement: AUROC = 0.89 Sensitivity = 0.97 Specificity = 0.34 NPV = 0.94 PPV = 0.51 NB. Table 3 per Erratum (Erratum: Validation of a Host Response Assay, SeptiCyte® LAB, for Discriminating Sepsis from Systemic Inflammatory Response Syndrome in the ICU. [No authors listed] Am J Respir Crit Care Med. 2020 Jul 1;202(1):155. doi: 10.1164/rccm.v202erratum2. PMID: 32609017) Unanimous expert panel agreement: AUROC = 0.89 Sensitivity = 0.97 Specificity = 0.33 NPV = 0.93 PPV = 0.50.
SeptiCyte® RAPID provides Clinicians with Actionable Results Sooner than Pathogen Detection Systems	Balk, R., et al. (2022). Validation of SeptiCyte® RAPID to discriminate sepsis from non-infectious systemic inflammation. Submitted for review and publication September 2022. https://doi.org/10.1101/2022.07.20.22277648. See prior study description	The test has a hands-on time of ~two (2) min and a turnaround time of ~one (1) hour. SeptiCyte® RAPID scores were verified to be independent of the white blood cell (WBC) count across an input range of 25 to 25,000 WBC/ul.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	

SeptiCyte® RAPID Effectively Differentiates Sepsis from Infection Negative Systemic Inflammation (SIRS) in Various Clinical Conditions.	Davis, R.F., Navalkar, K.A., van der Poll, T., Schultz, M.J., Cremer, O.L., Bonten, M., & Zimmerman, J.J. (2021). SeptiCyte® RAPID in sepsis cases with malignancy or treated with antineoplastics or immunosuppressants. Poster presentation for the 50th Critical Care Conference. Brief study description: Evaluate the clinical performance of SeptiCyte® RAPID in sepsis patients with systemic inflammation and a hematologic or metastatic malignancy or those being treated with immunosuppressant or antineoplastic agents.	AUROC for various Sepsis vs SIRS Comparisons Sepsis cases treated or with Malignancy vs SIRS cases: 0.83 – 0.97 Sepsis cases NOT treated or with Malignancy vs SIRS cases: 0.85 – 0.89.
	Verboom, D.M., Koster-Brouwer, M.E., Ruurda, J.P., van Hillegersberg, R., van Berge Henegouwen, M.I., Gisbertz, S.S., Scicluna, B.P., Bonten, M.J.M., & Cremer, O.L. (2019). A pilot study of a novel molecular host response assay to diagnose infection in patients after high-risk gastro-intestinal surgery. Journal of Critical Care, 54, 83-87. https://doi.org/10.1016/j.jcrc.2019.07.020. Brief study description: Evaluate the clinical performance of SeptiCyte® in sepsis patients with systemic inflammation and a hematologic or metastatic malignancy or those being treated with immunosuppressant or antineoplastic agents.	AUROC for SeptiCyte® in confirmed infections vs definite non-infectious complications: SeptiCyte® Confirmed Infections: AUROC = 0.87 SeptiCyte® plus CRP in Confirmed Infections: AUROC = 0.88 SeptiCyte® in non-infectious complications: AUROC = 0.76.
	Gravrand, V., Mellot, F., Ackerman, F., Ballester, M-C., Zuber, B., Kirk, J.T., Navalkar, K., Yager, T.D., Petit, F., Pascreau, T., Farfour, E., & Vasse, M. (2002). Stratification of COVID-19 Severity Using SeptiCyte® RAPID, a Novel Host Immune Response Test. Unpublished. https://doi.org/10.1101/2022.09.15.22279735. Brief study description: Evaluate the performance and clinical utility of SeptiCyte® RAPID as a triage tool for ICU care of hospitalized COVID-19 patients.	AUROC In COVID-19 Based ON Patient Location Patient Discharged vs ICU Admission: AUROC = 0.86 (P<0.0007) ICU vs Non-ICU Hospitalization: AUROC = 0.83 (P<0.0005) Page 16, Figure 3B SeptiCyte RAPIDSeptiCyte® RAPID AUROC in COVID-19 CT Scan Severity: Mild/Moderate CT scan vs Severe/Critical CT scan: AUROC = 0.86 (P<0.001).
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available.		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Outcomes or findings cited by the applicant from supporting evidence to support its statements**
SeptiCyte® RAPID 1 Hour Turn Around Time Allows for Prompt Attention to Infection Source Control.	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.	
SeptiCyte® RAPID Aids Improved Compliance with the Centers for Medicare & Medicaid Services (CMS) SEP-1 and Surviving Sepsis Campaign 3-Hour Bundle Compliance.	McHugh, L.C. (2018). Modeling Improved Patient Management and Hospital Savings with SeptiCyte® LAB in the Diagnosis of Sepsis at ICU admission. Abstract at IDWeek 2018. Brief study description: Determine SeptiCyte®'s ability to accurately identify sepsis in addition to clinician assessment.	Change in Initial Diagnosis with SeptiCyte® over Standard of Care True Negatives: Increase 9.4% False Positives: Decrease 4.5% Indeterminate, sepsis presumed decrease 9.4%

	Balk, R. et al. (2022). Validation of SeptiCyte® RAPID to discriminate sepsis from non-infectious systemic inflammation. Submitted for review and publication September 2022. https://doi.org/10.1101/2022.07.20.22277648. See prior study description	AUROC of 32,767 possible logistic combinations of 14 variables (SeptiCyte®, PCT, Lactate, various laboratories, minimum and maximum vital signs, demographics. For discrimination between sepsis and SIRS. Approximate AUROC: Clinical Variables Only (without SeptiCyte® or PCT): 0.68 PCT alone: 0.77 PCT with Clinical Variables, without SeptiCyte®: 0.80 SeptiCyte® Alone: 0.84 SeptiCyte® with PCT and Clinical Variables: 0.87
	Remy K, Hejal R et al. A quality improvement initiative to evaluate SeptiCyte® RAPID in Patients with suspected sepsis. Unpublished study. Presented October 12th at Sepsis Alliance Clinical Community Innovation Sponsor Day. Brief study description: Evaluate and compare clinician's perceptions of SeptiCyte® RAPID score as an addition to the clinicians clinical assessment of sepsis.	Sepsis Bundle Compliance based on SeptiCyte® Bands 1 & 2: 50% Bands 3 & 4: 65.5% Slide # 62 Clinical Sepsis Assessment Band 1 & 2 Band 3 & 4 None/Possible 58.8%: 40.6% Probable/Definite 41.2%: 59.4%
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
SeptiCyte® RAPID Aids Sepsis Antibiotic Initiation Consistent with Current Consensus Guidelines.	Miller lll, R.R., Lopansri, B.K., Burke, J.P., et al. (2018). Validation of a Host Response Assay, SeptiCyte® LAB, for Discriminating Sepsis from Systemic Inflammatory Response Syndrome in the ICU. American Journal of Respiratory and Critical Care Medicine, 198(7), 903-913. https://doi.org/10.1164/rccm.201712-2472oc. See prior study description	Sepsis (n=180) SIRS (n=230) SeptiCyte® Band 1, n (%) 10 (5.6) 79 (34.3) SeptiCyte® Band 2, n (%) 20 (11.1) 82 (35.6) SeptiCyte® Band 3, n (%) 45 (25.0) 49 (21.3) SeptiCyte® Band 4, n (%) 105 (58.3) 20 (8.7) Page 909, Table 3 Unanimous expert panel agreement: AUROC 0.89 Sensitivity 0.97 Specificity 0.34 NPV 0.94 PPV 0.51

BILLING CODE 4120–01–C

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26873), after reviewing the information provided by the applicant, we stated that we had the following concerns regarding whether SeptiCyte® RAPID meets the substantial clinical improvement criterion. First, we noted that the applicant submitted two studies [105] [106] of SeptiCyte® LAB, the predicate device, to support its assertions as to why SeptiCyte® RAPID represents a substantial clinical improvement. The applicant did not present any clinical data to compare SeptiCyte® RAPID to SeptiCyte® LAB. Second, the studies provided showed that SeptiCyte® RAPID is not a definitive test and that resulting SeptiScores® in Bands 2 and 3 are inconclusive. We noted that the applicant stated that SeptiCyte® RAPID should be used in conjunction with clinical assessments and other laboratory findings. If additional diagnostic tests are needed in conjunction with SeptiCyte® RAPID to determine a diagnosis of sepsis or SIRS, we questioned whether SeptiCyte® RAPID can provide an earlier diagnosis and affect the management of the patient. In addition, we stated that the applicant did not provide evidence for this claim other than the 1-hour turnaround time for SeptiCyte® RAPID to provide test results. Additionally, we noted that the applicant did not provide any clinical data demonstrating that the SeptiCyte® RAPID affects the management of the patient, or that it improves clinical outcomes.

We invited public comments on whether SeptiCyte® RAPID meets the substantial clinical improvement criterion.

Comment: We received several comments in support of new technology add-on payments for SeptiCyte® RAPID. A few of the commenters stated their belief that SeptiCyte® RAPID has the potential to greatly improve patient care because of its high level of sensitivity, short turnaround time, and advantages over existing sepsis diagnostic tools. A commenter who recently evaluated SeptiCyte® RAPID's impact on sepsis bundle compliancy at their community hospital emergency department stated they had very encouraging findings and believe SeptiCyte® RAPID has the potential for clinical utility in the care of its sepsis patients, as well as the potential for improved antibiotic stewardship and reduced costs. A few commenters also explained that SeptiCyte® RAPID provides clinicians with the probability of sepsis to facilitate real-time decision making in patients with suspected sepsis. One commenter noted that SeptiCyte® RAPID has the potential to impact the morbidity and mortality of critically ill patients. A few commenters stated their support for approval of SeptiCyte® RAPID's new technology add-on payment application because approval for the payments would encourage adoption of the technology by hospitals and health systems who may otherwise delay usage of SeptiCyte® RAPID.

[105] Balk, R, Esper AM, Martin GS, et al. Validation of SeptiCyte® RAPID to discriminate sepsis from non-infectious systemic inflammation. Submitted for review and publication September 2022. Available as pre-print at *https://doi.org/10.1101/2022.07.20.22277648*.

[106] McHugh, L.C. (2018). Modeling Improved Patient Management and Hospital Savings with SeptiCyte® LAB in the Diagnosis of Sepsis at ICU admission. Abstract at IDWeek 2018.

Response: We thank the commenters for their input and have taken it into consideration in our determination of whether SeptiCyte® RAPID meets the substantial clinical improvement criterion, discussed later in this section.

Comment: The applicant submitted a public comment regarding the substantial clinical improvement criterion and provided responses to concerns raised in the proposed rule. With respect to whether studies of SeptiCyte® LAB accurately represent clinical data from SeptiCyte® RAPID, the applicant stated that SeptiCyte® RAPID was compared to SeptiCyte® LAB and the two devices had a high correlation ($r^2 = 0.94$), which measured the linear association between the two tests.

With respect to CMS's concern about whether SeptiCyte® RAPID is a definitive test and that SeptiScores® in Bands 2 and 3 are inconclusive, the applicant stated that SeptiCyte® RAPID scores indicate the sepsis likelihood ratios based upon its four bands with high specificity and sensitivity for 80 percent of all patients. The applicant explained that for the remaining 20 percent of patients, whose SeptiScores® fall into Band 3, probability can be derived in conjunction with other lab variables. The applicant further explained that the high sensitivity of Band 1 and the high specificity of the test in Band 4 provides clinicians with rule-in or rule-out information, which is strong patient management information that is unavailable with current technologies.[107]

With respect to whether SeptiCyte® RAPID should be used in conjunction with clinical assessments and other laboratory findings, the applicant stated that with the lack of a ''Gold Standard'' to effectively define sepsis, currently available diagnostic tools for suspected sepsis are inadequate, with high false positivity rates due to limited specificity (for example, C-reactive protein (CRP)), lengthy turnaround time for actionable results, and low sensitivity (for example, blood cultures). The applicant further stated that when used in conjunction with clinical assessments, vital signs, and laboratory findings, SeptiCyte® RAPID alone, or in combination with typically used biomarkers, is superior to existing technologies in differentiating sepsis from non-infectious systemic inflammation.[108] The applicant also asserted that SeptiCyte® RAPID significantly differentiated between sepsis and non-infectious systematic inflammation in 143 patients where an expert panel of sepsis physicians was unable to retroactively diagnose sepsis or non-infectious systemic inflammation. In addition, the applicant noted that SeptiCyte® RAPID has been independently clinically validated for its role in triage and risk stratification of patients with severe COVID, which according to the applicant is a proxy for sepsis.

With respect to whether SeptiCyte® RAPID can provide an earlier diagnosis and affect the management of the patient, the applicant reasserted that SeptiCyte® RAPID allows for earlier differentiation of sepsis from non-infectious systematic inflammation, thereby impacting the management of patients by allowing for earlier therapeutic intervention as well as antibiotic and diagnostic stewardship. The applicant stated that literature provides well documented evidence that patient management aligned with Surviving Sepsis Campaign guidelines and meeting CMS quality metrics of 1- or 3-hour bundles improves care and clinical outcomes for sepsis patients. The applicant explained that this evidence supports its belief that the 1-hour turnaround time and significant likelihood ratios of SeptiCyte® RAPID for differentiating sepsis versus non-infectious systemic inflammation can impact sepsis bundle compliance and clinical outcomes.

With respect to CMS's concern about the absence of clinical data demonstrating that the SeptiCyte® RAPID affects the management of the patient or that it improves clinical outcomes, the applicant reiterated its belief that by providing early and accurate differentiation between sepsis and non-infectious systemic inflammation, SeptiCyte® can decrease the time to diagnoses and treat sepsis resulting in improved outcomes and reduced mortality. To support this claim, the applicant included eight case studies which they stated demonstrate SeptiCyte® RAPID's impact on the care process, antibiotic stewardship, and diagnostic stewardship. More specifically, the applicant provided a case study to demonstrate SeptiCyte® RAPID's utility in each of the following: (1) monitoring patients post-operatively for secondary hospital acquired sepsis; (2) monitoring severe burn patients to differentiate infection negative systemic inflammation from infection positive systemic inflammation and sepsis; (3) diagnosing sepsis in an immunocompromised patient admitted with neutropenia and a recurrence of cancer who received chemotherapy; (4) confirming the presence of sepsis despite negative blood cultures; (5) evaluating the probability of sepsis in a patient with a change in clinical status and determining whether a de-escalation of antibiotics was appropriate; (6) differentiating infection negative systemic inflammation from infection positive systemic inflammation and sepsis; and (7/8) aiding the diagnosis of secondary sepsis following a central nervous system bleed and surgical procedure.

The first case study provided by the applicant pertains to a 64-year-old female admitted for a right hemi hepatectomy for hepatobiliary carcinoma. After 19 days in the hospital, the patient exhibited clinical deterioration and an altered mental status. The patient was transferred to the intensive care unit (ICU), where the patient underwent blood cultures, SeptiCyte® RAPID, and an abdominal computed (CT) scan. The SeptiScore® was 7.5, within Band 4, indicating a high probability of sepsis. The CT showed a perihepatic abscess, which was drained, and the fluid was cultured. As a result of these tests, the patient started antibiotics. After 24 hours, SeptiCyte® RAPID showed a SeptiScore® of 8.8, within Band 4, and blood cultures showed Escherichia coli and Candida, confirming sepsis. The patient received treatment for 7 days and was transferred from the ICU to the ward with a SeptiScore® of 7.1, within Band 3, indicating an intermediate risk of sepsis. The applicant stated that the patient developed a post-operative infection and an abscess, and SeptiCyte® RAPID was used to confirm sepsis and to monitor the patient for evidence of secondary hospital acquired sepsis.

The second case study included in the applicant's comment pertains to a 40-year-old male admitted to the burn unit with thermal burns covering 30 percent of his total body surface area (TBSA), with 10 percent of his TBSA deeply burned. At admission, SeptiCyte® RAPID was administered showing a SeptiScore® of 4, within Band 1, indicating a low probability of sepsis. During day 3 of admittance, the patient developed increased respiratory distress and another SeptiCyte® RAPID was administered. The SeptiScore® was

[107] Balk, R, Esper AM, Martin GS, et al. Validation of SeptiCyte® RAPID to discriminate sepsis from non-infectious systemic inflammation. Submitted for review and publication September 2022. Available as pre-print at *https://doi.org/10.1101/2022.07.20.22277648*.

[108] Balk, R, Esper AM, Martin GS, et al. Validation of SeptiCyte® RAPID to discriminate sepsis from non-infectious systemic inflammation. Submitted for review and publication September 2022. Available as pre-print at *https://doi.org/10.1101/2022.07.20.22277648*.

12.8, within Band 4, indicating a high probability of sepsis. The patient's sputum sample showed great Haemophilus influenzae and blood cultures were negative. As a result, the patient started antibiotics. On day 10, the patient developed fever, tachycardia, and leukocytosis. As a result, blood, urine, and cutaneous cultures were drawn and SeptiCyte® RAPID was administered. The SeptiScore® was 10.1, within Band 4, indicating a high probability of sepsis. The cutaneous cultures showed Enterococcus faecalis and Pseudomonas aeruginosa. The patient received antibiotics. The applicant stated that severe burn patients frequently develop an inflammatory response due to repeated surgeries, debridement, thrombotic complications, and other treatments. The applicant also stated that this case study demonstrates the use of SeptiCyte® RAPID to monitor the patient following a baseline low SeptiScore® on admission and repeating the SeptiCyte® RAPID test at the time of developing SIRS and possible infection. The applicant explained that the high SeptiScore® in the presence of SIRS supports the early diagnosis of a hospital acquired infection and sepsis.

The applicant stated that the third case study is intended to demonstrate the role of SeptiCyte® RAPID in the diagnosis of sepsis in an immunocompromised patient with neutropenia and recurrence of cancer who was receiving chemotherapy. A 47-year-old patient with a history of cervical cancer considered to be in remission was admitted with a hemorrhagic stroke. An examination revealed recurrence of the cancer with hepatic and cerebral metastatic lesions. As a result, the patient began chemotherapy. On day 7, the patient developed a fever and had an absolute neutrophil count of 200 per microliter. Blood and urine cultures were negative, and the patient was treated with antibiotics for seven days, after which chemotherapy was restarted. On day 30, the patient developed fever, tachycardia, anuria, and hypotension. The patient received blood tests and a clinical assessment that showed a decrease in neutrophils to 0 per microliter, down from 170 two days prior; a c-reactive protein 0 of 166 mg/L; and a blood pressure of 70/40 mmHg. The patient was admitted to the ICU where volume and vasopressors were started, and blood and urine cultures obtained. In addition, the patient's SeptiScore® was 9, within Band 4, representing a high probability of sepsis. These clinical tests also showed growth of *Enterococcus faecalis* in the urine, and the patient started triple antibiotics and discontinued chemotherapy. The applicant stated that this case demonstrates SeptiCyte® RAPID's diagnostic capability of detecting sepsis much earlier in a patient with severe neutropenia and immunosuppression, confirming sepsis and prompting initiation of antibiotics and cessation of chemotherapeutics.

The applicant explained that the fourth case study represented an example of how SeptiCyte® RAPID is used to confirm the presence of sepsis despite negative blood cultures. A 79-year-old male with diabetes mellitus and chronic obstructive pulmonary disease was admitted for endoscopic devolvulation of a sigmoid volvulus. The patient developed dyspnea and productive cough with decreasing consciousness and increasing work of breathing. The patient was intubated and admitted to the ICU where he was placed on vasopressors and intermittent mandatory ventilation. The patient had a Sequential Organ Failure Assessment (SOFA) score of 9, a white blood cell count of 14,000, a lactate of 1.6 mm/L, a negative urine antigen test, and a chest x-ray that showed diffuse bilateral infiltrates. The patient's SeptiScore® was 7.7, within Band 4, indicating a high probability of sepsis. Blood and urine cultures were also obtained. The patient started triple antibiotics. The applicant stated that the SeptiScore® confirmed a high probability of sepsis resulting in early initiation of appropriate antibiotics and early source investigation and control.

The applicant explained that the fifth case study is an example of how SeptiCyte® RAPID was used to evaluate an in-hospital change in clinical status and de-escalation of antibiotic therapy. A 63-year-old male with a history of diabetes mellitus and non-dialysis chronic renal failure was admitted to the ICU with bilateral SARS–CoV–2 pneumonia and respiratory failure. The patient's 78 day stay in the ICU included mechanical ventilation, tracheostomy, dialysis for acute renal failure, ventilator-associated pneumonia from *Enterobacter cloacae,* and two episodes of hospital-acquired bacteremia with *Enterococcus faecalis* and *Staphylococcus aureus.* Once the patient was transferred to the ward, his tracheostomy was removed, and dialysis was discontinued. Five days later, the patient presented a low-grade fever, shortness of breath, purulent sputum, and tachypnea and was readmitted to the ICU with hypoxic respiratory failure and intubated. At this time, the patient had a blood pressure of 70/50 mmHg, a SOFA score of 8, a white blood cell count of 9.800 with 89 percent neutrophils, and a chest x-ray that showed bilateral infiltrates and pulmonary edema. Blood and sputum cultures were also obtained, and the patient began antibiotics. The patient's SeptiScore® was 3.7, within Band 1, representing a low probability of sepsis. Considering prompt clinical improvement with ventilation and diuresis, no culture growth after 24 hours, and a SeptiScore® of 3.7, antibiotics were discontinued. The applicant explained that this case study shows how SeptiCyte® RAPID confirms low probability of sepsis in the presence of negative cultures and clinical improvement allowed for the appropriate discontinuation of antibiotics, driving antibiotic stewardship and de-escalation of unnecessary therapy.

The applicant described in the sixth case study how SeptiCyte® RAPID was used to differentiate infection negative systemic inflammation from infection positive systemic inflammation or sepsis in a 74-year-old patient with deteriorating mental status, loss of consciousness and tachypnea. The patient had normal initial diagnostic and laboratory studies and blood, sputum, urine cultures were ordered, and results were pending. The patient had SeptiCyte® RAPID which showed a SeptiScore® of 5, Band 1 which is a low risk of sepsis. The care team discontinued antibiotics due to SeptiCyte® RAPID in conjunction with negative cultures after 3 days. Further evaluation showed mass in left upper lobe of the lung with metastases in adrenal gland.

The applicant stated that, in the seventh and eighth case studies, SeptiCyte® RAPID aided in the diagnosis of sepsis after CNS bleed and surgical procedure. There were two patients who were both admitted to the ICU post subarachnoid hemorrhage with complicating secondary hydrocephalus requiring external ventricular drain placement. During the ICU stay, both patients developed fever and delirium, and both received CSF analysis with results that came back after 3 hours that showed high WBC count and protein but was gram stain negative. The patients received SeptiCyte® RAPID SeptiScore®'s of 8.8 and 7, respectively, both elevated with high probability of sepsis with a 1-hour turnaround. The CSF culture grew Klebsiella pneumoniae 24 hours after collection. The applicant stated that SeptiCyte® RAPID's 1-hour turnaround time confirmed the presence of systemic infection in both patients, prompting

early appropriate antibiotic therapy pending bacterial confirmation and sensitivity testing.

Response: We thank the applicant and other commenters for their input. After further review, we continue to have concerns as to whether SeptiCyte® RAPID meets the substantial clinical improvement criterion to be approved for new technology add-on payments. Based on the additional information we received, we remain unclear whether SeptiCyte® RAPID offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods or that it changes the management of patients. While the applicant asserted that the technology allows for earlier differentiation of sepsis from SIRS, and thereby impacts the management of patients, it has not demonstrated that Septicyte® RAPID actually leads to changes in the management of patients such as initiating or discontinuing antibiotics. We note that the applicant stated it believes that the 1-hour time to results with SeptiCyte® RAPID can impact sepsis bundle compliance, and cited literature that meeting sepsis guidelines and quality metrics improves outcomes for sepsis patients. However, no evidence was presented to demonstrate that the technology improves compliance with guidelines or improves outcomes; this is only inferred. Although the applicant asserted that SeptiCyte® RAPID was independently clinically validated for its role in triage and risk stratification of patients with severe COVID–19, we could not determine that this is a proxy for sepsis. The applicant included case studies in support of SeptiCyte® RAPID's ability to improve monitoring of patients at risk of sepsis, or as a confirmation test, and a diagnostic aid. We are unable to determine, based on these case studies, that the clinical data demonstrates that SeptiCyte® RAPID itself directly affects management of patients or improves clinical outcomes. For example, we believe that in the clinical scenarios presented, antibiotics would have been started or stopped based on clinical presentation alone in some cases, and with the additional diagnostic tests in other cases. The case studies did not describe when SeptiCyte® RAPID was performed or when results were received in relation to the other tests performed, and also did not describe at what point during the timeline of tests the antibiotics were started/discontinued (that is, before or after the results of the SeptiCyte® RAPID test or other tests were received. Therefore, it did not appear that any change in management was initiated directly as a result of receiving the SeptiCyte® RAPID test results in any of the scenarios, despite the 1-hour turnaround time. Instead, it appears that, in these scenarios, SeptiCyte® RAPID was used to confirm results from standard of care procedures, rather than providing actionable results resulting in a change in patient antibiotic use before blood culture or molecular pathogen detection results. For example, with regards to Case Study #1, it appears that patient clinical deterioration and altered mental status following high risk abdominal surgery prompted standard of care procedures, and that antibiotics were started after an abdominal CT noted a perihepatic abscess, with results confirmed by blood and abscess cultures and SeptiCyte® RAPID results. Further, it is unclear how substantial clinical improvement based on these scenarios can be demonstrated without a comparison to diagnosis and management of these patients using standard of care (SOC) methods alone. While other commenters stated that SeptiCyte® RAPID has the potential to improve health outcomes and patient management, clinical evidence to support those statements was not provided.

After review of the information submitted by the applicant as part of its FY 2024 new technology add-on payment application for SeptiCyte® RAPID and consideration of the comments received, we are unable to determine that SeptiCyte® RAPID meets the substantial clinical improvement criteria for the reasons discussed in the proposed rule and in this final rule, and therefore we are not approving new technology add-on payments for SeptiCyte® RAPID for FY 2024.

h. SPEVIGO® (Spesolimab)

Boehringer Ingelheim Pharmaceuticals, Inc. (BIPI), submitted an application for new technology add-on payments for SPEVIGO® for FY 2024. SPEVIGO® is a humanized antagonistic monoclonal immunoglobulin G1 antibody blocking human IL36R signaling for the treatment of flares in adult patients with generalized pustular psoriasis (GPP). We noted that the applicant submitted an application for new technology add-on payments for SPEVIGO® for FY 2023, under the name spesolimab, as summarized in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28108 through 28746), but the technology did not meet the deadline of July 1, 2022, for FDA approval or clearance of the technology and, therefore, was not eligible for consideration for new technology add-on payments for FY 2023 (87 FR 48920).

Please refer to the online application posting for SPEVIGO®, available at *https://mearis.cms.gov/public/publications/ntap/NTP2210146275W*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, according to the applicant, the BLA for SPEVIGO® was approved by FDA on September 1, 2022, for the treatment of GPP flares in adults. According to the applicant, SPEVIGO® is administered as a single 900 mg (2 × 450 mg/7.5 mL vials) intravenous infusion over 90 minutes, and an additional intravenous 900 mg dose may be administered 1 week after the initial dose if flare symptoms persist. The applicant indicated that, while there may be cases where a second dose is needed, there is insufficient frequency to impact the reported weighted average of one dose per patient.

The applicant stated that effective October 1, 2022, the following ICD–10–PCS code may be used to uniquely describe procedures involving the use of SPEVIGO®: XW03308 (Introduction of spesolimab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 8). The applicant stated that L40.1 (Generalized pustular psoriasis) may be used to currently identify the indication for SPEVIGO® under the ICD–10–CM coding system.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purposes of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that SPEVIGO® is not substantially similar to other currently available technologies because, in the absence of an FDA-approved therapy specifically indicated for GPP, immunomodulatory therapies, including biologic products, are used in the treatment of GPP despite these medications being approved for plaque psoriasis, which is a different subtype of psoriasis. Additionally, there is limited evidence on the efficacy and safety of these therapies in the treatment of GPP. Due to the rarity of the disease, there are no high-quality clinical trials providing evidence for treatment options in GPP. Therefore, the applicant asserts that the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for SPEVIGO® for the applicant's complete statements in support of its assertion that SPEVIGO® is not substantially similar to other currently available technologies.

Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	SPEVIGO® inhibits IL-36R signaling which is differentiated from TNF-α, integrin and IL-23 inhibitory pathways by directly and simultaneously blocking both inflammatory and pro-fibrotic pathways.
Is the technology assigned to the same MS-DRG as existing technologies?	No	There is no MS-DRG for SPEVIGO®
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	The clinical, pathological, and genetic features associated with GPP establish it as a distinct disease entity from plaque psoriasis that is being managed with existing therapies. There are no other FDA approved therapies to treat GPP.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26882), we stated the following concerns with regard to the newness criterion, similar to concerns raised in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28280). First, we noted that, when describing current treatments for the disease, the applicant stated that there are no FDA-approved therapies specifically indicated for GPP. However, we questioned whether there are any treatments that may be indicated for psoriasis generally that may therefore be considered an on-label use for subtypes of psoriasis such as GPP, and requested additional information on any such treatments and how they compare to SPEVIGO® with regard to substantial similarity. We also noted that while the applicant stated that SPEVIGO® has no DRG to which it maps, the applicant also provided a list of four MS–DRGs that cases eligible for the use of the technology would map to, and we believed these are the same MS–DRGs to which other treatments for GPP would map.

We invited public comments on whether SPEVIGO® is substantially similar to existing technologies and whether SPEVIGO® meets the newness criterion.

Comment: The applicant submitted a comment to address CMS's concerns regarding the newness criterion. With respect to the request for additional information on currently available treatments and how they compare to SPEVIGO®, the applicant stated that SPEVIGO® is the only FDA approved therapy for the treatment of GPP flares in adults. The applicant noted that prior to SPEVIGO®, there was no consensus standard of care for GPP flares. Per the applicant, due to historical lack of robust clinical trial evidence or previously approved therapies for GPP flares, systemic agents were experimented with clinically in patients with GPP flares, based mainly on clinical experience in patients with plaque psoriasis (PSO). The applicant stated that even with treatment with these agents, many patients still had residual symptoms. Patients with GPP report a poorer quality of life compared with those with PSO, with greater severity of itch, pain, and fatigue, and a greater impact on work and daily activities. Per the applicant, treatments approved for PSO, including oral systemic therapies and biologic products, may have a slow time to response in patients with GPP flares. Regarding currently available treatments indicated for PSO and their on-label use for GPP, the applicant stated that aside from SPEVIGO®, there are no FDA-approved therapies indicated for the treatment of GPP flares in adults. The applicant noted that GPP flares have acute systemic presentation, with unpredictable and rapid periods of worsening disease and complications resulting from systemic inflammation and neutrophilic influx, often requiring hospitalization; PSO, on the other hand, is a chronic disease affecting mainly the skin, and is typically managed in an outpatient setting. The applicant noted that although historically considered a variant of PSO, GPP is a phenotypically, genetically, and histopathologically distinct entity from PSO.[109] [110] [111] According to the applicant, GPP is characterized clinically by widespread eruption of neutrophilic, non-infectious pustules, while PSO is characterized by localized discrete plaques with excess scale resulting from abnormal differentiation of keratinocytes.[112] The applicant stated that the pathways driving GPP and PSO are distinct. This is relevant to specifically targeting GPP. Specifically, GPP results from dysregulation of the innate immune system involving disruption of the interleukin IL–36 signaling pathway leading to uncontrolled systemic inflammation and a large influx of

[109] Bachelez H, Barker J, Burden AD, et al. (Oct 2022). Generalized pustular psoriasis is a disease distinct from psoriasis vulgaris: evidence and expert opinion. *Expert Rev Clin Immunol.* 18(10):1033–1047. doi: 10.1080/1744666X.2022.2116003. Epub 2022 Sep 20. PMID: 36062811.

[110] Navarini AA, Burden AD, Capon F, et al.; for the ERASPEN Network. European consensus statement on phenotypes of pustular psoriasis. *J Eur Acad Dermatol Venereol.* 201 (1): 1792–1799 doi:lO.lll l/jdv.14386.

[111] Gooderham MJ, Van Voorhees AS, Lebwohl MG. (Sep 2019). An update on generalized pustular psoriasis. *Expert Rev Clin Immunol.* 15(9):907–919. doi: 10.1080/1744666X.2019.1648209. Epub 2019 Sep 5. PMID: 31486687.

[112] Bachelez, et al. (2022), *op.cit.*

neutrophils. On the other hand, PSO is driven by the adaptive immune system, with dysregulation of the IL–17/IL–23 pathway being a key characteristic, leading to an inflammatory impact that is mainly observed on the skin.[113] The applicant maintained that because of its extreme systemic impact, GPP has a considerable clinical burden, and symptoms related to GPP have been reported to affect everyday tasks such as walking and sleeping.[114] Patients with GPP report a poorer quality of life compared with patients with PSO with greater severity of itch, pain, and fatigue, and a greater impact on work and daily activities).[115] Per the applicant, without a consensus standard of care for GPP flares (prior to SPEVIGO), various off-label PSO treatments have been used in an attempt to control flare symptoms. Due to the historical lack of robust clinical trial evidence and no previously approved therapies for GPP flares, systemic agents have been experimented with clinically in patients with GPP flares, based mainly on clinical experience in patients with PSO. According to the applicant, an important result of this is that, even with treatment with these agents, many patients still have residual symptoms.[116] [117] [118] Treatments approved for PSO, including oral systemic therapies and biologic products, may have a slow time to response in patients with GPP flares. The applicant stated that in a recently published consensus, a panel of international dermatology experts agreed that rapid response was critical to alleviate systemic and potentially life-threatening symptoms of GPP flares.[119] In addition, there are well-documented safety concerns with long-term use of some of these systemic agents, making them inappropriate for continuous use. To name a few examples, retinoids are associated with teratogenic effects, liver toxicity, and skeletal abnormalities; [120] cyclosporine has been associated with systemic hypertension and nephrotoxicity; [121] and respiratory complications, myelosuppression, and hepatic impairment have reported with methotrexate.[122] The applicant noted that with respect to biologic products used for treating PSO, many are specifically indicated for and tested in randomized, controlled trials of patients with PSO; however, there have been no results from randomized, placebo-controlled trials of any agent other than SPEVIGO® in patients with GPP flares; therefore, comparisons (even cross-trial) cannot be made, nor can assumptions that PSO agents would benefit patients with GPP flares. Per the applicant, some of these agents approved for the treatment of PSO have been studied in patients with GPP in Japan; however, none of the studies were randomized, controlled trials, most of the patient populations were mixed and included a small number of patients with GPP, and all of the trials used endpoints that were not specific to GPP. The applicant also stated that no study, aside from those of SPEVIGO®, has specifically reported the outcome of pustular clearance, and there are limited data on systemic improvements with these agents.[123] [124] [125] [126] With regard to whether SPEVIGO® may be mapped to the same MS–DRGs as other current treatments for GPP, the applicant maintained that since SPEVIGO® is the only FDA approved treatment for GPP flares, it would be the only therapy to be mapped for patients with GPP flares. The applicant also argued that once approved, other off-label therapies would not be expected to be used for treating GPP flares.

Response: We thank the applicant for its comment regarding the newness criterion. Based on our review of comments received and information submitted by the applicant as part of its FY 2024 new technology add-on payment application for SPEVIGO®, we agree with the applicant that SPEVIGO® has a new mechanism of action because it is a humanized anti-interleukin-36 (IL–36) receptor monoclonal antibody that targets the IL–36 pathogenetic pathway in the treatment of GPP. Therefore, we agree with the applicant that SPEVIGO® is not substantially similar to existing treatment options and meets the newness criterion. We consider the beginning of the newness period to commence on September 1, 2022, when SPEVIGO® was FDA approved for the treatment of GPP flares in adults.

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for SPEVIGO®, the applicant searched the FY 2021 MedPAR file for cases reporting ICD–10–CM diagnosis code L40.1 (Generalized pustular psoriasis). Using the inclusion/exclusion criteria described in the following table, the applicant identified 64 cases mapping to 4 MS–DRGs listed in the table in this section. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $387,414, which exceeded the average case-weighted threshold amount of

[113] *Ibid.*

[114] Burden AD, Choon SE, Gottlieb AB, et al. (Jan 2022). Clinical Disease Measures in Generalized Pustular Psoriasis. *Am J Clin Dermatol.* 23(Suppl 1):39–50. doi: 10.1007/s40257–021–00653–0. Epub 2022 Jan 21. PMID: 35061231; PMCID: PMC8801406.

[115] Lebwohl M, Langley RG, Paul C, et al. (2022). Evolution of Patient Perceptions of Psoriatic Disease: Results from the Understanding Psoriatic Disease Leveraging Insights for Treatment (UPLIFT) Survey. *Dermatol Ther (Heidelb).* 12(1):61–78. doi: 10.1007/s13555–021–00635–4. Epub 2021 Oct 25. Erratum in: *Dermatol Ther (Heidelb).* PMID: 34704231; PMCID: PMC8547901.

[116] Kara Polat, A.; Alpsoy, E.; Kalkan, G.; et al. (2022). Sociodemographic, clinical, laboratory, treatment and prognostic characteristics of 156 generalized pustular psoriasis patients in Turkey: A multicentre case series. *J. Eur. Acad. Dermatol. Venereol.* 36, 1256–1265.

[117] Choon SE, Lai NM, Mohammad NA, et al. (2014). Clinical profile, morbidity, and outcome of adult-onset generalized pustular psoriasis: analysis of 102 cases seen in a tertiary hospital in Johor, Malaysia. *Int J Dermatol.* 53(6):676–684. doi:10.1111/ijd.12070.

[118] Strober B, Kotowsky N, Medeiros R, et al. (2021). Unmet medical needs in the treatment and management of generalized pustular psoriasis flares: evidence from a survey of Corrona registry dermatologists. *Dermatol Ther (Heidelb).* 1 1 (2):529–541. doi: O. 1007/s 13555–021–00493–0.

[119] Puig, L, Choon, SE, Gottlieb, AB, et al. (2023). Generalized pustular psoriasis: A global Delphi consensus on clinical course, diagnosis, treatment goals and disease management. *J Eur Acad Dermatol Venereol.* 37: 737– 752. *https://doi.org/10.1111/jdv.18851.*

[120] David M, Hodak E, Lowe NJ. (Jul-Aug 1988) Adverse effects of retinoids. *Med Toxicol Adverse Drug Exp.* 3(4):273–88. doi: 10.1007/BF03259940. PMID: 3054426.

[121] Neoral. Prescribing Information. 2009 (available at *https://www.accessdata.fda.gov/drugsatfda_docs/label/2009/050715s027, 050716s028lbl.pdf*).

[122] Kim BR, Ohn J, Choi CW, et al. (Jun 2017). Methotrexate in a Real-World Psoriasis Treatment: Is It Really a Dangerous Medication for All? *Ann Dermatol.* 29(3):346–348. doi: 10.5021/ad.2017.29.3.346. Epub 2017 May 11. PMID: 28566915; PMCID: PMC5438945.

[123] Imafuku S, Honma M, Okubo Y, et al. (Sep 2016). Efficacy and safety of secukinumab in patients with generalized pustular psoriasis: A 52-week analysis from phase III open-label multicenter Japanese study. *J Dermatol.* 43(9):1011–7. doi: 10.1111/1346–8138.13306. Epub 2016 Feb 26. PMID: 26919410.

[124] Sano S, Kubo H, Morishima H, et al. (May 2018). Guselkumab, a human interleukin-23 monoclonal antibody in Japanese patients with generalized pustular psoriasis and erythrodermic psoriasis: Efficacy and safety analyses of a 52-week, phase 3, multicenter, open-label study. *J Dermatol.* 45(5):529–539. doi: 10.1111/1346–8138.14294. Epub 2018 Mar 22. PMID: 29569397; PMCID: PMC5947137.

[125] Saeki H, Kabashima K, Tokura Y (Aug 2017). Efficacy and safety of ustekinumab in Japanese patients with severe atopic dermatitis: a randomized, double-blind, placebo-controlled, phase II study. *Br J Dermatol.* 177(2):419–427. doi: 10.1111/bjd.15493. Epub 2017 Jun 27. PMID: 28338223.

[126] Morita A, Yamazaki F, Matsuyama T, et al. (Dec 2018). Adalimumab treatment in Japanese patients with generalized pustular psoriasis: Results of an open-label phase 3 study. *J Dermatol.* 45(12):1371–1380. doi: 10.1111/1346–8138.14664. Epub 2018 Oct 10. PMID: 30302793; PMCID: PMC6585693.

$46,244. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that SPEVIGO® meets the cost criterion.

BILLING CODE 4120–01–P

SPEVIGO® COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of ICD-10-CM codes	L40.1 (Generalized pustular psoriasis)
List of MS-DRGs	603 (Cellulitis without MCC) 607 (Minor Skin Disorders without MCC) 871 (Septicemia or Severe Sepsis without MV >96 hours with MCC) 872 (Septicemia or Severe Sepsis without MV >96 hours without MCC)
Inclusion/exclusion criteria	The applicant identified cases by using the ICD-10-CM diagnosis code L40.1 (Generalized pustular psoriasis) and limited the data to PPS hospitals by identifying claims with a claim type code of 60. The analysis was limited to DRGs with a case count of 11 or greater. The applicant also removed Medicare Advantage cases, cases with total charges or covered charges less than zero, and cases with a length of stay of zero. The applicant calculated the average unstandardized charge per case for each MS-DRG.
Charges removed for prior technology	The applicant did not remove any charges for prior technology because no FDA approved treatments for GPP existed prior to the FDA approval of SPEVIGO®. The applicant also did not remove any indirect charges related to prior technologies.
Standardized charges	The applicant used the standardization formula provided in Technical Appendix A of the application. The applicant used all relevant values reported in the standardizing file posted with the FY 2023 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied the four-year inflation rate of 1.28134 to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule.
Charges added for the new technology	The charges added for the new technology were for the cost of SPEVIGO®, based on the WAC price. The applicant added charges for the new technology by dividing the cost of SPEVIGO® by the national average CCR for drugs which is 0.184 from the FY 2023 IPPS/LTCH PPS final rule.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26825), we noted the applicant stated that removing charges for prior technology was not applicable to SPEVIGO®; however, to the extent patients were treated with other treatments before SPEVIGO®, we questioned whether it may be appropriate to remove some portion of these charges to avoid inappropriately inflating the average charge per case. We invited public comments on whether it may be appropriate to remove charges for the prior technology and whether SPEVIGO® meets the cost criterion.

Comment: The applicant submitted a comment in response to our concerns pertaining to cost criterion. With respect to the appropriateness of not removing charges for prior technologies SPEVIGO®, the applicant responded that because there are no approved therapies specifically indicated for the treatment of GPP flares, and due to the severe condition of patients with GPP flares, off-label treatments may be experimented with, including those indicated for PSO. As a result, patients receiving SPEVIGO® may have altered utilization of the first- or second-line off-label therapies historically used to treat GPP flares. The applicant maintained that SPEVIGO® will replace the off-label PSO treatments as the primary standard of care based on the substantial clinical improvement demonstrated by SPEVIGO® in a robust clinical trial. The applicant stated that while removal of charges can be difficult with no consensus off-label standard of care previously, they provided an updated cost analysis in which they have removed all drug cost center charges (one of the 19 cost centers defined by CMS as part of the relative weight calculation process) to avoid any concern of costs from prior off-label therapies. According to the applicant's updated cost analysis, the final inflated case-weighted average standardized charge per case of $361,189 exceeded the case-weighted threshold of $46,244, and the applicant therefore maintained that SPEVIGO® meets the cost criterion.

Response: We thank the applicant for the updated cost analysis. Based on the additional information received, we agree that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. Therefore, SPEVIGO® meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that SPEVIGO® represents a substantial clinical improvement over existing technologies by being the first FDA approved drug for GPP, and existing treatments were associated with slow resolution of GPP flares and complete clearance of pustules and skin was not always achieved. The applicant further stated that in clinical trials, SPEVIGO® was associated with clinically significant improvements in patient-reported psoriasis symptoms, including fatigue, and significant decreases in markers of systemic inflammation. The applicant provided one study to support these claims. The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for SPEVIGO® for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Outcome(s) or findings cited by the applicant from supporting evidence to support its statements**
SPEVIGO®® is a treatment specifically indicated for GPP	Bachelez H et al. N Engl J Med 2021;385:2431-40. Brief study description: Effisayil-1 Phase II trial randomized 2:1 spesolimab vs placebo (n=53)	A total of 52 of the 53 enrolled patients completed the first week of the trial. Data for 1 patient in the spesolimab group were missing for the primary and key secondary end points and were imputed as no response. At day 8, a total of 12 patients (34%) in the spesolimab group and 15 patients (83%) in the placebo group received an open-label dose of spesolimab. After day 8, a total of 32 patients (91%) who were randomly assigned to receive spesolimab and 17 patients (94%) who were randomly assigned to receive placebo completed the 12-week follow-up period, during which 4 and 2 patients, respectively, received rescue treatment with spesolimab. After completing 12 weeks of treatment, 39 patients were enrolled in the open-label extension trial. Efficacy - Primary and Key Secondary Efficacy End Points At the end of week 1, a total of 19 of the 35 patients (54%) who were assigned to the spesolimab group and 1 of the 18 patients (6%) who were assigned to the placebo group had a GPPGA pustulation subscore of 0 (no visible pustules) (difference, 49 percentage points; 95% confidence interval [CI], 21 to 67; P<0.001) (Table 2.) A total of 15 patients (43%) who were assigned to the spesolimab group and 2 patients (11%) who were assigned to the placebo group had a GPPGA total score of 0 or 1 (clear or almost clear skin) (difference, 32 percentage points; 95% CI, 2 to 53; P=0.02. The results of the post hoc sensitivity analyses of the primary and key secondary end points to adjust for the observed baseline imbalances in sex, race, and GPPASI score were consistent with the results of the primary analysis.
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available.		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Outcome(s) or findings cited by the applicant from supporting evidence to support its statements**
SPEVIGO® is associated with improved psoriasis symptom scale, functional assessment, and reduced markers of inflammation	Bachelez H et al. N Engl J Med 2021;385:2431-40., phase II randomized trial See prior study description	At baseline, 46% of the patients in the spesolimab group and 39% of those in the placebo group had a GPPGA pustulation subscore of 3, and 37% and 33%, respectively, had a pustulation subscore of 4. At the end of week 1, a total of 19 of 35 patients (54%) in the spesolimab group had a pustulation subscore of 0, as compared with 1 of 18 patients (6%) in the placebo group (difference, 49 percentage points; 95% confidence interval [CI], 21 to 67; P<0.001). A total of 15 of 35 patients (43%) had a GPPGA total score of 0 or 1, as compared with 2 of 18 patients (11%) in the placebo group (difference, 32 percentage points; 95% CI, 2 to 53; P=0.02). Drug reactions were reported in 2 patients who received spesolimab, in 1 of them concurrently with a drug-induced hepatic injury. Among patients assigned to the spesolimab group, infections occurred in 6 of 35 (17%) through the first week; among patients who received spesolimab at any time in the trial, infections had occurred in 24 of 51 (47%) at week 12. Antidrug antibodies were detected in 23 of 50 patients (46%) who received at least one dose of spesolimab.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26886), after review of the information provided by the applicant, we stated that we had the following concerns regarding whether SPEVIGO® meets the substantial clinical improvement criterion. With regard to the Effisayil-1 study, we noted that it is not designed to compare SPEVIGO® to current treatment options. While the applicant stated that SPEVIGO® will be the first GPP treatment targeting the IL–36 pathway, we noted that per the applicant, other treatments are available, and we therefore questioned whether placebo was the most appropriate comparator. In particular, we noted that the Effisayil-1 trial primarily assessed clearance of skin manifestations, not systemic symptoms which the applicant noted differentiates GPP from other forms of psoriasis. We noted the applicant has stated in its application that existing treatments for

GPP are not specifically indicated for GPP and that it would not be appropriate to consider these treatments on-label for GPP. However, we noted that there are treatments that are indicated for psoriasis generally, such as methotrexate [127] or retinoids,[128] which may be considered an on-label use for subtypes of psoriasis such as GPP. Therefore, it was unclear whether there is a patient population ineligible for or unresponsive to existing technologies that could be treated with SPEVIGO®. In addition, although the applicant stated that SPEVIGO® represents a substantial clinical improvement over existing technologies where complete clearances were not always achieved, it seemed that complete clearance is also not always achieved with SPEVIGO®. As demonstrated in the Effisayil-1 study cited by the applicant, 54.3 percent of the patients achieved complete pustular clearance in the SPEVIGO® arm.

We noted that GPP occurs most frequently between the ages of 15–20 years with a smaller peak occurring at 55–60 years.[129] The mean age in the Effisayil-1 study was 43.2 years for the SPEVIGO® arm and 42.6 years for the placebo group. Given the age range of patients, we questioned the generalizability of the outcomes demonstrated in a study of otherwise generally healthy patients with GPP to patients with GPP in the Medicare population who would likely be eligible for Medicare based on disabilities that could potentially present comorbidities for which SPEVIGO® would not be appropriate or effective. In addition, the study administered SPEVIGO® to the placebo group after one week, after which only outcomes with SPEVIGO® were assessed, and the study concluded at 12 weeks. Given that the applicant did not provide any comparative data on existing technologies to demonstrate improved outcomes with SPEVIGO®, in addition to the short duration of the single study provided and the often variable, remitting, and intermittent course of the disease in which most flares last between 2 and 5 weeks, we questioned whether the information we had supports a finding of substantial clinical improvement. We stated that additional information to support the applicant's assertion of superiority over existing technologies would be helpful in better informing our assessment of this criterion.[130] [131]

We invited public comments on whether SPEVIGO® meets the substantial clinical improvement criterion.

Comment: The applicant submitted a comment in response to CMS's concerns pertaining to the substantial clinical improvement criterion. With respect to the appropriateness of comparing SPEVIGO® to placebo instead of other current treatment options and of the sparsity of systemic end points, the applicant maintained that because there has been no established standard of care for GPP flares prior to the approval of SPEVIGO®, numerous biologic and oral systemic agents indicated for PSO have been used anecdotally in clinical practice in attempts to treat GPP flares. The applicant stated that no other treatment approved for PSO has been tested in a randomized controlled trial in GPP flares, and evidence for these treatments come from small, single-arm, uncontrolled studies of mixed patient populations that did not evaluate clinically robust endpoints specific to GPP. The applicant further noted that because these treatments have variable efficacy and safety profiles, it becomes challenging to propose one of them as an active comparator for a trial in GPP flares. According to the applicant, due to the lack of FDA-approved treatments as well as consensus on standard of care for GPP flares, placebo can be considered an appropriate comparator. Per the applicant, FDA also considered placebo to be appropriate and requested the inclusion of the placebo arm for a robust and well controlled study. Regarding the selection of endpoints, the applicant mentioned that while the primary endpoint of the Effisayil-1 trial was complete pustular clearance, the trial also examined the impact of SPEVIGO® on additional endpoints, including measures of systemic inflammation like C-reactive protein (CRP) levels and neutrophil count over time. Per the applicant, both the CRP levels and neutrophil count over time were shown, in conjunction with skin clearance, to improve to normal levels in the trial and were maintained throughout the course of the trial. With regard to whether there is a patient population ineligible for or responsive to existing technologies that could be treated with SPEVIGO®, the applicant noted that there are distinct differences in the dysregulation of IL pathways between GPP and PSO. As the only GPP-indicated therapy, SPEVIGO® offers patients an effective therapy targeting the GPP-specific IL–36 pathway. According to the applicant, it has been well-documented that GPP and psoriasis vulgaris (PV, also called plaque psoriasis) are separate clinical conditions, requiring specific treatment approaches.[132] The applicant cited a recent longitudinal case series of patients with GPP as an example of the limited efficacy of the nontargeted immunomodulatory therapies (for example, methotrexate, retinoids) to treat GPP flares. [133] Per the applicant, the result of these studies showed that despite the use of methotrexate and retinoids, which were among the most frequently used agents for treating GPP flares, the rates of emergency department visits and hospitalizations among GPP patients during the follow-up period remained at approximately 40 percent. Per the applicant, this suggested that these systemic agents are inadequate for controlling GPP flares. With regard to the result of the Effisayil-1 study that 54.3 percent of the patients achieved complete pustular clearance in the SPEVIGO® arm, the applicant cited recent guidance, based on global expert consensus, that the goals of treatment of GPP flares are to achieve rapid and sustained clearance of pustules, inflammatory erythema, scaling, crust, and skin lesions; and to rapidly alleviate systemic symptoms and reduce pain while maintaining a favorable safety profile.[134] According to the applicant, the primary endpoint was a Generalized Pustular Psoriasis Physician Global Assessment (GPPGA) pustulation subscore of zero at week 1, a highly stringent endpoint, according to many international dermatology experts. According to the applicant, 54.3 percent of the patients from the Effisayil-1 study achieved the GPPGA pustulation subscore of zero (complete pustular clearance) in the SPEVIGO® arm after one dose. Moreover, in patients who received up to 2 doses of SPEVIGO®, 66 percent achieved a GPPGA pustulation subscore of zero at week 2. The applicant added that of the patients randomized to placebo and who received a dose of SPEVIGO® at week 1, 73 percent had a GPPGA pustulation score of zero at week 2 (one week after receiving their first dose of SPEVIGO®) and 60 percent of patients maintained a GPPGA pustulation subscore of 0 out to week 12. The applicant asserted that,

[127] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/008085Orig1s071lbl.pdf.*

[128] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/019821s028lbl.pdf.*

[129] Samotij et al. Generalized pustular psoriasis: divergence of innate and adaptive immunity. Int J Mol Sci 2021;22(16):9048.

[130] Krueger et al. Treatment options and goals for patients with generalized pustular psoriasis. Am J Clin Dermatol 2022:23(suppl 1):51–64.

[131] Choon et al. Clinical course and characteristics of generalized pustular psoriasis. Am J Clin Dermatol 2022;23(suppl 1):21–9.

[132] Bachelez et al, 2022, *op.cit.*

[133] Noe et al. (2022), *op.cit.*

[134] Bachelez et al (2022), *op.cit.*

based upon the data from Effisayil-1, SPEVIGO® treatment of GPP flares was associated with rapid pustular clearance within 1 week with clinically significant and prolonged normalizations in inflammatory markers, like CRP and neutrophil count in a robust, randomized clinical trial. The applicant maintained that these results were consistent with some of the treatment goals set forth by international dermatology experts and demonstrated substantial clinical improvement in this extremely burdensome and potentially life-threatening disease for which no standard of care previously existed. With regard to the generalizability of Effisayil-1 study results to the Medicare population, the applicant stated that the median onset of GPP is between 40 to 60 years of age, and while it is true that the average patient age was younger than the Medicare population in the Effisayil-1 study, most patients with GPP are not considered by dermatology experts to be generally healthy, particularly during a flare. The applicant stated that patients with GPP often have multiple comorbidities, including hyperlipidemia, type 2 diabetes, chronic obstructive pulmonary disease (COPD), chronic kidney disease, and obesity[28], making these patients not so dissimilar to the Medicare population. The applicant also noted that patients with these comorbidities were not excluded from the Effisayil-1 trial. According to the applicant, based on their internal data, 30 percent of treated patients since launch were Medicare beneficiaries. The applicant also stated that Medicare beneficiaries, including those with disabilities or comorbidities, are not excluded per the FDA label. With regard to the adequacy of the study length, the applicant argued that despite the short duration of the placebo-controlled portion of the Effisayil-1 trial, it was compelling that 54 percent of patients in the SPEVIGO® arm experienced complete pustule resolution at week 1, and 60 percent of these patients maintained pustule resolution out to 12 weeks, given the disease burden of GPP and its negative impact on daily activities. Per the applicant, these results demonstrated a stark clinical improvement, compared to the residual symptoms that many GPP patients experienced on the current off-label treatments. The applicant also noted that both the placebo and SPEVIGO® arms were eligible to receive a single, open-label, dose of SPEVIGO® at week 1 if a patient had prolonged symptoms, since it would be unethical to prevent GPP patients from receiving treatment after prolonged GPP flare symptoms.

Response: We thank the applicant for their comments regarding the substantial clinical improvement criterion. Based on the additional information received, we agree that SPEVIGO® represents a substantial clinical improvement because the technology offers a treatment option for generalized pustular psoriasis (GPP) flares in adults, for which it is the first FDA approved treatment.

After consideration of the public comments, we have determined that SPEVIGO® meets the criteria for approval for new technology add-on payment. Therefore, we are approving new technology add-on payments for this technology for FY 2024. Cases involving the use of SPEVIGO® that are eligible for new technology add-on payments will be identified by ICD–10–PCS code XW03308 (Introduction of spesolimab monoclonal antibody into peripheral vein, percutaneous approach, new technology group 8).

In its application, the applicant estimated that the average inpatient cost of SPEVIGO® is $51,133 for one 900 mg dose, comprised of two 450 mg/7.5 mL (60 mg/mL) vials. Therefore, the average cost per patient for SPEVIGO® is $51,133. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of SPEVIGO® is $33,236.45 for FY 2024.

i. TECVAYLI™ (Teclistamab-cqyv)

Johnson & Johnson Health Care Systems, Inc. submitted an application for new technology add-on payments for TECVAYLI™ for FY 2024. According to the applicant, TECVAYLI™ is the only bispecific antibody approved for the treatment of multiple myeloma (MM), specifically adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-cluster of differentiation (CD)38 monoclonal antibody. The applicant stated that the structure of TECVAYLI™ is advantageous versus other bispecific platforms since its full size is designed to mimic naturally-occurring immunoglobulin G (IgG) antibodies. We note that Johnson & Johnson Health Care Systems, Inc. submitted an application for new technology add-on payments for TECVAYLI™ for FY 2023 under the name teclistamab, as summarized in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28283 through 28287) and withdrew it prior to the issuance of the FY 2023 IPPS/LTCH PPS final rule (87 FR 48920).

Please refer to the online application posting for TECVAYLI™, available at *https://mearis.cms.gov/public/publications/ntap/NTP221017MFYGL*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, according to the applicant, TECVAYLI™ was granted BLA approval from FDA on October 25, 2022, for the treatment of adult patients with RRMM who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. According to the applicant, the product became commercially available on November 9, 2022. Commercial availability was delayed because of the need to complete final supply chain readiness activities. Per the applicant, patients in the hospital for their initial TECVAYLI™ treatment will receive three doses subcutaneously—a 0.06 mg/kg loading dose, a 0.30 mg/kg loading dose, and the first 1.5 mg/kg treatment dose—during the hospital stay. The applicant stated that patients who are under 102 kgs will use two 30 mg and one 153 mg vials during their hospitalization. Patients over 102 kg will use three 30 mg and two 153 mg vials during their hospitalization. According to real world evidence and clinical studies, 89 percent of TECVAYLI™ patients will be less than 102 kg. Due to the risk of CRS and neurologic toxicity, patients should be hospitalized for 48 hours after administration of all doses within the step-up dosing schedule. Therefore, according to the applicant, all three doses will be administered in a single inpatient hospitalization.

The applicant stated that effective October 1, 2022, the following ICD–10–PCS code may be used to uniquely describe procedures involving the use of TECVAYLI™: XW01348 (Introduction of teclistamab antineoplastic into subcutaneous tissue, percutaneous approach, new technology group 8).

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that TECVAYLI™ is not substantially

similar to other currently available technologies because it has a distinct mechanism of action, with a novel approach to engage a patient's own T-cells to generate a myeloma-specific immune response and is the first therapy of its type for the treatment of RRMM, and therefore meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for TECVAYLI™ for the applicant's complete statements in support of its assertion that TECVAYLI™ is not substantially similar to other currently available technologies.

Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	TECVAYLI™ has a unique mechanism of action with a full-sized antibody containing 2 distinct binding domains that simultaneously bind the BCMA target on tumor cells and the CD3 T-cell receptor. Unlike ide-cel and cilta-cel, it engages the patient's existing immune system without the requirement for cell extraction and engineering. TECVALYI™ is the only commercially available bispecific antibody for MM. It is a novel and distinct molecule from the only other approved bispecific antibodies: blinatumomab and amivantamab. Blinatumumab is a bispecific T-cell engager (BiTE) targeting CD3 and CD19 and is approved only for pre-B-cell acute lymphoblastic lymphoma. The structure is different from TECVAYLI™ in that it is not a full-sized antibody but rather two Fab fragments held together by a chemical linker. Amivantamab, while also a bispecific antibody that targets two antigens, epidermal growth factor (EGF) and MET receptors, is specific to lung cancer cells. It does not induce T-cell redirection as its mechanism of action, as it does not contain a CD3-binding domain. In summary, TECVAYLI™ is a bispecific T-cell engaging antibody therapy that uses the patient's own T-cells re-directed to BCMA expressing T-cells using a full-sized IgG antibody with bispecificity for BCMA and CD3 (the main T-cell receptor). TECVAYLI™ is not substantially similar to other existing bispecific antibodies like 1) blinatumomab or 2) amivantamab due to its 1) Duobody structure (versus BiTEs as previously discussed) and targeting of BCMA versus CD19 and 2) targeting of CD3 and BCMA versus the lung cancer antigens, cMET and EGFR. Because TECVAYLI™ has a novel structure and unique mechanism of action, it is unlike any existing technology utilized to treat MM.
Is the technology assigned to the same MS-DRG as existing technologies?	Yes	The use of TECVAYLI™ in treating a patient's MM is not expected to change the DRG assignment of the case.
Does the use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	Yes	TECVAYLI™ 's indication is for the treatment of adult patients with RRMM who have received at least four prior lines of therapy, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. This indication is similar to approved therapies for MM patients who have failed four prior therapies or lines of therapy.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26887), we noted that TECVAYLI™ may have a similar mechanism of action to that of elranatamab, for which we received an application for new technology add-on payments for FY 2024 for the treatment of adult patients with relapsed or refractory multiple myeloma after three or more prior therapies, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. Per the application for elranatamab, elranatamab is substantially similar to TECVAYLI™. Elranatamab's mechanism of action is described as a bispecific antibody, meaning it has two parts, one that recognizes the cancer cell and one that recognizes and engages the T-cell, and brings them together to facilitate T-cell killing of the MM cell. For elranatamab, the two targets are barcoded medication administration (BCMA) (which has high specific expression on normal plasma cells and on MM cells) and CD3 (which is expressed on T-cells). Elranatamab binds to the CD3 on the T-cells and binds to the BCMA on the MM cells thereby bringing the cells in close proximity. The engagement of the CD3 on the T-cell activates the T-cell, leading to the T-cells releasing cytokines that result in the killing of the close-proximity MM cell. Because of the apparent similarity with the bispecific antibody that uses binding domains that simultaneously bind the BCMA target on tumor cells and the CD3 T cell receptor, we believed that the mechanism of action for TECVAYLI™ may be the same or similar to that of elranatamab.

We believed that TECVAYLI™ and elranatamab may also treat the same or similar disease (RRMM) in the same or similar patient population (patients who have previously received a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and an anti-CD38 antibody). Accordingly, as it appears

that TECVAYLI™ and elranatamab are purposed to achieve the same therapeutic outcome using the same or similar mechanism of action and would be assigned to the same MS–DRG, we believed that these technologies may be substantially similar to each other such that they should be considered as a single application for purposes of new technology add-on payments if elranatamab receives FDA approval by July 1, 2023. We stated that we were interested in information on how these two technologies may differ from each other with respect to the substantial similarity criteria and newness criterion, to inform our analysis of whether TECVAYLI™ and elranatamab are substantially similar to each other and therefore should be considered as a single application for purposes of new technology add-on payments.

We invited public comment on whether TECVAYLI™ meets the newness criterion, including whether TECVAYLI™ is substantially similar to elranatamab and whether these technologies should be evaluated as a single technology for purposes of new technology add-on payments.

Comment: The applicant submitted a comment regarding the newness criterion, reiterating that TECVAYLI® meets the overall requirements of the newness criterion as it does not meet all three criteria required to be deemed substantially similar to existing technology. With regard to whether TECVAYLI™ and elranatamab are substantially similar and should be treated as a single technology for the purposes of new technology add-on payments, the applicant stated that while elranatamab and TECVAYLI™ are both bispecific antibodies, the antibody for each product is meaningfully different, and therefore the mechanism of action for these two products should be considered distinct. The applicant explained that TECVAYLI™ is a humanized IgG4 antibody, whereas elranatamab is a humanized IgG2a antibody, and IgG4 antibodies have a high affinity for Fc gamma receptor subtype I (FcγRI) but weak affinities for all other Fc gamma receptor subtypes and are poor inducers of Fc-mediated effector functions, while IgG2 antibodies have a high affinity for the H131 form of Fc gamma receptor subtype IIA (FcγRIIA) but no measurable or weak affinity for FcγRI and all other Fc gamma receptors. The applicant agreed that both TECVAYLI™ and elranatamab are bispecific T-cell engaging antibodies that exert their efficacy primarily by re-directing the patient's own T-cells to BCMA-expressing multiple myeloma cells, but stated they are distinctly and importantly different in regards to the whether the binding of the bispecific antibodies to Fc gamma receptors may activate immune effector cells that may lead to a pro-inflammatory state and contribute to cytokine release syndrome and other toxicities. The applicant asserted that the biological difference between TECVAYLI™ and elranatamab may result in meaningful clinical differences, and that therefore, CMS should consider these technologies separately for new technology add-on payments. The applicant added that elranatamab is not yet FDA-approved and therefore should not be considered as an existing technology for inclusion in meeting the substantial similarity criteria.

Another commenter, the manufacturer for elranatamab, stated that it believed that TECVAYLI™ and elranatamab are substantially similar and should be considered under a single application on the basis of (1) the mechanism of action (BCMA-directed bispecific antibody), (2) the patient population and disease intended to be treated (RRMM in patients who have received four or more prior lines of therapy including a proteasome inhibitor (PI), immunomodulatory drug (IMiD), and anti-CD38 monoclonal antibody), and (3) MS–DRG assignment.

Response: We thank the applicant and other commenter for their comments regarding newness. As discussed previously, elranatamab has not been FDA approved as of the July 1 deadline and is therefore no longer eligible for consideration for new technology add-on payments for FY 2024, and we further note that the technology has not yet been FDA approved as of the time of the development of this final rule. Therefore, we agree with the applicant that elranatamab is not considered an existing technology for the purposes of the substantial similarity determination at this time.

Based on our review of comments received and information submitted by the applicant as part of its FY 2024 new technology add-on payment application for TECVAYLI™, we agree with the applicant that TECVAYLI™ has a unique mechanism of action as a bispecific antibody containing 2 distinct binding domains that simultaneously bind the BCMA target on myeloma cells and the CD3 T-cell receptor to treat RRMM. Therefore, we believe that TECVAYLI™ is not substantially similar to existing treatment options and meets the newness criterion. We consider the beginning of the newness period to commence on the date the product became commercially available, on November 9, 2022.

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for TECVAYLI™, the applicant searched the FY 2021 MedPAR file for cases reporting one of the following ICD–10–CM codes in one of the first five diagnosis code positions: C90.00 (Multiple myeloma not having achieved remission), C90.01 (Multiple myeloma in remission), or C90.02 (Multiple myeloma in relapse). The applicant provided calculations for 2 cohorts. Based on the clinical advice of experts, for the first cohort, the applicant limited the analysis to cases assigned to MS–DRGs 846 (Chemotherapy Without Acute Leukemia as Secondary Diagnosis with MCC), 847 (Chemotherapy Without Acute Leukemia as Secondary Diagnosis with CC) and 848 (Chemotherapy Without Acute Leukemia as Secondary Diagnosis without CC/MCC), because the experts believed that TECVAYLI™ would mostly likely be administered in cases assigned to these MS–DRGs. This analysis was completed prior to the drug being available. Based on additional information gathered since TECVAYLI™ was FDA approved, the applicant included in the second cohort the following MS–DRGs in addition to the MS–DRGs included in the first cohort: 840 (Lymphoma and Non-Acute Leukemia with MCC), 841 (Lymphoma and Non-Acute Leukemia with CC), and 842 (Lymphoma and Non-Acute Leukemia without CC/MCC). For both cohorts, no cases were identified for MS–DRG 848 (Chemotherapy Without Acute Leukemia as Secondary Diagnosis without CC/MCC). Using the inclusion/exclusion criteria described in the following table, the applicant identified 600 claims for cohort 1 and 4,335 claims for cohort 2. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $119,279 for cohort 1 and $145,374 for cohort 2, both of which exceeded the average case-weighted threshold amount of $58,291 and $73,551, respectively. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in both scenarios, the applicant asserted that TECVAYLI™ meets the cost criterion.

TECVAYLI™ COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of ICD-10-PCS codes	Cohort 1 and 2 C90.00 (Multiple myeloma not having achieved remission) C90.01 (Multiple myeloma in remission) C90.02 (Multiple myeloma in relapse)
List of MS-DRGs	Cohort 1: 846 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with MCC), 847 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with CC) 848 (Chemotherapy without Acute Leukemia as Secondary Diagnosis without CC/MCC) Cohort 2: 840 (Lymphoma and Non-Acute Leukemia with MCC), 841 (Lymphoma and Non-Acute Leukemia with CC), 842 (Lymphoma and Non-Acute Leukemia without CC/MCC), 846 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with MCC), 847 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with CC) 848 (Chemotherapy Without Acute Leukemia as Secondary Diagnosis without CC/MCC)
Inclusion/exclusion criteria	The applicant required the presence of a diagnosis code in this table in one of the first five diagnosis code positions. For cohort 1, the MS-DRGs were limited based on the clinical advice of experts. For cohort 2, the MS-DRGs were broadened based on additional information since FDA approval.
Charges removed for prior technology	Per the applicant, patients receiving TECVAYLI™ would receive three doses of the drug during their inpatient stay. This would replace other drug therapies. Because it is generally not possible to differentiate between different drugs on inpatient claims, the applicant removed all charges in the drug cost center.
Standardized charges	The applicant used the standardization formula provided in Technical Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied the two-year inflation rate of 1.13218 to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule.
Charges added for the new technology	Per the applicant, patients in the hospital for their initial TECVAYLI™ treatment will receive three doses subcutaneously—a 0.06 mg/kg loading dose, a 0.30 mg/kg loading dose, and the first 1.5 mg/kg treatment dose—during the hospital stay. Due to the risk of CRS and neurologic toxicity patients should be hospitalized for 48 hours after administration of all doses within the step-up dosing schedule. Therefore, all three doses will be administered in a single inpatient hospitalization. TECVAYLI™ is provided in two different dosage vials – a 30 mg/3 mL vial and a 153 mg/mL vial. Patients who are under 102 kgs will use two 30 mg/3mL and one 153 mg/mL vials during their hospitalization. Patients over 102 kg will use three 30 mg and two 153 mg vials during their hospitalization. According to real world evidence and clinical studies, 89% of TECVAYLI™ patients will be less than 102 kg. Therefore, the applicant weighted the average cost per patient. The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.184 for drugs from the FY 2023 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

We invited public comments on whether TECVAYLI™ meets the cost criterion.

Comment: The applicant submitted a comment describing the analyses provided in the proposed rule and reiterating that, because the average charge per case for cases eligible for TECVAYLI® exceeded the threshold in both analyses, TECVAYLI® meets the cost criterion.

Response: We thank the applicant for its comment. We agree that the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. Therefore, TECVAYLI™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that TECVAYLI™ represents a substantial clinical improvement over existing technologies because its indication is less restrictive than some other treatments, making it available to patients who do not qualify for the other drugs that treat RRMM. In addition, the applicant stated that TECVAYLI™ may be more immediately accessible than the BCMA CAR T-cell therapies due to restrictions in site of care, manufacturing complexities, and other concerns with respect to the BCMA CAR T-cell therapies. Finally, the applicant stated that TECVAYLI™ improves clinical outcomes and results in less serious side effects than other off the shelf RRMM therapies. The applicant provided one study to support these

claims, as well as 11 background articles about other available treatments for RRMM.[135] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for TECVAYLI™ for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Outcome(s) or finding(s) cited by the applicant from supporting evidence to support its statements**
Other therapies have indications and side effects that restrict the treatment population. TECVAYLI™ is available to some of these restricted patient populations.	Moreau P, Garfall AL, van de Donk NWCJ, et al. Teclistamab in relapsed or refractory multiple myeloma. NEJM. 2022; 387(6): 495-505. Brief study description: Multi-center, Phase 1-2 MajesTEC-1 study of 165 adult patients with RRMM.	Two out of 165 patients discontinued teclistamab because of adverse events (grade 3 adenoviral pneumonia and grade 4 progressive multifocal leukoencephalopathy). One patient had a dose reduction during cycle 21 because of recurrent neutropenia, and 104 patients (63.0%) skipped a dose because of adverse events. No patients discontinued teclistamab owing to the development of cytokine release syndrome. No patients discontinued therapy because of neurotoxic events.
	The applicant provided additional background information to support this claim, which can be accessed via the online posting for the technology.	
TECVAYLI™ may be a preferred treatment for patients unable to access CAR T-cell therapy.	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.	
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available.		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Outcome(s) or finding(s) cited by the applicant from supporting evidence to support its statements**
Cytokine Release Syndrome (CRS) is less serious and less frequent for patients treated with TECVAYLI™ than with BCMA CAR T-cells	Moreau P, Garfall AL, van de Donk NWCJ, et al. Teclistamab in relapsed or refractory multiple myeloma. NEJM. 2022; 387(6): 495-505. See prior study description.	Most events of CRS were grade 1 or 2 in severity and fully resolved, except for one grade 3 event, the median time until the onset of CRS was 2 days (range, 1 to 6) after the most recent dose, and the median duration was 2 days (range, 1 to 9)
	The applicant provided additional background information to support this claim, which can be accessed via the online posting for the technology.	
TECVAYLI™ improves clinical outcomes relative to other off-the-shelf therapies	Moreau P, Garfall AL, van de Donk NWCJ, et al. Teclistamab in relapsed or refractory multiple myeloma. NEJM. 2022; 387(6): 495-505. See prior study description	At the median follow-up of 14.1 months (range 0.3 to 24.2), responses occurred in 104 of 165 patient for an overall response rate of 63% (95% CI 55.2 to 70.4) with 58.8% achieving a very good partial response or better.
	The applicant provided additional background information to support this claim, which can be accessed via the online posting for the technology.	

BILLING CODE 4120–01–C

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26890 through 26891), after review of the information provided by the applicant, we had the following concerns regarding whether TECVALI™ meets the substantial clinical improvement criterion. The applicant claimed that other therapies have indications and side effects that restrict the treatment population and TECVAYLI™ is available to some of these restricted patient populations. Regarding this claim, the applicant discussed restrictions for two other treatment options for RRMM in its application, XPOVIO® (selinexor) and BLENREP (belantamab mafodotin-blmf). However, there are two other therapies for RRMM, ciltacabtagene autoleucel and idecabtagene vicleucel, that the applicant did not discuss that have a similar indication to TECVAYLI™ and appear to target a similar population. Therefore, we questioned the basis for the applicant's assertion that TECVAYLI™ will fill a gap for patients unresponsive to or ineligible for current treatments.

With regard to the claim that TECVAYLI™ may be a preferred treatment for patients unable to access CAR T-cell therapy, the applicant provided data on the number of patients who received CAR T-cell therapy from studies for CD19 CAR T-cell therapies used for B-cell lymphomas. For example, the applicant provided data from a survey of CAR T-cell treatment centers across the U.S. indicating only 25 percent of potential patients were reported to receive CD19 CAR T-cell

[135] Background articles are not included in the following table but can be accessed via the online posting for the technology.

therapy, with a median wait time of 6 months.[136] The applicant noted that the data was for CAR T-cell therapy used to treat B-cell lymphoma, because these treatments were approved prior to approvals for CAR T-cell therapies for MM, so there is more accumulated evidence for the former. However, given that B-cell lymphoma is a different disease than MM and the T-cell therapies used to treat these two diseases are different, we questioned whether the evidence related to B-cell lymphoma is applicable to T-cell therapies used to treat MM.

The applicant claimed that CRS is less serious and less frequent for patients treated with TECVAYLI™ than with BCMA CAR T-cell therapies. Notably, the applicant compared data from separate, single-arm, open-label studies of these technologies.[137] [138] [139] In review, CRS occurrence rates were 72.1 percent, 95 percent and 84 percent for TECVAYLI™, ciltacabtagene autoleucel, and idecabtagene vicleucel, respectively. In addition, only 0.6 percent of the CRS events for TECVAYLI™ were of grade 3 or higher, compared to 4 percent for ciltacabtagene autoleucel and 5 percent for idecabtagene vicleucel. This improved safety claim, however, focused on only a single metric in the studies' overall assessment of the safety and efficacy of these three drugs. The overall response rates reported in the studies were 63 percent, 97 percent and 73 percent for TECVAYLI™, ciltacabtagene autoleucel, and idecabtagene vicleucel respectively. When comparing across studies, other metrics of efficacy noted in these studies also appeared to support a superiority of the CAR T-cell therapies compared to TECVAYLI™ in the treatment of patients with RRMM. However, we also noted these comparisons are not matched cases within a comparative study. Therefore, we questioned the conclusions drawn by the applicant regarding the relative efficacy and safety profiles across these studies.

The applicant claimed that TECVAYLI™ improves clinical outcomes relative to other off-the-shelf therapies. The applicant stated the overall response rate (ORR) for XPOVIO® and BLENREP were 25 percent and 31 percent, while the ORR for TECVAYLI™ was 63 percent. However, this claim did not consider the higher ORR for CAR T-cell therapies compared to TECVAYLI™ when comparing across studies, as previously mentioned. While this claim compared TECVAYLI™ only to other off-the-shelf therapies, which would not include CAR T-cell therapies, we questioned whether there is significant clinical improvement compared to existing therapies, which include CAR T-cell therapies.

We invited public comments on whether TECVAYLI™ meets the substantial clinical improvement criterion.

Comment: We received a public comment stating that BCMA-directed bispecific antibody therapies indicated for the treatment of RRMM represent a substantial clinical improvement over existing treatment options. Specifically, the commenter stated while XPOVIO® may be an option for late-line patients with RRMM who are ineligible for or unable to access CAR T-cell therapies, they are unlikely to be treated with XPOVIO® due to the unfavorable benefit/risk ratio. Additionally, the commenter pointed out that BLENREP is no longer available on the U.S. market and is therefore not a treatment option for these patients. Furthermore, the commenter stated many patients do not have access to CAR T-cell therapies because of general access issues or because the disease is progressing quickly, and they are unable to wait for CAR T-cell therapy. Thus, the commenter continued that for nearly all RRMM patients, the choice will not be CAR T-cell therapy or a BCMA-directed bispecific antibody, it will be a BCMA-directed bispecific antibody therapy or potentially nothing.

Response: We thank the commenter for its input and have taken it into consideration in our determination of whether TECVAYLI® meets the substantial clinical improvement criterion, discussed later in this section.

Comment: The applicant submitted a comment reiterating that TECVAYLI® meets the substantial clinical improvement criterion because the technology demonstrates improved clinical outcomes for patients with RRMM and plays an important role in addressing an unmet need for patients, including Medicare beneficiaries, who are otherwise ineligible for, or unable to access, other treatments for RRMM. The applicant also responded to the concerns raised by CMS in the proposed rule. With respect to whether CAR T-cell therapies are also options for patients ineligible for XPOVIO® and BLENREP, the applicant claimed certain beneficiaries are ineligible to receive CAR T-cell therapies based on their clinical profile. Specifically, the applicant stated beneficiaries that are not clinically fit, including those with poor performance status and inadequate organ function, are not always appropriate candidates for CAR T-cell therapy and its related safety profile. Based on CAR T-cell therapy clinical trials and their labeling, the applicant noted that some of the medically significant factors that might limit a patient's ability to receive a BCMA CAR T-cell therapy include any cardiac conditions (that is, upper limit of normal and left ventricular ejection fraction <45%), pre-existing cytopenias prior to the start of therapy (that is, absolute neutrophil count <1000 cells/mm3 and platelet count <50,000/mm3), or impaired renal function (that is, creatinine clearance <40–45 mL/min).

With respect to whether CAR T-cell therapy availability data was in reference to B-cell lymphoma, the applicant stated that, in contrast with TECVAYLI™, even with very strong CAR T-cell therapy patient support programs, the requirements on the patient and their family can be both financially and logistically challenging. For example, the applicant stated patients are required to have a personal caregiver present for several weeks following dosing, and such caregiver requirements may not be possible for some beneficiaries. The applicant added, unlike TECVAYLI™, CAR T-cell therapies require a specialized healthcare setting certification necessary for the collection and handling of patient cells prior to and after the engineering of the product. The applicant stated while steadily increasing, only a limited number of institutions in the U.S. have the necessary requirements to obtain this certification, and it will take time for additional centers to ramp up, therefore limiting the availability of CAR T-cell therapies to those patients who can access the certified centers. The applicant noted this growth has increased demand for certified CAR T-cell therapy centers and has further compounded the access issues, with the certified CAR T-cell therapy centers experiencing limited availability and

[136] Kourelis T, Bansal R, Patel KK, et al. Ethical challenges with CAR T slot allocation with idecabtagene vicleucel manufacturing access. Journal of Clinical Oncology. 2022;40(16_suppl):e20021–e20021.

[137] Moreau P, Garfall AL, van de Donk NWCJ, et al. Teclistamab in relapsed or refractory multiple myeloma. NEJM. 2022; 387(6): 495–505.

[138] Berdeja JG, Madduri D, Usmani SZ, Jakubowiak A, Agha M et al. (2021). Ciltacabtagene autoleucel, a B-cell maturation antigen-directed chimeric antigen receptor T-cell therapy in patients with relapsed or refractory multiple myeloma (CARTITUDE-1): a phase 1b/2 open-label study. Lancet 398 (10297): 314–324.

[139] Munshi NC, Anderson LD, Jr., Shah N, Madduri D, Berdeja J et al. (2021). Idecabtagene Vicleucel in Relapsed and Refractory Multiple Myeloma. N Engl J Med 384 (8): 705–716.

waitlists. Since the approvals of the CAR T-cell technologies in the MM space, the applicant stated studies have highlighted the lack of accessibility of CAR T-cell products to MM patients. The applicant specified one study published this year showed that out of 20 centers with MM CAR T-cell therapies that were surveyed, 17 have a median allotment of one patient slot per month (per center), and the median number of patients per center on the waitlist since the FDA's approval of idecabtagene vicleucel (ABECMA®) is 20 (range, 5 to 100). Furthermore, the applicant noted patients remain on the waitlist for a median of six months (range, 2 to 8 months) prior to leukapheresis, which is the first step in the CAR T-cell manufacturing process, and the centers participating in the study estimated that only 25 percent of waitlisted patients eventually receive a slot for commercial CAR T-cell therapy, approximately 25 percent die or enroll in hospice, and the remaining 50 percent of patients are enrolled in clinical trials. According to the applicant, certain patients do not have a realistic chance of receiving a CAR T-cell product, and a percentage of these patients may not have access to an appropriate clinical trial due to eligibility criteria or distance from a large academic center with available studies, whereas these beneficiaries are eligible for TECVAYLI™. The applicant asserted for these patients starting their fifth line of therapy who may be on waitlists or otherwise unable to access CAR T-cell therapy, TECVAYLI™ provides a more readily available option that does not require the complex T-cell collection, genetic engineering, and cell manufacturing, or lymphodepleting chemotherapy prior to administration of therapy.

In response to CMS's concerns pertaining to the lack of comparative safety data with CAR T-cell therapies, the applicant stated that there is not direct comparison data available, but that TECVAYLI™ has a strong safety profile concerning cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS) compared with the BCMA CAR T-cell products. The applicant stated in the pivotal study of TECVAYLI™, CRS occurred in 72 percent of patients, including 50 percent in Grade 1, 21 percent in Grade 2, and 0.6 percent in Grade 3.[140] ICANS occurred in 6 percent of patients. CRS occurred in 85 percent (108/127) of patients receiving ABECMA® Grade 3 or higher CRS (Lee grading system 1) occurred in 9 percent (12/127) of patients, with Grade 5 CRS reported in one (0.8%) patient. The applicant added that CAR T-cell-associated neurotoxicity occurred in 28 percent (36/127) of patients receiving ABECMA®, including Grade 3 in 4 percent (5/127) of patients.[141] CARVYKTI® was associated with CRS in 95 percent of patients, including 5 percent Grade 3–5 CRS and 1 percent Grade 5 CRS. ICANS occurred in 23 percent of patients, including Grade ¾ ICANS in 3 percent of all patients and Grade 5 ICANS in 2 percent of patients.[142] The applicant noted Hemophagocytic Lymphohistiocytosis (HLH)/Macrophage Activation Syndrome (MAS) occurred in the pivotal studies of both ABECMA® and CARVYKTI® but was not observed in the pivotal study of TECVAYLI™. Concerning non-CAR T-cell therapies, the applicant stated fewer than 1 percent of TECVAYLI™ patients discontinued therapy due to adverse events,[143] while this was 27 percent of selinexor patients.[144] The applicant claimed TECVAYLI™ is an important treatment alternative to CAR T-cell therapies, with a median DOR of 21.6 months (ABECMA® is 11.0 months, and CARVYKTI® is 21.8 months). Additionally, the applicant stated the incidence and severity of both CRS and ICANS are less for TECVAYLI™ compared to the BCMA CAR T-cell products, and severe and potentially fatal HLH/MAS was not observed in the pivotal study of TECVAYLI™.

Response: We thank the applicant and commenters for their statements regarding the substantial clinical improvement criterion. Based on the additional information received and the information submitted in the application, we agree with the applicant that TECVAYLI™ represents a substantial clinical improvement over existing technologies because TECVAYLI™ offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments. We agreed with the commenters that TECVAYLI™ offers a treatment option for patients ineligible for CAR T-cell therapy or for who CAR T-cell therapy is not an available therapy and who are ineligible for XPOVIO®.

After consideration of the public comments we received, and the information included in the applicant's new technology add-on payment application, we have determined that TECVAYLI™ meets the criteria for approval for new technology add-on payment. Therefore, we are approving new technology add-on payments for this technology for FY 2024. Cases involving the use of TECVAYLI™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS code XW01348.

In its application, the applicant estimated that the cost of TECVAYLI is $13,754.67 per patient, as discussed previously. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of TECVAYLI™ is $8,940.54 for FY 2024.

j. TERLIVAZ® (Terlipressin)

Mallinckrodt Hospital Products, Inc. submitted an application for new technology add-on payments for TERLIVAZ® for FY 2024. Per the applicant, TERLIVAZ® is a pharmacologic therapy administered via IV bolus for the treatment of hepatorenal syndrome (HRS) with rapid reduction in kidney function. The applicant stated that TERLIVAZ® is a V1-receptor synthetic vasopressin analogue that acts as a pro-drug of lysine-vasopressin and has pharmacologic activity on its own. According to the applicant, TERLIVAZ® is the first and only FDA-approved treatment indicated to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function. We note that Mallinckrodt Hospital Products, Inc. submitted an application for new technology add-on payments for TERLIVAZ® for FY 2022 under the name Mallinckrodt Pharmaceuticals, as summarized in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25339 through 25344), that it withdrew prior to the issuance of the FY 2022 IPPS/LTCH PPS final rule (86 FR 44979). We note that the applicant also submitted an application for new technology add-on payments for FY 2023 under the name Mallinckrodt Pharmaceuticals, as summarized in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28287 through 28296), that it withdrew prior to the issuance of the FY 2023 IPPS/LTCH PPS final rule (87 FR 48920).

[140] Moreau P, Garfall AL, van de Donk NWCJ, et al. Teclistamab in relapsed or refractory multiple myeloma. *N Engl J Med.* 2022;387(6):495–505.

[141] *https://www.fda.gov/media/147055/download* [Package Insert; ABECMA®].

[142] *https://reference.medscape.com/drug/carvykti-ciltacabtagene-autoleucel-4000224.*

[143] Moreau P, Garfall AL, van de Donk NWCJ, et al. Teclistamab in relapsed or refractory multiple myeloma. N Engl J Med. 2022;387(6):495–505.

[144] Chari A, Vogl DT, Gavriatopoulou M, Nooka AK, Yee AJ et al. (2019a). Oral Selinexor-Dexamethasone for Triple-Class Refractory Multiple Myeloma. N Engl J Med 381 727–738.

Please refer to the online application posting for TERLIVAZ®, available at *https://mearis.cms.gov/public/publications/ntap/NTP221014UR3R2*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, according to the applicant, TERLIVAZ®'s NDA was approved by FDA on September 14, 2022, for the improvement of kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function. According to the applicant, TERLIVAZ® became commercially available on October 14, 2022. Per the applicant, there was a delay in market availability because TERLIVAZ® received FDA approval three months earlier than expected, and the company needed additional time to conduct market commercialization, including labeling and packaging. Per the applicant, TERLIVAZ® is administered as an IV bolus injection. The applicant stated that for the first 3 days, the recommended dosage is 0.85 mg (1 vial) TERLIVAZ® every 6 hours by slow IV bolus injection. The applicant stated that on day 4, the serum creatinine level is assessed against the baseline level obtained prior to initiating the treatment. The applicant noted that if the serum creatinine has decreased by 30 percent or more from the baseline, then 0.85 mg TERLIVAZ® can continue to be administered every 6 hours. The applicant stated that if the serum creatinine has decreased by less than 30 percent from the baseline, then TERLIVAZ® may be increased to 1.7 mg (2 vials) every 6 hours. According to the applicant, TERLIVAZ® can continue to be administered until 24 hours after the patient achieves a second consecutive serum creatinine value of ≤1.5mg/dL at least 2 hours apart or for a maximum of 14 days. The applicant also stated that if, on day 4, serum creatine is at or above the baseline serum creatinine level, then TERLIVAZ® should be discontinued. According to the applicant, the mean treatment duration with TERLIVAZ® in the CONFIRM trial was 6.2 days, using 27 vials.

The applicant stated that, effective October 1, 2021, the following ICD–10–PCS codes may be used to uniquely describe procedures involving the administration of TERLIVAZ®: XW03367 (Introduction of terlipressin into peripheral vein, percutaneous approach, new technology group 7), or XW04367 (Introduction of terlipressin into central vein, percutaneous approach, new technology group 7). The applicant stated that diagnosis code K76.7 (Hepatorenal syndrome) may be used to currently identify the indication for TERLIVAZ® under the ICD–10–CM coding system.

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that TERLIVAZ® is not substantially similar to other currently available technologies because it offers a novel mechanism of action that allows for selective vasoconstrictive effects on the splanchnic vasculature via activation of V1 vasopressin receptors. The applicant also stated that TERLIVAZ® is the first and only FDA-approved pharmacologic therapy to satisfactorily treat patients with HRS and offers efficacy among patients who fail previous treatment. Therefore, the applicant asserted that the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for TERLIVAZ® for the applicant's complete statements in support of its assertion that TERLIVAZ® is not substantially similar to other currently available technologies.

Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	TERLIVAZ® is the first and only FDA-approved treatment indicated to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function, so no other therapies exist that FDA has found to be safe and effective. With this understanding, midodrine in combination with octreotide and norepinephrine have both been used off-label to treat HRS prior to the FDA approval of TERLIVAZ®. TERLIVAZ® offers a unique mechanism of action compared to these other treatments that allows for targeting of the splanchnic vasculature, rather than affecting the systemic circulation. Midodrine and norepinephrine both act as sympathomimetic alpha-adrenergic agonists that bind to alpha-1 adrenoreceptors on peripheral vascular smooth muscle to promote smooth muscle contraction. Octreotide is a sympathomimetic somatostatin analogue that binds to somatostatin receptors and works in combination with midodrine to activate alpha-1 adrenergic receptors of arteriolar and venous vasculature, resulting in an increase in vascular tone and elevation in blood pressure. In contrast, TERLIVAZ® is a non-sympathomimetic, long-acting vasopressin analogue with selective affinity for the V1 vasopressin receptors that are predominantly located in the smooth muscle of arterial vasculature in the splanchnic region. In this way, TERLIVAZ® provides selective and potent vasoconstrictor and antidiuretic properties to elevate arterial pressure, leading to improved renal perfusion.
Is the technology assigned to the same MS-DRG as existing technologies?	No	There is no FDA approved technology for adults with HRS with rapid reduction in kidney function prior to the approval of TERLIVAZ®.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	No	TERLIVAZ® is the first and only FDA-approved treatment for HRS with rapid reduction in kidney function, so there are no existing therapies with established efficacy and safety to treat this patient population. While midodrine, octreotide, and norepinephrine may be indicated and used in other disease states, clinical trials have not sufficiently supported their effective use in the HRS patient population. In the patient population that does not respond to first-line treatment with these therapies, TERLIVAZ® offers a new treatment option. Per the applicant, in the CONFIRM trial, 61% of TERLIVAZ®-treated patients had received prior treatment with midodrine and octreotide and 72.9% had received treatment with any vasopressor. Among patients who had received prior midodrine and octreotide, verified HRS reversal was achieved in 31.4% of patients in the TERLIVAZ® group vs 16.4% of patients in the placebo group. This demonstrates that TERLIVAZ® can be an effective treatment in patients who failed previous therapies.

Similar to our discussion in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25340), and the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28290), in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26892) we noted that while TERLIVAZ® may address an unmet need because it is the first treatment indicated specifically for the treatment of HRS, the applicant's assertion that TERLIVAZ® does not involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology, on the basis that there is a subset of patients for whom current treatments are ineffective and for whom TERLIVAZ® will offer a new treatment option, did not necessarily speak to the treatment of a new patient population for HRS.

We invited public comments on whether TERLIVAZ® is substantially similar to existing technologies and whether TERLIVAZ® meets the newness criterion.

Comment: Several commenters provided support for TERLIVAZ®'s eligibility for new technology add-on payments, indicating that there are currently no FDA-approved medications indicated specifically for the treatment of HRS–1.

Response: We thank the commenters for their input and have taken it into consideration, as discussed later in this section.

Comment: The applicant submitted a comment regarding the newness criterion. With regard to whether TERLIVAZ® involves treatment of the same/similar type of disease and the same/similar type of patient population when compared to an existing technology, the applicant stated that TERLIVAZ® offers an effective treatment for patients with HRS with rapid reduction in kidney function who are unresponsive to existing off-label therapies. The applicant noted that a large proportion of patients in the CONFIRM trial had failed prior therapy for HRS, and had received combination midrodrine and octreotide before enrollment. The applicant further stated that in this subgroup of patients, treatment with TERLIVAZ® was associated with a greater rate of verified HRS reversal compared to placebo,

leading to improved renal function in a population who did not respond to existing standard of care. The applicant also stated that TERLIVAZ® is listed as the preferred therapy for HRS by several U.S. and international guidelines, and these clinical recommendations provide greater support for the use of TERLIVAZ® compared to existing off-label therapies, suggesting that TERLIVAZ® may offer a treatment option for patients who would not respond to other available treatments.[145] [146] [147] [148]

Response: We thank the applicant for its comment. Based on our review of comments, we agree with the applicant and commenters that TERLIVAZ® has a unique mechanism of action for selective vasoconstrictive effects on the splanchnic vasculature via activation of V1 vasopressin receptors as the first and only FDA-approved treatment for HRS. Therefore, we believe that TERLIVAZ® is not substantially similar to existing treatment options and meets the newness criterion. We consider the beginning of the newness period to commence on the date TERLIVAZ® became commercially available: October 14, 2022.

[145] Biggins SW, Angeli P, Garcia-Tsao G, et al. Diagnosis, evaluation, and management of ascites, spontaneous bacterial peritonitis and hepatorenal syndrome: 2021 Practice Guidance by the American Association for the Study of Liver Diseases. *Hepatology.* 2021;74(2):1014–1048.

[146] European Association for the Study of the Liver. EASL Clinical Practice Guidelines for the management of patients with decompensated cirrhosis. *J Hepatol.* 2018;69(2):406–460.

[147] Bajaj JS, O'Leary JG, Lai LC, et al. Acute-on-chronic liver failure clinical guidelines. *Am J Gastroenterol.* 2022;117(2):225–252.

[148] Flamm SL, Wong F, Ahn J, Kamath PS. AGA clinical practice update on the evaluation and management of acute kidney injury in patients with cirrhosis: expert review. *Clin Gastroenterol Hepatol.* 2022;20(12):2707–2716.

With respect to the cost criterion, the applicant provided multiple analyses to demonstrate that it meets the cost criterion. To identify potential cases representing patients who may be eligible for TERLIVAZ®, the applicant searched the FY 2021 MedPAR file for cases reporting ICD–10–CM code K76.7 (Hepatorenal syndrome). The applicant used the inclusion/exclusion criteria described in the following table. Each analysis differed with respect to the position of the ICD–10–CM code on the claim (that is, whether the ICD–10–CM code was the primary and/or admitting diagnosis code, or was in any position on the claim). Each analysis also differed with respect to requirements for the presence or absence of ICU-related charges (identified with the ICU indicator in the MedPAR with each analysis either including claims with ICU charges or claims without ICU charges), or whether ICU usage was not a consideration (the analysis included both claims with and without ICU charges). The applicant then presented six defined cohort analyses, and used the factors in the following table to define the cohorts. Please see Table 10.24.A.—TERLIVAZ® Codes (Analyses 1–6)—FY 2024 associated with the proposed rule for the complete list of MS–DRGs that the applicant included in its cost analysis for each cohort. The applicant followed the order of operations described in the following table.

For the first cohort analysis, the applicant identified 471 claims mapping to nine MS–DRGs. The applicant calculated a final inflated average case-weighted standardized charge per case of $279,135, which exceeded the average case-weighted threshold amount of $77,358.

For the second cohort analysis, the applicant identified 7,273 claims mapping to 183 MS–DRGs. The applicant then calculated a final inflated average case-weighted standardized charge per case of $319,685, which exceeded the average case-weighted threshold amount of $90,714.

For the third cohort analysis, the applicant identified 480 claims mapping to five MS–DRGs. The applicant then calculated a final inflated average case-weighted standardized charge per case of $189,783, which exceeded the average case-weighted threshold amount of $66,195.

For the fourth cohort analysis, the applicant identified 6,497 claims mapping to 173 MS–DRGs. The applicant then calculated a final inflated average case-weighted standardized charge per case of $211,960, which exceeded the average case-weighted threshold amount of $76,483.

For the fifth cohort analysis, the applicant identified 918 claims mapping to nine MS–DRGs. The applicant then calculated a final inflated average case-weighted standardized charge per case of $233,361, which exceeded the average case-weighted threshold amount of $69,919.

For the sixth cohort analysis, the applicant identified 12,801 claims mapping to 217 MS–DRGs. The applicant then calculated a final inflated average case-weighted standardized charge per case of $265,448, which exceeded the average case-weighted threshold amount of $81,949.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount for all scenarios, the applicant asserted that TERLIVAZ® meets the cost criterion.

BILLING CODE 4120–01–P

TERLIVAZ® COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR File
List of ICD-10-CM codes	K76.7 (Hepatorenal syndrome)
List of MS-DRGs	Please see Table 10.24.A.– TERLIVAZ® Codes (Analyses 1-6) - FY 2024 associated with the proposed rule for the complete list of MS-DRGs provided by the applicant for each scenario.
Inclusion/ exclusion criteria	Scenario 1: For the first scenario, the applicant included cases with the ICD-10-CM code, as previously listed, in the primary/admitting position, with ICU indicators (ICU charges reported on the claim), and stays of 2+ days only. Scenario 2: For the second scenario, the applicant included cases with the ICD-10-CM code, as previously listed, in any position, with ICU indicators (ICU charges reported on the claim), and stays of 2+ days only. Scenario 3: For the third scenario, the applicant included cases with the ICD-10-CM code, as previously listed, in the primary/admitting position, with no ICU indicators (no ICU charges reported on the claim), and stays of 2+ days only. Scenario 4: For the fourth scenario, the applicant included cases with the ICD-10-CM code, as previously listed, in any position, with no ICU indicators (no ICU charges reported on the claim), and stays of 2+ days only. Scenario 5: For the fifth scenario, the applicant included cases with the ICD-10-CM code, as previously listed, in the primary/admitting position, without requirements regarding ICU usage (claims with or without ICU charges reported on the claim), and stays of 2+ days only. Scenario 6: For the sixth scenario, the applicant included cases with the ICD-10-CM code, as previously listed, in any position, without requirements regarding ICU usage (claims with or without ICU charges reported on the claim), and stays of 2+ days only. For all scenarios, after case selection, data were trimmed to include only claims that would be used for Medicare IPPS rate setting (fee-for-service IPPS discharges, plus Maryland hospital discharges). Case counts less than 11 were imputed to have 11 claims. The applicant then calculated the average unstandardized charge per case for each MS-DRG.
Charges removed for prior technology	The applicant converted the costs of HRS-1 dosing regimens for norepinephrine (AnalySource 2018 U.S. Pricing) to charges dividing by the national average drug CCR of 0.184. These charges were removed in all cases with ICU usage. The applicant converted the costs of HRS-1 dosing regiments for midodrine plus octreotide (AnalySource 2018 U.S. Pricing) dividing by the national average drug CCR of 0.184. The applicant then removed these charges in all cases where there was no ICU usage. In some situations, the charges removed were larger than the total charges on the claim. In these situations, according to the applicant, it is clear that the charges replaced by TERLIVAZ® were overestimated. However, the applicant stated that TERLIVAZ® still meets the cost threshold in all scenarios. The applicant did not remove indirect charges related to the prior technology.
Standardized charges	The applicant used the standardization formula provided in Technical Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied the two-year inflation rate of 1.13218 to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant assumed a mean duration of treatment of 6.2 days, using 27 vials, based on the results of the clinical trial of the technology. Using the wholesale acquisition cost (WAC) per vial of TERLIVAZ®, the applicant calculated an average cost for TERLIVAZ®. The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.184 for drugs from the FY 2023 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

We are invited public comments on whether TERLIVAZ® meets the cost criterion.

We did not receive any comments on whether TERLIVAZ® meets cost criterion. Based on the information submitted by the applicant as part of its FY 2024 new technology add-on payment application for TERLIVAZ®, as previously summarized, the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount. Therefore, TERLIVAZ® meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that TERLIVAZ® represents a substantial clinical improvement over existing technologies because among HRS patients who failed previous therapy with available off-label treatments, TERLIVAZ® has been shown

to significantly improve renal function. Additionally, the applicant stated that TERLIVAZ® remains the preferred treatment for HRS-acute kidney injury (AKI) according to several guidelines and guidance based on its significant efficacy, as shown by randomized clinical trials. The applicant asserted that for these reasons TERLIVAZ® offers a treatment option for HRS patients unresponsive to currently available treatments (for example, norepinephrine, midodrine, and octreotide), and it significantly improves clinical outcomes among HRS patients as compared to placebo as well as currently available treatments (for example, norepinephrine, midodrine and octreotide). The applicant provided 14 studies to support these claims. The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for TERLIVAZ® for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Outcome(s) or findings cited by the applicant from supporting evidence to support its statements**
Patients in the CONFIRM trial with systemic inflammatory response syndrome (SIRS) at baseline achieved significant improvements	Wong F, Pappas SC, Curry MP, et al. Terlipressin plus albumin for the treatment of type 1 hepatorenal syndrome. N Engl J Med. 2021;384(9):818-828.	Primary endpoint was verified reversal of HRS, defined as two consecutive serum creatinine (SCr) measurements of ≤1.5 mg/dL at least 2 hours apart up to Day 14 and survival without renal replacement therapy (RRT) for at least an additional 10

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.		
in renal function with TERLIVAZ® treatment compared to placebo.	Brief study description: Randomized, double-blind, placebo-controlled, multi-center U.S. Phase 3 trial The purpose of the study was to evaluate efficacy and safety of terlipressin plus albumin in adults with HRS-1.	days. Four secondary efficacy endpoints were adjusted for multiple comparisons: HRS reversal; durability of HRS reversal, defined as HRS reversal without RRT at Day 30; HRS reversal among patients with SIRS; and verified HRS reversal without recurrence of HRS by Day 30. HRS reversal in SIRS patients was noted in 31 patients (37%) with TERLIVAZ® and 3 patients (6%) with placebo (P<0.001).
The primary endpoint of CONFIRM, verified HRS reversal, is a clinically significant and appropriate measure of improvement in renal function.	Data on File. Mallinckrodt Pharmaceuticals. Brief study description: This is a copy of data on file from the CONFIRM trial clinical study report. The purpose of the CONFIRM study was to evaluate efficacy and safety of terlipressin plus albumin in adults with HRS-1.	The primary endpoint, verified HRS reversal, was defined as the percentage of patients with two consecutive SCr values ≤1.5 mg/dL, obtained at least 2 hours apart while on treatment by Day 14 or discharge, and alive without RRT (eg, dialysis) for at least an additional 10 days. This was achieved in 29.1% of TERLIVAZ® patients and 15.8% of placebo patients (P=0.012). This endpoint demonstrates a robust and clinically significant improvement in renal function, emphasizes the durability of this improvement in renal function, and establishes the effect of treatment on a key clinical outcome of short-term survival. Combined, the three components of verified HRS reversal provide a strong, clinically meaningful measure of efficacy in the setting of multiple competing comorbidities.
	TERLIVAZ®. Prescribing information. Mallinckrodt Hospital Products Inc. Brief study description: This is the TERLIVAZ® U.S. prescribing information. TERLIVAZ® is the first and only FDA-approved treatment indicated to improve kidney function in adults with hepatorenal syndrome with rapid reduction in kidney function.	The efficacy of TERLIVAZ® was evaluated in patients with cirrhosis, ascites, and a diagnosis of HRS-1 with a rapidly progressive worsening in renal function to a SCr of ≥2.25 mg/dL. A total of 300 patients were enrolled, with the primary endpoint of verified HRS reversal, defined as the percentage of patients with two consecutive SCr values ≤1.5 mg/dL, obtained at least 2 hours apart while on treatment by Day 14 or discharge. This endpoint was achieved in 29.1% of patients with TERLIVAZ® vs placebo group of 15.8% (P=0.012).
Among patients in the CONFIRM trial, the majority failed prior therapy with available options, yet this subgroup achieved a statistically significant improvement in renal function with TERLIVAZ®.	Data on File. Mallinckrodt Pharmaceuticals. See prior description.	The primary endpoint, verified HRS reversal, was defined as the percentage of patients with two consecutive SCr values ≤1.5 mg/dL, obtained at least 2 hours apart while on treatment by Day 14 or discharge, and alive without RRT (eg, dialysis) for at least an additional 10 days. In the subgroup of patients who received prior midodrine and octreotide therapy, 31.4% vs 16.4% (P=0.030) achieved verified HRS reversal with TERLIVAZ® vs placebo, respectively, and 38.8% vs 18.0% (P=0.004) achieved HRS reversal with TERLIVAZ® vs placebo, respectively. In the study intention-to-treat (ITT) population, of which 72.9% received prior vasopressor therapy, the primary endpoint of verified

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.		
		HRS reversal was achieved in 29.1% of TERLIVAZ-treated patients and 15.8% of placebo patients (P=0.012).
Patients in the CONFIRM trial with alcoholic hepatitis at baseline achieved improvements in renal function with TERLIVAZ® treatment compared to placebo.	Data on File. Mallinckrodt Pharmaceuticals. See prior description.	In CONFIRM, alcoholic hepatitis was present in 41% (81 patients) of the TERLIVAZ® group and 39% (39 patients) of the placebo group. In this patient subgroup, verified HRS reversal was achieved in 30.9% of the TERLIVAZ® group compared to 7.7% of the placebo group. The P value was not reported for this endpoint.
Verified HRS reversal has been accepted by multiple professional societies as a clinically significant measure of treatment efficacy for HRS patients.	European Association for the Study of the Liver. EASL clinical practice guidelines for the management of patients with decompensated cirrhosis. J Hepatol. 2018;69(2):406-460. Brief study description: EASL's most recently published clinical practice guidelines regarding management of patients with decompensated cirrhosis define HRS as a functional renal failure caused by intrarenal vasoconstriction, which occurs in patients with end-stage liver disease, as well as patients with acute liver failure or alcoholic hepatitis. These guidelines recommend terlipressin as the first-line therapeutic option for patients diagnosed with HRS-AKI.	This recommendation was based on studies of TERLIVAZ® that showed improvements in rates of response (including complete and partial response), rates of complete response, renal function, and short-term survival.
	Biggins SW, Angeli P, Garcia‐Tsao G, et al. Diagnosis, evaluation, and management of ascites and hepatorenal syndrome: 2021 Practice Guidance by the American Association for the Study of Liver Diseases. Hepatology. 2021;74(2):1014-1048. Brief study description: A comprehensive guidance on the diagnosis, evaluation, and management of ascites and HRS in patients with chronic liver disease. The treatment of choice in this guidance for HRS-AKI is vasoconstrictor drugs in combination with albumin. The preferred drug is terlipressin, administered as either IV bolus or continuous IV infusion.	This recommendation was based on results from the CONFIRM trial, in which TERLIVAZ® treatment resulted in a higher likelihood of HRS reversal and 10-day survival without RRT (29.1% vs 15.8% [P=0.012]). Additionally, the guidance notes that vasoconstrictors, including TERLIVAZ® and norepinephrine, have demonstrated response rates of between 20% and 80%, with an average around 50%.
Substantial Clinical Improvement Assertion #2: The technology significantly improves clinical outcomes relative to services or technologies previously available.		
TERLIVAZ® is listed by the 2021 AASLD guidance as the preferred therapy for HRS-AKI.	Biggins SW, Angeli P, Garcia‐Tsao G, et al. Diagnosis, evaluation, and management of ascites and hepatorenal syndrome: 2021 Practice Guidance by the American Association for the Study of Liver Diseases. Hepatology. 2021;74(2):1014-1048. Brief study description: A comprehensive guidance on the diagnosis, evaluation, and management of ascites and HRS in patients with chronic liver disease.	A comprehensive guidance on the diagnosis, evaluation, and management of ascites and HRS in patients with chronic liver disease. The treatment of choice in this guidance for HRS-AKI is vasoconstrictor drugs in combination with albumin. The preferred drug is TERLIVAZ® administered as either IV bolus or continuous IV infusion.
In an ex-U.S. head-to-head, randomized clinical trial comparing TERLIVAZ® to	Cavallin M, Kamath PS, Merli M, et al. Terlipressin plus albumin versus midodrine and octreotide plus albumin in the treatment of	The primary endpoint of the study was complete response at completion of treatment. A significantly higher rate of

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.		
midodrine and octreotide for HRS, TERLIVAZ® treatment resulted in significantly greater rates of response.	hepatorenal syndrome: a randomized trial. Hepatology. 2015;62(2):567-574. Brief study description: Randomized, controlled trial in Italy. The purpose of this study was to compare the effectiveness of TERLIVAZ® plus albumin vs midodrine and octreotide plus albumin in the treatment of HRS.	recovery of renal function was seen in the TERLIVAZ® group (19/27, 70.4%) compared to the midodrine and octreotide group (6/21, 28.6%) (P=0.01). Secondary endpoints were survival at 1 and 3 months. No significant statistical difference was noted between the groups; however, improvement in renal function and lower baseline MELD score were associated with better survival. Only response to treatment was found to be a predictor of 3-month survival in the univariate analysis. Regarding previous comments received related to the lack of significant survival benefit with TERLIVAZ® seen in the Cavallin et al. study, please refer to the previous discussion that provides an explanation for why survival of HRS patients is not the most appropriate efficacy outcome for treatments intended to improve kidney function. Overall, survival is dependent on the severity of liver disease and other comorbidities, such as SBP and multiorgan failure. While TERLIVAZ® improves renal function in this population, it does not address the underlying liver dysfunction faced by these patients and, therefore, it is not appropriate to measure the efficacy of TERLIVAZ® entirely based on overall survival. Instead, HRS reversal and complete response are common and accepted endpoints used to evaluate treatments for HRS-AKI.
Among patients aged 65 years and older, TERLIVAZ® has been associated with increased rates of verified HRS reversal, durable HRS reversal, and verified HRS reversal without recurrence.	Mujtaba M, Gamilla-Cruda AK, Merwat S, et al. Terlipressin, in combination with albumin, is an effective therapy for hepatorenal syndrome type 1 in patients aged ≥65 years. Poster presented at: NKF Spring Clinical Meeting, April 6-10, 2022; Boston, MA. Brief study description: Oral presentation of pivotal data from CONFIRM (NCT02770716), a randomized, double-blind, placebo-controlled, multi-center U.S. Phase 3 trial. The purpose of this subgroup analysis was to evaluate the efficacy and safety of TERLIVAZ® as a treatment for HRS in patients aged ≥65 years using data from the CONFIRM trial.	The primary endpoint was verified HRS reversal, defined as the percentage of patients with two consecutive SCr values ≤1.5 mg/dL, obtained at least 2 hours apart while on treatment by Day 14 or discharge, and alive without RRT (eg, dialysis) for at least an additional 10 days. This was achieved in 31.4% of TERLIVAZ® patients and 11.1% of placebo patients (P=0.177). Secondary endpoints and results are as follows: HRS reversal (34.3% vs 16.7%; P=0.225), durable HRS reversal (31.4% vs 16.7%; P=0.333) and verified HRS reversal without recurrence by Day 30 (31.4% vs 11.1%; P=0.177) in the TERLIVAZ® vs placebo groups, respectively. Mean length of study site hospital stay was recorded: 21.7 days in the TERLIVAZ® groups and 31.6 days in the placebo group. RRT requirements through 90 days were reported in TERLIVAZ® and placebo groups, respectively: 20.8% vs 41.2% (P=0.158) at Day 14, 23.8% vs 46.2% (P=0.176) at Day 30, 22.2% vs 54.5% (P=0.114) at Day 60, 29.4% vs 66.7% (P=0.067) at Day 90, and

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.		
		0% vs 83.3% (P=0.003) post-liver transplant (Figure 3).
TERLIVAZ® treatment has been shown to improve outcomes in HRS patients who receive a liver transplant, as shown by a reduction in RRT requirements both pre- and post-transplant vs placebo.	Data on File. Mallinckrodt Pharmaceuticals. Brief study description: See prior study description	In CONFIRM, 34.8% of transplanted patients treated with TERLIVAZ® required RRT prior to transplant vs 62.1% of the placebo group. The P value for these data was not provided. In addition, the rate of RRT after transplant was significantly reduced with TERLIVAZ® treatment, with 19.6% of the TERLIVAZ® group vs 44.8% of the placebo group requiring RRT (P=0.036).
In an ex-U.S. open-label, randomized clinical trial, TERLIVAZ® demonstrated significant improvements in HRS reversal rate, response rate, and RRT requirements compared to norepinephrine.	Arora V, Maiwall R, Rajan V, et al. Terlipressin is superior to noradrenaline in the management of acute kidney injury in acute on chronic liver failure. Hepatology. 2019;71(2):600-610. Brief study description: An open-label, randomized controlled trial (RCT) in a single center in India The purpose of the study was to compare norepinephrine and TERLIVAZ® for treatment of Acute on chronic liver failure (ACLF) patients with HRS-AKI. The primary endpoint was noted as reversal of HRS-AKI at Day 14, and secondary endpoints were to compare early response to norepinephrine and TERLIVAZ® at Days 4 and 5 and assess 28-day survival.	Compared to norepinephrine, TERLIVAZ® achieved greater response at Day 4 (26.1% vs 11.7%; P=0.03) and Day 7 (41.7% vs 20%; P=0.01). Reversal of HRS was also greater in the TERLIVAZ® group (40% vs 16.7%; P=0.004), with a significant reduction in RRT (56.6% vs 80%; P=0.006) and improved 28-day survival (48.3% vs 20%; P=0.001). As mentioned in previous comments related to the design of the Arora et al. study, an open-label study design was used; however, there is a paucity of data directly comparing TERLIVAZ® and norepinephrine for the treatment of HRS. To date, there are no large, high-quality, double-blind studies to compare TERLIVAZ® with either norepinephrine or midodrine/octreotide, or simply to support the efficacy and safety of either of these current therapies for HRS. In contrast, the safety and efficacy of TERLIVAZ® is supported by multiple large, double-blind, randomized, placebo-controlled trials. It is for this reason that the American Association for the Study of Liver Diseases (AASLD) guidance, American College of Gastroenterology (ACG) guidelines, American Gastroenterological Association (AGA) clinical practice update, and EASL guidelines all offer higher level recommendations for the use of TERLIVAZ® as the preferred treatment for HRS-AKI compared to norepinephrine.
Treatment with TERLIVAZ® has been associated with reductions in RRT requirements.	Wong F, Pappas SC, Curry MP, et al. Terlipressin plus albumin for the treatment of type 1 hepatorenal syndrome. N Engl J Med. 2021;384(9):818-828. See prior study description	Results show the rates of RRT in TERLIVAZ® vs placebo groups, respectively, at the following time points: Day 14 was 23% vs 35%, Day 30 was 26% vs 36%, Day 60 was 28% vs 38%, and Day 90 was 29% vs 39%. P values were not provided for these data.
The newly published AGA clinical practice update also lists terlipressin as the preferred option for treatment of HRS-AKI.	Flamm SL, Wong F, Ahn J, Kamath PS. AGA clinical practice update on the evaluation and management of acute kidney injury in patients with cirrhosis: expert review. Clin Gastroenterol Hepatol. Published online September 2022. Brief study summary:	The recommended medication for the management of patients with cirrhosis and AKI is TERLIVAZ®. Should TERLIVAZ® not be available, either a combination therapy of octreotide and midodrine or norepinephrine could be used. Therapy is continued until 24 hours following return of SCr to within 0.3 mg/dL of baseline for

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.		
	This update from the AGA pertains to management of patients with cirrhosis and AKI and was based on best available published evidence.	2 consecutive days or for a total of 14 days of therapy. This guideline cited four randomized controlled trials, one in Europe and three in North America, totaling 646 patients and compared the efficacy of TERLIVAZ® combined with albumin vs placebo for reversing HRS. Of note, there was no difference in overall survival or transplant-free survival between TERLIVAZ® or placebo. In the most recent study carried out in the U.S. and Canada, 29% of patients reversed their HRS and survived for an additional 10 days after completion of treatment without needing RRT, which may allow for more time for liver transplantation.
TERLIVAZ® has been associated with significant improvements in sustained renal function improvement to Day 30.	TERLIVAZ®. Prescribing information. Mallinckrodt Hospital Products Inc. See prior study description	The efficacy of TERLIVAZ® was evaluated in patients with cirrhosis, ascites, and a diagnosis of HRS-1 with a rapidly progressive worsening in renal function to a SCr of ≥2.25 mg/dL in the CONFIRM trial. A total of 300 patients were enrolled, with 199 randomized to TERLIVAZ® and 101 randomized to placebo. One of the secondary endpoints was durability of HRS reversal, which was measured as the percentage of patients with a SCr value ≤1.5 mg/dL while on treatment, by Day 14, or discharge, and who did not require RRT by Day 30. This was achieved in 31.7% in the TERLIVAZ® group and 15.8% in the placebo group (P=0.003).
International guidelines also list TERLIVAZ® in combination with albumin as one of the first-line therapeutic options for the treatment of HRS-AKI.	European Association for the Study of the Liver. EASL clinical practice guidelines for the management of patients with decompensated cirrhosis. J Hepatol. 2018;69(2):406-460 See prior study description	TERLIVAZ® is the most commonly used therapy for HRS in Europe and has had efficacy proven in many studies. The total rates of response in recent studies (complete or partial response) range from 64% to 76%, and complete response from 46% to 56%. Alternatives to TERLIVAZ® have limited study information available, mainly norepinephrine and midodrine plus octreotide.
	Xu X, Duan Z, Ding H, et al. Chinese guidelines on the management of ascites and its related complications in cirrhosis. Hepatol Int. 2019;13:1-21. Brief study summary: The Chinese Society of Hepatology invited experts in hepatology, gastroenterology, infectious disease, clinical pharmacology, and methodology to develop guideline recommendations for the appropriate diagnosis, treatment, and prevention of ascites and related complications.	These guidelines recommend vasoconstrictors as drug therapy for HRS patients to help improve hyperdynamic circulation and increase peripheral arterial pressure to increase renal blood flow. The vasoconstrictors listed are TERLIVAZ®, midodrine, norepinephrine, and octreotide. The guidelines state that studies of TERLIVAZ® have shown improvements in renal function, with efficacy rates of approximately 40%-50%.
	Angeli P, Gines P, Wong F, et al. Diagnosis and management of acute kidney injury in patients	These guidelines recommend that patients who meet diagnostic criteria for

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.		
	with cirrhosis: revised consensus recommendations of the International Club of Ascites. J Hepatol. 2015;62:968-974. Brief study summary: The ICA clinical practice guidelines provide updated consensus recommendations for the diagnosis and treatment of AKI in patients with cirrhosis.	HRS should be treated with vasoconstrictors plus albumin. The guidelines do not provide a specific recommendation for use of one vasoconstrictor over another, but they do state that TERLIVAZ® in combination with albumin is the most investigated and effective treatment for HRS-1.
Treatment with TERLIVAZ® has been associated with a significantly greater response rate compared to placebo.	Data on File. Mallinckrodt Pharmaceuticals. See prior study description	Complete response was defined as return of SCr to a value within 0.3 mg/dL above the baseline value, while partial response was defined as regression of AKI stage with a reduction of SCr to at least 0.3 mg/dL above baseline. In this population, combined rates of complete and partial response were 46.8% (30.7% complete response and 16.1% partial response) in the TERLIVAZ® group and 22.8% (9.9% complete response and 12.9% partial response) in the placebo group (P<0.001). Baseline characteristics of the study population are included in the tables on pages 2 and 3.
TERLIVAZ® has been associated with significant improvements in renal function, as measured by HRS reversal rate.	Wong F, Pappas SC, Curry MP, et al. Terlipressin plus albumin for the treatment of type 1 hepatorenal syndrome. N Engl J Med. 2021;384(9):818-828. See prior study description	The secondary endpoint of HRS reversal was defined as any SCr level of ≤1.5 mg/dL while receiving TERLIVAZ® or placebo, and it was achieved in 39% of the TERLIVAZ® group vs 18% of the placebo group (P<0.001).
TERLIVAZ® is the first and only FDA-approved treatment for HRS because it has been associated with significant improvements in renal function, as measured by verified HRS reversal rate.	TERLIVAZ®. Prescribing information. Mallinckrodt Hospital Products Inc; 2022. See prior study description	The efficacy of TERLIVAZ® was evaluated in patients with cirrhosis, ascites, and a diagnosis of HRS-1 with a rapidly progressive worsening in renal function to a SCr of ≥2.25 mg/dL. A total of 300 patients were enrolled, with the primary endpoint of verified HRS reversal, defined as the percentage of patients with 2 consecutive SCr values ≤1.5 mg/dL, obtained at least 2 hours apart while on treatment by Day 14 or discharge. This endpoint was achieved in 29.1% of patients with TERLIVAZ® vs placebo group of 15.8% (P=0.012).
	Data on File. Mallinckrodt Pharmaceuticals. See prior study description	The primary endpoint, verified HRS reversal, was defined as the percentage of patients with two consecutive SCr values ≤1.5 mg/dL, obtained at least 2 hours apart while on treatment by Day 14 or discharge, and alive without RRT (for example, dialysis) for at least an additional 10 days. This was achieved in 29.1% of TERLIVAZ® patients and 15.8% of placebo patients (P=0.012) (Section 11.4.1/P3). This endpoint demonstrates a robust and clinically significant improvement in renal function, emphasizes the durability of this improvement in renal function, and establishes the effect of treatment on a key clinical outcome of short-term

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.		
		survival. Combined, the three components of verified HRS reversal provide a strong, clinically meaningful measure of efficacy in the setting of multiple competing comorbidities.
The overall rates of adverse events (AEs) and serious adverse events (SAEs) were similar between TERLIVAZ® and placebo groups in the CONFIRM trial.	Data on File. Mallinckrodt Pharmaceuticals. See prior study description	The rates of AEs were 88.0% in the TERLIVAZ® group vs 88.9% in the placebo group, while the rates of SAEs were 65.0% in the TERLIVAZ® group vs 60.6% in the placebo group. In general, for statistical reasons, P values are not calculated for safety endpoints, so a statistically significant difference between groups cannot be determined.
TERLIVAZ® is also listed for the treatment of HRS-AKI, with higher quality evidence compared to norepinephrine in the 2022 ACG guidelines.	Bajaj JS, O'Leary JG, Lai JC, et al. Acute-on-chronic liver failure clinical guidelines. Am J Gastroenterol. 2022;117(2):225-252. Brief study summary: The purpose of this guideline was to synthesize the current and emerging data on ACLF as a major entity in patients with chronic liver disease.	This guideline defined ACLF as a potentially reversible condition in patients with chronic liver disease with or without cirrhosis that is associated with the potential for multiple organ failure and mortality within 3 months of absence of treatment of the underlying liver condition. Furthermore, kidney failure is the most common organ failure in patients with ACLF, no matter how it is defined. In hospitalized patients with cirrhosis and HRS-AKI without high-grade ACLF or disease, these guidelines suggest TERLIVAZ® (moderate quality, conditional recommendation) or norepinephrine (low quality, conditional recommendation) to improve the renal function. The most commonly used vasoconstrictor worldwide for HRS-AKI/HRS-1 is TERLIVAZ®, which is associated with a response rate of up to 44%. This guideline was developed prior to FDA approval of TERLIVAZ®.
In a study of real-world practice patterns, current standard of care in the U.S. is not adequately treating HRS patients, as response rates are low.	Sanyal AJ, Reddy KR, Brown KA, et al. Hepatorenal syndrome patient characteristics, treatment, and clinical response by disease severity: real-world practice patterns from 11 U.S. hospitals. Poster presented at: AASLD – The Liver Meeting, November 12-15, 2021; virtual. Brief study summary: Oral presentation of retrospective chart review data from 11 U.S. tertiary care hospitals. The purpose of the study was to describe characteristics of HRS-AKI patients in the U.S. and assess real-world treatment patterns and clinical outcomes based on disease severity.	Endpoints and results in the standard vs severe groups, respectively, are as follows: mean change in SCr from baseline to Day 14 was -0.2 mg/dL vs +0.7 mg/dL (P=0.006), overall response rates were 23.0% vs 34.3% (P=0.3), median time from initiation of vasopressors to response was 14 days in both groups, and median overall survival was 1.5 months vs 0.6 months. All results described can be found in the Clinical Outcomes and Survival sections of the poster.
Among HRS patients aged 65 years and older, TERLIVAZ® has been associated with reduced hospital length of stay and RRT requirements vs placebo.	Mujtaba M, Gamilla-Cruda AK, Merwat S, et al. Terlipressin, in combination with albumin, is an effective therapy for hepatorenal syndrome type 1 in patients aged ≥65 years. Poster presented at: NKF Spring Clinical Meeting, April 6-10, 2022; Boston, MA. See prior study description	The primary endpoint was verified HRS reversal, defined as the percentage of patients with 2 consecutive SCr values ≤1.5 mg/dL, obtained at least 2 hours apart while on treatment by Day 14 or discharge, and alive without RRT (for example, dialysis) for at least an additional 10 days. This was achieved in 31.4% of TERLIVAZ® patients and 11.1% of

Substantial Clinical Improvement Assertion #1: The technology offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.		
		placebo patients (P=0.177). Secondary endpoints and results are as follows: HRS reversal (34.3% vs 16.7%; P=0.225), durable HRS reversal (31.4% vs 16.7%; P=0.333), and verified HRS reversal without recurrence by Day 30 (31.4% vs 11.1%; P=0.177) in the TERLIVAZ® vs placebo groups, respectively. Mean length of study site hospital stay was recorded: 21.7 days in the TERLIVAZ® groups and 31.6 days in the placebo group. RRT requirements through 90 days were reported in TERLIVAZ® and placebo groups, respectively: 20.8% vs 41.2% (P=0.158) at Day 14, 23.8% vs 46.2% (P=0.176) at Day 30, 22.2% vs 54.5% (P=0.114) at Day 60, 29.4% vs 66.7% (P=0.067) at Day 90, and 0% vs 83.3% (P=0.003) post-liver transplant (Figure 3).

BILLING CODE 4120–01–C

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26903 through 26904), after review of the information provided by the applicant, we stated that we had the following concerns regarding whether TERLIVAZ® meets the substantial clinical improvement criterion. With respect to the applicant's assertion that TERLIVAZ® offers a treatment option for a patient population unresponsive to currently available treatments because among patients in the CONFIRM trial, patients that had failed prior therapy with available options achieved a statistically significant improvement in renal function with TERLIVAZ®, we noted that the applicant provided evidence from data on file for the clinical study report of the CONFIRM trial. We noted that this data on file appears to be a post-hoc analysis of the trial. As this was a post-hoc analysis, we stated we were cautious about drawing conclusions from this analysis alone without additional outcome data.

We also noted that the applicant asserts that the primary endpoint of the CONFIRM trial, verified HRS reversal, is a clinically significant and appropriate measure of improvement in renal function. However, as we noted in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25344) and FY 2023 IPPS/LTCH proposed rule (87 FR 28295), in the CONFIRM trial, while the proportion of patients with verified HRS reversal without HRS recurrence by Day 30 was numerically greater in the TERLIVAZ® group than placebo, the difference between groups was not statistically significant (26% vs 17%, p=0.08).[149] We also noted that the potential for HRS recurrence among patients treated with TERLIVAZ® after 30 days is unclear. We questioned whether a statistically significant difference in verified HRS reversal in the TERLIVAZ® group at 14 days was sufficient to provide evidence of the durability of improvement in renal function.

With respect to the applicant's assertion that TERLIVAZ® significantly improves clinical outcomes, we noted that the applicant provided evidence from data on file for the clinical study report of the CONFIRM trial that appear to consist of post-hoc analyses of patient subgroups, for example, improvement in renal function for patients with alcoholic hepatitis at baseline, and reduction in RRT requirements in patients who received a liver transplant. Similar to our earlier concern, we questioned if we were able to draw conclusions from these post-hoc analyses alone without additional outcome data.

We also noted that the poster presentation for Mujtaba et al. is a post-hoc analysis of a subpopulation of patients aged ≥65 years from the CONFIRM trial, which was not powered to assess differences in clinical outcomes between the TERLIVAZ® and placebo groups in this subpopulation. As such, we noted that differences between the TERLIVAZ® and placebo groups in verified HRS reversal, HRS reversal, durability of HRS reversal, verified HRS reversal without HRS recurrence by Day 30, and length of study site hospital stay in days were not statistically significant. We also noted that the difference in RRT requirements through 90 days in the CONFIRM study among surviving patients aged ≥65 years was not statistically significant. Although the results numerically favored the TERLIVAZ® group, for those reasons, we questioned whether this analysis provided sufficient evidence of improved clinical outcomes in the Medicare population.

Finally, regarding the study conducted by Arora et al., we noted in the FY 2022 IPPS/LTCH PPS (86 FR 25344) and FY 2023 IPPS/LTCH PPS (87 FR 28296) proposed rules that this study included patients with a diagnosis of ACLF as well as HRS–AKI, which may have contributed to the differences observed between the TERLIVAZ® arm and the norepinephrine arm in this study.[150]

We invited public comments on whether TERLIVAZ® meets the substantial clinical improvement criterion.

Comment: We received several comments in support of new technology add-on payments for TERLIVAZ®. The commenters supported the substantial clinical improvement assertations for TERLIVAZ®, and described high mortality and significant rates of HRS–1-related readmissions in this patient

[149] Wong F, Pappas, S.C, Curry M.P, et al. Terlipressin plus Albumin for the Treatment of Type 1 Hepatorenal Syndrome. New England Journal of Medicine. 2021;384(9):818–828. doi: 10.1056/NEJMoa2008290.

[150] Arora V, Maiwall R, Rajan V, et al. Terlipressin Is Superior to Noradrenaline in the Management of Acute Kidney Injury in Acute on Chronic Liver Failure. Hepatology. 2020;71(2):600–610.

population. Commenters cited the results of randomized, placebo-controlled trials where the use of TERLIVAZ® was associated with a reduced rate of mortality and more rapid resolution of the disease process as compared to the placebo. Furthermore, commenters indicated that the CONFIRM trial demonstrated the substantial clinical improvement of TERLIVAZ® as compared with placebo on multiple outcomes, including: verified HRS reversal, verified HRS reversal in patients with prior midodrine and octreotide use, durability of HRS reversal, HRS reversal in the systemic inflammatory response syndrome subgroup, decreased incidence of RRT through Day 14, and decreased incidence of RRT after liver transplant. Several commenters noted that the HRS–1 patient population has substantial need for an effective treatment for this disease, and that outcomes have not improved for these patients since 2002.[151] Additionally, several commenters indicated the clinical guidelines recommend using vasoconstrictors in combination with albumin as the first-line treatment to counteract splanchnic arterial vasodilation and that TERLIVAZ® is considered the first line treatment of choice in treating HRS–1 patients in European and Asian countries.[152] [153] A commenter further stated that the CONFIRM study demonstrated that TERLIVAZ® has an acceptable safety profile for this high-morbidity patient population.

Response: We thank the commenters for their input and have taken it into consideration in our determination regarding substantial clinical improvement, discussed later in this section.

Comment: The applicant submitted public comments regarding the substantial clinical improvement criterion, in response to CMS's concerns raised in the proposed rule. With respect to CMS's concern that the applicant provide evidence that TERLIVAZ® offers a treatment option for a patient population unresponsive to currently available treatments from a post-hoc analysis of the trial from which we were cautious about drawing conclusions without additional outcome data, the applicant indicated that although these were findings from a post hoc analysis, the data was derived from the largest multicenter, double-blind, randomized, placebo-controlled clinical trial of TERLIVAZ® to date. The applicant further stated the study of a prospective, randomized, head-to-head trial by Cavallin et al. (2015), in which patients with HRS receiving TERLIVAZ® were compared against patients receiving combination midodrine and octreotide demonstrated that TERLIVAZ®-treated patients attained complete response (decrease in serum creatinine to ≤1.5 mg/dL) at significantly higher rates (55.5%) than midodrine and octreotide-treated patients (4.8%; $p < 0.001$),[154] providing greater confidence in the post hoc results from the CONFIRM trial. The applicant also noted that guidance and international guidelines stated that the efficacy of midodrine and octreotide is lower than that of TERLIVAZ®, and should only be used if TERLIVAZ® is unavailable or contraindicated. The applicant noted that these recommendations were further supported by real-world efficacy data from the United Kingdom, demonstrating that TERLIVAZ® addresses an unmet need and may offer a treatment option for patients who do not respond to existing therapies.

In response to CMS's concern that in the CONFIRM trial, while the proportion of patients with verified HRS reversal without HRS recurrence by Day 30 was numerically greater in the TERLIVAZ® group than placebo, the difference between groups was not statistically significant, and that the potential for HRS recurrence after 30 days was unclear, the applicant stated that verified HRS reversal was the primary endpoint of the CONFIRM trial, and based on study timing, was likely measured beyond Day 14 in most patients. The applicant stated that furthermore, although verified HRS reversal without recurrence was achieved in approximately 50 percent more patients treated with TERLIVAZ® compared to placebo, this endpoint was reported inconsistently, as recurrence was based on investigator judgment. The applicant stated that the endpoint of durability of HRS reversal was a more objective measure of sustained improvements in renal function than verified HRS reversal without HRS recurrence, and reached statistical significance in the CONFIRM trial. In addition, the applicant explained that regarding the potential for HRS recurrence beyond 30 days, HRS develops due to the hemodynamic alterations that occur from portal hypertension and cirrhosis and that TERLIVAZ® is not intended to resolve these complications. The applicant noted that patients whose underlying advanced liver disease is not corrected via transplant may develop HRS again if there is a new precipitating event, and that ultimately, the rate of HRS recurrence beyond 30 days would not be a reflection of TERLIVAZ efficacy, but an effect of patients' underlying liver disease.

With respect to CMS's request for additional outcome data to support post-hoc analyses of patient subgroups, the applicant stated that although the data was derived from post hoc analyses, the CONFIRM trial is the largest multicenter, double-blind, randomized, placebo-controlled clinical trial of TERLIVAZ® to date, and that the incidence of RRT through Day 90 was a prespecified endpoint for the full trial population. The applicant further stated that overall, data from the full intention-to-treat (ITT) population of the CONFIRM trial; data from the pooled analysis of the CONFIRM, REVERSE, and OT–0401 trials; and pre-transplant and long-term data from the subgroup of patients in the CONFIRM trial who received a liver transplant all consistently support that treatment with TERLIVAZ® reduced the incidence of RRT compared to placebo. Thus, TERLIVAZ® treatment offers significant clinical efficacy by helping patients avoid RRT,[155] and has been associated with significant reductions in intensive care unit (ICU) length of stay because it can be administered on the general medicine floor. The applicant further stated that in the subgroup analysis of patients with alcoholic hepatitis, post hoc data from CONFIRM was consistent with published pooled data from all 3 trials, CONFIRM, REVERSE, and OT–0401, and showed that TERLIVAZ® led to significant improvements in renal function compared to placebo.[156] The

[151] Thomson MJ, Taylor A, Sharma P, et al. Limited Progress in Hepatorenal Syndrome (HRS) Reversal and Survival 2002–2018: A Systematic Review and Meta-Analysis. Dig Dis Sci. 2019;30. doi: 10.1007/s10620–019–05858–2.

[152] Low G, Alexander GJM, Lomas DJ. Hepatorenal Syndrome: Aetiology, Diagnosis, and Treatment. Gastroenterology Research and Practice. 2015;2015:207012.

[153] Angeli P, Bernardi M, Villanueva C, et al. EASL Clinical Practice Guidelines for the management of patients with decompensated cirrhosis. Journal of Hepatology. 2018;69(2):406–460.

[154] Cavallin M, Kamath PS, Merli M, et al. Terlipressin plus albumin versus midodrine and octreotide plus albumin in the treatment of hepatorenal syndrome: a randomized trial. *Hepatology.* 2015;62(2):567–574.

[155] Weinberg EM, Wong F, Vargas HE, et al. Pretransplant terlipressin treatment for hepatorenal syndrome decreases the need for renal replacement therapy both pre- and posttransplant: a 12-month follow-up analysis of the CONFIRM trial. *Hepatology.* 2022;76(S1):S145–S146.

[156] Sigal SH, Sanyal AJ, Frederick RT, Weinberg EM, Pappas SC, Jamil K. Terlipressin treatment is associated with reversal of hepatorenal syndrome in

Continued

applicant further stated that there was a significant improvement in renal function in the pooled population subgroup, with 38.0 percent of the TERLIVAZ® group vs 13.1 percent of the placebo group achieving HRS reversal ($p<0.001$). Additionally, the applicant noted that significantly more patients were alive without RRT and maintained HRS reversal to Day 30 in the TERLIVAZ® group (33.9% vs 10.7%; $p<0.001$), consistently demonstrating that TERLIVAZ® treatment led to significant improvements in renal function among patients with alcoholic hepatitis.

With respect to whether the analysis submitted by the applicant provides sufficient evidence of improved clinical outcomes in the Medicare population given that the CONFIRM trial was not powered to assess differences in clinical outcomes in the subpopulation of patients aged ≥65 years, the applicant stated that HRS is a rare disease, and that therefore, it is difficult to enroll an adequate sample size to conduct large clinical trials that are powered to achieve statistical significance among specific subgroups. The applicant further stated that while the CONFIRM trial was not powered to detect a difference between therapies in patients aged 65 years and older, the mean age in the CONFIRM trial was 54 years, and approximately 18 percent of patients in each treatment group were aged 65 years and older. The applicant further stated that although the endpoints shown in the poster by Mujtaba et al.[157] did not reach statistical significance based on the small sample size, each endpoint trended toward improvement in the TERLIVAZ® group compared to placebo and that as a result treatment with TERLIVAZ® in patients aged ≥65 years has shown efficacy results consistent with those of the larger CONFIRM population, and that available pharmacokinetic data does not suggest an older population would have a poorer response or tolerance to TERLIVAZ®. In a separate comment, the applicant also shared a manuscript, with data previously reported in the poster by Mujtaba et al.[158] in abstract form, that had been accepted for publication in Annals of Hepatology.[159] The applicant stated that the manuscript consisted of a pooled analysis of the CONFIRM, REVERSE, and OT–0401 trials that revealed positive results in patients aged 65 years or older with HRS, indicating that treatment with TERLIVAZ® and albumin was associated with clinical improvements for patients aged 65 years and older, and that no new safety signals were revealed in this analysis.

With respect to CMS's concern that the study by Arora et al. included patients with a diagnosis of ACLF as well as HRS–AKI, which may have contributed to the differences observed between the TERLIVAZ® arm and the norepinephrine arm, the applicant responded that ACLF and HRS are often comorbid conditions and both were seen in all patients included in the CONFIRM trial.[160] The applicant further specified that though it was not specifically required in the inclusion criteria, every patient enrolled in the CONFIRM trial had at least ACLF grade 1 at study entry. The applicant conclude that the patient population studied in the Arora et al. was similar to that of the CONFIRM trial and can be used to demonstrate that the improved outcomes seen with TERLIVAZ® compared to norepinephrine is expected in patients with HRS who meet ACLF criteria.

Response: We thank the applicant for its comments and the additional information provided regarding the substantial clinical improvement criterion. Based on the comments and additional information received, we agree that TERLIVAZ® represents a substantial clinical improvement over existing technologies because it is the only FDA-approved treatment for HRS patients, and significantly improves clinical outcomes among HRS patients by improving renal function, compared to placebo as well as currently available treatments, as demonstrated by statistically significant differences in HRS reversal rates, resulting in reduced RRT requirements and hospital length of stay.

After consideration of the public comments we received and the information included in the applicant's new technology add-on payment application, we have determined that TERLIVAZ® meets the criteria for approval for new technology add-on payment. Therefore, we are approving new technology add-on payments for this technology for FY 2024. Cases involving the use of TERLIVAZ® that are eligible for new technology add-on payments will be identified by ICD–10–PCS codes: XW03367 (Introduction of terlipressin into peripheral vein, percutaneous approach, new technology group 7) or XW04367 (Introduction of terlipressin into central vein, percutaneous approach, new technology group 7).

Per the applicant, the WAC of TERLIVAZ® is $950 per vial, and the mean treatment duration with TERLIVAZ® in the CONFIRM trial was 6.2 days, using 27 vials. In its application, the applicant estimated that the average cost of therapy for TERLIVAZ® is $25,650 per patient ($950 × 27 vials). Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, the maximum new technology add-on payment for a case involving the use of TERLIVAZ® is $16,672.50 for FY 2024.

k. XENOVIEW™ (Xenon Xe 129 Hyperpolarized)

Polarean, Inc. and The Institute for Quality Resource Management (collectively referred to as ''applicant'') submitted an application for new technology add-on payments for XENOVIEW™ (xenon Xe 129 hyperpolarized) for FY 2024. Per the applicant, XENOVIEW™ is prepared using an FDA approved hyperpolarization process from a dose of Xenon ^{129}Xe Gas Blend. The applicant stated that the imaging signal is specifically created to address the unmet needs to quantitively diagnose early pulmonary oxygen deficiency, at the level of the alveoli oxygen exchange, without exposing the patient to ionizing radiation to inform management of patients with diseases manifested by diminished lung function. The applicant explained that after inhalation, HP ^{129}Xe freely diffuses from the airspaces through alveolar-capillary barrier (comprised of alveolar epithelial cells, interstitial tissues, and capillary endothelial cells) and subsequently into the red blood cells (RBCs). The applicant noted that HP ^{129}Xe exhibits distinct magnetic resonance (MR) frequency shifts in the airspace, barrier, and RBCs, allowing separate imaging of its distribution in all three compartments, and that such imaging

patients with alcoholic hepatitis. *Clin Gastroenterol Hepatol.* Published online February 26, 2023. doi:10.1016/j.cgh.2023.02.015.

[157] Mujtaba M, Gamilla-Cruda AK, Merwat S, et al. Terlipressin, in combination with albumin, is an effective therapy for hepatorenal syndrome type 1 in patients aged ≥65 years. Poster presented at: National Kidney Foundation Spring Clinical Meeting; April 6–10, 2022; Boston, MA.

[158] *Ibid.*

[159] Mujtaba, M.A., Gamilla-Crudo, A.K., Merwat, S.N., Hussain, S.A., Kueht, M., Karim, A., Khattak, M.W., Rooney, P.J., & Jamil, K. (2023). Terlipressin in combination with albumin as a therapy for hepatorenal syndrome in patients aged 65 years or older. *Annals of hepatology, 28*(5), 101126. Advance online publication. *https://doi.org/10.1016/j.aohep.2023.101126.*

[160] Wong F, Pappas SC, Reddy KR, et al. Terlipressin use and respiratory failure in patients with hepatorenal syndrome type 1 and severe acute-on-chronic liver failure. *Aliment Pharmacol Ther.* 2022;56(8):1284–1293.

23. Low G, Alexander GJM, Lomas.

has been used to spatially characterize disease burden across a range of pulmonary disorders (for example, chronic obstructive pulmonary disease (COPD) and asthma). We note that the applicant submitted an application for new technology add-on payments for XENOVIEW™ for FY 2023, as summarized in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28307 through 28317), that it withdrew prior to the issuance of the FY 2023 IPPS/LTCH PPS final rule (87 FR 48920).

Please refer to the online application posting for XENOVIEW™ available at *https://mearis.cms.gov/public/publications/ntap/NTP221017PBF9L*, for additional detail describing the technology and the diseases diagnosed by the technology.

With respect to the newness criterion, according to the applicant, XENOVIEW™ was granted NDA approval from FDA on December 23, 2022, for the use of XENOVIEW™ (xenon Xe 129 hyperpolarized) with magnetic resonance imaging (MRI) for evaluation of lung ventilation in adults and pediatric patients aged 12 years and older. According to the applicant, XENOVIEW™ was commercially available immediately following the NDA approval. The applicant stated that the dose for patients 12 years and older is 75 mL to 100 mL dose equivalent (DE, where DE = [total volume Xe gas] × [^{129}Xe isotopic enrichment] × [polarized percent]) of HP ^{129}Xe by oral inhalation of the entire contents of one XENOVIEW™ Dose Delivery Bag. The applicant explained that each bag contains at least 75 mL DE with a recommended target DE range of 75 mL to 100 mL in a volume of 250 mL to 750 mL total xenon with additional nitrogen, National Formulary (NF) (99.999% purity) added to reach a total volume of 1,000 mL measured 5 minutes before inhalation.

The applicant stated that effective October 1, 2022, the following ICD–10–PCS procedure code may be used to uniquely describe procedures involving the use of XENOVIEW™: BB34Z3Z (Magnetic resonance imaging (MRI) of bilateral lungs using hyperpolarized xenon 129 (Xe–129)).

As previously discussed, if a technology meets all three of the substantial similarity criteria under the newness criterion, it would be considered substantially similar to an existing technology and would not be considered ''new'' for the purpose of new technology add-on payments.

With respect to the substantial similarity criteria, the applicant asserted that XENOVIEW™ is not substantially similar to other currently available technologies because HP ^{129}Xe, a new chemical entity, and new lung MRI signaling agent, is created on-site following an FDA approved method, for oral inhalation. The applicant explained that absent ionizing radiation, XENOVIEW™ identifies lung abnormalities reporting ventilation defect percent (VDP) diagnosing early deteriorating lung function to inform, guide and monitor therapy. The applicant explained that XENOVIEW™'s properties cause diffusion through the lung and distal alveoli, and that novelty mechanistically lies in the gas preparation, where HP creates a quantitative distinct volume DE for the patient's anatomy. Therefore, the applicant asserted that the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for XENOVIEW™ for the applicant's complete statements in support of its assertion that XENOVIEW™ is not substantially similar to other currently available technologies.

BILLING CODE 4120–01–P

Substantial Similarity Criteria	Applicant Response	Applicant assertions regarding this criterion
Does the technology use the same or similar mechanism of action to achieve a therapeutic outcome?	No	HP ^{129}Xe is a new chemical entity performing as a signaling agent when used in chest MRI to evaluate lung function throughout the lung, including the pulmonary vascular capillary network. There are no other imaging modalities that can visualize functional gas exchange in the smallest airways, known to be the nexus of disease. Furthermore, the unique properties of ^{129}Xe (as compared to other noble gas isotopes ^{133}Xe or ^{3}He), including a difference resonance frequency in the airspace, lung barrier tissue, or in association with red blood cells, allows quantitative functional imaging of each of these 3 compartments at the level of the alveoli. No other signaling agent can achieve direct imaging of lung function at this level of specificity as the unique inhaled drug ^{129}Xe, and no other imaging modality can do it with the benign safety profile of the MRI. As such, the combination of this new chemical entity and its application in MRI represents a completely new imaging modality.
Is the technology assigned to the same MS-DRG as existing technologies?	No	Lung imaging ICD-10-PCS codes do not determine the MS-DRG assignment upon discharge. The set of imaging ICD-10-PCS codes related to lung or pulmonary imaging are not assigned to any specific MS-DRG. For patients with lung disease that may be prescribed an HP ^{129}Xe MRI, the resulting MS-DRGs are determined by the patient's diagnosis codes, not the XENOVIEW™ MRI or any other lung imaging. Using the FY 2022 Optum 360 DRG Expert publication it was verified these ICD-10-PCS codes did not determine or cause assignment of any MS-DRG during an inpatient admission, and certainly not MS-DRG 190, 191, 192, 202 and 203 related to the population of patients who may require a medically necessary XENOVIEW™ MRI. XENOVIEW™ MRI is medically necessary to verify a patient's exact lung ventilation defect percentage (VDP) to aid treatment planning and to monitor the patient for response to pharmacologic options. While the MS-DRGs for a patient population with lung disease represent the likely patients to be recommended a XENOVIEW™ MRI, this is a novel diagnostic, using a completely different chemical entity with a mechanism of action to enable regional VDP measurements to aid patient treatment. For patients with lung disease that may be prescribed an XENOVIEW™ MRI the resulting MS-DRGs are determined by the patient's diagnosis codes, not the XENOVIEW™ MRI or any other lung imaging.
Does new use of the technology involve the treatment of the same/similar type of disease and the same/similar patient population when compared to an existing technology?	Yes	However, the new information opens treatment options because the pulmonologist receives information from the radiologist that they cannot otherwise obtain today. Existing technologies to measure pulmonary function cannot achieve the region specific quantified VDP. HP ^{129}Xe MRI is reported to detect oxygen deficient regions of the lung better than pulmonary function tests (PFTs). Conventional MRI, CT, or VQ scintigraphy would not be ordered to measure oxygen exchange of the lung tissue. These modalities cannot provide such an image. Therefore, from the use of an ICD-10-CMS diagnosis coding perspective, the patient populations with disease that may benefit from a XENOVIEW™ MRI are different than those using conventional modalities. Patients with early disease can now be identified and physicians can obtain information to enhance their patients' treatment to live a higher quality of life.

Similar to our discussion in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28308), we noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26917 through 26918) that although the applicant states that XENOVIEW™ has not been assigned to an MS–DRG and cannot be compared to an existing technology, we believed that based on its indication, cases involving the use of XENOVIEW™ would be assigned to the same MS–DRGs as cases involving the use of other MRIs and imaging modalities for pulmonary function and imaging of the lungs.

We invited public comments on whether XENOVIEW™ is substantially similar to existing technologies and whether XENOVIEW™ meets the newness criterion.

Comment: The applicant submitted a comment maintaining that XENOVIEW™ meets the newness criterion. With respect to mechanism of action, the applicant stated that XENOVIEW™ creates a distinct image

requiring a special coil and multinuclear scanner for the MRI to respond to the HP Xe 129, and therefore does not use the same or similar mechanism of action as other imaging agents. Furthermore, the applicant stated that XENOVIEW™ is FDA-approved as a new chemical entity and that no conventional existing imaging or pulmonary function testing can report region specific quantified VDP. The applicant also explained that conventional MRI, CT, or VQ scintigraphy would not be ordered to measure oxygen exchange of lung tissue, therefore XENOVIEW™ MRI treats a population with respiratory disease by reporting findings not otherwise obtainable.

With respect to whether cases involving the use of XENOVIEW™ would be assigned to the same MS–DRGs as cases involving the use of other MRIs and imaging modalities for pulmonary function and imaging of the lungs, the applicant stated that XENOVIEW™ would not be assigned to the same MS–DRGs as cases involving the use of other MRIs or advanced imaging because medical necessity, images, spatial anatomy, and information obtained from the XENOVIEW™ MRI are different from the information from a conventional MRI, CT, and nuclear medicine lung imaging. The applicant further stated a patient's principal diagnosis (specifically asthma, COPD, interstitial lung disease, Bronchiolitis Obliterans, cystic fibrosis, or complication post lung transplant), underlying comorbidities, and surgical procedures drive the MS–DRG assignment at the time of discharge, and creation of a new MS–DRG is not required. The applicant stated that XENOVIEW™ would be assigned within MS–DRGs 190–192, 196–198, 202–206 and 951 when ICD–10–PCS code BB34Z3Z (Magnetic resonance imaging (MRI) of bilateral lungs using hyperpolarized xenon 129 (Xe–129)) is used. The applicant explained that within Major Diagnostic Category (MDC) 004—Diseases & Disorders of the Respiratory System, 0.12 percent of cases included lung or pulmonary ICD–10–PCS codes for CT, MRI, or nuclear imaging, and that these imaging services are not ordered to report quantitative lung ventilation, therefore the ICD–10–CM diagnosis code of patients who benefit from XENOVIEW™ are different from those with diagnosis codes where conventional CT, MRI, or nuclear imaging would be ordered. The applicant explained that XENOVIEW™ is ordered for patients with respiratory disease, using the VDP as new information to guide treatment decisions and improve patient outcomes.

Response: We thank the applicant for the clarification regarding MS–DRG assignment for XENOVIEW™. Based on our review of comments received and information submitted by the applicant as part of its FY 2024 new technology add-on payment application for XENOVIEW™, we disagree with the applicant that XENOVIEW™ would not be assigned to the same MS–DRGs as cases involving the use of other MRIs or advanced imaging. We do not believe that the low volume of CT, MRI, or nuclear imaging cases within MDC 004 indicates that XENOVIEW™ would not be assigned to the same MS–DRGs as these technologies. As the applicant noted, for patients with lung disease who may be prescribed XENOVIEW™, the resulting MS–DRGs are determined by the patient's primary diagnosis codes, not the XENOVIEW™ MRI ICD–10–PCS procedure code. Therefore, we believe that cases involving the use of XENOVIEW™ or other MRIs and imaging modalities for pulmonary function and imaging of the lungs that have the same primary diagnosis codes would be assigned to the same MS–DRGs.

However, we agree with the applicant that XENOVIEW™ uses a new mechanism of action for the diagnosis of respiratory conditions when compared to existing diagnostics because there are currently no FDA-approved or cleared technologies that use imaging with an inhaled hyperpolarized contrast agent that reports VDP quantitatively to provide a detailed, quantifiable image of gas distribution in regions of the lung. Therefore, we believe that XENOVIEW™ is not substantially similar to existing diagnostic options and meets the newness criterion. We consider the newness period to begin on December 23, 2022, when XENOVIEW™ was approved by FDA for the evaluation of lung ventilation in adults and pediatric patients aged 12 years and older.

With respect to the cost criterion, the applicant searched the FY 2021 MedPAR file for potential cases representing patients who may be eligible for XENOVIEW™. The applicant limited its analysis to eight MS–DRGs, listed in the following table, as it believes these MS–DRGs represent patients most likely eligible for treatment with XENOVIEW™ (that is, patients with lung and pulmonary challenges, confirmed pulmonary disease, asthma, and COPD). Using the inclusion/exclusion criteria described in the following table, the applicant identified 87,801 claims mapping to these eight MS–DRGs. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $55,652, which exceeded the average case-weighted threshold amount of $46,624. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that XENOVIEW™ meets the cost criterion.

XENOVIEW™ COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of MS-DRGs	190 (Chronic Obstructive Pulmonary Disease with MCC) 191 (Chronic Obstructive Pulmonary Disease with CC) 192 (Chronic Obstructive Pulmonary Disease without CC/MCC) 196 (Interstitial Lung Disease with MCC) 197 (Interstitial Lung Disease with CC) 202 (Bronchitis and Asthma with CC/MCC) 203 (Bronchitis and Asthma without CC/MCC) 951 (Other Factors Influencing Health Status)
Inclusion/exclusion criteria	The applicant limited its analysis to eight MS-DRGs, as previously listed, as it believes these MS-DRGs represent patients most likely eligible for treatment with XENOVIEW™. Hospitals reporting at least 11 cases per identified MS-DRG were included. The applicant excluded hospitals not listed in the impact file posted with the FY 2021 IPPS/LTCH PPS final rule. The applicant calculated the average unstandardized charge per case for each MS-DRG.
Charges removed for prior technology	Per the applicant, no charges were removed for a prior technology because XENOVIEW™ MRI is an added procedure that is not intended to replace prior technology, but is rather selected due to the need for new information. The applicant also noted that it is not realistic to remove prior technology costs as only 0.06% of the relevant MS-DRG cases reported any lung type imaging.
Standardized charges	The applicant used the standardization formula provided in Technical Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2021 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied 3-year inflation factor of 20.5% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule.
Charges added for the new technology	The applicant added charges for the new technology by dividing the cost of the initial drug obtained from the ^{129}Xe gas preparation blend for inhalation cylinder by the national average cost-to-charge ratio of 0.184 for drugs from the FY 2023 IPPS/LTCH PPS final rule. The applicant added indirect charges for the new technology for hospital costs to create the HP ^{129}Xe dose for one patient oral inhalation of the defined DE using FDA approved instructions with XENOVIEW™ specific instrumentation. The applicant added these charges by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.137 for radiation from the FY 2023 IPPS/LTCH PPS final rule.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26918) we noted that the applicant limited its analysis to eight MS–DRGs. We were interested in information as to whether the technology would map to other MS–DRGs, such as other MS–DRGs under Major Diagnostic Category 004—Diseases & Disorders of the Respiratory System, as the indication for the technology regarding lung ventilation seems very broad. We invited public comments on whether XENOVIEW™ meets the cost criterion.

Comment: With respect to whether XENOVIEW™ would map to other MS–DRGs under Major Diagnostic Category 004—Diseases & Disorders of the Respiratory System, the applicant submitted a comment verifying that Version 40.1 of the FY 2023 MS–DRG grouper comparing diagnosis codes for the MS–DRGs within MDC 004 unique to the population that would benefit from XENOVIEW™ for lung ventilation returned the following: MS–DRGs 190–192, 196–198, 202–206 and 951. The applicant stated that they added MS–DRGs 204–206 and emphasized that not all MS–DRGs within MDC 004 related to diagnoses that would result in ordering XENOVIEW™ for lung ventilation VDP measurement. For example, the applicant stated that MS–DRGs 163–168 are specific to thoracic surgical procedures and argued that XENOVIEW™ would not map to the assignment of these MS–DRGs and would likely not be used during that inpatient admission. Furthermore, the applicant stated that MS–DRGs 174 and 176 are specific to pulmonary embolism, not a diagnosis for XENOVIEW™. The applicant also stated that MS–DRGs 177–179, 186–188, 189, 193–195 and 199–201 represent specific respiratory diseases with primary diagnosis codes not related to the diagnosis codes for XENOVIEW™. The applicant stated that MS–DRGs 207–208 are specific to patients on a ventilator with diagnosis codes not related to the primary diagnosis codes for XENOVIEW™. The applicant stated that lung imaging procedures were identified with MS–DRG 177; however, such imaging was ordered to monitor the accumulation of mucus in the lungs.

After adding MS–DRGs 204–206 to the cost criterion analysis, the applicant calculated a final inflated average case-weighted standardized charge per case of $58,328, which exceeded the average case-weighted threshold amount of $47,107. The applicant asserted that because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, XENOVIEW™ meets the cost criterion.

Response: We thank the applicant for their revised cost analysis with the addition of MS–DRGs 204–206. We agree the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, and therefore XENOVIEW™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that XENOVIEW™ represents a substantial clinical improvement over existing technologies because HP ^{129}Xe gas for oral inhalation with MRI offers an effective option for patients with pulmonary challenges to obtain quantitative information regarding their lung ventilation as it relates to their progression of disease without subjecting the patient to ionizing

radiation or the half-life of nuclear imaging agents. The applicant further stated that HP ^{129}Xe MRI images are sharp and discrete, providing visual evidence of oxygen impairment across the barrier tissues leading to a quantifiable metric to follow patients' treatment. The applicant asserted that XENOVIEW™ offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. The applicant provided 10 studies to support these claims. The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for XENOVIEW™ for additional details on the applicant's statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Substantial Clinical Improvement Assertion #1: The technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods.		
Applicant statements in support	**Supporting evidence provided by the applicant**	**Outcome(s) or findings cited by the applicant from supporting evidence to support its statements**
In patients with idiopathic pulmonary fibrosis (IPF), HP ^{129}Xe MRI can predict disease progression in patient population where fibrosis is not detectable by traditional CT.	Hahn, AD, Carey KJ, Barton GP, Torres, LA, Kammerman J, et al. Hyperpolarized 129Xe MR Spectroscopy in the Lung Shows 1-year Reduced Function in Idiopathic Pulmonary Fibrosis. Radiology 2022; 000:1–9. Brief study description: Participants with IPF were followed up with forced vital capacity percent predicted (FVC%p), diffusing capacity of the lungs for carbon monoxide percent predicted (DLco%p), and clinical outcome at 1 year. IPF progression was defined as reduction in FVC%p by at least 10%, reduction in DLco%p by at least 15%, or admission to hospice care. CT and MRI were spatially coregistered and a measure of pulmonary gas transfer (red blood cell [RBC]-to-barrier ratio) and high-ventilation percentage of lung volume were compared across groups and across fibrotic versus normal-appearing regions at CT by using Wilcoxon signed rank tests.	HP ^{129}Xe MRI, red blood cell (RBC)-to-barrier ratio (measure of gas exchange) and high-ventilation percent were reduced at baseline in participants with IPF who progressed in the year after imaging. The results also suggested that HP ^{129}Xe MRI helps to detect reduced RBC-to-barrier ratio in participants with IPF progression compared with participants without progression in nonfibrotic lung, despite both groups showing the expected lower overall RBC-to-barrier ratio in fibrotic lung compared with nonfibrotic lung. This study demonstrates that functional measures of gas exchange and ventilation measured at HP 129Xe MRI and the extent of fibrotic structure at CT are associated with disease progression in IPF at 1 year later.
	Gleeson F, Fraser E. Hyperpolarized Xenon MRI, Further Evidence of Its Use in Progressive Pulmonary Fibrosis? Radiology 2022; 00:1–2. Brief study description: This editorial comments on the importance of the Hahn 2022 study[161] to provide information to aid use of HP ^{129}Xe MRI into clinical practice, particularly to use the information to aid diagnoses of the image and the functional information simultaneously obtained.	Until recently, treatment options for non-IPF interstitial lung disease were limited to immunosuppressive agents that, in the case of predominantly fibrotic rather than cellular disease (such as in chronic hypersensitivity pneumonitis), had a limited evidence base and for many came with considerable long-term side effects. Evidence from Hahn suggests that Xe MRI can aid in understanding if patients on new therapies are progressing or not to

[161] Hahn, AD, Carey KJ, Barton GP, Torres, LA, Kammerman J, et al. Hyperpolarized 129Xe MR Spectroscopy in the Lung Shows 1-year Reduced Function in Idiopathic Pulmonary Fibrosis. Radiology 2022; 000:1–9.

Substantial Clinical Improvement Assertion #1: The technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods.		
		advance treatment effectiveness as a means of ensuring that treatment is prescribed appropriately to patients. The absence of radiation, ease of use, and rapid clearance from the body allows Xe MRI to advance a quantitative MR imaging approach to validate response to expensive treatment in time to make clinical effective treatment decisions.
In patients with Long-COVID, HP ^{129}Xe MRI identifies patients with gas exchange abnormalities that are undetectable by standard CT.	Grist JT, Collier GJ, Walters H, Kim M, Chen M, et al. Lung abnormalities depicted with hyperpolarized xenon MRI in patients with long COVID. Radiology 2022;in press:1–26. Brief study description: This is a prospective study to assess alveolar gas transfer in 11 non-hospitalized post-COVID-19 (NHLC) patients and 12 post-hospitalized COVID-19 (PHC) patients with normal CT exam results.	In a prospective study with a total of 23 participants, there were significant differences in mean red blood cell tissue plasma between healthy controls (13) and post-hospitalized COVID (0.46 ± 0.07, [0.43-0.47] vs (0.31 ± 0.10, [0.24-0.37], respectively, p = 0.02) and between healthy controls and non-hospitalized long COVID participants (0.37 ± 0.10, [0.31-0.44], p = 0.03; see page 9), indicating differences in lung function. Non-hospitalized long COVID participants had near-normal CT scores, and DLco (%) was significantly lower between NHLC and PHC participants (76 ± 8%, [73-83] vs 86 ± 8%, [80-91] respectively, p = 0.04), potentially indicating a decrease in lung function but not structure. Fig 2 pg.17, Fig 4 pg.19, Fig 5 pg.20.
	Grist JT, Chen M, Collier GJ, Raman B, Abueid G, et al. Hyperpolarized ^{129}XE MRI abnormalities in dyspneic patients 3 months after COVID-19 pneumonia: Preliminary results. Radiology 2021;301:E353–E360. Brief study description: This is a prospective study to assess alveolar gas transfer in 5 healthy patients (recruited from asymptomatic local staff who had a negative PCR test result and no history of cardiac or respiratory disease) and 9 patients that were previously hospitalized with COVID-19 and at least 3 months post-hospital discharge	HP ^{129}Xe MRI revealed a significant difference in RBC:TP ratio between COVID-19 patients and healthy subjects (0.3 ± 0.1 vs. 0.5 ± 0.1, respectively; p = 0.001; effect size = 1.36). Furthermore, there was a significant difference in full width at half maximum during the RBC and gas phases (median ± range: 567 ± 1 Hz vs. 507 ± 81 Hz [p = 0.002] and 104 ± 2 Hz vs. 122 ± 17 Hz [p = 0.004]), but not in the tissue phase (420 ± 2 Hz vs. 418 ± 57 Hz; p = 0.72). Both COVID-19 patients and healthy subjects recorded high intraclass correlation coefficients (0.82 and 0.88, respectively). There were no significant correlations between the RBC:TP ratio and DL_{CO}, age, D-dimer, hemoglobin, forced expiratory volume, or forced vital capacity, nor between the gas phase full width at half maximum and the tissue phase full width at half maximum, but there was a significantly strong correlation between the gas and RBC phase full width at half maximum (R^2 = 0.99; p = 0.04) and between the gas phase full width at half maximum and DL_{CO} (R^2 = 0.94; p = 0.04).
	Parraga G, Matheson AM. Step on the ^{129}Xe gas: The MRI race to uncover drivers of post-COVID-19 symptoms. Radiology 2022;in press:1–8.	The editorial described study results of significantly lower HP ^{129}Xe MRI RBC-to-barrier ratio in never-hospitalized and previously hospitalized subgroups

Substantial Clinical Improvement Assertion #1: The technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods.		
	Brief study description: This editorial reviewed a study (Grist et al., 2022)[162] that used HP ^{129}Xe MRI to better understand the underlying cause of post-COVID-19 symptoms and limitations in recently discharged patients with COVID-19	compared to the healthy group and no difference between measurements in the two COVID-19 subgroups. There were also no significant differences in spirometry measurements between the two subgroups, but mean DL_{CO} was significantly lower in the never-hospitalized subgroup than the previously hospitalized subgroup despite still being normal. Chest CT imaging results of all patients were normal or near-normal. The editorial also noted a potential relationship between HP ^{129}Xe MRI RBC-to-barrier ratio and dyspnea score (p = 0.06–0.08).
In patients with severe asthma and/or COPD, HP ^{129}Xe MRI can identify an early treatment effect not possible with CT due to repeat imaging without repeated radiation exposure.	McIntosh M, Eddy RL, Knipping D, Barker AL, Lindenmaier TJ, Yamashita C, et al. Response to benralizumab in severe asthma: 129Xe MRI, oscillometry and clinical measurements. Am J Respir Crit Care Med 2020;201:A6244. Brief study description: This study abstract compared metrics from HP ^{129}Xe MRI, pulmonary function tests, and oscillometry in 18 patients with severe asthma before and after application of bronchodilator at baseline and 28 days post-benralizumab injection (and at 14 days post-benralizumab injection for 6 patients). Results for ventilation defect percent (VDP) from HP ^{129}Xe MRI, forced expiratory volume per one second (FEV1) from pulmonary function tests, oscillometry, lung clearance index, and questionnaires were obtained.	Post-bronchodilator VDP improved significantly between baseline and 28 days post-benralizumab injection (p = 0.03) whereas FEV1 did not. Of the 6 patients assessed at 14 days post-benralizumab injection, 4 patients reported VDP improvement ≥MCID at 14 days and 28 days post-benralizumab injection and 2 patients reported a ≥100 mL FEV1 improvement at 14 days post-benralizumab injection.
	Mummy DG, Coleman EM, Wang Z, Bier EA, Lu J, Driehuys B, Huang YC. Regional gas exchange measured by ^{129}Xe magnetic resonance imaging before and after combination bronchodilators treatment in chronic obstructive pulmonary disease. J Magn Reson Imaging 2021;54(3):964–974. Brief study description: This prospective study aimed to assess treatment-related changes in HP ^{129}Xe gas transfer function following administration of an inhaled long-acting beta agonist/long-acting muscarinic receptor antagonist (LABA/LAMA) bronchodilator. This prospective cohort study of 17 COPD (GOLD II/III classification per Global Initiative for Chronic Obstructive Lung Disease criteria) were imaged before and after 2 weeks of LABA/LAMA therapy.	HP ^{129}Xe MRI recorded a significant decrease in ventilation defect percent and the percentage of voxels in the lowest or next lowest classification bins ($ven_{def+low}$) (57.8 ± 8.4% to 52.5 ± 10.6%; p < 0.05) and ventilation defect percent (33.7 ± 8.9% vs. 29.5 ± 11.4%, p < 0.05) in subjects with chronic obstructive pulmonary disorder before and after bronchodilator therapy, which was consistent with improved spirometry measurements (p < 0.05 for forced expiratory volume over one second [FEV1] and forced vital capacity [FVC]). Although no significant changes were found for barrier uptake (p=0.23), red blood cell transfer (p=0.21), dissolving capacity of the lung for carbon monoxide (DLCO) (p=0.80), total lung capacity (p=0.16), or residual volume (p=0.24). improved ventilation after bronchodilator therapy was correlated

[162] Grist JT, Collier GJ, Walters H, Kim M, Chen M, et al. Lung abnormalities depicted with hyperpolarized xenon MRI in patients with long COVID. Radiology 2022;in press:1–26.

Substantial Clinical Improvement Assertion #1: The technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods.		
		with baseline HP ^{129}Xe barrier uptake (r = 0.49, p = 0.05), while only one pulmonary function test (DL_{CO}) and no spirometry measurement showed a similar level of correlation
In patients with cystic fibrosis, HP ^{129}Xe MRI was a more sensitive measure than spirometry to identify patients with mild/early disease.	Thomen RP, Walkup LL, Roach DJ, Cleveland ZI, Clancy JP, Woods JC. Hyperpolarized ^{129}Xe for investigation of mild cystic fibrosis lung disease in pediatric patients. J Cyst Fibros 2016;16(2):275–282. Brief study description: This study compared the ventilation defect percent (VDP) determined by HP ^{129}Xe MRI and forced expiratory volume per one second (FEV1) scores from pulmonary function tests between 11 healthy patients and 11 patients with cystic fibrosis (age 8–16 years; 9 of which had normal FEV1 scores [>85%]).	FEV1 was not significantly different between healthy patients (100.3 ± 8.5%) and cystic fibrosis patients (97.9 ± 16.0%, p = 0.672; pg. 279). VDP was significantly different between healthy patients (6.4 ± 2.7%) and cystic fibrosis patients (18.3 ± 8.6%, p < 0.001), even when only cystic fibrosis patients with 'normal' FEV1 values (> 85%) were considered (FEV1: 103.1 ± 12.3%, p = 0.57; VDP: 15.4 ± 6.3%, p = 0.002; pg. 279).
In patients with COPD, HP ^{129}Xe MRI provides a higher degree of diagnostic information that is undetectable by spirometry.	Labaki WW, Han MK. State of the Art Improving Detection of Early Chronic Obstructive Pulmonary Disease. Dec. 2018. Ann Am Thorac Soc Vol 15, Supplement 4, pp S243–S248. Brief study description: This state-of-the-art paper is seeking a method to accurately diagnose the underlying phenotypes to aid in prognostication and treatment for COPD, particularly of those who may rapidly progress, where a monitored intervention may be most effective.	33% -50% of individuals with chronic airway obstruction carry a formal diagnosis of COPD. To decrease the impact of COPD on healthcare costs and patient morbidity early detection is needed. Labaki (2018) does not discuss ^{129}Xe MRI, yet defines a desired optimal method that is noninvasive, non-radioactive, non-effort dependent, laying a path for ^{129}Xe MRI. Methods to measure regions of lung tissue not imaged by CT, nor measured by pulmonary function tests (PFT) are discussed, requesting a need for a reliable measure to identify patients that will rapidly progress to COPD and of those who may be monitored for treatment.
	Mummy DG, Coleman M, Wang Z, Bier EA, Lu J, Driehuys D, Huang YC. J. Regional Gas Exchange Measured by ^{129}Xe Magnetic Resonance Imaging Before and After Combination Bronchodilators Treatment in Chronic Obstructive Pulmonary Disease. J Magn Reson Imaging 54(3): 964–974. DOI: 10.1002/jmri.27662. See prior study description.	Mummy's prospective study of patients with COPD receiving treatment compared to healthy controls reveals the accuracy of ^{129}Xe MRI to detect tissue changes indicative of alveolar damage to inform selection of treatment. Reduced ^{129}Xe barrier signal and DL_{CO} are both consistent with an emphysema-predominant COPD phenotype in which the alveolar septa have been destroyed. This reduces the alveolar surface area available for gas diffusion into the blood and leads to airway collapse. PFT FEV1 did not identify this patient set. Conversely, patients with relatively preserved measures of barrier uptake and DL_{CO} may have airway obstruction that is caused by a bronchitis-predominant phenotype. It is this subset who appeared more likely to respond to the LABA/LAMA treatment as measured by ^{129}Xe ventilation MRI. This is further supported by the observation that mean barrier uptake increased after treatment, suggesting that newly exposed regions of

Substantial Clinical Improvement Assertion #1: The technology offers the ability to diagnose a medical condition in a patient population where that medical condition is currently undetectable or offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods.		
		the lung had preserved surface area for gas exchange.
In patients with asthma and/or COPD, HP ^{129}Xe MRI identified patients with unique disease characteristics despite normal PFTs.	Marshall H, Smith LJ, Biancardi A, Collier GJ, Chan HF, et al. 129Xe MRI Patterns of lung function in patients with asthma and/or COPD in the NOVELTY study. Proc. Intl. Soc. Mag. Reson. Med. 30 2022. Brief study description: 164 patients were recruited from primary care and assessed with asthma and/or COPD to take part in the NOVELTY study. Metrics attained were ventilation defect percent (VDP), coefficient of variation of signal intensity (CV), mean diffusive length scale (Lm_D), alveolar surface area to volume ratio (SA/V), ratio of HP ^{129}Xe dissolved in blood to gaseous HP ^{129}Xe in the airspaces (RBC/gas), ratio of HP ^{129}Xe dissolved in lung tissue and plasma to gaseous HP ^{129}Xe in the airspaces (TP/gas), and RBC/TP (a measure of alveolar gas exchange). The patients underwent spirometry and were divided into three groups based on physician-assigned diagnosis: asthma, COPD, or asthma+COPD.	In patients with normal FEV1, when imaged with HP ^{129}Xe MRI ventilation defects were prevalent and ventilation MRI metrics showed significant differences between asthma (n=78) and asthma+COPD (n=37), and between asthma and COPD (n=10). Patients with COPD or asthma+COPD had significantly higher VDP, CV, and Lm_D and significantly lower SA/V, RBC/TP, RBC/gas, and TP/gas than patients with asthma (all $p < 0.05$; see Fig. 2, pg. 5). Patients with only COPD also had significantly higher Lm_D and significantly lower RBC/gas and TP/gas than patients with asthma+COPD (all $p < 0.05$). COPD patients had significantly lower Lm_D in the lower-upper, mid-upper, and anterior-posterior regions compared to patients with asthma and significantly lower Lm_D in the anterior-posterior region compared to patients with asthma+COPD (all $p < 0.05$). Patients with asthma had significantly higher RBC/TP in the proximal-peripheral region compared to patients with COPD and significantly lower TP/gas in the anterior-posterior region compared to patients with either asthma+COPD or only COPD (all $p < 0.05$).

BILLING CODE 4120–01–C

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26923 through 26924), after reviewing the information the applicant provided, we stated we had the following concerns regarding whether XENOVIEW™ meets the substantial clinical improvement criterion. We noted that, similar to our discussion in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28312), with respect to the evidence provided by the applicant to support its assertion that XENOVIEW™ is able to diagnose a medical condition in a patient population where the medical condition is currently undetectable and diagnose a medical condition earlier than currently available methods, the studies do not appear to provide evidence showing that use of the technology to make a diagnosis affected the management of the patients, as required under § 412.87(b)(1)(ii)(B). Although the applicant provided studies demonstrating that XENOVIEW™ can detect gas diffusion abnormalities in patients that traditional imaging such as CT cannot, or can detect these abnormalities earlier than currently available methods, these studies did not appear to demonstrate that subsequently, treatment planning or disease management was affected.

For example, we noted that studies were designed to assess the ability of XENOVIEW™ to detect changes in lung function before and after treatment in comparison to other technologies, rather than a change in patient management. For example, in the Mummy et al. (2021) study,[163] HP ^{129}Xe MRI was used to observe treatment effects in COPD patients before and after receiving biologic therapy. Even though the study demonstrated that XENOVIEW™ may have more sensitivity in providing measurements of lung functioning in structurally normal areas of the lung, there were no additional follow-ups on patients who appeared to be non-responsive to therapy based on HP ^{129}Xe MRI imaging. Without this information, it was difficult to determine whether using XENOVIEW™ to observe the effects of treatment has an impact on clinical decision-making for patients with COPD. Similarly, although the study abstract for McIntosh et al. (2020) [164] noted that clinically relevant VDP improvements were observed 14-days post-benralizumab in patients with minimal response detected using spirometry, it was not clear from the study abstract if the use of XENOVIEW™ to observe the effects of treatment impacted the clinical decision-making for these patients. In addition, we questioned the clinical significance of the findings in the Hahn et al. (2022) study [165] to support the applicant's statement that in patients with IPF, HP ^{129}Xe MRI can predict disease progression in patient

[163] Mummy DG, Coleman M, Wang Z, Bier EA, Lu J, Driehuys D, Huang YC. J. Regional Gas Exchange Measured by 129Xe Magnetic Resonance Imaging Before and After Combination Bronchodilators Treatment in Chronic Obstructive Pulmonary Disease. J Magn Reson Imaging 54(3): 964–974. DOI: 10.1002/jmri.27662.

[164] McIntosh M, Eddy RL, Knipping D, Barker AL, Lindenmaier TJ, Yamashita C, et al. Response to benralizumab in severe asthma: 129Xe MRI, oscillometry and clinical measurements. Am J Respir Crit Care Med 2020;201:A6244.

[165] Hahn, AD, Carey KJ, Barton GP, Torres, LA, Kammerman J, et al. Hyperpolarized 129Xe MR Spectroscopy in the Lung Shows 1-year Reduced Function in Idiopathic Pulmonary Fibrosis. Radiology 2022; 000:1–9.

population where fibrosis is not detectable by traditional CT, as the study authors suggested that findings need to be verified in a longitudinal multicenter study with more rigorous testing of the repeatability of the MRI-based measurements of gas exchange and ventilation in a larger sample of participants with IPF.

Furthermore, although the applicant stated that HP ^{129}Xe MRI could be used to quantify abnormalities across three compartments of alveolar gas-exchange (in the airspaces (ventilation), barrier tissue of the lung parenchyma, and transfer to red blood cells (RBCs)), we questioned whether the detection of such abnormalities allows for a specific diagnosis of disease. For example, in the Grist et al. (2022) study,[166] a follow-up to the Grist et al. (2021) study,[167] the authors noted that the relationship of the HP ^{129}Xe MRI abnormalities detected and the breathlessness experienced by the wider population of post-COVID–19 condition participants was unclear. The authors stated that caution is necessary in the use of HP ^{129}Xe MRI for the detection of disease, as it was unknown whether participants with other respiratory tract infections, such as flu, had abnormal HP ^{129}Xe MRI gas transfer months after infection. The authors also stated that it was not known whether the abnormalities detected were of clinical importance. The authors of the Mummy et al. (2021) [168] study also indicated that HP ^{129}Xe MRI ventilation measurements in COPD had not been well characterized, which limited the authors' ability to determine a clinically meaningful change in ventilation metrics. In addition, we noted that the Thomen et al. (2016) [169] study provided by the applicant consists of a pediatric population, and we questioned whether such detection of ventilation abnormalities by XENOVIEW™ would be generalizable to a Medicare population.

In summary, we questioned whether the evidence provided demonstrates that earlier detection of alveolar gas-exchange defects using XENOVIEW™ results in earlier diagnosis and subsequent changes to clinical decision-making following an earlier diagnosis. As such, we were interested in additional evidence to support the applicant's assertion that use of XENOVIEW™ to make a diagnosis affects the management of the patient.

We invited public comments on whether XENOVIEW™ meets the substantial clinical improvement criterion.

Comment: We received several comments in support of new technology add-on payments for XENOVIEW™, including one from the applicant, in response to CMS's concerns in the FY 2024 IPPS/LTCH PPS proposed rule regarding whether XENOVIEW™ meets the substantial clinical improvement criterion.

The applicant asserted that the technology informs on spatial lung ventilation defects, leading to treatment decisions that positively impact patient outcomes. The applicant stated that VDP is able to provide quantitative information about a patient's specific region of ventilation and oxygen defect across all functional regions of the lung, unlike conventional chest CT, MRI, nuclear imaging, or pulmonary function tests (PFTs), and therefore can be used to identify treatment effects of drug therapy and guide physicians in making adjustments. The applicant explained that, as a diagnostic test, XENOVEW™ MRI would not be expected to directly change health outcomes; rather, a diagnostic test affects health outcomes through changes in disease management, and that the usefulness of a test result is constrained by the available treatment options. The applicant also noted that XENOVIEW™ is not effort dependent, unlike for patients who have difficulty with spirometry or PFTs. The applicant further asserted that XENOVIEW™ provides an objective quantified measure specific to the individual patient, which removes health disparities and improves equality in healthcare outcomes of chronic diseases where marginalized populations have few options for unbiased lung ventilation evaluation.

The applicant stated that outcomes of interest for the technology as a diagnostic test include beneficial or adverse clinical effects, such as changes in management due to test findings or preferably, improved health outcomes for Medicare beneficiaries. The applicant asserted that results from XENOVIEW™ MRI lead physicians to prescribe different and better treatments, and that those patients whose treatments are changed by test results remain on the regimen and achieve better long-term lung disease control. The applicant asserted that the evidence provided demonstrates the utility of the technology to accurately identify those patients who will, if untreated with improved treatment protocols, suffer the morbidity and mortality of lung disease. The applicant explained that peer-reviewed publications across patients with asthma, COPD, and asthma plus COPD with underlying risk factors demonstrated a reliable measurement of VDP with XENOVIEW™ proprietary software. The applicant stated that XENOVIEW™ VDP is an unbiased, quantitative measure compared to the patient's own lung, rather than a population-based standard as in PFTs, and can detect subtle differences that cannot be captured by spirometry for PFTs. The applicant explained that higher rates of COPD diagnoses in non-Hispanic whites lends credibility to the inequity and bias in understanding and managing this disease, and asserted that XENOVIEW™ MRI can be used to reduce disparities in healthcare and improve management of chronic disease.

The applicant asserted that XENOVIEW™ MRI could be used to inform treatment outcomes to make changes as needed. The applicant referenced the Hahn et al. (2022) study, and explained that the study identified patients where VDP could explain the patient symptoms that were unable to be diagnosed by conventional spirometry or lung CT imaging.[170] The applicant also referenced the study abstract for McIntosh et al. (2020),[171] stating that the results support practical clinical use of VDP to inform treatment change, as it allowed for the differentiation between non-responders from responders to benralizumab therapy in patients with severe asthma. The applicant stated that the study provided evidence that the technology effectively measures gas exchange and functional ventilation in a population of asthma patients, and

[166] Grist JT, Collier GJ, Walters H, Kim M, Chen M, et al. Lung abnormalities depicted with hyperpolarized xenon MRI in patients with long COVID. Radiology 2022;in press:1–26.

[167] Grist JT, Chen M, Collier GJ, Raman B, Abueid G, et al. Hyperpolarized 129XE MRI abnormalities in dyspneic patients 3 months after COVID–19 pneumonia: Preliminary results. Radiology 2021;301:E353–E360.

[168] Mummy DG, Coleman M, Wang Z, Bier EA, Lu J, Driehuys D, Huang YC. J. Regional Gas Exchange Measured by 129Xe Magnetic Resonance Imaging Before and After Combination Bronchodilators Treatment in Chronic Obstructive Pulmonary Disease. J Magn Reson Imaging 54(3): 964–974. DOI: 10.1002/jmri.27662.

[169] Thomen RP, Walkup LL, Roach DJ, Cleveland ZI, Clancy JP, Woods JC. Hyperpolarized ^{129}Xe for investigation of mild cystic fibrosis lung disease in pediatric patients. J Cyst Fibros 2016;16(2):275–282.

[170] Hahn, AD, Carey KJ, Barton GP, Torres, LA, Kammerman J, et al. Hyperpolarized 129Xe MR Spectroscopy in the Lung Shows 1-year Reduced Function in Idiopathic Pulmonary Fibrosis. Radiology 2022; 000:1–9.

[171] McIntosh M, Eddy RL, Knipping D, Barker AL, Lindenmaier TJ, Yamashita C, et al. Response to benralizumab in severe asthma: 129Xe MRI, oscillometry and clinical measurements. Am J Respir Crit Care Med 2020;201:A6244.

allows clinically meaningful longitudinal follow-up. The applicant also referenced the Mummy et al. (2021) study, and stated it provided further evidence of treatment effect as VDP significantly improved in subjects with COPD before and after bronchodilator therapy. The applicant also asserted that without VDP measurements, physicians prescribe drugs without quantitative measures to document the treatment effect, and referenced a study by Hall et al. (2021).[172] The applicant explained that the use of bronchial thermoplasty (BT) in severe asthma has been limited by peri procedure adverse events, therefore VDP offers physicians an option to guide treatment to the specific region that will benefit. The applicant explained that the Hall et al. (2021) [173] study randomly assigned 30 patients to BT treatment of the six most involved airways in the first session (XENOVIEW™ MRI VDP guided group) or a standard three-session BT (unguided group). The applicant stated that statistically significant findings in XENOVIEW™ MRI guided BT patients resulted in actionable changes in the patient's management, and that VDP guided patients experienced a better outcome with fewer adverse asthmatic events. The applicant stated although there were no significant difference in quality of life after one guided BT compared with three unguided BTs (guided = 0.91 [95% confidence interval, 0.28–1.53]; unguided = 1.49 [95% confidence interval, 0.84–2.14]; P = 0.201); VDP guided patients, however, had a statistically significant greater reduction in the percentage of poorly and nonventilated lung from baseline when compared with unguided BT treatments (217.2%; p = 0.009). The applicant further noted that 33 percent of patients experienced asthma exacerbations after one guided BT compared with 73 percent after three unguided BTs (p = 0.028).

Additional commenters supported the use of XENOVIEW™ MRI to aid in the characterization of the individual patient's disease and impact clinical decision-making and patient management. One commenter suggested XENOVIEW™ may help characterize an individual's disease and inform treatment decisions in an inpatient setting as it provides information about lung disease severity and activity beyond what is available with conventional PFTs. The commenter added that they foresaw Xenon MRI playing an important role in: (1) patients with respiratory symptoms but normal spirometry or PFTs to assess for lung disease; (2) patients undergoing bronchoscopic treatment of lung disease to guide regional treatments; (3) patients with lung disease who are not responding to treatment to quantify response to treatment or determine if a different treatment was required; and (4) patients with respiratory symptoms but a confusing clinical picture. The commenter stated that hyperpolarized gas MRI is more sensitive than the spirometry or pulmonary function testing in detecting mild or early disease and changes with treatment; has no ionizing radiation compared to CT; and can be used to identify regional lung function defects not seen with other modalities. The commenter stated they envisioned using XENOVIEW™ in longitudinal assessment of a patient's response to therapy to stop or intensify treatments, and/or serve as an adherence tool to show patients their positive response to therapy and motivate continued compliance. The commenter explained that quantitative measures of VDP and the apparent diffusion coefficient-based emphysema index (ADC) can be safely obtained with hyperpolarized Xe MRI. The commenter also explained that hyperpolarized gas MRI is advantageous compared to spirometry because each patient serves as their own normative value, and may be particularly helpful in populations that struggle with spirometry maneuvers.

Another commenter also asserted that XENOVIEW™ fills the current clinical gaps for the diagnosis and management of pulmonary diseases. The commenter stated that there are no clinical tests that can assess regional lung function with high resolution as PFT measures global lung function, while a CT scan provides structural details, but not direct functional measurement, and has a radiation risk. The commenter stated that ventilation/perfusion scans lack the resolution for diagnosing lung disease, except pulmonary embolism. The commenter stated that XENOVIEW is non-invasive, is sensitive to changes in ventilation abnormalities, and provides novel information on VDP and the apparent diffusion coefficient-based emphysema index (ADC), which would allow clinicians to develop personalized care for patients to increase patient's compliance with medications and decrease the need for unnecessary testing. The commenter described four common pulmonary conditions where XENOVIEW™ would be useful. The commenter suggested XENOVIEW could provide an early triage point in the clinical pathway for patients with unexplained dyspnea on exertion (DOE). The commenter provided a clinical scenario of a patient with DOE, and stated that if XENOVIEW™ had been available, they would have ordered the technology, which would have likely revealed ventilation defects that would have helped them diagnose small airway disease asthma with more confidence and chose the appropriate medications. The commenter stated that chronic cough with failed treatments was another common pulmonary condition, which may be a result of cough-variant asthma that is difficult to diagnose with current clinical tests, and that if XENOVIEW™ were available, it would assist with disease diagnosis and treatment. The commenter further suggested the use of XENOVIEW™ in patients with COPD to differentiate between two clinical phenotypes, chronic bronchitis and emphysema. The commenter noted that patients with ventilation patterns more consistent with chronic bronchitis tended to respond better to LABA/LAMA, even if there was minimal response in PFT,[174] and that this information would help clinicians change medications earlier in the ''non-responders''. Finally, the commenter noted that patients with asthma may have a normal PFTs and other test results, while remaining symptomatic. The commenter referenced two studies using ^{129}Xe MRI that had shown the presence of ventilation defects in stable asthma patients even if PFT was normal, and ventilation defects improved after treatment.[175] [176] The commenter explained that ventilation defects on XENOVIEW™ could alert clinicians that the asthma may not have been well controlled.

An additional commenter affirmed that XENOVIEW™, when available in the clinical setting, would inform and/or change their treatment decisions due

[172] Hall CS, Quirk JD, Goss CW, Lew D, Kozlowski J., et. al. Single-Session Bronchial Thermoplasty Guided by 129Xe Magnetic Resonance Imaging A Pilot Randomized Controlled Clinical Trial. American Journal of Respiratory and Critical Care Medicine. 2020; 202(4): 529–534.

[173] *Ibid.*

[174] Mummy DG, Coleman EM, Wang Z, et al. Regional Gas Exchange Measured by (129) Xe Magnetic Resonance Imaging Before and After Combination Bronchodilators Treatment in Chronic Obstructive Pulmonary Disease. Journal of magnetic resonance imaging: JMRI 2021; 54(3): 964–74.

[175] Serajeddini H, Eddy RL, Licskai C, McCormack DG, Parraga G. FEV1 and MRI ventilation defect reversibility in asthma and COPD. The European respiratory journal 2020; 55(3).

[176] Ebner L, He M, Virgincar RS, et al. Hyperpolarized 129Xenon Magnetic Resonance Imaging to Quantify Regional Ventilation Differences in Mild to Moderate Asthma: A Prospective Comparison Between Semiautomated Ventilation Defect Percentage Calculation and Pulmonary Function Tests. Investigative radiology 2017; 52(2): 120–7.

to knowledge of the underlying respiratory defect in a variety of clinical settings, and could serve as an adherence tool to motivate continued compliance. The commenter stated that children born prematurely have complex respiratory phenotypes, and that hyperpolarized Xe would allow simultaneous investigation of those phenotypes, and allow for targeted therapeutics. The commenter also stated that the technology could be used to detect, and therefore allow for treatment of, early onset obliterative bronchiolitis. The commenter noted that Xe MRI offered an alternative to assess lung function for children who were unable to cooperate with PFTs. The commenter stated that PFTs are insensitive to evaluate regional changes in lung function, and that XENOVIEW™ MRI can be used to identify regions of the lung with poor ventilation, changes in alveolar size, and gas exchange abnormalities to inform treatment options. The commenter stated that the technology would be able to image pulmonary anatomy not imaged by CT, while avoiding ionizing radiation, which would be particularly critical in children.

With respect to CMS's question as to whether the detection of ventilation abnormalities by XENOVIEW™ in a study consisting of a pediatric population would be generalizable to a Medicare population, the applicant asserted that it would be because each XENOVIEW™ VDP measure is unique to individual patients across all ages, as it is compared to their own lung and not a contrived calculation as with PFTs. The applicant explained that as each XENOVIEW™ MRI is patient specific, the VDP relationship with poor regions of lung ventilation would be correctly identified in an adult when applying studies from patients under 18 years of age. The applicant stated that clinical trial evidence from studies of patients with cystic fibrosis could be related to an adult population. The applicant stated that approximately 14 percent of patients with cystic fibrosis have Medicare, and that therefore, data for this population is relevant to CMS beneficiaries.

In response to the same concern, a commenter stated they had performed hyperpolarized gas MRI in patients ranging from infants to those 80+ years, and asserted that results of research studies in lung diseases in the pediatric population are applicable to these diseases in the adult population since the underlying disease processes are the same. Another commenter stated that their group had successfully and safely implemented Xe MRI throughout childhood from birth through adolescence to gather clinically applicable information, highlighting the ability of hyperpolarized Xe technology to influence care across the lifespan.

Response: We thank the applicant and other commenters for their comments. Based on our review of comments received and additional information submitted by the applicant as part of its FY 2024 new technology add-on payment application for XENOVIEW™, we continue to have concerns as to whether XENOVIEW™ meets the substantial clinical improvement criterion to be approved for new technology add-on payments. In particular, we remain concerned that although XENOVIEW™ may be able to diagnose pulmonary conditions, it remains unclear that use of the technology to make a diagnosis affected the management of patients. Although commenters provided statements as to how they believed XENOVIEW™ could be used in clinical settings to impact patient management, we note that these testimonials appear to consist of hypothetical use cases, and we are uncertain if these testimonials would reflect the actual use of XENOVIEW™ in the inpatient Medicare population.

In particular, we note that neither the applicant nor the other commenters submitted evidence that demonstrated the use of XENOVIEW™ MRI to actually affect the management of patients, such as a change in diagnosis, a change in treatment planning, or discontinuation of or intensification of treatment regimens. For example, the study by Ebner et al. (2017) [177] assessed the correlation between VDP and PFTs in asthmatic patients versus healthy controls, but did not describe changes in patient management due to VDP findings. In addition, we note that the study by Serajeddini et al. (2020) [178] was a retrospective evaluation of spirometry and hyperpolarized ^{3}He MRI measurements, and as such, does not appear to speak to the use of XENOVIEW™.

As described in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26923 and 26924), we continue to have concerns about the Hahn et al. (2022), McIntosh et al. (2020), and Mummy et al. (2021) studies described in the applicant's comment, and to continue to believe that these studies assess the ability of XENOVIEW™ to detect changes in lung function before and after treatment in comparison to other technologies, rather than a change in patient management. For the same reason, we have concerns that the Thomen et al. (2016) study [179] does not demonstrate a change in patient management, as the study assessed the feasibility of ^{129}Xe MRI usage and if usage would demonstrate ventilation defects in mild CF with greater sensitivity than FEV_1. Therefore, we note the technology was not used to diagnose CF in the study, as patients were known to be either healthy control volunteers or cystic fibrosis patients, nor was there a change in diagnosis or treatment due to ^{129}Xe MRI usage. In addition, we continue to have concerns with the preliminary results presented in the Grist et al. (2021) study [180] referenced by commenters, as it was aimed to determine if hyperpolarized ^{129}Xe MRI imaging could identify the possible cause of breathlessness in patients after hospital discharge following COVID–19 infection, and did not assess for changes in patient management due to those findings. Furthermore, although the applicant shared a study [181] of Xe-MRI VDP guided bronchial thermoplasty (BT) treatment compared to standard of care, with statistically significant findings reporting that Xe-MRI guided BT patients resulted in actionable changes in the patient's management due to VDP measure of lung ventilation, we note that the study provided, associated with clinical trial number NCT01832363, utilized the MagniXene® technology by Xemed LLC. We note that it is unclear if the XENOVIEW™ technology from Polarean, Inc. is the same as the MagniXene® technology from Xemed LLC, or what differences may exist between the technologies. Therefore, we are unable to conclude that use of the XENOVIEW™ technology affects the management of the patient.

[177] Ebner L, He M, Virgincar RS, et al. Hyperpolarized 129Xenon Magnetic Resonance Imaging to Quantify Regional Ventilation Differences in Mild to Moderate Asthma: A Prospective Comparison Between Semiautomated Ventilation Defect Percentage Calculation and Pulmonary Function Tests. Investigative radiology 2017; 52(2): 120–7.

[178] Serajeddini H, Eddy RL, Licskai C, McCormack DG, Parraga G. FEV1 and MRI ventilation defect reversibility in asthma and COPD. The European respiratory journal 2020; 55(3).

[179] Thomen RP, Walkup LL, Roach DJ, Cleveland ZI, Clancy JP, Woods JC. Hyperpolarized ^{129}Xe for investigation of mild cystic fibrosis lung disease in pediatric patients. J Cyst Fibros 2016;16(2):275–282.

[180] Grist JT, Chen M, Collier GJ, Raman B, Abueid G, et al. Hyperpolarized 129XE MRI abnormalities in dyspneic patients 3 months after COVID–19 pneumonia: Preliminary results. Radiology 2021;301:E353–E360.

[181] Hall CS, Quirk JD, Goss CW, Lew D, Kozlowski J., et. al. Single-Session Bronchial Thermoplasty Guided by 129Xe Magnetic Resonance Imaging A Pilot Randomized Controlled Clinical Trial. American Journal of Respiratory and Critical Care Medicine. 2020; 202(4): 529–534.

After review of the information submitted by the applicant as part of its FY 2024 new technology add-on payment application for XENOVIEW™ and consideration of the comments received, we are unable to determine that XENOVIEW™ meets the substantial clinical improvement criterion for the reasons discussed in the FY 2024 IPPS/LTCH PPS proposed rule and in this final rule, and therefore we are not approving new technology add-on payments for XENOVIEW™ for FY 2024.

7. FY 2024 Applications for New Technology Add-On Payments (Alternative Pathways)

As discussed previously, beginning with applications for FY 2021, a medical device designated under FDA's Breakthrough Devices Program that has received marketing authorization as a Breakthrough Device, for the indication covered by the Breakthrough Device designation, may qualify for the new technology add-on payment under an alternative pathway. Additionally, beginning with FY 2021, a medical product that is designated by the FDA as a Qualified Infectious Disease Product (QIDP) and has received marketing authorization for the indication covered by the QIDP designation, and, beginning with FY 2022, a medical product that is a new medical product approved under FDA's Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) and used for the indication approved under the LPAD pathway, may also qualify for the new technology add-on payment under an alternative pathway. Under an alternative pathway, a technology will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS and will not need to meet the requirement that it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. These technologies must still be within the 2-to-3-year newness period to be considered ''new,'' and must also still meet the cost criterion.

As discussed previously, in the FY 2023 IPPS/LTCH PPS final rule, we finalized our proposal to publicly post online applications for new technology add-on payment beginning with FY 2024 applications (87 FR 48986 through 48990). As noted in the FY 2023 IPPS/LTCH PPS final rule, we stated in the proposed rule that we are continuing to summarize each application in the proposed rule. However, we stated that while we are continuing to provide discussion of the concerns or issues we identified with respect to applications submitted under the alternative pathway, we are providing more succinct information as part of the summaries in the proposed and final rules regarding the applicant's assertions as to how the medical service or technology meets the applicable new technology add-on payment criteria. We refer readers to *https://mearis.cms.gov/public/publications/ntap* for the publicly posted FY 2024 new technology add-on payment applications and supporting information (with the exception of certain cost and volume information, and information or materials identified by the applicant as confidential or copyrighted). In addition, we noted that we made available separate tables listing the ICD–10–CM codes, ICD–10–PCS codes, and/or MS–DRGs related to the analyses of the cost criterion for certain technologies for the FY 2024 new technology add-on payment applications in Table 10 associated with the proposed rule, available via the internet on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps*. Click on the link on the left side of the screen titled ''FY 2024 IPPS Proposed Rule Home Page'' or ''Acute Inpatient—Files for Download''. Please see section VI of the Addendum of the proposed rule for additional information regarding tables associated with the proposed rule.

We received 27 applications for new technology add-on payments for FY 2024 under the new technology add-on payment alternative pathway. Seven applicants withdrew applications prior to the issuance of the proposed rule. Subsequently, prior to the issuance of this final rule, seven additional applicants withdrew their respective applications for Selux NGP System, Total Ankle Talar Replacement, Transdermal GFR Measurement System utilizing Lumitrace, Ceribell Delirium Monitor, NUsurface, 4WEB Ankle Truss System, and the Nelli® Seizure Monitoring System. One applicant, LimFlow (the applicant for the LimFlow System), did not meet the July 1 deadline for FDA approval or clearance of the technology and, therefore, the technology is not eligible for consideration for new technology add-on payments for FY 2024. Of the remaining 12 applications, we are approving 11 and conditionally approving 1 for new technology add-on payments for FY 2024. A discussion of these 12 applications is presented in this final rule, including 9 technologies that have received a Breakthrough Device designation from FDA and 3 that were designated as a QIDP by FDA.

In accordance with the regulations under § 412.87(e)(2), applicants for new technology add-on payments for FY 2024, including Breakthrough Devices, must have FDA marketing authorization by July 1 of the year prior to the beginning of the fiscal year for which the application is being considered. Under the policy finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58742), we revised the regulations at § 412.87 by adding a new paragraph (e)(3) which provides for conditional approval for a technology for which an application is submitted under the alternative pathway for certain antimicrobial products (QIDPs and LPADs) at § 412.87(d) that does not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments. We refer the reader to the FY 2021 IPPS/LTCH final rule for a complete discussion of this policy (85 FR 58737 through 58742).

As we did in the FY 2023 IPPS/LTCH PPS proposed rule, for applications under the alternative new technology add-on payment pathway, in the FY 2024 IPPS/LTCH PPS proposed rule we proposed to approve or disapprove each of these 12 applications for FY 2024 new technology add-on payments. Therefore, in this section of the preamble of this final rule, we provide background information on each of the remaining 12 alternative pathway applications and our determinations as to whether each technology is eligible for new technology add-on payments for FY 2024 or not. Consistent with our standard approach, we are not including in this final rule the description and discussion of applications that were withdrawn or that are ineligible for consideration for FY 2024 due to not meeting the July 1 deadline, described previously, which were included in the FY 2024 IPPS/LTCH PPS proposed rule. We are also not summarizing nor responding to public comments received regarding these withdrawn or ineligible applications in this final rule.

a. Alternative Pathway for Breakthrough Devices

(1) Aveir™ AR Leadless Pacemaker

Abbott Cardiac Rhythm Management submitted an application for new technology add-on payments for the

Aveir™ AR Leadless Pacemaker for FY 2024. Per the applicant, the Aveir™ AR Leadless Pacemaker is a programmable system comprised of a single leadless pacemaker implanted into the right atrium that provides single-chamber pacing therapy without the need for traditional ''wired'' leads. According to the applicant, this technology contains both the generator and electrodes within the device and is anticipated to be indicated for one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia, or any combination of those symptoms. We note that the applicant also submitted an application for new technology add-on payments for FY 2024 for the Aveir™ Leadless Pacemaker (herein referred to as the Aveir™ Dual-Chamber Leadless Pacemaker), discussed separately in the following section.

Please refer to the online application posting for Aveir™ AR Leadless Pacemaker, available at *https://mearis.cms.gov/public/publications/ntap/NTP221017AH7JC*, for additional detail describing the technology and the disease treated by the technology.

According to the applicant, Aveir™ AR Leadless Pacemaker received Breakthrough Device designation from FDA on March 27, 2020, under the Breakthrough Device designation for the Leadless Dual Chamber System for the following proposed indication: Pacemaker implantation is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia, or any combination of those symptoms. The proposed indications for the use of the Leadless Dual Chamber System included all four of the following: (1) Rate-Modulated Pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. Chronotropic incompetence has not been rigorously defined. A conservative approach, supported by the literature, defines chronotropic incompetence as the failure to achieve an intrinsic heart rate of 70 percent of the age-predicted maximum heart rate or 120 bpm during exercise testing, whichever is less, where the age-predicted heart rate is calculated as $197 - (0.56 \times \text{age})$. (2) Dual-Chamber Pacing is indicated for those patients exhibiting: sick sinus syndrome; chronic, symptomatic second- and third-degree AV block; recurrent Adams-Stokes syndrome; symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out. (3) Atrial Pacing is indicated for patients with sinus node dysfunction and normal AV and intraventricular conduction systems. (4) Ventricular Pacing is indicated for patients with significant bradycardia and normal sinus rhythm with only rare episodes of AV block or sinus arrest; chronic atrial fibrillation; severe physical disability.

According to the applicant, the relevant indications for single-chamber atrial leadless pacing are the first and third indications, Rate-Modulated Pacing and Atrial Pacing. The applicant further stated that the Breakthrough Device designation applies to two clinical scenarios: a de novo system where a patient receives the Aveir™ Dual-Chamber Leadless Pacemaker (that is, both the Aveir™ AR Leadless Pacemaker and the Aveir™ VR Leadless Pacemaker are implanted within the same procedure), or an upgrade system where a patient already has a ventricular leadless pacemaker and is upgraded to the Aveir™ Dual-Chamber Leadless Pacemaker by receiving the Aveir™ AR Leadless Pacemaker. The applicant stated that it received FDA premarket approval for both the atrial leadless pacemaker (Aveir™ AR Leadless Pacemaker) and the dual chamber leadless pacemaker (Aveir™ Dual-Chamber Leadless Pacemaker) on June 29, 2023, for the same indications. We stated in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26927) that while the intended indications for the Aveir™ AR Leadless Pacemaker would appear to match sections of the Breakthrough Device designation, the Breakthrough Device designation provided by the applicant is for the Leadless Dual Chamber System, rather than the Aveir™ Dual-Chamber Leadless Pacemaker. Therefore, although the Aveir™ AR Leadless Pacemaker may be one component of the system, it appeared that the Aveir™ AR Leadless Pacemaker on its own is not the subject of the Breakthrough Device designation and would not be considered a Breakthrough Device once FDA approved. As discussed, a device must be designated under FDA's Breakthrough Devices Program to be eligible under the alternative pathway. Accordingly, because the Aveir™ AR Leadless Pacemaker appeared to only be eligible under the alternative pathway for procedures involving the full dual-chamber system (that is, where patients are upgraded to the Aveir™ Dual-Chamber Leadless Pacemaker by receiving the Aveir™ AR Leadless Pacemaker), we stated in the proposed rule that we believe any eligible use of the Aveir™ AR Leadless Pacemaker would be included under the new technology add-on payment application for the Aveir™ Dual-Chamber Leadless Pacemaker. We invited public comment on the eligibility of the Aveir™ AR Leadless Pacemaker under the alternative pathway.

Comment: The applicant submitted a comment regarding the eligibility of the Aveir™ AR Leadless Pacemaker for new technology add-on payments. The applicant asserted that FDA granted Breakthrough Device designation to the modular Leadless Dual Chamber System, which consists of the Aveir™ VR (ventricular leadless pacemaker) and the Aveir™ AR (atrial leadless pacemaker). The applicant stated it developed the modular Leadless Dual Chamber System with bidirectional implant-to-implant (i2i) communication to accommodate all pacing indications. According to the applicant, the i2i technology provides beat-to-beat communication and synchrony between two leadless pacemakers, a necessary foundation of dual-chamber leadless pacing therapy. The applicant stated that this system allows the two devices to communicate with each other—sensing for delayed or missed heartbeat and then pacing the appropriate chamber of the heart. According to the applicant, the Aveir™ system is modular, such that a single device can be implanted in a heart chamber initially, and the second pacemaker added to the other heart chamber in the future should the clinical need arise. The applicant asserted that the Aveir™ AR Leadless Pacemaker specifically corresponds to the Atrial Pacing configuration listed by FDA in the Breakthrough Device designation, which is distinct from Ventricular Pacing and Dual-Chamber Pacing. The applicant asserted that it would be incongruous for Aveir™ AR Leadless Pacemaker not to be a Breakthrough Device since it is the precise device that provides Atrial Pacing. The applicant stated that new technology add-on payment designation for the standalone Aveir™ AR Leadless Pacemaker would enable CMS to recognize that the costs to hospitals are different when a single leadless pacemaker is implanted in the right atrium compared with implantation of both a leadless ventricular pacemaker and atrial leadless pacemaker in the same procedure. The applicant commented that the Aveir™ AR Leadless Pacemaker with i2i technology also enables physicians to implant for single chamber pacing indications and adapt treatment if symptoms progress

and the patient requires dual-chamber pacing.

Response: We appreciate the information submitted by the applicant regarding the eligibility of the Aveir™ AR Leadless Pacemaker. However, we still note that Breakthrough Device designation was granted for the combination product. We agree with the applicant that the bidirectional i2i communication and synchrony between two leadless pacemakers is distinct from what is offered on implantation of the either the Aveir™ AR or the Aveir™ VR leadless pacemakers individually. While we understand that implantation of the Aveir™ AR Leadless Pacemaker alone during a procedure could be included under the Breakthrough Device designation, it is our understanding that that would only be the case with a prior implanted Aveir™ VR Pacemaker to trigger the i2i communication, and not with a future implant. Therefore, we believe that eligible uses of the Aveir™ AR Leadless Pacemaker would be procedures that result in a dual-chamber leadless system (whether as part of an initial dual-chamber insertion procedure or as part of an upgrade procedure to a dual-chamber device, as described previously). Since the Aveir™ AR Leadless Pacemaker on its own was not granted Breakthrough Device designation, it is therefore not eligible for consideration under the alternative pathway for Breakthrough Devices as a standalone device.

Comment: The applicant provided a list of clinical scenarios and procedure codes for which it believed either the Aveir™ AR Leadless Pacemaker or the Aveir™ Dual-Chamber Leadless Pacemaker qualified for the Breakthrough Device designation. The applicant asserted: (1) X2H63V9 and X2HK3V9 (Insertion of dual-chamber intracardiac pacemaker into right atrium, percutaneous approach, new technology group 9, Insertion of dual-chamber intracardiac pacemaker into right ventricle, percutaneous approach, new technology group 9) could be used for de novo insertion, or removal and replacement of the dual chamber leadless system; (2) the procedure code X2H63V9 could be used for upgrading to dual chamber leadless system (Aveir™ AR insertion when patient has existing Aveir™ VR), or removal and replacement of right atrial component of dual chamber leadless system (Aveir™ AR removal and replacement); and (3) the procedure code X2H63V9 could be used for de novo insertion of atrial only single chamber leadless pacemaker, or removal and replacement of right atrial single chamber leadless pacemaker.

Another commenter requested that CMS clarify in the final rule the clinical scenarios to which the new technology add-on payment would apply if approved and provide guidance on appropriate coding to facilitate claims processing to ensure the new technology add-on payment is triggered only in cases that meet the alternative pathway requirements.

Response: We thank the commenters for the comments. As discussed previously, only use of the Aveir™ AR Leadless Pacemaker as part of an upgrade procedure to dual chamber pacemaker, or as part of a De Novo insertion of a dual chamber pacemaker (discussed in further detail in the following section for Aveir™ Dual Chamber Leadless Pacemaker), are relevant for the purposes of new technology add-on payments. As noted later in this section, the Aveir™ AR Leadless Pacemaker was granted approval for the following procedure code effective October 1, 2023: X2H63V9 (Insertion of dual-chamber intracardiac pacemaker into right atrium, percutaneous approach, new technology group 9), which describes upgrade procedures to dual-chamber pacing by implanting a leadless pacemaker into the atrium only where the patient already has a ventricular leadless pacemaker. We do not believe it would be appropriate to utilize X2H63V9 for a procedure that does not result in a dual-chamber pacemaker (such as implantation of an atrial-only pacemaker). We further note that single-chamber pacing is not intended to be captured by the new code, and additional codes are utilized for removal/replacement procedures in addition to insertion codes.

The applicant stated that the following ICD–10–PCS code may be used to uniquely describe procedures involving the use of Aveir™ AR Leadless Pacemaker effective beginning FY 2017: 02H63NZ (Insertion of intracardiac pacemaker into right atrium, percutaneous approach). The applicant also submitted a request for approval for a unique ICD–10–PCS code for the Aveir™ AR Leadless Pacemaker beginning in FY 2024 and was granted approval for the following procedure code effective October 1, 2023: X2H63V9 (Insertion of dual-chamber intracardiac pacemaker into right atrium, percutaneous approach, new technology group 9). The applicant stated that I49.9 (Cardiac arrythmia, unspecified) may be used to currently identify the proposed indication for Aveir™ AR Leadless Pacemaker under the ICD–10–CM coding system.

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for the Aveir™ AR Leadless Pacemaker, the applicant searched the FY 2021 MedPAR file for cases reporting ICD–10–PCS code 02H63NZ (Insertion of intracardiac pacemaker into right atrium, percutaneous approach). Using the inclusion/exclusion criteria described in the following table, the applicant identified 1,186 claims mapping to 43 MS–DRGs. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $207,890, which exceeded the average case-weighted threshold amount of $158,574. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the Aveir™ AR Leadless Pacemaker meets the cost criterion.

AVEIR™ AR LEADLESS PACEMAKER COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of ICD-10-PCS codes	02H63NZ Insertion of intracardiac pacemaker into right atrium, percutaneous approach
List of MS-DRGs	Please see Table 10.3.A. - Aveir™ AR Leadless Pacemaker Codes – FY 2024 for the complete list of MS-DRGs provided by the applicant
Inclusion/Exclusion Criteria	The applicant identified cases by using the ICD-10-PCS code 02H63NZ (Insertion of intracardiac pacemaker into right atrium, percutaneous approach) used to describe implantation of a single-chamber leadless atrial pacemaker system.
Charges Removed for Prior Technology	The applicant removed 100% of charges associated with Medical/Surgical Supplies and Devices (revenue centers 027x, and 0624), as the use of the Aveir™ AR System is expected to replace all devices utilized in these cases. The applicant did not remove indirect charges related to the prior technology.
Standardized Charges	The applicant used the standardization formula provided in Technical Appendix A of the application. The applicant used all relevant values reported in the standardizing file posted with the FY 2021 IPPS/LTCH PPS final rule.
Inflation Factor	The applicant applied an inflation factor of 20.5% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule.
Charges Added for the New Technology	The applicant stated that the average sales price of the technology has yet to be determined, and that when the price is available, a revised cost analysis will be provided that includes estimated hospital charges for the technology.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26928), we stated that we have the following concerns regarding the cost criterion. As summarized in the following section, the applicant stated that the Aveir™ Dual-Chamber Leadless Pacemaker is identified using both ICD–10–PCS code 02H63NZ (used for the cost analysis for the Aveir™ AR Leadless Pacemaker) and ICD–10–PCS code 02HK3NZ (Insertion of Intracardiac Pacemaker into Right Ventricle, Percutaneous Approach). We questioned whether, by not excluding cases reporting ICD–10–PCS code 02HK3NZ as part of the case selection for the cost analysis for the Aveir™ AR Leadless Pacemaker, cases involving use of the dual chamber system could have been included as part of this analysis. Also, while it was our understanding that procedure code 02H63NZ was approved to describe procedures involving the use of intracardiac atrial pacemakers effective beginning FY 2017, the applicant stated that there are no technologies on the market eligible to be coded with procedure code 02H63NZ as the Aveir™ AR Leadless Pacemaker will be the first atrial leadless pacemaker, if approved. Therefore, we were unsure why the applicant searched for cases reporting procedure code 02H63NZ within the FY 2021 MedPAR file if there should not be any technologies coded with procedure code 02H63NZ until FY 2022 (when the applicant stated clinical trials for the Aveir™ AR Leadless Pacemaker began). We further questioned in the proposed rule which technology the cases identified in the MedPAR data represent. We questioned whether searching for cases utilizing standard pacemakers instead of leadless pacemakers (with relevant adjustments to remove/add charges as necessary) would better reflect the technology that the applicant anticipates Aveir™ AR Leadless Pacemaker will be replacing.

Subject to the applicant adequately addressing these concerns, in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26928), we agreed that the technology meets the cost criterion and proposed to approve the Aveir™ AR Leadless Pacemaker for new technology add-on payments for FY 2024, subject to the technology receiving Breakthrough Device designation and FDA marketing authorization as a Breakthrough Device for the indication corresponding to the Breakthrough Device designation by July 1, 2023.

The applicant had not provided an estimate for the cost of the Aveir™ AR Leadless Pacemaker at the time of the proposed rule. We stated in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26928) that we expected the applicant to submit cost information prior to the final rule, and that we would provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule. We stated that any new technology add-on payment for the Aveir™ AR Leadless Pacemaker would be subject to our policy under § 412.88(a)(2) where we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case.

We invited public comments on whether the Aveir™ AR Leadless Pacemaker meets the cost criterion and our proposal to approve new technology add-on payments for the Aveir™ AR Leadless Pacemaker for FY 2024 subject to the technology receiving Breakthrough Device designation and FDA marketing authorization as a Breakthrough Device for the indication corresponding to the Breakthrough Device designation by July 1, 2023.

Comment: We received a comment in support of our proposal to approve new technology add-on payments for the Aveir™ AR Leadless Pacemaker. The commenter stated that the Aveir™ AR Leadless Pacemaker allows for mapping prior to fixation and reduces the number of repositioning attempts. According to the commenter, positioning capabilities may result in better long-term outcomes for patients, and in addition to an increased battery life– twice the battery life of other leadless pacemakers—it may lead to fewer procedures and reduce patient risk.

Response: We thank the commenter for the comments.

Comment: The applicant submitted a comment regarding the cost criterion and provided an alternate cost analysis in response to CMS's concerns identified in the proposed rule regarding whether cases utilizing standard pacemakers instead of leadless pacemakers would better reflect the technology that the applicant anticipates Aveir™ AR Leadless Pacemaker will be replacing. In the updated analysis, the applicant searched for cases using a combination of ICD–10–PCS codes for implanting a standard dual-chamber pacemaker plus the insertion of the additional lead in the right atrium (rather than codes for leadless pacemakers) based on the assertion that this would appropriately describe patients who already have a leadless right ventricle pacemaker who are implanted with the Aveir™ AR Leadless Pacemaker. The applicant removed 100 percent of the charges from revenue centers 0275, 0278, 0279, and 0624 from the 1,317 identified discharges to be as conservative as possible. Because the final inflated average case-weighted standardized charge per case of $252,073 for a device upgrade exceeded the average case-

weighted threshold amount of $122,326 in the updated cost analysis, the applicant asserted that the Aveir™ AR Leadless Pacemaker met the cost criterion.

With respect to CMS's question why the applicant searched for cases reporting procedure code 02H63NZ, the applicant stated that it included these cases in the original analysis with the expectation that CMS would seek that data because it is a code specific to a leadless pacemaker, notwithstanding that its technology was not reported until FY 2022. The applicant noted that it updated the analysis using traditional transvenous pacemaker codes and omitted this code, based on CMS's suggestion, and as described previously.

In addition, the applicant provided an additional cost analysis for insertion of atrial only single chamber pacemaker in the right atrium to complement the prior analysis and other clinical scenarios, as it stated that Aveir AR™ Leadless Pacemaker with i2i technology also enables physicians to implant for single chamber pacing indications and adapt treatment if symptoms progress and the patient requires dual-chamber pacing. In the new cost analysis, because the final inflated average case-weighted standardized charge per case of $276,818 for an atrial-only pacemaker exceeded the average case-weighted threshold amount of $137,401, the applicant maintained that the device meets the cost criterion.

Response: We thank the applicant for its comments and appreciate the updated and additional cost analyses. We agree that the technology meets the cost criterion based on the first updated analysis where the applicant searched for cases utilizing standard pacemakers and implanting an atrial lead during insertion of a dual-chamber system. As previously stated, the Breakthrough Device designation was granted for the dual-chamber product and not for the Aveir™ AR Leadless Pacemaker, and therefore eligible uses of the Aveir™ AR Leadless Pacemaker would be procedures that result in the insertion of a dual-chamber system, and it is not eligible for consideration under the alternative pathway for Breakthrough Devices as a standalone device.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe Aveir™ AR Leadless Pacemaker meets the cost criterion. The technology received FDA premarket approval on June 29, 2023, as a Breakthrough Device when used as part of the Dual-Chamber system, with an indication for one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia, or any combination of those symptoms. Therefore, we are finalizing our proposal to approve new technology add-on payments for Aveir™ AR Leadless Pacemaker for FY 2024. We note, as discussed previously, that only the use of the technology resulting in the insertion of a dual-chamber system is relevant for the purposes of new technology add-on payments. We consider the beginning of the newness period to commence on June 29, 2023, the date on which technology received FDA marketing authorizationfor the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of Aveir™ AR Leadless Pacemaker is $16,500, including one Aveir™ AR atrial leadless pacemaker, one delivery catheter, and one introducer. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of Aveir™ AR Leadless Pacemaker is $10,725 for FY 2024 (that is, 65 percent of the average cost of the technology). Cases involving the use of the Aveir™ AR Leadless Pacemaker that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code X2H63V9 (Insertion of dual-chamber intracardiac pacemaker into right atrium, percutaneous approach, new technology group 9).

(2) Aveir™ Leadless Pacemaker (Dual-Chamber)

Abbott Cardiac Rhythm Management submitted an application for new technology add-on payments for the Aveir™ Leadless Pacemaker (herein referred to as the Aveir™ Dual-Chamber Leadless Pacemaker) for FY 2024. According to the applicant, the Aveir™ Dual-Chamber Leadless Pacemaker is a modular programmable system comprised of two implanted leadless pacemakers that provide dual-chamber pacing therapy: a ventricular leadless pacemaker intended for direct implantation into the right ventricle, and an atrial leadless pacemaker intended for direct implantation into the right atrium. The applicant stated that the Aveir™ Dual-Chamber Leadless Pacemaker has built-in power supply and electrodes, is designed to be retrievable by a dedicated retrieval catheter, and enables two separate pacemakers to function as one dual-chamber pacing system. The applicant stated that pacemaker implantation is generally indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia, or any combination of those symptoms. As discussed separately in the previous section, the applicant also submitted an application for FY 2024 new technology add-on payments for the Aveir™ AR Leadless Pacemaker, which provides atrial pacing.

Please refer to the online application posting for the Aveir™ Dual-Chamber Leadless Pacemaker, available at *https://mearis.cms.gov/public/publications/ntap/NTP221017AJNQH*, for additional detail describing the technology and the disease treated by the technology.

According to the applicant, the Aveir™ Dual-Chamber Leadless Pacemaker was granted Breakthrough Device designation from FDA on March 27, 2020, under the Breakthrough Device designation for the Leadless Dual Chamber System for the following proposed indication: Pacemaker implantation is indicated in one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia, or any combination of those symptoms. The proposed indications for use of the Leadless Dual Chamber System include all four of the following: (1) Rate-Modulated Pacing is indicated for patients with chronotropic incompetence, and for those who would benefit from increased stimulation rates concurrent with physical activity. Chronotropic incompetence has not been rigorously defined. A conservative approach, supported by the literature, defines chronotropic incompetence as the failure to achieve an intrinsic heart rate of 70 percent of the age-predicted maximum heart rate or 120 bpm during exercise testing, whichever is less, where the age-predicted heart rate is calculated as $197 - (0.56 \times \text{age})$; (2) Dual-Chamber Pacing is indicated for those patients exhibiting: sick sinus syndrome; chronic, symptomatic second- and third-degree AV block; recurrent Adams-Stokes syndrome; symptomatic bilateral bundle branch block when tachyarrhythmia and other causes have been ruled out; (3) Atrial Pacing is indicated for patients with: sinus node dysfunction and normal AV and intraventricular conduction systems; (4) Ventricular Pacing is indicated for patients with: significant bradycardia and normal sinus rhythm with only rare episodes of AV block or

sinus arrest; chronic atrial fibrillation; severe physical disability.

The applicant further stated that the Breakthrough Device designation applies to two clinical scenarios: a de novo system where a patient receives the Aveir™ Dual-Chamber Leadless Pacemaker, or an upgrade system where a patient already has a ventricular leadless pacemaker and is upgraded to the Aveir™ Dual-Chamber Leadless Pacemaker by receiving the Aveir™ AR Leadless Pacemaker. The applicant stated that it received FDA premarket approval for the Aveir™ Dual-Chamber Leadless Pacemaker on June 29, 2023, for the same indications.

According to the applicant, the following ICD–10–PCS procedure codes can currently be used to distinctly identify the Aveir™ Dual-Chamber Leadless Pacemaker effective beginning FY 2017: 02H63NZ (Insertion of intracardiac pacemaker into right atrium, percutaneous approach) and 02HK3NZ (Insertion of intracardiac pacemaker into right ventricle, percutaneous approach). The applicant stated that there are other systems also in development that will use this combination of ICD–10–PCS codes but that the Aveir™ Dual-Chamber Leadless Pacemaker will be the first dual chamber leadless pacemaker system on the market. The applicant also submitted a request for approval for a unique ICD–10–PCS code for the Aveir™ Dual-Chamber Leadless Pacemaker beginning in FY 2024 and was granted approval for the following procedure code combination effective October 1, 2023: X2H63V9 (Insertion of dual-chamber intracardiac pacemaker into right atrium, percutaneous approach, new technology group 9) and X2HK3V9 (Insertion of dual-chamber intracardiac pacemaker into right ventricle, percutaneous approach, new technology group). Both codes would be reported for this procedure to identify the percutaneous insertion of a dual-chamber leadless cardiac pacemaker system. The applicant stated that diagnosis code I49.9 (Cardiac arrythmia, unspecified) may be used to currently identify the proposed indication for Aveir™ Dual-Chamber Leadless Pacemaker under the ICD–10–CM coding system.

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for the Aveir™ Dual-Chamber Leadless Pacemaker, the applicant searched the FY 2021 MedPAR file for cases reporting ICD–10–PCS code 02H63NZ (Insertion of intracardiac pacemaker into right atrium, percutaneous approach) in combination with ICD–10–PCS code 02HK3NZ (Insertion of intracardiac pacemaker into right ventricle, percutaneous approach). Using the inclusion/exclusion criteria described in the following table, the applicant identified 991 claims mapping to 38 MS–DRGs. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $206,636, which exceeded the average case-weighted threshold amount of $159,357. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the Aveir™ Dual-Chamber Leadless Pacemaker meets the cost criterion.

AVEIR™ DUAL-CHAMBER LEADLESS PACEMAKER COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of ICD-10-PCS Codes	02H63NZ Insertion of intracardiac pacemaker into right atrium, percutaneous approach in combination with 02HK3NZ Insertion of intracardiac pacemaker into right ventricle, percutaneous approach
List of MS-DRGs	Please see Table 10.4.A. - Aveir™ Dual-Chamber Leadless Pacemaker Codes – FY 2024 associated with the proposed rule for the complete list of MS-DRGs provided by the applicant.
Inclusion/Exclusion Criteria	The applicant identified cases by using the ICD-10-PCS code combination listed previously, which describes implantation of a dual-chamber leadless pacemaker system.
Charges Removed for Prior Technology	Per the applicant, the Aveir™ Dual-Chamber Leadless Pacemaker will replace all of the current device charges included in the claims. The applicant noted that it removed all charges associated with Medical/Surgical Supplies and Devices (revenue centers 027x, and 0624). The applicant did not remove indirect charges related to the prior technology.
Standardized Charges	The applicant used the standardization formula provided in Technical Appendix A of the application. The applicant used all relevant values reported in the standardizing file posted with the FY 2021 IPPS/LTCH PPS final rule.
Inflation Factor	The applicant applied an inflation factor of 20.5% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule.
Charges Added for the New Technology	The applicant stated that the average sales price of the technology has yet to be determined, and that when the price is available, a revised cost analysis will be provided that includes estimated hospital charges for the technology.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26930), we stated that we have the following concern regarding the cost criterion. It was our understanding that procedure codes 02H63NZ and 02HK3NZ were approved for use in describing procedures involving intracardiac pacemakers effective beginning FY 2017. The applicant stated that there are no technologies on the market eligible to be coded with procedure code 02H63NZ as the Aveir™ AR Leadless Pacemaker will be the first atrial leadless pacemaker, if approved, and there are no dual-chamber leadless pacemakers currently available. Therefore, we were unsure why the applicant searched for cases reporting procedure code 02H63NZ within the FY 2021 MedPAR file if there should not be any technologies coded with 02H63NZ until FY 2022 (when the applicant stated clinical trials for the Aveir™ AR and Dual-Chamber Leadless Pacemaker began). We further questioned in the proposed rule which technology the cases identified in the MedPAR data represent. We questioned whether searching for cases utilizing standard

pacemakers instead of leadless pacemakers (with relevant adjustments to remove/add charges as necessary) would better reflect the technology that the applicant anticipates Aveir™ Dual-Chamber Leadless Pacemaker will be replacing.

Subject to the applicant adequately addressing this concern, in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26930), we agreed with the applicant that the technology meets the cost criterion and therefore proposed to approve the Aveir™ Dual-Chamber Leadless Pacemaker for new technology add-on payments for FY 2024, subject to the technology receiving FDA marketing authorization as a Breakthrough Device for the indication corresponding to the Breakthrough Device designation by July 1, 2023.

The applicant had not provided an estimate for the cost of the Aveir™ Dual-Chamber Leadless Pacemaker at the time of the proposed rule. We stated in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26930) that we expected the applicant to submit cost information prior to the final rule, and that we would provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule. We stated that any new technology add-on payment for the Aveir™ Dual-Chamber Leadless Pacemaker would be subject to our policy under § 412.88(a)(2) where we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case.

We invited public comments on whether the Aveir™ Dual-Chamber Leadless Pacemaker meets the cost criterion and our proposal to approve new technology add-on payments for the Aveir™ Dual-Chamber Leadless Pacemaker for FY 2024 subject to the technology receiving FDA marketing authorization as a Breakthrough Device for the indication corresponding to the Breakthrough Device designation by July 1, 2023.

Comment: The applicant submitted an alternate cost analysis in response to CMS's concerns identified in the proposed rule whether cases utilizing standard dual-chamber pacemakers instead of leadless pacemakers would be more representative of the discharges Aveir™ Dual-Chamber Leadless Pacemaker would be replacing. The applicant asserted that the cases selected in the updated cost analysis appropriately describe traditional transvenous dual-chamber de novo implant procedures and provide a good comparator for procedures it anticipates would be replaced with Aveir™ Dual-Chamber Leadless Pacemaker. The applicant removed 100 percent of the charges from revenue centers 0275, 0278, 0279, and 0624 from the 47,425 identified discharges to be as conservative as possible. In the updated cost analysis, because the final inflated average case-weighted standardized charge per case of $201,227 still exceeded the average case-weighted threshold amount of $115,421, the applicant asserted that Aveir™ Dual-Chamber Leadless Pacemaker meets the cost criterion.

With respect to CMS's concern that whether cases coded with 02HK3NZ should be included in the analysis, the applicant stated that its original analysis included cases reporting 02H63NZ for purposes of completeness and in expectation that CMS would seek data on codes specific to a leadless pacemaker, notwithstanding that its specific technology was not reported until FY 2022. According to the applicant, the updated analysis used only the traditional transvenous pacemaker codes listed previously based on the CMS's suggestion and omitted 02H63NZ.

Response: We thank the applicant for the comments and the alternate cost analysis.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe Aveir™ Dual-Chamber Leadless Pacemaker meets the cost criterion. The technology received FDA premarket approval on June 29, 2023, as a Breakthrough Device, with an indication for one or more of the following permanent conditions: syncope, presyncope, fatigue, disorientation due to arrhythmia/bradycardia, or any combination of those symptoms. Therefore, we are finalizing our proposal to approve new technology add-on payments for Aveir™ Dual-Chamber Leadless Pacemaker for FY 2024. We consider the beginning of the newness period to commence on June 29, 2023, the date on which technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of Aveir™ Dual-Chamber Leadless Pacemaker is $24,000, including two leadless pacemakers (Aveir™ AR atrial leadless pacemaker and Aveir™ VR ventricular leadless pacemaker), two delivery catheters (one for each leadless pacemaker), and one introducer. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of Aveir™ Leadless Pacemaker is $15,600 for FY 2024 (that is, 65 percent of the average cost of the technology). Cases involving the use of Aveir™ Leadless Pacemaker that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes X2H63V9 (Insertion of dual-chamber intracardiac pacemaker into right atrium, percutaneous approach, new technology group 9) in combination with X2HK3V9 (Insertion of dual-chamber intracardiac pacemaker into right ventricle, percutaneous approach, new technology group). We note that both codes would be reported for this procedure to identify the percutaneous insertion of a dual-chamber leadless cardiac pacemaker system relevant for new technology add-on payments.

(3) Canary Tibial Extension (CTE) With Canary Health Implanted Reporting Processor (CHIRP) System

Zimmer Biomet submitted an application for new technology add-on payments for the Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System for FY 2024. Per the applicant, the CTE with CHIRP System is a tibial extension implant containing electronics and software, used with the Zimmer Persona Personalized Knee System. According to the applicant, the CTE with CHIRP System collects kinematic data pertaining to a patient's gait and activity level following total knee arthroplasty (TKA) surgery using internal motion sensors (3–D accelerometers and 3–D gyroscopes).

Please refer to the online application posting for the CTE with CHIRP System, available at *https://mearis.cms.gov/public/publications/ntap/NTP221014KYAL1*, for additional detail describing the technology and its intended use.

According to the applicant, the CTE with CHIRP System received Breakthrough Device designation from FDA on October 24, 2019, for the following proposed indication: for use with the Zimmer Persona Personalized Knee System (K113369) for TKA. The CTE with CHIRP System is intended to provide objective kinematic data from the implanted medical device to assist the patient and clinician during a patient's TKA post-surgical care. The kinematic data is intended as an adjunct to standard of care and physiological parameter measurement tools applied or

utilized by the physician during the course of patient monitoring and treatment post-surgery. FDA granted De Novo classification to the CTE with CHIRP System on August 27, 2021, for the following indication: to provide objective kinematic data from the implanted medical device during a patient's TKA post-surgical care. The kinematic data is an adjunct to other physiological parameter measurement tools applied or utilized by the physician during the course of patient monitoring and treatment post-surgery. The device is indicated for use in patients undergoing a cemented TKA procedure that are normally indicated for at least a 58 mm sized tibial stem extension. The applicant stated that the technology was not immediately available for sale due to production delays related to COVID–19 and because of the need to negotiate data agreements with customer hospitals, but it became commercially available on October 4, 2021.

The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the CTE with CHIRP System beginning in FY 2024 and was granted approval for the following procedure code(s) effective October 1, 2023: XNHG0F9 (Insertion of tibial extension with motion sensors into right tibia, open approach, new technology group 9), or XNHH0F9 (Insertion of tibial extension with motion sensors into left tibia, open approach, new technology group 9).

With respect to the cost criterion, the applicant provided the following analysis to demonstrate that it meets the cost criterion. To identify potential cases representing patients who may be eligible for the CTE with CHIRP System, the applicant searched the FY 2021 MedPAR file for cases reporting the ICD–10–PCS codes describing cemented replacement of the knee joint with a synthetic device via an open approach, as listed in the following table. Using the inclusion/exclusion criteria described in the following table, the applicant identified 74,654 claims mapping to 60 MS–DRGs. See Table 10.5.A.—CTE with CHIRP System Codes—FY 2024 associated with the proposed rule for the complete list of MS–DRGs provided by the applicant. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $90,599, which exceeded the average case-weighted threshold amount of $84,613. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the CTE with CHIRP System meets the cost criterion.

CTE with CHIRP SYSTEM COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of ICD-10-PCS Codes	0SRC0J9 (Replacement of right knee joint with synthetic substitute, cemented, open approach) 0SRC0JZ (Replacement of right knee joint with synthetic substitute, open approach) 0SRD0J9 (Replacement of left knee joint with synthetic substitute, cemented, open approach) 0SRD0JZ (Replacement of left knee joint with synthetic substitute, open approach)
List of MS-DRGs	Please see Table 10.5.A. - CTE with CHIRP System Codes - FY 2024 associated with the proposed rule for the complete list of MS-DRGs provided by the applicant.
Inclusion/Exclusion Criteria	The applicant identified cases reporting one of the four ICD-10-PCS procedure codes previously listed. The sample was limited to IPPS cases that would be used in rate-setting following the CMS methodology. Any MS-DRG with a total discharge count less than 11 was imputed with a count of 11. The applicant calculated the average unstandardized charge per case for each MS-DRG.
Charges Removed for Prior Technology	The applicant removed 25% of charges associated with Medical/Surgical Supplies and Devices (revenue centers 027x, and 0624). The applicant stated that the use of the CTE with CHIRP System is expected to replace minimal devices utilized in these cases. The applicant did not remove indirect charges related to the prior technology.
Standardized Charges	The applicant used the standardization formula provided in Technical Appendix A of the application. The applicant used all relevant values reported in the standardizing file posted with the FY 2021 IPPS/LTCH PPS final rule.
Inflation Factor	The applicant applied an inflation factor of 20.5% to the standardized charges based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule.
Charges Added for the New Technology	The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.281 for Implantable Devices from the FY 2023 IPPS/LTCH PPS final rule.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26931), we agreed with the applicant that the technology meets the cost criterion and therefore proposed to approve the CTE with CHIRP System for new technology add-on payments for FY 2024 for the indication to provide objective kinematic data from the implanted medical device during a patient's TKA post-surgical care. The kinematic data is an adjunct to other physiological parameter measurement tools applied or utilized by the physician during the course of patient monitoring and treatment post-surgery. The device is indicated for use in patients undergoing a cemented TKA procedure that are normally indicated for at least a 58 mm sized tibial stem extension.

Based on preliminary information from the applicant at the time of the proposed rule, the total cost of the CTE with CHIRP System to the hospital was approximately $1,654 per knee. This included $1,309 for the CTE and $345 for the Canary Medical Home Base Station. We noted that per the applicant, the Home Base Station System is intended for use in the patient's home environment and is used to query the CTE while the patient is asleep. We further noted that the Home Base Station provided to the patient to set up and connect to their home Wi-Fi prior to surgery. We therefore stated that we believe the relevant inpatient costs for the add-on payment would include only the cost of the CTE.[182] We noted that the cost information for this technology would be updated in the final rule based on revised or additional information CMS received prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of the CTE with CHIRP System would be $850.85 for one knee (or $1,701.70 for two knees) for FY 2024 (that is, 65

[182] *https://canarymedical.com/clinicians/additional-information-for-clinicians/.*

percent of the average cost of the technology).

We invited public comments on whether the CTE with CHIRP System meets the cost criterion and our proposal to approve new technology add-on payments for the CTE with CHIRP System for the indication to provide objective kinematic data from the implanted medical device during a patient's TKA post-surgical care.

Comment: The applicant submitted a comment regarding the cost of the technology relevant for add-on payments. Per the applicant, while they agreed that the home base station is used in the patient's home, the CTE with CHIRP is a system requiring both the CTE and the home base station components for the system to function. The applicant noted that the home base station is necessary for the communication of data to an external server, is paired to only one patient (that is, it is not reusable), and though it is paid for by the facility, it becomes the property of the patient. Thus, it is not a piece of equipment, an instrument, apparatus, implement or item for which depreciation and financing expenses are recovered by the hospital. The applicant maintained that the home base station is different from the operating room base station, which they agreed is not applicable to the new technology add-on payment calculation and was not included in their application because it is given to the hospital, and remains with the hospital, to be used intraoperatively to activate the CHIRP System in multiple patients. The applicant requested that CMS recognize that the CTE with CHIRP is one system and include the $345 cost of the home base station in the new technology add-on payment calculation to bring the maximum new technology add-on payment to $1,075.10 per knee ($1,654 × 65%).

Response: We thank the applicant for its input. However, as stated in the proposed rule, we are concerned that that the Home Base Station is provided to the patient to set up and connect to their home Wi-Fi prior to surgery. The Home Base Station is not an item administered to the patient during the hospital that leaves the hospital with the patient upon discharge. While the applicant states that the Home Base Station is not a piece of equipment, an instrument, apparatus, implement or item for which depreciation and financing expenses are recovered by the hospital, we still are unclear if the Home Base Station is billable in the inpatient setting. Therefore, for this final rule we are excluding the Home Base Station from the add on payment and the relevant inpatient costs for the add-on payment would include only the cost of the CTE. We welcome additional information from the applicant in the future on whether the Home Base Station should be included in the add on payment.

Comment: Another commenter submitted a comment stating that the kinematic data generated by the CTE with CHIRP System has not demonstrated any clinical benefits or outcomes and is not intended to be utilized for clinical decision-making, and raised questions regarding how the technology would be used.

Response: We thank the commenter for its comment. We note, as discussed previously, that a technology that applies under an alternative pathway does not need to meet the requirement that it represents an advance that substantially improves, relative to technologies previously available, the diagnosis or treatment of Medicare beneficiaries. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for a discussion of the development of these alternative pathways (84 FR 42292 through 42297).

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comment we received, we believe the CTE with CHIRP System meets the cost criterion. The technology received De Novo classification on August 27, 2021, as a Breakthrough Device for the following indication which is covered by its Breakthrough Device designation: to provide objective kinematic data from the implanted medical device during a patient's total knee arthroplasty (TKA) post-surgical care. The device is indicated for use in patients undergoing a cemented TKA procedure that are normally indicated for at least a 58 mm sized tibial stem extension. Therefore, we are finalizing our proposal to approve new technology add-on payments for CTE with CHIRP for FY 2024. We consider the beginning of the newness period to commence on October 4, 2021, the date on which the technology became commercially available for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, as stated previously, the relevant inpatient costs for the add-on payment would include only the cost of the CTE. The cost per case of the CTE with CHIRP System is $1,309 per knee. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the CTE with CHIRP System is $850.85 for one knee (or $1,701.70 for two knees) for FY 2024 (that is, 65 percent of the average cost of the technology). Cases involving the use of the CTE with CHIRP System that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XNHG0D9 (Insertion of tibial extension with motion sensors into right tibia, open approach, new technology group 9) or XNHH0D9 (Insertion of tibial extension with motion sensors into left tibia, open approach, new technology group 9).

(4) Ceribell Status Epilepticus Monitor

Ceribell, Inc. submitted an application for new technology add-on payments for the Ceribell Status Epilepticus Monitor for FY 2024. According to the applicant, the Ceribell Status Epilepticus Monitor is a medical device system comprised of proprietary software and two cleared, proprietary products: a single-use signal acquisition headband (the Ceribell EEG Headband) and a recorder (the Ceribell Pocket EEG). Per the applicant, the software utilizes a machine learning model to analyze EEG signals to detect features indicative of electrographic status epilepticus (ESE) to provide more effective diagnosis of ESE.

Please refer to the online application posting for the Ceribell Status Epilepticus Monitor, available at *https://mearis.cms.gov/public/publications/ntap/NTP22101439A1J*, for additional detail describing the technology.

The applicant stated that the Ceribell Status Epilepticus Monitor received Breakthrough Device designation from FDA on October 25, 2022, for the following proposed indication: the Ceribell Status Epilepticus Monitor software is intended for the diagnosis of ESE in adult patients at risk for seizure. The Ceribell Status Epilepticus Monitor software analyzes EEG waveforms and identifies patterns consistent with ESE as defined in the American Clinical Neurophysiology Society's Guideline 14. The applicant stated that the technology received 510(k) clearance from FDA on May 23, 2023, for the same indication. In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26933), we noted that the Ceribell EEG Headband and Ceribell Pocket EEG were not included on the Breakthrough Device designation, and it therefore appeared that only the software would be designated as the Breakthrough Device once market authorized, such that only the software would be eligible for new technology add-on payments under the alternative pathway. We note that the

510k clearance for the technology provided by the applicant was also for the software only.

The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the Ceribell Status Epilepticus Monitor beginning in FY 2024 and was granted approval for the following procedure code effective October 1, 2023: XX20X89 (Monitoring of brain electrical activity, computer-aided detection and notification, new technology group 9).

With respect to the cost criterion, the applicant provided multiple updated analyses to demonstrate that it meets the cost criterion. For the first two analyses, to identify potential cases representing patients who may be eligible for treatment involving the Ceribell Status Epilepticus Monitor, the applicant searched the FY 2021 MedPAR file for cases reporting charges in the revenue codes 020X (Intensive Care Unit) and 021X (Coronary Care Unit) as this is where the technology is expected to be utilized based on the expected FDA label of the technology. The first analysis used 100 percent of all cases reporting charges in the two revenue code categories because these cases could be monitored for Status Epilepticus, and the second analysis used 75 percent of all such cases. The applicant also provided sensitivity analyses limited to cases reporting the diagnosis codes that were believed to identify cases with the highest risk of Status Epilepticus. The third analysis used 100 percent of these cases and the fourth analysis used 75 percent of these cases. The applicant followed the order of operations described in the following table.

Under the first analysis (100 percent of all cases within the revenue code categories), the applicant identified 2,985,030 claims mapping to 754 MS–DRGs (see Table 10.7.A.—Ceribell Status Epilepticus Monitor Codes (Analyses 1–2)—FY 2024 associated with the proposed rule for a complete list of MS–DRGs provided by the applicant) and calculated a final inflated average case-weighted standardized charge per case of $114,238, which exceeded the average case-weighted threshold amount of $85,765.

Under the second analysis (75 percent of all cases within the revenue code categories) the applicant identified 2,243,140 claims mapping to 92 MS–DRGs (see Table 10.7.B.—Ceribell Status Epilepticus Monitor Codes (Analyses 1–2)—FY 2024 associated with the proposed rule for a complete list of MS–DRGs provided by the applicant) and calculated a final inflated average case-weighted standardized charge per case of $110,949, which exceeded the average case-weighted threshold amount of $85,280.

Under the third analysis, in addition to searching for cases reporting charges in the two revenue code categories listed previously, the applicant limited the cases by selecting claims reporting diagnosis codes that it believed reflected the cases for patients age 65 or older with the highest risk of Status Epilepticus (see Table 10.7.B.—Ceribell Status Epilepticus Monitor Codes (Analyses 3–4)—FY 2024 associated with the proposed rule for a complete list of the diagnosis codes provided by the applicant). According to the applicant, the diagnosis codes identified fall into four categories: Neurological Disorders, Infection/Toxicity, Respiratory Failure and Cardiac Arrest. The applicant identified 981,013 claims mapping to 672 MS–DRGs (see Table 10.7.B.—Ceribell Status Epilepticus Monitor Codes (Analyses 3–4)—FY 2024 associated with the proposed rule for a complete list of MS–DRGs provided by the applicant) and calculated a final inflated average case-weighted standardized charge per case of $127,942, which exceeded the average case-weighted threshold amount of $89,219.

Under the fourth analysis, using 75 percent of all cases reporting the diagnosis codes used in scenario 3, the applicant identified 734,908 claims mapping to 59 MS–DRGs (see Table 10.7.B.—Ceribell Status Epilepticus Monitor Codes (Analyses 3–4)—FY 2024 associated with the proposed rule for a complete list of MS–DRGs provided by the applicant), and calculated a final inflated average case-weighted standardized charge per case of $123,446, which exceeded the average case-weighted threshold amount of $88,063.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios, the applicant asserted that the Ceribell Status Epilepticus Monitor meets the cost criterion.

CERIBELL STATUS EPILEPTICUS MONITOR COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of ICD-10-CM Codes	Scenario 3 and 4: Please see Table 10.7.B. - Ceribell Status Epilepticus Monitor Codes (Analyses 3-4) - FY 2024 associated with the proposed rule for a complete list of ICD-10-CM codes provided by the applicant
List of MS-DRGs	Scenario 1-2: Please see Table 10.7.A. - Ceribell Status Epilepticus Monitor Codes (Analyses 1-2) - FY 2024 associated with the proposed rule for a complete list of MS-DRGs provided by the applicant. Scenario 3-4: Please see Table 10.7.B. - Ceribell Status Epilepticus Monitor Codes (Analyses 3-4) - FY 2024 associated with the proposed rule for the complete lists of MS-DRGs provided by the applicant.
Inclusion/Exclusion Criteria	Scenario 1 and 2: The applicant identified cases by revenue codes 020X (Intensive Care Unit) and 021X (Coronary Care Unit). Scenario 3 and 4: The applicant limited the cases in scenarios 1 and 2 to claims reporting the ICD-10-CM diagnosis codes in Table 10.7.B. - Ceribell Status Epilepticus Monitor Codes (Analyses 3-4) - FY 2024, which it stated reflected the cases with the highest risk of Status Epilepticus. Scenarios 1-4: Any MS-DRG with a total discharge count less than 11 was imputed with a count of 11. The applicant calculated the average unstandardized charge per case for each MS-DRG.
Charges Removed for Prior Technology	The applicant did not remove any charges for the prior technology. Per the applicant, for charges related to the technology, the use of the technology is expected to help diagnose status epilepticus and thereby reduce time (and corresponding charges) in the Intensive Care Unit (ICU) and Coronary Care Unit (CCU). To account for a reduction in the ICU and CCU charges due to the use of the Ceribell Status Epilepticus Monitor, the applicant removed a conservative estimate of 50% of these charges.
Standardized Charges	The applicant used the standardization formula provided in Technical Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2021 IPPS/LTCH PPS correction notice.
Inflation Factor	The applicant applied an inflation factor of 20.5% to the standardized charges, which is the same inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule.
Charges Added for the New Technology	The applicant stated that the average sales price of the technology is $2,600 per patient (comprised of $1,800 for the software and $800 for the required headband). The cost was divided by the national CCR of 0.341 for Intensive Days to estimate hospital charges7,625.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26934), we agreed that the technology meets the cost criterion and therefore proposed to approve the Ceribell Status Epilepticus Monitor for new technology add-on payments for FY 2024 subject to the technology receiving FDA marketing authorization as a Breakthrough Device for the indication corresponding to the Breakthrough Device designation by July 1, 2023.

Based on preliminary information from the applicant at the time of the proposed rule, the applicant anticipated the total cost of the Ceribell Status Epilepticus Monitor to the hospital to be $2,600 per patient (comprised of $1,800 for the software and $800 for the required headband). We stated in the proposed rule, however, that as discussed previously, it seemed that only the software would be eligible for the new technology add-on payment under the alternative pathway as it was the subject of the Breakthrough Device designation. We further noted, as discussed with regard to the Ceribell Delirium Monitor, that the Ceribell EEG headband appeared to have been 510(k)–cleared by FDA since August 2017 [183] and was therefore no longer new. Therefore, it appeared any add-on payment for the Ceribell Status Epilepticus Monitor would include only the cost of the software ($1,800). We welcomed comment on including only the cost of the software in determining the add-on payment amount for the Ceribell Status Epilepticus Monitor. We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS received prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of the Ceribell Status Epilepticus Monitor would be $1,170 ($1,800 × 0.65) for FY 2024 (that is, 65 percent of the average cost of the technology for the software).

We invited public comments on whether the Ceribell Status Epilepticus Monitor meets the cost criterion and our proposal to approve new technology add-on payments for the Ceribell Status Epilepticus Monitor for FY 2024 for the diagnosis of ESE in adult patients at risk for status epilepticus.

Comment: The applicant submitted a comment and a revised cost analysis. In its comment, the applicant noted that they have updated their pricing structure to commercialize the Status Epilepticus Monitor software through a subscription-based pricing model. Under this model, a hospital will pay a fixed monthly subscription for use of the software that allows the hospital to utilize the technology without limitations on volume. Per the applicant, their rationale for charging hospitals a monthly subscription fee is based on prior experience using a similar charge structure for launching their current EEG technology in 2020. The applicant noted that because they anticipated a lot of overlap in the use of their current EEG technology and the anticipated use of the Status Epilepticus Monitor, they plan to also commercialize the Status Epilepticus Monitor using a subscription-based pricing model. According to the applicant, to arrive at the updated per-patient cost, they estimated the number of patients expected to be evaluated using the Status Epilepticus Monitor software and divided that number by

[183] *https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171459.pdf.*

the projected monthly subscription cost. According to the applicant, it arrived at an estimated annual utilization of the Status Epilepticus Monitor per hospital based on the median annual utilization of their customers' existing EEG system over the three-year timeframe of 2020, 2021, and 2022. This resulted in a per case charge of $1,406 (instead of $1,800 in the proposed rule); the cost of the headband was unchanged at $800. Thus, the updated per patient cost is $2,206, per the applicant.

Using the new per patient cost, the applicant updated its cost analysis. According to the applicant, the updated analysis was consistent with what they had provided in the past, with the cost per patient as the only change. In their revised first analysis, in which the applicant used 100 percent of all cases within the revenue code categories, the final inflated average case-weighted standardized charge per case was $113,082, which exceeded the average case-weighted threshold amount of $85,765. In the revised second analysis, the applicant used 75 percent of all cases within the revenue code categories, the final inflated average case-weighted standardized charge per case was $109,784, which exceeded the average case-weighted threshold amount of $85,280. In the revised third analyses, in which the applicant provided sensitivity analyses limited to 100 percent of all the cases with the highest risk of Status Epilepticus, the inflated average case-weighted standardized charge per case was $125,611, which exceeded the average case-weighted threshold amount of $88,778. In their revised fourth analysis, in which the applicant provided sensitivity analyses limited to 75 percent of all the cases with the highest risk of Status Epilepticus, the final inflated average case-weighted standardized charge per case was $121,188, which exceeded the average case-weighted threshold amount of $87,583. Per the applicant, all the revised cost analyses have demonstrated that the technology still meets cost criterion.

Response: We thank the applicant for the updated information. We agree that the technology continues to meet the cost criterion using the revised pricing structure based on a subscription-based pricing model. We also thank the commenter for providing an explanation how it computed the per discharge amount based on a subscription-based pricing model.

Comment: Several commenters submitted public comments providing general support for Ceribell Status Epilepticus Monitor. A commenter noted that diagnosing status epilepticus is often challenging, as community hospitals often lack EEG technicians or specialized providers. A commenter stated that this technology will be helpful to patients in both the emergency department and the inpatient setting, especially in the intensive care unit, where patients likely have altered awareness and need to have status epilepticus diagnosed or excluded timely. Several of the commenters disagreed with our proposal to cover only the Ceribell Status Epilepticus Monitor software and not the Ceribell headband. They stated that the technology is only operational as a complete system, and that the Ceribell Status Epilepticus Monitor software requires the use of the Ceribell headband. They therefore argued in favor of including the Ceribell headband in any new technology add-on payment for the Ceribell Status Epilepticus Monitor.

Response: We thank the commenters for their comments. We note that, under the eligibility criteria for approval under the alternative pathway for certain transformative new devices, only the use of the Ceribell Status Epilepticus Monitor software is relevant for purposes of the new technology add-on payment application for FY 2024. Since only the software was designated as a Breakthrough Device by FDA, the Ceribell EEG Headband is not eligible to be included in the Ceribell Status Epilepticus Monitor add-on payment amount.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the Ceribell Status Epilepticus Monitor meets the cost criterion. The Ceribell Status Epilepticus Monitor System received 510(k) clearance from FDA on May 23, 2023, for the diagnosis of Electrographic Status Epilepticus in adult patients at risk for seizure, which is covered by its Breakthrough Device designation. We consider the beginning of the newness period to commence on May 23, 2023, the date on which Ceribell Status Epilepticus Monitor was 510(K)–cleared by FDA for the indication covered in its Breakthrough Device designation.

As noted earlier, the applicant updated their pricing structure to commercialize the Status Epilepticus Monitor software through a subscription-based pricing model. Based on the information available at the time of this final rule, the cost per case of the Ceribell Status Epilepticus Monitor (using a per discharge amount based on a subscription-based pricing model) is $1,406, based on the cost per patient of the software only. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the new technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the Ceribell Status Epilepticus Monitor is $913.90 for FY 2024 (that is, 65 percent of the average cost of the technology). Cases involving the use of the Ceribell Status Epilepticus Monitor that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code XX20X89 (Monitoring of brain electrical activity, computer-aided detection and notification, new technology group 9).

(5) DETOUR System

Endologix, Inc., submitted an application for new technology add-on payments for the DETOUR System for FY 2024. According to the applicant, the DETOUR System is a fully percutaneous approach to femoral-popliteal bypass. Per the applicant, under fluoroscopic guidance, a proprietary TORUS Stent Graft System is deployed from the popliteal artery into the femoral vein, and from the femoral vein into the superficial femoral artery (SFA) in a continuous, overlapping fashion through two independent anastomoses. The applicant stated that the intended result is a large lumen endograft bypass, that delivers unobstructed, pulsatile flow from the SFA ostium to the popliteal artery.

Please refer to the online application posting for the DETOUR System, available at *https://mearis.cms.gov/public/publications/ntap/NTP2210149Y5M6*, for additional detail describing the technology and the disease treated by the technology.

According to the applicant, the DETOUR System received Breakthrough Device designation from FDA on September 2, 2020, for percutaneous revascularization of symptomatic femoropopliteal lesions 200mm to 460mm with a chronic total occlusion 100mm to 425mm, and/or moderate-to-severe calcification, and/or in-stent-restenosis in patients with severe peripheral arterial disease. The applicant received FDA premarket approval on June 7, 2023, for the same indication. According to the applicant, the device became available on the market immediately upon FDA approval.

The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for DETOUR System beginning in FY 2024 and was granted

approval for the following procedure codes effective October 1, 2023: X2KH3D9 (Bypass right femoral artery using conduit through femoral vein to superficial femoral artery, percutaneous approach, new technology group 9), X2KH3E9 (Bypass right femoral artery using conduit through femoral vein to popliteal artery, percutaneous approach, new technology group 9), X2KJ3D9 (Bypass left femoral artery using conduit through femoral vein to superficial femoral artery, percutaneous approach, new technology group 9), or X2KJ3E9 (Bypass left femoral artery using conduit through femoral vein to popliteal artery, percutaneous approach, new technology group 9). Per the applicant, diagnosis codes 170.92 (Chronic total occlusion of artery of the extremities), 170.2XX (Atherosclerosis of native arteries of the extremities), and 173.9 (Peripheral vascular disease, unspecified) may be used to currently identify the indication for the DETOUR System under the ICD–10–CM system.

With respect to the cost criterion, the applicant provided two analyses to demonstrate that it meets the cost criterion. For both analyses, the applicant searched the FY 2021 MedPAR file for potential cases representing patients who may be eligible for the DETOUR System femoral-popliteal bypass procedures using either a synthetic substitute or an autologous venous tissue graft.

Under the first analysis, the applicant searched the FY 2021 MedPAR file for cases reporting one of the ICD–10–PCS codes listed in the following table and included 100 percent of the cases identified. Using the inclusion/exclusion criteria described in the following table, the applicant identified 3,110 cases mapping to 63 MS–DRGs. Please see Table 10.25.A.—The DETOUR System Codes—FY 2024 associated with the proposed rule for the complete list of MS–DRGs that the applicant indicated were included in its cost analysis. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $146,323, which exceeded the average case-weighted threshold amount of $106,123.

Under the second analysis, the applicant searched the FY 2021 MedPAR file for cases reporting one of the ICD–10–PCS codes listed in the table that follows and included 67.3 percent of the cases identified. Using the inclusion/exclusion criteria described in the following table, the applicant limited the search to the top three MS–DRGs as listed in the table and identified 2,094 cases. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $111,332, which exceeded the average case-weighted threshold amount of $96,526. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in both analyses, the applicant asserted that the DETOUR System meets the cost criterion.

the DETOUR System COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR File
List of ICD-10-PCS Codes	041K09L (Bypass right femoral artery to popliteal artery with autologous venous tissue, open approach) 041L09L (Bypass left femoral artery to popliteal artery with autologous venous tissue, open approach) 041K3JQ (Bypass right femoral artery to lower extremity artery with synthetic substitute, percutaneous approach) 041L3JQ (Bypass left femoral artery to lower extremity artery with synthetic substitute, percutaneous approach)
List of MS-DRGs	Scenario 1: Please see Table 10.25.A. - The DETOUR System Codes - FY 2024 associated with the proposed rule for the complete list of MS-DRGs included in the cost analysis. Scenario 2: The applicant also identified the three MS-DRGs with the highest volume of cases: 252 (Other vascular procedures with MCC), 253 (Other vascular procedures with CC), and 254 (Other vascular procedures without CC/MCC)
Inclusion/Exclusion Criteria	Scenario 1: 100% of cases reporting the previously listed ICD-10-PCS codes. Any MS-DRG with a total discharge count less than 11 was imputed with a count of 11. Scenario 2: 67.3% of cases reporting the previously listed ICD-10-PCS codes. The applicant limited the cases in both analyses to IPPS cases that would be used in ratesetting following the CMS methodology.
Charges Removed for Prior Technology	To provide a conservative estimate of the charges, the applicant removed 100% of charges associated with Medical/Surgical Supplies and Devices (revenue centers 027x, and 0624).
Standardized Charges	The applicant used the standardization formula provided in Technical Appendix A of the application. The applicant used all relevant values reported in the standardizing file posted with the FY 2021IPPS/LTCH PPS correction notice.
Inflation Factor	The applicant applied an inflation factor of 20.4686% to the standardized charges based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS final rule.
Charges Added for the New Technology	The applicant stated that the average sales price of the technology has yet to be determined, and that when the price is available, a revised cost analysis will be provided that includes estimated hospital charges for the technology.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26950), we agreed with the applicant that the DETOUR System meets the cost criterion and proposed to approve the DETOUR System for new technology add-on payments for FY 2024, subject to the technology receiving FDA marketing authorization as a Breakthrough Device for the indication corresponding to the Breakthrough Device designation by July 1, 2023.

We stated in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26950) that we expected the applicant to submit cost information prior to the final rule, and we would provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule. Any new technology add-on payment for the DETOUR System would be subject to our policy under § 412.88(a)(2) where we limit new technology add-on payments to the lesser of 65 percent of

the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case.

We invited public comments on whether the DETOUR System meets the cost criterion and our proposal to approve new technology add-on payments for the DETOUR System for FY 2024 subject to the technology receiving FDA marketing authorization as a Breakthrough Device for the indication corresponding to the Breakthrough Device designation by July 1, 2023.

Comment: We received a comment from the applicant in support of CMS's proposal to approve the technology for new technology add-on payments. The applicant stated that the DETOUR System provides a transformative approach for the treatment of individuals with complex peripheral artery disease (PAD) through a novel, minimally invasive procedure referred to as percutaneous transmural arterial bypass (PTAB).

Response: We thank the commenter for its support.

Based on the information provided in the application for new technology add-on payments, we believe the DETOUR System meets the cost criterion. The technology received FDA marketing authorization on June 7, 2023, as a Breakthrough Device with an indication for percutaneous revascularization of symptomatic femoropopliteal lesions 200mm to 460mm with a chronic total occlusion 100mm to 425mm, and/or moderate-to-severe calcification, and/or in-stent-restenosis in patients with severe peripheral arterial disease, which is covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the DETOUR System for FY 2024. We consider the beginning of the newness period to commence on June 7, 2023, the date on which the technology became commercially available for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the DETOUR System is $25,000 for the single-use system comprised of the TORUS Stent Graft(s) and the ENDOCROSS device. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the DETOUR System is 65 percent of $16,250 for FY 2024 (that is, 65 percent of the average cost of the technology). Cases involving the use of the DETOUR System that are eligible for new technology add-on payments will be identified by one of the following ICD–10–PCS procedure codes: X2KH3D9 (Bypass right femoral artery using conduit through femoral vein to superficial femoral artery, percutaneous approach, new technology group 9), X2KH3E9 (Bypass right femoral artery using conduit through femoral vein to popliteal artery, percutaneous approach, new technology group 9), X2KJ3D9 (Bypass left femoral artery using conduit through femoral vein to superficial femoral artery, percutaneous approach, new technology group 9), or X2KJ3E9 (Bypass left femoral artery using conduit through femoral vein to popliteal artery, percutaneous approach, new technology group 9).

(6) EchoGo Heart Failure 1.0

Ultromics Limited submitted an application for EchoGo Heart Failure 1.0 for FY 2024. According to the applicant, EchoGo Heart Failure 1.0 is an automated machine learning-based decision support system, indicated as a diagnostic aid for patients undergoing routine functional cardiovascular assessment using echocardiography. Per the applicant, when utilized by an interpreting physician, this device provides information that may be useful in detecting heart failure with preserved ejection fraction (HFpEF).

Please refer to the online application posting for EchoGo Heart Failure 1.0, available at *https://mearis.cms.gov/public/publications/ntap/NTP2210172L1HN*, for additional detail describing the technology and the medical condition the technology is intended for.

According to the applicant, EchoGo Heart Failure 1.0 received Breakthrough Device designation from FDA on February 24, 2022, as an automated machine learning-based decision support system, indicated as a diagnostic aid for patients undergoing routine functional cardiovascular assessment using echocardiography. When utilized by an interpreting clinician, this device provides information that may be useful in detecting heart failure with preserved ejection fraction (HFpEF). EchoGo Heart Failure 1.0 is indicated in adult populations over 25 years of age. Patient management decisions should not be made solely on the results of the EchoGo Heart Failure 1.0 analysis. EchoGo Heart Failure 1.0 takes as input an apical 4-chamber view of the heart that has been captured and assessed to have an ejection fraction ≥50 percent. The applicant received FDA 510(k) clearance on November 23, 2022, for the same indication.

The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for EchoGo Heart Failure 1.0 beginning in FY 2024 and was granted approval for the following procedure code effective October 1, 2023: XXE2X19 (Measurement of cardiac output, computer-aided assessment, new technology group 9). The applicant provided a list of diagnosis codes that may be used to currently identify the indication for EchoGo Heart Failure 1.0 under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant.

With respect to the cost criterion, the applicant provided multiple analyses to demonstrate that it meets the cost criterion. For each analysis, the applicant searched the FY 2021 MedPAR file using a combination of MS–DRGs and ICD–10–CM codes to identify potential cases representing patients who may be eligible for EchoGo Heart Failure 1.0. The applicant explained that it ran eight additional simulations as a sensitivity analysis, in which the applicant used combinations of MS–DRGs and/or ICD–10–CM codes to identify potential cases. Each analysis followed the order of operations described in the following table.

For the first analysis, the applicant searched for specific ICD–10–CM codes in the primary diagnosis position mapped to specific MS–DRGs representing patients likely to undergo routine functional cardiovascular assessment using echocardiography and likely to use EchoGo Heart Failure 1.0 to detect HFpEF. Please see Table 10.12.A.—EchoGo Heart Failure 1.0 Codes (Analyses 1–5)—FY 2024 associated with the proposed rule for the complete list of ICD–10–CM codes and MS–DRGs that the applicant indicated were included in its cost analysis 1. Using the inclusion/exclusion criteria described in the following table, the applicant identified 407,813 claims mapping to 17 MS–DRGs. The applicant calculated a final inflated average case-weighted standardized charge per case of $66,144, which exceeded the average case-weighted threshold amount of $52,548.

For the second analysis, the applicant searched for cases that had a primary diagnosis from the applicant's ICD–10–CM list, in any MS–DRG. Please see Table 10.12.A.—EchoGo Heart Failure 1.0 Codes (Analyses 1–5)—FY 2024 associated with the proposed rule for the complete lists of ICD–10–CM codes

and MS–DRGs that the applicant indicated were included in its cost analysis 2. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 496,879 claims mapping to 92 MS–DRGs. The applicant calculated a final inflated average case-weighted standardized charge per case of $88,203, which exceeded the average case-weighted threshold amount of $66,971.

For the third analysis, the applicant used all cases (without the use of any ICD–10–CM or ICD–10–PCS codes) in any of the MS–DRGs included on the applicant's list of specific MS–DRGs representing patients likely to undergo routine functional cardiovascular assessment using echocardiography and likely to use the EchoGo Heart Failure 1.0 to detect HFpEF. Please see Table 10.12.A.—EchoGo Heart Failure 1.0 Codes (Analyses 1–5)—FY 2024 associated with the proposed rule for the complete list of MS–DRGs that the applicant indicated were included in its cost analysis 3. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 572,720 claims mapping to 20 MS–DRGs. The applicant calculated a final inflated average case-weighted standardized charge per case of $69,126, which exceeded the average case-weighted threshold amount of $54,038.

For the fourth analysis, the applicant searched for any Medicare fee-for-service (FFS) case with an admitting diagnosis from the applicant's ICD–10–CM codes list, in any MS–DRG. Please see Table 10.12.A.—EchoGo Heart Failure 1.0 Codes (Analyses 1–5)—FY 2024 associated with the proposed rule for the complete lists of ICD–10–CM codes and MS–DRGs that the applicant indicated were included in its cost analysis 4. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 267,378 claims mapping to 493 MS–DRGs. The applicant calculated a final inflated average case-weighted standardized charge per case of $97,027, which exceeded the average case-weighted threshold amount of $72,813.

For the fifth analysis, the applicant searched for any case with a primary or secondary diagnosis from the applicant's ICD–10–CM codes list, in any MS–DRG. Please see Table 10.12.A.—EchoGo Heart Failure 1.0 Codes (Analyses 1–5)—FY 2024 associated with the proposed rule for the complete list of ICD–10–CM codes and MS–DRGs that the applicant indicated were included in its cost analysis 5. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 2,277,736 claims mapping to 746 MS–DRGs, with none exceeding more than 15 percent of the total identified cases. The applicant calculated a final inflated average case-weighted standardized charge per case of $107,796, which exceeded the average case-weighted threshold amount of $76,632.

According to the applicant, the ICD–10–CM codes for systolic HF were included in the initial cost criterion analysis as the provider may not know if the patient has either systolic or diastolic HF unless the provider has ordered an echo and subsequently EchoGo Heart Failure 1.0. Symptoms are often identical, and systolic HF is defined by low ejection fraction which the applicant stated is an incredibly variable measurement. In addition, in acute decompensated HF, these patients can present as HFpEF and transition to systolic HF or vice versa within a single inpatient stay. As such, the applicant asserted that ordering EchoGo Heart Failure 1.0 would be appropriate. To understand the impact of removing the cases where the only inclusion criteria met was one of the ICD–10–CM codes for systolic HF, the applicant conducted additional analyses six through nine, removing ICD–10–CM codes for systolic heart failure: I50.20 (Unspecified systolic (congestive) heart failure), I50.21 (Acute systolic (congestive) heart failure), I50.22 (Chronic systolic (congestive) heart failure), and I50.23 (Acute on chronic systolic (congestive) heart failure). Please see Table 10.12.B.—EchoGo Heart Failure 1.0 Codes (Analyses 6–9)—FY 2024 associated with the proposed rule for the complete list of ICD–10–CM codes and MS–DRGs that the applicant indicated were included in its cost analyses 6–9. Inclusion/exclusion criteria for analyses six through nine are detailed in the table that follows.

The sixth analysis mirrored the first analysis, except that cases with ICD–10–CM systolic heart failure codes were excluded. Under this analysis, the applicant identified 398,398 claims mapping to 17 MS–DRGs. The applicant calculated a final inflated average case-weighted standardized charge per case of $66,245, which exceeded the average case-weighted threshold amount of $52,651.

The seventh analysis mirrored the second analysis, except that cases with systolic heart failure ICD–10–CM codes were excluded. Under this analysis, the applicant identified 485,027 claims mapping to 92 MS–DRGs. The applicant calculated a final inflated average case-weighted standardized charge per case of $88,149, which exceeded the average case-weighted threshold amount of $66,991.

The eighth analysis mirrored the fourth analysis, except that cases with ICD–10–CM systolic heart failure codes were excluded. Under this analysis, the applicant identified 244,399 claims mapping to 491 MS–DRGs. The applicant calculated a final inflated average case-weighted standardized charge per case of $97,453, which exceeded the average case-weighted threshold amount of $72,735.

The ninth analysis mirrored the fifth analysis, except that cases with ICD–10–CM systolic heart failure codes were excluded. Under this analysis, the applicant identified 2,214,393 claims mapping to 746 MS–DRGs. The applicant calculated a final inflated average case-weighted standardized charge per case of $107,201, which exceeded the average case-weighted threshold amount of $76,389.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios, the applicant asserted that the EchoGo Heart Failure 1.0 meets the cost criterion.

BILLING CODE 4120–01–P

ECHOGO HEART FAILURE 1.0 COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of ICD-10-CM Codes	Analysis 1-5: Please see Table 10.12.A. - EchoGo Heart Failure 1.0 Codes (Analyses 1-5) – FY 2024 associated with the proposed rule for the complete list of codes that the applicant indicated were included in its cost analyses 1-5. Analysis 6-9: Please see Table 10.12.B. EchoGo Heart Failure 1.0 Codes (Analyses 6-9) – FY 2024 associated with the proposed rule for the complete lists of codes that the applicant indicated were included in its cost analyses 6-9. The ICD-10-CM code list for analyses 6-9 mirrors the list for analysis 1-5, but with the exclusion of the following systolic ICD-10-CM codes: I50.20 (Unspecified systolic (congestive) heart failure); I50.21 (Acute systolic (congestive) heart failure); I50.22 (Chronic systolic (congestive) heart failure); and I50.23 (Acute on chronic systolic (congestive) heart failure).
List of MS-DRG	Analyses 1 and 3 searched the applicant's predetermined list of MS-DRGs, while analysis 2, 4, and 5 resulted in lists of MS-DRGs based on the search of ICD-10-CM codes. Please see Table 10.12.A. - EchoGo Heart Failure 1.0 Codes (Analyses 1-5) – FY 2024 associated with the proposed rule for the complete lists of MS-DRGs that the applicant indicated were included in its cost analyses 1-5. Analysis 6 searched the applicant's predetermined list of MS-DRGs, while analysis 7, 8, and 9 resulted in lists of MS-DRGs. Please see Table 10.12.B. - EchoGo Heart Failure 1.0 Codes (Analyses 6-9) – FY 2024 associated with the proposed rule for the complete lists of MS-DRGs that the applicant indicated were included in its cost analyses 6-9.
Inclusion/Exclusion Criteria	Analysis 1: The applicant identified cases by using any ICD-10-CM code listed in Table 10.12.A. - EchoGo Heart Failure 1.0 Codes (Analyses 1-5) – FY 2024 associated with the proposed rule in the primary diagnosis position, and a MS-DRG from the applicant's predetermined MS-DRG list, which can also be found in the same table. Analysis 2: The applicant identified cases using any ICD-10-CM code listed in Table 10.12.A. - EchoGo Heart Failure 1.0 Codes (Analyses 1-5) – FY 2024 associated with the proposed rule in the primary diagnosis position, in any MS-DRG. Analysis 3: The applicant identified all cases in any of the applicant's predetermined MS-DRGs listed in Table 10.12.A. - EchoGo Heart Failure 1.0 Codes (Analyses 1-5) – FY 2024 associated with the proposed rule. Analysis 4: The applicant identified any case with an admitting diagnosis from the ICD-10-CM list in Table 10.12.A. - EchoGo Heart Failure 1.0 Codes (Analyses 1-5) – FY 2024 associated with the proposed rule, in any MS-DRG. Analysis 5: The applicant identified any cases with a primary or secondary diagnosis from the ICD-10-CM codes listed in Table 10.12.A. - EchoGo Heart Failure 1.0 Codes (Analyses 1-5) – FY 2024 associated with the proposed rule, in any MS-DRG. Analysis 6: The applicant used the same inclusion/exclusion criteria from Analysis 1, but with ICD-10-CM systolic heart failure codes excluded from the list of ICD-10-CM codes used for analyses 1-5. Analysis 7: The applicant used the same inclusion/exclusion criteria from Analysis 2, but with ICD-10-CM systolic heart failure codes excluded from the list of ICD-10-CM codes used for analyses 1-5. Analysis 8: The applicant used the same inclusion/exclusion criteria from Analysis 4, but with ICD-10-CM systolic heart failure codes excluded from the list of ICD-10-CM codes used for analyses 1-5. Analysis 9: The applicant used the same inclusion/exclusion criteria from Analysis 5, but with ICD-10-CM systolic heart failure codes excluded from the list of ICD-10-CM codes used for analyses 1-5. See Table 10.12.B. - EchoGo Heart Failure 1.0 Codes (Analyses 6-9) – FY 2024 associated with the proposed rule for the modified list of ICD-10-CM codes, and the MS-DRG lists from analyses 6-9. The applicant calculated the average unstandardized charge per case for each MS-DRG. Only inpatient fee-for-service (FFS) cases were identified for inclusion across the analyses.
Charges Removed for Prior Technology	Per the applicant, EchoGo Heart Failure 1.0 is not expected to replace prior technologies or replace the costs associated with prior technologies. Therefore, no costs associated with prior technologies were removed.
Standardized Charges	The applicant used the standardization formula provided in Technical Appendix A of the application. The applicant used all relevant values reported in the standardizing file posted with the FY 2023 IPPS/LTCH PPS final rule.
Inflation Factor	The applicant applied an inflation factor of 20.4686% to the standardized charges, which is based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule.

ECHOGO HEART FAILURE 1.0 COST ANALYSIS	
Charges Added for the New Technology	According to the applicant, EchoGo Heart Failure 1.0 technology is estimated to be priced at $1,575. The applicant converted costs to charges by dividing the average cost per patient of $1,575 by the national average cost-to-charge ratio (CCR) of 0.137 for the radiology cost center from the FY 2023 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26937), we agreed with the applicant that EchoGo Heart Failure 1.0 meets the cost criterion and therefore proposed to approve EchoGo Heart Failure 1.0 for new technology add-on payments for FY 2024.

Based on preliminary information from the applicant at the time of the proposed rule, the applicant's anticipated cost per patient for EchoGo Heart Failure 1.0 was $1,575. According to the applicant, the EchoGo Heart Failure 1.0 is charged on a per patient basis with no monthly subscription to the hospital. We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS received prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of EchoGo Heart Failure 1.0 would be $1,023.75 for FY 2024 (that is, 65 percent of the average cost of the technology).

We invited public comments on whether EchoGo Heart Failure 1.0 meets the cost criterion and our proposal to approve new technology add-on payments for EchoGo Heart Failure 1.0 for FY 2024 for the indication as an automated machine learning-based decision support system, indicated as a diagnostic aid for patients undergoing routine functional cardiovascular assessment using echocardiography that corresponds to the Breakthrough Device designation.

Comment: The applicant submitted a public comment expressing support for the approval of EchoGo Heart Failure 1.0 for the new technology add-on payment for FY 2024. The applicant also supported CMS's proposed maximum new technology add-on payment amount.

Response: We thank the applicant for its comments.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe EchoGo Heart Failure 1.0 meets the cost criterion. The technology was granted FDA marketing authorization on November 23, 2022, as a Breakthrough Device, with an indication for use as an automated machine learning-based decision support system, indicated as a diagnostic aid for patients undergoing routine functional cardiovascular assessment using echocardiography. When utilized by an interpreting clinician, this device provides information that may be useful in detecting heart failure with preserved ejection fraction (HFpEF). EchoGo Heart Failure 1.0 is indicated in adult populations over 25 years of age. Patient management decisions should not be made solely on the results of the EchoGo Heart Failure 1.0 analysis. EchoGo Heart Failure 1.0 takes as input an apical 4-chamber view of the heart that has been captured and assessed to have an ejection fraction ≥50 percent. This indication is covered by its Breakthrough Device Designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for EchoGo Heart Failure 1.0 for FY 2024. We consider the beginning of the newness period to commence on November 23, 2022, the date on which technology received its FDA 510(k) clearance for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of EchoGo Heart Failure 1.0 is $1,575. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of EchoGo Heart Failure 1.0 is $1,023.75 for FY 2024 (that is, 65 percent of the average cost of the technology). Cases involving the use of EchoGo Heart Failure 1.0 that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code XXE2X19 (Measurement of cardiac output, computer-aided assessment, new technology group 9).

(7) Phagenyx® System

Phagenesis Ltd. submitted an application for new technology add-on payments for the Phagenyx® System for FY 2024. The Phagenyx® System treats neurogenic dysphagia using electrical pulses to stimulate sensory nerves in the oropharynx. We note that Phagenesis Ltd. submitted an application for new technology add-on payments for the Phagenyx® System for FY 2022 and 2023, as summarized in the FY 2022 and 2023 IPPS/LTCH PPS proposed rules (86 FR 25382 through 25384 and 87 FR 28342 through 28344), but the technology did not meet the deadline of July 1, 2021/2022 for FDA approval or clearance of the technology and, therefore, was not eligible for consideration for new technology add-on payments for the FY 2022 or 2023 IPPS/LTCH PPS final rules (86 FR 45126 through 45127 and 87 FR 48780).

Please refer to the online application posting for the Phagenyx® System, available at *https://mearis.cms.gov/public/publications/ntap/NTP221013D2MDC,* for additional detail describing the technology and the disorder treated by the technology.

According to the applicant, the Phagenyx® System received Breakthrough Device designation from FDA on January 29, 2021, for the treatment of non-progressive neurogenic dysphagia in adult patients. Non-progressive neurogenic dysphagia is defined as all neurogenic dysphagia excluding that arising solely as a result of a progressive neurodegenerative disease or condition. The Phagenyx® System was granted De Novo Classification from FDA on September 16, 2022, as a neurostimulation device delivering electrical stimulation to the oropharynx, to be used in addition to standard dysphagia care, as an aid to improve swallowing in patients with severe dysphagia post stroke. In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26943) we noted that since the indication for which the applicant received 510(k) clearance is included within the scope of the Breakthrough Device designation, and FDA considers this marketing authorization to be the Breakthrough Device,[184] it appears that the 510(k) indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria.

According to the applicant, Phagenesis Ltd is based in Manchester,

[184] List of Breakthrough Devices with Marketing Authorization: *https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program.*

United Kingdom and currently setting up business operations infrastructure to commercially market and sell Phagenyx. This includes but is not limited to establishing an importing agent, third party warehousing and logistics, tax IDs in all states, a corporate office, and hiring staff. The applicant stated that for these reasons, April 1, 2023, was the expected commercial availability date for the Phagenyx® System.

The applicant stated that, effective October 1, 2021, the ICD–10–PCS code XWHD7Q7 (Insertion of neurostimulator lead into mouth and pharynx, via natural or artificial opening, new technology group 7) may be used to uniquely describe procedures involving the use of the Phagenyx® System. The applicant provided a list of diagnosis codes that may be used to currently identify the indication for the Phagenyx® System under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant.

With respect to the cost criterion, the applicant searched the FY 2021 MedPAR file for potential cases representing patients who may be eligible for the Phagenyx® System to demonstrate that it meets the cost criterion. The applicant searched for cases reporting a combination of the ICD–10–CM codes that may be used to currently identify the indication for the Phagenyx® System under the ICD–10–CM coding systems. Please see the following table for the complete list of ICD–10–CM codes provided by the applicant. Using the inclusion/exclusion criteria described in the following table, the applicant identified 79,056 claims mapping to 551 MS–DRGs (see Table 10.16.A.—Phagenyx® System Codes—FY 2024 associated with the proposed rule for a list of MS–DRGs that the applicant indicated were included in its cost analysis). The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $130,440, which exceeded the average case-weighted threshold amount of $82,183. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the Phagenyx® System meets the cost criterion.

Phagenyx® System COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR File
List of ICD-10-CM Codes	ICD-10-CM codes for dysphagia: R13.10 (Dysphagia unspecified) R13.12 (Dysphagia oropharyngeal phase) R13.13 (Dysphagia pharyngeal phase) R13.14 (Dysphagia pharyngoesophageal phase) R13.19 (Other dysphagia) ICD-10-CM codes for stroke: I60x (Nontraumatic subarachnoid hemorrhage) I61x (Nontraumatic intracerebral hemorrhage) I62x (Other and unspecified nontraumatic intracranial hemorrhage) I63x (Cerebral infarction) Dysphagia sequala codes: I69.091 (Dysphagia following nontraumatic subarachnoid hemorrhage) I69.191 (Dysphagia following nontraumatic intracerebral hemorrhage) I69.291 (Dysphagia following other nontraumatic intracranial hemorrhage) I69.391 (Dysphagia following cerebral infarction)
List of MS-DRGs	See Table 10.16.A. - Phagenyx® System Codes – FY 2024 associated with the proposed rule for a list of the MS-DRGs that the applicant indicated were included in its cost analysis.
Inclusion/Exclusion Criteria	Using the ICD-10-CM codes listed in this table, the applicant identified all discharges with any of the ICD-10-CM codes for dysphagia and an ICD-10-CM code for stroke. In addition to cases identified with both a dysphagia code and a stroke code, the applicant included discharges with one of the four dysphagia sequala codes. The applicant included only inpatient discharges paid as fee-for-service claim type ''60.'' Medicare Advantage discharges were excluded. The applicant excluded discharges where the MedPAR ''GHO Paid'' indicator field on the claim record is equal to ''1'' or when the MedPAR DRG payment field, which represents the total payment for the claim, is equal to the MedPAR ''Indirect Medical Education (IME)'' payment field. The applicant used MS-DRG grouper version 40 to identify the MS-DRG distribution. The applicant excluded cases where a standardized charge could not be calculated.
Charges Removed for Prior Technology	The applicant stated that the Phagenyx® System does not replace any prior technologies, and therefore they did not remove any prior or related technology charges.
Standardized Charges	The applicant used the standardization formula provided in Technical Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2021 IPPS/LTCH PPS correction notice.
Inflation Factor	The applicant applied the 3-year rate of inflation factor of 20.4686% to the standardized charges based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule.
Charges Added for the New Technology	The applicant added charges for the new technology by dividing the cost of the new technology's single use, per patient catheter ($5,000) by the national average cost-to-charge ratio of 0.311 for supplies & equipment from the FY 2023 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26944), we agreed with the applicant that the Phagenyx® System meets the cost criterion and therefore proposed to approve the Phagenyx® System for new technology add-on payments for FY 2024.

Based on preliminary information from the applicant at the time of the proposed rule, the applicant anticipated the cost to the hospital for the Phagenyx® System to be $5,000, which is the price of the single use, per patient catheter. We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of the Phagenyx® System would be $3,250 for FY 2024 (that is, 65 percent of the average cost of the technology).

We invited public comments on whether the Phagenyx® System meets the cost criterion and our proposal to approve new technology add-on payments for the Phagenyx® System for FY 2024 as a neurostimulation device delivering electrical stimulation to the oropharynx, to be used in addition to standard dysphagia care, as an aid to improve swallowing in patients with severe dysphagia post stroke, which corresponds to the Breakthrough Device designation.

Comment: The applicant submitted a public comment expressing support for the approval of the Phagenyx® System for the new technology add-on payment for FY 2024. The applicant reiterated that the Phagenyx® System meets the cost criterion and confirmed the proposed cost of the Phagenyx® System. The applicant also restated that the ICD–10–PCS code XWHD7Q7 (Insertion of neurostimulator lead into mouth and pharynx, via natural or artificial opening, new technology group 7) must be used to appropriately describe the procedure. The applicant provided an update on the availability of the device, stating the actual commercial availability of the device was established when FDA cleared the product from U.S. customs on April 12, 2023.

Response: Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the Phagenyx® System meets the cost criterion. The technology was granted FDA marketing authorization on September 16, 2022, as a Breakthrough Device with an indication as a neurostimulation device delivering electrical stimulation to the oropharynx, to be used in addition to standard dysphagia care, as an aid to improve swallowing in patients with severe dysphagia post stroke, which corresponds to the Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the Phagenyx® System for FY 2024. We consider the beginning of the newness period to commence on April 12, 2023, the date that the technology became commercially available for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the Phagenyx® System is $5,000. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the Phagenyx® System is $3,250 for FY 2024 (that is, 65 percent of the average cost of the technology). Cases involving the use of the Phagenyx® System that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code XWHD7Q7 (Insertion of neurostimulator lead into mouth and pharynx, via natural or artificial opening, new technology group 7).

(8) SAINT Neuromodulation System

Magnus Medical, Inc. submitted an application for new technology add-on payments for the SAINT Neuromodulation System for FY 2024. The SAINT Neuromodulation System is a non-invasive repetitive transcranial magnetic stimulation (rTMS) system that identifies an individualized target and delivers navigationally directed repetitive magnetic pulses to that individualized target located within the left dorsolateral prefrontal cortex (L–DLPFC) to treat Major Depressive Disorder (MDD) in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode. The SAINT Neuromodulation System consists of hardware devices (for example, stimulator with treatment coil and neuro-navigation) designed to deliver SAINT Therapy to a targeted area within the L–DLPFC, as well as cloud software that identifies the personalized target. We note that Magnus Medical, Inc. submitted an application for new technology add-on payments for the SAINT Neuromodulation System for FY 2023 under the name Magnus Neuromodulation System with SAINT Technology, as summarized in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28339 through 28341), that it withdrew prior to the issuance of the FY 2023 IPPS/LTCH PPS final rule (87 FR 48960).

Please refer to the online application posting for the SAINT Neuromodulation System, available at *https://mearis.cms.gov/public/publications/ntap/NTP2210157HBCW,* for additional detail describing the technology and the disorder treated by the technology.

According to the applicant, the SAINT Neuromodulation System received Breakthrough Device designation from FDA on July 2, 2021, for the treatment of MDD in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode. According to the applicant, the Magnus Neuromodulation System (SAINT Neuromodulation System) received 510(k) clearance from FDA on September 1, 2022, for the same indication. In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26945), the applicant noted that the technology is not anticipated to become available for sale until March 29, 2024, as several components of the SAINT Neuromodulation System are currently being integrated into a single unit to simplify and improve ease of use, and the applicant is bringing up scalable manufacturing of production systems to optimize commercial adoption of the technology. We noted that the applicant has submitted the application for new technology add-on payments for FY 2024 with a Breakthrough Device designation that corresponds to the SAINT Neuromodulation System, as it was assessed by FDA. Changes to the system to integrate components may require a reassessment by FDA to determine if the integrated, single unit system still meets the current Breakthrough Device designation, or if a new application for Breakthrough Device designation and additional 510(k) clearance is required. We noted that a device must be designated under FDA's Breakthrough Devices Program to be eligible under the alternative pathway, and that we would be interested in additional information regarding the Breakthrough Device status of the integrated, single unit system as it becomes available.

The applicant stated that ICD–10–PCS code X0Z0X18 (Computer-assisted

transcranial magnetic stimulation of prefrontal cortex, new technology group 8) may be used to uniquely describe procedures involving the use of the SAINT Neuromodulation System, effective October 1, 2022. The applicant stated that ICD–10–CM codes F32.2 (Major depressive disorder, single episode, severe without psychotic features) and F33.2 (Major depressive disorder, recurrent severe without psychotic features) may be used to currently identify the indication for the SAINT Neuromodulation System under the ICD–10–CM coding system.

With respect to the cost criterion, the applicant provided the following analysis to demonstrate that it meets the cost criterion. To identify potential cases representing patients who may be eligible for the SAINT Neuromodulation System, the applicant searched the FY 2021 MedPAR file for cases reporting one of the following ICD–10–CM codes: F32.2 (Major depressive disorder, single episode, severe without psychotic features) and F33.2 (Major depressive disorder, recurrent severe without psychotic features). Only MS–DRG 885 (Psychoses) had significant volume; all other MS–DRGs accounted for 1 percent or less of cases by volume. Using the inclusion/exclusion criteria described in the following table, the applicant identified 19,181 claims mapping to MS–DRG 885 (Psychoses). The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $94,697, which exceeded the average case-weighted threshold amount of $39,071. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the SAINT Neuromodulation System meets the cost criterion.

SAINT Neuromodulation System COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of ICD-10-CM Codes	F32.2 (Major depressive disorder, single episode, severe without psychotic features) F33.2 (Major depressive disorder, recurrent severe without psychotic features)
List of MS-DRGs	MS-DRG 885 (Psychoses)
Inclusion/Exclusion Criteria	The applicant searched for cases with ICD-10-CM diagnosis code F32.2 (Major depressive disorder, single episode, severe without psychotic features) or F33.2 (Major depressive disorder, recurrent severe without psychotic features). Only approved charges were used in the calculation of charges. Hospitals were removed from the calculation of charges if they were identified within the MedPAR data but not present within the FY 2023 Standardizing File provided by CMS.
Charges Removed for Prior Technology	The applicant stated that there are no charges for the prior technology, or the technology being replaced as analogous technologies are currently performed almost exclusively on an outpatient basis. Similarly, the applicant did not remove indirect charges related to the prior technology.
Standardized Charges	The applicant used the standardization formula provided in Technical Appendix A of the application. The applicant used all relevant values reported in the standardizing and impact files posted with the FY 2023 IPPS/LTCH PPS final rule and/or correction notice.
Inflation Factor	The applicant applied an inflation factor of 20.47% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS final rule.
Charges Added for the New Technology	The applicant added charges for the new technology by dividing the $19,500.00 cost of the new technology by the national average cost-to-charge ratio of 0.359 for the Other Services from the FY 2023 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26946), we agreed with the applicant that SAINT Neuromodulation System meets the cost criterion and therefore proposed to approve SAINT Neuromodulation System for new technology add-on payments for FY 2024 for the treatment of MDD in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

Based on preliminary information from the applicant at the time of the proposed rule, the applicant anticipated the total cost of the SAINT Neuromodulation System to the hospital to be $19,500.00 per patient, including personalized target identification using the SAINT software, neuro-navigation, and treatment for 50 sessions over 5 days. We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of the SAINT Neuromodulation System would be $12,675.00 for FY 2024 (that is, 65 percent of the average cost of the technology).

We invited public comments on whether the SAINT Neuromodulation System meets the cost criterion and our proposal to approve new technology add-on payments for the SAINT Neuromodulation System for FY 2024 for the treatment of MDD in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode, which corresponds to the Breakthrough Device designation.

Comment: Several commenters expressed support for our proposal to approve new technology add-on payments for the SAINT Neuromodulation System. Many commenters shared anecdotal experiences with transcranial magnetic stimulation (TMS) and advocated for implementing the SAINT Neuromodulation System in the inpatient setting. Some commenters emphasized the importance of the inpatient schedule of treatment. Many commenters stated that this technology will not be available to Medicare patients without a new technology add-on payment. There were a multitude of comments directly from people who participated in trials of the SAINT

Neuromodulation System who were supportive of CMS's proposal to approve new technology add-on payments and attributed significant and remarkable relief from depression resulting from use of the SAINT Neuromodulation System.

Response: We thank the commenters for their support and feedback.

Comment: Several commenters asserted that the SAINT Neuromodulation System meets the cost criterion and supported the applicant's use of MS–DRG 885 (Psychoses), and ICD–10–CM codes F32.2 (Major depressive disorder, single episode, severe without psychotic features) and F33.2 (Major depressive disorder, recurrent severe without psychotic features) in their analyses.

Response: We thank the commenters for their input.

Comment: A couple of commenters urged CMS to consider a higher reimbursement rate than what was proposed, stating that neuro-navigated TMS costs significantly more in the outpatient setting, than that of the SAINT Neuromodulation System's $19,500 inpatient technology cost. Commenters suggested that patients could resort to hospitalization to save on procedure costs, as a result. The commenters advocated for an increased rate of payment.

Response: It is unclear what the commenters are referring to by advocating for an increased rate of payment. The cost of the technology of $19,500 is based on information directly from the manufacturer. While the commenter may have concerns with regard to reimbursement in the outpatient setting, we believe the information for the cost per case of the SAINT Neuromodulation System in this final rule for the inpatient setting is accurate for the purposes of new technology add-on payments. We also rely on clinicians to determine whether to treat a patient in the inpatient or outpatient setting.

Comment: The applicant submitted a public comment in support of our proposal to approve new technology add-on payments for FY 2024 for the SAINT Neuromodulation System. The applicant reiterated that the SAINT Neuromodulation System meets the cost criterion, and reaffirmed the selection of codes and the MS–DRG used in the cost analysis, as discussed in the proposed rule. The applicant confirmed the proposed cost of the SAINT Neuromodulation System to the hospital of $19,500.00 per patient, including personalized target identification using the SAINT software, neuro-navigation, and treatment for 50 sessions over 5 days. The applicant also stated that they will commercially launch the SAINT Neuromodulation System, which is the subject of the Breakthrough Device designation (BDD) and is currently cleared by the FDA (510k number K220177, obtained September 1, 2022), on April 15, 2024. The applicant explained that the interval between the 510(k) clearance and the April 2024 launch date represents the time necessary to manufacture an adequate supply of SAINT Neuromodulation Systems and prepare for commercial launch. The applicant also stated that the company is also continuing to develop future versions of the technology but intends that any future modifications to the hardware system will be substantially equivalent to the hardware components in the current system, and that no changes to the BDD SAINT treatment are contemplated.

Response: We thank the applicant for this information and support to approve new technology add-on payments for the SAINT Neuromodulation System. As we have discussed in prior rulemaking (86 FR 45132; 77 FR 53348), generally, our policy is to begin the newness period on the date of FDA approval or clearance or, if later, the date of availability of the product on the U.S. market. The applicant states that the SAINT Neuromodulation System will be commercially available on April 15, 2024, but it is unclear whether the technology would be available for sale, prior to that date. At this time, we cannot determine a definitive, future newness date based on a documented delay in the technology's availability on the U.S. market. Absent additional information, we therefore consider the newness date for this technology to be September 1, 2022. We welcome updates from the applicant once the technology becomes commercially available for future rulemaking.

Comment: A comment was submitted on behalf of the applicant, Magnus Medical, stating that if the manufacturer makes changes to the SAINT Hardware System to integrate certain components but retains the same indication for use and intended patient population, the new version will continue to be recognized under the SAINT Neuromodulation System's existing Breakthrough Device designation (BDD). The commenter further requested general confirmation that new technology add-on payment eligibility for devices qualified under the alternative pathway for transformative new devices will continue to apply to a future iteration of the device as long as: (1) FDA determines the device versions to be substantially equivalent via the 510(k) review and clearance process; and (2) the new version continues to meet the requirements of the new technology add-on payment program (for example, the indication for the new 510(k) is the indication covered by the Breakthrough Device designation).

Response: We thank the commenter for its comment. As discussed previously, eligible devices under the alternative pathway for Breakthrough Devices are devices that are designated and market authorized by FDA as a Breakthrough Device for the indication covered by the Breakthrough Device designation. We understand that Magnus has outreached FDA on whether a subsequent cleared version of a device would still be considered a Breakthrough Device. We appreciate updates as they become available.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comments we received, we believe the SAINT Neuromodulation System meets the cost criterion. The technology was granted FDA marketing authorization on September 1, 2022, as a Breakthrough Device for the treatment of MDD in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode. Therefore, we are finalizing our proposal to approve new technology add-on payments for the SAINT Neuromodulation System for FY 2024. Absent additional information from the applicant, we consider the beginning of the newness period to commence on September 1, 2022, the date of FDA marketing authorization for the indication covered by its Breakthrough Device designation.

Based on the information available at the time of this final rule, the cost per case of the SAINT Neuromodulation System is $19,500.00. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the SAINT Neuromodulation System is $12,675.00 for FY 2024 (that is, 65 percent of the average cost of the technology). Cases involving the use of the SAINT Neuromodulation System that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code X0Z0X18 (Computer-assisted transcranial magnetic stimulation of prefrontal cortex, new technology group 8).

(9) TOPS™ System

Premia Spine, Inc. submitted an application for new technology add-on payments for the TOPS™ System for FY 2024. According to the applicant, the TOPS™ System is a motion preserving device inserted and affixed during spinal surgery after open posterior decompression to preserve normal spinal motion and provide stabilization of the lumbar intervertebral segment. The applicant stated that the TOPS™ System replaces anatomical structures, such as the lamina and the facet joints, which are removed during spinal decompression treatment to alleviate pain. We note that Premia Spine, Inc. submitted an application for new technology add-on payments for the TOPS™ System for FY 2023, as summarized in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28346), that it withdrew prior to the issuance of the FY 2023 IPPS/LTCH PPS final rule (87 FR 48960).

Please refer to the online application posting for the TOPS™ System, available at *https://mearis.cms.gov/public/publications/ntap/NTP2210146W0H2*, for additional detail describing the technology and the disease treated by the technology.

According to the applicant, the TOPS™ System received Breakthrough Device designation from FDA on October 26, 2020, for patients between 35 and 80 years of age suffering from neurogenic claudication resulting from degenerative spondylolisthesis up to Grade I with moderate to severe lumbar spinal stenosis and either the thickening of the ligamentum flavum or scaring facet joint capsule at one level from L2 to L5. The applicant stated that it was seeking premarket approval from FDA for the following indication: for patients between the ages 35 and 80 years suffering from degenerative spondylolisthesis up to Grade I with moderate to severe lumbar spinal stenosis and either the thickening of the ligamentum flavum or scarring facet joint capsule at one level from L2 to L5. We noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26950) that the proposed premarket approval indication did not include limitation to neurogenic claudication as noted in the Breakthrough Device designation. We noted that, as previously stated, under the eligibility criteria for approval under the alternative pathway for certain transformative devices, only the use of the technology for the indication that corresponds to the technology's Breakthrough Device designation would be eligible for the new technology add-on payment for FY 2024. The applicant subsequently received premarket approval from FDA on June 15, 2023, for patients between 35 and 80 years of age with symptomatic degenerative spondylolisthesis up to Grade I, with moderate to severe lumbar spinal stenosis and either the thickening of the ligamentum flavum and/or scarring of the facet joint capsule at one level from L3 to L5.

The applicant stated that effective October 1, 2021, the following ICD–10–PCS procedure code may be used to uniquely describe procedures involving the use of TOPS™ System: XRHB018 (Insertion of posterior spinal motion preservation device into lumbar vertebral joint, open approach, new technology group 8). The applicant stated that ICD–10–CM codes M43.16 (Spondylolisthesis, lumbar region), M48.061 (Spinal stenosis, lumbar region, without neurogenic claudication) and M48.062 (Spinal stenosis, lumbar region, with neurogenic claudication) may be used to currently identify the indication for the TOPS™ System under the ICD–10–CM coding system. We noted that ICD–10–CM code M48.061 was not relevant for identification of the indication under Breakthrough Device designation.

With respect to the cost criterion, the applicant provided the following analysis to demonstrate that it meets the cost criterion. To identify potential cases representing patients who may be eligible for the TOPS™ System, the applicant searched the FY 2021 MedPAR file for cases reporting one of the ICD–10–PCS codes listed in table 10.2.A.—TOPS™ System Codes—FY 2024 associated with the proposed rule. Using the inclusion/exclusion criteria described in the following table, the applicant identified 669 claims mapping to MS–DRG 518. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $175,574, which exceeded the average case-weighted threshold amount of $123,029. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the TOPS™ System meets the cost criterion.

TOPS™ SYSTEM COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of ICD-10-PCS Codes	Please see Table 10.2.A. - TOPS™ System Codes - FY 2024 associated with the proposed rule for the complete list provided by the applicant.
List of MS-DRGs	518 (Back and Neck Procedures Except Spinal Fusion with MCC Or Disc Device Neurostimulator)
Inclusion/Exclusion Criteria	The applicant identified cases reporting any ICD-10-CM code listed in Table 10.2.A. TOPS™ System Codes - FY 2024 associated with the proposed rule. The applicant limited its analysis to MS-DRG 518 as this is the single MS-DRG to which the ICD-10-PCS code (XRHB018) created effective FY 2022 to describe the TOPS System maps. Any MS-DRG with a total discharge count less than 11 was imputed with a count of 11. The applicant limited the analysis to IPPS cases that would be used in rate-setting following the CMS methodology.
Charges Removed for Prior Technology	Per the applicant, use of the TOPS™ System is expected to replace a portion of devices included in these claims, although it will not replace all devices, nor any medical supplies required to perform the procedure. However, an estimate of the percentage of these total charges for devices that would be replaced could not be determined. To be as conservative as possible, the analysis removed 100% of charges associated with Medical/Surgical Supplies and Devices (revenue centers 027x, and 0624). According to the applicant, the financial impact of utilizing the TOPS™ System on hospital resources compared to prior technologies is minimal. The applicant did not remove indirect charges related to the prior technology.
Standardized Charges	The applicant used the standardization formula provided in Technical Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2021 IPPS/LTCH PPS correction notice.
Inflation Factor	The applicant applied an inflation factor of 20.4686% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule.
Charges Added for The New Technology	The applicant estimated the average sales price of the TOPS™ System for a single level construct to be $17,500. The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio of 0.281 for implantable devices from the FY 2023 IPPS/LTCH PPS final rule. No other hospital charges were assumed to be required for implanting the TOPS™ System and cost was estimated by the applicant at $0.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26951), we agreed with the applicant that the TOPS™ System meets the cost criterion and therefore proposed to approve the TOPS™ System for new technology add-on payments for FY 2024, subject to the technology receiving FDA marketing authorization as a Breakthrough Device for the indication corresponding to the Breakthrough Device designation by July 1, 2023.

Based on preliminary information from the applicant at the time of the proposed rule, the applicant anticipated the total cost of the TOPS™ System to the hospital to be $17,500 for a single level construct. Per the applicant, as the TOPS™ System is anticipated to only be implanted at one level, the per-patient anticipated cost to the hospital is $17,500. We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 65 percent of the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case. As a result, we that the maximum new technology add-on payment for a case involving the use of the TOPS™ System would be $11,375 for FY 2024 (that is, 65 percent of the average cost of the technology).

We invited public comments on whether the TOPS™ System meets the cost criterion and our proposal to approve new technology add-on payments for the TOPS™ System for FY 2024 subject to the technology receiving FDA marketing authorization as a Breakthrough Device for the indication corresponding to the Breakthrough Device designation by July 1, 2023.

We did not receive any comments any public comments related to the TOPS™ System. Based on the information provided in the application for new technology add-on payments, we believe the TOPS™ System meets the cost criterion. The technology received FDA premarket approval on June 15, 2023 as a Breakthrough Device, with an indication for patients between 35 and 80 years of age with symptomatic degenerative spondylolisthesis up to Grade I, with moderate to severe lumbar spinal stenosis and either the thickening of the ligamentum flavum and/or scarring of the facet joint capsule at one level from L3 to L5, which is covered by its Breakthrough Device designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for the TOPS™ System for FY 2024. We consider the beginning of the newness period to commence on June 15, 2023, the date on which technology received FDA marketing authorization for the indication covered by its Breakthrough Device designation. We note that, under the eligibility criteria for approval under the alternative pathway for certain transformative new devices, only the use of TOPS™ for patients suffering from neurogenic claudication resulting from degenerative spondylolisthesis, and the FDA Breakthrough Device designation it received for that use, are relevant for purposes of the new technology add-on payment application for FY 2024. Since the Breakthrough Device designation is limited to patients with neurogenic claudication specifically, as opposed to the PMA indication for patients with symptomatic disease, only use of the technology for patients with neurogenic claudication is relevant for new technology add-on payment purposes.

Based on the information available at the time of this final rule, the cost per case of the TOPS™ System is $17,500 for a single level construct. Per the applicant, as the TOPS™ System is anticipated to only be implanted at one level, the per-patient anticipated cost to the hospital is $17,500. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of the TOPS™ System is $11,375 for FY 2024 (that is, 65 percent of the average cost of the technology). Cases involving the use of the TOPS™ System that are eligible for new technology add-on payments will be identified by ICD–10–PCS code XRHB018 (Insertion of posterior spinal motion preservation device into lumbar

vertebral joint, open approach, new technology group 8) in combination with ICD–10–CM code M48.062 (Spinal stenosis, lumbar region, with neurogenic claudication).

b. Alternative Pathways for Qualified Infectious Disease Products (QIDPs)

(1) taurolidine/heparin

CorMedix Inc. submitted an application for new technology add-on payments for taurolidine/heparin for FY 2024. Per the applicant, taurolidine/heparin is a proprietary formulation of taurolidine, a thiadiazinane antimicrobial, and heparin, an anti-coagulant, that is under development for use as catheter lock solution, with the aim of reducing the risk of catheter-related bloodstream infections (CRBSI) from in-dwelling catheters in patients undergoing hemodialysis (HD) through a central venous catheter (CVC). We note that CorMedix Inc. submitted an application for new technology add-on payments for taurolidine/heparin for FY 2023 under the name DefenCath™ and received conditional approval for new technology add-on payments for FY 2023, subject to DefenCath™ receiving FDA marketing authorization before July 1, 2023 (87 FR 48978 through 48982). In the proposed rule, we explained that if DefenCath™ receives FDA marketing authorization before July 1, 2023, the new technology add-on payment for cases involving the use of this technology would be made effective for discharges beginning in the first quarter after FDA marketing authorization is granted. We stated that if the FDA marketing authorization is received on or after July 1, 2023, no new technology add-on payments would be made for cases involving the use of DefenCath™ for FY 2023. We noted that the applicant stated that it submitted this second new technology add-on payment application for FY 2024 in the event it does not obtain FDA approval prior to July 1, 2023. We further noted that in the event DefenCath™ does receive FDA marketing authorization before July 1, 2023, evaluation of this FY 2024 application would no longer be necessary, and we would propose to instead continue the new technology add-on payment for DefenCath™ for FY 2024. We note that Defencath™ did not receive FDA marketing authorization by July 1, 2023, and therefore no add-on payments will be made for this technology for FY 2023, and we are instead making a determination regarding this application for FY 2024.

Please refer to the online application posting for taurolidine/heparin, available at *https://mearis.cms.gov/public/publications/ntap/NTP221014UJ89G*, for additional detail describing the technology and the disease treated by the technology.

According to the applicant, taurolidine/heparin received QIDP designation from FDA in 2015 for the prevention of CRBSI in patients with end-stage renal disease (ESRD) receiving HD through a CVC and has been granted FDA Fast Track status. The applicant indicated that it was pursuing an NDA under FDA's LPAD for the same indication. The applicant noted that FDA issued a Complete Response Letter, and the NDA is pending resubmission.

The applicant stated that effective October 1, 2022, the following ICD–10–PCS code may be used to uniquely describe procedures involving the use of taurolidine/heparin: XY0YX28 (Extracorporeal introduction of taurolidine anti-infective and heparin anticoagulant, new technology group 8).

With respect to the cost criterion, the applicant provided two analyses to demonstrate that it meets the cost criterion. For each analysis, the applicant searched the FY 2021 MedPAR file using a different combination of codes to identify potential cases representing patients who may be eligible for taurolidine/heparin.

Per the applicant, taurolidine/heparin will be used for patients receiving HD through a CVC. The applicant stated that coding to identify this population is difficult because the available CVC codes only describe the insertion of a CVC. The applicant asserted that it is not possible to identify in the MedPAR file those patients who had previously received a CVC and are now hospitalized and receiving HD. Therefore, the applicant developed two sets of selection criteria. Analysis A searched for claims with presence of a diagnosis code for ESRD, chronic kidney disease (CKD), AKI, or ATN in combination with diagnosis and procedure codes for HD. Analysis B searched for claims with presence of a diagnosis code for ESRD, CKD, AKI, or ATN with codes for both HD (diagnosis and procedure codes) and CVC (procedure codes). The applicant explained that Analysis A overstates the population of patients eligible for taurolidine/heparin because it includes any patient receiving HD, regardless of whether a central venous catheter is used. The applicant further explained that Analysis B undercounts the potential cases because CVC codes are not always available on inpatient claims. Please see Table 10.10.A Taurolidine/Heparin Codes—FY 2024 associated with the proposed rule for a complete list of ICD–10–CM and ICD–10–PCS codes provided by the applicant.

Under Analysis A, using the inclusion/exclusion criteria described in the following table, the applicant identified 412,436 claims mapping to 494 MS–DRGs. Please see Table 10.10.A.—Taurolidine/Heparin Codes—FY 2024 associated with the proposed rule for a complete list of MS–DRGs provided by the applicant. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $230,720, which exceeded the average case-weighted threshold amount of $141,035.

Under Analysis B, using the inclusion/exclusion criteria described in the following table, the applicant identified 66,861 claims mapping to 410 MS–DRGs. Please see Table 10.10.A.—Taurolidine/Heparin Codes—FY 2024 associated with the proposed rule for a complete list of MS–DRGs provided by the applicant. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $313,587, which exceeded the average case-weighted threshold amount of $201,755.

Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all scenarios, the applicant asserted that taurolidine/heparin meets the cost criterion.

Taurolidine/Heparin COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR File
ICD-10-CM Codes	Analysis A and B N17.0 Acute kidney failure with tubular necrosis N17.9 Acute kidney failure, unspecified N18.1 Chronic kidney disease, stage 1 N18.2 Chronic kidney disease, stage 2 (mild) N18.30 Chronic kidney disease, stage 3 unspecified N18.31 Chronic kidney disease, stage 3a N18.32 Chronic kidney disease, stage 3b N18.4 Chronic kidney disease, stage 4 N18.5 Chronic kidney disease, stage 5 N18.6 End stage renal disease N18.9 Chronic kidney disease, unspecified
ICD-10-PCS Codes	Analysis A and B: Please see Table 10.10.A. - Taurolidine/Heparin Codes - FY 2024 associated with the proposed rule for a complete list of ICD-10-PCS codes included in the cost analysis.
List of MS-DRGs	Analysis A and B: Please see Table 10.10.A. - Taurolidine/Heparin Codes - FY 2024 associated with the proposed rule for a complete list of MS-DRGs included in the cost analysis.
Inclusion/Exclusion Criteria	The applicant stated that it imputed a case count of 11 to any MS-DRG with fewer than 11 cases. Data were trimmed to include only claims that would be used for Medicare IPPS rate setting (fee-for-service IPPS discharges, plus Maryland hospital discharges).
Charges Removed for Prior Technology	The applicant stated that taurolidine/heparin does not replace any prior technologies, and therefore they did not remove any prior or related technology charges.
Standardized Charges	The applicant used the standardization formula provided in Technical Appendix A of the application. The applicant used all relevant values reported in the impact file posted with the FY 2023 IPPS/LTCH PPS final rule.
Inflation Factor	The applicant applied the 2-year inflation factor of 13.2% to the standardized charges (to inflate the data from 2021 to 2024), based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule.
Charges Added for the New Technology	The applicant stated that the average per patient cost of the taurolidine/heparin to the hospital will be $22,815. The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio (CCR) of 0.184 for drugs from the FY 2023 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26957), we agreed with the applicant that taurolidine/heparin meets the cost criterion based on the analysis presented. We also welcomed additional information on using additional codes and/or criteria to better target cases of taurolidine/heparin for the cost criterion.

We stated that therefore, if taurolidine/heparin does not receive FDA approval by July 1, 2023, to receive new technology add-on payments beginning with FY 2023, per § 412.87(e)(3), we proposed to conditionally approve taurolidine/heparin for new technology add-on payments for FY 2024, subject to the technology receiving FDA marketing authorization by July 1, 2024. If taurolidine/heparin receives FDA marketing authorization before July 1, 2024, the new technology add-on payment for cases involving the use of this technology would be made effective for discharges beginning in the first quarter after FDA marketing authorization is granted. If FDA marketing authorization is received on or after July 1, 2024, no new technology add-on payments will be made for cases involving the use of taurolidine/heparin for FY 2024. If taurolidine/heparin receives FDA marketing authorization prior to July 1, 2023, we proposed to continue making new technology add-on payments for taurolidine/heparin in FY 2024.

Based on preliminary information from the applicant at the time of the proposed rule, the applicant stated the Wholesale Acquisition Cost of taurolidine/heparin is $1,170 per three milliliter vial taurolidine/heparin. The applicant noted that two vials of taurolidine/heparin (one vial for each lumen) will be used for each HD session and that while HD typically occurs three times/week for patients in the outpatient setting, inpatients may receive HD daily or every other day, depending on the severity of their disease. According to the applicant, on average, patients would receive 9.75 HD treatments per inpatient stay based upon the average length of stay of 13.3 days, which would require 19.5 vials of taurolidine/heparin. Thus, the applicant anticipated the cost of taurolidine/heparin to the hospital per patient to be $22,815. We stated in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26957) that we were interested in additional information as to how the length of stay for patients on HD and the estimation of daily or every other day dialysis were determined for purposes of estimating the anticipated average cost. We also noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS receives prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments for QIDPs to the lesser of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of taurolidine/heparin would be $17,111.25 for FY 2024 (that is, 75 percent of the average cost of the technology).

We invited public comments on whether taurolidine/heparin meets the cost criterion and our proposal to approve new technology add-on payments for taurolidine/heparin for FY 2024 for the prevention of CRBSI in patients with ESRD receiving HD through a CVC.

Comment: A commenter submitted a comment in support of the implementation of add-on payments for taurolidine/heparin for the treatment of CRBSI from in-dwelling catheters in ESRD patients undergoing HD through a CVC as well CMS's proposal for conditional approval.

Response: We thank the commenter for its support.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comment we received, we believe taurolidine/heparin meets the cost criterion. Therefore, we are granting conditional approval for taurolidine/heparin for new technology add-on payments for FY 2024, subject to the technology receiving FDA marketing authorization by July 1, 2024 (that is, by July 1 of the fiscal year for which the applicant applied for new technology add-on payments (2024)). In the proposed rule we stated that as an application submitted under the alternative pathway for certain antimicrobial products at § 412.87(d), taurolidine/heparin is eligible for conditional approval for new technology add-on payments if it does not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments (that is, July 1, 2024) (88 FR 26956 to 26957). If taurolidine/heparin receives FDA marketing authorization before July 1, 2024, the new technology add-on payment for cases involving the use of this technology would be made effective for discharges beginning in the first quarter after FDA marketing authorization is granted. If FDA marketing authorization is received on or after July 1, 2024, no new technology add-on payments will be made for cases involving the use of taurolidine/heparin for FY 2024.

Based on the information available at the time of this final rule, the cost per case of taurolidine/heparin is $22,815. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of taurolidine/heparin is $17,111.25 for FY 2024 (that is, 75 percent of the average cost of the technology). Cases involving the use of taurolidine/heparin that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure code XY0YX28 (Extracorporeal introduction of taurolidine anti-infective and heparin anticoagulant, new technology group 8).

(2) REZZAYO™ (Rezafungin for Injection)

Cidara Therapeutics submitted an application for new technology add-on payments for REZZAYO™ (rezafungin for injection) for FY 2024. According to the applicant, REZZAYO™ is an echinocandin antifungal drug for the treatment of candidemia and invasive candidiasis in patients 18 years of age or older.

Please refer to the online application posting for REZZAYO™, available at *https://mearis.cms.gov/public/publications/ntap/NTP221017057WN*, for additional detail describing the technology and the disease treated by the technology.

According to the applicant, REZZAYO™ received QIDP designation from FDA on June 27, 2017, for treatment of candidemia and/or invasive candidiasis. The applicant stated that the NDA for REZZAYO™ was approved on March 22, 2023, for use in patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis. Approval of this indication is based on limited clinical safety and efficacy data for REZZAYO™. The applicant stated that REZZAYO™ would not be commercially available until July 2023, but we note that a rationale for the delay in market availability was not provided. Due to the timing of receipt of FDA approval, we stated in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26958) that we were interested in additional information on whether the technology is considered a QIDP under this NDA.

The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for REZZAYO™ beginning in FY 2024 and was granted approval for the following procedure codes effective October 1, 2023: XW033R9 (Introduction of rezafungin into peripheral vein, percutaneous approach, new technology group 9) and XW043R9 (Introduction of rezafungin into central vein, percutaneous approach, new technology group 9).

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for REZZAYO™, the applicant searched the FY 2021 MedPAR file for cases reporting one of the ICD–10–CM diagnosis codes for candidemia or invasive candidiasis (in any position) listed in the table in this section. Using the inclusion/exclusion criteria described in the following table, the applicant identified 50,939 claims mapping to 540 MS–DRGs. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $177,099.74, which exceeded the average case-weighted threshold amount of $97,375.67. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that REZZAYO™ meets the cost criterion.

REZZAYO™ COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
ICD-10-CM Codes	B37.1 Pulmonary candidiasis (Candidal bronchitis, Candidal pneumonia) B37.4 Candidiasis of other urogenital sites B37.49 Other urogenital candidiasis B37.5 Candida meningitis B37.6 Candida Endocarditis B37.7 Candida Sepsis B37.81 Candidiasis of other sites B37.82 Candida Enteritis B37.89 Other sites of candidiasis
List of MS-DRGs	Please see Table 10.18.A. - REZZAYO™ Codes - FY 2024 associated with the proposed rule for a complete list of MS-DRGs provided by the applicant
Inclusion/Exclusion Criteria	The applicant identified cases by using the ICD-10-CM diagnosis codes previously listed, in any diagnosis position. Managed care cases, claims submitted only for graduate medical education payments, claims with ancillary costs of zero and claims that were statistical outliers within the MS-DRG were excluded. The applicant calculated the average charge per case for each MS-DRG, using only covered departmental charges used by CMS for ratesetting. Charges for organ acquisition were not included.
Charges Removed for Prior Technology	Per the applicant, REZZAYO™ would replace the use of existing echinocandins, the class of antifungal drugs used to treat candidemia and invasive candidiasis. The applicant stated that Micafungin was the predominant echinocandin in the market in 2021 (about 82% per IQVIA Drug Distribution Data in 2021) while other therapies are mostly generic and have lower costs. Using the per day cost of Micafungin ($100), average sales price in 2021 ($1.00 per 1 mg), and an average dose of 100 mg/day for acute treatment, the applicant multiplied the per day cost by the length of stay reported on the discharge. The applicant then converted the cost per stay to a charge using the drugs departmental national CCR of 0.184 from the FY 2023 IPPS/LTCH PPS final rule to calculate an average charge amount per MS-DRG. The applicant did not remove indirect charges related to the prior technology.
Standardized Charges	The applicant used the standardization formula provided in Technical Appendix A of the application. The applicant used all relevant values reported in the standardizing file posted with the FY 2023 IPPS/LTCH PPS final rule.
Inflation Factor	The applicant applied an inflation factor of 20.5% to the standardized charges, based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule.
Charges Added for the New Technology	The applicant stated that the average sales price of the technology has yet to be determined, and that when the price is available, a revised cost analysis will be provided that includes estimated hospital charges for the technology.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26958), we agreed with the applicant that REZZAYO™ meets the cost criterion and therefore proposed to approve REZZAYO™ for new technology add-on payments for FY 2024 for use in patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis.

The applicant had not provided an estimate for the cost of REZZAYO™ at the time of the proposed rule. According to the applicant, REZZAYO™ is to be administered once weekly by intravenous infusion, with an initial loading dose of 400 mg and followed by a 200 mg dose once weekly thereafter. According to the applicant, in the pivotal trial, on average patients received 14 days of IV treatment and that data also showed that patients stay in the hospital after being diagnosed with invasive candidiasis for 14 days. Therefore, the applicant estimated the average dose of medication during an inpatient stay to be 600 mg, given the initial 400 mg dose plus one 200 mg maintenance dose prior to discharge from the hospital. We stated that we expected the applicant to submit cost information prior to the final rule, and we would provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule. Any new technology add-on payment for REZZAYO™ would be subject to our policy under § 412.88(a)(2) where we limit new technology add-on payments for QIDPs to the lesser of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS–DRG payment for the case.

We invited public comments on whether REZZAYO™ meets the cost criterion and our proposal to approve new technology add-on payments for REZZAYO™ for FY 2024 for use in patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis.

Comment: The applicant submitted a public comment urging CMS to finalize its proposal to approve REZZAYO™ for new technology add-on payments and reiterating that REZZAYO™ meets the criteria for approval. The applicant also stated that the wholesale acquisition cost of REZZAYO™ will be $1,950 per 200 mg vial. Per the applicant, as discussed in the proposed rule, the estimated average dose during an inpatient stay is 600mg and therefore the average cost of the technology would be $5,850 per inpatient stay. The applicant recommended a maximum add-on payment of $4,387.50 or 75 percent of the average cost of REZZAYO™ of $5,850.

Response: We thank the applicant for its support and the additional information.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comment we received, we believe REZZAYO™ meets the cost criterion. The technology was granted FDA marketing authorization on March 22, 2023, with an indication for use in patients 18 years of age or older who have limited or no alternative options for the treatment of candidemia and invasive candidiasis, which is covered by its QIDP designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for REZZAYO™ for FY 2024. The applicant has stated that the technology is not yet available for sale but has not provided information regarding a documented delay in market availability. Absent additional information, we therefore consider the newness period to commence on the date of marketing authorization, March 22, 2023.

Based on the information available at the time of this final rule, the cost per case of REZZAYO™ is $5,850. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that

the maximum new technology add-on payment for a case involving the use of REZZAYO™ is $4,387.50 for FY 2024 (that is, 75 percent of the average cost of the technology). Cases involving the use of REZZAYO™ that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes: XW033R9 (Introduction of rezafungin into peripheral vein, percutaneous approach, new technology group 9) or XW043R9 (Introduction of rezafungin into central vein, percutaneous approach, new technology group 9).

(3) XACDURO® (Sulbactam/Durlobactam)

Entasis Therapeutics, Inc. submitted an application for new technology add-on payments for XACDURO® (sulbactam/durlobactam, referred to as ''SUL–DUR'' in the proposed rule) for FY 2024. According to the applicant, XACDURO® is a penicillin derivative and classified as a β-lactamase inhibitor but also has intrinsic antibacterial activity against Acinetobacter baumannii and other members of the Acinetobacter baumannii-calcoaceticus complex (ABC). According to the applicant, sulbactam, in combination with durlobactam, will be used for the treatment of hospital-acquired and ventilator-associated bacterial pneumonia (HABP/VABP) and bloodstream infections (BSI) due to Acinetobacter baumannii.

Please refer to the online application posting for XACDURO®, available at *https://mearis.cms.gov/public/publications/ntap/NTP221017F5WKE*, for additional detail describing the technology and the disease treated by the technology.

According to the applicant, XACDURO® received QIDP designation for the treatment of HABP/VABP and bloodstream infections due to Acinetobacter baumannii. The applicant stated that it was seeking approval of a broader NDA from FDA for the treatment of adults with infections due to Acinetobacter baumannii-calcoaceticus complex organisms, including multidrug-resistant and carbapenem-resistant strains. According to the applicant, patients are expected to receive 1 to 1.5 grams sulbactam and 1 to 1.5 grams durlobactam every 6 hours for an average of 10 days. In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26959), we noted that, under the eligibility criteria for approval under the alternative pathway for certain antimicrobial products, only the use of XACDURO® for the treatment of HABP/VABP and bloodstream infections due to Acinetobacter baumannii, and the FDA QIDP designation it received for that use, were relevant for purposes of the new technology add-on payment application for FY 2024. We also noted that, as an application submitted under the alternative pathway for certain antimicrobial products at § 412.87(d), XACDURO® was eligible for conditional approval for new technology add-on payments if it did not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology receives FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments (that is, July 1, 2024). The applicant stated that XACDURO® received FDA approval on May 23, 2023, with an indication for use in patients 18 years of age and older for the treatment of HABP/VABP, caused by susceptible isolates of Acinetobacter baumanni-calcoaceticus complex. Since the indication for which the technology received FDA approval is included within the scope of the QIDP designation, it appears that the proposed FDA indication is appropriate for new technology add-on payment under the alternative pathway criteria.

The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for XACDURO® beginning in FY 2024 and was granted approval for the following procedure codes effective October 1, 2023: XW033K9 (Introduction of sulbactam-durlobactam into peripheral vein, percutaneous approach, new technology group 9) and XW043K9 (Introduction of sulbactam-durlobactam into central vein, percutaneous approach, new technology group 9). The applicant provided a list of diagnosis codes that may be used to currently identify the indication for XACDURO® under the ICD–10–CM coding system. Please refer to the online application posting for the complete list of ICD–10–CM codes provided by the applicant. We noted that the applicant included ICD–10–CM codes that correspond to the broader anticipated NDA indication. As previously noted, only use of the technology for the indications corresponding to the QIDP designation would be relevant for new technology add-on payment purposes. We believed the relevant ICD–10–CM codes to identify the QIDP-designated indications were: Y95 and J15.6 (describing HABP due to Acinetobacter baumannii); or J95.851 and B96.89 (describing VABP due to Acinetobacter baumannii); or A41.59 (Other Gram-negative sepsis) for bloodstream infection due to Acinetobacter baumannii. We note that since the approved NDA indication is limited to HABP and VABP due to Acinetobacter baumannii and does not include bloodstream infections, we believe ICD–10–CM code A41.59 is no longer is relevant to describe the indication relevant for new technology add-on payment purposes.

With respect to the cost criterion, the applicant provided two analyses to demonstrate that it meets the cost criterion. For each analysis, the application searched the FY 2021 MedPAR file using a different combination of codes to identify potential cases representing patients who may be eligible for XACDURO®. The applicant explained that it used different codes to demonstrate different cohorts that may be eligible for the technology. Each analysis followed the order of operations described in the following table.

According to the applicant, XACDURO® was anticipated to be indicated in adults for the treatment of infections due to ABC complex including multi-drug resistant and carbapenem-resistant strains upon FDA approval. Therefore, in the first analysis, the applicant identified ICD–10–CM codes that reflect the anticipated FDA indication. According to the QIDP designation, XACDURO® was designated for the treatment of HABP/VABP and bloodstream infections due to Acinetobacter baumannii. Therefore, in the second analysis, the applicant identified ICD–10–CM codes that reflect the QIDP-designated indications. Please see Table 10.23.A.—XACDURO® Codes—FY 2024 associated with the proposed rule for the complete list of codes provided by the applicant.

For Analysis 1, using the inclusion/exclusion criteria described in the following table, the applicant identified 440,756 cases mapping to 452 MS–DRGs. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $182,553, which exceeded the average case-weighted threshold amount of $76,364.

For Analysis 2, using the inclusion/exclusion criteria described in the following table, the applicant identified 214,694 claims mapping to 330 MS–DRGs. The applicant followed the order of operations described in the following table and calculated a final inflated average case-weighted standardized charge per case of $202,171, which exceeded the average case-weighted threshold amount of $85,665.

Because the final inflated average case-weighted standardized charge per

case exceeded the average case-weighted threshold amount in both analyses, the applicant asserted that XACDURO® meets the cost criterion.

XACDURO® COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of MS-DRGs and ICD-10-CM codes	Please see the Table 10.23.A. - XACDURO® Codes - FY 2024 for the list of MS-DRGs and ICD-10-CM codes included in each cost analysis.
Inclusion/Exclusion Criteria	Analysis 1: Per the applicant, as there is no ICD-10-CM diagnosis code to identify patients treated for infections due to Acinetobacter baumannii-calcoaceticus complex organisms, including multidrug-resistant and carbapenem-resistant strains, therefore, ICD-10-CM diagnosis codes for infection, pneumonia, and respiratory failure indicative of complications and comorbidities for the purposes of MS-DRG payment and in the primary diagnosis position were used. The applicant stated that in addition to these ICD-10-CM diagnosis codes, ICD-10-CM diagnosis codes for local skin infection and nosocomial condition coded in diagnosis code positions 2-25 and indicated as not present on admission (present on admission indicator equal to N, U, W, 1) were used to identify proxy cases. MS-DRGs with case volume less than 11 total cases were excluded. Analysis 2: The applicant only included ICD-10-CM diagnosis codes specific to the QIDP's designated indications. Therefore, ICD-10-CM diagnosis codes related to HABP/VABP and bloodstream infections. MS-DRGs with case volume less than 11 total cases were excluded.
Charges Removed for Prior Technology	Per the applicant, it removed 100% of drug charges from cases to estimate the reduction in drug use and charges due to the use of XACDURO®. The applicant did not remove indirect charges related to the prior technology.
Standardized Charges	The applicant used the standardization formula provided in Technical Appendix A of the application. The applicant used all relevant values reported in the standardizing file posted with the FY 2021 IPPS/LTCH PPS final rule.
Inflation Factor	The applicant applied a three-year inflation factor of 20.5% to the standardized charges, which was used for the FY 2021 MedPAR analysis, to update the charges from FY 2021 to FY 2024.
Charges Added for the New Technology	Per the applicant, the anticipated average cost of XACDURO® is $15,000 per stay. The applicant stated that patients are expected to receive 1 to 1.5 grams sulbactam and 1 to 1.5 grams durlobactam every 6 hours for an average of 10 days. The cost per patient was converted to charges by dividing the cost by the national average cost-to-charge ratio of 0.184 for drugs from the FY 2023 IPPS/LTCH PPS proposed rule. The applicant did not add indirect charges related to the new technology.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26960), we agreed with the applicant that XACDURO® meets the cost criterion and therefore proposed to approve XACDURO® for new technology add-on payments for FY 2024 for the treatment of HABP/VABP and bloodstream infections due to Acinetobacter baumannii, subject to the technology receiving FDA marketing authorization for the indication corresponding to the QIDP designation by July 1, 2023. We stated that as an application submitted under the alternative pathway for certain antimicrobial products at § 412.87(d), XACDURO® was eligible for conditional approval for new technology add-on payments if it did not receive FDA marketing authorization by the July 1 deadline specified in § 412.87(e)(2), provided that the technology received FDA marketing authorization by July 1 of the particular fiscal year for which the applicant applied for new technology add-on payments (that is, July 1, 2024). If XACDURO® received FDA marketing authorization before July 1, 2024, the new technology add-on payment for cases involving the use of this technology would be made effective for discharges beginning in the first quarter after FDA marketing authorization is granted. If FDA marketing authorization was received on or after July 1, 2024, no new technology add-on payments would be made for cases involving the use of XACDURO® for FY 2024.

Based on preliminary information from the applicant at the time of the proposed rule, the applicant stated that the anticipated cost of XACDURO® was $15,000 per stay based upon the expectation that patients would receive 1 to 1.5 grams sulbactam and 1 to 1.5 grams durlobactam every 6 hours for an average of 10 days. The applicant did not provide the cost per vial and did not supply supporting information with regard to the average of 10 days. Therefore, we stated in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26960) that we were interested in information regarding the cost per vial and the average of 10 days to support the anticipated average cost of $15,000 provided by the applicant. We noted that the cost information for this technology may be updated in the final rule based on revised or additional information CMS received prior to the final rule. Under § 412.88(a)(2), we limit new technology add-on payments for QIDPs to the lesser of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS–DRG payment for the case. As a result, we proposed that the maximum new technology add-on payment for a case involving the use of XACDURO® when used for the treatment of HABP/VABP and bloodstream infections due to Acinetobacter baumannii would be $11,250 for FY 2024 (that is, 75 percent of the average cost of the technology).

We invited public comments on whether XACDURO® meets the cost criterion and our proposal to approve new technology add-on payments for XACDURO® for FY 2024 for the treatment of HABP/VABP and bloodstream infections due to Acinetobacter baumannii subject to the technology receiving marketing authorization consistent with its QIDP designation by July 1, 2023.

Comment: The applicant submitted a public comment in support of its application and responding to questions raised by CMS in the proposed rule

regarding the cost information. In its comment letter, the applicant stated that XACDURO® for injection is supplied as a kit containing 3 single-dose vials. Per the applicant, one vial contains sulbactam 1g and 2 vials each contains durlobactam 0.5g. The applicant stated that the expected dosing schedule for XACDURO varies, but most patients will receive one infusion every 6 hours, for a total of 4 kits per 24-hour period. The applicant provided the following table showing the dosage of XACDURO® based on renal function.

Dose of Sulbactam and Durlobactam (g) Sulbactam and Durlobactam (g)	Estimated CLcr (mL/min)	Frequency
Sulbactam 1g and Durlobactam 1g	Greater than or equal to 130	Every 4 hours
	45 to 129	Every 6 hours
	30 to 44	Every 8 hours
	15 to 29	Every 12 hours
	Less than 15	For patients initiating XACDURO®: every 12 hours for the first 3 doses (0, 12, and 24 hours) followed by every 24 hours after the third dose. For patients currently receiving XACDURO® whose CLcr declines to less than 15 mL/min: every 24 hours

BILLING CODE 4120–01–C

The applicant stated that the recommended duration of treatment is 7 to 14 days and should be guided by the severity and site of infection and the patient's clinical and bacteriological progress.

Per the applicant, the claims data analysis would not allow for identifying XACDURO® dosing based on creatinine clearance utilizing ICD–10–CM, HCPCS Level I (CPT) and HCPCS Level II codes. Therefore, the applicant was unable to determine any XACDURO® dosing adjustments of different time intervals based on the coding in claims data.

In response to CMS questions regarding cost and duration of treatment, the applicant submitted a change to the proposed average of days of treatment from 10 days to 9.6 days. The applicant calculated a weighted average duration of treatment (in days) across the treatment arms in the trial. In Part A of the study, there were 91 patients with an average of 9.3 days of treatment duration. In part B, there were 28 patients with an average treatment duration of 10.6 days. The weighted average days of treatment across both groups is 9.6 days. Based on an average estimated length of stay of 9.6 days, the applicant submitted a change to the expected cost for treatment per stay to be $18,240.

Based on the revised expected cost of treatment per stay, the applicant provided an updated analysis for the second analysis which matches the final approved indication and cost. The revised final inflated average case-weighted standardized charge per case was $219,780, which exceeded the average case-weighted threshold amount of $85,665. The applicant asserted that XACDURO® still met the cost criterion threshold.

Response: We thank the applicant for it comments and the additional information.

Based on the information provided in the application for new technology add-on payments, and after consideration of the public comment we received, we believe XACDURO® meets the cost criterion. The technology was granted FDA marketing authorization on May 23, 2023, for the treatment of hospital-acquired bacterial pneumonia (HABP) and ventilator-associated bacterial pneumonia (VABP) caused by susceptible strains of bacteria called Acinetobacter baumannii-calcoaceticus complex, for patients 18 years of age and older, which is covered by its QIDP designation. Therefore, we are finalizing our proposal to approve new technology add-on payments for XACDURO® for FY 2024. We consider the beginning of the newness period to commence on May 23, 2023, the date on which the technology received FDA market authorization for the indication covered by its QIDP designation.

Based on the information available at the time of this final rule, the average cost per case of XACDURO® is $18,240. Under § 412.88(a)(2), we limit new technology add-on payments to the lesser of 75 percent of the average cost of the technology, or 75 percent of the costs in excess of the MS–DRG payment for the case. As a result, we are finalizing that the maximum new technology add-on payment for a case involving the use of XACDURO® is $13,680 for FY 2024 (that is, 75 percent of the average cost of the technology). Cases involving the use of XACDURO® that are eligible for new technology add-on payments will be identified by ICD–10–PCS procedure codes XW033K9 (Introduction of sulbactam-durlobactam into peripheral vein, percutaneous approach, new technology group 9) or XW043K9 (Introduction of sulbactam-durlobactam into central vein, percutaneous approach, new technology group 9) in combination with one of the following ICD–10–CM codes: Y95 and J15.6 (describing HABP due to Acinetobacter baumannii); or J95.851 and B96.89 (describing VABP due to Acinetobacter baumannii)

8. Other Comments

We received several public comments requesting changes to the new technology add-on payment policies, such as increasing the add-on payment amount to 85 percent or more, creating new alternative pathway categories for different FDA designations or types of treatments, and expanding the conditional approval process to additional types of technologies or designations, that were outside the scope of the proposals included in the FY 2024 IPPS/LTCH PPS proposed rule and we are therefore not addressing them in this final rule. We appreciate these comments and may consider them for possible proposals in future rulemaking.

9. Modification of New Technology Add-On Payment Application Eligibility Requirements Related to FDA Application Status and Moving the Deadline for FDA Marketing Authorization from July 1 to May 1 for Technologies that Are Not Already FDA Market Authorized

As noted in section II.E.1.f. of this final rule, applicants for new technology add-on payments for new medical

services or technologies must submit to CMS a formal request, including a full description of the clinical applications of the medical service or technology and the results of any clinical evaluations demonstrating that the new medical service or technology represents a substantial clinical improvement (unless the application is under one of the alternative pathways). In addition, as reflected in the application, applicants must submit information about the technology's FDA marketing authorization status and the status of any relevant designations required for new technology add-on payment eligibility.

As set forth in 42 CFR 412.87(e)(1), CMS considers whether a technology meets the criteria for the new technology add-on payment and announces the results as part of its annual updates and changes to the IPPS. Accordingly, in drafting the proposed rule, CMS reviews each new technology add-on payment application it receives under the pathway specified by the applicant at the time of application submission, along with any supplemental information obtained from the applicant, information provided at the Town Hall meeting, and comments received in response to the Town Hall meeting. As part of the new technology add-on payment application process, CMS summarizes in the IPPS/LTCH PPS proposed rule the information submitted as part of each new technology add-on payment application. This generally includes summarizing and/or providing the public with information on the applicant's explanation of what the technology does, background on the disease process, status of FDA approval or clearance, and the applicant's assertions and supporting data on how the technology meets the new technology add-on payment criteria under § 412.87. As discussed in prior rulemaking, our goal is to ensure that the public has sufficient information to facilitate public comment on whether the medical service or technology meets the new technology add-on payment criteria.

In the FY 2023 IPPS/LTCH PPS final rule, to increase transparency, enable increased stakeholder engagement, and improve and streamline our new technology add-on payment review process, we finalized a policy that, beginning with FY 2024, new technology add-on payment applications and certain related materials would be publicly posted online (87 FR 48986 through 48990). We noted that we believed making this information publicly available may help to further engage the public and foster greater input and insights through public comments on the new medical services and technologies presented annually for consideration for new technology add-on payments. Consistent with this finalized policy, the FY 2024 applications for new technology add-on payments are available at *https://mearis.cms.gov/public/publications/ntap*.

Building on our efforts to further increase transparency, facilitate public input, and improve the review process, we are finalizing as proposed modifications to both the new technology add-on payment application eligibility requirements and the date by which applicants must receive FDA marketing authorization in order to be eligible for consideration. Specifically, we are finalizing our proposed policies to modify the new technology add-on payment application eligibility requirements for technologies that are not already FDA market authorized to require such applicants to have a complete and active FDA marketing authorization request at the time of new technology add-on payment application submission, and to move the FDA marketing authorization deadline from July 1 to May 1, beginning with applications for FY 2025. As we discuss in further detail later in this section, we believe these changes will significantly improve our ability to evaluate whether a technology is eligible for new technology add-on payment.

We accept new technology add-on payment applications annually, each fall. As previously discussed, CMS considers whether the technology meets the criteria for the new technology add-on payment and announces the results as part of the annual IPPS rulemaking. To provide maximum flexibility for applicants for new technology add-on payments, we have not historically specified how complete an application must be at the time of its submission. This has resulted in a significant number of applicants submitting new technology add-on payment applications that lack critical information that is needed to evaluate whether the technology meets the eligibility criteria at § 412.87(b), (c), or (d), particularly with regard to having information available for the proposed rule and during the comment period. Specifically, many applicants submit new technology add-on payment applications prior to submitting a request to FDA for the necessary marketing authorization, and applicants have stated that information missing from their applications, which is needed to evaluate the technology for the add-on payment, will not become available until after submission to FDA. With regard to the alternative pathways, such applications may also be missing information that would help inform understanding of the details and interrelationship between the intended indication and FDA Breakthrough Device or QIDP designation, which is the basis for a product's eligibility for the alternative pathway.

Ultimately, it is difficult for CMS to review and for interested parties to comment on a product that has not yet been submitted to FDA, as multiple sections of the new technology add-on payment applications lack preliminary information that is more likely to be available after an FDA submission. Public input is an important part of our assessment of whether a technology meets the new technology add-on payment criteria, particularly as technology becomes more complex and specialized.

Thus, we believe that requiring applicants to have already submitted a marketing authorization request to FDA at the time of submission of the new technology add-on payment application will further increase transparency and improve the evaluation process, including the identification of critical questions in the proposed rule, particularly as the number and complexity of the applications have been increasing over time. By requiring applicants to submit their FDA marketing authorization requests prior to submitting an application for new technology add-on payments, the public and the agency will be able to more knowledgeably analyze the new technology add-on payment applications and supporting data and evidence to inform an assessment of the technology's eligibility for the add-on payment.

Therefore, we proposed that beginning with the new technology add-on payment applications for FY 2025, to be eligible for consideration for the new technology add-on payment, an applicant must have already submitted an FDA marketing authorization request before submitting an application for new technology add-on payments. We proposed that, for the purposes of this policy, submission of a request for marketing authorization by FDA would mean that the applicant has submitted a complete application to FDA, and that the application has an active status with FDA (such as not in a Hold status or having received a Complete Response Letter). An applicant must provide documentation of the marketing authorization request at the time of submission of its new technology add-

on payment application to CMS. We stated our belief that requiring an FDA acceptance or filing letter will provide the clearest and most effective means of documenting that the applicant has submitted a complete request to FDA and therefore proposed to require this approach to documentation. We proposed that the applicant would also indicate on the new technology add-on payment application whether the FDA request has an active status with FDA. We noted that applicants for technologies that have already received FDA marketing authorization for the indication for which they are applying for new technology add-on payments would not be required to submit an FDA acceptance or filing letter and would continue to be eligible for consideration for new technology add-on payments. We proposed to amend 42 CFR 412.87 to reflect this proposal by redesignating current paragraph (e) as paragraph (f) and adding a new provision at 42 CFR 412.87(e) to state that CMS will only consider, for add-on payments for a particular fiscal year, an application for which the medical service or technology is either FDA market authorized for the indication that is the subject of the new technology add-on payment application or for which the medical service or technology is the subject of a complete and active FDA marketing authorization request and documentation of FDA acceptance or filing is provided to CMS at the time of new technology add-on payment application submission.

In the FY 2009 IPPS/LTCH PPS final rule (73 FR 48562 through 48563), we finalized our proposal to set July 1 of each year as the deadline by which IPPS new technology add-on payment applications must receive FDA marketing authorization. We noted that while we prefer that technologies have FDA approval or clearance at the time of application, this may not always be feasible. At that time, we believed that the July 1 deadline would provide an appropriate balance between the necessity for adequate time to fully evaluate the applications, the requirement to publish the IPPS final rule by August 1 of each year, and addressing commenters' concerns that potential new technology applicants have some flexibility with respect to when their technology receives FDA approval or clearance.

However, with the increased complexity and volume of applications for new technology add-on payments since finalization of this policy in the FY 2009 IPPS/LTCH PPS final rule, we believe the July 1 deadline may no longer provide sufficient time to fully evaluate the new technology applications in advance of the issuance of the final rule, including information that does not become available until FDA approval or clearance. The technologies that are the subject of new technology add-on payment applications are increasingly complex, such as fourth- and fifth-line therapies and devices utilizing artificial intelligence algorithms. The volume of new technology add-on payment applications has also risen substantially. In the first 20 years of the new technology add-on payment program, CMS received on average 2–10 applications per year. Applications have risen by 200 percent from FY 2020 to FY 2024 alone.

The increased volume and complexity of applications makes it more challenging to mitigate information gaps in advance of the final rule, particularly with regard to analysis and validation of information necessary to make determinations regarding whether technologies meet the add-on payment criteria. For traditional pathway applications, this may involve submission of new clinical studies and/or a different final indication, which can change the relevant comparators for consideration. For alternative pathway applications, CMS must assess the relevant designations in connection with the applicable indications and how the necessary marketing authorization relates to the designated technology, which often necessitates coordination with FDA and other components of HHS. As new technology continues to be developed, we expect both the complexity and the number of applications to increase, further increasing the need for additional time to fully evaluate the applications in advance of the final rule. We also believe that providing the opportunity for interested parties to review the FDA approved indications and the clinical data that often only becomes available after receiving, and may only be available in, FDA marketing authorization will strengthen the quality of the public comments and allow for more informed decision-making in the final rule.

Accordingly, to allow adequate time to fully evaluate the new technology add-on payment criteria for FDA-authorized technologies in advance of the final rule, and to further facilitate and inform public comment, we proposed requiring applicants to receive FDA approval or clearance by May 1 in order to be eligible for consideration for the new technology add-on payment for the upcoming fiscal year. We said we believed that this May 1 deadline would strike a balance between providing adequate time to fully evaluate the applications while also continuing to preserve flexibility for manufacturers. We proposed to amend proposed redesignated § 412.87(f)(2) to reflect this proposed change by revising the date by which new medical services or technologies must receive FDA marketing authorization from July 1 to May 1 and making other conforming changes to the regulatory text.

Consistent with our current approach, we will not include in the final rule the description and discussion of new technology add-on payment applications which were included in the proposed rule that were withdrawn or that were ineligible for consideration for the upcoming fiscal year due to not meeting the proposed May 1 deadline. We will also neither summarize nor respond to public comments received regarding these withdrawn or ineligible applications in the final rule.

We noted that we were not proposing to change the July 1 deadline for technologies for which an application is submitted under the alternative pathway for certain antimicrobial products because they would continue to be eligible for conditional approval under § 412.87(e)(3) (to be redesignated as § 412.87(f)(3)), as finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58740). However, we proposed to amend the redesignated § 412.87(f)(3) to revise the current cross-reference to § 412.87(e)(2) in light of the previously discussed amendments being proposed.

We sought public comment on our proposal to modify the new technology add-on payment application eligibility requirements for technologies that are not already FDA market authorized to require such applicants to have a complete and active FDA marketing authorization request at the time of new technology add-on payment application submission, to provide documentation of FDA acceptance or filing to CMS at the time of application submission, and to move the FDA marketing authorization deadline from July 1 to May 1, beginning with applications for FY 2025.

Comment: We received several public comments regarding the stated policy goals behind our proposal of promoting transparency, facilitating public input, and improving the review process. As part of improving the new technology add-on payment review process, we stated that as new technologies continue to be developed, we expect both the complexity and the number of applications to increase, further increasing the need for additional information earlier in the new technology add-on payment review

process in order to fully evaluate the applications. As discussed further in this section, many commenters stated that they understood our policy goals but provided alternatives as to how to achieve those goals or asked for a delay in implementation. We discuss the specific comments concerning alternatives to our proposal and asking for a delay in implementation later in this section.

Other commenters stated that it is unclear how the proposal would improve transparency, facilitate public input, and improve the review process, or disagreed that it would do so. One commenter specifically stated that it did not understand how our proposal would further facilitate and inform public comment, as the proposed rule is released in April and the information from the full FDA approval would not be available in the proposed rule at that time. A number of commenters asserted that the intent of these policies is to reduce the number of applications or decrease CMS's workload, and some of these commenters expressed the view that the proposal is unlikely to address the increasing volume and complexity of applications or reduce CMS's review time. Commenters also stated that they did not believe the volume of applications would decline because they believe that applicants will likely continue to pursue a new technology add-on payment application as a ''just in case'' strategy, or to solicit information on what concerns CMS may have with a future application, even if they are unlikely to receive FDA approval until well after the proposed May 1 deadline. One commenter noted that even those with Priority Review status [185] may not receive FDA approval until after May 1, and that technologies subject to the standard review timeline may not receive approval until late fall.

A few of the commenters noted that applicants who do not receive new technology add-on payment approval due to missing the marketing authorization deadline would likely apply again during the following application cycle and CMS would have to repeat this process the following year, resulting in a greater burden on both manufacturers and CMS. A few of these commenters also disagreed that our proposal would improve transparency nor materially impact the volume or complexity of applications, specifically for technologies with Breakthrough Device designations for which the new technology add-on payment applications only contain limited information as compared to traditional pathway applications that contain newness and SCI information.

One commenter stated that complete new technology add-on payment applications should provide CMS with sufficient information to assess the medical technology in question regardless of whether the FDA application has been formally submitted, and another commenter stated that CMS currently has the discretion not to approve applications that are missing data, regardless of the status of the FDA marketing authorization application.

Response: We thank commenters for their comments. While a number of commenters noted their belief that the intent of these policies is to reduce the number of applications or decrease CMS's workload, the intent of our proposal is instead to address the ever-increasing complexity and number of applications lacking critical information that is needed to evaluate whether the technology meets the eligibility criteria at § 412.87(b), (c), or (d), by enhancing transparency and improving the evaluation process, as described in the proposed rule. Specifically, applications for technologies that have not yet received FDA marketing authorization often have incomplete information about the indication, lack cost information, and provide limited clinical information and supporting data (where applicable), all of which are necessary for a thorough analysis of new technology add-on payment criteria. Thus, the application summaries and lists of relevant CMS concerns in the proposed rule may be limited and the public may not have all of the necessary information on the new technology being considered for new technology add-on payment. Public commenters in previous final rules have noted that they cannot meaningfully comment on a product that has not yet been FDA approved because multiple sections of the new technology add-on payment applications are informed by the marketing authorization approval process. Public input on the new technology add-on payments is highly valued and an important consideration in our assessment of whether a new technology add-on payment application meets the eligibility criteria. This is especially important given that new technologies are becoming more complex and specialized and the volume of applications for new technology add-on payments is increasing.

Therefore, we believe more comprehensive applications at the time of submission will allow CMS to better identify critical questions in the proposed rule and will enable more comprehensive evaluation by commenters during the public comment process. In summary, the goal of the proposal is to increase the quality of the information contained in the application to allow the public and the agency to more knowledgeably review and analyze the applications, supporting data, and evidence to inform an assessment of a technology's eligibility for the new technology add-on payment.

Although a commenter stated that complete new technology add-on payment applications should provide CMS with sufficient information to assess the medical technology in question regardless of whether an application has been formally submitted to FDA, as noted previously, applications for technologies that have not yet received FDA marketing authorization often have incomplete information about the indication, lack cost information, and provide limited clinical information and supporting data (where applicable). In addition, in regard to the commenter that stated CMS has the discretion not to approve applications that are missing data, this does not address our intent to increase the quality of the information contained in the application, as previously described.

CMS recognizes that some applicants who submit new technology add-on payment applications prior to submitting applications for FDA marketing authorization may be doing so strategically to identify information regarding concerns CMS may have with new technology that is the subject of the new technology add-on payment application as early as possible, as described by a commenter. While we acknowledge that it could be advantageous for an applicant to learn of CMS's concerns regarding eligibility of its product for new technology add-on payments, we do not believe it is an appropriate use of resources to evaluate applications for technologies that will not be eligible in time for that particular rulemaking cycle. In addition, over the last 4 years, 50 to 75 percent of applications (depending on the fiscal year) did not meet the July 1 deadline for obtaining FDA marketing authorization. We believe that this proposal will serve to mitigate these practices to some extent, though this is

[185] A priority review designation means FDA's goal is to take action on the marketing application within 6 months of receipt (compared with 10 months under standard review). *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/expedited-programs-serious-conditions-drugs-and-biologics.*

not the goal behind the proposal, as described previously.

Regarding the comments that stated that applicants who miss the marketing authorization deadline would likely apply again during the following application cycle, resulting in a greater burden on both manufacturers and CMS, we note that this would not be a change from our current policy. As noted previously, even with a July 1 deadline, 50–75 percent of applications do not meet the deadline and many reapply the following year. As described later in this section, we believe requiring technologies to have submitted FDA marketing authorization requests prior to submitting applications for new technology add-on payments would mitigate this issue, as we believe applications for which a ''complete and active'' FDA application has been accepted or filed have a greater chance of meeting the deadline for FDA marketing authorization for new technology add-on payment eligibility purposes.

Additionally, with regard to commenters' assertion that our proposal would not improve transparency and materially impact the volume or complexity of Breakthrough Device applications, we believe that requiring a FDA marketing authorization request to have been submitted and in an active status at the time of application for technologies with Breakthrough Device designations will lead to applicants submitting information in their new technology add-on payments applications that address the criteria needed to determine eligibility, such as the marketing authorization indication and other information that would help inform understanding of the details and interrelationship between the intended indication and FDA Breakthrough Device designation, which is the basis for a product's eligibility for the alternative pathway, and whether the device that is the subject of the application is the same device designated as a Breakthrough Device. We note, as we have gained more experience with applications for technologies with Breakthrough Device designations, these applications are increasingly complex and involve many considerations and nuances across multiple aspects of the application, not just the cost criterion. This requirement will enhance the quality of information CMS receives at the time of application for all application pathways, making more information available to the public and providing CMS with more robust information to evaluate the application.

Although a commenter mentioned that the proposed rule is released in April and therefore, information from the full FDA approval would not be available in the proposed rule, we note that a May 1 deadline allows for information necessary to determine whether a technology meets the requirements for new technology add-on payment eligibility, such as the full FDA marketing authorization indication and information for which release is dependent on that approval, to be publicly available during the comment period in time for consideration by the public and the agency, since this deadline would generally occur approximately 30 days before the public comment period closes. A technology's FDA marketing authorization may differ from the proposed indication, which may require additional consideration when contemplating new technology add-on payment eligibility; for example, with respect to how the final marketing authorization indication compares to an alternative pathway designation, or what would be the appropriate comparators for newness and substantial clinical improvement for traditional pathway applications. Access to this information will enhance the quality of the review process and improve transparency for the public prior to the final rule.

Comment: One commenter was fully supportive of our proposal and agreed that increasing transparency is critical for the new technology add-on payment process. The commenter stated applications that lack information at the time of submission make it difficult for CMS and the public to assess whether the technology meets the new technology add-on payment criteria. The commenter believed that the vast majority of applicants, if not virtually all, who apply for new technology add-on payments before they are ready to submit an application for marketing authorization to FDA, do not end up receiving FDA approval in time for the new technology add-on payment determination, which leads to a tremendous use of resources to review technologies and put them through the proposed rule and comment period, just to have the applications be withdrawn from new technology add-on payment consideration at the last minute. The commenter further asserted that due to the increased volume and complexity of applications over the years, these issues may have been compounded. The commenter noted that spreading limited resources over a large number of applications with an extremely short deadline to review the applications could result in a less than thorough review process.

Response: We thank the commenter who was supportive of the proposal and agree that the policy will increase our stated goals of transparency, facilitating public input, and improving the review process.

Comment: Many commenters who opposed our proposal stated that one or both aspects of the proposal would create a barrier to beneficiary and provider access to innovative technologies. A few commenters recommended that CMS analyze the proposal's impact on beneficiary access. Some of the commenters explained that the proposal would impact the timeliness of reimbursement for the new technology. One commenter stated that new technology add-on payments are often not in place until more than a year after a product receives marketing authorization from FDA and that the proposal would further delay that payment. Another commenter encouraged CMS to maintain the existing timelines as reducing the duration of the new technology add-on payment could reduce patient access to therapies like CAR T-cell therapy. One commenter raised concerns about the proposal having a negative effect on applicants that rely on new technology add-on payments to sustain a viable market entry point.

Several commenters noted that the proposal would worsen the lag time between FDA marketing authorization and new technology add-on payments and create disruptions, and thus delay beneficiary access to new technologies, which would be the opposite of the intent of the new technology add-on payment process. A few commenters stated that this proposal would negatively affect therapies intended to treat serious conditions and address unmet needs, and one commenter raised several concerns about timing for new technology add-on payment approvals for, and patient access to, certain types of newly approved FDA therapies, such as cell and gene therapies and therapies treating orphan conditions and rare diseases. One commenter stated that there is risk that the policies would have a disproportionately negative effect on drugs that utilize the FDA ''rolling review'' process,[186] delaying patient access to these drugs.

[186] Rolling Review means that a drug company can submit completed sections of its Biologic License Application (BLA) or New Drug Application (NDA) for review by FDA, rather than waiting until every section of the NDA is completed before the entire application can be reviewed. BLA or NDA review usually does not begin until the drug company has submitted the entire application to the FDA *https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track.*

Response: We thank the commenters for sharing their concerns. CMS shares the goal of ensuring Medicare beneficiaries and their providers have access to new technologies. However, as described in the FY 2005 final rule (69 FR 49003 and 49009), patient access to these technologies should not be adversely affected if a technology does not qualify to receive new technology add-on payments, as CMS continues to pay for new technologies through the regular payment mechanism established by the MS–DRG methodology. We further note that whether a technology receives new technology add-on payments or not does not affect coverage of the technology or the ability for hospitals to provide a technology to patients where appropriate.

Comment: Many commenters raised concerns that our proposals to require a complete and active FDA marketing authorization request at the time of submission of the new technology add-on payment application and to move the FDA approval deadline from July 1 to May 1 for technologies to receive FDA marketing authorization would adversely impact their ability to enjoy maximum flexibility with respect to when to apply to FDA and when they apply for new technology add-on payment.

One commenter stated that the proposal could discourage applicants from applying for a new technology add-on payment. Another commenter noted a manufacturer could be working closely and actively with FDA through the FDA's voluntary pre-submission process, which is intended to improve the quality of subsequent submissions, shorten total review times, and facilitate the development process for new devices. The commenter explained that the proposal would discourage industry collaboration with FDA in its voluntary pre-submission process since the policy could potentially delay eligibility for a new technology add-on payment by a full year. A commenter stated that CMS should consider a flexible approach for submitting additional documentation on a rolling basis that corresponds with the type of technology's FDA review process to account for the variation in FDA review processes across new technologies and avoid creating new burdens on FDA.

One commenter noted that manufacturers' timelines are driven primarily by trial enrollment so they may not be able to submit a BLA prior to the new technology add-on payment application submission or get approved by the May 1 deadline. A few commenters asserted that the proposal would jeopardize the ability of manufacturers to submit applications within the window of time necessary to be eligible to receive new technology add-on payments, leading to fewer products being eligible for approval each year.

A few commenters noted how the proposal does not reflect the variations in FDA processes and timelines for different types of new technologies, whereas the new technology add-on payment designation is the same and only occurs once a year. Additionally, commenters noted that the FDA provides estimates of timeline, but it does not provide applicants with definitive timelines of when the product will be approved or provide feedback on what is needed. A few commenters raised concerns about how the FDA submission process can be impacted by several factors, including timing of interactions with the FDA and manufacturing readiness. One commenter noted that there are examples of technologies receiving FDA clearance after submitting their new technology add-on payment application and meeting the new-technology add-on payment criteria, and that as long as new technology add-on payments can only be awarded annually, applicants should be able to apply for new technology add-on payments as long as there is potential for FDA clearance prior to the July 1 deadline.

Response: We understand the commenters' concerns with regard to the impact of having maximum flexibility with respect to when they apply for FDA marketing authorization and when they apply for new technology add-on payments. We believe the new technology add-on payment application timeline with the same deadline for submission of a request for FDA marketing authorization is appropriate regardless of how long it takes for a technology to receive FDA approval. To date, we have not specified how complete an application for new technology add-on payments must be at the time of its submission, and used a late deadline of July 1 for the requirement for FDA approval, in order to maximize flexibility for applicants. But as noted earlier, currently, many applicants submit new technology add-on payment applications prior to submitting a request to FDA for marketing authorization, and applicants have stated that information missing from their applications, which is needed to evaluate the eligibility of the technology for the add-on payment, will not become available until after submission to FDA. Our policy will further increase transparency and improve the evaluation process, including enabling CMS to identify critical questions regarding the technology's eligibility for add-on payments in the proposed rule. It will also reduce the number of applications that CMS receives that contain limited information.

We further note that even under the current policy with the flexibilities mentioned by the commenters, most applicants do not receive FDA marketing authorization by the July 1 deadline. As noted previously, over the last 4 years, more than 50 percent of applications each year did not receive FDA marketing authorization by the July 1 deadline and were therefore ineligible for new technology add-on payments for the fiscal year for which they applied. As the commenters noted, there are many factors (including timing of interactions with FDA and manufacturing readiness) that can impact a technology's approval or clearance by FDA, despite expected FDA timelines based on review time or submission planning. This is true regardless of whether the deadline for FDA approval is May 1 or July 1.

We note that this policy does not eliminate flexibilities built into the new technology add-on payment process, as FDA marketing authorization is not required at the time of application, and applicants can continue to provide information as it becomes available according to our standard processes (such as the December supplemental deadline and the public comment period). We believe in providing maximum flexibility to applicants where feasible, but due to the increasing complexity and volume of applications lacking critical information that is needed to evaluate whether the technology meets the eligibility criteria at § 412.87(b), (c), or (d), as we have noted previously, we will require information related to FDA submission at the time of application beginning with applications for FY 2025.

We do not anticipate that the policy of requiring an applicant to have already submitted its marketing authorization application to FDA will discourage applicants from applying for new technology add-on payments, since they would be able to reasonably provide sufficient information at the time of application in order for CMS to identify critical questions regarding the technology's eligibility for add-on payments and to allow the public to assess the relevant new technology evaluation criteria in the proposed rule. In addition, the extent to which an applicant decides to collaborate with FDA is independent from the application process for new technology

add-on payment, and the applicants retain the autonomy to decide if, when, and how to collaborate with the FDA. Applicants are not precluded from continuing to work with FDA as appropriate, and can continue to submit applications to FDA based on their individual readiness and internal timelines.

Comment: Many commenters expressed specific concerns regarding moving the FDA approval deadline to May 1 and how it would impact how long technologies may be eligible for a new technology add-on payment. Several of the commenters asserted that this policy change would prevent a 3-year new technology add-on payment duration for almost all applicants, as only those technologies that receive FDA marketing authorization in April would get 3 years of new technology add-on payments, shortening the window from 3 months under the current policy to just 1 month (April 1 until July 1, vs April 1 until May 1).[187] One commenter stated that few new technology add-on payment applications have had a full three-year duration of add-on payments under existing policy, potentially limiting Medicare beneficiary access, and this new policy would exacerbate the issue. Further, another commenter provided an example of the potential impact of this policy by referring to Table II.P.–01 in the proposed rule that details the technologies that are scheduled to continue new technology add-on payments in FY 2024. The commenter noted that of the 11 technologies listed, seven (64%) received FDA approval/clearance between May 5 and June 30, and stated that if this policy had been in place at the time these new technology add-on payment applications were evaluated, each of these would not have been granted new technology add-on payments the following October, representing a delay of 12 months.

Some commenters recommended that if CMS finalizes the aspect of its proposal to move the FDA approval date to May 1, it also adjust its regulations to provide that all devices that receive approval for a new technology add-on payment be granted 3 fiscal years of reimbursement from the time of approval for the new technology add-on payment, independent of the timing of the FDA approval. A few commenters noted that the shortened period resulting from decreasing the window for 3 years of payment for new technology add-on payments to 1 month (April 1 until May 1) would mean CMS would have less claims data available to determine the MS–DRG payment rate.

Several commenters believed our proposal would worsen lag times between FDA approval and the new technology add-on payment designation, resulting in an FDA-approved product being on the market for up to 17–18 months without being approved to receive new technology add-on payments and reducing the potential length of new technology add-on payment eligibility from a possible 3-year period to a 2-year period.

Some commenters performed analyses to demonstrate the potential impact of the proposed May 1 deadline policy: one commenter noted that if the policy were currently in effect then new technology add-on payments would have been delayed for 4 out of the 25 technologies that received approval between 2019 and 2023; another noted that if this policy had already been implemented, then 9 out of the current 19 traditional applications would be disqualified for consideration for the FY 2024 rule; and another commenter noted that almost all renewals proposed for FY 2024 would have had new technology add-on payments delayed by a year as their newness periods begin in May/June. One commenter noted that 20 percent of FY 2022 approved technologies and 30 percent of FY 2023 approved technologies had FDA approval dates between May 2 and July 1, and that based on this data, the commenter estimated the proposed May 1 deadline would delay access by a full year for between one-in-three and one-in-five therapies. Another commenter cited a study finding that, historically, over 25 percent of new technology add-on payment denials were due to applicants being unable to meet the existing July 1 deadline, stating that the May 1 deadline would result in even more products experiencing delays in new technology add-on payments.

Response: We thank the commenters for their feedback. We note that it appears that commenters' analyses may have conflated FDA approval dates with newness period start dates. For example, with respect to the commenter that referred to Table II.P.–01 in the proposed rule, we note that this table does not provide FDA approval/clearance dates, but rather the newness period start dates, for these technologies. Furthermore, the commenters' analyses of technologies in previous fiscal years that received approvals for new technology add-on payments with newness period start dates between May 2 and July 1 do not necessarily indicate that these technologies would have received a denial for new technology add-on payments for those respective fiscal years. In certain circumstances, the newness start date may occur after the FDA marketing authorization date. Applicants may have also applied for new technology add-on payments after receiving FDA marketing authorization. It is also possible that some of these manufacturers may have delayed their submission of their FDA marketing authorization application in an attempt to align that approval as much as possible with the existing new technology add-on payment timelines, rather than applying at a sooner time that could have resulted in an FDA marketing authorization date prior to May 1. With regard to the commenter that stated that 9 out of the current 19 traditional applications would be disqualified for consideration for the FY 2024 rule if CMS had already implemented an FDA marketing authorization deadline of May 1st, we note that of those 9 applications, 7 withdrew or were ineligible for new technology add-on payments.

We also note that even under the current policy with the flexibilities mentioned by the commenters, not all applicants receive the full three years of new technology add on payments. As the commenters noted, there are many factors (including timing of interactions with the FDA and manufacturing readiness) that can delay a technology's approval by the FDA that would disrupt a technologies ability to receive the full three years of payment.

We note that our data analysis of applications over the last 3 years demonstrates that nearly all applicants who submit new technology add-on payment applications prior to FDA submission in fact do not receive FDA approval by the July 1 deadline. Between FY 2021 and FY 2023, only 3.7 percent of applicants that applied for a new technology add-on payment prior to having submitted its marketing authorization application to FDA received FDA marketing authorization prior to the July 1 deadline. We believe this may result in part from strategically planning the timing of application submission to FDA, as noted by commenters. However, while we expect that applicants are applying for new technology add-on payments with the expectation that they will receive FDA marketing authorization by the deadline, we agree that this choice to

[187] We have generally followed a guideline that uses a 6-month window before and after the start of the fiscal year to determine whether to extend the add-on payment for an additional year. In general, we extend new technology add-on payments for an additional year only if the 3-year anniversary date of the product's entry onto the U.S. market occurs in the latter half of the fiscal year (70 FR 47362).

''time'' an application submission to FDA by applicants may not change with implementation of this policy. As stated previously, the goals of this policy are to increase transparency, facilitate public input, and improve the review process, and we believe that by receiving relevant information earlier (both in terms of the time of application and in terms of final FDA marketing authorization prior to the close of the comment period), these goals will be fostered and advanced. We further note that between FY 2021 and FY 2023, only 4 applications out of 107 received FDA marketing authorization between May 1 and July 1 and were approved for new technology add-on payments. Based on this analysis, however, we note that it appears that changing the FDA approval date from July 1 to May 1 would still have affected only a small percentage of new technology add-on payment applications.

We further note that section 1886(d)(5)(K)(ii) of the Act establishes a period of not less than two years and not more than three years for the collection of data with respect to the costs of new services or technologies; a full 3 years is not required. As previously stated, consistent with the statute and our implementing regulations, a technology is no longer considered ''new'' once it is more than 2 to 3 years old, irrespective of how frequently the medical service or technology has been used in the Medicare population (70 FR 47349). As such, once a technology has been available on the U.S. market for more than 2 to 3 years, we consider the costs to be included in the MS–DRG relative weights regardless of whether the technology's use in the Medicare population has been frequent or infrequent. Therefore, we do not believe that 2 years' worth of data would be insufficient to inform rate-setting for the inpatient setting.

However, we have noted commenters' concerns regarding the possibility that moving the FDA approval deadline from July 1 to May 1 may limit the ability of new technology add-on payment recipients to receive three years of add-on payments, due to the shortened time period between April 1 and May 1. We note that we anticipate considering for future rulemaking changes to how we assess new technology add-on payment eligibility in the third year of newness, such as consideration of adjusting the April 1 cut-off to allow for a longer window of eligibility.

Comment: One commenter supported this aspect of the proposal, agreeing that moving the deadline to May 1 would allow interested parties to review the FDA-approved indications and clinical data that often becomes available only after receiving FDA marketing authorization, and would strengthen the quality of the public comments, allowing for a more informed decision-making process in the final rule.

Response: We thank the commenter and agree that the policy will increase our stated goals of transparency, facilitating public input, and improving the review process.

Comment: Commenters asked for clarifications or raised concerns with the terminology used in the proposal regarding the requirement for a complete and active FDA marketing authorization request at the time of new technology add-on payment application submission and providing documentation of FDA acceptance or filing to CMS at the time of application submission.

Some commenters requested that CMS clarify what constitutes a ''complete and active FDA marketing authorization request.'' Some of these commenters stated it was unclear what the terms ''complete and active FDA marketing authorization'' means, as they are not defined in statute, regulation, or guidance, or adequately defined in the proposed rule. A few commenters noted that these terms do not correlate with the terms used by the FDA and that there is currently no certification provided by the FDA indicating such a status. Some commenters suggested this would create further confusion between FDA, CMS, and interested parties.

A few commenters noted the FDA application status at the time of the new technology add-on payment application submission is not always an accurate representation of the maturity of the FDA application. A few commenters stated that the FDA application process is dynamic and could switch from ''active'' to ''on hold'' at any time for various reasons including temporary pauses for minor questions or the request of supplemental materials, and noted that a temporary hold may be lifted with submission of supplemental materials.

Some commenters raised concerns about what documentation is sufficient to demonstrate that a product was submitted to FDA for approval or review at the time of submission of the new technology add-on payment application and requested additional clarification from CMS. One commenter recommended that CMS accept a copy of the first page of the marketing authorization request cover letter submitted to the FDA as sufficient documentation. Another commenter raised concerns that this would increase the burden on the FDA to provide applicants with proof of a ''complete and active'' application status.

One commenter requested clarification about whether a ''Refuse to File'' letter from the FDA would prevent an applicant from applying for new technology add-on payments, recommending that a ''Refuse to File'' letter should not preclude an applicant from applying for new technology add-on payments because the applicant could correct the filing error and re-submit their NDA or BLA and still meet the current July 1 FDA marketing authorization deadline.

Response: We thank the commenters for the feedback and sharing their concerns. We note that we collaborated with the FDA in developing the terminology used in this proposal, and the intent behind using the terms we did was to ensure that the requirement could apply to and be inclusive of the different types of FDA applications for different types of drugs and devices. Many of the commenters only referenced terms used for either drugs or for devices, and because a variety of types of technologies, with different FDA marketing authorization application requirements, can be eligible for new technology add-on payment, we are not using terms defined in statute or existing regulations or terms defined by FDA.

We consider, for the purposes of new technology add-on payment applications, an FDA marketing authorization application to be ''complete'' when the full application has been submitted to FDA. Specifically, for relevant FDA application types, a full application includes all modules or all information following a rolling review or Real-Time Oncology Review (RTOR).[188] We will only accept new technology add-on payment applications once FDA has received all of the information to determine whether it will accept (such as in the case of a 510k application or De Novo Classification request) or file (such as in the case of a PMA, NDA, or BLA) the application, as demonstrated by the acceptance/filing letter that is already provided by FDA to indicate that FDA has determined that the application is sufficiently complete to allow for substantive review by FDA. Additionally, for the purposes of new technology add-on payment applications, we consider an FDA marketing authorization application to be in an ''active'' status when the application has been determined by

[188] *https://www.fda.gov/about-fda/oncology-center-excellence/real-time-oncology-review.*

FDA to be sufficiently complete to permit substantive review by FDA, and when it is still under review at the time of new technology add-on payment application submission (that is, it is not in an inactive status such as withdrawn, the subject of a Complete Response Letter or final decision from FDA to refuse to approve the application, or on hold). We have received a number of applications over the years for technologies that have received a Complete Response Letter (CRL) or not approvable status from FDA, or are in a hold status with up to 360 days allowed for submission of additional information. Applications that are submitted to CMS without a new submission to FDA or additional information submitted to FDA addressing the relevant issues leading to the inactive review status would still be missing significant relevant information to inform assessment of the add-on payment criteria. For these reasons, applications submitted for new technology add-on payments must be in an active status with FDA at the time of new technology add-on payment application submission, and must provide that information as part of their new technology add-on payment application. We believe that those technologies for which a ''complete and active'' FDA application has been accepted or filed also have a greater chance of meeting the deadline for FDA marketing authorization for new technology add-on payment eligibility purposes. We do not believe this process will increase the burden on FDA; we are requiring that applicants provide us with the initial acceptance or filing letter that is already provided by FDA after its initial administrative review (which can vary based on the FDA application type) which demonstrates FDA has begun substantive review of the application in full, as described further in this section. Aside from that, we do not require specific documentation from FDA to demonstrate continued ''active status'' after initial FDA acceptance or filing, as we believe applicants are aware of any changes to their FDA application status and would be able to provide this information to CMS in their new technology add-on payment application. We acknowledge that the FDA application process is dynamic and could switch from ''active'' to ''on hold'' at any time for various reasons, and do not intend for our requirement to exclude applicants that have submitted to FDA; the intention is that applicants apply for new technology add-on payments if they can indicate that the FDA application has an ''active status'' at the time of new technology add-on payment application submission. As described previously, the intent of this requirement is to ensure that applicants are far enough along in the FDA review process that applicants would be able to reasonably provide sufficient information at the time of application for CMS to identify critical questions regarding the technology's eligibility for add-on payments and to allow the public to assess the relevant new technology evaluation criteria in the proposed rule.

Regarding the documentation that would suffice for the purposes of this policy, as described previously, we are requiring the documentation provided to applicants by FDA after FDA concludes that the application is sufficiently complete to permit a substantive review. We note that when FDA instead provides applicants with a ''Refuse to File'' (RTF) (or ''Refusal to Accept'' (RTA)) letter, this specifically indicates that FDA has determined the application is not complete and therefore those applicants that have received an RTF or RTA letter will not be eligible to apply for new technology add-on payment until the application is resubmitted to FDA and an acceptance/filing letter is received.

Comment: A few commenters requested exceptions for QIDPs and LPADs to one or both aspects of the proposal. The commenters stated that since applications for these technologies only require the cost criterion, they should be exempt from the proposal, as the proposal could delay access to QIDPs and LAPDs.

Response: We thank commenters for their feedback. We note that we did not propose to change the July 1 deadline for technologies for which an application is submitted under the alternative pathway for certain antimicrobial products because they would continue to be eligible for conditional approval under § 412.87(e)(3) (as finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58740)). However, we do not believe it is appropriate to exempt any technology from the requirement to request FDA marketing authorization prior to applying for new technology add-on payments. As discussed previously, this proposal is intended to increase transparency for the proposed rule, and as such, receiving the most information possible at the time of application would result in robust analysis and discussion for the proposed rule to maximize public input. Furthermore, as discussed previously, with regard to the alternative pathways, such applications may also be missing information that would help inform understanding of the details and interrelationship between the intended indication and FDA QIDP (or Breakthrough Device) designation, which is the basis for a product's eligibility for the relevant alternative pathway.

Comment: Several commenters requested that if CMS finalizes its proposal, it should delay implementing until after FY 2025. The commenters recommended that CMS provide more notice to manufacturers and delay implementation of the proposed new policies until FY 2026 or later to provide more time for manufacturers to adjust their development processes. Some commenters raised concerns that planning for the FY 2025 cycle is already underway and if these policy changes are implemented in this final rule, they would no longer be able to apply for a new technology add-on payment in the next cycle as they anticipated, which raises the risk that Medicare beneficiaries would not have reliable access to these new technologies for more than a year after FDA approval. One commenter also noted that it takes about 6–10 months from the initial FDA application request to receive an approval decision, and that by the time the final rule releases in August, if the policy is finalized, it may be too late for manufacturers to apply and receive FDA approval before the May 1 deadline. Other commenters specifically noted that this could require Breakthrough Devices/510k applications to submit applications to FDA earlier, such as 4–6 months sooner (since their FDA timeline is shorter), which would mean a year delay in add-on payments if the deadline is missed, since they can currently apply to FDA as late as April and still anticipate approval by July 1.

Response: We thank the commenters for their recommendations regarding delay of implementation of the proposal. It seems that commenters are suggesting that manufacturers may strategically time the submission of an application to the FDA in an attempt to align an expected decision by the FDA with the timelines for new technology add-on payment eligibility. We encourage manufacturers to pursue the appropriate regulatory processes to bring new products to market as soon as practical. While FDA reviews often have standard estimated timeframes from application to approval, we understand that there can be many variables in the review, including FDA seeking new or additional information, that may result in a longer or shorter timeframe to approval than estimated. We further note that CMS continues to pay for new

technologies through the regular payment mechanism established by the MS–DRG methodology, with or without new technology add-on payments, and whether a technology receives new technology add-on payments or not does not affect coverage of the technology or ability for hospitals to provide a technology to patients where appropriate.

As discussed previously and in the FY 2024 IPPS/LTCH PPS proposed rule, we believe these policies will help facilitate a more transparent process that will improve public engagement and help improve and streamline our review processes. Many of these products are novel and complex, and CMS has a responsibility to appropriately and thoroughly review applications for eligibility for new technology add-on payments against our established eligibility criteria. Therefore, we do not intend to delay implementation of the proposed new policies because we believe that such a delay would not lead to improved transparency and more robust applications or otherwise align with the issues this policy would address.

Comment: Many commenters stated that the proposal was unlikely to achieve CMS's stated goals or to decrease workload, and would instead negatively impact beneficiary access or manufacturer flexibility. The commenters therefore recommended alternatives that they believed would maximize flexibility and improve access in line with the intent of new technology add-on payments, as described further in this section.

Commenters recommended that rather than finalizing the proposal, CMS consider increasing the frequency of new technology add-on payment application reviews. Specifically, some commenters requested that CMS conduct quarterly or biannual reviews that align with existing CMS processes for the hospital outpatient transitional pass-through payments and ICD–10 coding cycles. One commenter supported the proposal to require applicants to submit their FDA marketing authorization requests prior to submitting a new technology add-on payment application only if the new technology add-on payment eligibility determinations are conducted biannually.

For instance, a few commenters suggested the effective dates of a semiannual new technology add-on payment application process to begin making new technology add-on payments could fall on April 1 and October 1. Some of the commenters suggested a biannual cycle as follows: For an October 1 add-on payment start date, new technology add-on payment applications could have a deadline of April 1, with a public meeting in early/mid-May, with new technology add-on payment proposals issued in early/mid-June allowing for a 30-day comment period leading to final new technology add-on payment decisions in late August with an effective date of October 1; the second cycle would follow a similar timeline with a new technology add-on payment application deadline of October 1 and April 1 add-on payment start date. This commenter stated that this proposed timeline would be consistent with the statute and would allow for more new technology add-on payment determinations, which would, in theory, enhance the quantity and quality of claims data used for ratesetting. Other commenters also noted that biannual new technology add-on payment reviews could also theoretically result in more claims data to analyze in the next fiscal year.

Another commenter asserted that section 1886(d)(5)(K)(vii) of the Act does not prevent the agency from approving new technology add-on payment applications more than once a year, but mandates only that the Secretary provide the addition of new diagnosis and procedure codes on April 1, while giving the Secretary discretion to adjust the payment. One commenter proposed that the 60-day comment period could be avoided by CMS going through rulemaking to establish the substantive legal standards used to determine whether a product qualifies for new technology add-on payment, as well as the process, including the opportunity for public comment, for applying those standards. The commenter noted precedent for similar approaches under the Medicare program, including the Clinical Laboratory Fee Schedule rate setting process and the process for approving applications for transitional pass-through payment under the Outpatient Prospective Payment System. Another commenter stated that the statute [189] does not preclude CMS from considering applications prior to the required public meeting, and accordingly supported a quarterly review process.

A few commenters suggested that more frequent reviews could help address patient access challenges, reduce the volume of applications per application cycle, provide CMS with additional time to fully review and analyze applications and reduce the administrative burden on the agency, and ensure timely reimbursement for new technologies. Other commenters recommended that CMS consider expanding alternative pathways and conditional approvals to more types of technologies, for example, products designated as Breakthrough Therapies and Regenerative Medicine Advanced Therapies (RMAT) by the FDA, innovative therapies, cell and gene therapies, in-vitro diagnostics, etc., to reduce workload and accelerate review timelines. Some commenters recommended that CMS expand the new technology add-on payment conditional approval pathway to include all technologies approved or cleared by the FDA through the Breakthrough Device Program to reduce workload and improve access.

One commenter stated that CMS should consider more frequent application cycles or other mechanisms that allow for faster NTAP eligibility, and indicated that certain technologies, such as antimicrobial products, have unique characteristics or policy needs recognized by CMS that warrant bespoke new technology add-on payment policies. The commenter stated that CMS should consider adopting a similar mechanism in other contexts to allow a new technology add-on payment to be implemented on a rolling or quarterly basis, especially in situations where there is a heightened policy need to facilitate new technology add-on payment availability.

A number of commenters suggested that CMS not finalize these policies and instead gather additional input from interested parties to assist with finding alternative policies, such as convening various interested parties to discuss potential alternatives or issuing a separate request for information (RFI) related to the new technology add-on payment applications process. One commenter stated that a 200 percent increase in new technology add-on payment applications would require additional resources but recommended that CMS work with interested parties to explore other options before finalizing any policy and ensure that any future changes to the new technology add-on payment process maintain transparency into the agency's decisions and provide applicants and the public the opportunity to provide comments.

A few commenters recommended that instead of requiring proof of active FDA review by the application deadline, CMS should require that proof by the December supplemental information deadline. They stated that this could account for the lag between FDA submission and the acknowledgment letter CMS is proposing to require, and

[189] See SSA sec. 1886(d)(5)(K)(viii)(III).

this modification to the proposed policy would enable CMS to achieve the stated intent of striking a balance between being able to fully evaluate applications and preserving flexibility for manufacturers.

Response: We thank the commenters for their suggestions and recommendations. We believe at the heart of these comments is a shared interest among commenters and CMS in the goal of the new technology add-on payment program, which is to facilitate access to innovative new technologies for Medicare beneficiaries. We understand that the goals of other new technology payment pathways, such as transitional pass-through payments under the OPPS, may be similar.

However, there are a number of complexities, both legal and operational, that CMS would need to consider before proposing and finalizing an increase in the frequency of new technology add-on payment application review cycles, and not all of these complexities are the same in other new technology payment programs, such as transitional pass-through payment under the Outpatient Prospective Payment System. For example, the assessment of whether new technology add-on payment applicants meet the newness criterion intersects with other requirements associated with MS–DRG development and assessment, which is tied to fiscal year rulemaking and ratesetting. We note that we did not propose increasing the frequency of the new technology add-on payment application review cycle, and as such, we believe it is most appropriate to consider the feasibility of taking such steps in future years, so that we could solicit public comment through a full notice-and-comment rulemaking cycle.

Regarding the comments that recommended CMS should require proof of active FDA review by the December supplemental information deadline instead of the new technology add-on payment application deadline, as stated previously, we believe the new technology add-on payment application timeline with a simultaneous deadline for submission of a request for FDA marketing authorization is appropriate because when applicants submit new technology add-on payment applications prior to submitting a request to FDA for marketing authorization, missing information from their applications, which is needed to evaluate the eligibility of the technology for the add-on payment, will not become available until after submission to FDA.

With regard to expanding conditional approvals to other types of technologies, we note that we only recently established the pathway of conditional approvals. To date, no application that has gone through the conditional approval pathway has received FDA approval after being granted conditional new technology add-on payment approval and we therefore do not yet have sufficient experience with the conditional approval process. We do not currently have any reasonable expectation that expansion of eligibility for conditional approvals would advance our policy goals of promoting transparency, facilitating public input, and improving the review/evaluation process, or lead to additional technologies being granted conditional approval based on other new technology add-on payment criteria that we are required to assess. In addition, we have stated in prior rulemaking that we do not believe it is appropriate for CMS to determine whether a medical service or technology represents a substantial clinical improvement over existing technologies before FDA makes a determination as to whether the medical service or technology is safe and effective, and therefore we are unable to extend conditional approval to traditional applications (86 FR 45049).

With regard to expanding alternative pathways, we will continue to consider these issues for future rulemaking, including suggestions previously made by commenters to develop other ways pursuant to which a technology could qualify for new technology add-on payments, such as technologies that are designated for an FDA expedited program for drugs or devices (85 FR 58432).

We appreciate all the comments and various suggested alternatives to our proposal, as well as the recognition of our efforts toward greater transparency, public input, and streamlining of the new technology add-on application process. We acknowledge the concerns raised by commenters regarding flexibility and clarification of our policy. While commenters were concerned about our proposal, they did not address our concerns with regard to transparency. However, after having reviewed and carefully considered the comments and suggestions we received, we have determined that the additional information that will be made available by requiring a complete and active FDA marketing application prior to submission of a new technology add-on payment application, and the increased time for final review of such application made available by changing the FDA authorization deadline from July 1 to May 1, supports our decision to finalize these policy changes in this final rule. We have also further clarified the requirements for documentation and the meaning of ''complete and active'' under this policy, as described previously.

Therefore, for the reasons discussed previously and in the FY 2024 IPPS/LTCH proposed rule, we are finalizing our proposal to require applications to have a complete and active FDA marketing authorization request at the time of the new technology add-on payment application submission, and to move up the FDA marketing authorization deadline from July 1 to May 1, beginning with applications for FY 2025. As stated previously, we have noted commenters' concern regarding the potential impact of the shortened time period between April 1 and May 1, and we anticipate considering potential changes to the April 1 cut-off for future rulemaking. As previously noted, we are not making changes to the July 1 deadline for applications submitted under the alternative pathway for certain antimicrobial products because they would continue to be eligible for conditional approval under § 412.87(e)(3) (redesignated as § 412.87(f)(3)) in this final rule), as finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58740). We are also finalizing our proposal to redesignate § 412.87(e)(3) as § 412.87(f)(3), and to amend the redesignated § 412.87(f)(3) to revise the current cross-reference to § 412.87(e)(2), in light of the previously discussed proposed amendments.

III. Changes to the Hospital Wage Index for Acute Care Hospitals

A. Background

1. Legislative Authority

Section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. We currently define hospital labor market areas based on the delineations of statistical areas established by the Office of Management and Budget (OMB). A discussion of the FY 2024 hospital wage index based on the statistical areas appears under section III.A.2. of the preamble of this final rule.

Section 1886(d)(3)(E) of the Act requires the Secretary to update the wage index annually and to base the update on a survey of wages and wage-

related costs of short-term, acute care hospitals. CMS collects these data on the Medicare cost report, CMS Form 2552–10, Worksheet S–3, Parts II, III, IV. The OMB control number for this information collection request is 0938–0050, which expires on September 30, 2025. Section 1886(d)(3)(E) of the Act also requires that any updates or adjustments to the wage index be made in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. The adjustment for FY 2024 is discussed in section II.B. of the Addendum to this final rule.

As discussed in section III.I. of the preamble of this final rule, we also take into account the geographic reclassification of hospitals in accordance with sections 1886(d)(8)(B) and 1886(d)(10) of the Act when calculating IPPS payment amounts. Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amounts so as to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B), 1886(d)(8)(C), and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. The budget neutrality adjustment for FY 2024 is discussed in section II.A.4.b. of the Addendum to this final rule.

Section 1886(d)(3)(E) of the Act also provides for the collection of data every 3 years on the occupational mix of employees for short-term, acute care hospitals participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index. (The OMB control number for approved collection of this information is 0938–0907, which expires on January 31, 2026.) A discussion of the occupational mix adjustment that we are applying to the FY 2024 wage index appears under sections III.E. and F. of the preamble of this final rule.

2. Core-Based Statistical Areas (CBSAs) for the FY 2024 Hospital Wage Index

The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on OMB-established Core-Based Statistical Areas (CBSAs). The current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. OMB Bulletin No. 13–01 established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas in the United States and Puerto Rico based on the 2010 Census, and provided guidance on the use of the delineations of these statistical areas using standards published in the June 28, 2010, **Federal Register** (75 FR 37246 through 37252). We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 49951 through 49963 and 49973 through 49982) for a full discussion of our implementation of the OMB statistical area delineations beginning with the FY 2015 wage index.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses through OMB Bulletins. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provided updates to and superseded OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provided detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15–01 were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2012, and July 1, 2013. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56913), we adopted the updates set forth in OMB Bulletin No. 15–01 effective October 1, 2016, beginning with the FY 2017 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 15–01, we refer readers to the FY 2017 IPPS/LTCH PPS final rule. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38130), we continued to use the OMB delineations that were adopted beginning with FY 2015 to calculate the area wage indexes, with updates as reflected in OMB Bulletin No. 15–01 specified in the FY 2017 IPPS/LTCH PPS final rule.

On August 15, 2017, OMB issued OMB Bulletin No. 17–01, which provided updates to and superseded OMB Bulletin No. 15–01 that was issued on July 15, 2015. The attachments to OMB Bulletin No. 17–01 provided detailed information on the update to statistical areas since July 15, 2015, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2014 and July 1, 2015. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41362 through 41363), we adopted the updates set forth in OMB Bulletin No. 17–01 effective October 1, 2018, beginning with the FY 2019 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 17–01, we refer readers to the FY 2019 IPPS/LTCH PPS final rule. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42300 through 42301), we continued to use the OMB delineations that were adopted beginning with FY 2015 (based on the revised delineations issued in OMB Bulletin No. 13–01) to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15–01 and 17–01.

On April 10, 2018 OMB issued OMB Bulletin No. 18–03 which superseded OMB Bulletin No. 17–01 (August 15, 2017). On September 14, 2018, OMB issued OMB Bulletin No. 18–04 which superseded OMB Bulletin No. 18–03 (April 10, 2018). Historically OMB bulletins issued between decennial censuses have only contained minor modifications to CBSA delineations based on changes in population counts. However, OMB's 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates created a larger mid-decade redelineation that takes into account commuting data from the American Commuting Survey. As a result, OMB Bulletin No. 18–04 (September 14, 2018) included more modifications to the CBSAs than are typical for OMB bulletins issued between decennial censuses.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58743 through 58755) we adopted the updates set forth in OMB Bulletin No. 18–04 effective October 1, 2020, beginning with the FY 2021 wage index. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 18–04, we refer readers to the FY 2021 IPPS/LTCH PPS final rule.

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04 that was issued on September 14, 2018. The attachments to OMB Bulletin No. 20–01 provided detailed information on the update to statistical areas since September 14, 2018, and were based on the application of the 2010 Standards for Delineating Metropolitan and Micropolitan Statistical Areas to Census Bureau population estimates for July 1, 2017, and July 1, 2018. After reviewing OMB Bulletin No. 20–01, we determined that the changes in Bulletin 20–01 encompassed delineation changes that would not affect the Medicare wage

index for FY 2022. While we adopted the updates set forth in OMB Bulletin No. 20–01 in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45163 through 45164) consistent with our general policy of adopting OMB delineation updates, we also noted that specific wage index updates would not be necessary for FY 2022 as a result of adopting these updates. In other words, the updates set forth in OMB Bulletin No. 20–01 would not affect any hospital's geographic area for purposes of the wage index calculation for FY 2022. For a complete discussion of the adoption of the updates set forth in OMB Bulletin No. 20–01, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45163 through 45164).

For FY 2024, we will continue to use the OMB delineations that were adopted beginning with FY 2015 (based on the revised delineations issued in OMB Bulletin No. 13–01) to calculate the area wage indexes, with updates as reflected in OMB Bulletin Nos. 15–01, 17–01, 18–04 and 20–01.

3. Codes for Constituent Counties in CBSAs

CBSAs are made up of one or more constituent counties. Each CBSA and constituent county has its own unique identifying codes. There are two different lists of codes associated with counties: Social Security Administration (SSA) codes and Federal Information Processing Standard (FIPS) codes. Historically, CMS has listed and used SSA and FIPS county codes to identify and crosswalk counties to CBSA codes for purposes of the hospital wage index. As we discussed in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), we have learned that SSA county codes are no longer being maintained and updated. However, the FIPS codes continue to be maintained by the U.S. Census Bureau. We believe that using the latest FIPS codes will allow us to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts and labor market conditions.

The Census Bureau's most current statistical area information is derived from ongoing census data received since 2010; the most recent data are from 2020. The Census Bureau maintains a complete list of changes to counties or county equivalent entities on the website at *https://www.census.gov/programs-surveys/geography/technical-documentation/county-changes.html*. We believe that it is important to use the latest counties or county equivalent entities in order to properly crosswalk hospitals from a county to a CBSA for purposes of the hospital wage index used under the IPPS. Per the schedule published in a July 16, 2021 OMB Notice of Decision, we expect revised delineations based on the 2020 decennial census data to be available in July 2023 (86 FR 37775). We intend to address these revisions in future rulemaking.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130), we adopted a policy to discontinue the use of the SSA county codes and began using only the FIPS county codes for purposes of cross walking counties to CBSAs. In addition, in the same rule, we implemented the latest FIPS code updates, which were effective October 1, 2017, beginning with the FY 2018 wage indexes. These updates have been used to calculate the wage indexes in a manner generally consistent with the CBSA-based methodologies finalized in the FY 2005 IPPS final rule and the FY 2015 IPPS/LTCH PPS final rule. We refer the reader to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38129 through 38130) for a complete discussion of our adoption of FIPS county codes.

For FY 2024, we are continuing to use only the FIPS county codes for purposes of crosswalking counties to CBSAs. For FY 2024, Tables 2 and 3 associated with this final rule and the County to CBSA Crosswalk File and Urban CBSAs and Constituent Counties for Acute Care Hospitals File posted on the CMS website reflect the latest FIPS code updates.

B. Worksheet S–3 Wage Data for the FY 2024 Wage Index

The FY 2024 wage index values are based on the data collected from the Medicare cost reports submitted by hospitals for cost reporting periods beginning in FY 2020 (the FY 2023 wage indexes were based on data from cost reporting periods beginning during FY 2019).

1. Included Categories of Costs

The FY 2024 wage index includes all of the following categories of data associated with costs paid under the IPPS (as well as outpatient costs):

- Salaries and hours from short-term, acute care hospitals (including paid lunch hours and hours associated with military leave and jury duty).
- Home office costs and hours.
- Certain contract labor costs and hours, which include direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services, and certain contract indirect patient care services (as discussed in the FY 2008 final rule with comment period (72 FR 47315 through 47317)).
- Wage-related costs, including pension costs (based on policies adopted in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51586 through 51590) and modified in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49505 through 49508)) and other deferred compensation costs.

2. Excluded Categories of Costs

Consistent with the wage index methodology for FY 2023, the wage index for FY 2024 also excludes the direct and overhead salaries and hours for services not subject to IPPS payment, such as skilled nursing facility (SNF) services, home health services, costs related to GME (teaching physicians and residents) and certified registered nurse anesthetists (CRNAs), and other subprovider components that are not paid under the IPPS. The FY 2024 wage index also excludes the salaries, hours, and wage-related costs of hospital-based rural health clinics (RHCs), and Federally Qualified Health Centers (FQHCs) because Medicare pays for these costs outside of the IPPS (68 FR 45395). In addition, salaries, hours, and wage-related costs of CAHs are excluded from the wage index for the reasons explained in the FY 2004 IPPS final rule (68 FR 45397 through 45398). For FY 2020 and subsequent years, other wage-related costs are also excluded from the calculation of the wage index. As discussed in the FY 2019 IPPS/LTCH final rule (83 FR 41365 through 41369), other wage-related costs reported on Worksheet S–3, Part II, Line 18 and Worksheet S–3, Part IV, Line 25 and subscripts, as well as all other wage-related costs, such as contract labor costs, are excluded from the calculation of the wage index.

3. Use of Wage Index Data by Suppliers and Providers Other Than Acute Care Hospitals Under the IPPS

Data collected for the IPPS wage index also are currently used to calculate wage indexes applicable to suppliers and other providers, such as SNFs, home health agencies (HHAs), ambulatory surgical centers (ASCs), and hospices. In addition, they are used for prospective payments to IRFs, IPFs, and LTCHs, and for hospital outpatient services. We note that, in the IPPS rules, we do not address comments pertaining to the wage indexes of any supplier or provider except IPPS providers and LTCHs. Such comments should be made in response to separate proposed rules for those suppliers and providers. We did not receive any comments on the discussion in this section.

C. Verification of Worksheet S–3 Wage Data

The wage data for the FY 2024 wage index were obtained from Worksheet S–3, Parts II, III and IV of the Medicare cost report, CMS Form 2552–10 (OMB Control Number 0938–0050 with an expiration date September 30, 2025) for cost reporting periods beginning on or after October 1, 2019, and before October 1, 2020. For wage index purposes, we refer to cost reports beginning on or after October 1, 2019, and before October 1, 2020, as the ''FY 2020 cost report,'' the ''FY 2020 wage data,'' or the ''FY 2020 data.'' Instructions for completing the wage index sections of Worksheet S–3 are included in the Provider Reimbursement Manual (PRM), Part 2 (Pub. 15–2), Chapter 40, sections 4005.2 through 4005.4. The data file used to construct the FY 2024 wage index includes FY 2020 data submitted to us as of June 2023. As in past years, we performed an extensive review of the wage data, mostly through the use of edits designed to identify aberrant data.

Consistent with the IPPS and LTCH PPS ratesettings, our policy principles with regard to the wage index include generally using the most current data and information available which is usually data on a 4-year lag (for example, for the FY 2022 wage index we used cost report data from FY 2018). We stated in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48994) that we will be looking at the differential effects of the COVID–19 PHE on the audited wage data in future fiscal years. We also stated we plan to review the audited wage data, and the impacts of the COVID–19 PHE on such data and evaluate these data for future rulemaking. For the FY 2024 wage index, the best available data typically would be from the FY 2020 wage data.

In the proposed rule we stated that based on pre reclassified wage data, the changes in the wage data from FY 2019 to FY 2020 show the following compared to the annual changes for the most recent 3 year periods (that is, FY 2016 to FY 2017, FY 2017 to FY 2018 and FY 2018 to FY 2019):

- Approximately 85 percent of hospitals have an increase in their average hourly wage (AHW) from FY 2019 to FY 2020 compared to a range of 76–77 percent of hospitals for the most recent 3 year periods.
- Approximately 81 percent of all CBSA AHWs increased from FY 2019 to FY 2020 compared to a range of 73–75 percent of all CBSAs for the most recent 3 year periods.
- Approximately 36 percent of all urban areas have an increase in their area wage index from FY 2019 to FY 2020 compared to a range of 41–43 percent of all urban areas for the most recent 3 year periods.
- Approximately 2.8 percent of all rural areas have an increase in their area wage index from FY 2019 to FY 2020 compared to a range of 4–6 percent of all rural areas for the most recent 3 year periods.
- The unadjusted national average hourly wage increased by a range of 2.4–2.8 percent per year from FY 2016 to FY 2019. For FY 2020, the unadjusted national average hourly increased by 5.3 percent from FY 2019.

Even if the comparison with the historical trends had indicated greater differences at a national level in this context, we stated it is not apparent whether any changes due to the COVID–19 PHE differentially impacted the wages paid by individual hospitals. Furthermore, even if hypothetically changes due to the COVID–19 PHE did differentially impact the wages paid by individual hospitals over time, we further stated that it is not clear how those changes could be isolated from changes due to other reasons and what an appropriate potential methodology might be to adjust the data.

Lastly, we also noted that we did not identify any significant issues with the FY 2020 wage data itself in terms of our audits of this data. As usual, the data was audited by the MACs, and there were no significant issues reported across the data for all hospitals.

Taking all of these factors into account, we stated that we believe the FY 2020 wage data is the best available wage data to use for FY 2024. Therefore, we proposed to use the FY 2020 wage data for FY 2024.

We also noted that AHW data by provider and CBSA, including the data upon which the comparisons as previously described are based, is available in our Public Use Files released with each proposed and final rule each fiscal year. The Public Use Files for the respective FY Wage Index Home Page can be found on the Wage Index Files web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files*.

Comment: One commenter stated that CMS should not be utilizing any data from FY 2020 due to the impacts of COVID–19.

Another commenter stated that based on the agency's description in the proposed rule, the specifics of the analysis above are unclear, as the agency does not reference specific tables or files for the public to review to confirm the agency's conclusion. The commenter further stated that while CMS states that the data does not show a significant discrepancy from prior years' data, when compared to trends from the previous three fiscal years, the FY 2020 data does not follow the same trends. Also, the commenter noted that the extent of the wage increases is important to consider, not just the percentage of hospitals that saw an hourly wage increase. The commenter stated that without knowing what other sources of data are available for future wage index calculations or evaluating a comparison of other data sources to identify any potential discrepancies, the commenter is concerned that the impact of the COVID–19 PHE may not be easily parsed out of future years' data.

The commenter also commented that while CMS states that it does not believe the PHE alone is responsible for these changes, and that it is difficult to parse out what impact the PHE had versus other factors that may be driving up wages, the commenter is concerned that the agency does not provide alternate methods for calculating the wage index to try to account for the impact of COVID–19. Although the impact of the PHE may not have been apparent on wage data until partially through FY 2020, the commenter believes that CMS should consider approaches to best account for the wage spikes and changes that are a result of the pandemic. The commenter cited data from Vizient's May 2023 Workforce Intelligence Report [190] that contract labor rates are expected to stay 15% above pre-pandemic levels due to inflation and other external economic factors. The commenter also noted that numerous nursing workforce trends changed once the pandemic began in 2020, including those related to nursing overtime hours as a percentage of hours work, burnout, and turnover and asserted that these trends are not sustainable. The commenter also stated that if hospitals were to adopt and use strategies to address staffing challenges (*e.g.,* ensure nurses are practicing at the top of their license, plan ahead for seasonable contract labor use, using technology as an enabler but not a standalone solution) they would impact the wage index and such trends are not considered by CMS. The commenter encouraged CMS to share additional information regarding its analysis and other information the agency needs so stakeholders can better understand the

[190] *https://vizientinc-delivery.sitecorecontenthub.cloud/api/public/content/c372877070484a40be8cde3b480606f9.*

agency's position and respond accordingly. The commenter further encouraged CMS to begin exploring alternate data sources and analyses to better understand how to account for the impact of the pandemic in the wage index given enduring employment trends that were triggered by the pandemic. The commenter concluded that CMS should work with stakeholders on further developing or refining such an approach to promote stability and accuracy.

Response: We are unsure what the commenter means when it states that the agency does not reference specific tables or files for the public to review to confirm the agency's conclusion. As stated above, AHW data by provider and CBSA, including the data upon which the comparisons, as previously described are based, is available in our Public Use Files released with each proposed and final rule each fiscal year. The Public Use Files for the respective FY Wage Index Home Page can be found on the Wage Index Files web page at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files*. Therefore, any comparisons that CMS made within the current year data and prior year data can easily be replicated by the public by utilizing standard, commonly known statistical methods.

Also, the commenter states that the FY 2020 data does not follow the same trends as prior years. However, as stated earlier, for the reasons described above (it is not apparent whether any changes due to the COVID–19 PHE differentially impacted the wages paid by individual hospitals; even if hypothetically changes due to the COVID–19 PHE did differentially impact the wages paid by individual hospitals over time, we further stated that it is not clear how those changes could be isolated from changes due to other reasons and what an appropriate potential methodology might be to adjust the data; we did not identify any significant issues with the FY 2020 wage data itself in terms of our audits of this data), we continue to believe the FY 2020 wage data is the best available wage data to use for FY 2024.

With regard to the use of alternative data, as stated above, we did not identify any significant issues with the FY 2020 wage data itself in terms of our audits of this data. As usual, the data was audited by the MACs, and there were no significant issues reported across the data for all hospitals. Also, as stated above, it is not apparent whether any changes due to the COVID–19 PHE *differentially* impacted the wages paid by individual hospitals. Furthermore, the commenters did not present any data from the actual wage data demonstrating the need to use alternative data. The commenter cited outside data sources with no actual data from our public use files. Additionally, the commenter is asking CMS to project potential changes hospitals may make to address potential staffing shortages without any supporting data. Also, if hospital workforce trends changed uniformly once the pandemic began in 2020 or if hospitals adopted strategies to address staffing shotages uniformly, then this would be reflected uniformly across the salaries and hours for all hospitals and areas (which is used to calculate an area's AHW) which would lead to a commensurate change to the national AHW and not the wage index itself. Therefore, we continue to believe the FY 2020 wage data is the best available wage data to use for FY 2024.

Comment: One commenter stated that as a result of high COVID–19 patient volume for more than two years and subsequent healthcare staff departures during the pandemic, hospitals are in the midst of a national staffing shortage. The commenter continued that inflation is simultaneously driving up healthcare costs during this workforce shortage. The commenter believes CMS should offer short-term assistance to the hospital community, considering inflationary updates to the wage index as necessary to preserve current service levels, which is a particular risk point for underserved populations. The commenter recommended a more time-sensitive and layered approach to wage index updates to account for excess labor costs driven by increased contract labor and reimbursement rates to preserve critical national hospital system infrastructure. The commenter stated that CMS could accomplish this by leveraging current Medicare surveys and reporting to develop a wage adjustment until the labor market stabilizes. The commenter concluded that this approach would account for regional disparities and impact, use known and accepted survey data, create a standardized and auditable system, and support hospitals without disrupting the baseline Medicare wage index.

Response: The commenter mentions that CMS could leverage current Medicare surveys and reporting to develop a wage adjustment until the labor market stabilizes. It is not clear what the commenter is requesting. As stated above, the latest audited wage data is from FY 2020. We do not possesss audited wage data from a more recent period. We also are unsure what type of adjustment the commenter is requesting and how this adjustment would account for regional adjustments. Without additional information we are unable to respond directly to the comment. Also, as previously noted, section 1886(d)(3)(E) of the Act requires that, as part of the methodology for determining prospective payments to hospitals, the Secretary adjust the standardized amounts for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. If the commenter is requesting a uniform adjustment to the salaries and hours then uniformly adjusting the salaries and hours for all areas (which is used to calculate an areas AHW) would lead to a commensurate change to the national AHW and not the wage index itself. This is because the wage index is required to be a relative measure.

Comment: One commenter urged CMS to reconsider using FY 2020 cost report data to calculate the wage index. The commenter explained that CMS has stated that FY 2020 cost reports contained data that was significantly impacted by the COVID–19 PHE, which will disproportionately impact reimbursements for Massachusetts hospitals and cause these hospitals to be underpaid because of the ''Nantucket effect.'' That is, the commenter noted that, in general, Massachusetts hospitals saw heightened levels of COVID–19 patients in FY 2020, while one hospital located on the island of Nantucket saw almost no COVID–19 patients because the island was able to isolate from the rest of the state. As a result of this effect, the commenter contended that the Nantucket hospital's FY 2020 cost report is not reflective of the COVID burden experienced by other hospitals in the state. The commenter recommended that CMS use the FY 2022 cost reports, which better reflects its labor market.

Response: We believe the commeneter is referring to provider number 220110, Nantucket Cottage Hospital, as this is the only hospital from Nantucket included in the wage data. Within the wage data each fiscal year, there are hospitals that have different hiring practices and experiences. For example, some hospitals may be smaller than others and not provide the same complex services as another hospital in the area. Or one hospital may have more contracted workers compared to another hospital in the same area that has no contracted workers. Perhaps one hospital is focused on cancer patients compared to another hospital that tries

to provide all types of servies. But these are not reasons that would make a hospitals data aberrant. This simply means that hospitals provide different care, have different hiring practices or have different case mixes and are different than eachother; but it does not make the wage data aberrant or not reflective of the area. Similarly, a hospital that may have had a different experience with COVID does not mean the wage data of that hospital is aberrant or not reflective of the area. Also, we are unsure what issue the commenter is referring to with regard to including this hospital in its area as Nantucket Cottage Hospital is the only hospital located in rural Massachusetts. Finally, the data for the FY 2024 wage index uses FY 2020 cost report data which was audited by the MACs, and there were no significant issues reported across the data for all hospitals. Additionally, CMS used the most recent audited surveys and data to develop the FY 2024 wage index. Audited cost report data from FY 2022 will be used for FY 2026 and is not available at the time of this final rule. Therefore, we do not have any audited data from the FY 2022 cost reports available for use at the time of this final rule. We continue to believe the FY 2020 wage data is the best available wage data to use for FY 2024.

For the FY 2025 wage index, as in the past two fiscal years, we plan to review the audited wage data, and the impacts of the COVID–19 PHE on such data and evaluate these data for future rulemaking.

Section 1886(d)(3)(E) of the Act requires the Secretary to adjust the proportion of hospitals' costs attributable to wages and wage-related costs for area differences reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. In response to public comments, as previously stated in past final rules (the FY 2016 IPPS/LTCH PPS final rule (80 FR 49490 through 49491), the FY 2022 IPPS/LTCH PPS final rule (86 FR 45168 through 45169), and the FY 2023 IPPS/LTCH PPS final rule (87 FR 48996 through 48997)), we believe that, under this section of the Act, we have discretion to exclude aberrant hospital data from the wage index public use files (PUFs) to help ensure that the costs attributable to wages and wage-related costs in fact reflect the relative hospital wage level in the hospitals' geographic area. We refer the reader to our previous responses to comments at the **Federal Register** pages cited earlier with regard to the exclusion of hospitals' wage data from the wage index.

Comment: Commenters opposed the exclusion of audited hospitals' wage data which they contended was arbitrarily excluded from the proposed rule wage data. These commenters stated that excluding accurate and verified data is inconsistent with the extensive process established by CMS to ensure the accuracy and reliability of hospital wage index data. Commenters also stated the following concerns about the lawfulness of excluding wage data for these hospitals:

- Nothing in the applicable statute, section 1886(d)(3)(E), permits CMS to exclude general acute care hospitals from the wage index data simply because those hospitals' wages are higher than the wages of other hospitals in their area. Rather, as indicated by CMS in past rulemakings, the wages of all short-term acute care hospitals must be included unless such data are incomplete or inaccurate.
- Even if CMS had the authority to exclude certain hospitals despite the fact that their data were accurate and verifiable (which is the case with these hospitals), the exclusion of these hospitals would be arbitrary and capricious, as CMS has promulgated no standards to govern the exercise of its discretion. CMS has established an extensive process to ensure the accuracy and reliability of hospital wage data, which the excluded hospitals have been subjected to. Yet, where the agency does not like the result, it has decided to deviate from this process by arbitrarily excluding hospitals with accurate data.
- CMS' exclusion of these hospitals is procedurally improper, as CMS has failed to promulgate a rule in accordance with the Administrative Procedures Act (APA) and section 2886 of the Social Security Act that would define what constitutes aberrant data or authorize excluding hospitals with verifiable data from the Medicare wage index.
- CMS has failed to consider the relevant factors and has relied on factors that are not relevant under the applicable statute. As a result, its action is arbitrary and capricious. The commenter explained that because CMS has not conducted notice-and-comment rulemaking to establish standards for excluding hospitals from the wage index, it is unknown what factors CMS considered. Further, since CMS has not proposed any ascertainable standards, the public has no meaningful opportunity to comment on the factors that should be considered.
- The proposed exclusions for FFY 2024 will cause significant harm to not only IPPS hospitals, but also inpatient psychiatric hospitals, SNFs, inpatient rehabilitation hospitals (IRFs), and many others. The consequence of these exclusions negatively impacting more than the IPPS hospitals appear to be unintended by CMS, as it failed to even consider them in its regulatory fiscal impact analysis in the proposed rule, which it is legally required to do. Thus, the exclusions are legally impermissible.

Response: As discussed above, we responded to similar comments in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49490 through 49491) and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45168 through 45169). We provide summary responses below based on our responses to similiar comments from previous rulemaking. However, we refer commenters to the **Federal Register** pages cited earlier for our complete response to similar comments with regard to the exclusion of hospitals' wage data from the wage index.

Section 1886(d)(3)(E) of the Act requires the Secretary to adjust the proportion of hospitals' costs attributable to wages and wage-related costs for area differences reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level. As previously stated in those final rules, we believe that, under this section of the Act, we have discretion to exclude aberrant hospital data from the wage index PUFs to help ensure that the costs attributable to wages and wage-related costs in fact reflect the relative hospital wage level in the hospitals' geographic area.

Also, as discussed in response to comments in prior rules (80 FR 49490 and 86 FR 45168), as a standard part of the refinement of the annual wage index, CMS evaluates the wage data for both accuracy and reasonableness to ensure that the wage index is a relative measure of the labor value provided to a typical hospital in a particular labor market area. We have also previously stated that a hospital is included in the wage index if its data are reasonable, regardless of whether the hospital is open or whether it has terminated after the relevant past period, because the wage index is constructed to represent the relative average hourly wage for each labor market area in that past period. Thus, reasonableness and relativity to each area's average hourly wages have been longstanding tenets of the wage index development process that CMS has articulated in rulemaking.

We acknowledge the commenters' suggestions for increased transparency and disclosure of criteria for hospitals' exclusion. We believe performing analysis of hospitals' wage data quality

and conducting edits for reasonableness are inherent parts of conducting a survey of the wages and wage-related costs of subsection (d) hospitals. We note that it has never been CMS' policy to disclose audit protocol, because CMS is concerned that allowing hospitals to become familiar with our audit parameters—which are based on standard mathematical processes—would create opportunities for hospitals to take action to manipulate their data in order to game audit thresholds. However, in the future, we will continue to consider a limited proposal regarding criteria for excluding a hospital's data from the wage index due to its overall average hourly wage being either too high or too low, as well as utilizing additional methods of communicating with stakeholders regarding the adequacy of their wage data.

As discussed in response to comments in prior rules (80 FR 49491 and 86 FR 45169), just as CMS has excluded certain hospitals from the wage index with extraordinarily high average hourly wages relative to their labor market areas, CMS also has excluded hospitals with extraordinarily low average hourly wages relative to their labor market areas. Therefore, we disagree with commenters' assertions that we have been ''arbitrary and capricious'' in excluding hospitals from the wage index.

We also reiterate the following example of a hospital in California removed from the FY 2024 wage index. The hospital is located in CBSA 23420 (Fresno, California) and had a very high average hourly wage and was removed from the wage data even though the hospital's wage data was properly documented. However, the hospital does not merely have the highest average hourly wage in the CBSA; its average hourly wage is extremely and unusually high, significantly higher than the next highest average hourly wage in that CBSA and in the surrounding areas. While we believe this is a result of the unique salary structure and business model of the hospital's owner, not from a lack of reliability in its wage data, we believe the data is nonetheless aberrant and we therefore have authority to remove it. We do not believe that the average hourly wage of this particular hospital accurately reflects the economic conditions in its labor market area during the FY 2018 cost reporting period. Therefore, its inclusion in the wage index would not ensure that the FY 2024 wage index represents the labor market area's current wages as compared to the national average of wages. Rather, its inclusion would distort the average hourly wage of its labor market area. Accordingly, we have exercised our discretion to remove this hospital's wage data from the FY 2024 wage index.

With regard to the impact on facilities paid under other PPSs, we refer commenters to the rulemaking of those PPSs for comments on the wage index.

We requested that our MACs revise or verify data elements that result in specific edit failures. For the proposed FY 2024 wage index, we identified and excluded 88 providers with aberrant data that should not be included in the wage index. However, we stated that if data elements for some of these providers are corrected, we intended to include data from those providers in the final FY 2024 wage index. We also adjusted certain aberrant data and included these data in the wage index. For example, in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). We instructed MACs to complete their data verification of questionable data elements and to transmit any changes to the wage data no later than March 20, 2023. For the final FY 2024 wage index, we restored the data of 27 hospitals to the wage index, because their data was either verified or improved. Thus, 61 hospitals with aberrant data remain excluded from the FY 2024 wage index (88 − 27 = 61).

In constructing the proposed FY 2024 wage index, we included the wage data for facilities that were IPPS hospitals in FY 2020, inclusive of those facilities that have since terminated their participation in the program as hospitals, as long as those data did not fail any of our edits for reasonableness. We stated in the proposed rule (88 FR 26965 through 26967) that we believe that including the wage data for these hospitals is, in general, appropriate to reflect the economic conditions in the various labor market areas during the relevant past period and to ensure that the current wage index represents the labor market area's current wages as compared to the national average of wages. However, we excluded the wage data for CAHs as discussed in the FY 2004 IPPS final rule (68 FR 45397 through 45398); that is, any hospital that is designated as a CAH by 7 days prior to the publication of the preliminary wage index public use file (PUF) is excluded from the calculation of the wage index. For the proposed FY 2024 wage index, we removed 1 hospital that converted to CAH status on or after January 22, 2022, the cut-off date for CAH exclusion from the FY 2023 wage index, and through and including January 23, 2023, the cut-off date for CAH exclusion from the FY 2024 wage index. Since the proposed rule, we learned of 1 more hospital that converted to CAH status on or after January 22, 2022, and through and including January 23, 2023, the cut-off date for CAH exclusion from the FY 2024 wage index, for a total of 2 hospital that were removed from the FY 2024 wage index due to conversion to CAH status. In summary, we calculated the FY 2024 wage index using the Worksheet S–3, Parts II and III wage data of 3,129 hospitals.

For the FY 2024 wage index, we allotted the wages and hours data for a multicampus hospital among the different labor market areas where its campuses are located using campus full-time equivalent (FTE) percentages as originally finalized in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51591). Table 2, which contains the FY 2024 wage index associated with this final rule (available via the internet on the CMS website), includes separate wage data for the campuses of 28 multicampus hospitals. The following chart lists the multicampus hospitals by core service area (CSA) certification number (CCN) and the FTE percentages on which the wages and hours of each campus were allotted to their respective labor market areas:

BILLING CODE 4120–01–P

CCN of Main Campus of Multicampus Hospital	Full-Time Equivalent Percentage of Main Campus	CCN of Sub Campus of Multicampus Hospital	Full-Time Equivalent Percentage of Sub Campus
050121	0.86	05B121	0.14
070010	0.87	07B010	0.13
070022	0.99	07B022	0.01
070033	0.93	07B033	0.07
100029	0.51	10B029	0.49
100167	0.66	10B167	0.34
140010	0.83	14B010	0.17
220074	0.89	22B074	0.11
310069	0.80	31B069	0.20
330103	0.64	33B103	0.36
330195	0.89	33B195	0.11
330214	0.76	33B214	0.24
330234	0.79	33B234	0.21
340115	0.95	34B115	0.05
360020	0.97	36B020	0.03
390006	0.96	39B006	0.04
390115	0.84	39B115	0.16
390142	0.84	39B142	0.16
450033	0.99	45B033	0.01
450107	0.50	45B107	0.50
450330	0.98	45B330	0.02
460051	0.78	46B051	0.22
510022	0.94	51B022	0.06
520009	0.70	52B009	0.30
520030	0.95	52B030	0.05
670062	0.69	67B062	0.31
670107	0.69	67B107	0.31

BILLING CODE 4120–01–C

We note that, in past years, in Table 2, we have placed a ''B'' to designate the subordinate campus in the fourth position of the hospital CCN. However, for the FY 2019 IPPS/LTCH PPS proposed and final rules and subsequent rules, we have moved the ''B'' to the third position of the CCN. Because all IPPS hospitals have a ''0'' in the third position of the CCN, we believe that placement of the ''B'' in this third position, instead of the ''0'' for the subordinate campus, is the most efficient method of identification and interferes the least with the other, variable, digits in the CCN.

D. Method for Computing the FY 2024 Unadjusted Wage Index

As stated in the proposed rule (88 FR 26967 through 26970), the method used to compute the FY 2024 wage index without an occupational mix adjustment follows the same methodology that we used to compute the wage indexes without an occupational mix adjustment in the FY 2021 IPPS/LTCH PPS final rule (see 85 FR 58758 through 58761, September 18, 2020), and we did not propose any changes to this methodology. We have restated our methodology in this section of this rule.

Step 1.—We gathered data from each of the non-Federal, short-term, acute care hospitals for which data were reported on the Worksheet S–3, Parts II and III of the Medicare cost report for the hospital's cost reporting period relevant to the wage index (in this case, for FY 2024, these were data from cost reports for cost reporting periods beginning on or after October 1, 2019, and before October 1, 2020). In addition, we included data from some hospitals

that had cost reporting periods beginning before October 2019 and reported a cost reporting period covering all of FY 2020. These data were included because no other data from these hospitals would be available for the cost reporting period as previously described, and because particular labor market areas might be affected due to the omission of these hospitals. However, we generally describe these wage data as FY 2020 data. We note that, if a hospital had more than one cost reporting period beginning during FY 2020 (for example, a hospital had two short cost reporting periods beginning on or after October 1, 2019, and before October 1, 2020), we include wage data from only one of the cost reporting periods, the longer, in the wage index calculation. If there was more than one cost reporting period and the periods were equal in length, we included the wage data from the later period in the wage index calculation.

Step 2.—Salaries.—The method used to compute a hospital's average hourly wage excludes certain costs that are not paid under the IPPS. We note that, beginning with FY 2008 (72 FR 47315), we included what were then Lines 22.01, 26.01, and 27.01 of Worksheet S–3, Part II of CMS Form 2552–96 for overhead services in the wage index. Currently, these lines are lines 28, 33, and 35 on CMS Form 2552–10. However, we note that the wages and hours on these lines are not incorporated into Line 101, Column 1 of Worksheet A, which, through the electronic cost reporting software, flows directly to Line 1 of Worksheet S–3, Part II. Therefore, the first step in the wage index calculation is to compute a ''revised'' Line 1, by adding to the Line 1 on Worksheet S–3, Part II (for wages and hours respectively) the amounts on Lines 28, 33, and 35.) In calculating a hospital's Net Salaries (we note that we previously used the term ''average'' salaries in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51592), but we now use the term ''net'' salaries) plus wage-related costs, we first compute the following: Subtract from Line 1 (total salaries) the GME and CRNA costs reported on CMS Form 2552–10, Lines 2, 4.01, 7, and 7.01, the Part B salaries reported on Lines 3, 5 and 6, home office salaries reported on Line 8, and exclude salaries reported on Lines 9 and 10 (that is, direct salaries attributable to SNF services, home health services, and other subprovider components not subject to the IPPS). We also subtract from Line 1 the salaries for which no hours were reported. Therefore, the formula for Net Salaries (from Worksheet S–3, Part II) is the following:

((Line 1 + Line 28 + Line 33 + Line 35)— (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)).

To determine Total Salaries plus Wage-Related Costs, we add to the Net Salaries the costs of contract labor for direct patient care, certain top management, pharmacy, laboratory, and nonteaching physician Part A services (Lines 11, 12 and 13), home office salaries and wage-related costs reported by the hospital on Lines 14.01, 14.02, and 15, and nonexcluded area wage-related costs (Lines 17, 22, 25.50, 25.51, and 25.52). We note that contract labor and home office salaries for which no corresponding hours are reported are not included. In addition, wage-related costs for nonteaching physician Part A employees (Line 22) are excluded if no corresponding salaries are reported for those employees on Line 4. The formula for Total Salaries plus Wage-Related Costs (from Worksheet S–3, Part II) is the following:

((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15) + (Line 17 + Line 22 + 25.50 + 25.51 + 25.52).

Step 3.—Hours.—With the exception of wage-related costs, for which there are no associated hours, we compute total hours using the same methods as described for salaries in Step 2. The formula for Total Hours (from Worksheet S–3, Part II) is the following:

((Line 1 + Line 28 + Line 33 + Line 35) − (Line 2 + Line 3 + Line 4.01 + Line 5 + Line 6 + Line 7 + Line 7.01 + Line 8 + Line 9 + Line 10)) + (Line 11 + Line 12 + Line 13 + Line 14.01 + 14.02 + Line 15).

Step 4.—For each hospital reporting both total overhead salaries and total overhead hours greater than zero, we then allocate overhead costs to areas of the hospital excluded from the wage index calculation. First, we determine the ''excluded rate'', which is the ratio of excluded area hours to Revised Total Hours (from Worksheet S–3, Part II) with the following formula:

(Line 9 + Line 10)/(Line 1 + Line 28 + Line 33 + Line 35) − (Lines 2, 3, 4.01, 5, 6, 7, 7.01, and 8 and Lines 26 through 43).

We then compute the amounts of overhead salaries and hours to be allocated to the excluded areas by multiplying the previously discussed ratio by the total overhead salaries and hours reported on Lines 26 through 43 of Worksheet S–3, Part II. Next, we compute the amounts of overhead wage-related costs to be allocated to the excluded areas using three steps:

- We determine the ''overhead rate'' (from Worksheet S–3, Part II), which is the ratio of overhead hours (Lines 26 through 43 minus the sum of Lines 28, 33, and 35) to revised hours excluding the sum of lines 28, 33, and 35 (Line 1 minus the sum of Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, 9, 10, 28, 33, and 35). We note that, for the FY 2008 and subsequent wage index calculations, we have been excluding the overhead contract labor (Lines 28, 33, and 35) from the determination of the ratio of overhead hours to revised hours because hospitals typically do not provide fringe benefits (wage-related costs) to contract personnel. Therefore, it is not necessary for the wage index calculation to exclude overhead wage-related costs for contract personnel. Further, if a hospital does contribute to wage-related costs for contracted personnel, the instructions for Lines 28, 33, and 35 require that associated wage-related costs be combined with wages on the respective contract labor lines. The formula for the Overhead Rate (from Worksheet S–3, Part II) is the following:

(Lines 26 through 43—Lines 28, 33 and 35)/((((Line 1 + Lines 28, 33, 35)— (Lines 2, 3, 4.01, 5, 6, 7, 7.01, 8, and 26 through 43)) − (Lines 9 and 10)) + (Lines 26 through 43 − Lines 28, 33, and 35)).

- We compute overhead wage-related costs by multiplying the overhead hours ratio by wage-related costs reported on Part II, Lines 17, 22, 25.50, 25.51, and 25.52.
- We multiply the computed overhead wage-related costs by the previously described excluded area hours ratio.

Finally, we subtract the computed overhead salaries, wage-related costs, and hours associated with excluded areas from the total salaries (plus wage-related costs) and hours derived in Steps 2 and 3.

Step 5.—For each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2019, through April 15, 2021, for private industry hospital workers from the Bureau of Labor Statistics' (BLS') National Compensation Survey. We use the ECI because it reflects the price

increase associated with total compensation (salaries plus fringes) rather than just the increase in salaries. In addition, the ECI includes managers as well as other hospital workers. This methodology to compute the monthly update factors uses actual quarterly ECI data and assures that the update factors match the actual quarterly and annual percent changes. We also note that, since April 2006 with the publication of March 2006 data, the BLS' ECI uses a different classification system, the North American Industrial Classification System (NAICS), instead of the Standard Industrial Codes (SICs), which no longer exist. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we did not propose to make any changes to the usage of the ECI for FY 2024. The factors used to adjust the hospital's data are based on the midpoint of the cost reporting period, as indicated in this rule.

Step 6.—Each hospital is assigned to its appropriate urban or rural labor market area before any reclassifications under section 1886(d)(8)(B), 1886(d)(8)(E), or 1886(d)(10) of the Act. Within each urban or rural labor market area, we add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in that area to determine the total adjusted salaries plus wage-related costs for the labor market area.

Step 7.—We divide the total adjusted salaries plus wage-related costs obtained under Step 6 by the sum of the corresponding total hours (from Step 4) for all hospitals in each labor market area to determine an average hourly wage for the area.

Step 8.—We add the total adjusted salaries plus wage-related costs obtained in Step 5 for all hospitals in the nation and then divide the sum by the national sum of total hours from Step 4 to arrive at a national average hourly wage.

Step 9.—For each urban or rural labor market area, we calculate the hospital wage index value, unadjusted for occupational mix, by dividing the area average hourly wage obtained in Step 7 by the national average hourly wage computed in Step 8.

Step 10.—For each urban labor market area for which we do not have any hospital wage data (either because there are no IPPS hospitals in that labor market area, or there are IPPS hospitals in that area but their data are either too new to be reflected in the current year's wage index calculation, or their data are aberrant and are deleted from the wage index), we finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42305) that, for FY 2020 and subsequent years' wage index calculations, such CBSA's wage index would be equal to total urban salaries plus wage-related costs (from Step 5) in the State, divided by the total urban hours (from Step 4) in the State, divided by the national average hourly wage from Step 8 (see 84 FR 42305 and 42306, August 16, 2019). We stated that we believe that, in the absence of wage data for an urban labor market area, it is reasonable to use a statewide urban average, which is based on actual, acceptable wage data of hospitals in that State, rather than impute some other type of value using a different methodology. For calculation of the FY 2024 wage index, we note there is one urban CBSAs for which we do not have IPPS hospital wage data. In Table 3 (which is available via the internet on the CMS website) which contains the area wage indexes, we include a footnote to indicate to which CBSAs this policy applies. These CBSAs' wage indexes would be equal to total urban salaries plus wage-related costs (from Step 5) in the respective State, divided by the total urban hours (from Step 4) in the respective State, divided by the national average hourly wage (from Step 8) (see 84 FR 42305 and 42306, August 16, 2019). Under this step, we also apply our policy with regard to how dollar amounts, hours, and other numerical values in the wage index calculations are rounded, as discussed in this section of this rule.

We refer readers to section II. of appendix A of this final rule for the policy regarding rural areas that do not have IPPS hospitals.

Step 11.—Section 4410 of Public Law 105–33 provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. The areas affected by this provision are identified in Table 2 listed in section VI. of the Addendum to the final rule and available via the internet on the CMS website.

The following is our policy with regard to rounding of the wage data (dollar amounts, hours, and other numerical values) in the calculation of the unadjusted and adjusted wage index, as finalized in the FY 2020 IPPS/LTCH final rule (84 FR 42306, August 16, 2019). For data that we consider to be ''raw data,'' such as the cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we use such data ''as is,'' and do not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we round the dollar amounts to 2 decimals. For any hour amounts within the wage index calculations, we round such hour amounts to the nearest whole number. For any numbers not expressed as dollars or hours within the wage index calculations, which could include ratios, percentages, or inflation factors, we round such numbers to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

As discussed in the FY 2012 IPPS/LTCH PPS final rule, in ''Step 5,'' for each hospital, we adjust the total salaries plus wage-related costs to a common period to determine total adjusted salaries plus wage-related costs. To make the wage adjustment, we estimate the percentage change in the employment cost index (ECI) for compensation for each 30-day increment from October 14, 2019, through April 15, 2021, for private industry hospital workers from the BLS' *National Compensation Survey*. We have consistently used the ECI as the data source for our wages and salaries and other price proxies in the IPPS market basket, and we did not propose any changes to the usage of the ECI for FY 2024. The factors used to adjust the hospital's data are based on the midpoint of the cost reporting period, as indicated in the following table.

MIDPOINT OF COST REPORTING PERIOD

After	Before	Adjustment Factor
10/14/2019	11/15/2019	1.03524
11/14/2019	12/15/2019	1.03312
12/14/2019	01/15/2019	1.03102
01/14/2020	02/15/2020	1.02896
02/14/2020	03/15/2020	1.02694
03/14/2020	04/15/2020	1.02497
04/14/2020	05/15/2020	1.02305
05/14/2020	06/15/2020	1.02119
06/14/2020	07/15/2020	1.01923
07/14/2020	08/15/2020	1.01705
08/14/2020	09/15/2020	1.01465
09/14/2020	10/15/2020	1.01219
10/14/2020	11/15/2020	1.00987
11/14/2020	12/15/2020	1.00767
12/14/2020	01/15/2021	1.00540
01/14/2021	02/15/2021	1.00284
02/14/2021	03/15/2021	1.00000
03/14/2021	04/15/2021	0.99686

For example, the midpoint of a cost reporting period beginning January 1, 2020, and ending December 31, 2020, is June 30, 2020. An adjustment factor of 1.01923 was applied to the wages of a hospital with such a cost reporting period.

Previously, we also would provide a Puerto Rico overall average hourly wage. As discussed in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915), prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we calculated a Puerto Rico specific wage index that was applied to the labor-related share of the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. As we stated in the FY 2017 IPPS/LTCH PPS final rule (81 FR 56915 through 56916), because Puerto Rico hospitals are no longer paid with a Puerto Rico specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act, as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need to calculate a Puerto Rico specific average hourly wage and wage index. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national average hourly wage (unadjusted for occupational mix) and the national wage index, which is applied to the national labor-related share of the national standardized amount. Therefore, for FY 2024, there is no Puerto Rico-specific overall average hourly wage or wage index.

Based on the previously discussed methodology, we stated in the proposed rule (88 FR 26970) that the proposed FY 2024 unadjusted national average hourly wage was $50.33.

We did not receive any comments regarding the discussion of our method for computing the FY 2024 unadjusted wage index. Based on the previously described methodology, the final FY 2024 unadjusted national average hourly wage is the following:

Final FY 2024 Unadjusted National Average Hourly Wage	$50.39

E. Occupational Mix Adjustment to the FY 2024 Wage Index

As stated earlier, section 1886(d)(3)(E) of the Act provides for the collection of data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program, in order to construct an occupational mix adjustment to the wage index, for application beginning October 1, 2004 (the FY 2005 wage index). The purpose of the occupational mix adjustment is to control for the effect of hospitals' employment choices on the wage index. For example, hospitals may choose to employ different combinations of registered nurses, licensed practical nurses, nursing aides, and medical assistants for the purpose of providing nursing care to their patients. The varying labor costs associated with these choices reflect hospital management decisions rather than geographic differences in the costs of labor.

1. Use of 2019 Medicare Wage Index Occupational Mix Survey for the FY 2024 Wage Index

Section 304(c) of the Consolidated Appropriations Act, 2001 (Pub. L. 106–554) amended section 1886(d)(3)(E) of the Act to require CMS to collect data every 3 years on the occupational mix of employees for each short-term, acute care hospital participating in the Medicare program. As discussed in the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25402 through 25403) and final rule (86 FR 45173), we collected data in 2019 to compute the occupational mix adjustment for the FY 2022, FY 2023, and FY 2024 wage indexes. The FY 2024 occupational mix adjustment is based on the calendar year (CY) 2019 survey. Hospitals were required to submit their completed 2019 surveys (Form CMS–10079, OMB Number 0938–0907, expiration date January 31, 2026) to their MACs by September 3, 2021. The preliminary, unaudited CY 2019 survey data were posted on the CMS website on September 8, 2020. As with the Worksheet S–3, Parts II and III cost report wage data, as part of the FY 2022 desk review process, the MACs revised or verified data elements in hospitals' occupational mix surveys that resulted in certain edit failures.

2. Calculation of the Occupational Mix Adjustment for FY 2024

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26971), for FY 2024, we proposed to calculate the occupational mix adjustment factor using the same methodology that we have used since the FY 2012 wage index (76 FR 51582 through 51586) and to apply the occupational mix adjustment to 100 percent of the FY 2024 wage index. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308), we modified our methodology with regard to how dollar amounts, hours, and other numerical values in the unadjusted and adjusted wage index calculation are rounded, in order to ensure consistency in the calculation. According to the policy finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42308 and 42309), for data that we consider to be ''raw data,'' such as the cost report data on Worksheets S–3, Parts II and III, and the occupational mix survey data, we continue to use these data ''as is'', and not round any of the individual line items or fields. However, for any dollar amounts within the wage index calculations, including any type of summed wage amount, average hourly wages, and the national average hourly wage (both the unadjusted and adjusted for occupational mix), we round such dollar amounts to 2 decimals. We round any hour amounts within the wage index calculations to the nearest whole number. We round any numbers not expressed as dollars or hours in the wage index calculations, which could include ratios, percentages, or inflation factors, to 5 decimals. However, we continue rounding the actual unadjusted and adjusted wage indexes to 4 decimals, as we have done historically.

Similar to the method we use for the calculation of the wage index without occupational mix, salaries and hours for a multicampus hospital are allotted among the different labor market areas where its campuses are located. Table 2 associated with this final rule (which is available via the internet on the CMS website), which contains the final FY 2024 occupational mix adjusted wage index, includes separate wage data for the campuses of multicampus hospitals. We refer readers to section III.C. of the preamble of this final rule for a chart listing the multicampus hospitals and the FTE percentages used to allot their occupational mix data.

Because the statute requires that the Secretary measure the earnings and paid hours of employment by occupational category not less than once every 3 years, all hospitals that are subject to payments under the IPPS, or any hospital that would be subject to the IPPS if not granted a waiver, must complete the occupational mix survey, unless the hospital has no associated cost report wage data that are included in the FY 2024 wage index. For the proposed FY 2024 wage index, we used the Worksheet S–3, Parts II and III wage data of 3,103 hospitals, and we used the occupational mix surveys of 3,007 hospitals for which we also had Worksheet S–3 wage data, which represented a ''response'' rate of 97 percent (3,007/3,103). For the proposed FY 2024 wage index, we applied proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586). As a result of applying this methodology, the proposed FY 2024 occupational mix adjusted national average hourly wage was $50.27.

For the final FY 2024 wage index, we are using the Worksheet S3, Parts II and III wage data of 3,129 hospitals, and we are using the occupational mix surveys of 3,031 hospitals for which we also have Worksheet S–3 wage data, which is a ''response'' rate of 97 percent (3,031/3,129). For the final FY 2024 wage index, we are applying proxy data for noncompliant hospitals, new hospitals, or hospitals that submitted erroneous or aberrant data in the same manner that we applied proxy data for such hospitals in the FY 2012 wage index occupational mix adjustment (76 FR 51586). As a result of applying this methodology, the final FY 2024 occupational mix adjusted national average hourly wage is the following:

FY 2024 Occupational Mix Adjusted National Average Hourly Wage	$50.34

3. Deadline for Submitting the 2022 Medicare Wage Index Occupational Mix Survey for Use Beginning With the FY 2025 Wage Index

A new measurement of occupational mix is required for FY 2025. The FY 2025 occupational mix adjustment will be based on a new calendar year (CY) 2022 survey. The CY 2022 survey (Form CMS–10079, OMB Number 0938–0907, expiration date January 31, 2026) received OMB approval on January 3, 2023. The final CY 2022 Occupational Mix Survey Hospital Reporting Form is available on the CMS website at: *https://www.cms.gov/medicare/medicare-fee-service-payment/acuteinpatientpps/wage-index-files/2022-occupational-mix-survey-hospital*. Hospitals were required to submit their completed 2022 surveys to their MACs (not directly to CMS) by June 30, 2023. The preliminary, unaudited CY 2022 survey data was posted on the CMS website in mid-July 2023. As with the Worksheet S–3, Parts II and III cost report wage data, as part of the FY 2025 desk review process, the MACs will revise or verify data elements in hospitals' occupational mix surveys that result in certain edit failures.

Comment: We received comments with regard to the CY 2022 Occupational Mix Survey data. One commenter had concerns that the data may be skewed due to the PHE. Another commenter stated that CMS must ensure it is including all of the available data, including the data that were submitted

to the agency, when it constructs an occupational mix adjustment to the wage index. In addition, the commenter stated CMS must ensure that such data is corrected after the initial submission deadline.

Response: CMS has yet to audit and review the CY 2022 Occupational Mix Survey data. We plan to assess the CY 2022 Occupational Mix Survey data in the FY 2025 IPPS proposed rule. Additionally, per the FY 2025 wage index development timetable on the web at *https://www.cms.gov/files/document/fy2025-hospital-wage-index-development-timetable.pdf,* providers have until September 1, 2023, to request revisions to their Worksheet S–3 wage data and CY 2022 occupational mix data as included in the wage and occupational mix preliminary public use files. We refer the reader to the FY 2025 wage index development timetable for complete details.

F. Analysis and Implementation of the Occupational Mix Adjustment and the FY 2024 Occupational Mix Adjusted Wage Index

As discussed in section III.E. of the preamble of this final rule, for FY 2024, we are applying the occupational mix adjustment to 100 percent of the FY 2024 wage index. We calculated the occupational mix adjustment using data from the 2019 occupational mix survey data, using the methodology described in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51582 through 51586).

The FY 2024 national average hourly wages for each occupational mix nursing subcategory as calculated in Step 2 of the occupational mix calculation are as follows:

Occupational Mix Nursing Subcategory	Average Hourly Wage
National RN	$44.42
National LPN and Surgical Technician	$26.85
National Nurse Aide, Orderly, and Attendant	$18.53
National Medical Assistant	$19.51
National Nurse Category	$37.35

The national average hourly wage for the entire nurse category is computed in Step 5 of the occupational mix calculation. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of greater than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of less than 1.0. Hospitals with a nurse category average hourly wage (as calculated in Step 4) of less than the national nurse category average hourly wage receive an occupational mix adjustment factor (as calculated in Step 6) of greater than 1.0.

Based on the 2019 occupational mix survey data, we determined (in Step 7 of the occupational mix calculation) the following:

National Percentage of Hospital Employees in the Nurse Category	42%
National Percentage of Hospital Employees in the All Other Occupations Category	58%
Range of Percentage of Hospital Employees in the Nurse Category (CBSA Level)	Low of 20 Percent in one CBSA to a high of 68 percent in another CBSA

We compared the FY 2024 occupational mix adjusted wage indexes for each CBSA to the unadjusted wage indexes for each CBSA. Applying the occupational mix adjustment to the wage data resulted in the following:

Comparison of the FY 2024 Occupational Mix Adjusted Wage Indexes to the Unadjusted Wage Indexes by CBSA	
Number of Urban Areas Wage Index Increasing	228 (55.3%)
Number of Rural Areas Wage Index Increasing	26 (55.3 %)
Number of Urban Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 Percent	122 (29.6 %)
Number of Urban Areas Wage Index Increasing by 5 percent or More	5 (1.2%)
Number of Rural Areas Wage Index Increasing by Greater Than or Equal to 1 Percent But Less Than 5 Percent	12 (25.5 %)
Number of Rural Areas Wage Index Increasing by 5 Percent or More	0 (0%)
Number of Urban Areas Wage Index Decreasing	182 (44.2 %)
Number of Rural Areas Wage Index Decreasing	21 (44.7 %)
Number of Urban Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less Than 5 Percent	78 (18.9 %)
Number of Urban Areas Wage Index Decreasing by 5 Percent or More	3 (0.7 %)
Number of Rural Areas Wage Index Decreasing by Greater Than or Equal to 1 Percent But Less than 5 Percent	12 (25.5 %)
Number of Rural Areas Wage Index Decreasing by 5 Percent or More	0 (0%)
Largest Positive Impact for an Urban Area	7.12 %
Largest Positive Impact for a Rural Area	4.11 %
Largest Negative Impact for an Urban Area	-5.55 %
Largest Negative Impact for a Rural Area	-2.59 %
Urban Areas Unchanged by Application of the Occupational Mix Adjustment	2 (0.5 %)
Rural Areas Unchanged by Application of the Occupational Mix Adjustment	0 (0%)

G. Application of the Rural Floor, Application of the Imputed Floor, Application of the State Frontier Floor, Continuation of the Low Wage Index Hospital Policy, and Permanent Cap on Wage Index Decreases

1. Application of the Rural Floor

Section 4410(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33) provides that, for discharges on or after October 1, 1997, the area wage index applicable to any hospital that is located in an urban area of a State may not be less than the area wage index applicable to hospitals located in rural areas in that State. This provision is referred to as the rural floor. Section 3141 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) also requires that a national budget neutrality adjustment be applied in implementing the rural floor.

Based on the FY 2024 wage index associated with this final rule (which is available via the internet on the CMS website) and based on the calculation of the rural floor including the wage data of hospitals that have reclassified as rural under § 412.103 (as discussed in section III.K. of the preamble of this final rule), we estimate that 646 hospitals will receive the rural floor in FY 2024. The budget neutrality impact of the proposed application of the rural floor is discussed in section II.A.4.e. of the Addendum of this final rule.

a. Treatment of Hospitals Reclassified as Rural Under § 412.103 for the Rural Wage Index and Rural Floor Calculation

Section 1886(d)(8)(E)(i) of the Act, implemented at 42 CFR 412.103, requires that not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital that satisfies certain criteria, the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located.

In recent years, CMS's wage index and floor policies involving the treatment of § 412.103 hospitals have been the subject of frequent litigation. Courts have repeatedly held unlawful CMS wage index and floor policies that do not treat § 412.103 hospitals the same as geographically rural hospitals based on section 1886(d)(8)(E)(i) of the Act, which requires that ''the Secretary shall treat the [§ 412.103] hospital as being located in the rural area.''

For example, on July 23, 2015, the U.S. Court of Appeals for the Third Circuit issued a decision in *Geisinger Community Medical Center* v. *Secretary, United States Department of Health and Human Services,* 794 F.3d 383 (3d Cir. 2015). Geisinger challenged as unlawful a CMS regulation prohibiting hospitals with an active § 412.103 rural reclassification from applying for an additional reclassification for wage index purposes through the MGCRB. A divided panel of the Court of Appeals for the Third Circuit held that section 1886(d)(8)(E)(i) of the Act required the Secretary to treat § 412.103 hospitals the same as geographically rural hospitals for the purposes of MGCRB reclassification. Because geographically rural hospitals were eligible for MGCRB reclassification, the court held CMS's regulation prohibiting § 412.103 hospitals from seeking MGCRB reclassification was unlawful.

On February 4, 2016, the U.S. Court of Appeals for the Second Circuit issued its decision in *Lawrence + Memorial Hospital* v. *Burwell,* 812 F.3d 257 (2d Cir. 2016), agreeing with the Third Circuit's conclusion in *Geisinger.* The Second Circuit disagreed with CMS's argument that the impact of these decisions—allowing § 412.103 hospitals to be urban for wage index purposes and rural for others—was ''anomalous'': ''[T]his is simply a function of the many different roles that hospitals play and the many different contexts in which they operate . . . Section 401 simply increases the number of situations in which hospitals can be treated as rural for some purposes and urban for others, but there is nothing 'absurd' about such a measured approach.'' *Id.* At 267.

As a consequence of the *Geisinger* and *Lawrence + Memorial* decisions, CMS published an interim final rule with comment period (IFC) on April 21, 2016 (81 FR 23428 through 23438), revising the regulations to allow hospitals to hold simultaneous § 412.103 and MGCRB reclassifications, consistent with the courts' decisions. But commenters have since argued that CMS continued to treat § 412.103 hospitals differently from geographically rural hospitals in two respects. First, CMS only allowed MGCRB reclassifications for § 412.103 hospitals when the hospital's wages are at least 106 percent of the *urban* area in which it was geographically located, rather than the *rural* area to which it was reclassified under § 412.103 (*see* 81 FR 56925). Additionally, CMS would not include data from § 412.103 hospitals that are reclassified to an urban area by the MGCRB for wage index purposes when calculating the rural wage index for that state (81 FR 23434).

The first policy was held unlawful on May 14, 2020, when the United States District Court for the District of Columbia issued a decision in *Bates County Memorial Hospital* v. *Azar,* 464 F. Supp. 3d 43 (DDC 2020) (*Bates*). There, Bates County Memorial Hospital and five other geographically urban hospitals were reclassified to rural under § 412.103. They also applied for reclassification under the MGCRB but were denied because their wages were not at least 106 percent of the geographic urban area in which the hospitals were located. Each of the hospitals' average hourly wages were at least 106 percent of the 3-year average hourly wage of all other hospitals in the rural area of the state in which the hospitals were located. The Court agreed with the Plaintiffs that section 1886(d)(8)(E)(i) of Act requires that CMS consider the rural area to be the area in which a § 412.103 hospital is located for the wage comparisons required for MGCRB reclassifications.

CMS did not appeal this decision, and in the May 10, 2021 **Federal Register** (86 FR 24735), concurrent with the FY 2022 IPPS/LTCH PPS proposed rule, we published an interim final rule with comment period that amended our regulations to allow hospitals with a rural reclassification under the Act to reclassify through the MGCRB using the rural reclassified area as the geographic area in which the hospital is located. We stated that these changes implemented the *Bates* Court's interpretation of the requirement at section 1886(d)(8)(E)(i) of the Act that ''the Secretary shall treat the hospital as being located in the rural area,'' for all purposes of MGCRB reclassification, including the average hourly wage comparisons required by § 412.230(a)(5)(i) and (d)(1)(iii)(C).

The second policy was recently challenged in *Deaconess Hospital Inc.* v. *Becerra,* No. 1:22–cv–03136 (D.D.C. Oct. 14, 2022) and *Robert Packer* v. *Becerra,* No. 1:22–cv–03196 (D.D.C. Oct. 19, 2022). Specifically, plaintiffs in *Deaconess* and *Robert Packer* contend that CMS must include § 412.103 hospitals reclassified to another wage area under the MGCRB in the rural wage index and rural wage floor under the ''hold harmless'' provision in section 1886(d)(8)(C)(ii) of Act. That provision provides that if an MGCRB decision ''reduces the wage index for that rural area (as applied under this subsection), the Secretary shall calculate and apply such wage index under this subsection as if the hospitals so treated had not been excluded from calculation of the wage index for that rural area.''

The treatment of § 412.103 hospitals was again the subject of litigation in a recent case contesting our FY 2020 rural floor policy, under which we calculated the rural floor and the related budget neutrality adjustment without including

data from hospitals that reclassified from urban to rural (84 FR 42332 through 42336). On April 8, 2022, the district court in *Citrus HMA, LLC, d/b/a Seven Rivers Regional Medical Center* v. *Becerra,* No. 1:20–cv–00707 (D.D.C.) (*Citrus*) found that the Secretary did not have authority under section 4410(a) of the Balanced Budget Act of 1997 to establish a rural floor different from the rural wage index for a state.

Following our review of the *Citrus* decision (which we did not appeal) and the comments we received on the FY 2023 IPPS/LTCH PPS proposed rule, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49002 through 49004), we finalized a policy that calculates the rural floor as it was calculated before FY 2020. We stated that we understand that our policy of setting a rural floor lower than the rural wage index for a state was inconsistent with the district court's decision in *Citrus.* For FY 2023 and subsequent years, our policy is to include the wage data of hospitals that have reclassified from urban to rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103) and have no MGCRB reclassification in the calculation of the rural floor, and to include the wage data of such hospitals in the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act.[191] We stated that we will apply the same policy as prior to the FY 2020 final rule for calculating the rural floor, in which the rural wage index sets the rural floor.

In addition to the litigation, as previously described, CMS has received numerous public comments in recent years urging CMS to treat § 412.103 hospitals the same as geographically rural hospitals for the rural wage index and rural floor calculations. For example, we received many comments in response to our FY 2020 policy of excluding the wage data of § 412.103 hospitals from the calculation of the rural floor stating that excluding reclassified hospitals from the rural floor is inconsistent with the statutory language of section 1886(d)(8)(E) of the Act and section 4410(a) of the Balanced Budget Act of 1997. As summarized in greater detail in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42334), commenters stated that the statute does not draw any distinction between the ''rural areas'' used to calculate the rural floor under section 4410(a) of the Balanced Budget Act of 1997 and the ''rural areas'' that reclassified hospitals are to be treated as located in under section 1886(d)(8)(E) of the Act, and that under the *Geisinger* and *Lawrence & Memorial Hospital* cases, a § 412.103 hospital should be treated as a rural hospital for wage reclassification.

Also, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45181), a commenter disagreed with CMS's treatment of hospitals with dual § 412.103 and MGCRB reclassifications. The commenter stated that CMS's policy of considering the hospital's geographic CBSA and the urban CBSA to which the hospital is reclassified under the MGCRB for the wage index calculation violates the statutory requirement to treat § 412.103 hospitals the same as geographically rural hospitals. The commenter specifically requested that CMS include the wages of § 412.103 hospitals that also have an active MGCRB reclassification in calculating the rural wage of the state if not doing so would reduce the wage index for that area, in the same manner that geographically rural hospitals with a MGCRB reclassification are treated according to section 1886(d)(8)(C)(ii) of Act.

Again, in response to the FY 2023 IPPS/LTCH PPS proposed rule, commenters urged CMS to discontinue the policy of excluding the wage data of § 412.103 hospitals from the rural floor calculation (87 FR 49002). Spurred by the aforementioned district court's decision in *Citrus,* commenters urged CMS to acquiesce, stating their belief that the court's analysis was thorough and emphasizing that continuing the rural floor policy would only increase the agency's exposure to future lawsuits. Commenters asserted that the plain language of the statute does not provide for a free-floating rural floor that is not linked to the rural wage index.

As previously enumerated, CMS has made policy changes as a result of the courts' decisions and related public comments. Because these policy changes were implemented piecemeal in reaction to litigation, and many through IFCs rather than the usual proposed rule process, CMS has not had the opportunity to systematically revisit this regulatory framework.

In the proposed rule, CMS took the opportunity to revisit the case law, prior public comments, and the relevant statutory language. After doing so, we stated that we now agree—for the reasons expressed by the U.S. Courts of Appeals for the Second and Third Circuits, as well as the U.S. District Court for the District of Columbia—that the best reading of section 1886(d)(8)(E)'s text that CMS ''shall treat the [§ 412.103] hospital as being located in the rural area'' is that it instructs CMS to treat § 412.103 hospitals the same as geographically rural hospitals for the wage index calculation. We stated that while CMS has previously treated section 1886(d)(8)(E) reclassifications as one among many reclassifications provided for under section 1886(d) of the Act and so limited its scope in several ways, we now read it to provide that a § 412.103 reclassification functions the same as if the reclassifying hospital had physically relocated into a geographically rural area. We explained in the proposed rule that we are influenced by the fact that courts have largely adopted this interpretation of section 1886(d)(8)(E) of the Act, and that it requires considerable resources to unwind a wage index policy after adverse judicial decisions—often requiring an IFC outside the usual IPPS rulemaking schedule. We further note that such unwindings may have budget neutrality implications. *Cf. Amgen, Inc.* v. *Smith,* 357 F.3d 103, 112 (D.C. Cir. 2004) (collecting cases ''not[ing] the havoc that piecemeal review of OPPS payments could bring about'' in light of statutory budget neutrality requirements).

We acknowledged that this interpretation of section 1886(d)(8)(E) of the Act can lead to significant financial consequences. Many hospitals eligible for § 412.103 reclassifications have paired that reclassification with a MGCRB wage index reclassification to escalate their wage index beyond what would be otherwise available to them under the law. Section 1886(d)(3)(E)(i) of the Act states that any adjustments or updates made under subparagraph (E) for a fiscal year shall be made in a manner that assures that the aggregate payments under section 1886(d) of the Act in the fiscal year are not greater or less than those that would have been made without such adjustment, and therefore any increases to these hospitals' wage index inevitably decrease the payments Medicare makes to other hospitals. But, as the Second Circuit explained (*Lawrence + Memorial*

[191] We note in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49004), we stated that for FY 2023 and subsequent years, we are finalizing a policy to include the wage data of hospitals that have reclassified from urban to rural under section 1886(d)(8)(E) of the Act (as implemented in the regulations at § 412.103) and have no additional form of reclassification (MGCRB or Lugar) in the calculation of the rural floor, and to include the wage data of such hospitals in the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act. ''Lugar'' hospitals are geographically rural and will be included in the rural wage index calculation, unless excluded per the hold harmless provision at section 1886(d)(8)(C)(ii). The parenthetical reference to ''Lugar'' hospitals in the rule was included in error, and was not implemented in our rate setting methodology in FY 2023.

Hospital, 812 F.3d at 267), these payment consequences are ''a function of the many different roles that hospitals play and the many different contexts in which they operate.'' We solicited comments on our proposed interpretation of sections 1886(d)(8)(E) and 1886(d)(3)(E)(i) of the Act.

As additionally previously discussed, pending litigation and public comments in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45181 and 45182) have raised concerns that there is an additional wage index policy under which CMS does not treat § 412.103 hospitals the same as geographically rural hospitals: its policy of CMS excluding data from § 412.103 hospitals that are reclassified to an urban area by the MGCRB for wage index purposes when calculating the rural wage index for that state. We proposed to change that policy, consistent with our new proposed interpretation of section 1886(d)(8)(E) of the Act, as described in this section of this rule. Under the policy changes adopted in the FY 2023 IPPS/LTCH PPS final rule under which the rural floor is the same as the rural wage index (87 FR 49002 through 49004), we believe that this change to the wage index policy will also resolve the concerns about the rural floor raised in comments discussed previously. As far as we are aware, these are the only policies that our reinterpretation of section 1886(d)(8)(E) of the Act requires us to change, but we solicited comments on whether there are any remaining policies that CMS should reexamine in light of our proposed reinterpretation of section 1886(d)(8)(E) of the Act.

b. Current Calculation of the Rural Wage Index and Application of Various Hold Harmless Policies

Sections 1886(d)(8)(C)(ii) and (iii) of the Act are ''hold harmless'' provisions that may affect the wage index calculation when hospitals reclassify out of a state's rural area into another area. Section 1886(d)(8)(C)(ii) of the Act provides that if the application of section 1886(d)(8)(B) of the Act (''Lugar'' status) or a decision of the MGCRB or the Secretary under section 1886(d)(10) of the Act, by treating hospitals located in a rural county or counties as not being located in the rural area in a state, reduces the wage index for that rural area, the Secretary shall calculate and apply such wage index as if the hospitals so treated had not been excluded from calculation of the wage index for that rural area. Section 1886(d)(8)(C)(iii) of the Act provides that the application of section 1886(d)(8)(B) of the Act (''Lugar'' status) or a decision of the MGCRB or the Secretary under section 1886(d)(10) of the Act may not result in the reduction of any county's wage index to a level below the wage index for rural areas in the state in which the county is located.

In the FY 2006 IPPS final rule (70 FR 47378 and 47379), we adopted a regulatory hold harmless policy for situations where hospitals reclassify into a state's rural area under section 1886(d)(8)(E) of the Act. We stated that the wage data of an urban hospital reclassifying into the rural area are included in the rural area's wage index, if including the urban hospital's data increases the wage index of the rural area. Otherwise, the wage data are excluded. It has been CMS's policy since then to include hospitals with state-to-state MGCRB reclassifications to a nearby state's rural area along with hospitals reclassified under section 1886(d)(8)(E) of the Act in this regulatory hold harmless policy.

In the FY 2010 IPPS/LTCH PPS final rule (74 FR 43837 and 43838), as part of a summary of reclassification policies we had adopted, we stated that in cases where hospitals have reclassified to rural areas, such as urban hospitals reclassifying to rural areas under 42 CFR 412.103, the hospital's wage data are: (a) included in the rural wage index calculation, unless doing so would reduce the rural wage index; and (b) included in the urban area where the hospital is physically located. We further stated that the effect of this policy, in combination with the statutory requirement at section 1886(d)(8)(C)(ii) of the Act, is that rural areas may receive a wage index based upon the highest of: (1) wage data from hospitals geographically located in the rural area (calculation 1 in the table in this section of this rule); (2) wage data from hospitals geographically located in the rural area, but excluding all data associated with hospitals reclassifying out of the rural area under section 1886(d)(8)(B) or section 1886(d)(10) of the Act (calculation 2 in the table in this section of this rule); or (3) wage data associated with hospitals geographically located in the area plus all hospitals reclassified into the rural area (calculation 3 in the table in this section of this rule).

In the April 21, 2016 IFC (81 FR 23428 through 23438), referenced earlier in section III.G.1.a. of the preamble of this final rule, as a result of the *Geisinger* decision, we adopted a policy allowing hospitals to hold simultaneous § 412.103 and MGCRB reclassifications. In our wage index development process, we refer to these hospitals as having ''dual reclass'' status. We further stated in the IFC that we will exclude hospitals with § 412.103 reclassifications from the calculation of the reclassified rural wage index if they also have an active MGCRB reclassification to another area (81 FR 23434).

We also clarified in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25070) that if a hospital qualified for ''Lugar'' status and obtained § 412.103 rural status, we would apply the urban ''Lugar'' status for wage index purposes only. These geographically rural hospitals would be included in the rural wage index calculation in accordance with the previously described hold harmless policy.

The following chart summarizes the current calculation of the rural wage index algebraically and in accordance with the statutes and policies previously described:

Hospital Data
A=Geographically rural hospitals
A1=Subset of geographically rural hospitals with MGCRB or "Lugar" reclassification
B=Geographically urban hospitals with § 412.103 rural reclassification
B1=Subset of geographically urban hospitals with § 412.103 rural reclassification and MGCRB reclassification ("dual reclass" hospitals)
C=Cross-State MGCRB reclassification to rural area

	Current Calculation: Rural Wage Index is The Highest Of
Calculation 1	A
Calculation 2	A - A1
Calculation 3	A + (B - B1) + C

c. Modification to the Rural Wage Index Calculation Methodology

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45181 and 45182), we responded to a comment disagreeing with our treatment of ''dual reclass'' hospitals when calculating the rural floor. The commenter stated that CMS's policy of considering the hospital's geographic CBSA and the urban CBSA to which the hospital is reclassified under the MGCRB for the wage index calculation violates the statutory requirement to treat § 412.103 hospitals the same as hospitals geographically located in the rural area of the state. The commenter requested that CMS include the wages of § 412.103 hospitals that also have an active MGCRB reclassification in calculating the rural wage of the state if not doing so would reduce the wage index for that area, in the same manner that geographically rural hospitals with a MGCRB reclassification are treated according to section 1886(d)(8)(C)(ii) of the Act.

We responded that we did not propose the policy the commenter suggested, and noted that it would constitute a significant change with numerous and potentially negative effects on the IPPS wage index. We stated that we did not believe it would be appropriate to adopt such a policy without describing it in a proposed rule and obtaining public comments. Therefore, we did not adopt the policy the commenter suggested, but we stated that we would consider further addressing the issue in future rulemaking. We also received and responded to a similar comment in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49003). After further consideration of these comments and our proposed reinterpretation of section 1886(d)(8)(E) of the Act discussed earlier in this section, we proposed changing the rural wage index calculation methodology consistent with that proposed reinterpretation. We acknowledged the ongoing risk of the pending lawsuits cited previously, and recognized the challenge should we need to implement any future remedy in a budget neutral manner.

Beginning with FY 2024, we proposed to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and to exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. The following chart summarizes the current (as described in the table earlier in this section) and proposed rural wage index calculation algebraically:

Hospital Data
A=Geographically rural hospitals
A1=Subset of geographically rural hospitals with MGCRB or "Lugar" reclassification
B=Geographically urban hospitals with § 412.103 rural reclassification
B1=Subset of geographically urban hospitals with § 412.103 rural reclassification and MGCRB reclassification ("dual reclass" hospitals)
C=Cross-State MGCRB reclassification to rural area

	Current Calculation: Rural Wage Index is The Highest Of	**Proposed Calculation: Rural Wage Index is The Highest Of**
Calculation 1	A	A + B
Calculation 2	A - A1	(A - A1) + (B - B1)
Calculation 3	A + (B - B1) + C	A + B + C

As shown in the current calculation policy, as previously described, § 412.103 hospitals enter the rural wage index calculation in calculation 3, which reflects the regulatory hold harmless policy described in the FY 2006 IPPS final rule (70 FR 47378 and 47379) and previously referenced, preventing reclassification into a state's rural area from reducing the rural wage index. That is, we determine the effects for outbound reclassification (from the rural area to another area) and inbound reclassification (from another area into the rural area) separately when determining the highest rural wage index value. Under our proposal, as shown in the proposed calculation policy, as previously described, § 412.103 hospitals will no longer be treated as an inbound reclassification (calculation 3 of the current policy), but will instead be included in all calculations in which geographically rural hospitals are included (calculations 1–3 of the proposed policy). ''Dual reclass'' hospitals will be excluded (calculation 2 of the proposed policy) in accordance with the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act, along with other geographically rural hospitals with MGCRB or ''Lugar'' reclassification status.

As discussed earlier in section III.G.1.a. of the preamble of this final rule, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49004), we stated that we will apply the same policy as prior to the FY 2020 IPPS/LTCH PPS final rule for calculating the rural floor, in which the rural wage index sets the

rural floor. For FY 2023 and subsequent years, our current policy is to include the wage data of § 412.103 hospitals that have no MGCRB reclassification in the calculation of the rural floor, and to include the wage data of such hospitals in the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act. Consistent with the previously discussed proposal, beginning with FY 2024 we proposed to include the data of all § 412.103 hospitals (including those that have an MGCRB reclassification) in the calculation of the rural floor and the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act.

We acknowledged that these proposals will have significant effects on wage index values. As discussed in prior rulemaking (72 FR 47371 through 47373, 84 FR 42332, 85 FR 58788) and in this rule, CMS has expressed concern with hospitals' use of § 412.103 reclassification to increase the rural wage index and rural floor. However, as already mentioned, ''this is simply a function of the many different roles that hospitals play and the many different contexts in which they operate,'' *Lawrence + Mem'l Hosp.,* 812 F.3d at 267, and follows from our proposed interpretation of section 1886(d)(8)(E) of the Act—which encompasses the calculation of the State's rural wage index. We discuss the overall impact of these proposed changes on the rural wage index calculation methodology in detail in section II.A.4. of appendix A of this final rule.

As discussed in the previous section, in the FY 2006 IPPS final rule (70 FR 47378 and 47379), we adopted a regulatory hold harmless policy for situations where hospitals reclassify into a state's rural area. Hospitals reclassified under § 412.103 will no longer be affected by this policy, as we proposed to include them in the rural wage index calculation in the same manner as geographically rural hospitals. Therefore, only the effects of hospitals with state-to-state MGCRB reclassifications to a nearby state's rural area will be addressed by this policy. It has been CMS's longstanding policy that hospitals with state-to-state MGCRB reclassifications to a nearby state's rural area receive a ''combined'' wage index (calculation 3 of the current rural wage index calculation, as previously detailed in the chart) that includes the wage data for geographically rural hospitals and all hospitals reclassified into that rural area. Given our longstanding goal to mitigate potential negative impacts on rural hospitals, we proposed to continue the part of our hold harmless policy that excludes the data of hospitals reclassifying into a state's rural area if doing so would reduce that state's rural wage index. We proposed that these reclassified hospitals be assigned the ''combined'' wage index (calculation 3 of the proposed rural wage index calculation as previously detailed in the chart) that includes the wage data for geographically rural hospitals and all hospitals reclassified into that rural area (subject to any additional wage index adjustment policies for which those reclassified hospitals may be eligible).

Finally, we proposed to continue the policy to apply the deemed urban wage index value for § 412.103 hospitals that also qualify as ''Lugar'' under section 1886(d)(8)(B) of the Act. Prior to *Geisinger,* since section 1886(d)(8)(E) of the Act requires CMS to treat a reclassified hospital as being located in the rural area of the state, and section 1886(d)(8)(B) of the Act requires CMS to treat a rural hospital as being located in an urban area, our policy was that obtaining § 412.103 status would effectively waive a hospital's deemed urban ''Lugar'' status. We discussed in the FY 2017 IPPS/LTCH PPS proposed rule (81 FR 25070) that if a hospital qualified for ''Lugar'' status and obtained § 412.103 rural status, our policy is to apply the urban ''Lugar'' status for wage index purposes only.

Comment: Commenters strongly supported CMS's proposal to revise the rural wage index and rural floor calculation. Specifically, commenters supported CMS's proposed treatment of a § 412.103 hospital in the calculation of the rural wage index of its state even when the hospital has an MGCRB reclassification to another area. Commenters stated that the inclusion of § 412.103 hospitals in this manner represents a straightforward interpretation of the regulations and faithfully executes Congressional intent by treating § 412.103 hospitals ''as being located in the rural area'' as required by section 1886(d)(8)(E) of the Act. Commenters also supported CMS's proposed treatment of § 412.103 hospitals for the calculation at section 1886(d)(8)(C)(ii) of the Act, stating that they believe that treating § 412.103 hospitals the same as geographically rural hospitals is the only lawful interpretation of the Act. A commenter stated that the proposed changes in response to the court cases illustrate the complexity, inconsistency, and even irrationality of the wage index system. Commenters also encouraged CMS to continue the policy of setting a state's rural floor equal to its rural wage index as part of coherent and consistent treatment of § 412.103 hospitals.

Numerous commenters stressed the positive payment impact of these proposals on many hospitals. Similarly, a commenter noted that the proposed change to the calculation of the rural wage index and rural floor would help further reduce the disparity between high and low wage index hospitals due to its larger impact on hospitals with wage index values at or below the 25th percentile. This commenter provided its own wage index analysis in support of this finding.

Multiple commenters expressed concern regarding the increased rural floor budget neutrality factor due to the proposed changes. While some commenters acknowledged CMS's statutory budget neutrality requirement, another commenter requested that CMS not apply the rural floor budget neutrality factor to urban hospitals paid at the rural floor and to rural hospitals, stating that it was Congress's intent that these providers be excluded from this factor. Another commenter requested CMS provide a more complete summary of the specific impact of the proposed changes to the rural wage index calculation.

Response: We appreciate the commenters' support for our proposal. We reviewed the analysis a commenter provided that suggests the proposed change to the rural wage index calculation methodology would reduce the total level of adjustments made under the low wage policy, by raising the wage index of hospitals with wage index values currently at or below the 25th percentile As proposed, nearly half of all IPPS hospitals will be assigned their State's rural wage index,[192] either directly or through the application of the previously discussed ''floor'' policies. We expect that this number will increase in future years as hospitals adjust to the policy and as the relative value of States' rural wage index values increase due to the strategic inclusion of hospitals that obtain § 412.103 reclassification. An outcome of this trend would be that the majority of hospitals (if not all) will be assigned identical wage index values as all other hospitals within their states. This would greatly reduce wage index variations within a State but might dramatically increase wage index differentials between States.

We understand the other commenters' concern regarding the effect that the

[192] Some of these hospitals will receive an additional wage index adjustment due their county's out-migration adjustment, or via the 5 percent cap on wage index reductions.

proposed modification of the rural wage index calculation has on the rural floor budget neutrality factor. This policy will result in the rural wage index being greater than the wage index of most or all urban areas in that State. This will result in substantially more hospitals receiving the rural floor (and the section 1886(d)(8)(C)(iii) reclassification hold-harmless floor), and a consequently greater budget neutrality impact. We acknowledge tension between hospitals receiving identical wage index values and the broader structure of a national wage index to reflect relative differences in regional labor market costs. However, we believe this result would be unavoidable given the requirement of section 1886(d)(8)(E) of the Act to treat § 412.103 hospitals 'as being located in the rural area' of the state.

With regard to the commenter's assertion that urban hospitals paid at the rural floor and rural hospitals should be excluded from the application of the rural floor budget neutrality factor, we believe we have applied the rural floor budget neutrality adjustment correctly. Section 3141 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) requires that a national budget neutrality adjustment be applied in implementing the rural floor. There is a statutory requirement for budget neutrality, and the statute does not express intent to exempt certain hospitals as the commenter claims. Consistent with our longstanding methodology for implementing rural floor budget neutrality, we believe it is appropriate to continue to apply a budget neutrality adjustment to all hospitals' wage indexes so that the rural floor is implemented in a budget neutral manner.

With regard to the commenter requesting a summary of the specific impact of the changes to the rural wage index calculation, we refer the commenter to section II.A.4.e. of the Addendum of this final rule for a complete discussion of the budget neutrality impact of the application of the rural floor.

Comment: Several commenters expressed concern with the timing of our proposed policy as it relates to Medicare Advantage (MA) reimbursement funding for MA plans. Commenters cited locations that would have significant, sudden increases in hospital payment rates due to the proposed change in the calculation of the rural wage index values and cited potential severe financial hardships (including increased insurance rates) if such plans are not granted adequate time to transition and adjust to the implications of the policy change.

Another commenter stated that while budget neutrality may mitigate the impact of CMS's rural wage index adjustments overall, it does not prevent significant regional impacts. The commenter stated that MA organizations have limited mechanisms to account for any increased costs given that they must pay the FFS rate for non-contracted providers. The negative impacts would be greater on small, regional plans that do not provide services across a broad enough area to mitigate the effects. Commenters requested CMS delay changes to the rural wage index or implement a companion policy to counterbalance the effects of the policy.

Response: After reviewing the concerns submitted by commenters regarding the potential impact this policy would have on MA plan payments, we are not convinced that the impact of this specific policy is exceptionally unique (in either form or magnitude) from other policy proposals made in past cycles. That is, we note that any change in policy that has the effect of increasing the wage index of an area will always result in an increase in MA payment rates to non-contracted hospital providers in that area. It would be out of the scope of this rulemaking to implement any change in MA payment policy (for example, raising benchmark rates) and outside of our authority to change the statutory bidding deadline for MA organizations (the first Monday in June of the year preceding the payment and coverage year), and given the broad general support we received from other commenters, we find the benefits of the proposed policy outweigh the possible repercussions highlighted by the commenter. Further, MA rates (that is, the bidding benchmarks) are set, in part, using projections of national FFS per capita costs for the payment year combined with a localized cost index, or the average geographic adjustment (AGA). The AGA is based on the most recent five-years of historical FFS experience. The IPPS claims supporting the AGAs are repriced using the most recent available wage index, which is FY 2023 for the 2024 MA rates. (These projections are subject to specific statutory exclusions of certain costs that are explained in the annual Rate Announcement.)

In response to the specific request to delay IPPS payment changes because of non-contract MA claims, for the reason cited in the proposed rule (83 FR 26976 through 26977), we believe that any delay to the proposed changes to the rural wage index calculation would be detrimental to hospitals and would result in additional litigation. Consistent with sections 1852(a)(2), 1852(k)(1), and 1866(a)(1)(O) of the Act, non-contract providers must accept as payment in full payment amounts applicable in Original Medicare. We will take these comments regarding MA payment implications into consideration for future rulemaking.

Comment: A commenter requested that CMS provide clarification on how its proposed interpretation of § 412.103 impacts the distance and proximity requirements for MGCRB reclassification. The commenter specifically asked if a § 412.103 redesignated hospital can seek MGCRB reclassification to any CBSA within 35 miles of any point of the State's rural area or to any CBSA adjacent to the rural area.

Response: We believe the commenter is misunderstanding the current MGCRB reclassification rules. Hospitals with a § 412.103 reclassification will continue to use the 35-mile rural proximity criterion at § 412.230(b)(1). All reclassification proximity criteria that use mileage begin the measurement at the hospital's geographic address and end at the nearest point in the requested CBSA area.

After consideration of public comments received, we are adopting the proposed changes to the rural wage index calculations as described in the proposed rule. Specifically, we are adopting without change our proposed interpretation of section 1886(d)(8)(E) of the Act. Accordingly, we are finalizing our proposal to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and to exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. We are also finalizing the proposed policy that hospitals with state-to-state MGCRB reclassifications to a nearby state's rural area receive a ''combined'' wage index (calculation 3 of the rural wage index calculation as previously detailed in the chart) that includes the wage data for geographically rural hospitals and all hospitals reclassified into that rural area (subject to any additional wage index adjustment policies for which those reclassified hospitals may be eligible). Finally, we are finalizing our policy to continue to apply the deemed urban wage index value for § 412.103 hospitals that also qualify as ''Lugar'' under section 1886(d)(8)(B) of the Act, for wage index purposes only.

We note in this final rule that an additional corollary of the changes

being finalized regarding our treatment of hospitals reclassified under § 412.103 is that a hospital with a § 412.103 reclassification should be considered as being located in its State's rural area for the purposes of applying the hold harmless provision under section 1886(d)(8)(C)(iii) of the Act. This would prevent the rare situation where § 412.103 hospitals with the state-to-state rural MGCRB reclassification would be assigned a lower wage index than geographically rural hospitals with the same state-to-state rural MGCRB reclassification.

We note that this policy implication would not alter any wage index values for any hospital or CBSA for this FY 2024 rule, but will have some minor underlying budget neutrality implications, as several additional hospitals will be assigned their State's rural wage index prior to the application of the ''rural floor'' provision (insofar as CMS applies a budget neutrality adjustment in implementing the ''rural floor'').

2. Imputed Floor

In the FY 2005 IPPS final rule (69 FR 49109 through 49111), we adopted the imputed floor policy as a temporary 3-year regulatory measure to address concerns from hospitals in all urban States that have stated that they are disadvantaged by the absence of rural hospitals to set a wage index floor for those States. We extended the imputed floor policy eight times since its initial implementation, the last of which was adopted in the FY 2018 IPPS/LTCH PPS final rule and expired on September 30, 2018. We refer readers to further discussions of the imputed floor in the IPPS/LTCH PPS final rules from FYs 2014 through 2019 (78 FR 50589 through 50590, 79 FR 49969 through 49971, 80 FR 49497 through 49498, 81 FR 56921 through 56922, 82 FR 38138 through 38142, and 83 FR 41376 through 41380, respectively) and to the regulations at 42 CFR 412.64(h)(4). For FYs 2019, 2020, and 2021, hospitals in all-urban states received a wage index that was calculated without applying an imputed floor, and we no longer included the imputed floor as a factor in the national budget neutrality adjustment.

Section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2), enacted on March 11, 2021, amended section 1886(d)(3)(E)(i) of the Act and added section 1886(d)(3)(E)(iv) of the Act to establish a minimum area wage index for hospitals in all-urban States for discharges occurring on or after October 1, 2021. Specifically, section 1886(d)(3)(E)(iv)(I) and (II) of the Act provides that for discharges occurring on or after October 1, 2021, the area wage index applicable to any hospital in an all-urban State may not be less than the minimum area wage index for the fiscal year for hospitals in that State established using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018. Unlike the imputed floor that was in effect from FYs 2005 through 2018, section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index shall not be applied in a budget neutral manner. Section 1886(d)(3)(E)(iv)(IV) of the Act provides that, for purposes of the imputed floor wage index under clause (iv), the term all-urban State means a State in which there are no rural areas (as defined in section 1886(d)(2)(D) of the Act) or a State in which there are no hospitals classified as rural under section 1886 of the Act. Under this definition, given that it applies for purposes of the imputed floor wage index, we consider a hospital to be classified as rural under section 1886 of the Act if it is assigned the State's rural area wage index value.

Effective beginning October 1, 2021 (FY 2022), section 1886(d)(3)(E)(iv) of the Act reinstates the imputed floor wage index policy for all-urban States, with no expiration date, using the methodology described in 42 CFR 412.64(h)(4)(vi) as in effect for FY 2018. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45176 through 45178) for further discussion of the original imputed floor calculation methodology implemented in FY 2005 and the alternative methodology implemented in FY 2013.

Based on data available for this final rule, States that will be all-urban States as defined in section 1886(d)(3)(E)(iv)(IV) of the Act, and thus hospitals in such States that will be eligible to receive an increase in their wage index due to application of the imputed floor for FY 2024, are identified in Table 3 associated with this final rule. States with a value in the column titled ''State Imputed Floor'' are eligible for the imputed floor.

The regulations at § 412.64(e)(1) and (4) and (h)(4) and (5) implement the imputed floor required by section 1886(d)(3)(E)(iv) of the Act for discharges occurring on or after October 1, 2021. The imputed floor will continue to be applied for FY 2024 in accordance with the policies adopted in the FY 2022 IPPS/LTCH PPS final rule. For more information regarding our implementation of the imputed floor required by section 1886(d)(3)(E)(iv) of the Act, we refer readers to the discussion in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45176 through 45178).

3. State Frontier Floor for FY 2024

Section 10324 of Public Law 111–148 requires that hospitals in frontier States cannot be assigned a wage index of less than 1.0000. (We refer readers to the regulations at 42 CFR 412.64(m) and to a discussion of the implementation of this provision in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50160 through 50161).) In the FY 2024 IPPS/LTCH PPS proposed rule, we did not propose any changes to the frontier floor policy for FY 2024. In the proposed rule we stated 43 hospitals would receive the frontier floor value of 1.0000 for their FY 2024 proposed wage index. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming.

We did not receive any public comments on the application of the State frontier floor for FY 2024. In this final rule, 42 hospitals will receive the frontier floor value of 1.0000 for their FY 2024 wage index. These hospitals are located in Montana, North Dakota, South Dakota, and Wyoming. We note that while Nevada meets the criteria of a frontier State, all hospitals within the State currently receive a wage index value greater than 1.0000. The areas affected by the rural and frontier floor policies for the final FY 2024 wage index are identified in Table 2 associated with this final rule, which is available via the internet on the CMS website.

4. Continuation of the Low Wage Index Hospital Policy and Budget Neutrality Adjustment

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42339), we finalized a policy to address the artificial magnification of wage index disparities, based in part on comments we received in response to our request for information included in our FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20372 through 20377). In the FY 2020 IPPS/LTCH final rule, based on those public comments and the growing disparities between wage index values for high- and low-wage-index hospitals, we explained that those growing disparities are likely caused by the use of historical wage data to prospectively set hospitals' wage indexes. That lag creates barriers to hospitals with low wage index values from being able to increase employee compensation, because those hospitals will not receive corresponding increases in their Medicare payment for several years (84 FR 42327). Accordingly, we finalized a policy that provided certain low wage index hospitals with an opportunity to

increase employee compensation without the usual lag in those increases being reflected in the calculation of the wage index.[193] We accomplished this by temporarily increasing the wage index values for certain hospitals with low wage index values and doing so in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals, as well as by changing the calculation of the rural floor. As explained in the FY 2020 IPPS/LTCH proposed rule (84 FR 19396) and final rule (84 FR 42329), we indicated that the Secretary has authority to implement the lowest quartile wage index proposal under both section 1886(d)(3)(E) of the Act and under his exceptions and adjustments authority under section 1886(d)(5)(I) of the Act.

We increase the wage index for hospitals with a wage index value below the 25th percentile wage index value for a fiscal year by half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals (the low wage index hospital policy). We stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42328) our intention is that this policy will be effective for at least 4 years, beginning in FY 2020, in order to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation.

We note that the FY 2020 low wage index hospital policy and the related budget neutrality adjustment are the subject of pending litigation, including in *Bridgeport Hospital, et al.,* v. *Becerra,* No. 1:20–cv–01574 (D.D.C.) (hereafter referred to as *Bridgeport*). The district court in *Bridgeport* found that the Secretary did not have authority under section 1886(d)(3)(E) or 1886(d)(5)(I)(i) of the Act to adopt the low wage index hospital policy for FY 2020 and remanded the policy to the agency without vacatur. We have appealed the court's decision.

At the time the policy was originally promulgated, we stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42328) our intention that it would be in effect for at least 4 fiscal years beginning October 1, 2019. We stated we intended to revisit the issue of the duration of this policy in future rulemaking as we gained experience under the policy. At this time, we only have one year of relevant data (from FY 2020) that we could use to evaluate any potential impacts of this policy. As discussed in section III.B. of the preamble of this final rule, consistent with the IPPS and LTCH PPS ratesettings, our policy principles with regard to the wage index include generally using the most current data and information available, which is usually data on a 4-year lag (for example, for the FY 2023 wage index we used cost report data from FY 2019). Given our current lack of sufficient data with which to evaluate the low wage index hospital policy, we believe it is necessary to wait until we have useable data from additional fiscal years before making any decision to modify or discontinue the policy. Therefore, for FY 2024, we proposed to continue the low wage index hospital policy and the related budget neutrality adjustment (discussed in this section of this rule).

In order to offset the estimated increase in IPPS payments to hospitals with wage index values below the 25th percentile wage index value, for FY 2024 and for subsequent fiscal years during which the low wage index hospital policy is in effect, we proposed to apply a budget neutrality adjustment in the same manner as we applied it since FY 2020 as a uniform budget neutrality factor applied to the standardized amount. We refer readers to section II.A.4.f. of the Addendum to this final rule for further discussion of the budget neutrality adjustment for FY 2024. For purposes of the low wage index hospital policy, based on the data for this final rule, the table displays the 25th percentile wage index value across all hospitals for FY 2024.

FY 2024 25th Percentile Wage Index Value	0.8667

Comment: Several commenters supported the low wage index hospital policy. Numerous commenters indicated that they have used the increased payments resulting from the low wage index hospital policy as CMS intended, resulting in a positive impact on their workforce recruitment and retention. Commenters commended the extension of the policy and noted that there continues to be insufficient data to support modifying or discontinuing the policy. Commenters explained that CMS should continue to extend the policy until a full four-year period of wage data is gathered in order to more fully evaluate the effectiveness of the policy. Several commenters noted that the full 4 years of wage data gathered should be post-COVID–19 wage data in part due to ongoing workforce shortages and regional impacts as a result of the COVID–19 public health emergency (PHE). Specifically, one commenter explained that CMS should not be utilizing any data from FY 2020 due to the impacts of the PHE and other commenters urged CMS to continue the low wage index policy at least through FY 2030 in order to collect wage data outside of the PHE.

Some commenters asked that CMS provide clarification on its plans for this low-wage hospital policy moving forward, urging CMS to specify how many years of data it expects to need in order to evaluate whether the policy has increased wages for low-wage hospitals. Commenters also urged CMS to describe how it will account for the dramatic shifts in wage costs during the COVID–19 PHE, while explaining that doing so will help provide clarity and predictability to the field, especially during the current financial climate in which hospitals are operating.

A commenter explained that regardless of whether the low-wage hospital policy had its intended effect, CMS should now enter the evaluation phase, ending the artificial increase in the low quartile hospitals' wage indices after four years. According to the commenter, if CMS disagrees that four

[193] In the FY 2020 IPPS/LTCH proposed rule, we agreed with respondents to a request for information who indicated that some current wage index policies create barriers to hospitals with low wage index values from being able to increase employee compensation due to the lag between when hospitals increase the compensation and when those increases are reflected in the calculation of the wage index. (We noted that this lag results from the fact that the wage index calculations rely on historical data.) We also agreed that addressing this systemic issue did not need to wait for comprehensive wage index reform given the growing disparities between low and high wage index hospitals, including rural hospitals that may be in financial distress and facing potential closure (84 FR 19394 and 19395).

years of the policy is sufficient, it should better justify continuing the policy and lay out its criteria for evaluating the policy's potential success and at what point it should be terminated.

Response: We thank the many commenters expressing their support of the low wage index hospital policy and the continued feedback regarding achievement of the intended policy goal. We appreciate the commenters' requests to consider the impacts of COVID–19, to extend this policy beyond four years due to COVID–19, and to extend the policy until the intended goals of the policy are reached. We appreciate commenters' suggestions on how we might evaluate the effectiveness of the policy and may consider those suggestions in future rulemaking.

Regarding the comments requesting clarity about how many years of data are needed in order to evaluate whether the policy has increased wages for low-wage hospitals, as noted in the proposed rule and earlier in this section of the final rule, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42328) we stated our intention that this policy will be effective for at least 4 years, until the policy's effects could be reflected in the wage index data. As discussed in section III.B. of the preamble of this final rule, consistent with the IPPS and LTCH PPS ratesettings, our policy principles with regard to the wage index include generally using the most current data and information available, which is usually data on a 4-year lag (for example, for the FY 2023 wage index we used cost report data from FY 2019). At this time, we only have one year of relevant data (from FY 2020) that we could use to evaluate any potential impacts of this policy. Again, as described earlier in this section, when this policy was finalized in the FY 2020 IPPS/LTCH PPS final rule, it was our intention that it would be effective for at least 4 years, until the policy's effects could be reflected in the wage index data. Given our current lack of sufficient data with which to evaluate the low wage index hospital policy, currently having access to only one year of relevant data at this time due to the 4-year data lag also as described earlier in this section, we believe it is necessary to wait until we have useable data from additional fiscal years before making any decision to modify or discontinue the policy.

Comment: Several commenters expressed their support for the continued implementation of wage index payment increases for low-wage hospitals but urged CMS to do so in a non-budget-neutral manner. Commenters stated that implementing the policy with a budget neutrality adjustment merely redistributes funds from one hospital to another, arbitrarily causing some hospitals to experience a payment decrease and others an increase. One commenter stated that those hospitals that fall between approximately the 22nd and 25th percentile are receiving a reduction to the wage adjusted standardized rate because the amount of benefit received is less than the cost to fund the benefit. This commenter suggested holding hospitals under the 25th percentile harmless. Commenters also provided other suggestions for data and alternative methodologies to include: reducing the wage index for hospitals with values above the 75th percentile; working with Congress on a more permanent fix to address the disparities in the wage index by establishing a national floor for all hospitals; and seeking input from the hospital community on best overall reform options that will better avoid downstream consequences from wage index policy changes.

Response: We disagree with the commenters that the low wage index hospital policy should be implemented in a non-budget neutral manner. As we stated in response to similar comments in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42331 and 42332), the FY 2022 IPPS/LTCH PPS final rule (86 FR 45180), and the FY 2023 IPPS/LTCH PPS final rule (87 FR 49007), under section 1886(d)(3)(E) of the Act, the wage index adjustment is required to be implemented in a budget neutral manner. However, even if the wage index were not required to be budget neutral under section 1886(d)(3)(E) of the Act, we would consider it inappropriate to use the wage index to increase or decrease overall IPPS spending. As we stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42331), the wage index is not a policy tool but rather a technical adjustment designed to be a relative measure of the wages and wage-related costs of subsection (d) hospitals. As a result, as we explained in the FY 2020 IPPS/LTCH PPS final rule, if it were determined that section 1886(d)(3)(E) of the Act does not require the wage index to be budget neutral, we invoke our authority at section 1886(d)(5)(I) of the Act in support of such a budget neutrality adjustment.

With regard to the commenter's concern that application of the low wage index policy may result in a reduction to overall payment if the amount of benefit received from the wage index boost is less than the reduction to the standardized amount, we believe we have applied both the quartile policy and the budget neutrality policy appropriately. As we explained most recently in response to comments in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49007), the quartile adjustment is applied to the wage index, which results in an increase to the wage index for hospitals below the 25th percentile. The budget neutrality adjustment is applied to the standardized amount in order to ensure that the low wage index hospital policy is implemented in a budget neutral manner. Thus, consistent with our current methodology for implementing wage index budget neutrality under section 1886(d)(3)(E) of the Act and with how we implemented budget neutrality for the low wage index hospital policy in FY 2020, we believe it is appropriate to continue to apply a budget neutrality adjustment to the national standardized amount for all hospitals so that the low wage index hospital policy is implemented in a budget neutral manner for FY 2024.

Regarding the comment about reducing the wage index for hospitals with values above the 75th percentile, in the FY 2020 IPPS/LTCH final rule (84 FR 42329), we discussed that we originally proposed to reduce the wage index values for high wage index hospitals using a methodology analogous to the methodology used to increase the wage index values for low wage index hospitals described in section III.N.3.a. of the preamble of the proposed rule; that is, we proposed to decrease the wage index values for high wage index hospitals by a uniform factor of the distance between the hospital's otherwise applicable wage index and the 75th percentile wage index value for a fiscal year across all hospitals. In response to comments we received (84 FR 42329 and 42330), we acknowledged that some commenters presented reasonable policy arguments that we should consider further regarding the relationship between our proposed budget neutrality adjustment targeting high wage hospitals and the design of the wage index to be a relative measure of the wages and wage-related costs of subsection (d) hospitals in the United States. Therefore, in the FY 2020 IPPS/LTCH final rule, we did not finalize our proposal to target that budget neutrality adjustment on high wage hospitals (84 FR 42331). Regarding the comment about the establishment of a national floor for all hospitals, we noted in response to a similar comment in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42338 through 42339), as we

do not have evidence a national rural labor market exists or would be created if we were to adopt this alternative, this alternative would not increase the accuracy of the wage index. Also, we believe we have applied both the quartile policy and the budget neutrality policy appropriately, as we explained in response to comments in the FYs 2021 and 2022 IPPS/LTCH PPS final rules and most recently FY 2023 IPPS/LTCH PPS final rule (87 FR 49007). The quartile adjustment is applied to the wage index, which resulted in an increase to the wage index for hospitals below the 25th percentile. The budget neutrality adjustment is applied to the standardized amount in order to ensure that the low wage index hospital policy is implemented in a budget neutral manner.

Comment: Several commenters opposed the low wage index hospital policy, stating that it is inappropriately redistributive, ineffective, and outside the agency's statutory authority under section 1886(d)(3)(E) of the Act. Specifically, some commenters stated that although the policy is intended to help rural hospitals, some rural hospitals in certain states do not benefit from this policy. Furthermore, a commenter stated that the policy undermines the intent of the wage index by not recognizing real differences in labor costs.

Response: We believe we addressed the stated concerns in our responses to comments when we first finalized the policy and the related budget neutrality adjustment in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42332). Concerning the policy's redistributive effect, we refer readers to our response to the previous comments about budget neutrality. With regard to the policy's effectiveness, we continue to believe that the comments in support of the policy, specifically comments from relatively low-wage hospitals stating that the increased payments under the policy have allowed them to raise compensation for their workers, indicate that many low wage hospitals are benefiting from this policy. Furthermore, we stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42328) our intention that this policy will be effective for at least 4 years, until the policy's effects could be reflected in the wage index data. Regarding the policy's effect on rural hospitals, as we stated FY 2020 IPPS/LTCH PPS final rule (84 FR 42328), the wage index is a technical payment adjustment. The intent of the low wage hospital policy is to increase the accuracy of the wage index as a technical adjustment, and not to use the wage index as a policy tool to address non-wage issues related to rural hospitals, or the laudable goals of the overall financial health of hospitals in low wage areas or broader wage index reform. The low wage hospital policy aims to increase the accuracy of the wage index as a relative measure because it allows low wage index hospitals to increase their employee compensation in ways that we would expect if there were no lag between the time a hospital increases employee compensation and the time these increases are reflected in the wage index, and allows those increases to be more timely reflected in the wage index. While one effect of the policy may be to improve the overall well-being of low wage hospitals, and we would welcome that effect, that is not the primary rationale for our policy.

In response to comments stating the policy exceeds CMS's statutory authority, we refer the commenters to our prior discussion of the authority for the policy in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42326 through 42332).

In response to the assertion that the low wage index hospital policy does not recognize real differences in labor costs, we continue to believe, for the reasons stated in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42327 and 42328), that by preserving the rank order in wage index values, our policy continues to reflect meaningful distinctions between the employee compensation costs faced by hospitals in different geographic areas. Thus, under the low wage index hospital policy, we believe the wage index for low wage index hospitals appropriately reflects the relative hospital wage level in those areas compared to the national average hospital wage level.

Comment: Many commenters noted that the low wage index hospital policy is currently the subject of pending litigation in *Bridgeport.* A few commenters urged CMS not to finalize the policy for FY 2024, or to wait until a final court decision is reached. One such commenter suggested CMS should eliminate the budget neutrality adjustments for FYs 2020, 2021, 2022 and 2023 in light of *Bridgeport.* Many commenters applauded CMS's decision to appeal the district court's decision in *Bridgeport.* These commenters stated that the consequences of halting the policy would be dire.

Response: We appreciate the commenters' input. As noted previously, the FY 2020 low wage index hospital policy and the related budget neutrality adjustment are the subject of pending litigation, including in *Bridgeport Hospital, et al.,* v. *Becerra,* No. 1:20–cv–01574 (D.D.C.) (hereafter referred to as *Bridgeport*). The district court in *Bridgeport* found that the Secretary did not have authority under section 1886(d)(3)(E) or 1886(d)(5)(I)(i) of the Act to adopt the low wage index hospital policy for FY 2020 and remanded the policy to the agency without vacatur. We have appealed the court's decision.

After consideration of the comments we received, and for the reasons stated previously and in the proposed rule, we are finalizing as proposed to continue the low wage index hospital policy and the related budget neutrality adjustment for FY 2024.

5. Permanent Cap on Wage Index Decreases and Budget Neutrality Adjustment

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021), we finalized a wage index cap policy and associated budget neutrality adjustment for FY 2023 and subsequent fiscal years. Under this policy, we apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. A hospital's wage index will not be less than 95 percent of its final wage index for the prior FY. If a hospital's prior FY wage index is calculated with the application of the 5-percent cap, the following year's wage index will not be less than 95 percent of the hospital's capped wage index in the prior FY. Except for newly opened hospitals, we apply the cap for a FY using the final wage index applicable to the hospital on the last day of the prior FY. A newly opened hospital will be paid the wage index for the area in which it is geographically located for its first full or partial fiscal year, and it will not receive a cap for that first year, because it will not have been assigned a wage index in the prior year. The wage index cap policy is reflected at 42 CFR 412.64(h)(7). We apply the cap in a budget neutral manner through a national adjustment to the standardized amount each fiscal year. For more information about the wage index cap policy and associated budget neutrality adjustment, we refer readers to the discussion in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021).

Although we did not propose changes to the policy to apply a permanent cap on wage index decreases, we received comments which are summarized and responded to as follows.

Comment: Many commenters expressed their support for CMS's policy, as finalized in the FY 2023 IPPS/

LTCH PPS final rule (87 FR 49018 through 49021), to limit any decrease in a hospital's wage index value to be no greater than 5 percent as compared to the hospital's wage index value for the prior fiscal year, regardless of the circumstances causing the decline. According to commenters, the policy helps maintain stability and predictability to current and future payments under the IPPS by preventing abrupt variation in year-to-year wage data for affected hospitals, much of which may be beyond a hospital's control.

Response: We appreciate the support from commenters.

Comment: Several commenters that supported the policy to apply a permanent cap on wage index decreases, explained that CMS is not bound by statute to make the policy budget neutral and urged CMS to revisit how the policy is funded in order to implement the policy in a non-budget neutral manner. According to these commenters, the budget neutral aspect of the policy causes unintended consequences as payment rates are redistributed and undermines the intended benefit of the policy. Commenters asked CMS to examine alternatives to fund this policy so that the policy is funded using separate and additional funds, rather than in a budget neutral way that reduces the wage indexes of other hospitals. Furthermore, commenters explained that implementing this policy in a non-budget neutral manner would both stabilize provider reimbursement and avoid further unexpected reductions for other providers. Finally, commenters encouraged CMS to continue working with stakeholders and Congress to address the need for more comprehensive reforms.

Response: We thank the commenters for their input regarding the policy to apply a permanent cap on wage index decreases. As discussed in our response to comments in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49020), the budget neutrality adjustment associated with the permanent cap on wage index increases policy is implemented through our authority under sections 1886(d)(3)(E) and (d)(5)(I)(i) of the Act. Section 1886(d)(3)(E) gives the Secretary broad authority to adjust for area differences in hospital wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level, and requires those adjustments to be applied in a budget neutral manner. However, even if the wage index were not required to be budget neutral under section 1886(d)(3)(E) of the Act, we would not consider it an appropriate alternative to use the wage index and the proposed permanent cap on wage index decreases to increase or decrease overall IPPS spending. The wage index is not a policy tool but rather a technical adjustment designed to be a relative measure of the wages and wage-related costs of subsection (d) hospitals in the United States. Furthermore, our past policies involving a 5 percent cap on wage index decreases implemented in a budget neutral manner did not result in wage index volatility, and we expect the same for the overall budget neutrality adjustments associated with the permanent cap policy. For more information about the wage index cap policy and associated budget neutrality adjustment finalized in FY 2023 for FY 2023 and subsequent years, we refer readers to the discussion in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021). For FY 2024, we will apply the wage index cap and associated budget neutrality adjustment in accordance with the policies adopted in the FY 2023 IPPS/LTCH PPS final rule. We note that the budget neutrality adjustment will be updated, as appropriate, based on the final rule data. We refer readers to the Addendum of this final rule for further information regarding the budget neutrality calculations.

H. FY 2023 Wage Index Tables

In this FY 2024 IPPS/LTCH PPS final rule, we have included the following wage index tables: Table 2 titled ''Case-Mix Index and Wage Index Table by CCN''; Table 3 titled ''Wage Index Table by CBSA''; Table 4A titled ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act''; and Table 4B titled ''Counties redesignated under section 1886(d)(8)(B) of the Act (Lugar Counties).'' We refer readers to section VI. of the Addendum to this final rule for a discussion of the wage index tables for FY 2024.

I. Revisions to the Wage Index Based on Hospital Redesignations and Reclassifications

1. General Policies and Effects of Reclassification and Redesignation

Under section 1886(d)(10) of the Act, the Medicare Geographic Classification Review Board (MGCRB) considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. Hospitals must apply to the MGCRB to reclassify not later than 13 months prior to the start of the fiscal year for which reclassification is sought (usually by September 1). Generally, hospitals must be proximate to the labor market area to which they are seeking reclassification and must demonstrate characteristics similar to hospitals located in that area. The MGCRB issues its decisions by the end of February for reclassifications that become effective for the following fiscal year (beginning October 1). The regulations applicable to reclassifications by the MGCRB are located in 42 CFR 412.230 through 412.280. (We refer readers to a discussion in the FY 2002 IPPS final rule (66 FR 39874 and 39875) regarding how the MGCRB defines mileage for purposes of the proximity requirements.) The general policies for reclassifications and redesignations and the policies for the effects of hospitals' reclassifications and redesignations on the wage index are discussed in the FY 2012 IPPS/LTCH PPS final rule for the FY 2012 final wage index (76 FR 51595 and 51596).

In addition, in the FY 2012 IPPS/LTCH PPS final rule, we discussed the effects on the wage index of urban hospitals reclassifying to rural areas under 42 CFR 412.103. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42332 through 42336), we finalized a policy to exclude the wage data of urban hospitals reclassifying to rural areas under 42 CFR 412.103 from the calculation of the rural floor, but we reverted back to the pre-FY 2020 policy in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49002 through 49004). Hospitals that are geographically located in States without any rural areas are ineligible to apply for rural reclassification in accordance with the provisions of 42 CFR 412.103.

On April 21, 2016, we published an interim final rule with comment period (IFC) in the **Federal Register** (81 FR 23428 through 23438) that included provisions amending our regulations to allow hospitals nationwide to have simultaneous § 412.103 and MGCRB reclassifications. For reclassifications effective beginning FY 2018, a hospital may acquire rural status under § 412.103 and subsequently apply for a reclassification under the MGCRB using distance and average hourly wage criteria designated for rural hospitals. In addition, we provided that a hospital that has an active MGCRB reclassification and is then approved for redesignation under § 412.103 will not lose its MGCRB reclassification; such a hospital receives a reclassified urban wage index during the years of its active MGCRB reclassification and is still considered rural under section 1886(d) of the Act and for other purposes.

We discussed that when there is both a § 412.103 redesignation and an MGCRB reclassification, the MGCRB reclassification controls for wage index calculation and payment purposes. Prior to FY 2024, we excluded hospitals with § 412.103 redesignations from the calculation of the reclassified rural wage index if they also have an active MGCRB reclassification to another area. That is, if an application for urban reclassification through the MGCRB is approved, and is not withdrawn or terminated by the hospital within the established timelines, we consider the hospital's geographic CBSA and the urban CBSA to which the hospital is reclassified under the MGCRB for the wage index calculation. We refer readers to the April 21, 2016 IFC (81 FR 23428 through 23438) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56922 through 56930), in which we finalized the April 21, 2016 IFC, for a full discussion of the effect of simultaneous reclassifications under both the § 412.103 and the MGCRB processes on wage index calculations. For FY 2024 and subsequent years, we refer readers to section III.G.1 of the preamble of this final rule for discussion of our proposal to include hospitals with a § 412.103 redesignation that also have an active MGCRB reclassification to another area in the calculation of the reclassified rural wage index.

On May 10, 2021, we published an interim final rule with comment period (IFC) in the **Federal Register** (86 FR 24735 through 24739) that included provisions amending our regulations to allow hospitals with a rural redesignation to reclassify through the MGCRB using the rural reclassified area as the geographic area in which the hospital is located. We revised our regulation so that the redesignated rural area, and not the hospital's geographic urban area, is considered the area a § 412.103 hospital is located in for purposes of meeting MGCRB reclassification criteria, including the average hourly wage comparisons required by § 412.230(a)(5)(i) and (d)(1)(iii)(C). Similarly, we revised the regulations to consider the redesignated rural area, and not the geographic urban area, as the area a § 412.103 hospital is located in for the prohibition at § 412.230(a)(5)(i) on reclassifying to an area with a pre-reclassified average hourly wage lower than the pre-reclassified average hourly wage for the area in which the hospital is located. Effective for reclassification applications due to the MGCRB for reclassification beginning in FY 2023, a § 412.103 hospital could apply for a reclassification under the MGCRB using the State's rural area as the area in which the hospital is located. We refer readers to the May 10, 2021 IFC (86 FR 24735 through 24739) and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45187 through 45190), in which we finalized the May 10, 2021 IFC, for a full discussion of these policies.

2. MGCRB Reclassification and Redesignation Issues for FY 2024

a. FY 2024 Reclassification Application Requirements and Approvals

As previously stated, under section 1886(d)(10) of the Act, the MGCRB considers applications by hospitals for geographic reclassification for purposes of payment under the IPPS. The specific procedures and rules that apply to the geographic reclassification process are outlined in regulations under 42 CFR 412.230 through 412.280. There are 466 hospitals approved for wage index reclassifications by the MGCRB starting in FY 2024. Because MGCRB wage index reclassifications are effective for 3 years, for FY 2024, hospitals reclassified beginning in FY 2022 or FY 2023 are eligible to continue to be reclassified to a particular labor market area based on such prior reclassifications for the remainder of their 3-year period. There were 271 hospitals approved for wage index reclassifications in FY 2022 that will continue for FY 2024, and 325 hospitals approved for wage index reclassifications in FY 2023 that will continue for FY 2024. Of all the hospitals approved for reclassification for FY 2022, FY 2023, and FY 2024, 1062 (approximately 30 percent) hospitals are in a MGCRB reclassification status for FY 2024 (with 187 of these hospitals reclassified back to their geographic location).

Under the regulations at 42 CFR 412.273, hospitals that have been reclassified by the MGCRB are permitted to withdraw their applications if the request for withdrawal is received by the MGCRB any time before the MGCRB issues a decision on the application, or after the MGCRB issues a decision, provided the request for withdrawal is received by the MGCRB within 45 days of the date that CMS's annual notice of proposed rulemaking is issued in the **Federal Register** concerning changes to the inpatient hospital prospective payment system and proposed payment rates for the fiscal year for which the application has been filed. For information about withdrawing, terminating, or canceling a previous withdrawal or termination of a 3-year reclassification for wage index purposes, we refer readers to § 412.273, as well as the FY 2002 IPPS final rule (66 FR 39887 through 39888) and the FY 2003 IPPS final rule (67 FR 50065 through 50066). Additional discussion on withdrawals and terminations, and clarifications regarding reinstating reclassifications and ''fallback'' reclassifications were included in the FY 2008 IPPS final rule (72 FR 47333) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148 through 38150).

We note that in the FY 2021 IPPS/LTCH final rule (85 FR 58771 through 58778), CMS finalized an assignment policy for hospitals reclassified to CBSAs from which one or more counties moved to a new or different urban CBSA under the revised OMB delineations based on OMB Bulletin 18–04. We provided a table in that rule (85 FR 58777 and 58778) which described the assigned CBSA for all the MGCRB cases subject to this policy. For such reclassifications that continue to be active or are reinstated for FY 2024, the CBSAs assigned in the FY 2021 IPPS/LTCH final rule continue to be in effect.

Applications for FY 2025 reclassifications are due to the MGCRB by September 1, 2023. We note that this is also the deadline for canceling a previous wage index reclassification withdrawal or termination under 42 CFR 412.273(d). Applications and other information about MGCRB reclassifications may be obtained beginning in mid-July 2023 via the internet on the CMS website at *https://www.cms.gov/Regulations-andGuidance/Review-Boards/MGCRB/index.html*. This collection of information was previously approved under OMB Control Number 0938–0573 which expired on January 31, 2021. A reinstatement of this PRA package is currently being developed. The public will have an opportunity to review and submit comments regarding the reinstatement of this PRA package through a public notice and comment period separate from this rulemaking.

Comment: A commenter noted that the MGCRB issued determinations for FY 2024 on January 31, 2023. The commenter stated that this was earlier than in the past, when the MGCRB typically issued determinations mid-February, to meet the statutory requirement for decisions to be issued by the end of February. The commenter requested that CMS limit the MGCRB from issuing decisions prior to the first week of February to allow hospitals ample time to submit documentation of rural reclassification, SCH and RRC status to the Board or to submit a request to withdraw an application based on review of the January PUF. The commenter stated that without a

more definitive timeline, hospitals face uncertainty if their documentation will be accepted by the MGCRB and could be adversely affected by an early decision being issued by the Board.

Response: We disagree with the commenter that hospitals are disadvantaged by earlier issuance of MGCRB decisions. First, we believe hospitals should submit applications complete with supporting documentation at the time MGCRB applications are due. Hospitals taking advantage of the MGCRB's practice of accepting supporting documentation to supplement applications until the date of the MGCRB's review are aware that the review is not held on the same date annually. In fact, the MGCRB even issued determinations for FY 2024 on a *later* date in January than it issued determinations for FY 2023 (January 31, 2023, versus January 24, 2022). Furthermore, rural reclassification may be obtained at any time, and hospitals seeking benefits of rural status for MGCRB reclassification should plan accordingly. Finally, we note that hospitals dissatisfied with the MGCRB's decision may request the Administrator's review under § 412.278. With regard to hospitals requesting to withdraw a pending reclassification application following review of the January PUF, hospitals may withdraw a reclassification after the MGCRB has issued decisions, within 45 days of the date that CMS's annual notice of proposed rulemaking is issued in the **Federal Register**, per the regulations at § 412.273. Therefore, we do not believe hospitals are disadvantaged by the earlier timing of MGCRB decisions, because they can submit supporting documentation timely, obtain a rural reclassification in advance, request the Administrator's review of an MGCRB decision, and withdraw an unwanted reclassification.

3. Redesignations Under Section 1886(d)(8)(B) of the Act (Lugar Status Determinations)

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51599 through 51600), we adopted the policy that, beginning with FY 2012, an eligible hospital that waives its Lugar status in order to receive the out-migration adjustment has effectively waived its deemed urban status and, thus, is rural for all purposes under the IPPS effective for the fiscal year in which the hospital receives the out-migration adjustment. In addition, in that rule, we adopted a minor procedural change that allows a Lugar hospital that qualifies for and accepts the out-migration adjustment (through written notification to CMS within 45 days from the publication of the proposed rule) to waive its urban status for the full 3-year period for which its out-migration adjustment is effective. By doing so, such a Lugar hospital will no longer be required during the second and third years of eligibility for the out-migration adjustment to advise us annually that it prefers to continue being treated as rural and receive the out-migration adjustment. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 56930), we further clarified that if a hospital wishes to reinstate its urban status for any fiscal year within this 3-year period, it must send a request to CMS within 45 days of publication of the proposed rule for that particular fiscal year. We indicated that such reinstatement requests may be sent electronically to *wageindex@cms.hhs.gov*. In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38147 through 38148), we finalized a policy revision to require a Lugar hospital that qualifies for and accepts the out-migration adjustment, or that no longer wishes to accept the out-migration adjustment and instead elects to return to its deemed urban status, to notify CMS within 45 days from the date of public display of the proposed rule at the Office of the Federal Register. These revised notification timeframes were effective beginning October 1, 2017. In addition, in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38148), we clarified that both requests to waive and to reinstate ''Lugar'' status may be sent to *wageindex@cms.hhs.gov*. To ensure proper accounting, we request hospitals to include their CCN, and either ''waive Lugar'' or ''reinstate Lugar'', in the subject line of these requests.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42314 and 42315), we clarified that in circumstances where an eligible hospital elects to receive the out-migration adjustment within 45 days of the public display date of the proposed rule at the Office of the Federal Register in lieu of its Lugar wage index reclassification, and the county in which the hospital is located would no longer qualify for an out-migration adjustment when the final rule (or a subsequent correction notice) wage index calculations are completed, the hospital's request to accept the out-migration adjustment will be denied, and the hospital will be automatically assigned to its deemed urban status under section 1886(d)(8)(B) of the Act. We stated that final rule wage index values will be recalculated to reflect this reclassification, and in some instances, after taking into account this reclassification, the out-migration adjustment for the county in question could be restored in the final rule. However, as the hospital is assigned a Lugar reclassification under section 1886(d)(8)(B) of the Act, it would be ineligible to receive the county out-migration adjustment under section 1886(d)(13)(G) of the Act.

We received three timely requests in the *wageindex@cms.hhs.gov* mailbox from CCN 230005 (located in Lenawee County, PA), and CCNs 390183 and 390332 (located in Schuykill county, PA) to waive ''Lugar'' reclassification status to accept the county out-migration adjustment (OMA). These requests are approved. All three hospitals have current § 412.103 rural reclassifications. Per the regulation at § 412.103(g)(5), the rural reclassification status will be terminated, effective October 1, 2023. The status of these requests will be listed in Table 2 in the addendum of this final rule.

We received one request from CCN 150076 on June 13, 2023. The deadline to file a request to waive ''Lugar'' reclassification status to accept its county OMA was May 25, 2023; 45 days from the date of public display (April 10, 2023) of the proposed rule at the Office of the Federal Register. This request is therefore denied.

J. Out-Migration Adjustment Based on Commuting Patterns of Hospital Employees

In accordance with section 1886(d)(13) of the Act, as added by section 505 of Public Law 108–173, beginning with FY 2005, we established a process to make adjustments to the hospital wage index based on commuting patterns of hospital employees (the ''out-migration'' adjustment or OMA). The process, outlined in the FY 2005 IPPS final rule (69 FR 49061), provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different county (or counties) with a higher wage index.

Section 1886(d)(13)(B) of the Act requires the Secretary to use data the Secretary determines to be appropriate to establish the qualifying counties. When the provision of section 1886(d)(13) of the Act was implemented for the FY 2005 wage index, we analyzed commuting data compiled by the U.S. Census Bureau that were derived from a special tabulation of the 2000 Census journey-to-work data for all industries (CMS extracted data applicable to hospitals). These data were compiled from responses to the ''long-form'' survey, which the Census

Bureau used at that time and which contained questions on where residents in each county worked (69 FR 49062). However, the 2010 Census was ''short form'' only; information on where residents in each county worked was not collected as part of the 2010 Census. The Census Bureau worked with CMS to provide an alternative dataset based on the latest available data on where residents in each county worked in 2010, for use in developing a new out-migration adjustment based on new commuting patterns developed from the 2010 Census data beginning with FY 2016.

To determine the out-migration adjustments and applicable counties for FY 2016, we analyzed commuting data compiled by the Census Bureau that were derived from a custom tabulation of the American Community Survey (ACS), an official Census Bureau survey, utilizing 2008 through 2012 (5-year) Microdata. The data were compiled from responses to the ACS questions regarding the county where workers reside and the county to which workers commute. As we discussed in prior IPPS/LTCH PPS final rules, most recently in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49012), we have applied the same policies, procedures, and computations since FY 2012. We proposed to use them again for FY 2024, as we believe they continue to be appropriate. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49500 through 49502) for a full explanation of the revised data source.

For FY 2024, the out-migration adjustment will continue to be based on the data derived from the custom tabulation of the ACS utilizing 2008 through 2012 (5-year) Microdata. For future fiscal years, we may consider determining out-migration adjustments based on data from the next Census or other available data, as appropriate. For FY 2024, we did not propose any changes to the methodology or data source that we used for FY 2016 (81 FR 25071). (We refer readers to a full discussion of the out-migration adjustment, including rules on deeming hospitals reclassified under section 1886(d)(8) or section 1886(d)(10) of the Act to have waived the out-migration adjustment, in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51601 through 51602).)

Comment: A commenter stated that CMS should reconsider whether an out-migration adjustment should be applied to hospitals with a § 412.103 rural reclassification. The commenter stated that, in light of the proposed modification to treat § 412.103 hospitals the same as geographically rural hospitals in the wage index calculation methodology, a § 412.103 hospital without an MGCRB or ''Lugar'' designation should be eligible to receive its county's calculated OMA.

Response: We disagree that a hospital with an active § 412.103 rural reclassification is eligible to receive an OMA. Section 1886(d)(13)(G) of the Act states that a hospital that receives an OMA is not eligible for reclassification under section 1886(d)(8) or 1886(d)(10) of the Act. Section 1886(d)(8) of the Act describes both deemed urban status under section 1886(d)(8)(B) (''Lugar'' reclassification) and obtaining rural status under section 1886(d)(8)(E) of the Act (implemented by § 412.103). By voluntarily applying for a § 412.103 rural reclassification, a hospital is therefore waiving the application of the OMA, as described at section 1886(d)(13)(F) of the Act. Therefore, for the reasons set forth in this final rule and in the FY 2024 IPPS/LTCH PPS proposed rule, for FY 2024, we are finalizing our proposal, without modification, to continue using the same policies, procedures, and computations that were used for the FY 2012 out-migration adjustment and that were applicable for FYs 2016 through 2023.

Table 2 associated with this final rule (which is available via the CMS website) includes the proposed out-migration adjustments for the FY 2024 wage index. In addition, Table 4A associated with this final rule, ''List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act'' (also available via the internet on the CMS website), consists of the following: A list of counties that are eligible for the out-migration adjustment for FY 2024 identified by FIPS county code, the proposed FY 2024 out-migration adjustment, and the number of years the adjustment will be in effect. We refer readers to section V.I. of the Addendum of this final rule for instructions on accessing IPPS tables that are posted on the CMS websites identified in this final rule.

K. Reclassification From Urban to Rural Under Section 1886(d)(8)(E) of the Act Implemented at 42 CFR 412.103

Under section 1886(d)(8)(E) of the Act, a qualifying prospective payment hospital located in an urban area may apply for rural status for payment purposes separate from reclassification through the MGCRB. Specifically, section 1886(d)(8)(E) of the Act provides that, not later than 60 days after the receipt of an application (in a form and manner determined by the Secretary) from a subsection (d) hospital that satisfies certain criteria, the Secretary shall treat the hospital as being located in the rural area (as defined in paragraph (2)(D)) of the State in which the hospital is located. We refer readers to the regulations at 42 CFR 412.103 for the general criteria and application requirements for a subsection (d) hospital to reclassify from urban to rural status in accordance with section 1886(d)(8)(E) of the Act. The FY 2012 IPPS/LTCH PPS final rule (76 FR 51595 through 51596) includes our policies regarding the effect of wage data from reclassified or redesignated hospitals. We refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49004) for a discussion of our current policy to calculate the rural floor with the wage data of urban hospitals reclassifying to rural areas under 42 CFR 412.103. We also refer readers to section III.G.1. of the preamble of this final rule with regard to our proposal to modify how we calculate the rural wage index and its implications for the rural floor.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41369 through 41374), we codified certain policies regarding multicampus hospitals in the regulations at 42 CFR 412.92, 412.96, 412.103, and 412.108. We stated that reclassifications from urban to rural under 42 CFR 412.103 apply to the entire hospital (that is, the main campus and its remote location(s)). We also stated that a main campus of a hospital cannot obtain an SCH, RRC, or MDH status, or rural reclassification under 42 CFR 412.103, independently or separately from its remote location(s), and vice versa. In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49012 and 49013), we added 42 CFR 412.103(a)(8) to clarify that for a multicampus hospital, approved rural reclassification status applies to the main campus and any remote location located in an urban area, including a main campus or any remote location deemed urban under section 1886(d)(8)(B) of the Act. If a remote location of a hospital is located in a different CBSA than the main campus of the hospital, it is CMS's longstanding policy to assign that remote location a wage index based on its own geographic area in order to comply with the statutory requirement to adjust for geographic differences in hospital wage levels (section 1886(d)(3)(E) of the Act). Hospitals are required to identify and allocate wages and hours based on FTEs for remote locations located in different CBSA on Worksheet S–2, Part I, Lines 165 and 166 of form CMS–2552–10. In calculating wage index values, CMS identifies the allocated wage data for

these remote locations in Table 2 with a ''B'' in the 3rd position of the CCN. These remote locations of hospitals with 42 CFR 412.103 rural reclassification status in a different CBSA are identified in Table 2, and hospitals should evaluate potential wage index outcomes for its remote location(s) when withdrawing or terminating MGCRB reclassification, or canceling § 412.103 rural reclassification status.

Finally, in section V.C.2. of the preamble of this final rule, we are changing the effective date of rural reclassification for a hospital qualifying for rural reclassification under § 412.103(a)(3) by meeting the criteria for SCH status (other than being located in a rural area), and also applying to obtain SCH status under § 412.92, where eligibility for SCH classification depends on a hospital merger. Specifically, we are finalizing that in these circumstances, and subject to the requirements set forth at new § 412.92(b)(2)(vi), the effective date for rural reclassification will be as of the effective date set forth in new § 412.92(b)(2)(vi).

Also, in section V.C.2 of the preamble of this final rule, we are making a conforming change to the regulations at § 412.103(d) to modify the effective date of rural reclassification for a hospital qualifying for rural reclassification under § 412.103(a)(3) by meeting the criteria for SCH status (other than being located in a rural area), and also applying to obtain SCH status under § 412.92 where eligibility for SCH classification depends on a hospital merger. We are amending § 412.103(d)(1) and to add new paragraph § 412.103(d)(3) to provide that, subject to the hospital meeting the requirements set forth at new § 412.92(b)(2)(vi), the effective date for rural reclassification for such hospital will be as of the effective date determined under § 412.92(b)(2)(vi).

We refer the reader to section V.C.2. of the preamble of this final rule for complete details on these policies.

L. Process for Requests for Wage Index Data Corrections

1. Process for Hospitals To Request Wage Index Data Corrections

The preliminary, unaudited Worksheet S–3 wage data files and the CY 2019 occupational mix data files for the proposed FY 2024 wage index were made available on May 23, 2022, through the internet on the CMS website at *https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/fy-2024-wage-index-home-page*.

On January 30, 2023, we posted a public use file (PUF) at *https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/fy-2024-wage-index-home-page* containing FY 2024 wage index data available as of January 30, 2023. This PUF contains a tab with the Worksheet S–3 wage data (which includes Worksheet S–3, Parts II and III wage data from cost reporting periods beginning on or after October 1, 2019 through September 30, 2020; that is, FY 2020 wage data), a tab with the occupational mix data (which includes data from the CY 2019 occupational mix survey, Form CMS–10079), a tab containing the Worksheet S–3 wage data of hospitals deleted from the January 30, 2023, wage data PUF, and a tab containing the CY 2019 occupational mix data of the hospitals deleted from the January 30, 2023, occupational mix PUF. In a memorandum dated January 31, 2023, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the January 30, 2023, wage index data PUFs, and the process and timeframe for requesting revisions in accordance with the FY 2024 Hospital Wage Index Development Time Table available at *https://www.cms.gov/files/document/fy-2024-hospital-wage-index-development-time-table.pdf*.

In the interest of meeting the data needs of the public, beginning with the proposed FY 2009 wage index, we post an additional PUF on the CMS website that reflects the actual data that are used in computing the proposed wage index. The release of this file does not alter the current wage index process or schedule. We notify the hospital community of the availability of these data as we do with the current public use wage data files through our Hospital Open Door Forum. We encourage hospitals to sign up for automatic notifications of information about hospital issues and about the dates of the Hospital Open Door Forums at the CMS website at *https://www.cms.gov/Outreach-and-Education/Outreach/OpenDoorForums*.

In a memorandum dated May 3, 2022, we instructed all MACs to inform the IPPS hospitals that they service of the availability of the preliminary wage index data files and the CY 2019 occupational mix survey data files posted on May 23, 2022, and the process and timeframe for requesting revisions.

If a hospital wished to request a change to its data as shown in the May 23, 2022, preliminary wage data files and occupational mix data files, the hospital had to submit corrections along with complete, detailed supporting documentation to its MAC so that the MAC received them by September 2, 2022. Hospitals were notified of these deadlines and of all other deadlines and requirements, including the requirement to review and verify their data as posted in the preliminary wage index data files on the internet, through the letters sent to them by their MACs.

November 4, 2022, was the date by when MACs notified State hospital associations regarding hospitals that failed to respond to issues raised during the desk reviews. Additional revisions made by the MACs were transmitted to CMS throughout January 2023. CMS published the wage index PUFs that included hospitals' revised wage index data on January 30, 2023. Hospitals had until February 15, 2023, to submit requests to the MACs to correct errors in the January 30, 2023, PUF due to CMS or MAC mishandling of the wage index data, or to revise desk review adjustments to their wage index data as included in the January 30, 2023, PUF. Hospitals also were required to submit sufficient documentation to support their requests. Hospitals' requests and supporting documentation must be received by the MAC by the February deadline (that is, by February 15, 2023, for the FY 2024 wage index).

After reviewing requested changes submitted by hospitals, MACs were required to transmit to CMS any additional revisions resulting from the hospitals' reconsideration requests by March 20, 2023. Under our current policy as adopted in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38153), the deadline for a hospital to request CMS intervention in cases where a hospital disagreed with a MAC's handling of wage data on any basis (including a policy, factual, or other dispute) was April 3, 2023. Data that were incorrect in the preliminary or January 30, 2023, wage index data PUFs, but for which no correction request was received by the February 15, 2023 deadline, are not considered for correction at this stage. In addition, April 3, 2023, was the deadline for hospitals to dispute data corrections made by CMS of which the hospital was notified after the January 30, 2023, PUF and at least 14 calendar days prior to April 3, 2023 (that is, March 20, 2023), that do not arise from a hospital's request for revisions. The hospital's request and supporting documentation must be received by CMS (and a copy received by the MAC) by the April deadline (that is, by April 3, 2023, for the FY 2024 wage index). We refer readers to the FY 2024 Hospital Wage Index Development Time Table for complete details.

Hospitals were given the opportunity to examine Table 2 associated with the

proposed rule, which is listed in section VI. of the Addendum to the proposed rule and available via the internet on the CMS website at *https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/fy-2024-wage-index-home-page*. Table 2 associated with the proposed rule contained each hospital's proposed adjusted average hourly wage used to construct the wage index values for the past 3 years, including the proposed FY 2024 wage index which was constructed from FY 2020 data. We noted in the proposed rule that the proposed hospital average hourly wages shown in Table 2 only reflected changes made to a hospital's data that were transmitted to CMS by early February 2023.

We posted the final wage index data PUFs on April 28, 2023, on the CMS website at *https://www.cms.gov/medicaremedicare-fee-service-paymentacuteinpatientppswage-index-files/fy-2024-wage-index-home-page*. The April 2023 PUFs are made available solely for the limited purpose of identifying any potential errors made by CMS or the MAC in the entry of the final wage index data that resulted from the correction process (the process for disputing revisions submitted to CMS by the MACs by March 20, 2023, and the process for disputing data corrections made by CMS that did not arise from a hospital's request for wage data revisions as discussed earlier), as previously described.

After the release of the April 2023 wage index data PUFs, changes to the wage and occupational mix data can only be made in those very limited situations involving an error by the MAC or CMS that the hospital could not have known about before its review of the final wage index data files. Specifically, neither the MAC nor CMS will approve the following types of requests:

- Requests for wage index data corrections that were submitted too late to be included in the data transmitted to CMS by the MACs on or before March 20, 2023.
- Requests for correction of errors that were not, but could have been, identified during the hospital's review of the January 30, 2023, wage index PUFs.
- Requests to revisit factual determinations or policy interpretations made by the MAC or CMS during the wage index data correction process.

If, after reviewing the April 2023 final wage index data PUFs, a hospital believes that its wage or occupational mix data are incorrect due to a MAC or CMS error in the entry or tabulation of the final data, the hospital is given the opportunity to notify both its MAC and CMS regarding why the hospital believes an error exists and provide all supporting information, including relevant dates (for example, when it first became aware of the error). The hospital was required to send its request to CMS and to the MAC so that it was received no later than May 26, 2023. May 26, 2023, was also the deadline for hospitals to dispute data corrections made by CMS of which the hospital was notified on or after 13 calendar days prior to April 1, 2023 (that is, March 19, 2023), and at least 14 calendar days prior to May 26, 2023 (that is, May 12, 2023), that did not arise from a hospital's request for revisions. (Data corrections made by CMS of which a hospital was notified on or after 13 calendar days prior to May 26, 2023 (that is, May 13, 2023), may be appealed to the Provider Reimbursement Review Board (PRRB)). In accordance with the FY 2024 Hospital Wage Index Development Time Table posted on the CMS website at *https://www.cms.gov/files/document/fy-2024-hospital-wage-index-development-time-table.pdf*, the May appeals were required to be sent via mail and email to CMS and the MACs. We refer readers to the FY 2024 Hospital Wage Index Development Time Table for complete details.

Verified corrections to the wage index data received timely (that is, by May 26, 2023) by CMS and the MACs were incorporated into the final FY 2024 wage index, which will be effective October 1, 2023.

We created the processes previously described to resolve all substantive wage index data correction disputes before we finalize the wage and occupational mix data for the FY 2024 payment rates. Accordingly, hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute the MAC's decision with respect to requested changes. Specifically, our policy is that hospitals that do not meet the procedural deadlines as previously set forth (requiring requests to MACs by the specified date in February and, where such requests are unsuccessful, requests for intervention by CMS by the specified date in April) will not be permitted to challenge later, before the PRRB, the failure of CMS to make a requested data revision. We refer readers also to the FY 2000 IPPS final rule (64 FR 41513) for a discussion of the parameters for appeals to the PRRB for wage index data corrections. As finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156), this policy also applies to a hospital disputing corrections made by CMS that do not arise from a hospital's request for a wage index data revision. That is, a hospital disputing an adjustment made by CMS that did not arise from a hospital's request for a wage index data revision is required to request a correction by the first applicable deadline. Hospitals that do not meet the procedural deadlines set forth earlier will not be afforded a later opportunity to submit wage index data corrections or to dispute CMS' decision with respect to changes.

Again, we believe the wage index data correction process described earlier provides hospitals with sufficient opportunity to bring errors in their wage and occupational mix data to the MAC's attention. Moreover, because hospitals had access to the final wage index data PUFs by late April 2023, they have an opportunity to detect any data entry or tabulation errors made by the MAC or CMS before the development and publication of the final FY 2024 wage index by August 2023, and the implementation of the FY 2024 wage index on October 1, 2023. Given these processes, the wage index implemented on October 1 should be accurate. Nevertheless, in the event that errors are identified by hospitals and brought to our attention after May 26, 2023, we retain the right to make midyear changes to the wage index under very limited circumstances.

Specifically, in accordance with 42 CFR 412.64(k)(1) of our regulations, we make midyear corrections to the wage index for an area only if a hospital can show that: (1) The MAC or CMS made an error in tabulating its data; and (2) the requesting hospital could not have known about the error or did not have an opportunity to correct the error, before the beginning of the fiscal year. For purposes of this provision, ''before the beginning of the fiscal year'' means by the May deadline for making corrections to the wage data for the following fiscal year's wage index (for example, May 26, 2023, for the FY 2024 wage index). This provision is not available to a hospital seeking to revise another hospital's data that may be affecting the requesting hospital's wage index for the labor market area. As indicated earlier, because CMS makes the wage index data available to hospitals on the CMS website prior to publishing both the proposed and final IPPS rules, and the MACs notify hospitals directly of any wage index data changes after completing their desk reviews, we do not expect that midyear corrections will be necessary. However, under our current policy, if the correction of a data error changes the

wage index value for an area, the revised wage index value will be effective prospectively from the date the correction is made.

In the FY 2006 IPPS final rule (70 FR 47385 through 47387 and 47485), we revised 42 CFR 412.64(k)(2) to specify that, effective on October 1, 2005, that is, beginning with the FY 2006 wage index, a change to the wage index can be made retroactive to the beginning of the Federal fiscal year only when CMS determines all of the following: (1) The MAC or CMS made an error in tabulating data used for the wage index calculation; (2) the hospital knew about the error and requested that the MAC and CMS correct the error using the established process and within the established schedule for requesting corrections to the wage index data, before the beginning of the fiscal year for the applicable IPPS update (that is, by the May 26, 2023, deadline for the FY 2024 wage index); and (3) CMS agreed before October 1 that the MAC or CMS made an error in tabulating the hospital's wage index data and the wage index should be corrected.

In those circumstances where a hospital requested a correction to its wage index data before CMS calculated the final wage index (that is, by the May 26, 2023, deadline for the FY 2024 wage index), and CMS acknowledges that the error in the hospital's wage index data was caused by CMS's or the MAC's mishandling of the data, we believe that the hospital should not be penalized by our delay in publishing or implementing the correction. As with our current policy, we indicated that the provision is not available to a hospital seeking to revise another hospital's data. In addition, the provision cannot be used to correct prior years' wage index data; it can only be used for the current Federal fiscal year. In situations where our policies would allow midyear corrections other than those specified in 42 CFR 412.64(k)(2)(ii), we continue to believe that it is appropriate to make prospective-only corrections to the wage index.

We note that, as with prospective changes to the wage index, the final retroactive correction will be made irrespective of whether the change increases or decreases a hospital's payment rate. In addition, we note that the policy of retroactive adjustment will still apply in those instances where a final judicial decision reverses a CMS denial of a hospital's wage index data revision request.

2. Process for Data Corrections by CMS After the January 30 Public Use File (PUF)

The process set forth with the wage index timetable discussed in section III.L.1. of the preamble of this final rule allows hospitals to request corrections to their wage index data within prescribed timeframes. In addition to hospitals' opportunity to request corrections of wage index data errors or MACs' mishandling of data, CMS has the authority under section 1886(d)(3)(E) of the Act to make corrections to hospital wage index and occupational mix data in order to ensure the accuracy of the wage index. As we explained in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49490 through 49491) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 56914), section 1886(d)(3)(E) of the Act requires the Secretary to adjust the proportion of hospitals' costs attributable to wages and wage-related costs for area differences reflecting the relative hospital wage level in the geographic areas of the hospital compared to the national average hospital wage level. We believe that, under section 1886(d)(3)(E) of the Act, we have discretion to make corrections to hospitals' data to help ensure that the costs attributable to wages and wage-related costs in fact accurately reflect the relative hospital wage level in the hospitals' geographic areas.

We have an established multistep, 15-month process for the review and correction of the hospital wage data that is used to create the IPPS wage index for the upcoming fiscal year. Since the origin of the IPPS, the wage index has been subject to its own annual review process, first by the MACs, and then by CMS. As a standard practice, after each annual desk review, CMS reviews the results of the MACs' desk reviews and focuses on items flagged during the desk review, requiring that, if necessary, hospitals provide additional documentation, adjustments, or corrections to the data. This ongoing communication with hospitals about their wage data may result in the discovery by CMS of additional items that were reported incorrectly or other data errors, even after the posting of the January 30 PUF, and throughout the remainder of the wage index development process. In addition, the fact that CMS analyzes the data from a regional and even national level, unlike the review performed by the MACs that review a limited subset of hospitals, can facilitate additional editing of the data that may not be readily apparent to the MACs. In these occasional instances, an error may be of sufficient magnitude that the wage index of an entire CBSA is affected. Accordingly, CMS uses its authority to ensure that the wage index accurately reflects the relative hospital wage level in the geographic area of the hospital compared to the national average hospital wage level, by continuing to make corrections to hospital wage data upon discovering incorrect wage data, distinct from instances in which hospitals request data revisions.

We note that CMS corrects errors to hospital wage data as appropriate, regardless of whether that correction will raise or lower a hospital's average hourly wage. For example, as discussed in section III.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule (83 FR 41364), in situations where a hospital did not have documentable salaries, wages, and hours for housekeeping and dietary services, we imputed estimates, in accordance with policies established in the FY 2015 IPPS/LTCH PPS final rule (79 FR 49965 through 49967). Furthermore, if CMS discovers after conclusion of the desk review, for example, that a MAC inadvertently failed to incorporate positive adjustments resulting from a prior year's wage index appeal of a hospital's wage-related costs such as pension, CMS would correct that data error, and the hospital's average hourly wage would likely increase as a result.

While we maintain CMS' authority to conduct additional review and make resulting corrections at any time during the wage index development process, in accordance with the policy finalized in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156) and as first implemented with the FY 2019 wage index (83 FR 41389), hospitals are able to request further review of a correction made by CMS that did not arise from a hospital's request for a wage index data correction. Instances where CMS makes a correction to a hospital's data after the January 30 PUF based on a different understanding than the hospital about certain reported costs, for example, could potentially be resolved using this process before the final wage index is calculated. We believe this process and the timeline for requesting review of such corrections (as described earlier and in the FY 2018 IPPS/LTCH PPS final rule) promote additional transparency to instances where CMS makes data corrections after the January 30 PUF and provide opportunities for hospitals to request further review of CMS changes in time for the most accurate data to be reflected in the final wage index calculations. These additional appeals opportunities are

described earlier and in the FY 2024 Hospital Wage Index Development Time Table, as well as in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38154 through 38156).

M. Labor-Related Share for the FY 2023 Wage Index

Section 1886(d)(3)(E) of the Act directs the Secretary to adjust the proportion of the national prospective payment system base payment rates that are attributable to wages and wage-related costs by a factor that reflects the relative differences in labor costs among geographic areas. It also directs the Secretary to estimate from time to time the proportion of hospital costs that are labor-related and to adjust the proportion (as estimated by the Secretary from time to time) of hospitals' costs that are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the portion of hospital costs attributable to wages and wage-related costs as the labor-related share. The labor-related share of the prospective payment rate is adjusted by an index of relative labor costs, which is referred to as the wage index.

Section 403 of Public Law 108–173 amended section 1886(d)(3)(E) of the Act to provide that the Secretary must employ 62 percent as the labor-related share unless this would result in lower payments to a hospital than would otherwise be made. However, this provision of Public Law 108–173 did not change the legal requirement that the Secretary estimate from time to time the proportion of hospitals' costs that are attributable to wages and wage-related costs. Thus, hospitals receive payment based on either a 62-percent labor-related share, or the labor-related share estimated from time to time by the Secretary, depending on which labor-related share resulted in a higher payment.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45208), we rebased and revised the hospital market basket. We established a 2018-based IPPS hospital market basket to replace the FY 2014-based IPPS hospital market basket, effective October 1, 2021. Using the 2018-based IPPS market basket, we finalized a labor-related share of 67.6 percent for discharges occurring on or after October 1, 2021. In addition, in FY 2022, we implemented this revised and rebased labor-related share in a budget neutral manner (86 FR 45193, 45529, and 45530). However, consistent with section 1886(d)(3)(E) of the Act, we did not take into account the additional payments that would be made as a result of hospitals with a wage index less than or equal to 1.0000 being paid using a labor-related share lower than the labor-related share of hospitals with a wage index greater than 1.0000.

The labor-related share is used to determine the proportion of the national IPPS base payment rate to which the area wage index is applied. We include a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45204 through 45207), we included in the labor-related share the national average proportion of operating costs that are attributable to the following cost categories in the 2018-based IPPS market basket: Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; and All Other: Labor-Related Services. In the proposed rule, for FY 2024, we did not propose to make any further changes to the labor-related share. For FY 2024, we are finalizing the policy to continue to use a labor-related share of 67.6 percent for discharges occurring on or after October 1, 2023.

As discussed in section V.B. of the preamble of this final rule, prior to January 1, 2016, Puerto Rico hospitals were paid based on 75 percent of the national standardized amount and 25 percent of the Puerto Rico-specific standardized amount. As a result, we applied the Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage to the Puerto Rico-specific standardized amount. Section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113) amended section 1886(d)(9)(E) of the Act to specify that the payment calculation with respect to operating costs of inpatient hospital services of a subsection (d) Puerto Rico hospital for inpatient hospital discharges on or after January 1, 2016, shall use 100 percent of the national standardized amount. Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount as of January 1, 2016, under section 1886(d)(9)(E) of the Act as amended by section 601 of the Consolidated Appropriations Act, 2016, there is no longer a need for us to calculate a Puerto Rico-specific labor-related share percentage and nonlabor-related share percentage for application to the Puerto Rico-specific standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the national labor-related share and nonlabor-related share percentages that are applied to the national standardized amount. Accordingly, for FY 2024, we did not propose a Puerto Rico-specific labor-related share percentage or a nonlabor-related share percentage.

Tables 1A and 1B, which are published in section VI. of the Addendum to this FY 2024 IPPS/LTCH PPS final rule and available via the internet on the CMS website, reflect the national labor-related share. Table 1C, in section VI. of the Addendum to this FY 2024 IPPS/LTCH PPS final rule and available via the internet on the CMS website, reflects the national labor-related share for hospitals located in Puerto Rico. For FY 2024, for all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are less than or equal to 1.0000, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount. For all IPPS hospitals (including Puerto Rico hospitals) whose wage indexes are greater than 1.000, for FY 2024, we are applying the wage index to a labor-related share of 67.6 percent of the national standardized amount.

Comment: A commenter requested that CMS maintain the labor-related share from FY 2023 for FY 2024.

Response: We did not propose to make any further changes to the labor-related share for FY 2024. As discussed earlier, for FY 2024, we are continuing to use a labor-related share of 67.6 percent for discharges occurring on or after October 1, 2023.

IV. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2024 (§ 412.106)

A. General Discussion

Section 1886(d)(5)(F) of the Act provides for additional Medicare payments to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. The Act specifies two methods by which a hospital may qualify for the Medicare disproportionate share hospital (DSH) adjustment. Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to patients with low incomes. This method is commonly referred to as the ''Pickle method.'' The second method for qualifying for the DSH payment adjustment, which is the most common method, is based on a complex statutory formula under which the DSH payment

adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP).

A hospital's DPP is the sum of two fractions: the ''Medicare fraction'' and the ''Medicaid fraction.'' The Medicare fraction (also known as the ''SSI fraction'' or ''SSI ratio'') is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid, but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

DSH Eligibility	Qualifying Criteria
Statutory Formula	A hospital that has a DPP equal to or exceeding 15 percent may qualify for the Medicare DSH adjustment. We refer readers to 42 CFR 412.106 for the specific eligibility criteria and payment formulas.
"Pickle Method"	A hospital that is located in an urban area and has 100 or more beds may qualify to receive a Medicare DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to patients with low incomes.

Because the DSH payment adjustment is part of the IPPS, the statutory references to ''days'' in section 1886(d)(5)(F) of the Act have been interpreted to apply only to hospital acute care inpatient days. Regulations located at 42 CFR 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the IME adjustment under § 412.105(b).

Section 3133 of the Patient Protection and Affordable Care Act (Pub. L. 111–148), as amended by section 10316 of the same Act and section 1104 of the Health Care and Education Reconciliation Act (Pub. L. 111–152), added a section 1886(r) to the Act that modifies the methodology for computing the Medicare DSH payment adjustment. We refer to these provisions collectively as section 3133 of the Affordable Care Act. Beginning with discharges in FY 2014, hospitals that qualify for Medicare DSH payments under section 1886(d)(5)(F) of the Act receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments. This provision applies equally to hospitals that qualify for DSH payments under section 1886(d)(5)(F)(i)(I) of the Act and hospitals that qualify under the Pickle method under section 1886(d)(5)(F)(i)(II) of the Act.

The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has provided uncompensated care. These additional payments to each hospital for a fiscal year are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all hospitals that receive Medicare DSH payments for that fiscal year.

In summary, since FY 2014, section 1886(r) of the Act has required that hospitals that are eligible for DSH payments under section 1886(d)(5)(F) of the Act receive two separately calculated payments:

Medicare DSH Payment	An empirically justified DSH payment equal to 25% of the amount determined under the statutory formula in section 1886(d)(5)(F) of the Act.
Medicare DSH Uncompensated Care Payment	An uncompensated care payment determined as the product of 3 factors, as discussed in this section.

Specifically, section 1886(r)(1) of the Act provides that the Secretary shall pay to such subsection (d) hospital 25 percent of the amount the hospital would have received under section 1886(d)(5)(F) of the Act for DSH payments, which represents the empirically justified amount for such payment, as determined by the MedPAC in its March 2007 Report to Congress.[194] We refer to this payment as the ''empirically justified Medicare DSH payment.''

In addition to this empirically justified Medicare DSH payment, section 1886(r)(2) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay to such subsection (d) hospital an additional amount equal to the product of three factors. The first factor is the difference between the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if subsection (r) did not apply and the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year. Therefore, this factor amounts to 75 percent of the payments that would otherwise be made under section 1886(d)(5)(F) of the Act.

The second factor is, for FY 2018 and subsequent fiscal years, equal to 1 minus the percent change in the percent of individuals who are uninsured. For purposes of calculating this factor, the Secretary determines the percent change in the percent of individuals who are uninsured by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary

[194] *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/Mar07_EntireReport.pdf.*

based on data from the Census Bureau or other sources the Secretary determines appropriate, and certified by the Chief Actuary of CMS) and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified).

The third factor is a percent that, for each subsection (d) hospital, represents the quotient of the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data, including the use of alternative data where the Secretary determines that alternative data are available which are a better proxy for the costs of subsection (d) hospitals for treating the uninsured), and the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act. Therefore, this third factor represents a hospital's uncompensated care amount for a given time period relative to the uncompensated care amount for that same time period for all hospitals that receive Medicare DSH payments in the applicable fiscal year, expressed as a percent.

For each hospital, the product of these three factors represents its additional payment for uncompensated care for the applicable fiscal year. We refer to the additional payment determined by these factors as the ''uncompensated care payment.'' In brief, the uncompensated care payment for an individual hospital is determined as the product of the following 3 factors:

Factor 1	75% of the total amount of DSH payments that would otherwise be made under section 1886(d)(5)(F) of the Act.
Factor 2	1 minus the percent change in the percent of individuals who are uninsured (minus 0.2 percentage point for FYs 2018 and 2019). For FY 2020 and after, there is no additional reduction.
Factor 3	The hospital's uncompensated care amount relative to the uncompensated care amount for all DSH hospitals expressed as a percentage.

Section 1886(r) of the Act applies to FY 2014 and each subsequent fiscal year. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50620 through 50647) and the FY 2014 IPPS interim final rule with comment period (78 FR 61191 through 61197), we set forth our policies for implementing the required changes to the Medicare DSH payment methodology made by section 3133 of the Affordable Care Act beginning in FY 2014. In those rules, we noted that, because section 1886(r) of the Act modifies the payment required under section 1886(d)(5)(F) of the Act, it affects only the DSH payment under the operating IPPS. It does not revise or replace the capital IPPS DSH payment provided under 42 CFR part 412, subpart M, which was established through the exercise of the Secretary's discretion in implementing the capital IPPS under section 1886(g)(1)(A) of the Act.

Finally, section 1886(r)(3) of the Act provides that there shall be no administrative or judicial review under section 1869, section 1878, or otherwise of any estimate of the Secretary for purposes of determining the factors described in section 1886(r)(2) of the Act or of any period selected by the Secretary for the purpose of determining those factors. Therefore, there is no administrative or judicial review of the estimates developed for purposes of applying the three factors used to determine uncompensated care payments, or the periods selected to develop such estimates.

B. Eligibility for Empirically Justified Medicare DSH Payments and Uncompensated Care Payments

As explained earlier, the payment methodology under section 3133 of the Affordable Care Act applies to ''subsection (d) hospitals'' that would otherwise receive a DSH payment made under section 1886(d)(5)(F) of the Act. In addition, section 1886(r) of the Act states that hospitals must receive empirically justified Medicare DSH payments in a fiscal year to receive an additional Medicare uncompensated care payment for that year. Specifically, section 1886(r)(2) of the Act provides that, in addition to the empirically justified Medicare DSH payment made to a subsection (d) hospital under section 1886(r)(1), the Secretary will pay to ''such subsection (d) hospitals'' the uncompensated care payment. Section 1886(r)(2)'s reference to ''such subsection (d) hospitals'' refers to hospitals that receive empirically justified Medicare DSH payments under Section 1886(r)(1). Therefore, the uncompensated care payment provided for in Section 1886(r)(2) is limited to those hospitals that receive empirically justified Medicare DSH payments.

Accordingly, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and the FY 2014 IPPS interim final rule with comment period (78 FR 61193), we explained that hospitals that are not eligible to receive empirically justified Medicare DSH payments in a fiscal year will not receive uncompensated care payments for that year. We also specified that we would make a determination concerning eligibility for interim uncompensated care payments based on each hospital's estimated DSH status for the applicable fiscal year (using the most recent data that are available).[195] In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26988), we stated that we would estimate DSH status for all hospitals using the most recent available SSI ratios and information from the most recent available Provider Specific File.[196] We noted that FY 2020 SSI ratios available on the CMS website were the most recent available SSI ratios at the time of developing the proposed rule.[197] We stated that if more recent data on DSH eligibility become available before the final rule, we would use such data in the final rule. The FY 2020 SSI ratios were the most recent data available at the time of developing this FY 2024 IPPS/LTCH PPS final rule.

Our final determination of a hospital's eligibility for uncompensated care payments will be based on the hospital's actual DSH status at cost report settlement for FY 2024.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622) and in the rulemaking for subsequent fiscal years, we specified our policies regarding the eligibility of several specific classes of hospitals to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act.

[195] For more information on interim uncompensated care payments, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50624 through 50625).

[196] The file contains information about the facts specific to the provider that affect computations for the IPPS.

[197] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.*

Eligible hospitals include the following:

• *Subsection (d) Puerto Rico hospitals* that are eligible for DSH payments also are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act (78 FR 50623 and 79 FR 50006).

• *Sole community hospitals (SCHs) that are paid under the IPPS Federal rate* receive interim payments based on what we estimate and project their DSH status to be prior to the beginning of the Federal fiscal year (based on the best available data at that time) subject to settlement through the cost report. If an SCH receives interim empirically justified Medicare DSH payments in a fiscal year, it also will receive interim uncompensated care payments for that fiscal year on a per discharge basis, subject to settlement through the cost report. Final eligibility determinations will be made at the end of the cost reporting period at settlement, and both interim empirically justified Medicare DSH payments and uncompensated care payments will be adjusted accordingly (78 FR 50624 and 79 FR 50007).

• *Medicare-dependent, small rural hospitals (MDHs)* are paid based on the IPPS Federal rate or, if higher, the IPPS Federal rate plus 75 percent of the amount by which the updated hospital-specific rate from certain specified base years (76 FR 51684) exceeds the Federal rate. The IPPS Federal rate that is used in the MDH payment methodology is the same IPPS Federal rate that is used in the SCH payment methodology. Because MDHs are paid based on the IPPS Federal rate, they continue to be eligible to receive empirically justified Medicare DSH payments and uncompensated care payments if their DPP is at least 15 percent, and we apply the same process to determine MDHs' eligibility for interim empirically justified Medicare DSH and interim uncompensated care payments as we do for all other IPPS hospitals. Legislation has extended the MDH program into FY 2024. The MDH program was initially extended through December 17, 2022, by section 102 of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Pub. L. 117–180), and through December 24, 2022, by section 102 of the Further Continuing Appropriations and Extensions Act, 2023 (Pub. L. 117–229). Section 4102 of the Continuing Appropriations Act, 2023 (Pub. L. 117–328) amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to provide for an extension of the MDH program through October 1, 2024 (that is, for discharges occurring on or before September 30, 2024). We refer readers to section V.F. of the preamble of this final rule for further discussion of the MDH program. We continue to make determinations concerning an MDH's eligibility for interim uncompensated care payments based on the hospital's estimated DSH status for the applicable fiscal year.

• *IPPS hospitals that elect to participate in the Bundled Payments for Care Improvement Advanced (BPCI Advanced) model,* which started October 1, 2018, will continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. On October 13, 2022, CMS announced that the BPCI Advanced Model would be extended for two years. Accordingly, the Model's final performance year will end on December 31, 2025. For further information regarding the BPCI Advanced Model, we refer readers to the CMS website at *https://innovation.cms.gov/innovation-models/bpci-advanced*.

• *IPPS hospitals that participate in the Comprehensive Care for Joint Replacement Model* (80 FR 73300) continue to be paid under the IPPS and, therefore, are eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. We refer the reader to the interim final rule with request for comments that appeared in the November 6, 2020 **Federal Register** for a discussion of the Model (85 FR 71167 through 71173). In that interim final rule, we extended the Model's Performance Year 5 to September 30, 2021. In a subsequent final rule that appeared in the May 3, 2021 **Federal Register** (86 FR 23496), we further extended the Model for an additional three performance years. The Model's Performance Year 8 will end on December 31, 2024.

Ineligible hospitals include the following:

• *Maryland hospitals* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under the payment methodology of section 1886(r) of the Act because they are not paid under the IPPS. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41402 through 41403), CMS and the State have entered into an agreement to govern payments to Maryland hospitals under a new payment model, the Maryland Total Cost of Care (TCOC) Model. Under this Model, which began on January 1, 2019, and concludes on December 31, 2026, Maryland hospitals are not paid under the IPPS and are ineligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act.

• *SCHs that are paid under their hospital-specific rate* are not eligible for Medicare DSH and uncompensated care payments. (See 78 FR 50623 and 50624.)

• *Hospitals participating in the Rural Community Hospital Demonstration Program* are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments under section 1886(r) of the Act because they are not paid under the IPPS (78 FR 50625 and 79 FR 50008). The Rural Community Hospital Demonstration Program was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). The period of performance for this 5-year extension period ended December 31, 2016. Section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, again amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act), therefore requiring an additional 5-year participation period for the demonstration program. Section 15003 of Public Law 114–255 also required a solicitation for applications for additional hospitals to participate in the demonstration program. The period of performance for this second 5-year extension period ended December 31, 2021. The Consolidated Appropriations Act, 2021 (Pub. L. 116–260) amended section 410A of Public Law 108–173 to extend the Rural Community Hospital Demonstration Program for an additional 5-year period. The period of participation for the last hospital in the demonstration under this most recent legislative authorization will end on June 30, 2028. Under the payment methodology that applies during the third 5-year extension period for the demonstration program, participating hospitals do not receive empirically justified Medicare DSH payments, and they are excluded from receiving interim and final uncompensated care payments. At the time of development of this final rule, we expect 26 hospitals may participate in the demonstration program at the start of FY 2024.

We received a comment that was outside the scope of the proposed rule. The comment related to the eligibility of SCHs paid under hospital-specific rate and MDHs to receive DSH payments.

Because we consider this public comment to be outside the scope of the proposed rule, we are not addressing the comment in this final rule.

C. Empirically Justified Medicare DSH Payments

As we discussed earlier, section 1886(r)(1) of the Act requires the Secretary to pay 25 percent of the amount of the Medicare DSH payment that would otherwise be made under section 1886(d)(5)(F) of the Act to a subsection (d) hospital. Because section 1886(r)(1) of the Act merely requires the Medicare program to pay a designated percentage of these payments and does not revise the criteria governing eligibility for DSH payments or the underlying payment methodology, we stated in the FY 2014 IPPS/LTCH PPS final rule that we had determined that it was unnecessary to develop new operational mechanisms for making empirically justified DSH payments under section 1886(r)(1). Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50626), we implemented section 1886(r)(1) of the Act by advising Medicare Administrative Contractors (MACs) to simply adjust subsection (d) hospitals' interim claim payments to an amount equal to 25 percent of what would have been paid if section 1886(r) of the Act did not apply. We also made corresponding changes to the hospital cost report so that these empirically justified Medicare DSH payments can be settled at the appropriate level at the time of cost report settlement. We provided more detailed operational instructions and cost report instructions following issuance of the FY 2014 IPPS/LTCH PPS final rule, which are available on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/2014-Transmittals-Items/R5P240.html*.

D. Supplemental Payment for Indian Health Service (IHS) and Tribal Hospitals and Puerto Rico Hospitals

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49047 through 49051), we established a new supplemental payment for IHS/Tribal hospitals and hospitals located in Puerto Rico for FY 2023 and subsequent fiscal years. This payment was established to help to mitigate the impact of the decision to discontinue the use of low-income insured days as proxy for uncompensated care costs for these hospitals and to prevent undue long-term financial disruption for these providers. The regulations located at 42 CFR 412.106(h) govern the supplemental payment. In brief, the supplemental payment for a fiscal year is determined as the difference between the hospital's base year amount and its uncompensated care payment for the applicable fiscal year as determined under § 412.106(g)(1). The base year amount is the hospital's FY 2022 uncompensated care payment adjusted by one plus the percent change in the total uncompensated care amount between the applicable fiscal year (that is, FY 2024 for purposes of this rulemaking) and FY 2022, where the total uncompensated care amount for a year is determined as the product of Factor 1 and Factor 2 for that year. If the base year amount is equal to or lower than the hospital's uncompensated care payment for the current fiscal year, then the hospital would not receive a supplemental payment because the hospital would not be experiencing financial disruption in that year as a result of the use of uncompensated care data from the Worksheet S–10 in determining Factor 3 of the uncompensated care payment methodology.

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49048 and 49049), the eligibility and payment processes for the supplemental payment are consistent with the processes for determining eligibility to receive interim and final uncompensated care payments adopted in FY 2014 IPPS/LTCH final rule. We note that the MAC will make a final determination with respect to a hospital's eligibility to receive the supplemental payment for a fiscal year, in conjunction with its final determination of the hospital's eligibility for DSH payments and uncompensated care payments for that fiscal year.

Comment: Two commenters expressed continued support for these supplemental payments to lessen the impact of discontinuing the use of low-income patient days to calculate uncompensated care payments for IHS/Tribal hospitals and hospitals in Puerto Rico. Specifically, a commenter noted that the permanent supplemental payments will mitigate the undue long-term financial disruption that would have occurred due to the discontinuance of the previous methodology for calculating uncompensated care costs.

Many commenters reiterated their recommendations that were submitted in response to the proposal to establish these supplemental payments in last year's proposed rule. Specifically, these commenters recommended that CMS calculate the supplemental payment for Puerto Rico hospitals using a base year amount determined from Medicaid days and an SSI days proxy of at least 40 percent of the hospital's Medicaid days, instead of the proxy that applied from FY 2017 through FY 2022, consisting of 14 percent of the hospital's Medicaid days, and was developed based on national data regarding the relationship between Medicare SSI days and Medicaid days. In addition, these commenters requested that CMS make all acute care hospitals in Puerto Rico eligible to receive uncompensated care payments, including those that do not qualify for empirically justified DSH payments, which the commenters believe would be consistent with statutory language. As an alternative, these commenters requested that CMS determine a hospital's eligibility to receive uncompensated care payments and supplemental payments using the suggested proxy for Medicare SSI days of 40 percent of the hospital's Medicaid days. These commenters contend that hospitals that fail to qualify for empirically justified DSH payments might still qualify for uncompensated care payments by using the 40 percent metric.

Another commenter requested that CMS evaluate alternatives to the supplemental payment that would better support hospitals in Puerto Rico in instances of increasing uninsured days. This commenter argued that the supplemental payment only mitigates the anticipated impact of the changes to the uncompensated care payment methodology starting in FY 2023 relative to these hospitals' 2022 uncompensated care payment levels. However, the commenter stated that this approach is not helpful if uninsured patient volumes rise above the 2022 levels. The same commenter further expressed that they would alternatively support a return to the prior method of using a proxy to determine uninsured days for hospitals in Puerto Rico given the challenges around the collection of Worksheet S–10 data.

The Medicare Payment Advisory Commission (MedPAC) recommended that CMS alter its methodology for making interim supplemental payments as an add-on payment to the IPPS payment rates for Puerto Rico hospitals to avoid distorting Medicare Advantage (MA) benchmarks. MedPAC argued that the $80 million in supplemental payments to Puerto Rico hospitals in 2023 would inappropriately boost payments to MA plans operating in Puerto Rico by almost $1 billion per year.

Response: We appreciate the concerns and input raised by commenters regarding the supplemental payment for hospitals in Puerto Rico and IHS and Tribal hospitals that was established in

the FY 2023 IPPS/LTCH PPS final rule. We continue to recognize the unique financial circumstances and challenges faced by Puerto Rico hospitals and IHS and Tribal hospitals related to uncompensated care cost reporting on Worksheet S–10, with respect to uncompensated care due to structural differences in health care delivery and financing in these areas compared to the rest of the country (87 FR 49047). With respect to comments regarding SSI proxy recommendations, we refer readers to our response to a similar comment in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49049 and 49050).

Regarding the commenter's request that all acute care hospitals in Puerto Rico receive uncompensated care payments regardless of DSH eligibility, we refer readers to the policy initially adopted in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50622 and 50623), which explains that hospitals, including Puerto Rico hospitals, must be eligible to receive empirically justified Medicare DSH payments to receive an additional Medicare uncompensated care payment for that year. As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49048 and 49049), the processes for determining eligibility for the supplemental payment and making interim and final payments are consistent with the processes for determining eligibility to receive interim and final uncompensated care payments adopted in FY 2014 IPPS/LTCH final rule and the approach used to make interim uncompensated care payments on a per discharge basis.

With respect to the comments recommending that CMS determine eligibility to receive empirically justified DSH payments using the suggested proxy for SSI days of 40 percent of Medicaid days, we note that in the FY 2024 IPPS/LTCH PPS proposed rule, we did not propose to adopt a proxy for Puerto Rico hospitals' SSI days for use in determining eligibility to receive empirically justified Medicare DSH payments or the amount of such payments. Therefore, these comments are considered to be outside the scope of the FY 2024 proposed rule. However, we note that as discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49050), section 1886(d)(5)(F)(vi) of the Act prescribes the disproportionate patient percentage used to determine empirically justified Medicare DSH payments, and it specifically calls for the use of SSI days in the Medicare fraction and does not allow the use of alternative data. Therefore, we continue to disagree with the commenter's assertion that there is legal support for CMS to use a proxy for Puerto Rico hospitals' SSI days in the calculation of the empirically justified Medicare DSH payment or in the eligibility determination for this payment.

Regarding the comments encouraging CMS to evaluate alternatives to supplemental payments to support Puerto Rico hospitals in the case of increasing uninsured days, we note that prior to FY 2023, we used low-income insured days as a proxy for uncompensated care costs. In contrast, we have never directly considered fluctuations in uninsured days in the calculation of uncompensated care payments. Therefore, we continue to believe that the supplemental payments, which are based on the FY 2022 uncompensated care payments calculated for Puerto Rico hospitals and IHS and Tribal hospitals using the low-income insured days proxy, are an appropriate approach to address the difficulties for Puerto Rico and IHS and Tribal hospitals in reporting uncompensated care costs.

In response to MedPAC's comment, we continue to believe the combined amount of empirically justified DSH payments, uncompensated care payments, and supplemental payments to IHS/Tribal hospitals and Puerto Rico hospitals will be comparable to the amount these hospitals would have received if CMS had continued to use the low-income days proxy to determine Factor 3 of the uncompensated care payment methodology. As a result, the supplemental payments are expected to have no significant impact on MA benchmarks in Puerto Rico. We also note that for the past several years, the MA benchmark rates in Puerto Rico have excluded beneficiaries with coverage for only Medicare Part A or only Medicare Part B. For calendar years 2020 and 2021, about 70 percent of uncompensated care payments represented in Puerto Rico claim records were associated with Part A-only beneficiaries and thus excluded from the MA ratebook calculation. Accordingly, about 70 percent of any supplemental payments to Puerto Rico providers would be excluded from the MA ratebook development.

E. Uncompensated Care Payments

As we discussed earlier, section 1886(r)(2) of the Act provides that, for each eligible hospital in FY 2014 and subsequent years, the uncompensated care payment is the product of our estimate of three factors: (1) 75 percent of the amount of Medicare DSH payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if subsection (r) did not apply; (2) 1 minus the percent change in the national rate of uninsurance compared to the rate of uninsurance in 2013; and (3) each eligible hospital's estimated uncompensated care amount relative to the estimated uncompensated care amount for all eligible hospitals. In this section of this final rule, we discuss the data sources and methodologies for computing each of these factors, our final policies for FYs 2014 through 2023, and our final policies for FY 2024.

1. Calculation of Factor 1 for FY 2024

Section 1886(r)(2)(A) of the Act establishes Factor 1 in the calculation of the uncompensated care payment. Section 1886(r)(2)(A) of the Act states that this factor is equal to the difference between: (1) the aggregate amount of payments that would be made to subsection (d) hospitals under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year (as estimated by the Secretary); and (2) the aggregate amount of payments that are made to subsection (d) hospitals under section 1886(r)(1) of the Act for such fiscal year (as so estimated). Therefore, section 1886(r)(2)(A)(i) of the Act represents the estimated Medicare DSH payments that would have been made under section 1886(d)(5)(F) of the Act if section 1886(r) of the Act did not apply for such fiscal year. Under a prospective payment system, we would not know the precise aggregate Medicare DSH payment amount that would be paid for a Federal fiscal year until cost report settlement for all IPPS hospitals is completed, which occurs several years after the end of the Federal fiscal year. Therefore, section 1886(r)(2)(A)(i) of the Act provides authority to estimate this amount, by specifying that, for each fiscal year to which the provision applies, such amount is to be estimated by the Secretary. Similarly, section 1886(r)(2)(A)(ii) of the Act represents the estimated empirically justified Medicare DSH payments to be made in a fiscal year, as prescribed under section 1886(r)(1) of the Act. Again, section 1886(r)(2)(A)(ii) of the Act provides authority to estimate this amount.

Therefore, Factor 1 is the difference between our estimates of: (1) the amount that would have been paid in Medicare DSH payments for the fiscal year in the absence of section 1886(r) of the Act; and (2) the amount of empirically justified Medicare DSH payments that are made for the fiscal year. The second element of Factor 1 reflects the statutory requirement to pay subsection (d) hospitals 25 percent of what would have otherwise been paid under section

1886(d)(5)(F) of the Act. In other words, Factor 1 represents 75 percent (100 percent minus 25 percent) of our estimate of Medicare DSH payments that would be made for the fiscal year in the absence of section 1886(r) of the Act.

In the FY 2024 IPPS/LTCH PPS proposed rule, we proposed that to determine Factor 1 in the uncompensated care payment formula for FY 2024, we would continue the policy established in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50628 through 50630) and in the FY 2014 IPPS interim final rule with comment period (78 FR 61194). Accordingly, we proposed to determine Factor 1 by developing estimates of both the aggregate amount of Medicare DSH payments that would be made for FY 2024 in the absence of section 1886(r)(1) of the Act and the aggregate amount of empirically justified Medicare DSH payments to hospitals under section 1886(r)(1) of the Act. Consistent with the policy that we have applied in previous years, these estimates are not revised or updated subsequent to the publication of our final projections in this FY 2024 IPPS/LTCH PPS final rule.

Thus, in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26989 through 26992), we proposed that to determine the two elements of proposed Factor 1 for FY 2024, we would use the most recent available projections of Medicare DSH payments for the fiscal year, as calculated by CMS' Office of the Actuary (OACT) using the most recently filed Medicare hospital cost reports with Medicare DSH payment information and the most recent Medicare DSH patient percentages and Medicare DSH payment adjustments provided in the FY 2023 IPPS/LTCH PPS final rule's Impact File.[198] The determination of the amount of DSH payments is partially based on OACT's Part A benefits projection model. One of the components of this model is inpatient hospital spending. Projections of DSH payments require projections for expected increases in utilization and case-mix. The assumptions that were used in making these projections and the resulting estimates of DSH payments for FY 2021 through FY 2024 are discussed in the table titled ''Factors Applied for FY 2021 through FY 2024 to Estimate Medicare DSH Expenditures Using FY 2020 Baseline'' (88 FR 26991).

For purposes of calculating the proposed Factor 1 and modeling the impact of the FY 2024 IPPS/LTCH PPS proposed rule, we used OACT's January 2023 Medicare DSH estimates, which were based on data from the September 2022 update to the Medicare Hospital Cost Report Information System (HCRIS) and the FY 2023 IPPS/LTCH PPS final rule IPPS Impact File, published in conjunction with the FY 2023 IPPS/LTCH PPS final rule.[199] Because SCHs that are projected to be paid under their hospital-specific rate are ineligible for empirically justified Medicare DSH payments and uncompensated care payments, they were excluded from the January 2023 Medicare DSH estimates. Furthermore, because Maryland hospitals are not paid under the IPPS, they are also ineligible for empirically justified Medicare DSH payments and uncompensated care payments and were also excluded from the OACT's January 2023 Medicare DSH estimates. Finally, the 26 hospitals that CMS anticipates may participate in the Rural Community Hospital Demonstration Program in FY 2024 were excluded from these estimates because these hospitals are not eligible to receive empirically justified Medicare DSH payments or uncompensated care payments under the payment methodology that applies under the demonstration.

Using the data sources as previously discussed, OACT's January 2023 estimate of Medicare DSH payments for FY 2024 without regard to the application of section 1886(r)(1) of the Act was approximately $13.621 billion, as explained in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26990). Therefore, based on that January 2023 estimate, the estimate of empirically justified Medicare DSH payments for FY 2024, with the application of section 1886(r)(1) of the Act, was approximately $3.405 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2024). Under § 412.106(g)(1)(i), Factor 1 is the difference between these two OACT estimates. Thus, in the FY 2024 IPPS/LTCH PPS proposed rule, we proposed that Factor 1 for FY 2024 would be $10,216,040,319.50, which was equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2024 ($13.621 billion minus $3.405 billion). In the FY 2024 IPPS/LTCH PPS proposed rule, we noted that, consistent with our approach in previous rulemakings, OACT would use more recent data to project the final Factor 1 estimates for the FY 2024 IPPS/LTCH PPS final rule if such data became available prior to the development of the final rule.

In the FY 2024 IPPS/LTCH PPS proposed rule, we noted that the Factor 1 estimates for proposed rules are generally consistent with the economic assumptions and actuarial analysis used to develop the President's Budget estimates under current law, and that Factor 1 estimates for the final rules are generally consistent with those used for the Midsession Review of the President's Budget (88 FR 26990). For additional information on the development of the President's Budget, we refer readers to the Office of Management and Budget website at *https://www.whitehouse.gov/omb/budget*. Consistent with historical practice, we indicated in the proposed rule that we expected that the Midsession Review would have updated economic assumptions and actuarial analysis, which we would use to develop Factor 1 estimates in the FY 2024 final rule.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26990), we referred readers to the ''2022 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds,'' available on the CMS website at *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/reportstrustfunds* under ''Downloads'' for a general overview of the principal steps involved in projecting future inpatient costs and utilization. We also noted that the annual reports of the Medicare Boards of Trustees to Congress represent the Federal Government's official evaluation of the financial status of the Medicare Program. The actuarial projections contained in these reports are based on numerous assumptions regarding future trends in program enrollment, utilization and costs of health care services covered by Medicare, as well as other factors affecting program expenditures. In addition, although the methods used to estimate future costs based on these assumptions are complex, they are subject to periodic review by independent experts to ensure their validity and reasonableness. We also referred readers to the 2018 Actuarial Report on the Financial Outlook for Medicaid for a discussion of general issues regarding Medicaid projections (available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/MedicaidReport*).

[198] This file is used in estimating the payment impacts of various policy changes to the IPPS as described in the annual proposed and final IPPS/LTCH PPS rules.

[199] FY 2023 IPPS/LTCH PPS final rule IPPS Impact File, available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled ''FY 2023 IPPS Final Rule Home Page'' or ''Acute Inpatient—Files for Download.''

Comment: Some commenters requested greater transparency in the methodology used by CMS and OACT to calculate Factor 1. Several commenters specifically requested that a detailed description of the methodology and the data behind the assumptions be made public. Specifically, commenters requested more detail from CMS on the ''Other'' component. A few commenters emphasized their inability to replicate CMS' calculations and requested that the agency clarify how the effects of the COVID–19 Public Health Emergency (PHE) were accounted for in the ''Other'' factor. Some commenters suggested that CMS address this issue by disaggregating the variables that contribute to the ''Other'' factor and then demonstrating the impact of each of those variables on the final value, while a few other commenters requested that CMS publish a detailed methodology of its ''Other'' calculation, including how all the components contribute to its estimates from year to year. A couple of commenters requested that CMS clarify why the ''Other'' factor frequently varies in successive rulemaking cycles. Commenters requested that this information be provided in advance of the publication of the final rule and in the IPPS proposed rule each year going forward, so that the data is available to replicate CMS' DSH calculation and comment sufficiently in future years.

Additionally, a few commenters asserted that the lack of opportunity afforded to hospitals to review the data used in rulemaking is in violation of the Administrative Procedure Act. These commenters expressed concerns about the lack of transparency in how Factor 1 is calculated, arguing that hospitals cannot meaningfully comment on the methodology given the lack of details. In particular, these commenters asserted that the proposed rule provided neither sufficient details nor an explanation of the treatment of Medicaid expansions in the calculation for Factor 1.

Response: We thank the commenters for their input. We disagree with commenters' assertion regarding the lack of transparency with respect to the methodology and assumptions used in the calculation of Factor 1. As explained in the FY 2024 IPPS/LTCH PPS proposed rule and in this section of this final rule, we have been and continue to be transparent about the methodology and data used to estimate Factor 1. Regarding the commenters who reference the Administrative Procedure Act, we note that under the Administrative Procedure Act, a proposed rule is required to include either the terms or substance of the proposed rule or a description of the subjects and issues involved. In this case, the FY 2024 IPPS/LTCH PPS proposed rule included a detailed discussion of our proposed Factor 1 methodology and the data sources that would be used in making our final estimate. See 88 FR 26989 through 26992. Accordingly, commenters had sufficient information to meaningfully comment on our proposed estimate of Factor 1.

To provide additional context, we note that Factor 1 is not estimated in isolation from other projections made by OACT. As we explained in the FY 2024 IPPS/LTCH PPS proposed rule and in other previous rulemakings, Factor 1 estimates used in our proposed rules are generally consistent with the economic assumptions and actuarial analyses used to develop the President's Budget estimates under current law, which are publicly available, and the Factor 1 estimates used in our final rules are generally consistent with the economic assumptions and actuarial analyses used for the Midsession Review of the President's Budget. As we have in the past, we refer readers to the ''Midsession Review of the President's FY 2024 Budget'' for additional information on the development of the President's Budget and the specific economic assumptions used in the Midsession Review of the President's FY 2024 Budget, forthcoming on the Office of Management and Budget website at *https://www.whitehouse.gov/omb/budget*. We recognize that our reliance on the economic assumptions and actuarial analyses used to develop the President's Budget and the Midsession Review of the President's Budget in estimating Factor 1 has an impact on hospitals, health systems, and other impacted parties who wish to replicate the Factor 1 calculation, such as modeling the relevant Medicare Part A portion of the budget. Yet, commenters are able to meaningfully comment on our proposed estimate of Factor 1 without replicating the budget.

For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer readers to the ''2023 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds,'' available under ''Downloads'' on the CMS website at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html*. We note that the annual reports of the Medicare Boards of Trustees to Congress represent the Federal Government's official evaluation of the financial status of the Medicare Program. The actuarial projections contained in these reports are based on numerous assumptions regarding future trends in program enrollment, utilization and costs of health care services covered by Medicare, as well as other factors affecting program expenditures. In addition, although the methods used to estimate future costs based on these assumptions are complex, they are subject to periodic review by independent experts to ensure their validity and reasonableness (*https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/index.html*). We note that the annual reports of the Medicare Boards of Trustees to Congress represent the Federal Government's official evaluation of the financial status of the Medicare Program. The actuarial projections contained in these reports are based on numerous assumptions regarding future trends in program enrollment, utilization and costs of health care services covered by Medicare, as well as other factors affecting program expenditures. In addition, although the methods used to estimate future costs based on these assumptions are complex, they are subject to periodic review by independent experts to ensure their validity and reasonableness.

As described in more detail later in this section, in the FY 2024 IPPS/LTCH PPS proposed rule, we included information regarding the data sources, methods, and assumptions employed by the actuaries to determine OACT's estimate of Factor 1 (88 FR 26989 through FR 26992). We explained that the most recent Medicare DSH payment adjustments provided in the IPPS Impact File were used, and we provided the components of all update factors that were applied to the historical data to estimate the Medicare DSH payments for the upcoming fiscal year, along with the associated rationale and assumptions. This discussion also included a description of the ''Other'' and ''Discharges'' assumptions, as well as additional information regarding how we address the Medicaid and CHIP expansion.

For additional context, the ''Other'' factor column reflects the expectation that DSH payments will grow faster than IPPS payments in 2023. This expectation is based on the 2023 IPPS Impact File, which reflects the change in the mix of cases between 2019 and 2021. The ''Other'' factor varies in rulemaking cycles due to changing growth patterns for DSH payments and Medicaid enrollment. The impact of

Medicaid enrollment is captured in the ''Other'' column.

For further information on our assumptions regarding Medicaid expansion in the Factor 1 calculation, later in this section, we provide a discussion of more recent estimates and assumptions regarding the Medicaid expansion as part of the discussion of the final Factor 1 for FY 2024. This discussion also incorporates the estimated impact of the COVID–19 PHE.

Comment: Many commenters questioned the proposed rule's estimate of the ''Discharges'' component of the Factor 1 calculation. Some commenters requested that CMS align the discharge volume estimates in Factor 1 with the forecasted estimates for Federal fiscal year 2022 through Federal fiscal year 2024 cited in the March 2023 Medicare Trustee Report. Other commenters recommended that CMS use more recent data to reflect the changes in discharge volumes. Some commenters noted that the current assumptions of discharge volume may underestimate the growth in utilization in the Medicare fee-for-service (FFS) population. Four hospital associations questioned CMS' discharge factor for FY 2024 based on ''the assumption of recent trends recovering back to the long-term trend and the assumption related to how many beneficiaries will be enrolled in Medicare Advantage (MA) plans.'' These commenters noted that they expect that the discharge factor will continue to decrease, as half of Medicare beneficiaries are now enrolled in MA plans. These commenters further expressed concern about the effect of this decreasing trend on hospitals serving a disproportionate share of lower-income beneficiaries. The same commenters requested that CMS provide detailed calculations of the discharge estimates in the proposed rule each year going forward and welcomed the opportunity to work with CMS to examine the impacts of MA enrollment on FFS inpatient hospital payments. One commenter recommended that CMS exclude FY 2021 and FY 2022 discharges from the FY 2024 Factor 1 calculation, as data from those years include atypical trends in Medicare discharges resulting from the COVID–19 PHE.

Some commenters also raised concerns about the ''Case Mix'' update factor used in the proposed FY 2024 Factor 1 calculation. Commenters stated that the proposed ''Case Mix'' update factor underestimates the complexity of patients seeking care following the postponement or deferral of care during the COVID–19 PHE. Some commenters requested that CMS consider the impact of Medicaid disenrollment, which may inhibit care access and lead to worse outcomes, resulting in more complex cases and higher hospitalization rates. One commenter requested that CMS include an acuity factor to reflect the fact that COVID–19 patients have longer lengths of stay and higher acuity than the typical patient population.

Some commenters requested that CMS increase the FY 2022 market basket in the Factor 1 update factor by three percentage points to align with the ''trued up'' market basket cited in the March 2023 MedPAC report to Congress.[200] Some of these commenters further recommended that CMS apply the recommendation from MedPAC to increase the FY 2024 market basket in the Factor 1 update factor by an additional percentage point.

Response: We thank the commenters for their input on the impact the COVID–19 PHE may have had on the factors used to estimate DSH payments for FY 2024. In updating our estimate of Factor 1 for this final rule, we considered, as appropriate, the same set of factors that we used in the proposed rule using the most recent available data at the time of developing this final rule. The ''Discharges'' and ''Case Mix'' factors incorporate the latest estimates of the COVID–19 PHE's impact on the Medicare program. The ''Case Mix'' factor is specific for Medicare inpatient claims. In 2020, the COVID–19 PHE had a significant impact on the ''Case Mix'' factor, however its impact has lessened in subsequent years. The impact of COVID–19 discharges is captured in the 2021 and 2022 experience, which is the basis for the projections. The number of COVID–19 cases has dropped significantly since 2020, therefore we believe a separate acuity factor would not be necessary. We provide further details on the updated Factor 1 estimate and data sources as part of the discussion of the final Factor 1 estimate for FY 2024 in this section of the rule.

Regarding the comments requesting that we exclude FY 2021 and FY 2022 discharges due to the impacts of the COVID–19 PHE when estimating Factor 1 for FY 2024, we note that section 1886(r)(2)(A) of the Act specifies that Factor 1 is based on the amount of disproportionate share payments that would otherwise be made to subsection (d) hospitals for the fiscal year. As discussed further in this section, OACT's estimates of Medicare DSH payments used in the development of Factor 1 reflect the estimated impact of the COVID–19 PHE on DSH payments. Excluding data from certain periods is not necessary to estimate DSH payments during FY 2024 for purposes of the Factor 1 calculation. To reasonably make projections for FY 2024, the FY 2021 and FY 2022 claims data experience is necessary to inform trends. The FY 2021 and FY 2022 claims are not atypical, in contrast to FY 2020 claims. Furthermore, the FY 2021 claims data are used for the FY 2023 Impact File, which make it consistent and reliable to use in making projections of the amount of DSH payments in FY 2024.

Regarding the comments on the impacts of MA enrollment on the Medicare FFS discharge volume, we believe the ''Discharge'' factor is a reasonable projection for purposes of Factor 1 estimates using the latest available data. For a discussion on trends in MA enrollment, we refer readers to the 2023 Annual Report of the Boards of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, which contains actuarial projections and assumptions regarding future trends in program enrollment, utilization and costs of health care services covered by Medicare, as well as other factors affecting program expenditures. We also note that the estimates for the ''Discharges'' factor used to estimate Medicare DSH expenditures incorporate OACT's analyses of ''Discharges'' using only claims from the Medicare FFS program rather than claims from the MA program.

In response to commenters who requested that CMS align the discharge volume estimates in Factor 1 with the estimates in the March 2023 Medicare Trustee Report and that CMS consider using more recent data to reflect the changes in discharge volume, we have determined that the use of the most recent available data to calculate Factor 1 at proposed and final rulemaking is appropriate and consistent with our approach in previous rulemakings and will produce results that are generally consistent with the Medicare Trustee Report. In this final rule, OACT has updated the estimate of Factor 1 with more recent economic assumptions and actuarial analyses.

Regarding comments about the inpatient hospital update and the FY 2024 update factor in the Factor 1 estimate, we refer readers to the discussion in the section V.B. of the preamble of this final rule. Consistent with the inpatient hospital update discussion in section V.B. of the rule, OACT is using the most recent available

[200] *https://www.medpac.gov/document/march-2023-report-to-the-congress-medicare-payment-policy/.*

inpatient hospital update for the final FY 2024 update factor in the Factor 1 calculation.

After consideration of the public comments we received, we are finalizing, as proposed, the methodology for calculating Factor 1 for FY 2024. We discuss the resulting Factor 1 amount for FY 2024 in this final rule. For this final rule, OACT used the most recently submitted Medicare cost report data from the March 2023 update of HCRIS to identify Medicare DSH payments and the most recent Medicare DSH payment adjustments provided in the Impact File and applied update factors and assumptions for future changes in utilization and case-mix to estimate Medicare DSH payments for the upcoming fiscal year. The June 2023 OACT estimate for Medicare DSH payments for FY 2024, without regard to the application of section 1886(r)(1) of the Act, was approximately $13.354 billion. This estimate excluded Maryland hospitals participating in the Maryland All-Payer Model, hospitals participating in the Rural Community Hospital Demonstration, and SCHs paid under their hospital-specific payment rate. Therefore, based on this June 2023 estimate, the estimate of empirically justified Medicare DSH payments for FY 2024, with the application of section 1886(r)(1) of the Act, was approximately $3.338 billion (or 25 percent of the total amount of estimated Medicare DSH payments for FY 2024). Under § 412.106(g)(1)(i), Factor 1 is the difference between these two OACT estimates. Therefore, the final Factor 1 for FY 2024 is $10,015,191,021.88, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2024 ($13,353,588,029.18 minus $3,338,397,007.29).

OACT's estimates for FY 2024 for this final rule began with a baseline of $13.257 billion in Medicare DSH expenditures for FY 2020. The following table shows the factors applied to update this baseline through the current estimate for FY 2024:

Factors Applied for FY 2021 through FY 2024 to Estimate Medicare DSH Expenditures Using FY 2020 Baseline

FY	Update	Discharges	Case-Mix	Other	Total	Estimated DSH Payment (in billions)*
2021	1.029	0.940	1.029	0.9963	0.9919	13.150
2022	1.025	0.941	0.997	0.9939	0.9558	12.568
2023	1.043	0.959	1.005	1.0347	1.0398	13.068
2024	1.031	0.982	1.005	1.0043	1.0219	13.354

*Rounded.

In this table, the discharges column shows the changes in the number of Medicare FFS inpatient hospital discharges. The discharge figures for FY 2021 and FY 2022 are based on Medicare claims data that have been adjusted by a completion factor to account for incomplete claims data. We note that these claims data reflect the impact of the COVID–19 pandemic. The discharge figure for FY 2023 is based on preliminary data. The discharge figure for FY 2024 is an assumption based on recent historical experience and an assumed partial return to pre-COVID trends. In addition, this column reflects a decrease in FFS enrollment, as a growing share of beneficiaries have moved into MA plans. The discharge figures for FY 2021 to FY 2024 incorporate the actual impact and estimated future impact from the COVID–19 pandemic. The case-mix column shows the estimated change in case-mix for IPPS hospitals. The case-mix figures for FY 2021 and FY 2022 are based on actual claims data adjusted by a completion factor. We note that these claims data reflect the impact of the COVID–19 pandemic. The case-mix figure for FY 2023 is based on preliminary data, and the case-mix figure for FY 2024 is an assumption based on the recommendation of the 2010–2011 Medicare Technical Review Panel.[201] Accordingly, the case-mix factor figures for FY 2021 to FY 2024 incorporate the actual impact and estimated future impact from the COVID–19 pandemic.

The ''Other'' column reflects the change in other factors that contribute to the Medicare DSH estimates. These factors include the difference between the total inpatient hospital discharges and the IPPS discharges and various adjustments to the payment rates that have been included over the years but are not reflected in the other columns (such as the 20 percent add-on for COVID–19 discharges). In addition, the ''Other'' column includes a factor for the estimated changes in Medicaid enrollment. We note that this factor also includes the estimated impacts on Medicaid enrollment from the COVID–19 pandemic and the end of the PHE declaration. On May 11, 2023, the Biden Administration ended the national emergency declaration and PHE declaration.

Based on the most recent available data, Medicaid enrollment is estimated to change as follows: 12.3 percent in FY 2021, 8.2 percent in FY 2022, 4.2 percent in FY 2023, and −11.6 percent in FY 2024. In the future, the assumptions regarding Medicaid enrollment may change based on actual enrollment in the States.

We note that, in developing their estimates of the effect of Medicaid expansion on Medicare DSH expenditures, our actuaries have assumed that the new Medicaid enrollees are healthier than the average Medicaid recipient and, therefore, receive fewer hospital services. Specifically, based on the most recent available data at the time of developing the proposed rule, OACT assumed per capita spending for Medicaid beneficiaries who enrolled due to the expansion to be approximately 80 percent of the average per capita expenditures for a pre-expansion Medicaid beneficiary, due to the better health of these beneficiaries. The same assumption was used for the new Medicaid beneficiaries who enrolled in 2020 and thereafter due to the COVID–19 pandemic. This assumption is consistent with recent internal estimates of Medicaid per capita spending pre-

[201] *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/reportstrustfunds/downloads/technicalpanelreport2010-2011.pdf.*

expansion and post-expansion. In the future, the assumption about the average per-capita expenditures of Medicaid beneficiaries who enrolled due to the COVID–19 pandemic may change.

The following table shows the factors that are included in the ''Update'' column of the previous table:

FY	Market Basket Percentage	Productivity Adjustment	Documentation and Coding	Total Update Percentage
2021	2.4	0.0	0.5	2.9
2022	2.7	-0.7	0.5	2.5
2023	4.1	-0.3	0.5	4.3
2024	3.3	-0.2	0.0	3.1

Note: All numbers are the final inpatient hospital updates for the applicable year. We refer readers to section V.B. of the preamble of this final rule for a complete discussion of the changes in the inpatient hospital update for FY 2024.

2. Calculation of Factor 2 for FY 2024

a. Background

Section 1886(r)(2)(B) of the Act establishes Factor 2 in the calculation of the uncompensated care payment. Section 1886(r)(2)(B)(ii) of the Act provides that, for FY 2018 and subsequent fiscal years, the second factor is 1 minus the percent change in the percent of individuals who are uninsured, as determined by comparing the percent of individuals who were uninsured in 2013 (as estimated by the Secretary, based on data from the Census Bureau or other sources the Secretary determines appropriate and certified by the Chief Actuary of CMS) and the percent of individuals who were uninsured in the most recent period for which data are available (as so estimated and certified). We note that, unlike section 1886(r)(2)(B)(i) of the Act, which governed the calculation of Factor 2 for FYs 2014, 2015, 2016, and 2017, section 1886(r)(2)(B)(ii) of the Act permits the use of a data source other than the Congressional Budget Office (CBO) estimates to determine the percent change in the rate of uninsurance beginning in FY 2018, provided the Secretary determines that the data source is appropriate and the Chief Actuary of CMS certifies it. In addition, for FY 2018 and subsequent years, the statute does not require that the estimate of the percent of individuals who are uninsured be limited to individuals who are under 65 years of age. In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26992), we proposed to continue to use a methodology similar to the one that was used in FY 2018 through FY 2023 to determine Factor 2 for FY 2024.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38197 and 38198), we explained that we determined the data source for the rate of uninsurance that, on balance, best meets all of our considerations and is consistent with the statutory requirement that the estimate of the rate of uninsurance be based on data from the Census Bureau or other sources the Secretary determines appropriate, is the uninsured estimates produced by OACT as part of the development of the National Health Expenditure Accounts (NHEA). The NHEA are the Federal Government's official estimates of economic activity (spending) within the health sector. The information contained in the NHEA are used to study numerous topics related to the health care sector, including the following topics: changes in the amount and cost of health services purchased and the payers or programs that provide or purchase these services; the economic causal factors at work in the health sector; the impact of policy changes, including major health reform, on health care spending; and comparison of U.S. health care spending to other countries' health care spending.

Of relevance to the determination of Factor 2 is that the comprehensive and integrated structure of the NHEA creates an ideal tool for evaluating changes to the health care system, such as the mix of the insured and uninsured, because this information is integral to the well-established NHEA methodology. A full description of the methodology used to develop the NHEA is available on the CMS website at *https://www.cms.gov/files/document/definitions-sources-and-methods.pdf*. We note that the NHEA estimates of uninsurance are for the total resident-based U.S. population, including all people who usually reside in the 50 States or the District of Columbia, but excluding individuals living in Puerto Rico and areas under U.S. sovereignty, members of the U.S. Armed Forces overseas, and U.S. citizens whose usual place of residence is outside the U.S., plus a small (typically less that 0.2 percent of population) adjustment to reflect Census undercounts. Thus, the NHEA estimates of uninsurance account for U.S. residents of all ages and are not limited to a specific age cohort, such as the population under the age of 65. As we explained in the FY 2018 IPPS/LTCH PPS proposed and final rules, we believe it is appropriate to use an estimate that reflects the rate of uninsurance in the U.S. across all age groups. In addition, our view continues to be that a resident-based population estimate more fully reflects the levels of uninsurance in the U.S. that influence uncompensated care for hospitals than an estimate that reflects only legal residents.

The NHEA includes comprehensive enrollment estimates for total private health insurance (PHI) (including direct and employer-sponsored plans), Medicare, Medicaid, the Children's Health Insurance Program (CHIP), and other public programs, and estimates of the number of individuals who are uninsured. Estimates of total PHI enrollment are available for 1960 through 2021, estimates of Medicaid, Medicare, and CHIP enrollment are available for the length of the respective programs, and all other estimates (including the more detailed estimates of direct-purchased and employer-sponsored insurance) are available for 1987 through 2021. The NHEA data are publicly available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/index.html*.

To compute Factor 2, the first metric that is needed is the proportion of the total U.S. population that was uninsured in 2013. In developing the estimates for the NHEA, OACT's methodology included using the number of uninsured individuals for 1987 through 2009 based on the enhanced Current Population Survey

(CPS) from the State Health Access Data Assistance Center (SHADAC). The CPS, sponsored jointly by the U.S. Census Bureau and the U.S. Bureau of Labor Statistics (BLS), is the primary source of labor force statistics for the U.S. population. (We refer readers to the website at *https://www.census.gov/programs-surveys/cps.html*.) The enhanced CPS, available from SHADAC (available at *https://datacenter.shadac.org*) accounts for changes in the CPS methodology over time. OACT further adjusts the enhanced CPS for an estimated undercount of Medicaid enrollees (a population that is often not fully captured in surveys that include Medicaid enrollees due to a perceived stigma associated with being enrolled in the Medicaid program or confusion about the source of their health insurance).

To estimate the number of uninsured individuals for 2010 through 2018, OACT extrapolates from the 2009 CPS data through 2018 using data from the National Health Interview Survey (NHIS). The NHIS is one of the major data collection programs of the National Center for Health Statistics (NCHS), which is part of the Centers for Disease Control and Prevention (CDC). The estimate of the number of uninsured individuals in 2019 was extrapolated using the 2019/2018 trend from the American Community Survey (ACS). Because the 2020 ACS data were not available, the ACS data were not used for purposes of estimating the number of uninsured individuals for 2020.[202] Rather, the 2020 estimate was extrapolated using the 2020/2018 trend from the CPS as published by the Census Bureau. The 2021 estimate was based on the population share of the uninsured from the NHIS. The U.S. Census Bureau is the data collection agent for the NHIS, the ACS, and the CPS. The results from these data sources have been instrumental over the years in providing data to track health status, health care access, and progress toward achieving national health objectives. For further information regarding the NHIS, we refer readers to the CDC website at *https://www.cdc.gov/nchs/nhis/index.htm*. For further information regarding the ACS, we refer readers to the Census Bureau's website at *https://www.census.gov/programs-surveys/acs/*.

The next metrics needed to compute Factor 2 for FY 2024 are projections of the rates of uninsurance in CY 2023 and CY 2024. On an annual basis, OACT projects enrollment and spending trends for the coming 10-year period. The projections for the rates of uninsurance in the FY 2024 IPPS/LTCH PPS proposed rule were derived using the most recent NHEA projections that were available at the time the proposed rule was developed (published March 28, 2022, with historical data through 2021). The NHEA projection methodology accounts for expected changes in enrollment across all the categories of insurance coverage previously listed. The projected growth rates in enrollment for Medicare, Medicaid, and CHIP are developed to be consistent with the 2022 Medicare Trustees Report,[203] updated where possible with more recent data. Projected rates of growth in enrollment for private health insurance and the uninsured are based largely on OACT's econometric models, which rely on a set of macroeconomic assumptions that are generally based on the 2022 Medicare Trustees Report. Greater detail on these projected rates of growth in enrollment for private health insurance and the uninsured can be found in OACT's report titled ''Projections of National Health Expenditure and Health Insurance Enrollment: Methodology and Model Specification,'' which is available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/Downloads/ProjectionsMethodology.pdf*.

b. Factor 2 for FY 2024

Using these data sources and the previously described methodologies in section IV.E.2.a, at the time of developing the proposed rule, OACT had estimated that the uninsured rate for the historical, baseline year of 2013 was 14 percent, while the estimated rates of uninsurance for CYs 2023 and 2024 were 9.3 percent and 9.2 percent, respectively. As required by section 1886(r)(2)(B)(ii) of the Act, the Chief Actuary of CMS certified these estimates. We refer readers to OACT's Memorandum on Certification of Rates of Uninsured prepared for the FY 2024 IPPS/LTCH PPS proposed rule for further details on the methodology and assumptions that were used in the projection of these rates of uninsurance for the proposed rule.[204]

As with the CBO estimates on which we based Factor 2 for fiscal years before FY 2018, the NHEA estimates are for a calendar year. Under the approach originally adopted in the FY 2014 IPPS/LTCH PPS final rule, we have used a weighted average approach to project the rate of uninsurance for each fiscal year. We continue to believe that, to estimate the rate of uninsurance during a fiscal year accurately, Factor 2 should reflect the estimated rate of uninsurance that hospitals will experience during the fiscal year, rather than the rate of uninsurance during only one of the calendar years that the fiscal year spans. Accordingly, in the FY 2024 IPPS/LTCH PPS proposed rule, we proposed to continue to apply the weighted average approach used in past fiscal years to estimate the rate of uninsurance for FY 2024.

OACT certified the estimate of the rate of uninsurance for FY 2024 determined using this weighted average approach to be reasonable and appropriate for purposes of section 1886(r)(2)(B)(ii) of the Act. In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26993), we noted that we might also consider the use of more recent data that may become available for purposes of estimating the rates of uninsurance used in the calculation of the final Factor 2 for FY 2024. We noted the following examples of more up-to-date data that may become available for use in calculating Factor 2 for FY 2024: (1) data regarding the impacts of the expiration of the Families First Coronavirus Response Act's continuous enrollment provision for Medicaid, which permits states to actively begin disenrolling beneficiaries no longer eligible for the program starting on April 1, 2023; (2) data on the impact of the Inflation Reduction Act's extension of enhanced Marketplace premium tax credits through 2025; and (3) data on the impacts associated with the Internal Revenue Service's amended regulations that expanded eligibility for Marketplace subsidies by revising the affordability test of employer coverage for family members of employees (87 FR 61979 and 62003).

In the proposed rule, we outlined the calculation of the proposed Factor 2 for FY 2024 as follows:

Percent of individuals without insurance for CY 2013: 14 percent.

Percent of individuals without insurance for CY 2023: 9.3 percent.

Percent of individuals without insurance for CY 2024: 9.2 percent.

Percent of individuals without insurance for FY 2024 (0.25 times 0.093) + (0.75 times 0.092): 9.2 percent.

[202] For information regarding the data collection issues regarding the 2020 ACS, we refer readers to the Census Bureau's website at *https://www.census.gov/newsroom/blogs/random-samplings/2021/10/pandemic-impact-on-2020-acs-1-year-data.html*.

[203] *https://www.cms.gov/files/document/2022-medicare-trustees-report.pdf*.

[204] OACT Memorandum on Certification of Rates of Uninsured. March 3, 2023. Available at: *https://www.cms.gov/files/document/certification-rates-uninsured-2024-proposed-rule.pdf*.

$1 - |((0.14 - 0.092)/0.14)| = 1 - 0.3429 = 0.6571$ (65.71 percent).

For FY 2020 and subsequent fiscal years, section 1886(r)(2)(B)(ii) of the Act no longer includes any reduction to the previous calculation to determine Factor 2. Therefore, we proposed that Factor 2 for FY 2024 would be 65.71 percent.

The proposed FY 2024 uncompensated care amount was $10,216,040,319.50 * 0.6571 = $6,712,960,093.94.

Proposed FY 2024 Uncompensated Care Amount	$ 6,712,960,093.94

We invited public comments on our proposed Factor 2 for FY 2024.

Comment: Most commenters discussed Factor 2 in the context of the impact of the temporary COVID–19 PHE provisions on the uninsured rate, such as expiration of the Families First Coronavirus Response Act's Medicaid continuous coverage requirement and extension of the American Rescue Plan's Marketplace enhanced premium tax credits. Large and small healthcare organizations and associations opposed the proposed Factor 2 and the estimated FY 2024 uninsured rate and urged OACT to update its estimate of Factor 2 to account for the projected increases in the number of uninsured individuals as the COVID–19 PHE Medicaid continuous enrollment provisions expire.

Many commenters also indicated that they expect increases in the uninsured rates in their communities. To that end, these commenters urged CMS to use more recent and accurate data sources to account for the anticipated increases in the uninsured population, citing CMS' statement in the proposed rule that the agency may consider more recent data that may become available for the calculation of Factor 2 for the FY 2024 final rule. Some of these commenters urged CMS to monitor the forthcoming data to ensure that Factor 2 reflects the current coverage landscape considering the expiring COVID–19 PHE provisions. A few commenters expressed their concern that the NHEA data that CMS proposed to use for Factor 2 do not reflect current trends in the uninsured rate as the COVID–19 PHE ends, as they appear to be the same data utilized in the FY 2023 IPPS/LTCH PPS final rule. These commenters requested that CMS consider applying a one-time increase in Factor 2 to account for the data lag and the anticipated increase in the uninsured population in FY 2024 following the expiration of the Medicaid continuous enrollment provisions, if the agency chooses to continue with its proposal of utilizing the same NHEA data used in the FY 2023 rule. In addition, one commenter stated as an example that an additional 0.7 percentage point increase in the uninsured rate for FY 2024 (9.9 percent uninsured, reflecting a projection of approximately 2.4 million additional uninsured individuals) would increase the proposed uncompensated care payment amount by about $511 million compared to the proposed rule's uncompensated care amount.

Several commenters referenced various data sources and analyses that project between 3–18 million individuals will lose their Medicaid coverage in FY 2024, such as analyses by the Kaiser Family Foundation; the Congressional Budget Office; the Urban Institute; NORC at the University of Chicago; and HHS' Assistant Secretary for Planning and Evaluation (ASPE). Accordingly, these commenters requested that CMS increase Factor 2 to reflect the anticipated increase in the uninsured population.

A few commenters requested CMS maintain the same level of total uncompensated care payments as in the FY 2023 IPPS/LTCH PPS final rule. Several other commenters opposed the proposed decrease in the total uncompensated care payments from the level in FY 2023. These commenters noted that the proposed decrease would disproportionately impact safety-net hospitals and negatively impact vulnerable patients and hospitals that are already financially strained.

Response: We thank the commenters for their input regarding the estimate of proposed Factor 2 discussed in the proposed rule. In the FY 2024 IPPS/LTCH PPS proposed rule we used the most recent available estimates from the NHEA at that time, and we refer readers to OACT's Memorandum on Certification of Rates of Uninsured prepared for the proposed rule for further details on the methodology and assumptions used in the calculation of the proposed rule's projection of the uninsured rate.

We indicated that our projection of the rates of uninsurance for CY 2023 and CY 2024 were from the latest NHEA historical data available and accounted for expected changes in enrollment across all categories of insurance coverage. As detailed in the proposed rule, we believe that the most recently updated NHEA data, on balance, best meet all our considerations for ensuring that the data source used to estimate the rate of uninsurance meets the statutory requirement that the estimate be based on data from the Census Bureau, or other sources the Secretary determines appropriate, and will provide reasonable estimates for the rate of uninsurance that are available in conjunction with the IPPS rulemaking cycle.

For the final rule, we are using the NHEA data for the Factor 2 calculation because we continue to believe that it is the most appropriate measure of changes in the rate of uninsurance.

In response to the comments concerning the data sources used for calculating Factor 2, in this final rule we are updating Factor 2 using the most recently updated NHEA projections that were released in June 2023, which reflect the most recent historical data and updated expectations for the uninsurance rate. We also refer readers to the OACT memo that accompanies this final rule, which provides additional information regarding the development of the uninsurance rate projection.[205]

Regarding the comments requesting that CMS maintain total uncompensated care payments at the FY 2023 level or delay any proposed changes to mitigate the impact on safety-net hospitals and vulnerable patients, we believe estimating Factor 2 based on the best available data is appropriate and consistent with the requirements of section 1886(r)(2)(B)(ii) of the Act.

Comment: Several commenters urged CMS to be transparent in its calculation of Factor 2 and how it accounts for Medicaid expansion populations and the expiration of the COVID–19 PHE Medicaid continuous enrollment provisions. Other commenters urged CMS to be transparent regarding the data sources used for calculating Factor 2 and the assumptions behind the uninsured rate.

Response: In response to the comments concerning transparency, we note that the accompanying OACT memo contains additional background describing the methods used to derive the FY 2024 rate of uninsured for this final rule. For purposes of this final

[205] OACT Memorandum on Certification of Rates of Uninsured. July 3, 2024. Available at: *https://www.cms.gov/medicare/medicare-fee-for-service-Payment/AcuteInpatientPPS/dsh.*

rule, we are using the most recent NHEA estimates for the rate of uninsurance, which account for the legislative impacts from the expiration of the Families First Coronavirus Response Act's Medicaid continuous coverage requirement and extension of the American Rescue Plan's Marketplace enhanced premium tax credits and effects of the COVID–19 PHE on insurance coverage. Although Medicaid enrollment is expected to decrease significantly, the insured share of the population is only expected to decline in CY 2024 to 91.5 percent (from 92.3 percent in CY 2023), as many individuals who were not disenrolled from Medicaid during the public health emergency already had comprehensive coverage from another source (such as through an employer) and thus remain insured even when disenrolled from Medicaid. We note that the most recent NHEA projections are that the uninsured population will change from 25.7 million in CY 2023 to 28.6 million in CY 2024 and increase to 29.8 million in CY 2025. For more information about the methodology and data used to estimate Factor 2, we refer readers to NHEA's ''Health Insurance Enrollment and Enrollment Growth Rates'' table.[206]

Section 1886(r)(2)(B)(ii) of the Act permits us to use a data source other than CBO estimates to determine the percent change in the rate of uninsurance beginning in FY 2018. The NHEA data and methodology that were used to estimate Factor 2 for this final rule are transparent and best meet all of our considerations for ensuring reasonable estimates for the rate of uninsurance that are available in conjunction with the IPPS rulemaking cycle. We have concluded it is appropriate to update the projection of the FY 2024 rate of uninsurance using the most recent NHEA data.

After consideration of the public comments we received, we are updating the calculation of Factor 2 for FY 2024 using more recent data from NHEA. The final estimates of the percent of uninsured individuals have been certified by the Chief Actuary of CMS. The calculation of the final Factor 2 for FY 2024 using a weighted average of OACT's updated projections for CY 2023 and CY 2024 is as follows:

Percent of individuals without insurance for CY 2013: 14 percent.

Percent of individuals without insurance for CY 2023: 7.7 percent.

Percent of individuals without insurance for CY 2024: 8.5 percent.

Percent of individuals without insurance for FY 2024 (0.25 times 0.077) + (0.75 times 0.085): 8.3 percent.

$1 - |((0.14 - 0.083)/0.14)| = 1 - 0.4071 = 0.5929$ (59.29 percent).

Therefore, the final Factor 2 for FY 2024 is 59.29 percent. The final FY 2024 uncompensated care amount is $10,015,191,021.88 * 0.5929 = $5,938,006,756.87.

Final FY 2024 Uncompensated Care Amount	$ 5,938,006,756.87

3. Calculation of Factor 3 for FY 2024

a. General Background

Section 1886(r)(2)(C) of the Act defines Factor 3 in the calculation of the uncompensated care payment. As we have discussed earlier, section 1886(r)(2)(C) of the Act states that Factor 3 is equal to the percent, for each subsection (d) hospital, that represents the quotient of: (1) the amount of uncompensated care for such hospital for a period selected by the Secretary (as estimated by the Secretary, based on appropriate data (including, in the case where the Secretary determines alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating the uninsured, the use of such alternative data)); and (2) the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period (as so estimated, based on such data).

Therefore, Factor 3 is a hospital-specific value that expresses the proportion of the estimated uncompensated care amount for each subsection (d) hospital and each subsection (d) Puerto Rico hospital with the potential to receive Medicare DSH payments relative to the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the fiscal year for which the uncompensated care payment is to be made. Factor 3 is applied to the product of Factor 1 and Factor 2 to determine the amount of the uncompensated care payment that each eligible hospital will receive for FY 2014 and subsequent fiscal years. In order to implement the statutory requirements for this factor of the uncompensated care payment formula, it was necessary to determine: (1) the definition of uncompensated care or, in other words, the specific items that are to be included in the numerator (that is, the estimated uncompensated care amount for an individual hospital) and the denominator (that is, the estimated uncompensated care amount for all hospitals estimated to receive Medicare DSH payments in the applicable fiscal year); (2) the data source(s) for the estimated uncompensated care amount; and (3) the timing and manner of computing the quotient for each hospital estimated to receive Medicare DSH payments. The statute instructs the Secretary to estimate the amounts of uncompensated care for a period based on appropriate data. In addition, we note that the statute permits the Secretary to use alternative data in the case where the Secretary determines that such alternative data are available that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured.

In the course of considering how to determine Factor 3 during the rulemaking process for FY 2014, the first year for which section 1886(r) of the Act was in effect, we considered defining the amount of uncompensated care for a hospital as the uncompensated care costs of that hospital and determined that Worksheet S–10 of the Medicare cost report would potentially provide the most complete data regarding uncompensated care costs for Medicare hospitals. However, because of concerns regarding variations in the data reported on Worksheet S–10 and the completeness of these data, we did not use Worksheet S–10 data to determine Factor 3 for FY 2014, or for FY 2015, 2016, or 2017. Instead, we used alternative data on the utilization of insured low-income patients, as measured by patient days, which we believed would be a better proxy for the costs of hospitals in treating the uninsured and therefore appropriate to use in calculating Factor 3 for these years. However, we indicated our belief that Worksheet S–10 could ultimately serve as an appropriate source of more direct data regarding uncompensated care costs for purposes of determining Factor 3 once hospitals were submitting

[206] Table 17 Health Insurance Enrollment and Enrollment Growth Rates located under Downloads: NHE Projections—Tables. Available at: *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/nationalhealthaccountsprojected*.

more accurate and consistent data through this reporting mechanism.

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38202), we stated that we could no longer conclude that alternative data to the Worksheet S–10 are available for FY 2014 that are a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. Hospitals were on notice as of FY 2014 that Worksheet S–10 could eventually become the data source for CMS to calculate uncompensated care payments. Furthermore, hospitals' cost reports from FY 2014 had been publicly available for some time, and CMS had analyses of Worksheet S–10, conducted both internally and by stakeholders, demonstrating that Worksheet S–10 accuracy had improved over time. In the FY 2018 IPPS/LTCH PPS final rule, we finalized a methodology under which we calculated Factor 3 for all eligible hospitals, with the exception of Puerto Rico hospitals and Indian Health Service (IHS) and Tribal hospitals, using Worksheet S–10 data from FY 2014 cost reports in conjunction with low-income insured days proxy data based on Medicaid days and SSI days. The time period for the Medicaid days data was FY 2012 and FY 2013 cost reports, which reflected the most recent available information regarding these hospitals' low-income insured days before any expansion of Medicaid. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38208 through 38212) for a further discussion of the methodology used to determine Factor 3 for FY 2018.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41414), we stated that with the additional steps we had taken to ensure the accuracy and consistency of the data reported on Worksheet S–10 since the publication of the FY 2018 IPPS/LTCH PPS final rule, we continued to believe that we could no longer conclude that alternative data to the Worksheet S–10 were available for FY 2014 or FY 2015 that would be a better proxy for the costs of subsection (d) hospitals for treating individuals who are uninsured. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41428), we advanced the time period of the data used in the calculation of Factor 3 forward by one year and used Worksheet S–10 data from FY 2014 and FY 2015 cost reports in combination with the low-income insured days proxy for FY 2013 to determine Factor 3 for FY 2019. We note that, as discussed in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42366), the use of 3 years of data to determine Factor 3 for FY 2018 and FY 2019 had the effect of smoothing the transition from the use of low-income insured days to the use of Worksheet S–10 data.

As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41423 and 41424), we received overwhelming feedback from commenters emphasizing the importance of audits in ensuring the accuracy and consistency of data reported on the Worksheet S–10. We began auditing the Worksheet S–10 data for selected hospitals in the fall of 2018 so that the audited uncompensated care data from these hospitals would be available in time for use in the FY 2020 IPPS/LTCH PPS proposed rule.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42368), we finalized our proposal to use a single year of audited Worksheet S–10 cost report data from FY 2015 in the methodology for determining Factor 3 for FY 2020. Some commenters expressed support for the alternative policy of using the more recent FY 2017 Worksheet S–10 data to determine each hospital's share of uncompensated care costs in FY 2020. However, given the feedback from commenters in response to both the FY 2019 and FY 2020 IPPS/LTCH PPS proposed rules emphasizing the importance of audits in ensuring the accuracy and consistency of data reported on the Worksheet S–10, we concluded that the FY 2015 Worksheet S–10 data were the best available audited data to be used in determining Factor 3 for FY 2020. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42369), we also noted that we had begun auditing the FY 2017 data in July 2019, with the goal of having the FY 2017 audited data available for future rulemaking.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58823 through 58825), we finalized our proposal to use the most recent available single year of audited Worksheet S–10 data to determine Factor 3 for FY 2021 and subsequent fiscal years. We explained our belief that using the most recent audited data available before the applicable Federal fiscal year (FY) would more accurately reflect a hospital's uncompensated care costs, as opposed to averaging multiple years of unaudited and audited data. We explained that mixing audited and unaudited data for individual hospitals by averaging multiple years of data could potentially lead to a less smooth result. We also noted that if a hospital has relatively different data between cost report years, we potentially would be diluting the effect of our considerable auditing efforts and introducing unnecessary variability into the calculation if we were to use multiple years of data to calculate Factor 3. Therefore, we also believed using a single year of audited cost report data would be an appropriate methodology to determine Factor 3 for FY 2021 and subsequent years, except for IHS and Tribal hospitals and hospitals located in Puerto Rico. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58825), we finalized the use of a low-income insured days proxy to determine Factor 3 for FY 2021 for IHS and Tribal hospitals and Puerto Rico hospitals.

In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58825 through 58828), we also finalized the definition of ''uncompensated care'' for FY 2021 and subsequent fiscal years, for purposes of determining uncompensated care costs and calculating Factor 3. Specifically, ''uncompensated care'' is defined as the amount on Line 30 of Worksheet S–10, which is the cost of charity care (Line 23) and the cost of non-Medicare bad debt and non-reimbursable Medicare bad debt (Line 29). This is the same definition that we initially adopted in the FY 2018 IPPS/LTCH PPS final rule. We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58825 through 58828) for a discussion of additional topics related to the definition of uncompensated care.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45236 through 45243), consistent with the policy adopted in the FY 2021 IPPS/LTCH PPS final rule, we used a single year of Worksheet S–10 data from FY 2018 cost reports to calculate Factor 3 for FY 2022 for all eligible hospitals with the exception of IHS and Tribal hospitals and Puerto Rico hospitals that have a cost report for 2013. We continued to use the low-income insured days proxy to calculate Factor 3 for these IHS and Tribal hospitals and Puerto Rico hospitals for FY 2022.

b. Background on the Methodology Used To Calculate Factor 3 for FY 2023 and Subsequent Years

Section 1886(r)(2)(C) of the Act both governs the selection of the data to be used in calculating Factor 3 and allows the Secretary the discretion to determine the time periods from which we will derive the data to estimate the numerator and the denominator of the Factor 3 quotient. Specifically, section 1886(r)(2)(C)(i) of the Act defines the numerator of the quotient as the amount of uncompensated care for a subsection (d) hospital for a period selected by the Secretary. Section 1886(r)(2)(C)(ii) of the Act defines the denominator as the aggregate amount of uncompensated care for all subsection (d) hospitals that receive a payment under section 1886(r) of the Act for such period. In the FY

2014 IPPS/LTCH PPS final rule (78 FR 50638), we adopted a process of making interim payments with final cost report settlement for both the empirically justified Medicare DSH payments and the uncompensated care payments required by section 3133 of the Affordable Care Act. Consistent with that process, we also determined the time period from which to calculate the numerator and denominator of the Factor 3 quotient in a way that would be consistent with making interim and final payments. Specifically, we must have Factor 3 values available for hospitals that we estimate will qualify for Medicare DSH payments and for those hospitals that we do not estimate will qualify for Medicare DSH payments but that may ultimately qualify for Medicare DSH payments at the time of cost report settlement.

As described in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45237), commenters expressed concerns that the use of only 1 year of data to determine Factor 3 would lead to significant variations in year-to-year uncompensated care payments. Some stakeholders recommended the use of 2 years of historical Worksheet S–10 data. In that same final rule (86 FR 45237), we stated that we would consider using multiple years of data when the vast majority of providers had been audited for more than 1 fiscal year under the revised reporting instructions. Audited FY 2019 cost reports were available for the development of the FY 2023 IPPS/LTCH PPS proposed and final rule. Feedback from previous audits and lessons learned were incorporated into the audit process for the FY 2019 reports.

In consideration of the comments discussed in the FY 2022 IPPS/LTCH PPS final rule, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49036 through 49047), we finalized a policy of using a multi-year average of audited Worksheet S–10 data to determine Factor 3 for FY 2023 and subsequent fiscal years. We explained our belief that this approach would be generally consistent with our past practice of using the most recent single year of audited data from the Worksheet S–10, while also addressing commenters' concerns regarding year-to-year fluctuations in uncompensated care payments. Under this policy, we used a 2-year average of audited FY 2018 and FY 2019 Worksheet S–10 data to calculate Factor 3 for FY 2023. However, we also indicated that we expected FY 2024 would be the first year that 3 years of audited data would be available at the time of rulemaking. Accordingly, for FY 2024 and subsequent fiscal years, we finalized a policy of using a 3-year average of the uncompensated care data from the 3 most recent fiscal years for which audited data are available to determine Factor 3. Consistent with the approach that we followed when multiple years of data were previously used in the Factor 3 methodology, if a hospital does not have data for all 3 years used in the Factor 3 calculation, we will determine Factor 3 based on an average of the hospital's available data. We also discontinued the use of the low-income days proxy to determine Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals and instead finalized use of the same multi-year average of Worksheet S–10 data to determine Factor 3 for FY 2023 and subsequent fiscal years, as is used to determine Factor 3 for all other DSH-eligible hospitals.

Because we finalized our proposal to use multiple years of cost reports to determine Factor 3 starting in FY 2023, we determined that it would also be necessary to make a further modification to the policy regarding cost reports that start in one fiscal year and span the entirety of the following fiscal year. Specifically, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49041), we explained that in the rare cases when we use a cost report that starts in one fiscal year and spans the entirety of the subsequent Federal fiscal year to determine uncompensated care costs for the subsequent Federal fiscal year, we would not use the same cost report to determine the hospital's uncompensated care costs for the earlier fiscal year. We explained that using the same cost report to determine uncompensated care costs for both fiscal years would not be consistent with our intent to smooth year-to-year variation in uncompensated care costs. As an alternative, we finalized our proposal to use the hospital's most recent prior cost report, if that cost report spans the applicable period. In other words, in determining Factor 3 for FY 2023, we did not use the same cost report to determine the hospital's uncompensated care costs for both FY 2018 and FY 2019. Rather, we used the cost report that spans the entirety of FY 2019 to determine uncompensated care costs for FY 2019 and we used the hospital's most recent prior cost report to determine its uncompensated care costs for FY 2018, provided that cost report spans some portion of Federal fiscal year 2018.

(1) Scaling Factor

To address the effects of calculating Factor 3 using data from multiple fiscal years, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49042) we finalized a policy under which we apply a scaling factor to the Factor 3 values calculated for all DSH eligible hospitals so that total uncompensated care payments to hospitals that are projected to be eligible for DSH for a fiscal year will be consistent with the estimated amount available to make uncompensated care payments for that fiscal year. Specifically, we adopted a policy under which we divide 1 (the expected sum of all DSH eligible hospitals' Factor 3 values) by the actual sum of all DSH eligible hospitals' Factor 3 values and then multiply the quotient by the uncompensated care payment determined for each DSH eligible hospital to obtain a scaled uncompensated care payment amount for each hospital. This process is designed to ensure that the sum of the scaled uncompensated care payments for all hospitals that are projected to be DSH eligible is consistent with the estimate of the total amount available to make uncompensated care payments for the applicable fiscal year. We noted that a similar scaling factor methodology was previously used in both FY 2018 (82 FR 38214 and 38215) and FY 2019 (83 FR 41414), when the Factor 3 calculation also included multiple years of data.

(2) New Hospital Policy for Purposes of Factor 3

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49042), we modified the new hospital policy that was initially adopted in the FY 2020 IPPS/LTCH PPS final rule to determine Factor 3 for new hospitals. Consistent with our policy of using multiple years of cost reports to determine Factor 3, we defined new hospitals as hospitals that do not have cost report data for the most recent year of data being used in the Factor 3 calculation. Under this definition, the cut-off date for the new hospital policy is the beginning of the Federal fiscal year after the most recent year for which audits of the Worksheet S–10 data have been conducted. For FY 2023, the FY 2019 cost reports were the most recent year of cost reports for which audits of Worksheet S–10 data had been conducted. Thus, hospitals with CCNs (CMS Certification Numbers) established on or after October 1, 2019, were subject to the new hospital policy for FY 2023.

Under this modification to the new hospital policy, we continued the policy established in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42370) that if a new hospital has a preliminary projection of being eligible for DSH payments based on its most recent

available disproportionate patient percentage, it may receive interim empirically justified DSH payments. However, new hospitals will not receive interim uncompensated care payments because we would have no uncompensated care data from which to determine what those interim payments should be. The MAC will make a final determination concerning whether the hospital is eligible to receive Medicare DSH payments at cost report settlement.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49042), we also modified the methodology used to calculate Factor 3 for new hospitals. Specifically, while we continued to determine the numerator of the Factor 3 calculation using the new hospital's uncompensated care costs reported on Worksheet S–10 of the hospital's cost report for the current fiscal year, we adopted an approach under which we determine Factor 3 for new hospitals using a denominator based solely on uncompensated care costs from cost reports for the most recent fiscal year for which audits have been conducted. In addition, we applied a scaling factor to the Factor 3 calculation for a new hospital. We explained our belief that applying the scaling factor is appropriate for purposes of calculating Factor 3 for all hospitals, including new hospitals and hospitals that are treated as new hospitals, in order to improve consistency and predictability across all hospitals.

(3) Newly Merged Hospital Policy

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49042 and 49043), we stated that we would continue to treat hospitals that merge after the development of the final rule for the applicable fiscal year similar to new hospitals. As explained in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50021), for these newly merged hospitals, we do not have data currently available to calculate a Factor 3 amount that accounts for the merged hospital's uncompensated care burden. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50021 and 50022), we finalized a policy under which Factor 3 for hospitals that we do not identify as undergoing a merger until after the public comment period and additional review period following the publication of the final rule or that undergo a merger during the fiscal year will be recalculated similar to new hospitals.

Consistent with the policy adopted in the FY 2015 IPPS/LTCH PPS final rule, in the FY 2023 IPPS/LTCH PPS final rule, we stated that we would continue to treat newly merged hospitals in a similar manner to new hospitals, such that the newly merged hospital's final uncompensated care payment will be determined at cost report settlement where the numerator of the newly merged hospital's Factor 3 will be based on the cost report of only the surviving hospital (that is, the newly merged hospital's cost report) for the current fiscal year. However, if the hospital's cost reporting period includes less than 12 months of data, the data from the newly merged hospital's cost report will be annualized for purposes of the Factor 3 calculation. Consistent with the modification to the methodology used to determine Factor 3 for new hospitals described previously, we finalized a policy for determining Factor 3 for newly merged hospitals using a denominator that is the sum of the uncompensated care costs for all DSH-eligible hospitals, as reported on Worksheet S–10 of their cost reports for the most recent fiscal year for which audits have been conducted. In addition, we apply a scaling factor, as discussed previously, to the Factor 3 calculation for a newly merged hospital. We stated our belief that applying the scaling factor is appropriate for purposes of calculating Factor 3 for all hospitals, including new hospitals and hospitals that are treated as new hospitals, in order to improve consistency and predictability across all hospitals. We also explained that consistent with past policy, interim uncompensated care payments for the newly merged hospital will be based only on the data for the surviving hospital's CCN available at the time of the development of the final rule.

(4) CCR Trim Methodology

The calculation of a hospital's total uncompensated care costs on Worksheet S–10 requires the use of the hospital's cost to charge ratio (CCR). In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49043), we adopted a process for trimming CCRs under which we apply the following steps to determine the applicable CCR separately for each fiscal year that is included as part of the multi-year average used to determine Factor 3:

Step 1: Remove Maryland hospitals. In addition, we will remove all-inclusive rate providers because their CCRs are not comparable to the CCRs calculated for other IPPS hospitals.

Step 2: Calculate a CCR ''ceiling'' for the applicable fiscal year with the following data: for each IPPS hospital that was not removed in Step 1 (including non-DSH eligible hospitals), we use cost report data to calculate a CCR by dividing the total costs on Worksheet C, Part I, Line 202, Column 3 by the charges reported on Worksheet C, Part I, Line 202, Column 8. (Combining data from multiple cost reports from the same fiscal year is not necessary, as the longer cost report will be selected.) The ceiling is calculated as 3 standard deviations above the national geometric mean CCR for the applicable fiscal year. This approach is consistent with the methodology for calculating the CCR ceiling used for high-cost outliers. Remove all hospitals that exceed the ceiling so that these aberrant CCRs do not skew the calculation of the statewide average CCR.

Step 3: Using the CCRs for the remaining hospitals in Step 2, determine the urban and rural statewide average CCRs for the applicable fiscal year for hospitals within each State (including non-DSH eligible hospitals), weighted by the sum of total hospital discharges from Worksheet S–3, Part I, Line 14, Column 15.

Step 4: Assign the appropriate statewide average CCR (urban or rural) calculated in Step 3 to all hospitals, excluding all-inclusive rate providers, with a CCR for the applicable fiscal year greater than 3 standard deviations above the national geometric mean for that fiscal year (that is, the CCR ''ceiling'').

Step 5: For hospitals that did not report a CCR on Worksheet S–10, Line 1, we assign them the statewide average CCR for the applicable fiscal year as determined in Step 3.

After completing the previously described steps, we re-calculate the hospital's uncompensated care costs (Line 30) for the applicable fiscal year using the trimmed CCR (the statewide average CCR (urban or rural, as applicable)).

(5) Uncompensated Care Data Trim Methodology

After applying the CCR trim methodology, there are rare situations where a hospital has potentially aberrant uncompensated care data for a fiscal year that are unrelated to its CCR. Therefore, under the trim methodology for potentially aberrant uncompensated care costs (UCC) that was included as part of the methodology for purposes of determining Factor 3 in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58832), if the hospital's uncompensated care costs for any fiscal year that is included as a part of the multi-year average are an extremely high ratio (greater than 50 percent) of its total operating costs in the applicable fiscal year, we will determine the ratio of uncompensated care costs to the hospital's total operating costs from another available cost report, and apply that ratio to the total operating expenses

for the potentially aberrant fiscal year to determine an adjusted amount of uncompensated care costs for the applicable fiscal year. For example, if a hospital's FY 2018 cost report is determined to include potentially aberrant data, data from its FY 2019 cost report would be used for the ratio calculation.

However, we note that we have audited the Worksheet S–10 data that will be used in the Factor 3 calculation for a number of hospitals. Because the UCC data for these hospitals have been subject to audit, we believe that there is increased confidence that if high uncompensated care costs are reported by these audited hospitals, the information is accurate. Therefore, consistent with the policy that was adopted in the FY 2021 IPPS/LTCH PPS final rule, it is unnecessary to apply the trim methodology for a fiscal year for which a hospital's UCC data have been audited.

In rare cases, hospitals that are not currently projected to be DSH eligible and that do not have audited Worksheet S–10 data may have a potentially aberrant amount of insured patients' charity care costs (line 23 column 2). Accordingly, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49044), we stated that in addition to the UCC trim methodology, we will continue to apply a trim specific to certain hospitals that do not have audited Worksheet S–10 data for one or more of the fiscal years that are used in the Factor 3 calculation. For FY 2023 and subsequent fiscal years, in the rare case that a hospital's insured patients' charity care costs for a fiscal year are greater than $7 million and the ratio of the hospital's cost of insured patient charity care (line 23 column 2) to total uncompensated care costs (line 30) is greater than 60 percent, we will exclude the hospital from the prospective Factor 3 calculation. This trim will only impact hospitals that are not currently projected to be DSH-eligible and, therefore, are not part of the calculation of the denominator of Factor 3, which includes only uncompensated care costs for projected DSH-eligible hospitals. Consistent with the approach adopted in the FY 2022 IPPS/LTCH PPS final rule, if a hospital would be trimmed under both the UCC trim methodology and this alternative trim, we will apply this trim in place of the existing UCC trim methodology. We continue to believe this alternative trim more appropriately addresses potentially aberrant insured patient charity care costs compared to the UCC trim methodology, because the UCC trim is based solely on the ratio of total uncompensated care costs to total operating costs and does not consider the level of insured patients' charity care costs.

Similar to the approach initially adopted in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45245 and 45246), in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49044), we also stated that we would continue to use a threshold of 3 standard deviations from the mean ratio of insured patients' charity care costs to total uncompensated care costs (line 23 column 2 divided by line 30) and a dollar threshold that is the median total uncompensated care cost reported on the most recent audited cost reports for hospitals that are projected to be DSH-eligible. We stated that we continued to believe these thresholds were appropriate in order to address potentially aberrant data. However, we modified the calculation to include Worksheet S–10 data from IHS/Tribal hospitals and Puerto Rico hospitals consistent with our final policy decision to begin using Worksheet S–10 data to determine Factor 3 for these hospitals. In addition, we finalized a policy of applying the same threshold amounts originally calculated for the FY 2018 reports to identify potentially aberrant data for FY 2023 and subsequent fiscal years in order to facilitate transparency and predictability. If a hospital subject to this trim is determined to be DSH-eligible at cost report settlement, the MAC will calculate the hospital's Factor 3 using the same methodology used to calculate Factor 3 for new hospitals.

c. Methodology for Calculating Factor 3 for FY 2024

For FY 2024, we proposed to follow the same methodology as applied in FY 2023 and that is described in section IV.E.3.b. of the preamble of this final rule to determine Factor 3 using the most recent 3 years of audited cost reports from FY 2018, FY 2019, and 2020. For purposes of the FY 2024 IPPS/LTCH PPS proposed rule, we used reports from the December 2022 Healthcare Cost Report Information System (HCRIS) extract to calculate Factor 3. We noted that we intended to use the March 2023 update of HCRIS to calculate the final Factor 3 for the FY 2024 IPPS/LTCH PPS final rule.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49051), we finalized our proposal to determine Factor 3 for IHS and Tribal hospitals and Puerto Rico hospitals based on uncompensated care data reported on Worksheet S–10, and we discontinued the use of low-income insured days as a proxy for the uncompensated care costs of these hospitals. Beginning in FY 2023, we established a new supplemental payment for IHS/Tribal hospitals and Puerto Rico hospitals, because we recognized that discontinuing the use of the low-income insured days proxy and relying solely on Worksheet S–10 data to calculate Factor 3 of the uncompensated care payment methodology for IHS/Tribal hospitals and Puerto Rico hospitals could result in significant financial disruption for these hospitals. We refer readers to section IV.D of this final rule for a further discussion of these payments. We note that in the FY 2024 IPPS/LTCH PPS proposed rule, we did not propose any changes to the methodology for determining supplemental payments, and we will calculate the supplemental payments to eligible IHS/Tribal and Puerto Rico hospitals for FY 2024 consistent with the methodology described in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49047 through 49051) and in the regulations at § 412.106(h).

Consistent with the policy adopted in the FY 2023 IPPS/LTCH PPS final rule and codified in the regulations at § 412.106(g)(1)(iii)(C)(*11*), for FY 2024 and subsequent fiscal years, we will use 3 years of audited Worksheet S–10 data to calculate Factor 3 for all eligible hospitals, including IHS and Tribal hospitals and Puerto Rico hospitals that have a cost report for 2013.

Step 1: Select the hospital's longest cost report for each of the most recent 3 years of Federal fiscal year audited cost reports (FY 2018, FY 2019, and FY 2020). (Alternatively, in the rare case when the hospital has no cost report for a particular year because the cost report for the previous Federal fiscal year spanned the more recent Federal fiscal year, the previous Federal fiscal year cost report would be used in this step. In the rare case that using a previous Federal fiscal year cost report results in a period without a report, we would use the prior year report, if that cost report spanned the applicable period. (For example, if a hospital does not have a FY 2019 cost report because the hospital's FY 2018 cost report spanned the FY 2019 time period, then we would use the FY 2018 cost report that spanned the FY 2019 time period for this step. Using the same example, where the hospital's FY 2018 report is used for the FY 2019 time period, then we would use the hospital's FY 2017 report if it spans some of the FY 2018 time period. In other words, we would not use the same cost report for both the FY 2019 and the FY 2018 time periods.) In general, we note that, for purposes of the Factor 3 methodology, references to a fiscal year cost report are to the cost

report that spans the relevant Federal fiscal year period.

Step 2: Annualize the UCC from Worksheet S–10 Line 30, if a cost report is more than or less than 12 months. (If applicable, use the statewide average CCR (urban or rural) to calculate uncompensated care costs.)

Step 3: Combine adjusted and/or annualized uncompensated care costs for hospitals that merged using the merger policy.

Step 4: Calculate Factor 3 for all DSH eligible hospitals using annualized uncompensated care costs (Worksheet S–10 Line 30) based on cost report data from the most recent 3 years of audited cost reports (from Step 1, 2, or 3). New hospitals and other hospitals that are treated as if they are new hospitals for purposes of Factor 3 are excluded from this calculation.

Step 5: Average the Factor 3 values from Step 4; that is, add the Factor 3 values, and divide that amount by the number of cost reporting periods with data to compute an average Factor 3 for the hospital. Multiply the result by a scaling factor.

We received comments regarding the uncompensated care costs definition, Worksheet S–10 cost report audits, and Factor 3 calculation instructions.

Comment: Several commenters expressed their support for CMS' proposal in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26997 and 26998) to calculate Factor 3 for FY 2024 based on a three-year average of audited FY 2018, FY 2019, and FY 2020 Worksheet S–10 data, and the policy finalized in the FY 2023 IPPS/LTCH PPS final rule to implement a three-year average based on the most recent available audited data for subsequent fiscal years. Supporters of this proposal specified several benefits to the use of a multi-year average of Worksheet S–10 data, such as minimizing year-to-year volatility, promoting accuracy, and ensuring stability in future uncompensated care payments. One commenter noted their long-standing support for using audited Worksheet S–10 data to promote an accurate and consistent calculation of uncompensated care costs.

Notably, none of the commenters expressed opposition to using a three-year average of Worksheet S–10 data to calculate uncompensated care payments moving forward.

Response: We appreciate the commenters' support for our proposal to use a three-year average of audited FY 2018, FY 2019, and FY 2020 Worksheet S–10 data to determine each hospital's share of uncompensated care costs in FY 2024. As explained in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26995), we believe that using a multi-year average of Worksheet S–10 data will provide assurance that hospitals' uncompensated care payments remain stable and predictable and will not be subject to unpredictable swings and anomalies in a hospital's uncompensated care costs.

Comment: A few commenters suggested approaches to mitigating the impact of the COVID–19 PHE on the three-year average of Worksheet S–10 data. One commenter recommended that CMS exclude FY 2020 data entirely from FY 2024 DSH calculations, because the commenter believes the data are flawed due to COVID–19 PHE impacts. Another recommended that CMS hold the evaluation period of Worksheet S–10 data constant until data free of the impacts of the COVID–19 PHE are available. One commenter encouraged CMS to review the impact of the COVID–19 PHE may have on accurately capturing uncompensated care as the three-year average range includes more years with COVID–19 repercussions, while another recommended that CMS mitigate the effect of anomalies in FYs 2020–2022 cost report data that may adversely impact DSH payments in future years.

Response: Regarding requests that CMS account for the impact of the COVID–19 PHE on the three-year average of Worksheet S–10 cost report data, we note that we will continue to use the three-year average of the most recently audited cost report data for FY 2024 and subsequent years, as finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49038). In response to the comments requesting that we exclude FY 2020 data or hold data constant, we continue to believe using the three-year average will smooth the variation in year-to-year uncompensated care payments and lessen the impacts of the COVID–19 PHE and future unforeseen events. Further, we anticipate that there will be less fluctuation in cost report data as the PHE disruptions on healthcare utilization recover. We will continue to monitor the impacts of the PHE and will consider this issue further in future rulemaking, as appropriate.

Comment: Some commenters suggested alternative approaches to the uncompensated care payment calculation unrelated to methodological concepts concerning the blending of historical Worksheet S–10 data. Such recommendations included that CMS should consider the impact of the healthcare labor shortage on uncompensated care payments. One commenter recommended that CMS protect essential hospitals from fluctuations and cuts to uncompensated care payments, without reducing the payments to other DSH-eligible hospitals.

Another commenter requested that CMS modify the FY 2024 methodology to compensate safety-net hospitals for any decrease in FY 2020 uncompensated care payments inadvertently caused by the Factor 3 policies from the FY 2020 IPPS/LTCH PPS final rule. Specifically, this commenter's recommendation was that CMS should account for FY 2015 uncompensated care costs from reopened FY 2015 Worksheet S–10 on a one-time basis to calculate Factor 3 for FY 2024.

Further, a handful of commenters expressed concern about the proposed reduction in uncompensated care payments. These commenters indicated that the proposed decrease in payments in addition to the inadequate payment update would be insufficient for these hospitals in the current financial environment.

Response: With regard to commenters' concerns and suggestions unrelated to the previously discussed methodological concepts for the blending of historical Worksheet S–10 data, we consider these public comments to be outside the scope of the proposed rule, we are not addressing them in this final rule. However, we appreciate commenters' input and note that we may address these and other considerations in future rulemaking.

Concerning the commenter's suggestion to modify uncompensated care payments to account for payments from a previous year we are continuing to use Worksheet S–10 data from multiple years to mitigate fluctuations in the data and smooth variations in year-to-year uncompensated care payments. Regarding the commenter's suggestion to account for FY 2015 uncompensated care costs from reopened Worksheet S–10, we are not considering re-using FY 2015 cost reports or supplementing the FY 2024 uncompensated care payments with information from FY 2015. As explained in the FY 2024 IPPS/LTCH PPS proposed rule, we believe that using a multi-year average of the most recent audited Worksheet S–10 data will reflect the most recent available information regarding a hospital's uncompensated care costs. We note that MACs will continue to have discretion to determine if a provider revision may be accepted for amended or reopened cost reports, per 42 CFR 405.1885.

Comment: Many commenters indicated that CMS' proposed reduction to the DSH payment amount by nearly

half a billion dollars from FY 2023 will have a disparate impact on DSH hospitals as they continue to face financial challenges related to the COVID–19 PHE. These challenges include increasing labor and supply costs, increasing inflation, and potential Medicare sequestration cuts. One commenter noted that any payment reduction during a time of increased operating costs for hospitals could hinder progress in areas that are top priorities for hospitals. These areas include investments in value-based payment models, climate policies, and data collection that are needed to build a foundation for improving health equity.

Response: We thank the commenters for their feedback. We agree that the COVID–19 PHE presents unique challenges to hospitals' finances. Regarding the commenters' concerns regarding changes to the amount available to make uncompensated care payments in this rulemaking, we note that, as described in the FY 2024 IPPS/LTCH PPS proposed rule, the statute instructs the Secretary to estimate the amounts of uncompensated care for a period based on appropriate data, which for FY 2024 include data that reflect the COVID–19 PHE's effect on hospitals.

Comment: Some commenters proposed changes to the definition of uncompensated care and requested that CMS ensure its methodology accurately captures the full range of uncompensated care costs that hospitals incur in their provision of care for disadvantaged patients. One commenter urged CMS to include all patient care costs in the CCR, including those for teaching and providing physician and other professional services, to ensure an accurate distribution of uncompensated care payments to hospitals with the highest levels of uncompensated care. This commenter stated that doing so should include Graduate Medical Education (GME) costs, which are disproportionately detrimental to teaching hospitals. The commenter further suggested that CMS revise the data collected on Medicaid shortfalls to better capture actual shortfalls incurred by hospitals by allowing hospitals to include unpaid coinsurance and deductibles on Worksheet S–10. Another commenter suggested treating the unreimbursed portion of state or local indigent care as charity care.

Response: We appreciate commenters' suggestions for revisions and/or modifications to Worksheet S–10. We will consider modifications as necessary to further improve and refine the information that is reported on Worksheet S–10 to support collection of the information regarding uncompensated care costs.

Regarding the request to include costs for teaching and providing physician and other professional services, including GME costs when calculating the CCR, we note that because the CCR on Line 1 of Worksheet S–10 is obtained from Worksheet C, Part I, and is also used in other IPPS rate setting contexts (such as high-cost outliers and the calculation of the MS–DRG relative weights) from which it is appropriate to exclude the costs associated with supporting physician and professional services and GME costs, we remain reluctant to adjust CCRs in the narrower context of calculating uncompensated care costs. Therefore, as stated in past final rules, including the FY 2022 IPPS/LTCH PPS final rule (86 FR 45241 and 45242), we continue to believe that it is not appropriate to modify the calculation of the CCR on Line 1 of Worksheet S–10 to include any additional costs in the numerator of the CCR calculation.

With regard to the comments requesting that payment shortfalls from Medicaid and State and local indigent care programs be included in uncompensated care cost calculations, we have consistently stated in past final rules (85 FR 58826; 86 FR 45238; and 87 FR 49039) in response to similar comments that we believe there are compelling arguments for excluding such shortfalls from the definition of uncompensated care. We refer readers to those prior rules for further discussion.

Comment: Commenters expressed concern that the reductions in uncompensated care payments do not align with the Federal Government's focus on equity. One commenter stated that safety-net hospitals provide eight times more uncompensated care than other hospital types, which disproportionately impacts safety-net hospitals' payments. Another commenter requested that CMS revise the current payment policy to account for the proportion of low-income discharges for each hospital and the capacity of a hospital to absorb uncompensated care costs. This commenter recommended changing the uncompensated care payment calculation to be based on each hospital's uncompensated care and disproportionate share percentage.

Response: We thank commenters for their continued concern regarding the distribution of uncompensated care payments and the impact of uncompensated care payments on safety-net hospitals and for their recommendations for potential changes to the uncompensated care payment methodology. We may consider this issue further in future rulemaking, if appropriate.

We note that in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27187 through 27190), we included a Request for Information (RFI) that sought public feedback on the challenges faced by safety-net hospitals and potential approaches to help safety-net hospitals meet those challenges. We are in the process of reviewing the comments received in response to the RFI.

Comment: In relation to the accuracy of the Worksheet S–10 data, one commenter requested that CMS regularly review Worksheet S–10 cost reports for any irregular trends in the data.

Response: The use of the three-year average of the most recently audited cost report data for FY 2024 and subsequent years will smooth the variation in year-to-year uncompensated care payments and lessen the impacts of future unforeseen events, such as the COVID–19 PHE. Further, we anticipate that there will be less fluctuation in cost report data as the PHE has ended. We note that the audit process for Worksheet S–10 cost reports will continue to be an important part of identifying potential irregularities in the data.

Comment: One commenter commended CMS for the agency's efforts to develop and improve the audit process for Worksheet S–10 data. Echoing concerns expressed in previous years, other commenters encouraged CMS to work with MACs to make the audit process clearer, more consistent, and more complete. The same commenters recommended that CMS establish a standardized process across auditors and make audit instructions publicly available. A few commenters cited the Medicare wage index audit as a model that CMS could use to clarify the timeline and process for Worksheet S–10 revisions. Like in the wage index audit process, these commenters recommended that CMS utilize a public use file, rather than the HCRIS data file, which would make the audit process more transparent. One commenter suggested that CMS ensure that Worksheet S–10 audits impose minimal burden and are equitable and uniform across hospitals. The same commenter also suggested CMS consider making the audit process more transparent by disclosing criteria used to identify hospitals for audits and publishing audit protocols in advance to allow hospitals time and opportunity to respond to audits and address findings through notice and comment rulemaking. Given the high costs of

Worksheet S–10 audits, one commenter recommended that CMS select a discrete number of hospitals to audit every year. For example, in the case that CMS audits one third of DSH hospitals per year, every hospital would be audited once per 3-year cycle. Finally, this commenter also requested that CMS implement an informal, fast-track review process for audit appeals similar to the audit criteria the agency uses for retrospective DSH reimbursement, such that hospitals have the same protections afforded by the appeal rights for retrospective DSH reimbursement. One commenter expressed concern with the handling of Health Resources & Services Administration's (HRSA) COVID–19 claims and argued that claims not paid for by HRSA funds, but which are covered under the hospital's financial assistance policy (FAP), should be included on Worksheet S–10.

Response: We thank commenters for their feedback on the audits of the FY 2020 Worksheet S–10 data and their recommendations for future audits. As we have stated previously in response to comments regarding audit protocols, they are provided to the MACs in advance of the audit to assure consistency and timeliness in the audit process. CMS began auditing the FY 2020 Worksheet S–10 data for selected hospitals last year so that the audited uncompensated care data for these hospitals would be available in time for use in the FY 2024 IPPS/LTCH PPS proposed rule. We chose to focus the audit on the FY 2020 cost reports in order to maximize the available audit resources. We also note that FY 2020 data are the most recent year of audited data.

We appreciate all commenters' input and recommendations on how to improve our audit process and reiterate our commitment to continue working with MACs and providers on audit improvements, which include making changes to increase the efficiency of the audit process, building on the lessons learned in previous audit years. Regarding commenters' requests for a standard audit timeline, we do not intend to establish a fixed timeline for audits across MACs at this time, to ensure we can retain the flexibility to use our limited audit resources to address and prioritize audit needs across all CMS programs each year. We note that MACs collaborate with providers regarding scheduling dates during the Worksheet S–10 audit process. We also note that MACs work closely with providers to balance the time needed to complete the Worksheet S–10 audits and to minimize the burden on providers and will continue to do so.

Regarding commenters' requests that CMS make public the audit instructions and criteria, as we previously stated in the FY 2021 IPPS/LTCH PPS final rule and prior rules (81 FR 56964; 84 FR 42368; 85 FR 58822), we do not make review protocols public as CMS desk review and audit protocols are confidential and are for CMS and MAC use only. Concerning the request to promulgate the Worksheet S–10 audit policy and protocols, there is no requirement under either the Administrative Procedure Act or the Medicare statute that CMS adopt the audit protocols through notice and comment rulemaking. As previously discussed in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58822), at this point, to maximize our limited audit resources, we do not plan on introducing an audit appeals process.

Regarding commenters' recommendations that we establish a similar process to that used for the wage index audits, at this point we do not plan to introduce an audit process with such a structure in order to maximize limited audit resources.

We also note that the quarterly HCRIS data is published as a public use file, available at *https://www.cms.gov/research-statistics-data-and-systems/downloadable-public-use-files/cost-reports/cost-reports-by-fiscal-year.* The December HCRIS extract is available for providers to review at the time the IPPS/LTCH PPS proposed rule is issued and the March HCRIS is generally available during the comment period.

Regarding comments on the handling of claims under the HRSA-administered COVID–19 Uninsured Program and the audits of Worksheet S–10, providers should discuss with their MAC during the Worksheet S–10 audit process if they encounter issues. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58827), we noted that one term and condition of the HRSA Uninsured Program states as follows: ''The Recipient will not include costs for which Payment was received in cost reports or otherwise seek uncompensated care reimbursement through federal or state programs for items or services for which Payment was received.''

Comment: One commenter commended CMS for its efforts to provide clearer instructions for Worksheet S–10. Three commenters requested that CMS clarify whether Worksheet S–10 Part I or Part II should be utilized to calculate Factor 3. A few commenters recommended that CMS allow providers to submit Worksheet S–10 corrections following the March 2023 HCRIS deadline. These commenters noted that they were not aware of the March deadline until the publishing of the proposed rule. In addition, one commenter requested that CMS clarify the ''normal timeline'' MACs follow for allowing providers to amend or reopen previously audited Worksheet S–10 data used to calculate Factor 3. One commenter requested that CMS clarify inconsistent Worksheet S–10 instructions so that non-Medicare bad debt is not multiplied by CCR. This commenter stated that CMS' revised instructions indicated that non-reimbursed Medicare bad debt is not reduced by the CCR, but that cost report instructions state that non-Medicare bad debt is multiplied by the CCR.[207] This commenter indicated that such a practice is inconsistent with the way non-reimbursable Medicare bad debt is treated. The commenter also noted that CMS should provide opportunities for stakeholder feedback on Worksheet S–10 as well as additional educational outreach on revisions, extended submission deadlines, and training to hospital staff on accurately reporting data. Finally, one commenter proposed that CMS create a working group with industry and government stakeholders to develop standard specifications for the data fields and formats used for Worksheet S–10 cost reporting of uncompensated care, empirical DSH, and Medicare bad debt reimbursement.

Response: We appreciate commenters' concerns regarding the need for clarification of the Worksheet S–10 instructions, as well as their suggestions for form revisions to improve reporting. We reiterate our commitment to continuing to work with impacted parties to address their concerns regarding Worksheet S–10 instructions and reporting through provider education and further refinement of the instructions as appropriate. We also encourage providers to share with their respective MAC any questions regarding clarifications of instructions, reporting, and submission deadlines.

We continue to believe that our efforts to refine the instructions and guidance have improved provider understanding of the Worksheet S–10 and added clarity to the instructions. We also recognize that there are continuing opportunities to further improve the accuracy and consistency of the information that is reported on the Worksheet S–10, and to the extent that commenters have raised new questions and concerns regarding the reporting requirements, we will attempt to address them through future rulemaking and/or sub-regulatory guidance and subsequent outreach. However, as stated in previous rules, we continue to believe that the Worksheet

S–10 instructions are sufficiently clear and continue to allow hospitals to accurately complete Worksheet S–10.

Regarding commenters' requests for clarification on whether Worksheet S–10 Part I or Part II is used for the Factor 3 calculation for ''new'' hospital and ''newly merged'' hospitals, we would use information reported on the hospital's Worksheet S–10, Part I to determine Factor 3 if the hospital is determined to be DSH eligible at cost report settlement.

Concerning commenters' requests to submit Worksheet S–10 corrections after the March 2023 HCRIS, we note that the December HCRIS extract is publicly available for providers to review on the CMS website at the time of the publishing of the IPPS/LTCH PPS proposed rule. The March update of HCRIS is generally available during the comment period to the proposed rule. We are continuing to use the March HCRIS extract, which is the latest data available during this final rule's development, for Factor 3 calculations.

Concerning commenters' request that CMS clarify the timeline and procedures MACs follow to amend or reopen previously audited Worksheet S–10 data, we note that MACs will continue to have discretion to determine if a provider's report may be accepted. We also note that MACs will not reject requests related to Worksheet S–10 revisions solely due to the direct reimbursement not meeting current year amended cost report or reopening thresholds. For hospital-requested revisions to Worksheet S–10, MACs make a determination to accept or reject the amended cost report or cost report reopening consistent with the current instructions at CMS Pub. 100–06, Chapter 8, available at *www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms-items/cms019018*.

Regarding the commenters' request that CMS to clarify whether non-Medicare bad debt is multiplied by CCR, we believe that the Worksheet S–10 instructions are clear and indicate that the CCR will not be applied to the deductible and coinsurance amounts for insured patients approved for charity care and non-reimbursed Medicare bad debt.

Regarding the comments requesting changes to Worksheet S–10 and/or further clarification of the reporting instructions, we note that these comments fall outside the scope of this final rule.

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26998), for purposes of identifying new hospitals, for FY 2024, the FY 2020 cost reports are the most recent year of cost reports for which audits of Worksheet S–10 data have been conducted. Thus, hospitals with CCNs established on or after October 1, 2020, would be subject to the new hospital policy in FY 2024. If a new hospital is ultimately determined to be eligible for Medicare DSH payments for FY 2024, the hospital would receive an uncompensated care payment calculated using a Factor 3, where the numerator is the uncompensated care costs reported on Worksheet S–10 of the hospital's FY 2024 cost report, and the denominator is the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2020 cost reports for all DSH-eligible hospitals. In addition, we would apply a scaling factor, as discussed previously, to the Factor 3 calculation for a new hospital. As we explained in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49042), we believe applying the scaling factor is appropriate for purposes of calculating Factor 3 for all hospitals, including new hospitals and hospitals that are treated as new hospitals, in order to improve consistency and predictability across all hospitals.

In the proposed rule, we stated that for FY 2024, the eligibility of a newly merged hospital to receive interim uncompensated care payments and the amount of any interim uncompensated care payments, would be based on the uncompensated care costs from the FY 2018, FY 2019, and FY 2020 cost reports available for the surviving CCN at the time this final rule is developed. However, at cost report settlement, we would determine the newly merged hospital's final uncompensated care payment based on the uncompensated care costs reported on its FY 2024 cost report. That is, we would revise the numerator of Factor 3 for the newly merged hospital to reflect the uncompensated care costs reported on the newly merged hospital's FY 2024 cost report. The denominator would be the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2020 cost reports for all DSH-eligible hospitals, which is the most recent fiscal year for which audits have been conducted. We would also apply a scaling factor, as described previously.

Comment: A couple of commenters expressed support for the policy currently in place for newly merged hospitals. This policy states that uncompensated care payments for a merged hospital will be based on the surviving hospital's cost report for the current fiscal year, and that the final uncompensated care payments for these hospitals will be determined during cost report settlement. These commenters also indicated support for the policy in place for new hospitals, which states that MACs will make the final determination concerning whether hospitals are eligible to receive DSH payments at cost report settlement based on the new hospital's cost report.

Response: We appreciate the support for our policies for new and newly merged hospitals.

As we explained in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26998), for a hospital that is subject to the trim for potentially aberrant data and is ultimately determined to be DSH-eligible at cost report settlement, its uncompensated care payment should be calculated only after the hospital's reporting of insured charity care costs on its FY 2024 Worksheet S–10 has been reviewed. Accordingly, the MAC would calculate a Factor 3 for the hospital only after reviewing the uncompensated care information reported on Worksheet S–10 of the hospital's FY 2024 cost report. Then we would calculate Factor 3 for a hospital subject to this alternative trim using the same methodology used to determine Factor 3 for new hospitals. Specifically, the numerator would reflect the uncompensated care costs reported on the hospital's FY 2024 cost report, while the denominator would reflect the sum of the uncompensated care costs reported on Worksheet S–10 of the FY 2020 cost reports of all DSH-eligible hospitals. In addition, we would apply a scaling factor, as discussed previously, to the Factor 3 calculation for the hospital. We stated that we continue to believe applying the scaling factor is appropriate for purposes of calculating Factor 3 for all hospitals, including new hospitals and hospitals that are treated as new hospitals, in order to improve consistency and predictability across all hospitals.

We did not receive any comments on the discussion of CCR trim methodology or the UCC trim methodology.

For purposes of this final rule, the statewide average CCR was applied to 7 hospitals' FY 2018 reports, of which 3 hospitals had FY 2018 Worksheet S–10 data. The statewide average CCR was applied to 13 hospitals' FY 2019 reports, of which 6 hospitals had FY 2019 Worksheet S–10 data. The statewide average CCR was applied to 10 hospitals' FY 2020 reports, of which 3 hospitals had FY 2020 Worksheet S–10 data.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26999), we stated that for purposes of this FY 2024 IPPS/LTCH PPS final rule, we intended to use data from the March 2023 HCRIS extract to calculate Factor 3. We explained that the March HCRIS extract would be the

latest quarterly HCRIS extract that would be publicly available at the time of the development of this final rule.

Regarding requests from providers to amend and/or reopen previously audited Worksheet S–10 data for the most recent 3 cost reporting years that are used in the methodology for calculating Factor 3, we noted that MACs follow normal timelines and procedures. We explained that for purposes of the Factor 3 calculation for FY 2024, any amended reports and/or reopened reports would need to have completed the amended report and/or reopened report submission processes by the end of March 2023. In other words, if the amended report and/or reopened report was not available for the March HCRIS extract, then that amended and/or reopened report data would not be a part of the FY 2024 IPPS/LTCH PPS final rule's Factor 3 calculation. We noted that the March HCRIS data extract would be available during the comment period for the proposed rule if providers want to verify that their amended and/or reopened data is reflected in the March HCRIS extract.

Comment: One commenter commended CMS for using the latest available data (*i.e.,* the December 2022 HCRIS data) for determining DSH eligibility for the proposed rule and encouraged CMS to use the latest data that may become available prior to the development of the final rule (*i.e.,* the March 2023 HCRIS update as indicated in the proposed rule) to ensure the proper allocation of uncompensated care payments.

Response: We appreciate the commenter's support for our use of a later HCRIS extract for calculating Factor 3 for FY 2024. We are using the March HCRIS extract to calculate Factor 3 for this FY 2024 IPPS/LTCH PPS final rule. We believe on balance this is the best available data for the purposes of calculating Factor 3 for FY 2024. We also intend to continue utilizing the most recent data available for the applicable rulemaking, which generally means the respective December HCRIS extract for purposes of Factor 3 calculations in future proposed rules. Furthermore, as noted in the FY 2024 IPPS/LTCH PPS proposed rule, we continue to intend to use the respective March HCRIS extract for future final rules.

d. Per Discharge Amount of Interim Uncompensated Care Payments

Since FY 2014, we have made interim uncompensated care payments during the fiscal year on a per discharge basis. Typically, we use a 3-year average of the number of discharges for a hospital to produce an estimate of the amount of the hospital's uncompensated care payment per discharge. Specifically, the hospital's total uncompensated care payment amount for the applicable fiscal year is divided by the hospital's historical 3-year average of discharges computed using the most recent available data to determine the uncompensated care payment per discharge for that fiscal year.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45247 and 45248), we modified this calculation for FY 2022 to be based on an average of FY 2018 and FY 2019 historical discharge data, rather than a 3-year average that included data from FY 2018, FY 2019, and FY 2020. We explained our belief that computing a 3-year average with the FY 2020 discharge data would underestimate discharges, due to the decrease in discharges during the COVID–19 pandemic. In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49045), we calculated interim uncompensated care payments based on the 3-year average of discharges from FY 2018, FY 2019, and FY 2021.

Consistent with the approach adopted in the FY 2023 IPPS/LTCH PPS final rule, for FY 2024, we proposed to calculate the average of FY 2019, FY 2021, and FY 2022 historical discharge data, rather than a 3-year average of the most recent 3 years of discharge data from FY 2020, FY 2021, and FY 2022. We stated that we continued to believe that computing a 3-year average using the most recent 3 years of discharge data would potentially underestimate the number of discharges for FY 2024, due to the effects of the COVID–19 pandemic during FY 2020, which was the first year of the COVID–19 pandemic. Therefore, as explained in the FY 2024 IPPS/LTCH IPPS proposed rule (88 FR 26999), we believed that our proposed approach may result in a better estimate of the number of discharges during FY 2024, for purposes of the interim uncompensated care payment calculation. In addition, we noted that including discharge data from FY 2022 to compute this 3-year average would be consistent with the proposal to use FY 2022 Medicare claims in the IPPS ratesetting, as discussed in section I.E. of the preamble of this FY 2024 IPPS/LTCH PPS final rule. As discussed in the proposed rule, we would use the resulting 3-year average of the number of discharges to calculate a per discharge payment amount that would be used to make interim uncompensated care payments to each projected DSH-eligible hospital during FY 2024. The interim uncompensated care payments made to a hospital during the fiscal year would be reconciled following the end of the year to ensure that the final payment amount is consistent with the hospital's prospectively determined uncompensated care payment for the FY 2024.

We requested comments on our proposal to use data from FY 2019, FY 2021, and FY 2022 to compute a 3-year average of the number of discharges in order to calculate the per discharge amount for purposes of making interim uncompensated care payments to projected DSH eligible hospitals during FY 2024.

Comment: Several commenters supported CMS' proposal to exclude FY 2020 data from the per-discharge amount calculation for interim uncompensated care payments. In contrast, one commenter noted that the use of FY 2019, FY 2021, and FY 2022 data would overestimate the discharge volume and decrease interim uncompensated care payments in FY 2024. The same commenter recommended alternative approaches, such as using the average of the two most recent years (FY 2020 and FY 2021) and applying a national adjustment factor to normalize the data based on projected discharge trends.

Response: We agree with the commenter that using FY 2019 data to calculate the per-discharge amount for interim uncompensated care payments may overestimate the discharge volume, in general. For example, the updated claims data used to estimate the FY 2024 discharges in the Factor 1 calculation indicate that discharge volumes are not expected to return to pre-pandemic levels during FY 2024; therefore, we believe omitting FY 2019 data from the per-discharge amount calculation for interim uncompensated care payments may more accurately estimate FY 2024 discharges. However, we note that we continue to believe the FY 2020 discharge data would underestimate discharges due to the effects of the COVID–19 PHE in FY 2020. Accordingly, to address these concerns regarding the use of FY 2019 discharge data, we are finalizing our proposal with modification, and will calculate the per-discharge amount of uncompensated care payments using FY 2021 and FY 2022 discharge data.

As we explained in the FY 2024 IPPS/LTCH PPS proposed rule, we finalized a voluntary process in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58833 and 58834), through which a hospital may submit a request to its MAC for a lower per discharge interim uncompensated care payment amount,

including a reduction to zero, once before the beginning of the Federal fiscal year and/or once during the Federal fiscal year. In conjunction with this request, the hospital must provide supporting documentation demonstrating that there would likely be a significant recoupment (for example, 10 percent or more of the hospital's total uncompensated care payment or at least $100,000) at cost report settlement if the per discharge amount is not lowered. For example, a hospital might submit documentation showing a large projected increase in discharges during the fiscal year to support reduction of its per discharge uncompensated care payment amount. As another example, a hospital might request that its per discharge uncompensated care payment amount be reduced to zero midyear if the hospital's interim uncompensated care payments during the year have already surpassed the total uncompensated care payment calculated for the hospital.

Under the policy we finalized in the FY 2021 IPPS/LTCH PPS final rule, the hospital's MAC will evaluate these requests and the supporting documentation before the beginning of the Federal fiscal year and/or with midyear requests when the historical average number of discharges is lower than the hospital's projected discharges for the current fiscal year. If following review of the request and the supporting documentation, the MAC agrees that there likely would be significant recoupment of the hospital's interim Medicare uncompensated care payments at cost report settlement, the only change that will be made is to lower the per discharge amount either to the amount requested by the hospital or another amount determined by the MAC to be appropriate to reduce the likelihood of a substantial recoupment at cost report settlement. If the MAC determines it would be appropriate to reduce the interim Medicare uncompensated care payment per discharge amount, that updated amount will be used for purposes of the outlier payment calculation for the remainder of the Federal fiscal year. We refer readers to the Addendum in this FY 2024 IPPS/LTCH PPS final rule for the steps for determining the operating and capital Federal payment rate and the outlier payment calculation. No change would be made to the total uncompensated care payment amount determined for the hospital on the basis of its Factor 3. In other words, any change to the per discharge uncompensated care payment amount would not change how the total uncompensated care payment amount will be reconciled at cost report settlement.

We received comments related to the uncompensated care payment reconciliation process.

Comment: A couple of commenters recommended that CMS use the traditional payment reconciliation process to calculate final uncompensated care payments pursuant to section 1886(r)(2) of the Act. These commenters did not object to CMS using prospective estimates, derived from the best data available, to calculate interim payments for uncompensated care costs. However, the commenters stated that interim payments should be subject to later reconciliation based on estimates derived from actual data from the applicable Federal fiscal year. These same commenters noted that CMS' failure to provide meaningful explanations for uncompensated care payment calculations is in violation of the Administrative Procedure Act. Commenters also recommended that CMS satisfy its legal obligation by providing hospitals the opportunity to review and comment on the more recent data used in rulemaking before the agency publishes the final rule.

Response: Consistent with the position that we have taken in past rulemaking, we continue to believe that applying our best estimates of the three factors used in the calculation of uncompensated care payments to determine payments prospectively is most conducive to administrative efficiency, finality, and predictability in payments (78 FR 50628; 79 FR 50010; 80 FR 49518; 81 FR 56949; 82 FR 38195; 84 FR 42373; 85 FR 58833; 86 FR 45246; and 87 FR 49046). We continue to believe that, in affording the Secretary the discretion to estimate the three factors used to determine uncompensated care payments and by including a prohibition against administrative and judicial review of those estimates in section 1886(r)(3) of the Act, Congress recognized the importance of finality and predictability under a prospective payment system. As a result, we do not agree with the commenter's suggestion that we should establish a process for reconciling our estimates of uncompensated care payments, which would be contrary to the notion of a prospective payment system. Furthermore, we note that this rulemaking has been conducted consistent with the requirements of the Administrative Procedure Act and Title XVIII of the Act. Under the Administrative Procedure Act, a proposed rule is required to include either the terms or substance of the proposed rule, or a description of the subjects and issues involved. In this case, the FY 2024 IPPS/LTCH PPS proposed rule included a detailed discussion of our proposed methodology for calculating Factor 3 and the data that would be used. We made public the best data available at the time of the proposed rule to allow hospitals to understand the anticipated impact of the proposed methodology and submit comments, and we have considered those comments in determining our final policies for FY 2024.

After consideration of the comments received, we are finalizing our proposal to follow the same methodology used in the FY 2023 IPPS/LTCH PPS final rule to calculate Factor 3 for FY 2024 using data from the most recent 3 years of audited cost reports from FY 2018, FY 2019, and 2020, based on the March 2023 HCRIS extract. In addition, we are finalizing our proposal for determining the per-discharge amount of interim uncompensated care payments with modification. Specifically, for this FY2024 IPPS/LTCH PPS final rule, we calculated the per-discharge amount of interim uncompensated care payments using the FY 2021 and FY 2022 discharge data.

e. Process for Notifying CMS of Merger Updates and To Report Upload Issues

As we have done for every proposed and final rule beginning in FY 2014, in conjunction with this final rule, we will publish on the CMS website a table listing Factor 3 for hospitals that we estimate will receive empirically justified Medicare DSH payments in FY 2024 (that is, those hospitals that will receive interim uncompensated care payments during the fiscal year), and for the remaining subsection (d) hospitals and subsection (d) Puerto Rico hospitals that have the potential of receiving an uncompensated care payment in the event that they receive an empirically justified Medicare DSH payment for the fiscal year as determined at cost report settlement. However, we note that a Factor 3 will not be published for new hospitals and hospitals that are subject to the alternative trim for hospitals with potentially aberrant data that are not projected to be DSH-eligible.

We also will publish a supplemental data file containing a list of the mergers that we are aware of and the computed uncompensated care payment for each merged hospital. In the DSH uncompensated care supplemental data file, we list new hospitals and the 11 hospitals that would be subject to the alternative trim for hospitals with potentially aberrant data that are not

projected to be DSH-eligible, with a N/A in the Factor 3 column.

Hospitals had 60 days from the date of public display of the FY 2024 IPPS/LTCH PPS proposed rule in the **Federal Register** to review the table and supplemental data file published on the CMS website in conjunction with the proposed rule and to notify CMS in writing of issues related to mergers and/or to report potential upload discrepancies due to MAC mishandling of Worksheet S–10 data during the report submission process (for example, report not reflecting audit results due to MAC mishandling, or most recent report differs from previously accepted amended report due to MAC mishandling). In the proposed rule, we stated that comments raising issues or concerns that are specific to the information included in the table and supplemental data file should be submitted by email to the CMS inbox at *Section3133DSH@cms.hhs.gov*. We indicated that we would address comments related to mergers and/or reporting upload discrepancies submitted to the CMS DSH inbox as appropriate in the table and the supplemental data file that we publish on the CMS website in conjunction with the publication of the FY 2024 IPPS/LTCH PPS final rule. We also stated that all other comments submitted in response to our proposed policies for FY 2024 must be submitted in one of the three ways found in the **ADDRESSES** section of the proposed rule before the close of the comment period in order to be assured consideration. In addition, we noted that the CMS DSH inbox is not intended for Worksheet S–10 audit process related emails, which should be directed to the MACs.

Hospitals had 15 business days from the date of public display of the FY 2023 IPPS/LTCH PPS final rule to review and submit via email any updated information on mergers and/or to report upload discrepancies (87 FR 49047). We did not receive comments during this notification period regarding mergers or data upload issues. In the FY 2023 IPPS/LTCH PPS final rule, we also noted that historical cost reports are publicly available on a quarterly basis on the CMS website for analysis and additional review of cost report data, separate from the supplemental data file published with the annual final rule.

As we have stated in previous rulemaking (see, for example, 87 FR 49046 and 86 FR 45249), in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27000), we stated our belief that hospitals have sufficient opportunity during the comment period for the proposed rule to provide information about recent and/or pending mergers and/or to report upload discrepancies. Hospitals do not enter into mergers without advanced planning. A hospital can inform CMS during the comment period for the proposed rule regarding any merger activity not reflected in supplemental file published in conjunction with the proposed rule. Therefore, for FY 2024 and subsequent fiscal years, we proposed to discontinue the 15 business day period after display of the final rule for hospitals to submit any updated information on mergers and/or to report upload discrepancies, because there will have been sufficient opportunity for hospitals to provide information on these issues during the comment period for the proposed rule. We invited public comments on this proposal.

Comment: One commenter expressed disagreement with the proposal to discontinue the 15-day period for hospitals to notify CMS of any data discrepancies after display of the final rule. This commenter asserted that the proposal affects all hospitals, not only those with recent or pending mergers. The commenter stated that the time period after the final rule is an important opportunity to address errors and/or verify the final rule's DSH Supplemental File.

Response: We appreciate this commenter sharing their concerns regarding the proposal to discontinue the 15-day period following the final rule. However, we believe the opportunity for providers to notify CMS of discrepancies during the comment period on the proposed rule affords a sufficient opportunity to address data discrepancies and mergers. In addition, we note there is a policy for determining Factor 3 for hospitals that merge after the final rule's Factor 3 calculation (*i.e.,* newly merged hospitals during FY 2024). Accordingly, we are finalizing our proposal to discontinue the notification period following display of the final rule as proposed.

F. Counting Certain Days Associated With Section 1115 Demonstration in the Medicaid Fraction

1. Background

Section 1886(d)(5)(F) of the Social Security Act (the Act) provides for additional Medicare inpatient prospective payment system (IPPS) payments to subsection (d) hospitals [208] that serve a significantly disproportionate number of low-income patients. These payments are known as the Medicare disproportionate share hospital (DSH) adjustment, and the statute specifies two methods by which a hospital may qualify for the DSH payment adjustment.

- Under the first method, hospitals that are located in an urban area and have 100 or more beds may receive a DSH payment adjustment if the hospital can demonstrate that, during its cost reporting period, more than 30 percent of its net inpatient care revenues are derived from State and local government payments for care furnished to patients with low incomes. This method is commonly referred to as the ''Pickle method.''
- The second method for qualifying for the DSH payment adjustment, which is the most common method, is based on a complex statutory formula under which the DSH payment adjustment is based on the hospital's geographic designation, the number of beds in the hospital, and the level of the hospital's disproportionate patient percentage (DPP). A hospital's DPP is the sum of two fractions: the ''Medicare fraction'' and the ''Medicaid fraction.'' The Medicare fraction (also known as the ''SSI fraction'' or ''SSI ratio'') is computed by dividing the number of the hospital's inpatient days that are furnished to patients who were entitled to both Medicare Part A and Supplemental Security Income (SSI) benefits by the hospital's total number of patient days furnished to patients entitled to benefits under Medicare Part A. The Medicaid fraction is computed by dividing the hospital's number of inpatient days furnished to patients who, for such days, were eligible for Medicaid but were not entitled to benefits under Medicare Part A, by the hospital's total number of inpatient days in the same period.

Because the DSH payment adjustment is part of the IPPS, the statutory references to ''days'' in section 1886(d)(5)(F) of the Act have been interpreted to apply only to hospital acute care inpatient days. Regulations located at 42 CFR 412.106 govern the Medicare DSH payment adjustment and specify how the DPP is calculated as well as how beds and patient days are counted in determining the Medicare DSH payment adjustment. Under § 412.106(a)(1)(i), the number of beds for the Medicare DSH payment adjustment is determined in accordance with bed counting rules for the Indirect Medical Education (IME) adjustment under § 412.105(b).

Section 1115(a) of the Act gives the Secretary the authority to approve a demonstration requested by a State which, ''in the judgment of the Secretary, is likely to assist in

[208] Defined in section 1886(d)(1)(B) of the Act.

promoting the objectives of [Medicaid.]'' In approving a section 1115 demonstration, the Secretary may waive compliance with any Medicaid State plan requirement under section 1902 of the Act to the extent and for the period he finds necessary to enable the State to carry out such project. The costs of such project that would not otherwise be included as Medicaid expenditures eligible for Federal matching under section 1903 of the Act may be regarded as such federally matchable expenditures to the extent and for the period prescribed by the Secretary.

States use section 1115(a) demonstrations to test changes to their Medicaid programs that generally cannot be made using other Medicaid authorities, including to provide health insurance to groups that generally could not or have not been made ''eligible for medical assistance under a State plan approved under title XIX'' (Medicaid benefits). These groups, commonly referred to as expansion populations or expansion waiver groups, are specific, finite groups of people defined in the demonstration approval letter and special terms and conditions for each demonstration. (We note in the discussion that follows, we use the term ''demonstration'' rather than ''project'' and/or ''waiver'' and the term ''groups'' instead of ''populations,'' as this terminology is generally more consistent with the implementation of the provisions of section 1115 of the Act. Therefore, we refer in what follows to groups extended health insurance through a demonstration as ''demonstration expansion groups.'')

2. History of 42 CFR 412.106(b)(4) and the Deficit Reduction Act of 2005

Prior to 2000, some States had chosen to only cover Medicaid populations under their State plans when State plan coverage was mandatory under the statute, and they did not provide State plan coverage for populations for whom the statute made State plan coverage optional. Instead, coverage for these optional State plan coverage groups (as well as groups not eligible for even optional coverage) could be provided through demonstrations approved under section 1115 of the Act. We referred to these demonstration groups that could have been covered under optional State plan coverage as ''hypothetical'' groups—consisting of patients that could have been but were not covered under a State plan, but that received the same or very similar package of insurance benefits under a demonstration as did individuals eligible for those benefits under the State plan. Many other States, however, still elected to cover optional State plan coverage groups under their Medicaid State plans instead of through a demonstration. In order to avoid disadvantaging hospitals in States that covered such optional State plan coverage groups under a demonstration, CMS developed a policy of counting such hypothetical group patients in the numerator of the Medicaid fraction of the Medicare DSH calculation (hereinafter, the DPP Medicaid fraction numerator) as if those patients were eligible for Medicaid.

Such demonstrations could also include individuals who could not have been covered under a State plan, such as childless adults for whom, at the time, State plan coverage was not mandatory under the statute, nor was optional State plan coverage available. We refer to these groups as ''expansion'' groups. Prior to 2000, CMS did not include expansion groups in the DPP Medicaid fraction numerator, even if individuals in that group received the same package of hospital insurance benefits under a demonstration as hypothetical groups and those eligible for Medicaid under the State plan.

On January 20, 2000, we issued an interim final rule with comment period (65 FR 3136) (hereinafter, January 2000 interim final rule), followed by a final rule issued on August 1, 2000 (65 FR 47086 through 47087), that changed the Secretary's policy on how to treat the patient days of expansion groups that received Medicaid-like benefits under a section 1115 demonstration in calculating the Medicare DSH adjustment. The policy adopted in the January 2000 interim final rule (65 FR 3136) permitted hospitals to include in the DPP Medicaid fraction numerator all patient days of groups made eligible for title XIX matching payments through a section 1115 demonstration, whether or not those individuals were, or could be made, eligible for Medicaid under a State plan (assuming they were not also entitled to benefits under Medicare Part A). Speaking literally, neither expansion groups nor hypothetical groups were in fact ''eligible for medical assistance under a State plan''—meaning neither group was eligible for Medicaid benefits. But, in CMS' view, certain section 1115 demonstrations introduced an ambiguity into the DSH statute (section 1886(d)(5)(F)(vi) of the Act) that justified including both hypothetical and expansion groups in the DPP Medicaid fraction numerator. Specifically, CMS thought it appropriate to count the days of individuals in these demonstration groups because the demonstrations provided them the same or very similar benefits as the benefits provided to Medicaid beneficiaries under the State plan. As we explained in that rule (65 FR 3137), allowing hospitals to include patient days for section 1115 demonstration expansion groups in the DPP Medicaid fraction numerator is fully consistent with the Congressional goals of the Medicare DSH payment adjustment to recognize the higher costs to hospitals of treating low-income individuals covered under Medicaid. This policy was effective for discharges occurring on or after January 20, 2000.

In the FY 2004 IPPS final rule (68 FR 45420 and 45421), we further revised our regulations to limit the types of section 1115 demonstrations for which patient days could be counted in the DPP Medicaid fraction numerator. We explained that in allowing hospitals, in our 2000 rulemaking, to include patient days of section 1115 demonstration expansion groups, our intention was to include patient days of those groups who under a demonstration receive benefits, including inpatient hospital benefits, that are similar to the benefits provided to Medicaid beneficiaries under a State plan. But within a few years, we had become aware that certain section 1115 demonstrations provided some expansion groups with benefit packages so limited that the benefits were unlike the relatively expansive health insurance (including insurance for inpatient hospital services) provided to beneficiaries under a Medicaid State plan. Thus, we explained in the FY 2004 IPPS final rule that these limited section 1115 demonstrations extend benefits only for specific services and do not include similarly expansive benefits.

In the FY 2004 IPPS final rule we specifically discussed family planning benefits offered through a section 1115 demonstration as an example of the kind of demonstration days that should not be counted in the DPP Medicaid fraction numerator because the benefits granted to the expansion group are too limited, and therefore, unlike the package of benefits received as Medicaid benefits under a State plan. Our intention in discussing family planning benefits provided under a section 1115 demonstration was not to single out family planning benefits, but instead to provide a concrete example of how the changes being made in the FY 2004 IPPS final rule would refine the Secretary's prior policy set forth in the January 2000 interim final rule (65 FR 3136). This refinement was to allow only the days of those demonstration expansion groups who are provided benefits, and specifically inpatient hospital benefits, equivalent to the

health care insurance that Medicaid beneficiaries receive under a State plan, to be included in the DPP Medicaid fraction numerator. Moreover, this example was intended to illustrate the kind of benefits offered through a section 1115 demonstration that are so limited that the patients receiving them should not be considered eligible for Medicaid for purposes of the DSH calculation.

Because of the limited nature of the Medicaid benefits provided to expansion groups under some demonstrations, as compared to the benefits provided to the Medicaid population under a State plan, we determined it was appropriate to exclude the patient days of patients provided limited benefits under a section 1115 demonstration from the determination of Medicaid days for purposes of the DSH calculation. Therefore, in the FY 2004 IPPS final rule (68 FR 45420 and 45421), we revised the language of § 412.106(b)(4)(i) to provide that for purposes of determining the DPP Medicaid fraction numerator, a patient is deemed eligible for Medicaid on a given day only if the patient is eligible for inpatient hospital services under an approved State Medicaid plan or under a section 1115 demonstration. Thus, under our current regulations, hospitals are allowed to count patient days in the DPP Medicaid fraction numerator only if they are days of patients made eligible for inpatient hospital services under either a State Medicaid plan or a section 1115 demonstration, and who are not also entitled to benefits under Medicare Part A.

In 2005, the United States Court of Appeals for the Ninth Circuit held that demonstration expansion groups receive care ''under the State plan'' and that, accordingly, our pre-2000 practice of excluding them from the DPP Medicaid fraction numerator was contrary to the plain language of the Act. Subsequently, the United States District Court for the District of Columbia reached the same conclusion, reasoning that if our policy after 2000 of counting the days of demonstration expansion groups was correct, then patients in demonstration expansion groups were necessarily ''eligible for medical assistance under a State plan'' (that is, eligible for Medicaid), and the Act had always required including their days in the Medicaid fraction.

Shortly after these court decisions, in early 2006, Congress enacted the Deficit Reduction Act of 2005 (the DRA) (Pub. L. 109–171, February 8, 2006). Section 5002 of the DRA amended section 1886(d)(5)(F)(vi) of the Act to clarify the Secretary's discretion to regard as eligible for Medicaid those not so eligible and to include in or exclude from the DPP Medicaid fraction numerator demonstration days of patients regarded as eligible for Medicaid. First, by distinguishing between ''patients *who . . . were eligible* for medical assistance under a State plan approved under subchapter XIX'' (that is, Medicaid) and ''*patients not so eligible* but who are regarded as such because they receive benefits under a demonstration project,'' section 5002(a) of the DRA clarified that groups that receive benefits through a section 1115 demonstration are not ''eligible for medical assistance under a State plan approved under title XIX.'' This provision effectively overruled the earlier court decisions that held that expansion groups were made eligible for Medicaid under a State plan. Second, the DRA stated ''the Secretary may, to the extent and for the period the Secretary determines appropriate, include patient days of patients not so eligible but who are regarded as such because they receive benefits under a demonstration project approved under title XI.'' Thus, the statute provides the Secretary the discretion to determine ''the extent'' to which patients ''not so eligible'' for Medicaid benefits ''may'' be ''regarded as'' eligible ''because they receive benefits under a demonstration project approved under title XI.'' Third, this same language provides the Secretary with further authority to determine the days of which patients regarded as being eligible for Medicaid to include in the DPP Medicaid fraction numerator and for how long.

Having provided the Secretary with the discretion to decide whether and to what extent to include patients who receive benefits under a demonstration project, Congress expressly ratified in section 5002(b) of the DRA our prior and then-current policies on counting demonstration days in the Medicaid fraction. As stated before, our pre-2000 policy was not to include in the DPP Medicaid fraction numerator days of section 1115 demonstration expansion groups unless those patients could have been made eligible for Medicaid under a State plan (the ''hypothetical'' groups). We changed that policy in 2000 to include in the DPP Medicaid fraction numerator all patient days of demonstration expansion groups made eligible for matching payments under title XIX, regardless of whether they could have been made eligible for Medicaid under a State plan. And for FY 2004, before the DRA was enacted, CMS had further refined this policy and included in the DPP Medicaid fraction numerator the days of only a small subset of demonstration expansion group patients regarded as eligible for Medicaid: those that were eligible to receive inpatient hospital insurance benefits under the terms of a section 1115 demonstration. Thus, by ratifying the Secretary's pre-2000 policy, the January 2000 interim final rule, and the FY 2004 IPPS final rule, the DRA further established that the Secretary had always had the discretion to determine which demonstration expansion group patients to regard as eligible for Medicaid and whether or not to include any of their days in the DPP Medicaid fraction numerator.

Because at the time the DRA was passed the language of § 412.106(b)(4) already addressed the treatment of section 1115 days to exclude some expansion populations that received limited health insurance benefits through the demonstration, we did not believe it was necessary to update our regulations after the DRA explicitly granted us the discretion to include or exclude section 1115 days from the Medicaid fraction of the DSH calculation. We believed instead that the language of § 412.106(b)(4) reflected our view that only those eligible to receive inpatient hospital insurance benefits under a demonstration project could be ''regarded as'' ''eligible for medical assistance'' under Medicaid. Thus, considering this history and the text of the DRA, we understand the Secretary to have broad discretion to decide (1) whether and the extent to which to ''regard as'' eligible for Medicaid because they receive benefits under a demonstration those patients ''not so eligible'' under the State plan, and (2) of such patients regarded as Medicaid eligible, the days of which types of these patients to count in the DPP Medicaid fraction numerator and for what period of time to do so.

We do not believe that either the statute or the DRA permit or require the Secretary to count in the DPP Medicaid fraction numerator days of just any patient who is in any way related to a section 1115 demonstration. Rather, section 1886(d)(5)(F)(vi) of the Act limits including days of expansion group patients to those who may be ''regarded as'' ''eligible for medical assistance under a State plan approved under title XIX.''

3. Uncompensated/Undercompensated Care Funding Pools Authorized Through Section 1115 Demonstrations

CMS's overall policy for including section 1115 demonstration days in the DPP Medicaid fraction numerator has

rested on the presumption that the demonstration provided a package of health insurance benefits that were essentially the same as what a State provided to its Medicaid population. More recently, however, section 1115 demonstrations have been used to authorize funding a limited and narrowly circumscribed set of payments to hospitals. For example, some section 1115 demonstrations include funding for uncompensated/undercompensated care pools that help to offset hospitals' costs for treating uninsured and underinsured individuals. These pools do not extend health insurance to such individuals nor are they similar to the package of health insurance benefits provided to participants in a State's Medicaid program under the State plan. Rather, such funding pools ''promote the objectives of Medicaid'' as required under section 1115 of the Act, but they do so by providing funds directly to hospitals, rather than providing health insurance to patients. These pools help hospitals that treat the uninsured and underinsured stay financially viable so they can treat Medicaid patients.

By providing hospitals payment based on their uncompensated care costs, the pools directly benefit those providers, and, in turn, albeit less directly, the patients they serve. Unlike demonstrations that expand the group of people who receive health insurance beyond those groups eligible under the State plan and unlike Medicaid itself, however, uncompensated/undercompensated care pools do not provide inpatient health insurance to patients or, like insurance, make payments on behalf of specific, covered individuals.[209] In these ways, payments from these pools serve essentially the same function as Medicaid DSH payments under sections 1902(a)(13)(A)(iv) and 1923 of the Act, which are also title XIX payments to hospitals meant to subsidize the cost of treating the uninsured, underinsured, and low-income patients and that promote the hospitals' financial viability and ability to continue treating Medicaid patients. Notably, as numerous Federal courts across the country have universally held, the patients whose care costs are indirectly offset by such *Medicaid DSH* payments are not ''eligible for medical assistance'' under the *Medicare DSH* statute and are not included in the DPP Medicaid fraction numerator. See, for example, *Adena Regional Medical Center* v. *Leavitt*, 527 F.3d 176 (D.C. Cir. 2008); *Owensboro Health, Inc.* v. *HHS*, 832 F.3d 615 (6th Cir. 2016).

We also note that demonstrations can simultaneously authorize different programs within a single demonstration, thereby creating a group of people the Secretary regards as Medicaid eligible because they receive health insurance through the demonstration, while also creating a separate category of payments that do not provide health insurance to individuals, such as uncompensated/undercompensated care pools for providers.

4. Recent Court Decisions and Rulemaking Proposals on the Treatment of 1115 Days in the Medicare DSH Payment Adjustment Calculation

Several hospitals challenged our policy of excluding uncompensated/undercompensated care days and premium assistance days from the DPP Medicaid fraction numerator, which the courts have recently decided in a series of cases.[210] These decisions held that the current language of the regulation at § 412.106(b)(4) requires CMS to count in the DPP Medicaid fraction numerator patient days for which hospitals have received payment from an uncompensated/undercompensated care pool authorized by a section 1115 demonstration, as well as days of patients who received premium assistance under a section 1115 demonstration. Interpreting this regulatory language, which was adopted before the DRA was enacted, two courts concluded that if a hospital received payment for a patient's otherwise uncompensated inpatient hospital treatment, that patient is ''eligible for inpatient hospital services'' within the meaning of the current regulation, and therefore, their patient day must be included in the DPP Medicaid fraction. Likewise, a court concluded that patients who receive premium assistance to pay for private insurance that covers inpatient hospital services are ''eligible for inpatient hospital services'' within the meaning of the current regulation, and those patient days must be counted.

As discussed previously, it was never our intent when we adopted the current language of the regulation to include in the DPP Medicaid fraction numerator days of patients that benefitted so indirectly from a demonstration. In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25459) (hereinafter, the FY 2022 proposed rule), we stated that we continued to believe, as we have consistently believed since at least 2000, that it is not appropriate to include patient days associated with funding pools and premium assistance authorized by section 1115 demonstrations in the DPP Medicaid fraction numerator because the benefits provided patients under such demonstrations are not similar to Medicaid benefits provided beneficiaries under a State plan and may offset costs that hospitals incur when treating uninsured and underinsured individuals. In the FY 2022 proposed rule, we proposed to revise our regulations to more clearly state that in order for an inpatient day to be counted in the DPP Medicaid fraction numerator, the section 1115 demonstration must provide inpatient hospital insurance benefits directly to the individual whose day is being considered for inclusion. We specifically discussed that, under the proposed change, days of patients who receive premium assistance through a section 1115 demonstration and the days of patients for which hospitals receive payments from an uncompensated/undercompensated care pool created by a section 1115 demonstration would not be included in the DPP Medicaid fraction numerator. Because neither premium assistance nor uncompensated/undercompensated care pools are inpatient hospital insurance benefits directly provided to individuals, nor are they comparable to the breadth of benefits available under a Medicaid State plan, we stated that individuals associated with such assistance and pools should not be ''regarded as'' ''eligible for medical assistance under a State plan.''

Commenters generally disagreed with our proposal, arguing that both premium assistance programs and uncompensated/undercompensated care pools are used to provide individuals with inpatient hospital services, either by reimbursing hospitals for the same services as the Medicaid program in the case of uncompensated/undercompensated care pools or by allowing individuals to purchase insurance with benefits similar to Medicaid benefits offered under a State plan in the case of premium assistance. Thus, they argued, those types of days should be included in the DPP Medicaid fraction numerator. Following review of these comments, in the final rule with comment period that appeared in the December 27, 2021 **Federal Register**, which finalized certain provisions of the

[209] For more information on this distinction, as upheld by courts, we refer readers to *Adena Regional Medical Center* v. *Leavitt,* 527 F.3d 176 (D.C. Cir. 2008), and *Owensboro Health, Inc.* v. *HHS,* 832 F.3d 615 (6th Cir. 2016).

[210] *Bethesda Health, Inc.* v. *Azar*, 980 F.3d 121 (D.C. Cir. 2020); *Forrest General Hospital* v. *Azar*, 926 F.3d 221 (5th Cir. 2019); *HealthAlliance Hospitals, Inc.* v. *Azar*, 346 F. Supp. 3d 43 (D.D.C. 2018).

FY 2022 proposed rule related to Medicare graduate medical education payments for teaching and Medicare organ acquisition payment, we stated that after further consideration of the issue we had determined not to move forward with our proposal and planned to revisit the issue of section 1115 demonstration days in future rulemaking (86 FR 73418).

After considering the comments we received in response to the FY 2022 proposed rule, in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28398) (hereinafter, the FY 2023 proposed rule), we proposed to revise our regulation to explicitly reflect our interpretation of the language ''regarded as'' ''eligible for medical assistance under a State plan approved under title XIX'' in section 1886(d)(5)(F)(vi) of the Act to mean patients who (1) receive health insurance authorized by a section 1115 demonstration or (2) patients who pay for all or substantially all of the cost of health insurance with premium assistance authorized by a section 1115 demonstration, where State expenditures to provide the health insurance or premium assistance may be matched with funds from title XIX. Moreover, of the groups we regarded as Medicaid eligible, we proposed to use our discretion under the Act to include in the DPP Medicaid fraction numerator only (1) the days of those patients who obtained health insurance directly or with premium assistance that provides essential health benefits (EHB) as set forth in 42 CFR part 440, subpart C, for an Alternative Benefit Plan (ABP), and (2) for patients obtaining premium assistance, only the days of those patients for which the premium assistance is equal to or greater than 90 percent of the cost of the health insurance, provided in either case that the patient is not also entitled to Medicare Part A (87 FR 28398 through 28402).

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49051), we noted that the agency received numerous, detailed comments on our proposal. We indicated that due to the number and nature of the comments that we received, and after further consideration of the issue, we had determined not to move forward with the FY 2023 proposal. We stated that we expected to revisit the treatment of section 1115 demonstration days for purposes of the DSH adjustment in future rulemaking (87 FR 49051).

In a proposed rule published in the **Federal Register** on February 28, 2023 (88 FR 12623), hereinafter referred to as the February 2023 proposed rule, we proposed revisions to our regulations on the counting of days associated with individuals eligible for certain benefits provided by section 1115 demonstrations in the Medicaid fraction of a hospital's disproportionate patient percentage, as discussed in greater detail below. We proposed the revised regulation would be effective for discharges occurring on or after October 1, 2023.

5. Amendment to 42 CFR 412.106(b)(4)

Consistent with our interpretation of the Medicare DSH statute over more than two decades and the history of our policy on counting section 1115 demonstration days in the DPP Medicaid fraction numerator set forth in our regulations, considering the series of adverse cases interpreting the current regulation, in light of what we proposed in the FY 2022 and FY 2023 proposed rules and our consideration of the comments we received thereon, and considering the comments we received on the February 2023 proposed rule (88 FR 12623), we are amending the regulation at § 412.106(b)(4) as proposed. In order for days associated with section 1115 demonstrations to be counted in the DPP Medicaid fraction numerator, the statute requires those days to be of patients who can be ''regarded as'' eligible for Medicaid. Accordingly, and consistent with the proposed approach set forth in the FY 2023 proposed rule and with our longstanding interpretation of the statute and as amended by the DRA, and with the current language of § 412.106(b)(4), we are modifying our regulations to explicitly state our long-held view that only patients who receive health insurance through a section 1115 demonstration where State expenditures to provide the insurance may be matched with funds from title XIX can be ''regarded as'' eligible for Medicaid.

Similar to our statements in the FY 2023 and February 2023 proposed rules, and in further considering the comments received regarding the treatment of the days of patients provided premium assistance through a section 1115 demonstration to buy health insurance, we are finalizing our proposal that such patients can also be regarded as eligible for Medicaid under section 1886(d)(5)(F)(vi) of the Act. Therefore, we are finalizing our proposal for purposes of the Medicare DSH calculation in section 1886(d)(5)(F)(vi) of the Act to ''regard as'' ''eligible for medical assistance under a State plan approved under title XIX'' patients who (1) receive health insurance authorized by a section 1115 demonstration or (2) buy health insurance with premium assistance provided to them under a section 1115 demonstration, where State expenditures to provide the health insurance or premium assistance is matched with funds from title XIX.

Furthermore, of these expansion groups we proposed to regard as eligible for Medicaid, we are finalizing our proposal to include in the DPP Medicaid fraction numerator only the days of those patients who receive from the demonstration (1) health insurance that covers inpatient hospital services or (2) premium assistance that covers 100 percent of the premium cost to the patient, which the patient uses to buy health insurance that covers inpatient hospital services, provided in either case that the patient is not also entitled to Medicare Part A.

Finally, we are finalizing our proposed amendment of the regulation to state specifically that patients whose inpatient hospital costs are paid for with funds from an uncompensated/undercompensated care pool authorized by a section 1115 demonstration are not patients ''regarded as'' eligible for Medicaid, and the days of such patients may not be included in the DPP Medicaid fraction numerator.

As discussed previously, we continue to believe it is not appropriate to include in the DPP Medicaid fraction numerator days of all patients who may benefit in some way from a section 1115 demonstration. First, we do not believe the statute permits everyone receiving a benefit from a section 1115 demonstration to be ''regarded as'' ''eligible for medical assistance under a State plan approved under title XIX'' merely because they receive a limited benefit. Second, even if the statute were so to permit, as discussed herein, the Secretary believes the DRA provides him with discretion to determine which patients ''not so eligible'' for Medicaid under a State plan may be ''regarded as'' eligible. Thus, the Secretary is regarding as Medicaid eligible only those patients who receive as ''benefits'' from a demonstration health insurance or premium assistance to buy health insurance, because—at root—''medical assistance under a State plan approved under title XIX'' provides Medicaid beneficiaries with health insurance, not simply medical care. Third, the DRA also gives the Secretary the authority to decide which days of patients ''regarded as'' Medicaid eligible to include in the DPP Medicaid fraction numerator. Using this discretion, we are including only the days of those patients who receive from a demonstration (1) health insurance that covers inpatient hospital services or (2) premium assistance that

covers 100 percent of the premium cost to the patient, which the patient uses to buy health insurance that covers inpatient hospital services, provided in either case that the patient is not also entitled to Medicare Part A.

We note this policy is a change from the proposal included in the FY 2023 proposed rule, which would have required that the insurance provide EHB and the premium assistance cover at least 90 percent of the cost of the insurance. The feedback we received on that proposal from interested parties included concerns regarding, among other issues, the burden associated with verifying whether a particular insurance program in which an individual was enrolled provided EHB, how to determine whether a particular premium assistance program covered at least 90 percent of the cost of the insurance, and the difficulty in receiving accurate information on those issues in a timely manner. In light of this feedback, the rule we proposed in February 2023 and are now finalizing maintains the policy established in the regulations at least as far back as FY 2004 that days associated with individuals who obtain health insurance from a demonstration that covers inpatient hospital services be included in the DPP Medicaid fraction numerator. We do not believe that it would be unduly difficult for providers to verify that a particular insurance program includes inpatient benefits. (We refer readers to section XII.B.2. of this final rule for more information on the burden estimate associated with this final rule.) For those individuals who buy health insurance covering inpatient hospital services using premium assistance received from a demonstration, we proposed and are finalizing that the premium assistance cover 100 percent of the individual's cost of the premium to be included in the DPP Medicaid fraction numerator. Indeed, it may be difficult to distinguish between patients who, on the one hand, receive through a demonstration health insurance for inpatient hospital services or 100 percent premium assistance to purchase health insurance and patients who, on the other hand, are eligible for medical assistance under the State plan: all patients receive health insurance paid for with title XIX funds, and all may be enrolled in a Medicaid managed care plan. In the proposal, we stated that we also do not believe that it will be difficult for providers to verify that a particular demonstration covers 100 percent of the premium cost to the patient, as it is our understanding that all premium assistance demonstrations currently meet that standard. In other words, as a practical matter, if a hospital is able to document that a patient is in a demonstration that explicitly provides premium assistance, then that documentation would also document that a patient is in a demonstration that covers 100 percent of the individual's costs of the premium. We also stated in the proposal that we believe our proposed standard of 100 percent of the premium cost to the beneficiary is appropriate because it encapsulates all current demonstrations as a practical matter. We also said that if in the future there is a demonstration that explicitly provides premium assistance that does not cover 100 percent of the individual's costs for the premium, we may revisit this issue in future rulemaking.

As we have consistently stated, individuals eligible for medical assistance under title XIX are eligible for, among other things, specific benefits related to the provision of inpatient hospital services in the form of inpatient hospital insurance. Because funding pool payments to hospitals authorized by a section 1115 demonstration do not provide health insurance to any patient, nor do the payments inure to any specific individual, uninsured patients whose costs are subsidized by uncompensated/undercompensated care pool payments to hospitals do not receive benefits to the extent that or in a manner similar to the full equivalent of ''medical assistance'' available to those eligible under a Medicaid State plan. Uninsured or underinsured individuals, whether or not they benefit from uncompensated/undercompensated care pool payments to hospitals, do not have health insurance provided by the Medicaid program. Thus, we continue to believe that patients whose costs are associated with uncompensated/undercompensated care pools may not be ''regarded as'' Medicaid-eligible, and we are using the Secretary's discretion to not regard them as such. Even if they could be so regarded and irrespective of whether the Secretary has the discretion to not regard them as such, the Secretary also is using his authority to not include the days of such patients in the DPP Medicaid fraction numerator: Such patients have not obtained insurance under the demonstration, and including all uninsured patients associated with uncompensated/undercompensated care pools could distort the Medicaid proxy in the Medicare DSH calculation that is used to determine the low-income, non-senior population a hospital serves.[211] An uninsured patient who does not pay their hospital bill (thereby creating uncompensated care for the hospital) is not necessarily a low-income patient.

Accordingly, in this rule, we are finalizing our proposal to revise our regulations at § 412.106(b)(4) to explicitly reflect our interpretation of the language ''regarded as'' ''eligible for medical assistance under a State plan approved under title XIX'' ''because they receive benefits under a demonstration project approved under title XI'' in section 1886(d)(5)(F)(vi) of the Act to mean patients provided health insurance benefits by a section 1115 demonstration. Specifically, we are finalizing our proposal to regard as Medicaid eligible for purposes of the Medicare DSH payment adjustment patients (1) who receive health insurance through a section 1115 demonstration itself or (2) who purchase health insurance with the use of premium assistance provided by a section 1115 demonstration, where State expenditures to provide the insurance or premium assistance is matchable with funds from title XIX. In addition, even if the statute would permit a broader reading, the Secretary is exercising his discretion under section 1886(d)(5)(F)(vi) of the Act to ''regard as'' Medicaid eligible only those patients. Furthermore, whether or not the Secretary has discretion to determine who is ''regarded as'' Medicaid eligible, we are using the authority provided the Secretary to limit the days of those section 1115 demonstration patients included in the DPP Medicaid fraction numerator to only those of individuals who receive from the demonstration (1) health insurance that covers inpatient hospital services or (2) premium assistance that covers 100 percent of the premium cost to the patient, which the patient uses to buy health insurance that covers inpatient hospital services, provided in either case that the patient is not also entitled to Medicare Part A. And we are finalizing our proposal to explicitly exclude from the DPP Medicaid fraction numerator the days of patients with uncompensated care costs for which a hospital is paid from a funding pool authorized by a section 1115 demonstration project.

Finally, we are finalizing as proposed that our revised regulation would be effective for discharges occurring on or after October 1, 2023. As has been our practice for more than two decades, we

[211] See, *Becerra* v. *Empire Health Foundation*, 142 S. Ct. 2354, 2358 (2022) (the Medicaid fraction counts the low-income, non-senior population).

have made our periodic revisions to the counting of certain section 1115 patient days in the Medicare DSH calculation effective based on patient discharge dates. Doing so again here treats all providers similarly and does not impact providers differently depending on their cost reporting periods.

In developing the proposal we are finalizing, we considered counting the days of patients in the DPP Medicaid fraction numerator whose inpatient hospital costs are paid for with funds from an uncompensated/undercompensated care pool authorized by a section 1115 demonstration. However, after consideration, as discussed in the proposal and in greater detail herein, because of the Secretary's interpretation of the statute and electing to exercise his discretion for policy reasons, we did not propose to include counting in the DPP Medicaid fraction numerator the days of patients whose inpatient hospital costs are paid for with funds from an uncompensated/undercompensated care pool authorized by a section 1115 demonstration. We invited public comments with regard to our statutory interpretation and our election to exercise the Secretary's authority discussed above, as well as our proposal not to count in the DPP Medicaid fraction numerator days of patients whose inpatient hospital costs are paid to hospitals from uncompensated/undercompensated care pool funds authorized by a section 1115 demonstration.

6. Responses to Comments on CMS 1788–P

In section II.E. of the February 2023 proposed rule (88 FR 12629–12632), we addressed relevant comments the agency received on the proposed rules for FY 2022 and FY 2023 on the treatment of certain 1115 days in the Medicare DSH payment adjustment calculation (86 FR 25459 and 87 FR 28398). We direct the reader to section II.E. of the February 2023 proposed rule to review those comments and responses.

The agency received several timely comments on the February 2023 proposed rule. Many commenters submitted comments similar or identical to those that were submitted on the FY 2022 and FY 2023 proposals. Some of the comments we received on the February 2023 proposed rule were out of scope of the proposal. We will keep these comments in mind for future rulemaking.

Comment: Several commenters argued that CMS is prohibited from finalizing our proposed revisions with respect to days associated with 1115 demonstrations. Many of these commenters argued that section 1886(d)(5)(F)(vi) of the Act prohibits the Secretary from distinguishing days of patients that receive *any benefit* at all under a demonstration from patients made eligible under a demonstration for health insurance coverage that includes inpatient hospital services. In addition, many of these commenters also argued that two Federal appeals courts have held that the statute requires all patients who are ''capable of receiving a demonstration project's helpful or useful effect by reason of a demonstration project's authority'' be counted in the Medicare DSH DPP Medicaid numerator, citing *Forrest General Hospital* v. *Azar,* 926 F.3d 221 (5th Cir. 2019), and *Bethesda Health, Inc.* v. *Azar,* 980 F.3d 121 (D.C. Cir. 2020). Some commenters argued that CMS was prohibited from revising our regulations in light of these court decisions and the decision in *HealthAlliance Hospitals, Inc.* v. *Azar,* 346 F. Supp. 3d 43 (D.D.C. 2018).

Response: We thank commenters for their input but we continue to believe that the language ''regarded as'' ''eligible for medical assistance under a State plan approved under title XIX'' ''because they receive benefits under a demonstration project approved under title XI,'' in section 1886(d)(5)(F)(vi) of the Act, as amended by the Deficit Reduction Act of 2005, Public Law 109–171, 120 Stat. 4, 31 (Feb. 8, 2006) (''DRA'') sec. 5002, means patients provided health insurance by a section 1115 demonstration, because health insurance is what patients covered under a Medicaid State plan receive under title XIX.

As we explained in the FY 2023 proposed rule (87 FR 28108 and 28400) and reiterated again in the February 2023 proposed rule (88 FR 12623), we believe the statutory phrase ''regarded as such'' refers to patients who are regarded as eligible for medical assistance under a State plan approved under title XIX, and therefore, should be understood to refer to patients who receive benefits that are most like those that Medicaid-eligible patients get. Patients covered by a Medicaid State plan receive a guarantee of payment for an extensive list of medical services paid for with Medicaid funds—effectively health insurance. In other words, for the purposes of Medicare DSH, patients ''regarded as'' Medicaid-eligible under a demonstration are people the Medicaid program treats as if they are eligible for Medicaid because a demonstration approved under title XI provides them the same or very similar benefits that Medicaid beneficiaries receive under the State plan, and which are paid for with Medicaid funds. Patients who do not receive the same or very similar benefits, but who might receive from a demonstration a benefit that is not effectively health insurance (such as receiving treatment at a hospital) are not ''regarded as'' Medicaid-eligible.

Moreover, we believe the DSH statute also provides the Secretary the discretion to determine which patients to ''regard[ ] as'' ''eligible for medical assistance under a State plan approved under title XIX'' and to further determine, of those ''regarded as'' Medicaid-eligible, which patient days to include in the Medicare DSH DPP Medicaid fraction numerator. Therefore, under the Secretary's discretion, we are including in the DPP Medicaid fraction numerator only patients regarded as eligible for Medicaid who are provided by a section 1115 demonstration (1) health insurance that covers inpatient hospital services or (2) premium assistance that covers 100 percent of the premium cost to the patient, which the patient uses to buy health insurance that covers inpatient hospital services, provided in either case that the patient is not also entitled to Medicare Part A.

In amending the DSH statute in 2006, Congress in section 5002 of the DRA provided the Secretary with: (1) authority to determine which types of patients extended benefits through a section 1115 demonstration to regard as eligible for Medicaid; and (2) discretion to count or not count in the DPP Medicaid fraction numerator days of patients regarded as Medicaid-eligible. We know this because, as discussed above, DRA section 5002(a) confirmed that (1) groups that receive benefits through a section 1115 demonstration are not Medicaid-eligible (meaning they do not receive benefits under a State plan), and (2) the Secretary's pre-2000 policy of excluding expansion populations from the DPP (like patients in *Portland Adventist* and *Cookville* [212] who received the same benefits as Medicaid beneficiaries, only under a demonstration) was proper under the DSH statute at the time (*i.e.,* pre-DRA amendments). Thus, section 5002(a) of the DRA effectively overturned the *Portland Adventist* and *Cookville* cases that had held demonstration expansion groups received Medicaid benefits under a State plan. And by ratifying in DRA section 5002(b) the separate policies adopted in rulemaking in

[212] *Portland Adventist Med. Ctr.* v. *Thompson,* 399 F.3d 1091, 1096 (9th Cir. 2005); *Cookeville Reg'l Med. Ctr.* v. *Thompson,* 2005 U.S. Dist. LEXIS 33351, *18 (D.D.C. Oct. 28, 2005).

January 2000 and for FY 2004, in which the Secretary first included in the DSH calculation *all days* of expansion groups and then later limited the inclusion to only the days of expansion group patients receiving coverage of inpatient hospital services, Congress affirmed that the Secretary could determine the contours and limits of what it meant under the amended statute for patients to be ''regarded as [Medicaid-eligible] because they receive benefits under a demonstration project'' and the ''extent'' to which to include the days of those patients in the DSH DPP Medicaid fraction numerator.

In light of this history, we believe that commenters' reliance on the quotation from *Portland Adventist,* to say CMS ''has refused to implement the DSH provision in conformity with the intent behind the statute'' does not reflect the statute as amended and is therefore incorrect. In amending the DSH statute in the DRA, Congress effectively overturned *Portland Adventist* and clearly stated the authority the Secretary has, and has always had, to determine whether a recipient of benefits under a section 1115 demonstration may be regarded as Medicaid-eligible and, if so, that the Secretary may decide whether to include such patient day in the DPP Medicaid fraction numerator.

As earlier noted, Section 5002(b) of the DRA ratified CMS' January 2000 policy of including *all* demonstration expansion group days in the DPP Medicaid fraction numerator as those that the Secretary regarded as days of Medicaid-eligible patients. But Congress also ratified CMS' FY 2004 policy that narrowed the type of expansion days included in the DPP Medicaid fraction numerator to only those of patients receiving coverage of inpatient hospital services. In revising the DSH regulation (42 CFR 412.106(b)(4)) for FY 2004, the agency noted that hospitals were claiming days of patients in the DPP Medicaid fraction numerator who were extended only *limited* benefits (like coverage for family planning services) by a section 1115 demonstration. Thus, in amending the DSH regulation for FY 2004 under the pre-DRA DSH statute, the Secretary affirmed his view that a patient receiving such limited benefits from a demonstration was not similar enough to a patient eligible for Medicaid under a State plan to include the demonstration patient's day in the DPP Medicaid fraction numerator. In other words, the FY 2004 rule—the current regulation we are amending in this rule—underscored the Secretary's belief that patients receiving only *some* benefit provided by a demonstration, but not the more comprehensive coverage provided under a Medicaid State plan, was not enough to regard such patient as Medicaid-eligible and to count their patient days as Medicaid days for purposes of the DSH calculation.

Moreover, by amending the DSH statute in DRA section 5002(a) to explicitly permit the Secretary to consider certain demonstration days as Medicaid days and include them in the DSH calculation, and by ratifying in section 5002(b) the Secretary's policy of including only demonstration days of patients provided select benefits (coverage of inpatient hospital services), we disagree that the DSH statute *requires* counting as Medicaid days in the DPP Medicaid fraction numerator all days of patients merely ''considered or accounted to be capable of receiving a demonstration project's helpful or useful effects,'' as some commenters assert. Rather, the DSH statute, as amended by the DRA, permits demonstration expansion groups to be ''regarded as'' Medicaid-eligible only when they get benefits similar to those of State plan beneficiaries; provides the Secretary with discretion to determine, in the context of Medicare DSH calculations, whether populations that receive benefits under a section 1115 demonstration are ''regarded as'' eligible for Medicaid; and likewise provides the Secretary further discretion to determine ''the extent'' to which the days of those regarded as Medicaid-eligible may be included in the Medicare DSH DPP Medicaid fraction numerator. Therefore, considering our prior rulemakings on this subject and Congress' intervention in enacting section 5002 of the DRA, we disagree with commenters who read section 1886(d)(5)(F)(vi) of the Act to mandate that all days of patients who may benefit in any way from a section 1115 demonstration must be included in the DSH DPP Medicaid fraction numerator.

The text of the statute also confirms the Secretary's authority in these respects. The statute clearly uses discretionary language. It specifies that ''the Secretary *may,* to the extent and for the period the Secretary determines appropriate, include patient days of patients not so eligible but who are regarded as such because they receive benefits under a demonstration project approved under title XI.'' As the Supreme Court recently explained, ''may'' is quintessentially discretionary language and has repeatedly emphasized that the use of ''may'' in a statute is intended to confer discretion rather than establish a requirement.[213] ''The use of the word 'may' . . . thus makes clear that . . . the Secretary 'has the authority, but not the duty.' '' *Lopez* v. *Davis*, 531 U.S. 230, 241 (2001). So, while the DSH statute, section 1886(d)(5)(F)(vi)(II) of the Act, specifies the DPP Medicaid fraction numerator includes the days of patients ''eligible for medical assistance under a State plan approved under title XIX,'' (if they are not also entitled to Medicare Part A), the DRA provides that the Secretary *may include* the days of those ''not so eligible'' (that is, patients not eligible for Medicaid). The additional clause ''to the extent and for the period the Secretary determines appropriate'' provides even more evidence that Congress sought to give the Secretary the authority to determine which ''patient days of patients not so eligible [for Medicaid] but who are regarded as such'' to count in the DPP Medicaid fraction numerator. In other words, the statute expressly contemplates that the Secretary *may* include the days of patients who are not actually eligible for Medicaid under the State plan but who the Secretary treats for all intents and purposes under a section 1115 demonstration as if they were so eligible. But the statute does not command that the Secretary must count such patients. Accordingly, we disagree with commenters who stated that the statute requires we count in the DPP Medicaid fraction numerator all patients who benefit in any way from a demonstration. Rather, the plain reading of the statute authorizes the Secretary to determine, as ''the Secretary determines [is] appropriate,'' whether patients are regarded as being eligible for Medicaid and, if so, ''the extent'' to which to include their days in the DPP Medicaid fraction numerator. Moreover, even if we are incorrect in interpreting the statute to give the Secretary the authority to determine what patients may be ''regarded as'' Medicaid-eligible, the statute still clearly provides the Secretary authority to choose not to include all days of patients so regarded under a demonstration.

Some commenters disagreed with this position, suggesting that all patients who benefit from a demonstration (*e.g.* even if they are uninsured or do not receive 100 percent of their premium costs as premium assistance from a demonstration) must be regarded as eligible for Medicaid and included in the DPP Medicaid fraction numerator. While it is true that courts have

[213] See *Opati* v. *Republic of Sudan,* 140 S. Ct. 1601, 1609 (2020) (The Court has ''repeatedly observed'' that ''the word 'may' clearly connotes discretion.''). See also, for example, *Weyerhaeuser Co.* v. *United States Fish & Wildlife Serv.,* 139 S. Ct. 361, 371 (2018); *Jama* v. *Immigration & Customs Enforcement,* 543 U.S. 335, 346 (2005).

interpreted the regulation we are replacing with the rule we are finalizing in that manner, we note that the current regulation was drafted prior to the enactment of DRA section 5002 and, therefore, the regulation does not interpret the language the DRA added to the Medicare statute, which, as we explain above and previously, gives the Secretary wide discretion whether to consider demonstration days as Medicaid-eligible days and whether to count them in the Medicaid fraction. Our revised regulation uses the authority granted to the Secretary under the DRA to not regard as eligible for Medicaid individuals eligible for certain 1115 demonstration benefits; and in the event they are ''regarded as'' Medicaid-eligible, the revised regulation uses the authority granted the Secretary under the DRA to not count their days in the DPP Medicaid fraction numerator.

Also, to the extent commenters read the *Forrest General* or *Bethesda* cases as interpreting section 1886(d)(5)(F)(vi) of the Act to require that any patient who benefits from an approved demonstration is ''regarded as'' eligible for Medicaid and required to be included in the DPP Medicaid fraction, as their comments suggest, we respectfully disagree with that reading of those cases. Rather, we believe the better readings of *Forrest General* and *Bethesda* are that the courts determined that days of any patient who is ''regarded as'' eligible for medical assistance under the DSH regulation (which the courts found uninsured patients to be because they received the ''benefit'' of inpatient hospital services) must be included in the Medicaid fraction. While, for the reasons already stated, we also disagree with the courts' finding that uninsured patients can be ''regarded as'' eligible for Medicaid under the current regulation, we nonetheless believe this is the better reading of the courts' decisions and, indeed, is what has led us to revising our regulations. The commenters' readings of these cases cannot square the decisions with Congress' ratification in DRA section 5002(b) of the Secretary's rulemakings that at first included all demonstration days and then excluded many types of demonstration days from the DPP Medicaid fraction numerator. Additionally, we do not believe anything in the courts' decisions, or in the *HealthAlliance* decision, limits the Secretary's authority to amend his own regulations.

We believe that the revisions we have proposed are consistent with the amended DSH statute and our authority provided thereunder and, for the reasons stated above and in the February 2023 proposed rule, we believe that days associated with uncompensated/undercompensated care pools and premium assistance demonstrations which cover less than 100 percent of the costs of the premium to the patient should not be included in the DPP Medicaid fraction numerator. We are finalizing the proposed changes to the regulation in this rule to clarify who, under1886(d)(5)(F)(vi) of the Act, as amended, the Secretary regards as eligible for Medicaid because of benefits provided by a section 1115 demonstration and which patient days the Secretary will and will not include in the Medicare DSH DPP Medicaid fraction numerator. We believe that our revisions are consistent with the statute and our statutory authority and are not precluded by the court decisions cited by the commenters.

Comment: Some commenters argued that our proposal violated the Administrative Procedure Act because it is arbitrary and capricious and irrationally overbroad.

Response: For reasons we articulated both in the February 2023 proposed rule and above, we do not believe our proposal is arbitrary, capricious or overbroad. We believe that our proposal conforms with the DSH statute, as amended, and the authority given to the Secretary under the Act as it relates to calculating a hospital's disproportionate patient percentage.

Comment: Several commenters specifically objected to our proposal to exclude from counting in the DPP Medicaid fraction numerator days associated with uncompensated/undercompensated care funding pools authorized by section 1115 demonstrations. These commenters argued that patients whose hospital costs were paid for by a section 1115 funding pool must be ''regarded as'' Medicaid-eligible under the statute because such patients ''effectively'' receive insurance paid for with Medicaid funds under section 1115 demonstrations. Thus, they assert, these uninsured patients cannot reasonably be distinguished from patients who receive insurance from the Medicaid program. Commenters also asserted in the same vein that uninsured patients receive as benefits from a demonstration's uncompensated/undercompensated funding pool program inpatient hospital services that are the same inpatient benefits that Medicaid beneficiaries receive because the inpatient care they receive from hospitals is the same.

Response: We thank commenters for their input, however we respectfully disagree with the factual predicates and the legal conclusions of these assertions. First, we disagree with the proposition that uninsured patients whose costs may be partially paid to hospitals by uncompensated/undercompensated care pools effectively have insurance which includes inpatient hospital benefits. Therefore, we do not believe that these patients are indistinguishable from Medicaid beneficiaries and expansion group patients who receive health insurance under the State plan or demonstration, respectively, and whose days the Secretary includes in the DPP Medicaid fraction numerator. Uninsured patients, unlike Medicaid or expansion group patients, do not have health insurance.

It is clear, insurance is beneficial to specific patients in ways that uncompensated/undercompensated care pool payments to hospitals are not or could not possibly be to such patients.[214] Medicaid and other forms of health insurance are not merely mechanisms of payment to providers for costs of patient care: Health insurance provides a reasonable expectation on the part of the insurance holder that they can seek treatment without the risk of financial ruin. On the other hand, hospitals may bill uninsured patients for the full cost of their care and refer their medical debts to collection agencies when they are unable to pay, even if some of their medical treatment costs may be paid to the provider by an uncompensated/undercompensated care pool. Thus, it remains the case that uninsured patients may avoid treatment for fear of being unable to pay for it. For example, if two patients receive identical care from a hospital that accepts government-funded insurance, but one of them has insurance as a Medicaid beneficiary or receives insurance through a section 1115 demonstration and, therefore, is financially protected, while the other patient is uninsured and spends years struggling to pay their hospital bill—even if the hospital receives partial payment from a demonstration-authorized uncompensated/undercompensated care pool for that patient's treatment—the two patients have not received the same ''benefit'' from the government or one that could

[214] See Health Insurance Coverage and Health—What the Recent Evidence Tells Us (*https://www.nejm.org/doi/pdf/10.1056/nejmsb1706645*); Economic and Employment Effects of Medicaid Expansion Under ARP √ Commonwealth Fund (*https://www.commonwealthfund.org/publications/issue-briefs/2021/may/economic-employmenteffects-medicaid-expansion-under-arp*). To be clear, we mention these studies only in support of our assertion that having health insurance is fundamentally different than not having insurance.

reasonably be ''regarded as'' comparable. This distinction between insured and uninsured patients is meaningful in this context, and we believe it is a sound basis on which to distinguish the treatment of patient days in the DSH calculation of uninsured patients who may in some way benefit from a section 1115 demonstration-authorized uncompensated/undercompensated care pool and the days of patients provided health insurance as a Medicaid beneficiary under a State plan or through a demonstration as part of an expansion group.

Second, we also respectfully disagree with commenters who have stated that uninsured patients whose costs may be paid to hospitals by an uncompensated/undercompensated care pool receive the same benefits as patients eligible for Medicaid because the inpatient hospital care is likely the same for both groups. As stated above, within the meaning of section 1886(d)(5)(F)(vi) of the Act, the ''benefits'' provided to the individual by Medicaid and other forms of insurance a patient receives is the promise of a payment made on behalf of a specific patient to a provider of care for providing the care, not the care itself the hospital provides. The provision of inpatient hospital services and payment for such services are two distinct issues, and because a hospital treats a patient presenting a need for medical care does not indicate anything about whether or how the hospital may be paid for providing that care. And, similarly, the fact that a demonstration provides pool funding from which hospitals may be paid in no way creates an obligation under the demonstration to provide inpatient hospital care to any individual, nor does it create a reasonable expectation on behalf of a specific individual that a hospital must treat them or that such treatment will be paid for under the demonstration. Thus, the similarity of care a patient may receive and for which a hospital may receive some payment from a demonstration's uncompensated/undercompensated care fund is irrelevant to the question of whether the ''benefits'' provided a patient ''because'' of a demonstration may be ''regarded as'' something akin to ''medical assistance under a State plan approved under title XIX'' such that the Secretary could choose to count that patient's day in the DPP Medicaid fraction numerator. And even if hospitals that receive some Medicaid funds to provide similar treatment to uninsured patients permits or requires the Secretary to regard those patients as Medicaid-eligible for DSH calculation purposes, the Secretary has still rationally distinguished such patients from Medicaid-eligible patients and is choosing not to count them in the DPP Medicaid fraction numerator.

Comment: Some commenters argued that because partial payment of costs by a demonstration's uncompensated/undercompensated care fund to hospitals for the cost of treating uninsured/underinsured patients may be ''medical assistance'' within the meaning of the Medicaid statute, that the Medicare DSH statute requires the uninsured/underinsured patient to be ''regarded as'' eligible for Medicaid and their patient days included in the DPP Medicaid fraction numerator.

Response: We disagree with the conclusion that individuals who may benefit from a demonstration's uncompensated/undercompensated care pool payments to hospitals must be ''regarded as'' eligible for Medicaid because those payments may be considered ''medical assistance'' under the Medicaid statute and that their patient days must be included in the DPP Medicaid fraction numerator. We believe this conclusion is precluded in light of Congress' amendment of the DSH statute and its ratification of the then-existing DSH regulation, which we are amending through this rule.

As discussed above, Congress ratified the Secretary's FY 2004 regulation, which limited the agency's prior DSH policy of including in the DSH DPP Medicaid fraction *all* expansion days authorized by a section 1115 demonstration. In limiting the January 2000 regulation, the agency determined a demonstration needed to extend coverage for inpatient hospital services, one form of ''medical assistance'' (under SSA section 1905(a)(1)), to individuals to include the days of such patients in the DPP Medicaid fraction numerator. As an example of the limitation promulgated in the FY 2004 rule, no longer would the Secretary consider a demonstration's provision of coverage only for family planning services sufficiently similar to the comprehensive coverage Medicaid beneficiaries receive under a State plan. Thus, despite family planning services being ''medical assistance'' under section 1905(a)(4)(C) of the Act, the FY 2004 rulemaking precluded including in the DPP Medicaid fraction numerator the days of patients receiving only that limited ''medical assistance'' under a demonstration because it was not similar enough to the medical assistance benefits Medicaid-eligible patients received. Therefore, the days of expansion group patients who only received coverage of this particular type of medical assistance (family planning services) were no longer included in the DSH DPP Medicaid fraction. Congress ratified the FY 2004 regulation, thereby confirming that not every provision of ''medical assistance'' through a section 1115 demonstration constitutes a ''benefit'' under the DSH statute that requires the Secretary to regard the recipient as Medicaid-eligible and to include the patient day in the DSH DPP Medicaid fraction. Thus, even if the ''benefit'' an uninsured patient receives because a hospital is paid something under a section 1115 demonstration for providing that patient inpatient services could be considered ''medical assistance,'' the Secretary need not regard that patient as Medicaid-eligible for DSH purposes or include their patient day in the DPP Medicaid fraction numerator.

In keeping with this view, we continue to disagree with commenters that our prior discussions of court cases like *Adena Regional Medical Center* v. *Leavitt,* 527 F.3d 176 (D.C. Cir. 2008), and *Owensboro Health, Inc.* v. *HHS,* 832 F.3d 615 (6th Cir. 2016), are irrelevant to this discussion because those cases did not involve section 1115 demonstrations. We rely on these cases to refute the idea that the provision of something beneficial—like the provision of inpatient hospital services to the uninsured—even when paid for with Medicaid funds, transforms those things into ''medical assistance'' or makes the recipient of them ''eligible for medical assistance'' as those phrases are used in the Medicaid statute. The Medicaid program can subsidize the treatment of low-income uninsured patients without making those individuals eligible for ''medical assistance.'' The phrase, ''eligible for medical assistance under a state plan approved under title XIX'' is a term of art that Congress uses to identify patients that are eligible for Medicaid. As the D.C. Circuit put the point: ''Congress has, throughout the various Medicare and Medicaid statutory provisions, consistently used the words 'eligible' to refer to potential Medicaid beneficiaries and 'entitled' to refer to potential Medicare beneficiaries.'' *Northeast Hospital Corp.* v. *Sebelius,* 657 F. 3d 1, 12, (D.C. Cir. 2011). Congress simply followed suit when referring to the two programs in the Medicare DSH DPP provisions. *Becerra* v. *Empire Health Foundation,* 142 S. Ct. 2354 (2022). Indeed, the Medicaid DSH provision in section 1923 of the Act is a good example of how a Medicaid state plan may subsidize the treatment of low-income, uninsured patients without making those

individuals eligible for ''medical assistance'' as that phrase is used in the Medicaid statute. The Courts of Appeals have repeatedly rejected lawsuits that presented some variation of the argument that when hospitals received Medicaid DSH payments—*i.e.,* payments funded by title XIX—because they incurred costs treating low-income uninsured patients, it meant that the uninsured patients treated were thereby rendered eligible for Medicaid (or received ''medical assistance''). They were not. Likewise here, a subsidy approved under section 1115 to hospitals for costs they incur in treating un- and under-insured patients—*i.e.,* in the form of title XIX payments from a section 1115-approved uncompensated care fund—does not render the patients whose cost may be covered in part by those payments eligible for ''medical assistance.'' We therefore disagree with comments suggesting that patients whose costs may be offset by demonstration-authorized pool funding to hospitals receive ''medical assistance'' within the meaning of the Medicare DSH provision at section 1886(d)(5)(F)(vi) of the Act that would require the Secretary to regard such patients as eligible for Medicaid and that those patients days must be included in the DPP Medicaid fraction numerator.

Furthermore, even if uninsured patients could be regarded as eligible for Medicaid, we would not include them in the DPP Medicaid fraction numerator for policy reasons. The DPP is intended to be a proxy calculation for the percentage of low-income patients a hospital treats. Congress has defined the proxy to count in the Medicare fraction the days of patients entitled to Medicare Part A and SSI; the days of patients not entitled to Medicare but eligible for Medicaid are counted in the Medicaid fraction. Thus, because Medicaid has never covered everyone that could be considered low-income—for instance, it generally did not cover low-income, childless adults before passage of the Affordable Care Act—therefore not every low-income patient was ever necessarily accounted for in the DPP Medicaid proxy. If we counted all uninsured patients who could be said to have benefited from an uncompensated/undercompensated care pool (whether low income patients or not, because one need not be low-income to be uninsured and leave a hospital bill unpaid), we could potentially include in the DPP proxy not just all low-income patients in States with uncompensated/undercompensated care pools, including those who have never been, and in our view should not be accounted for int the DPP Medicaid proxy, but also patients who are not low-income but who do not have insurance and did not pay their hospital bill, who we also believe should not be included in the DPP Medicaid fraction numerator. This would be a distortion from how Congress intended the DSH calculation to work, where the DPP is a proxy for the percentage of low-income patients that hospitals serve based on patients covered by Medicare or Medicaid. We note that in contrast to an individual who could afford but elects not to buy insurance and lets bills go unpaid, an individual who receives insurance coverage under Medicaid or a section 1115 demonstration, by definition, must meet low-income standards.

Comment: Some commenters pointed out that in the recently approved Texas demonstration, the Special Terms and Conditions of that program only permit payment from the approved uncompensated/undercompensated care pool for costs incurred providing medical services to uninsured individuals as ''charity care'' and thus only the hospitals' costs of patients ''who demonstrated financial need according to the provider's charity care policy'' could be paid from such fund. They assert that this undercuts the above rationale for exercising the Secretary's discretion to exclude uncompensated/undercompensated care days from inclusion in the DPP Medicaid fraction numerator.

Response: We respectfully disagree that the provision in the Texas program undercuts our rationale. As stated above, we think the fact that an individual is provided health insurance through Medicaid or a demonstration is a salient and rational basis for distinguishing individuals that should and should not count in the low-income proxy that is the DPP Medicaid fraction numerator. Moreover, a policy that incentivizes states to expand Medicaid eligibility by including in the DPP Medicaid fraction numerator only the days of patients made eligible for health insurance under a State plan or section 1115 demonstration is sound policy. And while recognizing that the objectives of the Medicaid program can be advanced through the approval of uncompensated/undercompensated care pools in section 1115 demonstration programs because they help keep hospitals financially viable to provide services to Medicaid patients, these funding pools do not provide individuals with a right to seek medical care or any guarantee that the cost of any care will be made on their behalf. Thus, we continue to believe that there is a rational basis to distinguish for Medicare payment purposes days of uninsured patients from those who receive health insurance coverage under a Medicaid State plan or section 1115 demonstration.

Also, counting all patients that may be ''capable of receiving a demonstration project's helpful or useful effect by reason of a demonstration project's authority'' in States with uncompensated/undercompensated care pools could drastically and unfairly increase DSH payments to hospitals located in States with those programs in comparison to hospitals in States without them, even though the cost burden on hospitals of treating low-income, uninsured patients might be higher in States without uncompensated/undercompensated care pools, precisely because they do not have uncompensated/undercompensated care pools. The purpose ''of the DSH provisions is not to pay hospitals the most money possible; it is instead to compensate hospitals for serving a disproportionate share of low-income patients.'' [215] We do not believe that purpose would be furthered by regarding uninsured patients associated with uncompensated/undercompensated care pool funding as if they were patients eligible for Medicaid or counting them in the DPP Medicaid fraction numerator.

Thus, while we continue to believe that the statute does not permit patients who might indirectly benefit from uncompensated/undercompensated care pool funding to be ''regarded as'' eligible for Medicaid, if the statute permits us to regard such patients as eligible for medical assistance under title XIX, the statute also provides the Secretary with the discretion to determine whether to do so. We are electing to exercise the Secretary's discretion not to regard as eligible for Medicaid patients that may indirectly benefit from uncompensated/undercompensated funding pools. In any event, we believe the statute also expressly provides the Secretary with the authority to determine whether to include patient days of patients regarded as eligible for Medicaid in the DPP Medicaid fraction numerator ''to the extent and for the period'' that the Secretary deems appropriate. Thus, we are also exercising the Secretary's discretion not to include in the DPP Medicaid fraction numerator patient days of patients associated with

[215] *Becerra* v. *Empire Health Found.,* 142 S. Ct. 2354, 2367 (2022) (emphasis added).

uncompensated/undercompensated care pool payments.

Comment: Some commenters stated that because CMS does not have evidence that uncompensated/undercompensated care pools are improperly used, we lack the authority to exclude days associated with those programs from the numerator of the Medicaid fraction.

Response: Our interpretation of the DSH statute and policy choices we are finalizing in this rule to exclude counting patient days for which hospitals are paid from demonstration-approved uncompensated/undercompensated care pools is not based on any conclusion that such funding mechanisms are being improperly used; and for the reasons previously stated, we believe we have the authority to do so. To the extent approved by a section 1115 demonstration, funding pools can play a proper role in paying hospitals with title XIX funds for uncompensated costs they incur treating un- and under-insured patients. In doing so, these funding pools can further the objectives of the Medicaid program, as required by section 1115 of the Act, by helping to financially stabilize hospitals that serve Medicaid beneficiaries. We do not, however, agree that the fact that demonstration funding pools can be used properly under section 1115 of the Act requires us, under section 1886(d)(5)(F)(vi) of the Act, to count days associated with them in the DPP Medicaid fraction numerator. As we have stated, individuals who have the cost of their care partially offset through the use of uncompensated/undercompensated care pools do not receive ''medical assistance'' that is sufficiently similar to the benefits individuals eligible for Medicaid receive under title XIX for us to regard them as eligible for Medicaid for the purposes of Medicare DSH or to count them in the DPP Medicaid fraction numerator, even if they could be regarded as Medicaid eligible under the Medicare statute.

Comment: Many commenters objected to our proposal to exercise the Secretary's discretion to limit including in the DPP Medicaid fraction numerator days of patients who receive premium assistance under a section 1115 demonstration to only the days of those patients receiving such assistance that covers 100 percent of the premium cost to the patient and that are used to buy health insurance for inpatient hospital services. Some of these commenters stated that they believe CMS has ignored the burden of this proposal on hospitals.

A commenter noted that CMS stated that ''if in the future there is a demonstration that explicitly provides premium assistance that does not cover 100 percent of the individual's costs for the premium,'' that it ''may revisit this issue in future rulemaking.'' The commenter asserted it is unclear who would furnish this data to hospitals or how hospitals would obtain the patient-specific data that they would need to prove eligibility for each patient under the proposed rule. Therefore, the commenter believes that the proposed limitation on counting patients receiving premium assistance pursuant to a section 1115 waiver is arbitrary and capricious.

Another commenter stated that CMS does not adequately consider the undue burden on hospitals to obtain the information necessary to document these proposed requirements for each patient whose patient days the hospital is seeking to include. Another commenter noted that CMS's existing regulation at § 412.106(b)(4)(iii) requires providers ''of furnishing data adequate to prove eligibility for each Medicaid patient day.'' The commenter believes that the proposal would place an undue burden on hospitals to be able to count days associated with section 1115 premium assistance programs. The commenter also noted that CMS did not address adequately how hospitals are supposed to determine how much specific patients are paying in premiums to their private health plans or how much the premium assistance under the demonstration is funding for those patients. The commenter was also concerned that CMS has not clarified how hospitals would determine if the 100 percent threshold is met, thus potentially putting at risk even those waiver days that could qualify. The commenter also noted that if all the waiver programs already satisfy the standard of 100 percent of the individual's costs of the premium, it is unclear why CMS needs a new regulation to carve out premium assistance programs that do not even exist.

Response: As we explained both herein and in our proposal, we believe that premium assistance that covers 100 percent of the costs of the premium to the patient, used to purchase health insurance coverage of inpatient hospital services is the level and type of benefit that is most similar to the benefits provided by the Medicaid program under title XIX of the Act—namely, health insurance that covers inpatient hospital benefits. Therefore, because this threshold of premium assistance to buy health insurance covering inpatient services provides the same benefit to individuals as Medicaid beneficiaries receive, albeit obtained through a slightly different mechanism, we believe it is an appropriate threshold to distinguish between individuals we will count for the purposes of calculating Medicare DSH and those we will not. Thus, we are choosing to not include in the DPP Medicaid fraction numerator the days of patients who buy insurance with demonstration-authorized premium assistance that accounts for less than 100 percent of their premium costs because the benefit the government is providing is not similar enough to that which Medicaid-eligible beneficiaries receive. Additionally, we disagree with the commenters who believe that we have ignored the burden of this proposal on providers. In our February 2023 proposal, we stated that it was our understanding that all states with current 1115 premium assistance demonstration programs provide 100 percent premium assistance to individuals; and based on this understanding we quantified as best we could that it would cost 310 hospitals a total of approximately $18,350,169 annually to determine whether a patient received under a demonstration's premium assistance program 100 percent of the cost of their premium for inpatient hospital services coverage (88 FR 12632). While commenters may disagree as to the accuracy of our estimate, we believe that our estimate was reasonable and demonstrates that the burden to providers was not ignored.

We are unsure why some commenters have significant concerns with verifying an individual's section 1115 eligibility and the amount of premium assistance when hospitals are already communicating with their state Medicaid office to verify an individual's eligibility. We do not understand why it is unclear who would furnish this data to hospitals or how hospitals would obtain the patient-specific data that they would need to prove eligibility for each patient under the proposed premium assistance rule. The states have this information as part of the section 1115 demonstration requirements. Finally, as a commenter recognizes, it remains the hospitals' burden to furnish data adequate to prove eligibility for each Medicaid patient day it claims in the DPP Medicaid fraction numerator, and we believe that the state will continue to be able to furnish hospitals with the eligibility data necessary for the hospitals to do so.

We note, as discussed below, since our proposal it has come to our attention that, in addition to the current

1115 demonstrations that all provide 100 percent premium assistance to at least some individuals, at least one demonstration—Massachusetts' discussed in more detail below—also provides a sliding scale of premium assistance to other individuals, dependent on their income levels. Therefore, we are revising our burden estimate accordingly, as discussed in more detail below in section XII.B.2. of this final rule.

Comment: One commenter stated that the proposed requirement that premium assistance fund 100 percent of an individual's health insurance premium to have that patient's inpatient hospital day included in the DPP Medicaid fraction numerator ''will complicate and negate the counting of certain Medicaid patients.'' This commentator asserts that the Massachusetts 1115 demonstration provides premium assistance to enrollees in the state's Medicaid program (MassHealth), including those who have access to employer-sponsored health insurance (ESI), and to other non-Medicaid-eligible residents who purchase health insurance in the state's health insurance exchange (Health Connector). They claim setting the threshold at 100 percent of the patient's premium costs may cause an increased burden on Massachusetts and the state's providers to determine which patients receive 100 percent premium assistance.

Response: We acknowledge the commenter appears concerned that, by finalizing the premium assistance proposal, Medicaid enrollees made to participate in the MassHealth premium assistance program, where some enrollees may be responsible for paying a small portion of premiums, would not be counted in the DPP Medicaid fraction numerator. We believe, however, that concern is unfounded. Under our proposal, the days of such Medicaid enrollees *would* be counted in the DPP Medicaid fraction numerator (assuming such enrollees are not also entitled to Medicare Part A), notwithstanding some small premium cost sharing required of the enrollees. As described by the commenter, these individuals are *Medicaid enrollees under the State plan;* the fact that the Secretary has approved a section 1115 demonstration for Massachusetts to leverage available ESI with premium assistance does not change the nature of an individual's status as a Medicaid enrollee under the State plan, and their Medicaid patient days, as they have always been, will continue to be included in the DPP Medicaid fraction numerator as a Medicaid day (assuming these enrollees are not also entitled to Medicare Part A). The requirement that the demonstration cover 100 percent of the cost of the premium to the patient only applies to individuals who are *not* eligible for Medicaid under the State plan.

We also disagree that our premium assistance proposal will unreasonably burden hospitals or the state in determining which days of patients who receive premium assistance through an 1115 demonstration may properly be included in the DPP Medicaid fraction numerator. To the extent a hospital seeks to include a day in the DPP Medicaid fraction of a Medicaid enrollee who receives premium assistance to purchase ESI, we are not aware why the hospital would bear any greater burden to determine such patient's Medicaid-enrollee status than if such patient did not receive premium assistance. These patients are entitled to Medicaid under the State plan and should therefore be identifiable in any Medicaid eligibility system a state already maintains. Nothing in the comments we received suggests otherwise.

This commenter also notes that Massachusetts's section 1115 demonstration provides premium assistance to other, non-Medicaid-eligible individuals, and that while the premium assistance covers 100 percent of the patient's premium costs for some low-income individuals, others must contribute to the cost of their premiums depending on their income level and health plan choice. The commenter is concerned because they do not believe that current eligibility systems would inform hospitals whether an enrollee in the state's health exchange had their premium entirely covered or only partially covered with premium assistance provided through the demonstration, and thus, hospitals would be burdened with attempting to obtain this information, which may not be possible unless the state were to modify its own systems that communicate with providers.

While we acknowledge that the premium assistance policy we are finalizing will lead to an increased burden on Massachusetts and providers in that state to identify which non-Medicaid-eligible patients have received premium assistance that covers 100 percent of their premium costs for that patient day to be included in the DPP Medicaid fraction, we do not believe that the burden involved is unreasonable. The commenters did not provide any supporting information as to the extent of the burden or why they believe it would be unreasonable for Massachusetts or hospitals in that state to bear such burden.

While one commenter did point to a quotation in our proposed rule to support the difficulty in obtaining the required information, we believe that this quote has been misunderstood by the commenter. The commenter quotes our proposal as ''CMS notes it may be difficult for hospitals to distinguish between patients with premium assistance paid for by Medicaid from patients who are otherwise covered by Medicaid through fee-for-service or managed care.'' In the proposal (88 FR 12628), we stated in the context of acknowledging a change in our premium assistance proposal from the FY 2023 proposed rule, which would have required premium assistance that covered at least 90 percent of the cost of the patient's premium for EHB coverage to be included in the DPP Medicaid fraction numerator, that the February 2023 proposal would require premium assistance to cover 100 percent of the patient's premium cost for inpatient hospital coverage to count. As a basis for changing our proposal, we said, ''Indeed, it may be difficult to distinguish between patients who, on the one hand, receive through a demonstration health insurance for inpatient hospital services or 100 percent premium assistance to purchase health insurance and patients who, on the other hand, are eligible for medical assistance under the State plan: all patients receive health insurance paid for with title XIX funds, and all may be enrolled in a Medicaid managed care plan.'' Our point here was to show that those patients who receive under a demonstration 100 percent premium assistance to buy health insurance that provides inpatient hospital coverage look very similar to patients who receive health insurance under either a demonstration or a Medicaid State plan, thereby establishing why we have chosen to ''regard as'' Medicaid-eligible such premium assistance recipients and to count their patient days in the Medicare DSH DPP Medicaid numerator fraction. The proposal language the commenter noted was not a statement about the ease or difficulty a hospital may have in determining which patients receive—either under a State plan or 1115 demonstration—health insurance or premium assistance that covers 100 percent of a patient's premium costs for insurance coverage of inpatient hospital services.

We do not believe it will be unreasonably difficult for providers to obtain from the state information on whether certain non-Medicaid-eligible patients qualify through the demonstration to receive premium

assistance that covers 100 percent of the cost of their premium for insurance that covers inpatient hospital services. The current Massachusetts section 1115 demonstration provides premium assistance of 100 percent of the cost of premiums to individuals making 150 percent or less of the Federal Poverty Level (FPL), and it provides a sliding scale of premium assistance to non-Medicaid-eligible residents whose income levels range from above 150 percent to over 1,000 percent FPL. (See MassHealth Medicaid and CHIP Section 1115 Demonstration (Project Number 11–W–00030/1 and 21–00071/1), Special Terms and Conditions (STCs), attachment C (Cost Sharing), *https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/ma-masshealth-ca-demstrtn-aprvl-05192023.pdf*.) As stated in the September 28, 2022 Massachusetts Demonstration Extension Approval Letter, ''to evaluate the impact of the premium policy, the Commonwealth must continue to assess beneficiary access to and utilization of health care services, enrollment continuity, number and frequency of coverage gaps, and beneficiary experiences with care.'' Therefore, to comply with the terms of the section 1115 demonstration, Massachusetts can reasonably be expected to have information on the patients extended premium assistance through the demonstration, including patients' income levels relative to FPL and thus the level of premium assistance each patient receives, and to be able to provide that information to hospitals. See *https://www.medicaid.gov/medicaid/section-1115-demonstrations/downloads/ma-masshealth-ca1.pdf*, page 14. We believe that, because the state already collects the information hospitals would need to determine which individuals receive 100 percent premium assistance for insurance coverage of inpatient hospital services, there should be no significant hurdle to hospitals obtaining this information from the state.

Comment: One commenter noted that in the proposal, CMS listed a number of states the agency believed to have a section 1115 demonstration that may be affected by the premium assistance proposal, and that this list did not include Indiana. The commenter agreed that Indiana is not among those states that operate such a demonstration. Another commenter noted that Connecticut was not among the states listed as having a section 1115 premium assistance program and requested clarification that the Connecticut program would qualify.

Response: We appreciate the commenter's thoughts on Indiana's 1115 premium assistance demonstration as it might relate to the proposal we are finalizing; we agree with the commenter that Indiana does not currently operate a section 1115 premium assistance demonstration that would be affected by the rule we proposed and are finalizing.

With respect to Connecticut, we agree with the commenter that individuals eligible for premium assistance under the current demonstration (which was approved subsequent to the issuance of the NPRM) would be ''regarded as'' eligible for Medicaid under the revisions to our regulations and included in the DPP Medicaid numerator (if not also entitled to Medicare Part A) because the demonstration covers 100 percent of the costs of the premium to individuals eligible for it. We note, however, that should the Connecticut program, or any other currently approved premium assistance program authorized under section 1115 of the Act, be revised or approved in the future so that premium assistance under the demonstration does not cover 100 percent of the costs of the premium to the individual or does not cover 100 percent of the costs of the premium for all individuals eligible for it, only the days of those individuals for whom the demonstration covers 100 percent of the cost of the premium to the individuals may be included in the DPP Medicaid fraction numerator under our revised regulations. We have added Connecticut to the list of states in the final rule that currently operate premium assistance programs authorized by section 1115 of the Act.

Comment: Some commenters suggested that the Secretary cannot finalize either the uncompensated/undercompensated care days policy or the premium assistance policy we proposed and apply them to currently approved demonstrations because of providers' reliance interests. They argue once the Secretary approves a section 1115 demonstration ''for purposes of the Medicaid program,'' it cannot exclude patient days attributable to such demonstration ''for purposes of the Medicare DSH patient percentage.'' They argue for the Secretary to do so would constitute a ''take back'' and has no basis in the text of the Medicare statute. In the alternative, some commenters stated that even if CMS had the authority to finalize the proposal with respect to currently approved demonstrations, we should not or specifically requested that we not.

Response: We respectfully disagree with the commenters' interpretation of the statute and the effects of finalizing this rule. As stated above, we believe the Medicare statute provides the Secretary with the discretion to determine what patients may be ''regarded as'' Medicaid-eligible for purposes of being counted in the Medicare DSH DPP Medicaid fraction numerator and whether to include therein any or which days of patients so regarded. The Medicaid statute, section 1115(a) of the Act, separately provides the Secretary with the authority to authorize Medicaid demonstrations that waive Medicaid requirements and provide expenditure authority to states to incur costs not permitted under a State plan so that states may experiment with ways of using Medicaid funds to ''assist in promoting the objective of'' the Medicaid program. Thus, the Medicare DSH policies finalized here will not change the terms of any current demonstration or the calculations of *Medicaid* payments made thereunder. Therefore, by going through this notice and comment rulemaking to clarify our Medicare regulation (42 CFR 412.106(b)(4)) on the treatment of section 1115 patient days in the calculation of *Medicare DSH payment adjustments,* the Secretary is not ''taking back'' any *Medicaid payments* that hospitals or states might otherwise be entitled to under an approved Medicaid section 1115 demonstration. Nor does finalizing this prospective rule unsettle any legitimate reliance interest the hospitals may otherwise have in future Medicare DSH payment adjustments. With respect to the argument that CMS should not finalize the proposal with respect to currently approved demonstrations, for the reasons explained more fully in our February 2023 proposed rule and herein, we believe that, assuming CMS has the discretion to ''regard'' uninsured individuals as eligible for Medicaid (which we do not believe we can), we believe that the better policy is to exclude their days from the DPP Medicaid fraction numerator and to also exclude days of those receiving premium assistance that is less than 100 percent of the cost of their premiums for inpatient health insurance.

Comment: Some commenters state the proposed changes will have serious financial ramifications for hospitals at a time the hospitals can least afford it. Specifically, commenters raised the financial hardships hospitals have been experiencing over the last few years due to the Covid–19 pandemic, recent inflationary cost pressures, and other causes of financial strain, to suggest that reductions in DSH payments that may result from finalizing this proposal are

''reason alone'' the proposal should be withdrawn. Some of these commenters expressed concern that the proposal would have a negative effect on health equity in general and safety net hospitals specifically. Other commenters expressed concern that the proposed changes to our regulations would make it more difficult for hospitals to participate in the 340B Program.

Response: We appreciate the points the commenters raise and are sympathetic to the financial hardships faced by many hospitals and acknowledge that the proposed revisions to the regulations affect the calculation of the disproportionate patient percentage, which in turn affects the DSH adjustment, and that a certain DSH adjustment threshold is statutorily required for participation in the 340B Program as well as the unique concerns of safety net hospitals, and health equity remains an important goal of the Secretary. We note, however, as described above, that the Secretary is constrained by the statute as to which patients can be regarded as eligible for Medicaid under a demonstration, even though they are not actually Medicaid-eligible, and therefore whether such patient days may be included in the DPP Medicaid fraction numerator in calculating any DSH payment adjustment. And even if the statute does not require the Secretary to exclude from the DPP Medicaid fraction days of uninsured patients whose hospital care is paid to hospitals from uncompensated/undercompensated care pools or days of patients who receive less in premium assistance than 100 percent of their premium costs to purchase health insurance that covers inpatient hospital care, the Secretary believes that these parameters best further the goals of the Medicare DSH payment adjustment, which is to pay hospitals extra for treating a *disproportionate share* of low income patients. Additionally, maximizing the size of Factor 1 or the number of hospitals that qualify for HRSA's 340B Program is neither required by the Medicare statute nor an appropriate policy goal of Medicare DSH policy. As the Supreme Court recently said, the purpose ''of the DSH provisions is not to pay hospitals the most money possible; it is instead to compensate hospitals for serving a disproportionate share of low-income patients.'' [216] To the extent hospitals may be suffering financially because of the COVID–19 pandemic, recent inflationary cost pressures, and other causes of financial strain, the commenters have not demonstrated whether or how such strains have had the effect of causing hospitals to treat a disproportionate share of low-income patients, and therefore it is beyond the boundaries of this rule to address such financial strain.

By using our discretion to regard as Medicaid eligible for purposes of the DPP Medicaid fraction numerator only the days of demonstration patients for which the demonstration provides health insurance or premium assistance to purchase health insurance, and to only include the days of those patients that receive from a demonstration health insurance for inpatient hospital services or premium assistance to buy inpatient hospital insurance, where the premium assistance accounts for 100 percent of the premium cost to the patient, we believe we are acting in accordance with Congress' intent to count some, but not necessarily all, low-income patients in the proxy.

For the reasons stated previously, the DRA's ratification of the Secretary's prior regulations on including or excluding demonstration group patient days from the DPP Medicaid numerator also supports the Secretary having the discretion to exclude days of uninsured patients and patients that do not receive health insurance for inpatient hospital services, and for those receiving premium assistance, where the assistance is less than 100 percent of the premium cost to the patient. By ratifying the Secretary's prior regulation that explicitly stated that our intent was to include in the fraction only the days of those that most looked like Medicaid-eligible patients, the limits we are proposing here fully align with Congress's amendment of the statute.

In summary, we proposed to revise our regulations at § 412.106(b)(4) to explicitly reflect our interpretation of the language ''regarded as'' ''eligible for medical assistance under a State plan approved under title XIX'' ''because they receive benefits under a demonstration project approved under title XI'' in section 1886(d)(5)(F)(vi) of the Act to mean patients (1) who receive health insurance through a section 1115 demonstration itself or (2) who purchase health insurance with the use of premium assistance provided by a section 1115 demonstration, where State expenditures to provide the insurance or premium assistance may be matched with funds from title XIX. Alternatively, we proposed exercising the discretion the statute provides the Secretary to limit to those two groups the patients the Secretary ''regard[s] as'' ''eligible for medical assistance under a State plan'' ''because they receive benefits under a demonstration.'' Moreover, using the Secretary's authority to determine the days of which demonstration groups ''regarded as'' Medicaid eligible to include in the DPP Medicaid fraction numerator, we proposed that only the days of those patients who receive from the demonstration (1) health insurance that covers inpatient hospital services or (2) premium assistance that covers 100 percent of the premium cost to the patient, which the patient uses to buy health insurance that covers inpatient hospital services, are to be included, provided in either case that the patient is not also entitled to Medicare Part A. Finally, we proposed exercising the Secretary's discretion to not regard as Medicaid-eligible patients whose costs are paid to hospitals from uncompensated/undercompensated care pool funds authorized by a section 1115 demonstration; and we similarly proposed exercising the Secretary's authority to exclude the days of such patients from being counted in the DPP Medicaid fraction numerator, even if those patients could be ''regarded as'' ''eligible for medical assistance under a State plan authorized by title XIX.'' Thus, we proposed explicitly excluding from counting in the DPP Medicaid fraction numerator any days of patients for which hospitals are paid from demonstration-authorized uncompensated/undercompensated care pools.

Finally, we proposed our revised regulation would be effective for discharges occurring on or after October 1, 2023. As has been our practice for more than two decades, we have made our periodic revisions to the counting of certain section 1115 patient days in the Medicare DSH calculation effective based on patient discharge dates. Doing so again here treats all providers similarly and does not impact providers differently depending on their cost reporting periods.

For all the reasons stated in the February 2023 proposal and herein, after considering the comments received on this proposal, we are finalizing the rule as proposed. We are making some minor formatting changes to the regulation text to conform to the Office of Federal Register Document Drafting Handbook. See regulations text which appears at the end of this of final rule.

[216] *Becerra* v. *Empire Health Found.,* 142 S. Ct. 2354, 2367 (2022) (emphasis added).

V. Other Decisions and Changes to the IPPS for Operating System

A. Changes to MS–DRGs Subject to Postacute Care Transfer Policy and MS–DRG Special Payments Policies (§ 412.4)

1. Background

Existing regulations at 42 CFR 412.4(a) define discharges under the IPPS as situations in which a patient is formally released from an acute care hospital or dies in the hospital. Section 412.4(b) defines acute care transfers, and § 412.4(c) defines postacute care transfers. Our policy set forth in § 412.4(f) provides that when a patient is transferred and his or her length of stay is less than the geometric mean length of stay for the MS–DRG to which the case is assigned, the transferring hospital is generally paid based on a graduated per diem rate for each day of stay, not to exceed the full MS–DRG payment that would have been made if the patient had been discharged without being transferred.

The per diem rate paid to a transferring hospital is calculated by dividing the full MS–DRG payment by the geometric mean length of stay for the MS–DRG. Based on an analysis that showed that the first day of hospitalization is the most expensive (60 FR 45804), our policy generally provides for payment that is twice the per diem amount for the first day, with each subsequent day paid at the per diem amount up to the full MS–DRG payment (§ 412.4(f)(1)). Transfer cases also are eligible for outlier payments. In general, the outlier threshold for transfer cases, as described in § 412.80(b), is equal to the fixed-loss outlier threshold for nontransfer cases (adjusted for geographic variations in costs), divided by the geometric mean length of stay for the MS–DRG, and multiplied by the length of stay for the case, plus 1 day.

We established the criteria set forth in § 412.4(d) for determining which DRGs qualify for postacute care transfer payments in the FY 2006 IPPS final rule (70 FR 47419 through 47420). The determination of whether a DRG is subject to the postacute care transfer policy was initially based on the Medicare Version 23.0 GROUPER (FY 2006) and data from the FY 2004 MedPAR file. However, if a DRG did not exist in Version 23.0 or a DRG included in Version 23.0 is revised, we use the current version of the Medicare GROUPER and the most recent complete year of MedPAR data to determine if the DRG is subject to the postacute care transfer policy. Specifically, if the MS–DRG's total number of discharges to postacute care equals or exceeds the 55th percentile for all MS–DRGs and the proportion of short-stay discharges to postacute care to total discharges in the MS–DRG exceeds the 55th percentile for all MS–DRGs, CMS will apply the postacute care transfer policy to that MS–DRG and to any other MS–DRG that shares the same base MS–DRG. The statute at subparagraph 1886(d)(5)(J) to the Act directs CMS to identify MS–DRGs based on a high volume of discharges to postacute care facilities and a disproportionate use of postacute care services. As discussed in the FY 2006 IPPS final rule (70 FR 47416), we determined that the 55th percentile is an appropriate level at which to establish these thresholds. In that same final rule (70 FR 47419), we stated that we will not revise the list of DRGs subject to the postacute care transfer policy annually unless we are making a change to a specific MS–DRG.

To account for MS–DRGs subject to the postacute care policy that exhibit exceptionally higher shares of costs very early in the hospital stay, § 412.4(f) also includes a special payment methodology. For these MS–DRGs, hospitals receive 50 percent of the full MS–DRG payment, plus the single per diem payment, for the first day of the stay, as well as a per diem payment for subsequent days (up to the full MS–DRG payment (§ 412.4(f)(6))). For an MS–DRG to qualify for the special payment methodology, the geometric mean length of stay must be greater than 4 days, and the average charges of 1-day discharge cases in the MS–DRG must be at least 50 percent of the average charges for all cases within the MS–DRG. MS–DRGs that are part of an MS–DRG severity level group will qualify under the MS–DRG special payment methodology policy if any one of the MS–DRGs that share that same base MS–DRG qualifies (§ 412.4(f)(6)).

Prior to the enactment of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), under section 1886(d)(5)(J) of the Act, a discharge was deemed a ''qualified discharge'' if the individual was discharged to one of the following postacute care settings:

- A hospital or hospital unit that is not a subsection (d) hospital.
- A skilled nursing facility.
- Related home health services provided by a home health agency provided within a timeframe established by the Secretary (beginning within 3 days after the date of discharge).

Section 53109 of the Bipartisan Budget Act of 2018 amended section 1886(d)(5)(J)(ii) of the Act to also include discharges to hospice care provided by a hospice program as a qualified discharge, effective for discharges occurring on or after October 1, 2018. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41394), we made conforming amendments to § 412.4(c) of the regulation to include discharges to hospice care occurring on or after October 1, 2018, as qualified discharges. We specified that hospital bills with a Patient Discharge Status code of 50 (Discharged/Transferred to Hospice—Routine or Continuous Home Care) or 51 (Discharged/Transferred to Hospice, General Inpatient Care or Inpatient Respite) are subject to the postacute care transfer policy in accordance with this statutory amendment.

2. Changes for FY 2024

As discussed in section II.C. of the preamble of the proposed rule and this final rule, based on our analysis of FY 2022 MedPAR claims data, we proposed to make changes to a number of MS–DRGs, effective for FY 2024. Specifically, we proposed to do the following:

- Reassign procedures describing thrombolysis when performed for pulmonary embolism from MS–DRGs 166, 167, and 168 (Other Respiratory System O.R. Procedures with MCC, with CC, and without CC/MCC, respectively) to proposed new MS–DRG 173 (Ultrasound Accelerated and Other Thrombolysis for Pulmonary Embolism).
- Create proposed new base MS–DRG 212 (Concomitant Aortic and Mitral Valve Procedures) for cases reporting an aortic valve repair or replacement procedure and a mitral valve repair or replacement procedure in addition to another concomitant cardiovascular procedure.
- Reassign the procedures involving cardiac defibrillator implants by deleting MS–DRGs 222 through 227 (Cardiac Defibrillator Implant, with and without Cardiac Catheterization, with and without AMI/HF/shock, with and without MCC, respectively) and create proposed new MS–DRG 275 (Cardiac Defibrillator Implant with Cardiac Catheterization and MCC) for cases reporting cardiac defibrillator implant with cardiac catheterization with MCC, and proposed new MS–DRGs 276 and 277 (Cardiac Defibrillator Implant with MCC and without MCC, respectively) for cases reporting cardiac defibrillator implant.
- Reassign procedures describing thrombolysis performed on peripheral vascular structures from MS–DRGs 252, 253, and 254 (Other Vascular Procedures with MCC, with CC, and without CC/MCC, respectively) to proposed new MS–DRG 278 (Ultrasound Accelerated and Other

Thrombolysis of Peripheral Vascular Structures with MCC) and proposed new MS–DRG 279 (Ultrasound Accelerated and Other Thrombolysis of Peripheral Vascular Structures without MCC).

- Create proposed MS–DRGs 323 and 324 (Coronary Intravascular Lithotripsy with Intraluminal Device with MCC and without MCC, respectively) for cases reporting C–IVL with placement of an intraluminal device, create proposed new base MS–DRG 325 (Coronary Intravascular Lithotripsy without Intraluminal Device) for cases reporting C–IVL without the placement of an intraluminal device, delete MS–DRG 246 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent with MCC or 4+ Arteries or Stents), MS–DRG 247 (Percutaneous Cardiovascular Procedures with Drug-Eluting Stent without MCC), MS–DRG 248 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent with MCC or 4+ Arteries or Stents) and MS–DRG 249 (Percutaneous Cardiovascular Procedures with Non-Drug-Eluting Stent without MCC) and create proposed new MS–DRG 321 (Percutaneous Cardiovascular Procedures with Intraluminal Device with MCC or 4+ Arteries/Intraluminal Devices) and proposed new MS–DRG 322 (Percutaneous Cardiovascular Procedures with Intraluminal Device without MCC).
- Delete MS–DRGs 338 through 340 (Appendectomy with Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) and MS–DRGs 341 through 343 (Appendectomy without Complicated Principal Diagnosis with MCC, with CC, and without CC/MCC, respectively) describing appendectomy with and without a complicated principal diagnosis and create proposed new MS–DRGs 397, 398, and 399 (Appendix Procedures with MCC, with CC, without CC/MCC, respectively).

As discussed in the proposed rule, in light of the proposed changes to the MS–DRGs for FY 2024, according to the regulations under § 412.4(d), we evaluated the MS–DRGs using the general postacute care transfer policy criteria and data from the December 2022 update of the FY 2022 MedPAR file. If an MS–DRG qualified for the postacute care transfer policy, we also evaluated that MS–DRG under the special payment methodology criteria according to regulations at § 412.4(f)(6). We continue to believe it is appropriate to assess new MS–DRGs and reassess revised MS–DRGs when proposing reassignment of procedure codes or diagnosis codes that would result in material changes to an MS–DRG. We noted that while CMS proposed the reassignment of procedure codes from MS–DRGs 252, 253, and 254 to proposed new MS–DRGs 278 and 279, we do not consider the proposed revision to constitute a material change that would warrant reevaluation of the postacute care status of MS–DRGs 252, 253, and 254. We noted this base MS–DRG (MS–DRG 252) does not currently qualify for postacute care transfer status. CMS may further evaluate what degree of shifts in cases for existing MS–DRGs warrant consideration for the review of postacute care transfer and special payment policy status in future rulemaking.

We stated that proposed new MS–DRG 276 would qualify to be included on the list of MS–DRGs that are subject to the postacute care transfer policy. As described in the regulations at § 412.4(d)(3)(ii)(D), MS–DRGs that share the same base MS–DRG will all qualify under the postacute care transfer policy if any one of the MS–DRGs that share that same base MS–DRG qualifies. We therefore proposed to add proposed new MS–DRGs 276 and 277 to the list of MS–DRGs that are subject to the postacute care transfer policy. MS–DRGs 166, 167, and 168 are currently subject to the postacute care transfer policy. As a result of our review, these MS–DRGs, as proposed to be revised, would continue to qualify to be included on the list of MS–DRGs that are subject to the postacute care transfer policy. We note that, as discussed in section II. of this final rule, we are finalizing these proposed changes to the MS–DRGs.

CMS has updated its analysis using the March 2023 update of the FY 2022 MedPAR file, and has developed the following chart which sets forth the analysis of the postacute care transfer policy criteria completed for this final rule with respect to each of these new or revised MS–DRGs. We note that this chart is updated from the MedPAR file used in the proposed rule (the December 2022 update of the FY 2022 MedPAR file).

BILLING CODE 4120–01–P

LIST OF NEW OR REVISED MS–DRGs SUBJECT TO REVIEW OF POSTACUTE CARE TRANSFER POLICY STATUS FOR FY 2024

New or Revised MS–DRG	MS–DRG Title	Total Cases	Postacute Care Transfers (55th percentile: 1,045)	Short-Stay Postacute Care Transfers	Percent of Short-Stay Postacute Care Transfers to all Cases (55th percentile: 10.5086%)	FY 2023 Postacute Transfer Policy Status	Postacute Care Transfer Policy Status
166	OTHER RESPIRATORY SYSTEM O.R. PROCEDURES WITH MCC	7,802	4,100	1,301	16.68%	Yes	Yes
167	OTHER RESPIRATORY SYSTEM O.R. PROCEDURES WITH CC	4,226	1,362	253	5.99% *	Yes	Yes**
168	OTHER RESPIRATORY SYSTEM O.R. PROCEDURES WITHOUT CC/MCC	1,464	204 *	0	0.00% *	Yes	Yes**
173	ULTRASOUND ACCELERATED AND OTHER THROMBOLYSIS WITH PRINCIPAL DIAGNOSIS PULMONARY EMBOLISM	1,542	555 *	30	1.95% *	New	No
212	CONCOMITANT AORTIC AND MITRAL VALVE PROCEDURES	900	621 *	238	26.44%	New	No
275	CARDIAC DEFIBRILLATOR IMPLANT WITH CARDIAC CATHETERIZATION AND MCC	3,488	1,635	291	8.34% *	New	No
276	CARDIAC DEFIBRILLATOR IMPLANT WITH MCC	3,848	1,781	411	10.68%	New	Yes
277	CARDIAC DEFIBRILLATOR IMPLANT WITHOUT MCC	517	280 *	65	12.57%	New	Yes**
278	ULTRASOUND ACCELERATED AND OTHER THROMBOLYSIS OF PERIPHERAL VASCULAR STRUCTURES WITH MCC	4,141	911 *	143	3.45%	New	No
279	ULTRASOUND ACCELERATED AND OTHER THROMBOLYSIS OF PERIPHERAL VASCULAR STRUCTURES WITHOUT MCC	977	298 *	42	4.30% *	New	No
321	PERCUTANEOUS CARDIOVASCULAR PROCEDURES WITH INTRALUMINAL DEVICE WITH MCC OR 4+ ARTERIES/INTRALUMINAL DEVICES	40,910	11,829	1,073	2.62% *	New	No
322	PERCUTANEOUS CARDIOVASCULAR PROCEDURES WITH INTRALUMINAL DEVICE WITHOUT MCC	56,912	5,335	566	0.99% *	New	No
323	CORONARY INTRAVASCULAR LITHOTRIPSY WITH INTRALUMINAL DEVICE WITH MCC	2,109	713 *	107	5.07% *	New	No
324	CORONARY INTRAVASCULAR LITHOTRIPSY WITH INTRALUMINAL DEVICE WITHOUT MCC	2,188	283 *	19	0.87% *	New	No
325	CORONARY INTRAVASCULAR LITHOTRIPSY WITHOUT INTRALUMINAL DEVICE	410	64 *	3	0.73% *	New	No
397	APPENDIX PROCEDURES WITH MCC	1,186	402 *	45	3.79% *	New	No
398	APPENDIX PROCEDURES WITH CC	3,838	701 *	112	2.92% *	New	No
399	APPENDIX PROCEDURES WITHOUT CC/MCC	3,094	223 *	0	0.00% *	New	No

* Indicates a current postacute care transfer policy criterion that the MS–DRG did not meet.

** As described in the policy at 42 CFR 412.4(d)(3)(ii)(D), MS–DRGs that share the same base MS–DRG will all qualify under the postacute care transfer policy if any one of the MS–DRGs that share that same base MS–DRG qualifies.

During our annual review of proposed new or revised MS–DRGs and analysis of the December 2022 update of the FY 2022 MedPAR file, we reviewed the list of proposed revised or new MS–DRGs that qualify to be included on the list of

MS–DRGs subject to the postacute care transfer policy for FY 2024 to determine if any of these MS–DRGs would also be subject to the special payment methodology policy for FY 2024. Based on our analysis of proposed changes to MS–DRGs included in the proposed rule, we determined that proposed new MS–DRG 276 meets the criteria for the MS–DRG special payment methodology. As described in the regulations at § 412.4(f)(6)(iv), MS–DRGs that share the same base MS–DRG will all qualify under the MS–DRG special payment policy if any one of the MS–DRGs that share that same base MS–DRG qualifies. Therefore, we proposed that proposed new MS–DRG 277 also would be subject to the MS–DRG special payment methodology, effective for FY 2024. For this FY 2024 final rule, we updated this analysis using data from the March 2023 update of the FY 2022 MedPAR file.

LIST OF NEW OR REVISED MS–DRGs SUBJECT TO REVIEW OF SPECIAL PAYMENT POLICY STATUS FOR FY 2024

New or Revised MS–DRG	MS–DRG Title	Geometric Mean Length of Stay	Average Charges of 1-Day Discharges	50 Percent of Average Charges for all Cases within MS–DRG	FY 2023 Special Payment Policy Status	Special Payment Policy Status
166	OTHER RESPIRATORY SYSTEM O.R. PROCEDURES WITH MCC	8.385896	$39,911	$84,881	No	No
167	OTHER RESPIRATORY SYSTEM O.R. PROCEDURES WITH CC	3.460597	$47,236	$41,988	No	No
168	OTHER RESPIRATORY SYSTEM O.R. PROCEDURES WITHOUT CC/MCC	1.837013	$45,547	$32,813	No	No
276	CARDIAC DEFIBRILLATOR IMPLANT WITH MCC	6.296602	$182,624	$132,972	New	Yes
277	CARDIAC DEFIBRILATOR IMPLANT WITHOUT MCC	3.326289	$186,031	$106,855	New	Yes*

* As described in the policy at 42 CFR 412.4(f)(6)(iv), MS–DRGs that share the same base MS–DRG will all qualify under the special payment transfer policy if any one of the MS–DRGs that share that same base MS–DRG qualifies.

Comment: One commenter, citing extremely high early stay costs, expressed concern about adding MS–DRGs 276 and 277 to the post-acute transfer policy unless the full cost of the cardiac defibrillator and the cost to implant is covered. The commenter stated that payment to the transferring hospital for these MS–DRGs would be twice the per-diem amount the first day and with each subsequent day paid at the per-diem amount up until the full MS–DRG payment.

Response: The commenter described the payment methodology under the post-acute care transfer policy. However, CMS proposed that these MS–DRGs also be added to the list of MS–DRGs subject to the special payment policy. Under this policy, the transferring hospital would receive 50 percent of the full MS–DRG payment, plus a single per diem payment, for the first day of the stay, as well as a per diem payment for subsequent days (up to the full MS–DRG payment). The intent of the special payment policy is specifically to address MS–DRGs with high initial costs, such as the one-time cost of surgically implanted devices. We believe the proposed addition of MS–DRGs 276 and 277 to the special payment policy adequately addresses the specific concerns expressed by the commenter.

After consideration of public comments we received, we are finalizing our proposal to add new MS–DRGs 276 and 277 to the list of MS–DRGs that are subject to the postacute care transfer policy and the MS–DRG special payment methodology for FY 2024.

The postacute care transfer and special payment policy status of these MS–DRGs is reflected in Table 5 associated with this final rule, which is listed in section VI. of the Addendum to this final rule and available on the CMS website.

B. Changes in the Inpatient Hospital Update for FY 2024 (§ 412.64(d))

1. FY 2024 Inpatient Hospital Update

In accordance with section 1886(b)(3)(B)(i) of the Act, each year we update the national standardized amount for inpatient hospital operating costs by a factor called the ''applicable percentage increase.'' For FY 2024, we stated in the proposed rule that we are setting the applicable percentage increase by applying the adjustments listed in this section in the same sequence as we did for FY 2023. (We note that section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.) Specifically, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we stated that we are setting the applicable percentage increase by applying the following adjustments in the following sequence. The applicable percentage increase under the IPPS for FY 2024 is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to all of the following:

- A reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act.
- A reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act.
- An adjustment based on changes in economy-wide multifactor productivity (MFP) (the productivity adjustment).

Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the

Affordable Care Act, states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

We note, in compliance with section 404 of the MMA, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45204), we replaced the 2014-based IPPS operating and capital market baskets with the rebased and revised 2018-based IPPS operating and capital market baskets beginning in FY 2022.

We proposed to base the FY 2024 market basket update used to determine the applicable percentage increase for the IPPS on IHS Global Inc.'s (IGI's) fourth quarter 2022 forecast of the 2018-based IPPS market basket rate-of-increase with historical data through third quarter 2022, which was estimated to be 3.0 percent. We also proposed that if more recent data subsequently became available (for example, a more recent estimate of the market basket update), we would use such data, if appropriate, to determine the FY 2024 market basket update in the final rule.

Comment: Several commenters stated that hospitals continue to face significant inflationary pressures. Commenters specifically expressed concern that the proposed hospital IPPS payment update for FY 2024 does not adequately consider the cost growth that hospitals have faced over the last few years, noting cost increases related to workforce (including contract labor), drugs, medical supplies, personal protective equipment (PPE), and capital investment. The commenters stated that the significant inflation over the past several years has not been fully captured by the IPPS payment updates during the COVID years.

Several commenters requested that CMS use its exceptions and adjustments authority to increase the FY 2024 IPPS hospital market basket update higher than proposed. One commenter urged CMS to review the hospital cost data and the margin on Medicare reimbursement and readjust payment rates based on the new baseline cost of care that has resulted from supply shocks and labor shortages. A few commenters suggested CMS apply a market basket increase of at least 3.8 percent, reflecting MedPAC's March 2023 Report to Congress recommending a one-percent increase to the FY 2024 market basket and requested that CMS consider a FY 2024 market basket that more accurately represents inflation on hospital expenses. One commenter supported a higher market basket payment update under the IPPS to reflect the actual effects of inflation on hospital operating costs and endorsed an annual inflation-based payment update based on the full Medicare Economic Index (MEI) while one commenter requested CMS use its authority to increase the FY 2024 IPPS hospital payment update to at least 5 percent.

Many commenters stated that they have experienced their lowest margins in decades and anticipated additional worse operating losses in at least the next two fiscal years. One commenter stated that in its March 2023 report to Congress, MedPAC reported overall Medicare hospital margins were negative 6.2 percent in 2021 (after accounting for temporary COVID–19 relief funds). Moreover, the commenter stated that MedPAC also projected hospitals' Medicare margins in 2023 to be lower than in 2021, driven in part by the growth in hospitals' input costs, which exceeded the forecasts CMS used to set Medicare payment rate updates, and in part by the expected expiration of Federal relief funds and temporary Medicare payment increases related to the public health emergency. The commenter stated that MedPAC also projects that even ''relatively efficient'' hospitals' Medicare margins will fall below break-even in 2023.

One commenter stated that while the 2022 market basket increase of 4 percent provided some relief from the additional costs of COVID–19 for 2023, the proposed FY 2024 market basket update would not carry these elevated costs associated with COVID–19 forward into 2024 even though the commenter stated that additional costs of COVID–19 still exist. The commenter noted that hospitals are now faced with rebuilding long-term funds, paying longer-term inflated costs of supplies and equipment and high wages due to the lack of staffing that still exists as a result of COVID burn out. Several commenters stated that this year's proposed update is inadequate and requested that CMS address the market basket update in the final rule.

One commenter noted that CMS proposed ''that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2024 market basket update in the final rule.'' The commenter urged CMS to use more recent data that include the recent inflationary increases in cost; and in the absence of such data urged CMS to consider an alternative approach to better align the market basket increases with increases in cost to treat patients. A few commenters appreciated the proposed payment increase but also stated agreement with other commenters that the proposed increase is inadequate given inflation and labor and supply pressures that hospitals, particularly rural hospitals, have been facing and continue to face.

Many commenters had significant concerns that the proposed IPPS payment update does not adequately reflect labor costs. Commenters stated the significant increases in labor expenses over the last couple of years have been largely driven by increased utilization of contract staff (due to workforce shortages) and growth in employee salaries. One commenter cited their own analysis of payroll data to calculate the increased cost of labor, which it stated was significantly higher than the annual increases for compensation prices that CMS finalized over the last several years. Given what they stated was the significant difference between the increased cost of labor versus what CMS estimates using the ECIs, the commenters stated they had significant concerns that CMS' data source for estimating the cost of labor does not capture current market dynamics and underestimates the actual cost of healthcare labor. Many commenters cited analysis that nursing staff shortages are predicted to continue for the next several years. Specifically, commenters raised concerns about the CMS use of the Bureau of Labor Statistics' Employment Cost Index (ECI) in the IPPS market basket. Commenters stated they believe the BLS' ECI does not accurately reflect the shift from salaried employees to contract labor since the ECI does not collect data for contract staff, and thus does not capture extraordinary labor cost growth associated with hospitals' increased reliance on clinicians contracted through staffing agencies in response to supply shortages. One commenter highlighted their belief that a closely related measure—the Employer Costs for Employee Compensation (ECEC)—may be a better and more timely data source for growth in hospital compensation costs compared to the ECI. The commenter claimed that all else equal, if the hospital ECI growth had matched the hospital ECEC growth, this would have meant an additional three percentage point increase in the IPPS hospital market basket over the 2019 to 2022 time period. Several commenters recommended that CMS use its exceptions and adjustments authority to adopt new or supplemental data sources such as commercial databases on hospital payrolls, to ensure labor costs are adequately reflected in the FY 2024 payment update in the final rule.

One commenter also requested CMS identify more accurate data inputs and use its existing authority to calculate the

final rule ''base'' (before additional adjustments) market basket update with data that better reflect the rapidly increasing input prices facing hospitals. The commenter suggested that CMS should consider using the average growth rate in allowable Medicare costs per risk adjusted discharge for IPPS hospitals between FY 2019 and FY 2021 to calculate the FY 2024 final rule market basket update rather than using the growth in the ECI as the price proxy for compensation in the IPPS market basket. The commenter requested using Medicare cost report data from Worksheets D–1, Part II, Lines 48 and 49 and S–3, Part 1, Column 13 to determine the Medicare costs per discharge. The commenter stated that this growth rate will capture the increased cost of contract labor, unlike the ECI. Based on their analysis of Medicare cost report data, they found that this methodology would yield an unadjusted market basket update of 4.39 percent for FY 2024 rather than the 2.8 percent net market basket update proposed by CMS. The commenter also stated that Medicare margins have declined over the last 20 years and believes this is due to persistently inadequate Medicare market basket updates. They further stated that hospitals' financial situations are so precarious that MedPAC recommended to Congress that it increase IPPS and OPPS payments over current law to preserve access.

Response: We acknowledge commenters' concerns regarding recent trends in inflation. Section 1886(b)(3)(B)(iii) of the Act states the Secretary shall update IPPS payments based on a market basket percentage increase based on an index of appropriately weighted indicators of changes in wages and prices that are representative of the mix of goods and services included in such inpatient hospital services. The 2018-based IPPS market basket is a fixed-weight, Laspeyres-type price index that measures the change in price, over time, of the same mix of goods and services purchased by hospitals in the base period. As we discussed in response to similar comments in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49053), the IPPS market basket increase would reflect the prospective price pressures described by the commenters as increasing during a high inflation period (such as faster wage price growth or higher energy prices), but would inherently not reflect other factors that might increase the level of costs, such as the quantity of labor used or any shifts between contract and staff nurses (which would be reflected in the Medicare cost report data). We disagree that costs as reported on the Medicare cost report are a suitable data source for determining the trend in compensation prices for the market basket update. The Medicare cost report data also reflects factors that are beyond those that impact wage or price growth. For instance, overall Medicare costs per discharge as reported by hospitals on the Medicare cost report would also reflect observed IPPS case-mix (and associated higher payments to hospitals), which from 2019 to 2022 has increased faster than in prior years and would be associated with the use of more skilled care and medical/drug supplies needed to provide these services.

Regarding commenters' request that CMS consider other methods and data sources to calculate the final rule market basket update, we believe that the 2018-based IPPS market basket continues to appropriately reflect IPPS cost structures and we believe the price proxies used (such as those from BLS that reflect wage and benefit price growth) are an appropriate representation of price changes for the inputs used by hospitals in providing services. As discussed in appendix B of this final rule, in its March report, MedPAC recommended that the Congress update the inpatient hospital rates by the amount specified in current law plus one percent. Given that we believe the 2018-based IPPS market basket reflects an index of appropriately weighted indicators of changes in wages and prices that are representative of the mix of goods and services included in such inpatient hospital services and the percentage change of the 2018-based IPPS market basket is based on IGI's more recent forecast reflecting the prospective price pressures for FY 2024, we do not believe it would be appropriate to use our exceptions and adjustment authority to create a separate payment that would have the effect of modifying the current law update.

The ECI (published by the BLS) measures the change in the hourly labor cost to employers, independent of the influence of employment shifts among occupations and industry categories. We acknowledge that the ECI measures only reflect price changes and does not capture changes in quantity or mix of labor such as increased utilization of contract staff as noted by the commenter. We believe that the ECI for hospital workers is accurately reflecting the price change associated with the labor used to provide hospital care and appropriately does not reflect other factors that might affect labor costs (such as a shift in occupations that may occur due to increases in case-mix). The ECEC data cited by the commenter is limited in its usefulness in the market basket because it reflects averages across all employees (similar to another BLS wage series, Average Hourly Earnings, available from the Current Employment Statistics program). According to BLS documentation, the ECEC reflects average compensation in the economy at a point in time, including both changes in compensation and changes in employment. The wage measure in the market basket should not reflect changes in employment to be consistent with the statute that the market basket percentage increase be based on an index of appropriately weighted indicators of changes in wages and prices. The ECEC, an indicator that also includes changes in employment, is not as appropriate to use as the ECI in the IPPS market basket. For these reasons, we believe the ECI continues to be an appropriate measure to use in the IPPS market basket.

We note that the Medicare cost report data shows contract labor hours account for about 4 percent of total compensation hours (reflecting employed and contract labor staff) for IPPS hospitals in 2021. Therefore, while we acknowledge that the ECI measures only reflect price changes for employed staff, we believe that the ECI for hospital workers is accurately reflecting the price change associated with the labor used to provide hospital care (as employed workers' hours account for 96 percent of hospital compensation hours). Therefore, we believe it continues to be an appropriate measure to use in the IPPS market basket. We also note that when developing its forecast for the ECI for hospital workers, IGI considers overall labor market conditions (including rise in contract labor employment due to tight labor market conditions) as well as trends in contract labor wages, which both have an impact on wage pressures for workers employed directly by the hospital.

We would highlight that the market basket percentage increase is a forecast of the price pressures that are expected to be faced in 2024. As projected by IGI (a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the price proxies of the market baskets) and upward price pressures are expected to slow in FY 2024 relative to FY 2022 and FY 2023. As is our general practice, we proposed that if more recent data became available, we would use such data, if appropriate, to derive the final FY 2024 IPPS market basket update for the final rule. We appreciate the commenter's concern regarding inflationary pressure and the request to use more recent data to determine the

FY 2024 IPPS market basket update. For this final rule, we are incorporating a projection of the 2018-based IPPS market basket that is based on the most recent forecast from IHS Global Inc. For this final rule, based on the more recent IGI second quarter 2023 forecast with historical data through the first quarter of 2023, the projected 2018-based IPPS market basket increase factor for FY 2024 is 3.3 percent, which is 0.3 percentage point higher than the projected FY 2024 market basket increase factor in the proposed rule based on IGI's fourth quarter 2022 forecast, and reflects a projected increase in compensation prices of 4.3 percent. We would note that the 10-year historical average (2013–2022) growth rate of the 2018-based IPPS market basket is 2.5 percent reflecting a 10-year historical average (2013–2022) growth rate compensation prices equal to 2.4 percent.

Comment: One commenter recommended that CMS reevaluate the data sources it uses for rebasing its market basket and calculating the annual market basket update, including labor costs. They strongly encouraged CMS to adopt new or supplemental data sources in future rulemaking that more accurately reflect the costs to hospitals, such as through use of more real time data from the hospital community. They stated that they believe that the current market basket does not account for the higher costs of contract labor, which has become more common in hospitals in an era of clinical labor shortages. One commenter requested that CMS rebase the market baskets more frequently and at least every three years to ensure the market basket reflects the appropriate mix of services provided to Medicare beneficiaries.

Response: CMS appreciates the commenter's request to rebase more frequently. Section 404 of Public Law 108–173 states the Secretary shall establish a frequency for revising the cost weights of the IPPS market basket more frequently than once every 5 years. As published in the FY 2006 IPPS final rule (70 FR 47403), we established a rebasing frequency of every four years, in part because the cost weights obtained from the Medicare cost reports do not indicate much of a change in the weights from year to year. The most recent rebasing of the IPPS market basket was for the FY 2022 payment update and reflected a base year of 2018 costs. Given recent concerns raised by commenters regarding changes in costs as a result of recent inflation and the COVID–19 pandemic, we also have been regularly monitoring the Medicare cost report data to assess whether a rebasing is technically appropriate, and we will continue to do so in the future. Based on a preliminary analysis of the Medicare cost report data for IPPS hospitals for 2021 that became available for this final rule, the IPPS compensation cost weight for 2021 is estimated to be about 1 percentage point lower than the 2018-based IPPS market basket compensation cost weight of 53.0 percent, and reflects a combined decrease in the salary and benefit cost weights that is larger than the increase in the contract labor cost weight. The major cost categories that preliminarily show an increase in the cost weight over this period are pharmaceuticals (proxied by the PPI—Commodity—Special Index—Pharmaceuticals for human use, prescription) and home office contract labor compensation costs (which would be proxied by the ECI for Professional and Related workers). We plan to review the 2021 Medicare cost report data in more detail as well as 2022 Medicare cost report data as soon as complete information is available and evaluate these data for future rebasing of the IPPS market basket.

Regarding the comment about using new or supplemental data sources in future rulemaking, we believe the Medicare cost report data is the most complete, timely and relevant data source for the development of the cost weights. We also welcome feedback on alternative publicly available data sources that could be used to evaluate the cost conditions facing hospitals and the subsequent derivation of the market basket cost weights.

Comment: Several commenters, including many associations, urged CMS to use its special exceptions and adjustments authority under section 1886(d)(5)(I)(i) of the Act to implement a retrospective adjustment for FY 2024 to account for the difference between the market basket update that was implemented for FY 2022 and what the currently projected market basket is for FY 2022. Commenters stated this is, in large part, because the market basket is a time-lagged estimate that cannot fully account for unexpected changes that occur, such as historic inflation and increased labor and supply costs. They stated this is exactly what occurred at the end of the calendar year 2021 into calendar year 2022, which resulted in a large forecast error in the FY 2022 market basket update. Commenters stated the IPPS reimbursement has failed to keep pace with inflation as costs for drugs, supplies, insurance premiums, and labor have increased. They recommended that CMS utilize the FY 2024 update to include a retrospective adjustment and methodology change to make the FY 2022 actual 5.7 percent market basket percentage increase to be more reflective of the costs hospitals face, including the true impact of inflation. One commenter also urged CMS to reflect the forecast error in FY 2022 as well as an additional 1.0 percent on top of the proposed FY 2024 market basket increase. One commenter requested that CMS use its special exceptions and adjustment authority to make a one-time retrospective adjustment of 10–15 percent to the market basket to account for what it stated hospitals should have received in 2022 when accounting for inflation, while another commenter stated that at a minimum, CMS should address what it stated was the gross underpayment that occurred in FY 2022 via a one-time adjustment of at least 3 percent.

One commenter urged CMS to use its exceptions and adjustments authority to apply a one-time adjustment to course correct for its significantly lower estimates of costs for FY 2021 through FY 2023. The commenter stated that because the annual payment update builds on the prior year's payment rate, failing to correct what it described as CMS' gross underestimation of the payment updates during the pandemic will further perpetuate inaccuracies in the payment rate moving forward, resulting in a permanent cut to hospital payments. Similarly, another commenter stated that in three of the last five years for which they had data to compare, they observed that the forecasted hospital market basket data used to set IPPS payment rates has fallen short of actual market basket data. They estimated, based on actual expenditure data from the 2023 Medicare Trustees Report, that in 2021 hospitals may have lost nearly $1 billion and in 2022 hospitals may have lost more than $4 billion as a result of the forecast error assumptions.

Several commenters suggested CMS should consider implementing a market basket forecast error adjustment within the methodology for calculating the annual IPPS payment update. One commenter stated that this change would reduce the risk hospitals face when rapid inflation causes CMS's forecasted hospital market basket percentage increase to be out of alignment with the actual hospital market basket percentage increase. One commenter stated that CMS should do so if forecast error is more than 0.5 percentage point while another commenter recommended a threshold of 1.5 percentage points. One commenter stated that unlike other industries, hospitals cannot simply raise prices to

bring in additional revenue, but rather can only bring in additional revenue by renegotiating higher payments with employers and health insurers, something that is increasingly difficult in the current fiscal environment. They stated that if hospitals are unable to grow revenue from other sources, they must make cuts to important service lines just like any other business to remain financially viable.

One commenter also noted that for both the SNF PPS and the capital IPPS, CMS is making the forecast error adjustments based on a threshold level of difference between the update and the market basket that was adopted through rulemaking in prior years.

Response: While the projected IPPS hospital market basket updates for FY 2021 and FY 2022 were under forecast (actual increases less forecasted increases were positive), this was largely due to unanticipated inflationary and labor market pressures as the economy emerged from the COVID–19 PHE. However, an analysis of the forecast error of the IPPS market basket over a longer period of time shows the forecast error has been both positive and negative. For example, the 10-year cumulative forecast error showed a negative forecast error (that is, forecasted increases were greater than actual increases) of 1.1 percentage points (2013 through 2022). In addition, for each year from 2012 through 2020, the forecasted FY hospital market basket update implemented in the final rule was higher than the actual hospital market basket update once historical data were available, with 7 out of the 9 years having a negative forecast error greater than 0.5 percentage point (in absolute terms). Only considering the forecast error for years when the final hospital market basket update was lower than the actual market basket update does not consider the numerous years that providers benefited from the forecast error. Relatedly, the capital PPS and SNF PPS forecast error adjustments were adopted very early in both payment systems and, unlike what commenters are requesting here for the IPPS, forecast errors over many years have been consistently addressed within each of the Capital PPS and SNF PPS

For these reasons, we do not believe it is appropriate to include adjustments to the market basket update for future years based on the difference between the actual and forecasted market basket increase in prior years. We thank the commenters for their comments. After consideration of the comments received and consistent with our proposal, we are finalizing to use more recent data to determine the FY 2024 market basket update for the final rule. Specifically, based on more recent data available, we determined final applicable percentage increases to the standardized amount for FY 2024, as specified in the table that appears later in this section.

In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51689 through 51692), we finalized our methodology for calculating and applying the productivity adjustment. As we explained in that rule, section 1886(b)(3)(B)(xi)(II) of the Act, as added by section 3401(a) of the Affordable Care Act, defines this productivity adjustment as equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business MFP (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). The U.S. Department of Labor's Bureau of Labor Statistics (BLS) publishes the official measures of private nonfarm business productivity for the U.S. economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) was published by BLS as private nonfarm business multifactor productivity. Beginning with the November 18, 2021, release of productivity data, BLS replaced the term multifactor productivity (MFP) with total factor productivity (TFP). BLS noted that this is a change in terminology only and will not affect the data or methodology. As a result of the BLS name change, the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) is now published by BLS as private nonfarm business total factor productivity. However, as mentioned, the data and methods are unchanged. Please see *www.bls.gov* for the BLS historical published TFP data. A complete description of IGI's TFP projection methodology is available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch*. In addition, we note that beginning with the FY 2022 IPPS/LTCH PPS final rule, we refer to this adjustment as the productivity adjustment rather than the MFP adjustment to more closely track the statutory language in section 1886(b)(3)(B)(xi)(II) of the Act. We note that the adjustment continues to rely on the same underlying data and methodology.

For FY 2024, we proposed a productivity adjustment of 0.2 percent. Similar to the proposed market basket update, for the proposed rule, the estimate of the proposed FY 2024 productivity adjustment was based on IGI's fourth quarter 2022 forecast. As noted previously, we proposed that if more recent data subsequently became available, we would use such data, if appropriate, to determine the FY 2024 productivity adjustment for the final rule.

Comment: Several commenters expressed concern about the application of the productivity adjustment, stating that the PHE has had unimaginable impacts on hospital productivity. They state that even before the PHE, OACT indicated that hospital productivity will be less than the general economy-wide productivity, which is the measure that is required by law to be used to derive the productivity adjustment. Given that CMS is required by statute to implement a productivity adjustment to the market basket update, commenters asked the agency to work with Congress to permanently eliminate what they stated is an unjustified reduction to hospital payments. Further, they asked CMS to use its ''exceptions and adjustments'' authority to remove the productivity adjustment for any fiscal year that was covered under PHE determination (*i.e.,* 2020 (0.4 percent), 2021 (0.0 percent), 2022 (0.7 percent), and 2023 (0.3 percent) from the calculation of the market basket update for FY 2024 and any year thereafter. A few commenters expressed concerns about the proposed productivity adjustment given the extreme and uncertain circumstances under which hospitals and health systems are currently operating and urged CMS to eliminate the productivity cut for FY 2024.

Response: While we appreciate the commenters' concerns, section 1886(b)(3)(B)(xi) of the Act requires the application of the productivity adjustment. As required by statute, the FY 2024 productivity adjustment is derived based on the 10-year moving average growth in economy-wide productivity for the period ending FY 2024.

We thank the commenters for their comments. After consideration of the comments received and consistent with our proposal, we are finalizing as proposed to use more recent data to determine the FY 2024 productivity adjustment for the final rule.

Based on more recent data available for this FY 2024 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2023 forecast of the 2018-based IPPS market basket rate-of-increase with historical data through the first quarter of 2023), we estimate that the FY 2024 market basket update used to determine the applicable percentage increase for the IPPS is 3.3 percent. Based on more

recent data available for this FY 2024 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2023 forecast of the productivity adjustment), the current estimate of the productivity adjustment for FY 2024 is 0.2 percentage point.

As previously discussed, based on the more recent data available, for this final rule, we have determined four final applicable percentage increases to the standardized amount for FY 2024. For FY 2024, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the standardized amount, as specified in this table.

FY 2024 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS

FY 2024	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	3.3	3.3	3.3	3.3
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	-0.825	-0.825
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	-2.475	0.0	-2.475
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.2	-0.2	-0.2	-0.2
Applicable Percentage Increase Applied to Standardized Amount	**3.1**	**0.625**	**2.275**	**-0.2**

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42344), we revised our regulations at 42 CFR 412.64(d) to reflect the current law for the update for FY 2020 and subsequent fiscal years. Specifically, in accordance with section 1886(b)(3)(B) of the Act, we added paragraph (d)(1)(viii) to § 412.64 to set forth the applicable percentage increase to the operating standardized amount for FY 2020 and subsequent fiscal years as the percentage increase in the market basket index, subject to the reductions specified under § 412.64(d)(2) for a hospital that does not submit quality data and § 412.64(d)(3) for a hospital that is not a meaningful EHR user, less a productivity adjustment. (As previously noted, section 1886(b)(3)(B)(xii) of the Act required an additional reduction each year only for FYs 2010 through 2019.)

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Therefore, the update to the hospital-specific rates for SCHs and MDHs also is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. As discussed in section V.F. of the preamble of this final rule, section 4102 of the Consolidated Appropriations Act, 2023 (Public Law 117–328), enacted on December 29, 2022, extended the MDH program through FY 2024 (that is, for discharges occurring on or before September 30, 2024). We refer readers to section V.F. of the preamble of this final rule for further discussion of the MDH program.

For FY 2024, we proposed the following updates to the hospital-specific rates applicable to SCHs and MDHs: A proposed update of 2.8 percent for a hospital that submits quality data and is a meaningful EHR user; a proposed update of 0.55 percent for a hospital that submits quality data and is not a meaningful EHR user; a proposed update of 2.05 percent for a hospital that fails to submit quality data and is a meaningful EHR user; and a proposed update of −0.2 percent for a hospital that fails to submit quality data and is not an meaningful EHR user. We proposed that if more recent data subsequently became available (for example, a more recent estimate of the market basket update and the productivity adjustment), we would use such data, if appropriate, to determine the update in the final rule.

We did not receive any public comments on our proposed updates to hospital-specific rates applicable to SCHs and MDHs. The general comments we received on the proposed FY 2024 update (including the proposed market basket update and productivity adjustment) are discussed earlier in this section. For FY 2024, we are finalizing the proposal to determine the update to the hospital specific rates for SCHs and MDHs in this final rule using the more recent available data, as previously discussed.

For this final rule, based on more recent available data we are finalizing the following updates to the hospital specific rates applicable to SCHs and MDHs (the same update factor as for all other hospitals subject to the IPPS, consistent with the applicable percentage increases for the IPPS): An update of 3.1 percent for a hospital that submits quality data and is a meaningful EHR user; an update of 0.625 percent for a hospital that submits quality data and is not a meaningful EHR user; an update of 2.275 percent for a hospital that fails to submit quality data and is a meaningful EHR user; and an update of −0.2 percent for a hospital that fails to submit quality data and is not a meaningful EHR user.

2. FY 2024 Puerto Rico Hospital Update

Section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that subsection (d) Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016. In addition, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act

apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. Accordingly, for FY 2022, section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that any subsection (d) Puerto Rico hospital that is not a meaningful EHR user as defined in section 1886(n)(3) of the Act and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have ''three-quarters'' of the applicable percentage increase (prior to the application of other statutory adjustments), or three-quarters of the applicable market basket rate-of-increase, reduced by 33⅓ percent. The reduction to three-quarters of the applicable percentage increase for subsection (d) Puerto Rico hospitals that are not meaningful EHR users increases to 66⅔ percent for FY 2023, and, for FY 2024 and subsequent fiscal years, to 100 percent. (We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.) The regulations at 42 CFR 412.64(d)(3)(ii) reflect the current law for the update for subsection (d) Puerto Rico hospitals for FY 2022 and subsequent fiscal years. In the FY 2019 IPPS/LTCH PPS final rule, we finalized the payment reductions (83 FR 41674).

For FY 2024, consistent with section 1886(b)(3)(B) of the Act, as amended by section 602 of Public Law 114–113, we are setting the applicable percentage increase for Puerto Rico hospitals by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS for Puerto Rico hospitals will be equal to the rate of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for Puerto Rico hospitals not considered to be meaningful EHR users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to the productivity adjustment at section 1886(b)(3)(B)(xi) of the Act. As noted previously, section 1886(b)(3)(B)(xi) of the Act states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

Based on IGI's fourth quarter 2022 forecast of the 2018-based IPPS market basket update with historical data through third quarter 2022, in the FY 2024 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as discussed previously, for Puerto Rico hospitals we proposed a market basket update of 3.0 percent less a productivity adjustment of 0.2 percentage point. Therefore, for FY 2024, depending on whether a Puerto Rico hospital is a meaningful EHR user, we stated there would be two possible applicable percentage increases that could be applied to the standardized amount. Based on these data, we determined the following proposed applicable percentage increases to the standardized amount for FY 2024 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, we proposed a FY 2024 applicable percentage increase to the operating standardized amount of 2.8 percent (that is, the FY 2024 estimate of the proposed market basket rate-of-increase of 3.0 percent less 0.2 percentage point for the proposed productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, we proposed a FY 2024 applicable percentage increase to the operating standardized amount of 0.55 percent (that is, the FY 2024 estimate of the proposed market basket rate-of-increase of 3.0 percent, less an adjustment of 2.25 percentage point (the proposed market basket rate-of-increase of 3.0 percent × 0.75 for failure to be a meaningful EHR user), and less 0.2 percentage point for the proposed productivity adjustment).

As noted previously, we proposed that if more recent data subsequently became available, we would use such data, if appropriate, to determine the FY 2024 market basket update and the productivity adjustment for the FY 2024 IPPS/LTCH PPS final rule.

We did not receive any public comments on our proposed updates to the standardized amount for FY 2024 for Puerto Rico hospitals. The general comments we received on the proposed FY 2024 update (including the proposed market basket update and productivity adjustment) are discussed in greater detail earlier in this section. For FY 2024, we are finalizing the proposal to determine the update to the standardized amount for FY 2024 for Puerto Rico hospitals in this final rule using the more recent available data, as previously discussed.

As previously discussed in section V.A.1, based on more recent data available for this final rule (that is, IGI's second quarter 2023 forecast of the 2018-based IPPS market basket rate-of-increase with historical data through the first quarter of 2023), we estimate that the FY 2024 market basket update used to determine the applicable percentage increase for the IPPS is 3.3 percent and the productivity adjustment is 0.2 percent. For FY 2024, depending on whether a Puerto Rico hospital is a meaningful EHR user, there are two possible applicable percentage increases that can be applied to the standardized amount. Based on these data, accordance with section 1886(b)(3)(B) of the Act, we determined the following applicable percentage increases to the standardized amount for FY 2024 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, an applicable percentage increase to the FY 2024 operating standardized amount of 3.1 percent (that is, the FY 2024 estimate of the market basket rate-of-increase of 3.3 percent less an adjustment of 0.2 percentage point for the productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, an applicable percentage increase to the operating standardized amount of 0.625 percent (that is, the FY 2024 estimate of the market basket rate-of-increase of 3.3 percent, less an adjustment of 2.475 percentage point (the market basket rate-of-increase of 3.3 percent × 0.75 for failure to be a meaningful EHR user), and less an adjustment of 0.2 percentage point for the productivity adjustment).

FY 2024 APPLICABLE PERCENTAGE INCREASES FOR PUERTO RICO HOSPITALS UNDER THE IPPS

FY 2024	Hospital is a Meaningful EHR User	Hospital is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	3.3	3.3
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	-2.475
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.2	-0.2
Applicable Percentage Increase Applied to Standardized Amount	**3.1**	**0.625**

C. Sole Community Hospitals (SCHs) (§ 412.92)

1. Background

Section 1886(d)(5)(D) of the Act provides special payment protections under the IPPS to sole community hospitals (SCHs). Section 1886(d)(5)(D)(iii) of the Act defines an SCH in part as a hospital that the Secretary determines is located more than 35 road miles from another hospital or that, by reason of factors such as isolated location, weather conditions, travel conditions, or absence of other like hospitals (as determined by the Secretary), is the sole source of inpatient hospital services reasonably available to Medicare beneficiaries. The regulations at 42 CFR 412.92 set forth the criteria that a hospital must meet to be classified as an SCH. For more information on SCHs, we refer readers to the FY 2009 IPPS/LTCH PPS final rule (74 FR 43894 through 43897).

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41430), effective for SCH applications received on or after October 1, 2018, we modified the effective date of SCH classification from 30 days after the date of CMS's written notification of approval to the date that the MAC receives the complete SCH application. As we explained in that final rule, section 401 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act (BBRA) of 1999 (Pub. L. 106–113, Appendix F) amended section 1886(d)(8) of the Act to add paragraph (E) which authorizes reclassification of certain urban hospitals as rural if the hospital applies for such status and meets certain criteria. The effective date for rural reclassification status under section 1886(d)(8)(E) of the Act is set forth at 42 CFR 412.103(d)(1) as the filing date, which is the date CMS receives the reclassification application (§ 412.103(b)(5)). One way that an urban hospital can reclassify as rural under § 412.103 (specifically, § 412.103(a)(3)) is if the hospital would qualify as a rural referral center (RRC) as set forth in § 412.96, or as an SCH as set forth in § 412.92, if the hospital were located in a rural area. A geographically urban hospital may simultaneously apply for reclassification as rural under § 412.103(a)(3) by meeting the criteria for SCH status (other than being located in a rural area), and apply to obtain SCH status under § 412.92 based on that acquired rural reclassification. However, as we explained in the FY 2019 final rule, the rural reclassification is effective as of the filing date, whereas under our policy at that time, the SCH status was effective 30 days after approval. In addition, while § 412.103(c) states that the CMS Regional Office will review the application and notify the hospital of its approval or disapproval of the request within 60 days of the filing date, the regulations do not set a timeframe by which CMS must decide on an SCH request. We stated that therefore, geographically urban hospitals that obtain rural reclassification under § 412.103 for the purposes of obtaining SCH status may face a payment disadvantage because, under the policy at that time, they are paid as rural until the SCH application is approved and the SCH classification and payment adjustment become effective 30 days after approval.

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41430), to minimize the lag between the effective date of rural reclassification under § 412.103 and the effective date for SCH status, we revised our policy so that the effective date for SCH classification and for the payment adjustment would be the date that the MAC receives the complete SCH application, effective for SCH applications received on or after October 1, 2018, as reflected in § 412.92(b)(2)(i) and (iv). We stated that a complete application includes a request and all supporting documentation needed to demonstrate that the hospital meets criteria for SCH status as of the date of application. We also stated that for an application to be complete, all criteria must be met as of the date the MAC receives the SCH application. We further stated that a hospital applying for SCH status on the basis of a § 412.103 rural reclassification must submit its § 412.103 application no later than its SCH application in order to be considered rural as of the date the MAC receives the SCH application.

As we explained in the FY 2019 IPPS/LTCH PPS final rule, we believed that updating the regulations at § 412.92 to provide an effective date for SCH status that is consistent with the effective date for rural reclassification under § 412.103 would benefit hospitals by minimizing any payment disadvantage caused by the lag between the effective date of rural reclassification and the effective date of SCH status. We also stated that we believe that aligning the SCH effective date with the § 412.103 effective date supports agency efforts to reduce regulatory burden because it would provide for a more uniform policy.

In addition, we made parallel changes to the effective date for a Medicare dependent hospital (MDH) status determination under § 412.108(b)(4) such that for applications received on or after October 1, 2018, a determination of MDH status would be effective as of the date that the MAC receives the complete application, rather than the prior effective date of 30 days after the date the MAC provides written notification to the hospital. Similar to applications for SCH status, we stated that a complete application includes a request and all supporting documentation needed to demonstrate that the hospital meets criteria for MDH status as of the date of application. We further stated that for an application to be complete, all criteria must be met as of the date the MAC receives the MDH application. For example, a cost report must be settled at

the time of application for a hospital to use that cost report as one of the cost reports required in § 412.108(a)(1)(iv)(C).

We refer the reader to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41430) for further discussion of these changes to the effective dates of SCH and MDH status beginning with applications received on or after October 1, 2018.

As explained in the FY 2019 IPPS/LTCH PPS final rule, we specifically modified the effective date for SCH status for consistency with the effective date for rural reclassification in order to minimize any payment disadvantage caused by the lag between the effective date of rural reclassification and the effective date of SCH status for hospitals applying for both rural reclassification under § 412.103(a)(3) by meeting the criteria for SCH status (other than being located in a rural area), and applying to obtain SCH status under § 412.92 based on that acquired rural reclassification. As previously discussed, by meeting the criteria for SCH status (other than being located in a rural area), a hospital can qualify for rural reclassification per the regulations at § 412.103(a)(3), which then allows it to meet all the criteria for SCH status—including the rural requirement at § 412.92(a).

2. Change of Effective Date for SCH Status in the Case of a Merger

For some hospitals, eligibility for SCH classification may depend on the hospital's merger with a nearby ''like hospital'' as defined in § 412.92(c)(2) [217] and meeting other criteria at § 412.92(a). The merger allows the two hospitals involved to operate under a single provider agreement. The regulations at § 412.92(c)(2) define a like hospital as a nearby hospital that furnishes short-term acute care and whose total inpatient days attributable to units of the nearby hospital that provide a level of care characteristic of the level of care payable under the acute care hospital inpatient prospective payment system are greater than 8 percent of the similarly calculated total inpatient days of the hospital seeking SCH designation. In this scenario, prior to the merger, the applicant hospital was not eligible for SCH classification due to its proximity to a nearby like hospital. When the applicant hospital subsequently merges with the nearby like hospital, it is potentially eligible for SCH classification.

If an SCH application is approved, under current policy, the effective date of the SCH classification is the date the MAC receives the complete application. In situations where SCH classification is contingent on a merger, a hospital is not considered to have submitted a complete application to the MAC unless the application contains the notification that the merger was approved. We have heard concerns that in these situations the time difference between the effective date of the hospital merger, which may be retroactive, and the effective date of the SCH status, which is based on the date the complete application is received by the MAC, including the merger approval, may be problematic for hospitals because they cannot benefit from the special payment protections that are afforded to SCHs until the effective date of the SCH classification. We have also heard concerns that different merger requirements across states could potentially introduce an uneven playing field for providers seeking SCH classification because the timeframe for a merger approval could vary from one state or region to another.

Therefore, in an effort to address these concerns and in light of our continuing experience in applying these policies, in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27007), we proposed to revise § 412.92(b)(2) so that for SCH applications received on or after October 1, 2023, where (1) a hospital's SCH approval is dependent on its merger with another nearby hospital, and (2) the hospital meets the other SCH classification requirements, the SCH classification and payment adjustment would be effective as of the effective date of the approved merger if the MAC receives the complete application within 90 days of CMS' written notification to the hospital of the approval of the merger. We explained that this 90-day timeframe would provide sufficient time for a hospital to submit a complete SCH application, while addressing the concerns, as previously discussed, that merger approval may be delayed for reasons beyond a hospital's control. Under this proposal, if the MAC does not receive the complete application within 90 days of CMS' notification of the merger approval, SCH classification would be effective as of the date the MAC receives the complete application, including documentation of the merger approval, and in accordance with the regulations at § 412.92(b)(2)(i).

In connection with this proposal, we also proposed to change the effective date of rural reclassification for a hospital qualifying for rural reclassification under § 412.103(a)(3) by meeting the criteria for SCH status (other than being located in a rural area), and also applying to obtain SCH status under § 412.92, where eligibility for SCH classification depends on a hospital merger. Specifically, we proposed that in these circumstances, and subject to the requirements set forth at proposed new § 412.92(b)(2)(vi), the effective date for rural reclassification would be as of the effective date set forth in proposed new § 412.92(b)(2)(vi).

We note that we did not propose to modify any SCH classification requirements or what constitutes a ''complete application''. The SCH application must, therefore, include all required documentation that would constitute a ''complete application'' including documentation of the hospital's merger approval. We also note that we did not propose any change to the effective date for an SCH application that does not involve a merger.

In the proposed rule, we stated that we continue to believe that our current approach in determining the effective date for SCH classification where the SCH application is contingent on a hospital merger is reasonable. However, in light of our experience in applying these policies and the concerns we have heard about the timeframes involved, we believe that our proposed revision to the effective date for hospitals applying for SCH classification where that classification is dependent on a merger is also reasonable and appropriate and would benefit hospitals by minimizing the time difference between the effective date of the merger and the effective date of SCH status. We noted that we did not propose a parallel change to the effective date policy for MDH classification because eligibility for MDH classification is not dependent on proximity to nearby providers and, therefore, MDH classification would generally not be contingent on a merger taking place. However, we sought comment on the need for such a proposal, which we would consider for future rulemaking as appropriate.

Comment: Commenters supported CMS' proposed change to the effective date for SCH status for SCH applications received on or after October 1, 2023, in the case of a merger where eligibility for SCH classification depends on a hospital merger. Commenters also supported the proposed conforming change to the effective date of rural

[217] 42 CFR 412.92(c)(2): *Like hospital* means a hospital furnishing short-term, acute care. Effective with cost reporting periods beginning on or after October 1, 2002, for purposes of a hospital seeking sole community hospital designation, CMS will not consider the nearby hospital to be a like hospital if the total inpatient days attributable to units of the nearby hospital that provides a level of care characteristic of the level of care payable under the acute care hospital inpatient prospective payment system are less than or equal to 8 percent of the similarly calculated total inpatient days of the hospital seeking sole community hospital designation.

reclassification for a hospital qualifying for rural reclassification under § 412.103(a)(3) by meeting the criteria for SCH status (other than being located in a rural area), and also applying to obtain SCH status under § 412.92 where eligibility for SCH classification depends on a hospital merger.

Response: We appreciate the commenters' support.

Comment: Commenters requested that CMS apply these proposals retroactively and provided various ideas for a retroactive effective date. One commenter suggested that we apply our proposed change retroactively to FY 2019, when CMS last changed the effective date for SCHs (83 FR 41430). The commenter stated that the reasoning given to the FY 2019 modification of the SCH effective date would apply to providers submitting a combined merger and SCH application. Specifically, the commenter indicated that the FY 2019 regulatory change to the SCH effective date was intended to minimize any payment disadvantage caused by the lag between the effective date of rural reclassification and the effective date of SCH status, and to reduce regulatory burden by providing for a more uniform policy. The same commenter stated that different CMS Regional Offices and/or MACs have applied different requirements and effective dates for SCH classifications in the case of a merger where eligibility for SCH classification depends on a hospital merger, and in order to avoid differing treatment, CMS should adopt this proposal retroactively to FY 2019. Alternatively, the commenter suggested that CMS could apply the change to any situation for which the parties have preserved appeal rights over the effective date determination for an SCH approval. Other commenters suggested that CMS apply the change retroactively for providers who were seeking SCH classification during the COVID–19 pandemic and were affected by the lag time between their merger and SCH classification.

Response: We appreciate the commenters' ideas and suggestions. However, we do not agree that we should apply our proposed changes retroactively. The IPPS is a prospective system and, we generally make changes to IPPS regulations effective prospectively based on the date of discharge or the start of a cost reporting period within a certain Federal fiscal year. Under that approach, we believe that applying this change for a merger that already took place may constitute retroactive rulemaking—and would be a departure from our usual practice in IPPS—regardless of whether there's a pending administrative appeal. We believe that following our usual approach and adopting the new effective date policies for SCH and rural reclassification applications where SCH eligibility is dependent on a hospital merger that are received on or after October 1, 2023 will allow for the most equitable application among all IPPS providers seeking to qualify for SCH classification and rural reclassification (as applicable). For these reasons, we are finalizing, without modification, that our proposed changes to the SCH and the rural reclassification effective dates will apply prospectively for applications received on or after October 1, 2023.

Comment: Several commenters requested that CMS clarify its current policy definition of a ''complete application'' for cases contingent on a merger.

Response: As stated in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27008), we did not propose to modify any SCH classification requirements or what constitutes a ''complete application''. We refer the commenters to the Chapter 28 of the Provider Reimbursement Manual (PRM), section 2810. B. (*https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/p151_28.zip*), for a list of documentation that must be included with its request for SCH classification. In addition to the documentation list in the PRM, for an SCH application where eligibility for SCH classification is dependent on a hospital merger, that documentation must include confirmation that the merger has been approved by CMS (for example, a CMS tie-in notice recognizing the two CCNs as merged). We note that we intend to update the list of required documentation in the PRM to include documentation indicating that the merger has been approved by CMS for SCH classification requests that are dependent on a hospital merger.

After consideration of the public comments we received, we are finalizing our policies as proposed, without modification. Specifically, we are finalizing our proposal to revise § 412.92 by adding a new paragraph (b)(2)(vi) to specify that for applications received on or after October 1, 2023, where eligibility for SCH classification is dependent on a merger, the effective date of the SCH classification will be as of the effective date of the approved merger if the MAC receives the complete application within 90 days of CMS' written notification to the hospital of the approval of the merger. If the MAC does not receive the complete application within 90 days of CMS' written notification of the merger approval, SCH classification will be effective as of the date the MAC receives the complete application in accordance with the regulations at § 412.92(b)(2)(i). We are also finalizing our proposal to make conforming changes to the existing regulations at § 412.92(b) by adding an exception referencing paragraph § 412.92(b)(2)(vi) to the language describing the effective date for applications received on or after October 1, 2018 at § 412.92(b)(2)(i), and by revising and streamlining the language at § 412.92(b)(2)(ii)(C) and (b)(2)(iv) to reference § 412.92(b)(2)(i) as the effective date policy in effect for applications received on or after October 1, 2018. In addition, we are finalizing our proposed technical correction to paragraph (b)(1)(v) by revising the word ''forward'' to ''forwards''.

We are also finalizing our proposal to make a conforming change to the regulations at § 412.103(d) by modifying the effective date of rural reclassification for a hospital qualifying for rural reclassification under § 412.103(a)(3) by meeting the criteria for SCH status (other than being located in a rural area), and also applying to obtain SCH status under § 412.92 where eligibility for SCH classification depends on a hospital merger. We are finalizing our proposed amendment to § 412.103(d)(1) and the proposed addition of new § 412.103(d)(3) to provide that, subject to the hospital meeting the requirements set forth at § 412.92(b)(2)(vi), the effective date for rural reclassification for such hospital will be as of the effective date determined under § 412.92(b)(2)(vi).

D. Rural Referral Centers (RRCs) Annual Updates to Case-Mix Index (CMI) and Discharge Criteria (§ 412.96)

Under the authority of section 1886(d)(5)(C)(i) of the Act, the regulations at § 412.96 set forth the criteria that a hospital must meet in order to qualify under the IPPS as a rural referral center (RRC). RRCs receive special treatment under both the DSH payment adjustment and the criteria for geographic reclassification.

Section 402 of Public Law 108–173 raised the DSH payment adjustment for RRCs such that they are not subject to the 12-percent cap on DSH payments that is applicable to other rural hospitals. RRCs also are not subject to the proximity criteria when applying for geographic reclassification. In addition, they do not have to meet the requirement that a hospital's average hourly wage must exceed, by a certain

percentage, the average hourly wage of the labor market area in which the hospital is located.

Section 4202(b) of Public Law 105–33 states, in part, that any hospital classified as an RRC by the Secretary for FY 1991 shall be classified as such an RRC for FY 1998 and each subsequent fiscal year. In the August 29, 1997, IPPS final rule with comment period (62 FR 45999), we reinstated RRC status for all hospitals that lost that status due to triennial review or MGCRB reclassification. However, we did not reinstate the status of hospitals that lost RRC status because they were now urban for all purposes because of the OMB designation of their geographic area as urban. Subsequently, in the August 1, 2000 IPPS final rule (65 FR 47089), we indicated that we were revisiting that decision. Specifically, we stated that we will permit hospitals that previously qualified as an RRC and lost their status due to OMB redesignation of the county in which they are located from rural to urban, to be reinstated as an RRC. Otherwise, a hospital seeking RRC status must satisfy all of the other applicable criteria. We use the definitions of ''urban'' and ''rural'' specified in subpart D of 42 CFR part 412. One of the criteria under which a hospital may qualify as an RRC is to have 275 or more beds available for use (§ 412.96(b)(1)(ii)). A rural hospital that does not meet the bed size requirement can qualify as an RRC if the hospital meets two mandatory prerequisites (a minimum case-mix index (CMI) and a minimum number of discharges), and at least one of three optional criteria (relating to specialty composition of medical staff, source of inpatients, or referral volume). (We refer readers to § 412.96(c)(1) through (5) and the September 30, 1988, **Federal Register** (53 FR 38513) for additional discussion.) With respect to the two mandatory prerequisites, a hospital may be classified as an RRC if the hospital's—

- CMI is at least equal to the lower of the median CMI for urban hospitals in its census region, excluding hospitals with approved teaching programs, or the median CMI for all urban hospitals nationally; and
- Number of discharges is at least 5,000 per year, or, if fewer, the median number of discharges for urban hospitals in the census region in which the hospital is located. The number of discharges criterion for an osteopathic hospital is at least 3,000 discharges per year, as specified in section 1886(d)(5)(C)(i) of the Act.

In the FY 2022 final rule (86 FR 45217), in light of the COVID–19 PHE, we amended the regulations at § 412.96(h)(1) to provide for the use of the best available data rather than the latest available data in calculating the national and regional CMI criteria. We also amended the regulations at § 412.96(c)(1) to indicate that the individual hospital's CMI value for discharges during the same Federal fiscal year used to compute the national and regional CMI values is used for purposes of determining whether a hospital qualifies for RRC classification. We also amended the regulations § 412.96(i)(1) and (2), which describe the methodology for calculating the number of discharges criteria, to provide for the use of the best available data rather than the latest available or most recent data when calculating the regional discharges for RRC classification.

1. Case-Mix Index (CMI)

Section 412.96(c)(1) provides that CMS establish updated national and regional CMI values in each year's annual notice of prospective payment rates for purposes of determining RRC status. The methodology we used to determine the national and regional CMI values is set forth in the regulations at § 412.96(c)(1)(ii). The national median CMI value for FY 2024 is based on the CMI values of all urban hospitals nationwide, and the regional median CMI values for FY 2024 are based on the CMI values of all urban hospitals within each census region, excluding those hospitals with approved teaching programs (that is, those hospitals that train residents in an approved GME program as provided in § 413.75). These values are based on discharges occurring during FY 2022 (October 1, 2021 through September 30, 2022), and include bills posted to CMS' records through March 2023. Because this is the latest available data, we believe that it is the best available data for use in calculating the national and regional median CMI values and is consistent with our proposal to use the FY 2022 MedPAR claims data for FY 2024 ratesetting.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27009), we proposed that, in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2023, they must have a CMI value for FY 2022 that is at least—

- 1.8067 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The proposed median CMI values by region were set forth in the table in the proposed rule (88 FR 27010). We stated in the proposed rule that we intended to update the proposed CMI values in the FY 2024 final rule to reflect the updated FY 2022 MedPAR file, which will contain data from additional bills received through March 2023.

Comment: Commenters supported our proposal to use FY 2022 data to calculate the national and regional median CMI values for FY 2024.

Response: We appreciate the commenters' support.

Therefore, based on the best available data (FY 2022 bills received through March 2023), in addition to meeting other criteria, if rural hospitals with fewer than 275 beds are to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2023, they must have a CMI value for FY 2022 that is at least:

- 1.80655 (national—all urban); or
- The median CMI value (not transfer-adjusted) for urban hospitals (excluding hospitals with approved teaching programs as identified in § 413.75) calculated by CMS for the census region in which the hospital is located.

The final CMI values by region are set forth in the following table.

Region	Proposed Case-Mix Index Value
1. New England (CT, ME, MA, NH, RI, VT)	1.5272
2. Middle Atlantic (PA, NJ, NY)	1.5791
3. East North Central (IL, IN, MI, OH, WI)	1.6726
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.7392
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.65775
6. East South Central (AL, KY, MS, TN)	1.662
7. West South Central (AR, LA, OK, TX)	1.8348
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.8582
9. Pacific (AK, CA, HI, OR, WA)	1.8094

A hospital seeking to qualify as an RRC should obtain its hospital-specific CMI value (not transfer-adjusted) from its MAC. Data are available on the Provider Statistical and Reimbursement (PS&R) System. In keeping with our policy on discharges, the CMI values are computed based on all Medicare patient discharges subject to the IPPS MS–DRG-based payment.

3. Discharges

Section 412.96(c)(2)(i) provides that CMS set forth the national and regional numbers of discharges criteria in each year's annual notice of prospective payment rates for purposes of determining RRC status. As specified in section 1886(d)(5)(C)(ii) of the Act, the national standard is set at 5,000 discharges. In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27010), for FY 2024, we proposed to update the regional standards based on discharges for urban hospitals' cost reporting periods that began during FY 2021 (that is, October 1, 2020, through September 30, 2021). Because this is the latest available cost reporting data, we believe that it is the best available data for use in calculating the proposed median number of discharges by region and is consistent with our data proposal to use cost report data from cost reporting periods beginning during FY 2021 for FY 2024 ratesetting.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27010), we proposed that, in addition to meeting other criteria, a hospital, if it is to qualify for initial RRC status for cost reporting periods beginning on or after October 1, 2023, must have, as the number of discharges for its cost reporting period that began during FY 2021, at least—

- 5,000 (3,000 for an osteopathic hospital); or
- If less, the median number of discharges for urban hospitals in the census region in which the hospital is located. (We refer readers to the table set forth in the FY 2023 IPPS/LTCH PPS proposed rule at 88 FR 27010).

In the proposed rule, we stated that we intended to update to update these numbers in the FY 2024 final rule based on the latest available cost report data.

Comment: Commenters supported our proposal to use FY 2021 data to calculate median number of discharges by region for FY 2024.

Response: We appreciate the commenters' support.

Therefore, based on the best available discharge data at this time, that is, for cost reporting periods that began during FY 2021, the final median number of discharges for urban hospitals by census region are set forth in the following table.

Region	Proposed Number of Discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,497
2. Middle Atlantic (PA, NJ, NY)	9,251
3. East North Central (IL, IN, MI, OH, WI)	7,798
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	6,678
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	10,125
6. East South Central (AL, KY, MS, TN)	8,672
7. West South Central (AR, LA, OK, TX)	5,831
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	8,031
9. Pacific (AK, CA, HI, OR, WA)	8,455

We note that because the median number of discharges for hospitals in each census region is greater than the national standard of 5,000 discharges, under this final rule, 5,000 discharges is the minimum criterion for all hospitals, except for osteopathic hospitals for which the minimum criterion is 3,000 discharges.

E. Payment Adjustment for Low-Volume Hospitals (§ 412.101)

Section 1886(d)(12) of the Act provides for an additional payment to each qualifying low-volume hospital under the IPPS beginning in FY 2005. The low-volume hospital payment adjustment is implemented in the regulations at 42 CFR 412.101. The additional payment adjustment to a low-volume hospital provided for under section 1886(d)(12) of the Act is in

addition to any payment calculated under section 1886 of the Act. Therefore, the additional payment adjustment is based on the per discharge amount paid to the qualifying hospital under section 1886 of the Act. In other words, the low-volume hospital payment adjustment is based on total per discharge payments made under section 1886 of the Act, including capital, DSH, IME, and outlier payments. For SCHs and MDHs, the low-volume hospital payment adjustment is based in part on either the Federal rate or the hospital-specific rate, whichever results in a greater operating IPPS payment.

1. Recent Legislation

As discussed in the FY 2023 IPPS/LTCH PPS final rule, beginning with FY 2023, the low-volume hospital qualifying criteria and payment adjustment were set to revert to the statutory requirements that were in effect prior to FY 2011 (87 FR 49060). Subsequent legislation extended, for FYs 2023 and 2024, the temporary changes to the low-volume hospital qualifying criteria and payment adjustment originally provided for by section 50204 of the Bipartisan Budget Act of 2018 for FYs 2019 through 2022 as follows:

- Section 101 of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Pub. L. 117–180), enacted on September 30, 2022, through December 16, 2022.
- Section 101 of the Further Continuing Appropriations and Extensions Act, 2023 (Pub. L. 117–229), enacted on December 16, 2022, through December 23, 2022.
- Section 4101 of the Consolidated Appropriations Act, 2023 (CAA 2023) (Pub. L. 117–328), enacted on December 29, 2022, through September 30, 2024.

We discuss the extension of these temporary changes for FY 2023 and FY 2024 in greater detail in this section of this rule and in the FY 2024 IPPS/LTCH proposed rule (88 FR 27010 through 27011). Beginning in FY 2025, the low-volume hospital definition and payment adjustment methodology will revert back to the statutory requirements that were in effect prior to the amendments made by the Affordable Care Act, which were extended and modified through subsequent legislation.

2. Extension of the Temporary Changes to the Low-Volume Hospital Definition and Payment Adjustment Methodology for FYs 2023 and 2024

As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41398 through 41399), section 50204 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123) modified the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals for FYs 2019 through 2022. Specifically, the qualifying criteria for low-volume hospitals under section 1886(d)(12)(C)(i) of the Act were amended to specify that, for FYs 2019 through 2022, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 3,800 total discharges during the fiscal year. Section 1886(d)(12)(D) of the Act was also amended to provide that, for discharges occurring in FYs 2019 through 2022, the Secretary determines the applicable percentage increase using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges to a zero percent additional payment for low-volume hospitals with more than 3,800 discharges in the fiscal year. Consistent with the requirements of section 1886(d)(12)(C)(ii) of the Act, the term ''discharge'' for purposes of these provisions refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges).

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399), to implement this requirement, we specified a continuous, linear sliding scale formula to determine the low-volume hospital payment adjustment for FYs 2019 through FY 2022 that is similar to the continuous, linear sliding scale formula used to determine the low-volume hospital payment adjustment originally established by the Affordable Care Act and implemented in the regulations at § 412.101(c)(2)(ii) in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50240 through 50241). Consistent with the statute, we provided that qualifying hospitals with 500 or fewer total discharges will receive a low-volume hospital payment adjustment of 25 percent. For qualifying hospitals with fewer than 3,800 discharges but more than 500 discharges, the low-volume payment adjustment is calculated by subtracting from 25 percent the proportion of payments associated with the discharges in excess of 500. As such, for qualifying hospitals with fewer than 3,800 total discharges but more than 500 total discharges, the low volume hospital payment adjustment for FYs 2019 through FY 2022 was calculated using the following formula:

$$\textit{Low-Volume Hospital Payment Adjustment} = 0.25 - [0.25/3300] \times (\textit{number of total discharges} - 500) = (95/330) - (\textit{number of total discharges}/13{,}200)$$

For this purpose, we specified that the ''number of total discharges'' is determined as total discharges, which includes Medicare and non-Medicare discharges during the fiscal year, based on the hospital's most recently submitted cost report. The low-volume hospital payment adjustment for FYs 2019 through 2022 is set forth in the regulations at § 412.101(c)(3).

As described previously, recent legislation extended through FY 2024 the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals in effect for FYs 2019 through FY 2022 pursuant to the Bipartisan Budget Act of 2018. Specifically, under sections 1886(d)(12)(C)(i) and 1886(d)(12)(C)(i)(III) of the Act, as amended, for FY 2023 and FY 2024, a low-volume hospital must be more than 15 road miles from another subsection (d) hospital and have less than 3,800 discharges during the fiscal year.

In addition, under section 1886(d)(12)(D)(ii) of the Act, as amended, for FY 2023 and FY 2024, the low-volume hospital payment adjustment is determined using a continuous linear sliding scale ranging from 25 percent for low-volume hospitals with 500 or fewer discharges to 0 percent for low-volume hospitals with greater than 3,800 discharges.

TABLE V.E.-01: LOW-VOLUME HOSPITAL QUALIFYING CRITERIA AND PAYMENT ADJUSTMENT FOR FYs 2019 THROUGH 2024 AND FY 2025 AND SUBSEQUENT FYs

Fiscal Years	Road Miles	Total Discharges	Payment Adjustment
2019 through 2024	>15	<= 500	0.25
		> 500 < 3,800	0.25 - [0.25/3300] x (number of total discharges - 500) = (95/330) - (number of total discharges/13,200)
2025 and subsequent years	>25	< 200	0.25

Based on the current law, beginning with FY 2025, the low-volume hospital qualifying criteria and payment adjustment will revert to the statutory requirements that were in effect prior to FY 2011. Section 1886(d)(12)(C)(i) of the Act, as amended, defines a low-volume hospital, for FYs 2005 through 2010 and FY 2025 and subsequent years, as a subsection (d) hospital that the Secretary determines is located more than 25 road miles from another subsection (d) hospital and that has less than 800 discharges during the fiscal year. As previously noted, section 1886(d)(12)(C)(ii) of the Act further stipulates that the term ''discharge'' means an inpatient acute care discharge of an individual, regardless of whether the individual is entitled to benefits under Medicare Part A (except with respect to FYs 2011 through 2018). Therefore, for FYs 2005 through 2010 and FY 2019 and subsequent years, the term ''discharge'' refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges). Furthermore, as amended, section 1886(d)(12)(B) of the Act requires, for discharges occurring in FYs 2005 through 2010 and FY 2025 and subsequent years, that the Secretary determine an applicable percentage increase for these low-volume hospitals based on the ''empirical relationship'' between the standardized cost-per-case for such hospitals and the total number of discharges of such hospitals and the amount of the additional incremental costs (if any) that are associated with such number of discharges. The statute thus mandates that the Secretary develop an empirically justifiable adjustment based on the relationship between costs and discharges for these low-volume hospitals. Section 1886(d)(12)(B)(iii) of the Act limits the applicable percentage increase adjustment to no more than 25 percent. Based on an analysis we conducted for the FY 2005 IPPS final rule (69 FR 49099 through 49102), a 25-percent low-volume adjustment to all qualifying hospitals with less than 200 discharges was found to be most consistent with the statutory requirement to provide relief to low-volume hospitals where there is empirical evidence that higher incremental costs are associated with low numbers of total discharges. In the FY 2006 IPPS final rule (70 FR 47432 through 47434), we stated that multivariate analyses supported the existing low-volume adjustment implemented in FY 2005. Therefore, in order for a hospital to continue to qualify as a low-volume hospital on or after October 1, 2024, it must have fewer than 200 total discharges during the fiscal year and be located more than 25 road miles from the nearest ''subsection (d)'' hospital (see § 412.101(b)(2)(i)). We refer readers to the FY 2023 IPPS/LTCH PPS final rule for further discussion.

As discussed in section V.E.4. of the preamble of this final rule, we proposed to make conforming changes to the regulation text in § 412.101 to reflect the extension of the changes to the qualifying criteria and the payment adjustment methodology for low-volume hospitals through FY 2024.

Comment: Many commenters supported the extension of the changes to the low-volume hospital qualifying criteria and payment adjustment methodology for FYs 2023 and 2024.

Response: We appreciate the commenters sharing their support for the extension of the temporary changes to the low-volume hospital payment adjustment FYs 2023 and 2024.

As discussed later in the section, we are finalizing our proposals without modification on the extension of the changes to the qualifying criteria and the payment adjustment methodology for low-volume hospitals through FY 2024, after consideration of the public comments.

3. Extension of the Temporary Changes to the Low-Volume Hospital Definition and Payment Adjustment Methodology for FY 2023

Prior to the enactment of Public Law 117–180, the temporary changes to the low-volume hospital qualifying criteria and payment adjustment originally provided by section 50204 of the Bipartisan Budget Act of 2018 were set to expire October 1, 2022. As previously discussed, these temporary changes to the low-volume hospital payment policy were extended through December 16, 2022 by section 101 of Public Law 117–180, through December 23, 2022 by section 101 of Public Law 117–229, and through September 30, 2024 by section 4101 of Public Law 117–328. In accordance with section 1886(d)(12)(C)(i) of the Act, as amended, for FY 2023 a low-volume hospital must be more than 15 road miles from another subsection (d) hospital and must have less than 3,800 discharges during the fiscal year.

We addressed the extension provided by section 101 of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Pub. L. 117–180) for the portion of FY 2023 beginning on October 1, 2022, and ending on December 16, 2022 (in other words, occurring before December 17, 2022) in Change Request 12970 (Transmittal 117400), issued December 9, 2022. For additional information on this extension, please refer to the transmittal *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r11740otn*.

We subsequently addressed the additional extensions of these provisions for FY 2023, specifically, through December 23, 2022, as provided by section 101 of the Further Continuing Appropriations and Extensions Act, 2023 (Pub. L. 117–229) and through September 30, 2023, as provided by section 4101 of the CAA 2023 (Pub. L. 117–328) in Change Request 13103 (Transmittal 11878), issued February 23, 2023. For additional information, please refer to the transmittal *https://www.cms.gov/files/document/r11878otn.pdf*.

We proposed to make conforming changes to the regulations text in § 412.101 to codify these extensions for

FY 2023 as discussed in section V.E.4. of the preamble of this final rule.

Comment: Many commenters supported the extension of the definition and payment of the low-volume hospital payment adjustment for FY 2023. A commenter urged CMS to expeditiously process claims and provide instructions to MACs for extensions, especially in instances when extensions are made retroactively. The commenter indicated seamless transition of these payments are crucial for rural providers.

Response: We appreciate the commenters sharing their support for legislative action of the extension. As we have said in the past, we will make every effort to implement any extension of the low-volume payment policy as expeditiously as possible.

After consideration of the public comments we received regarding the temporary changes to the qualifying criteria and the payment adjustment methodology for low-volume hospitals through FY 2023, we are finalizing our proposal without modification for the FY 2023 extensions.

4. Payment Adjustment for FY 2024 and Conforming Changes to Regulations

As discussed earlier, section 4101 of the CAA 2023 extended through FY 2024 the modified definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals in effect for FYs 2019 through 2022. Specifically, under section 1886(d)(12)(C)(i) of the Act, as amended, for FYs 2019 through 2024, a subsection (d) hospital qualifies as a low-volume hospital if it is more than 15 road miles from another subsection (d) hospital and has less than 3,800 total discharges during the fiscal year. Under section 1886(d)(12)(D) of the Act, as amended, for discharges occurring in FYs 2019 through 2024, the Secretary determines the applicable percentage increase using a continuous, linear sliding scale ranging from an additional 25 percent payment adjustment for low-volume hospitals with 500 or fewer discharges to a zero percent additional payment for low-volume hospitals with more than 3,800 discharges in the fiscal year. Consistent with the requirements of section 1886(d)(12)(C)(ii) of the Act, the term ''discharge'' for purposes of these provisions refers to total discharges, regardless of payer (that is, Medicare and non-Medicare discharges).

As previously discussed, in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399), we specified a continuous, linear sliding scale formula to determine the low volume payment adjustment, as reflected in the regulations at § 412.101(c)(3)(ii). Consistent with the statute, we provided that qualifying hospitals with 500 or fewer total discharges will receive a low-volume hospital payment adjustment of 25 percent. For qualifying hospitals with fewer than 3,800 discharges but more than 500 discharges, the low-volume payment adjustment is calculated by subtracting from 25 percent the proportion of payments associated with the discharges in excess of 500. As such, for qualifying hospitals with fewer than 3,800 total discharges but more than 500 total discharges, the low-volume hospital payment adjustment at § 412.101(c)(3)(ii) is calculated using the following formula:

$$\textit{Low-Volume Hospital Payment Adjustment} = 0.25 - [0.25/3300] \times (\textit{number of total discharges} - 500) = (95/330) - (\textit{number of total discharges}/13{,}200)$$

For this purpose, the ''number of total discharges'' is determined as total discharges, which includes Medicare and non-Medicare discharges during the fiscal year, based on the hospital's most recently submitted cost report, as explained previously.

Consistent with the extension of the methodology for calculating the payment adjustment for low-volume hospitals through FY 2024, we proposed to continue using the previously specified continuous, linear sliding scale formula to determine the low-volume hospital payment adjustment for FY 2024. We also proposed to make conforming changes to the regulation text in § 412.101 to reflect the extensions of the changes to the qualifying criteria and the payment adjustment methodology for low-volume hospitals in accordance with provisions of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023, the Further Continuing Appropriations and Extensions Act, 2023, and the CAA 2023. Specifically, we proposed to make conforming changes to paragraphs (b)(2)(iii) and (c)(3) introductory text of § 412.101 to reflect that the low-volume hospital payment adjustment policy in effect for FY 2023 and FY 2024 is the same low-volume hospital payment adjustment policy in effect for FYs 2019 through 2022 (as described in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41398 through 41399)). In addition, in accordance with the provisions of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023, the Further Continuing Appropriations and Extensions Act, 2023, and the CAA 2023, for FY 2025 and subsequent fiscal years, we proposed to make conforming changes to paragraphs (b)(2)(i) and (c)(1) of § 412.101 to reflect that the low-volume hospital payment adjustment policy in effect for those years is the same the low-volume hospital payment adjustment policy in effect for FYs 2005 through 2010, as described previously.

Comment: In addition to expressing support for FY 2023, many commenters supported the extension to the FY 2024 definition and payment of the low-volume hospital payment adjustment.

Response: We appreciate the commenters sharing their support for the extension of the low-volume hospital definition and payment adjustment for FY 2024, and for legislative action for the permanent modification of the low-volume hospital payment policy.

Comment: Many commenters urged CMS to collaborate with Congress to make permanent the modifications to the low-volume hospital payment policy. Some commenters urged CMS to continue the temporary changes to the definition of a low-volume hospital and the methodology for calculating the payment adjustment for low-volume hospitals for FY 2024 and subsequent years. Commenters stated that not continuing these temporary changes would result in significant reductions in payment that could impede the services hospitals, including those in rural communities, provide in the communities they serve.

Response: We appreciate the feedback from comments urging CMS to explore ways to continue the enhanced low-volume hospital payment policy for FY 2024 and subsequent years, we note that the statute only extends the temporary changes to the low-volume hospital policy for FYs 2023 and 2024. Therefore, beginning with FY 2025, the low-volume hospital qualifying criteria and the amount of the payment adjustment to such hospitals will revert back to those policies that were in effect prior to the amendments made by recent legislation.

After consideration of the public comments on the payment adjustment methodology for low-volume hospitals through FY 2024, we are finalizing our proposal to codify these extensions to the regulation text in § 412.101 without modification.

5. Process for Requesting and Obtaining the Low-Volume Hospital Payment Adjustment for FY 2024

In the FY 2011 IPPS/LTCH PPS final rule (75 FR 50238 through 50275 and 50414) and subsequent rulemaking,

most recently in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49062 through 49063), we discussed the process for requesting and obtaining the low-volume hospital payment adjustment. Under this previously established process, a hospital makes a written request for the low-volume payment adjustment under § 412.101 to its MAC. This request must contain sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria. The MAC will determine if the hospital qualifies as a low-volume hospital by reviewing the data the hospital submits with its request for low-volume hospital status in addition to other available data. Under this approach, a hospital will know in advance whether or not it will receive a payment adjustment under the low-volume hospital policy. The MAC and CMS may review available data such as the number of discharges, in addition to the data the hospital submits with its request for low-volume hospital status, to determine whether or not the hospital meets the qualifying criteria. (For additional information on our existing process for requesting the low-volume hospital payment adjustment, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 through 41401).)

As explained earlier, for FY 2019 and subsequent fiscal years, the discharge determination is made based on the hospital's number of total discharges, that is, Medicare and non-Medicare discharges, as was the case for FYs 2005 through 2010. Under the revised § 412.101(b)(2)(i) and (iii), a hospital's most recently submitted cost report is used to determine if the hospital meets the discharge criterion to receive the low-volume payment adjustment in the current year. As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41399 and 41400), we use cost report data to determine if a hospital meets the discharge criterion because this is the best available data source that includes information on both Medicare and non-Medicare discharges. (For FYs 2011 through 2018, the most recently available MedPAR data were used to determine the hospital's Medicare discharges because non-Medicare discharges were not used to determine if a hospital met the discharge criterion for those years.) Therefore, a hospital must refer to its most recently submitted cost report for total discharges (Medicare and non-Medicare) to decide whether or not to apply for low-volume hospital status for a particular fiscal year.

As also discussed earlier, in addition to the discharge criterion, for FY 2019 and subsequent fiscal years, eligibility for the low-volume hospital payment adjustment is also dependent upon the hospital meeting the applicable mileage criterion specified in the revised § 412.101(b)(2)(i) or (iii) for the fiscal year. Specifically, to meet the mileage criterion for FY 2024, as noted earlier, a hospital must be located more than 15 road miles from the nearest subsection (d) hospital, as was the case for FYs 2019 through 2023. (We define in § 412.101(a) the term ''road miles'' to mean ''miles'' as defined in § 412.92(c)(1) (75 FR 50238 through 50275 and 50414).) For establishing that the hospital meets the mileage criterion, the use of a web-based mapping tool as part of the documentation is acceptable. The MAC will determine if the information submitted by the hospital, such as the name and street address of the nearest hospitals, location on a map, and distance from the hospital requesting low-volume hospital status, is sufficient to document that it meets the mileage criterion. If not, the MAC will follow up with the hospital to obtain additional necessary information to determine whether or not the hospital meets the applicable mileage criterion.

In accordance with our previously established process, a hospital must make a written request for low-volume hospital status that is received by its MAC by September 1 immediately preceding the start of the Federal fiscal year for which the hospital is applying for low-volume hospital status in order for the applicable low-volume hospital payment adjustment to be applied to payments for its discharges for the fiscal year beginning on or after October 1 immediately following the request (that is, the start of the Federal fiscal year). For a hospital whose request for low volume hospital status is received after September 1, if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC will apply the applicable low-volume hospital payment adjustment to determine payment for the hospital's discharges for the fiscal year, effective prospectively within 30 days of the date of the MAC's low-volume status determination.

Consistent with our previously established process, for FY 2024, we proposed that a hospital must submit a written request for low-volume hospital status to its MAC that includes sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria (as described earlier). Specifically, we proposed that for FY 2024, a hospital must make a written request for low-volume hospital status that is received by its MAC no later than September 1, 2023, in order for the low-volume, add-on payment adjustment to be applied to payments for its discharges beginning on or after October 1, 2023. If a hospital's written request for low-volume hospital status for FY 2024 is received after September 1, 2023, and if the MAC determines the hospital meets the criteria to qualify as a low-volume hospital, the MAC would apply the low-volume hospital payment adjustment to determine the payment for the hospital's FY 2024 discharges, effective prospectively within 30 days of the date of the MAC's low-volume hospital status determination.

Under this process, a hospital that qualified for the low-volume hospital payment adjustment for FY 2023 may continue to receive a low-volume hospital payment adjustment for FY 2024 without reapplying if it continues to meet both the discharge and the mileage criteria (which, as discussed previously, are the same qualifying criteria that apply for FY 2023). In this case, a hospital's request can include a verification statement that it continues to meet the mileage criterion applicable for FY 2023. (Determination of meeting the discharge criterion is discussed earlier in this section.) We note that a hospital must continue to meet the applicable qualifying criteria as a low-volume hospital (that is, the hospital must meet the applicable discharge criterion and mileage criterion for the fiscal year) to receive the payment adjustment in that fiscal year; that is, low-volume hospital status is not based on a ''one-time'' qualification (75 FR 50238 through 50275). Consistent with historical policy, a hospital must submit its request, including this written verification, for each fiscal year for which it seeks to receive the low-volume hospital payment adjustment, and in accordance with the timeline described earlier.

We did not receive any comments on our process for requesting and obtaining the low-volume payment adjustment for FY 2024. For the reasons discussed in this final rule and in the FY 2024 IPPS/LTCH PPS proposed rule, we are finalizing our proposal, without modification.

F. Medicare-Dependent, Small Rural Hospital (MDH) Program (§ 412.108)

1. Background

Section 1886(d)(5)(G) of the Act provides special payment protections, under the IPPS, to a Medicare-dependent, small rural hospital (MDH). Section 1886(d)(5)(G)(iv) of the Act defines a MDH as a hospital that is

located in a rural area, or is located in an all-urban State but meets one of the specified statutory criteria for rural reclassification (as added by section 50205 of the Bipartisan Budget Act of 2018, Pub. L. 115–123), has not more than 100 beds, is not an sole community hospital (SCH), and has a high percentage of Medicare discharges (that is, not less than 60 percent of its inpatient days or discharges during the cost reporting period beginning in FY 1987 or two of the three most recently audited cost reporting periods for which the Secretary has a settled cost report were attributable to inpatients entitled to benefits under Part A). The regulations at 42 CFR 412.108 set forth the criteria that a hospital must meet to be classified as an MDH. (For additional information on the MDH program and the payment methodology, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51683 through 51684).)

2. Implementation of Legislative Extension of MDH Program

Since the extension of the MDH program through FY 2012 provided by section 3124 of the Affordable Care Act, the MDH program has been extended multiple times by subsequent legislation, most recently for FYs 2023 through 2024, as discussed further in this section (that is, for discharges occurring before October 1, 2024.) (Additional information on the extensions of the MDH program after FY 2012 and through FY 2022 can be found in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49064).) As discussed in the FY 2023 IPPS/LTCH PPS final rule, the MDH program provisions at section 1886(d)(5)(G) of the Act were set to expire at the end of FY 2022 (87 FR 49064). Subsequently, the MDH program was extended by additional legislation as follows:

- Division D, Section 102 of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Public Law 117–180), enacted on September 30, 2022, amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to provide for an extension of the MDH program through December 16, 2022.
- Division C, Section 102 of the Further Continuing Appropriations and Extensions Act, 2023 (Pub. L. 117–229), enacted on December 16, 2022, amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to provide for an extension of the MDH program through December 23, 2022.
- Division FF, Section 4102 of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328), enacted on December 29, 2022, amended sections 1886(d)(5)(G)(i) and 1886(d)(5)(G)(ii)(II) of the Act to provide for an extension of the MDH program through FY 2024 (that is, for discharges occurring on or before September 30, 2024).

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27014), we proposed to make conforming changes to the regulations governing the MDH program at § 412.108(a)(1) and (c)(2)(iii) and the general payment rules at § 412.90(j) to reflect the extension of the MDH program through FY 2024.

We note that the legislative extensions of the MDH program provided by section 102 of Pub. L. 117–180 and section 102 of Public Law 117–229, which collectively extended the program through December 23, 2022, were signed into law prior to a statutory expiration of the MDH program. Generally, as a result of these extensions, a provider that was classified as an MDH as of September 30, 2022, continued to be classified as an MDH as of October 1, 2022, with no need to reapply for MDH classification. (For more information on the MDH extensions through December 23, 2022, see Change Request 12970 and Change Request 13103, which are available online at *https://www.cms.gov/files/document/R11740OTN.pdf* and *https://www.cms.gov/files/document/r11878otn.pdf*, respectively.) In contrast, the legislative extension provided by section 4102 of Public Law 117–328 was signed into law on December 29, 2022, after the December 24, 2022, expiration of the MDH program. Generally, as a result of this extension and consistent with previous extensions of the MDH program, a provider that was classified as an MDH as of December 23, 2022, was reinstated as a MDH effective December 24, 2022, with no need to reapply for MDH classification.

The regulations at § 412.92(b)(2)(v) allow MDHs to apply for classification as a SCH 30 days prior to the anticipated expiration of the MDH program, and if approved, to be granted such status effective with the expiration of the MDH program. As discussed in Change Requests 12970 and 13103, because the MDH program did not, in fact, expire as of the anticipated October 1, 2022, or December 17, 2022, expiration dates, any MDH that applied for SCH classification per the regulations at § 412.92(b)(2)(v) in anticipation of either of those expiration dates would not have been classified as a SCH as of October 1, 2022, or December 17, 2022, as applicable. Furthermore, we are not aware of any hospitals that applied for SCH classification in this manner in advance of the December 24, 2022, expiration of the MDH program. However, as discussed in Change Request 13103, if there are any such hospitals and those hospitals are unsure about their MDH status, those hospitals should contact their MACs. We note that in accordance with Change Request 13103, a provider affected by the MDH program extension that also applied for SCH classification per the regulations at § 412.92(b)(2)(v) or cancelled its rural reclassification under § 412.103 in anticipation of the expiration of the MDH program will receive a notice from its MAC detailing its status in light of the MDH program extension.

Therefore, as collectively provided by division D, section 102 of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023, division C, section 102 of the Further Continuing Appropriations and Extensions Act, 2023, and division FF, section 4102 of the Consolidated Appropriations Act, 2023, providers that were classified as MDHs as of September 30, 2022, generally continue to be classified as MDHs as of October 1, 2022, with no need to reapply for MDH classification. However, as discussed in Change Requests 12970 and 13103, if a MDH cancelled its rural classification under § 412.103(g) effective on or after October 1, 2022, its MDH status may not be applied continuously or automatically reinstated, as applicable (and as described previously). In order to meet the criteria to become an MDH, generally a hospital must be located in a rural area. To qualify for MDH status, some MDHs may have reclassified as rural under the regulations at § 412.103. With the anticipated expiration of the MDH provision, some of these providers may have requested a cancellation of their rural classification. Therefore, in order to qualify for MDH status, these providers must request to be reclassified as rural under 42 CFR 412.103(b) and reapply for MDH classification in accordance with the regulations at 42 CFR 412.108(b). As discussed, all other hospitals with MDH status as of September 30, 2022 continue to be classified as MDHs effective October 1, 2022. We refer readers to Change Requests 12970 and 13103 for further discussion on the extensions of the MDH program through FY 2023.

Comment: Commenters supported our proposals to make conforming changes to the regulations to reflect the legislation extending the MDH provision. Commenters also urged CMS to expeditiously process claims and provide instructions to MACs during program extensions, especially in instances when extensions are made

retroactively. They noted that seamless transition of programmatic support are crucial life lines for rural providers.

Response: We appreciate the commenters' support and their concern for the legislative interruption of Medicare programs that support rural providers. We note that in response to the multiple legislative extensions since the September 1, 2022, expiration (listed previously), CMS has issued multiple program instructions as expeditiously as possible to the MACs so that rural providers could benefit from the special payment protections afforded to MDHs.

After consideration of the public comments we received, we are adopting as final the proposed conforming changes to the regulations text at §§ 412.90 and 412.108 to reflect the extension of the MDH program through FY 2024 in accordance with division FF, section 4102 of the Consolidated Appropriations Act, 2023 (Pub. L. 117–328). We are finalizing the proposed changes in paragraphs (a)(1) and (c)(2)(iii) of § 412.108 and paragraph (j) of § 412.90 without modification.

G. Payment for Indirect and Direct Graduate Medical Education Costs (§§ 412.105 and 413.75 Through 413.83)

1. Background

Section 1886(h) of the Act, as added by section 9202 of the Consolidated Omnibus Budget Reconciliation Act (COBRA) of 1985 (Pub. L. 99–272) and as currently implemented in the regulations at 42 CFR 413.75 through 413.83, establishes a methodology for determining payments to hospitals for the direct costs of approved graduate medical education (GME) programs. Section 1886(h)(2) of the Act sets forth a methodology for the determination of a hospital-specific base-period per resident amount (PRA) that is calculated by dividing a hospital's allowable direct costs of GME in a base period by its number of full-time equivalent (FTE) residents in the base period. The base period is, for most hospitals, the hospital's cost reporting period beginning in FY 1984 (that is, October 1, 1983, through September 30, 1984). The base year PRA is updated annually for inflation. In general, Medicare direct GME payments are calculated by multiplying the hospital's updated PRA by the weighted number of FTE residents working in all areas of the hospital complex (and at nonprovider sites, when applicable), and the hospital's Medicare share of total inpatient days.

Section 1886(d)(5)(B) of the Act provides for a payment adjustment known as the indirect medical education (IME) adjustment under the IPPS for hospitals that have residents in an approved GME program, to account for the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment are located at 42 CFR 412.105. The hospital's IME adjustment applied to the DRG payments is calculated based on the ratio of the hospital's number of FTE residents training in either the inpatient or outpatient departments of the IPPS hospital (and, for discharges occurring on or after October 1, 1997, at non-provider sites, when applicable) to the number of inpatient hospital beds.

The calculation of both direct GME payments and the IME payment adjustment is affected by the number of FTE residents that a hospital is allowed to count. Generally, the greater the number of FTE residents a hospital counts, the greater the amount of Medicare direct GME and IME payments the hospital will receive. In an attempt to end the implicit incentive for hospitals to increase the number of FTE residents, Congress, through the Balanced Budget Act of 1997 (Pub. L. 105–33), established a limit on the number of allopathic and osteopathic residents that a hospital could include in its FTE resident count for direct GME and IME payment purposes. Under section 1886(h)(4)(F) of the Act, for cost reporting periods beginning on or after October 1, 1997, a hospital's unweighted FTE count of residents for purposes of direct GME may not exceed the hospital's unweighted FTE count for direct GME in its most recent cost reporting period ending on or before December 31, 1996. Under section 1886(d)(5)(B)(v) of the Act, a similar limit based on the FTE count for IME during that same cost reporting period is applied, effective for discharges occurring on or after October 1, 1997. Dental and podiatric residents are not included in this statutorily mandated cap.

2. Calculation of Prior Year IME Resident to Bed Ratio When There Is a Medicare GME Affiliation Agreement

Section 1886(d)(5)(B) of the Act provides that IPPS hospitals that have residents in an approved graduate medical education (GME) program receive an additional payment to reflect the higher indirect patient care costs of teaching hospitals relative to nonteaching hospitals. The regulations regarding the calculation of this additional payment, known as the indirect medical education (IME) adjustment, are located at § 412.105. The IME adjustment factor is calculated using a hospital's ratio of residents to beds, which is represented as r, and a statutorily set multiplier, which is represented as c, in the following equation: $c \times [(1 + r)^{.405} - 1]$. Section 1886(d)(5)(B)(ii)(XII) of the Act provides that, for discharges occurring during FY 2008 and fiscal years thereafter, the IME formula multiplier is 1.35. Thus, for FY 2024, the IME multiplier is 1.35. The formula is traditionally described in terms of a certain percentage increase in payment for every 10-percent increase in the resident-to-bed ratio. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51680) for a full discussion of the IME adjustment and IME adjustment factor.

Section 4621(b)(1) of the Balanced Budget Act of 1997 (Pub. L. 105–33) amended section 1886(d)(5)(B) of the Act by adding a clause (vi) to provide that, effective for cost reporting periods beginning on or after October 1, 1997, the resident-to-bed ratio may not exceed the ratio calculated during the prior cost reporting period (after accounting for the cap on the hospital's number of full-time equivalent (FTE) residents). We implemented this policy in the August 29, 1997, final rule with comment period (62 FR 46003) and the May 12, 1998 final rule (63 FR 26323) under regulations at § 412.105(a)(1). In general, the resident-to-bed ratio from the prior cost reporting period, which is to be used as the cap on the resident-to-bed ratio for the current cost reporting period, should reflect the prior year FTE count subject to the FTE cap on the number of allopathic and osteopathic residents, but not subject to the three-year rolling average. We note that the resident-to-bed ratio cap is a cap on the resident-to-bed ratio calculated for all residents, including allopathic, osteopathic, dental, and podiatry residents (63 FR 26324, May 12, 1998). However, as described in existing § 412.105(a)(1)(i), the numerator of the resident-to bed ratio cap may be adjusted to reflect an increase in the current cost reporting period's resident-to-bed ratio due to residents in a new GME program or new Rural Track Program, a Medicare GME affiliation agreement, or due to residents displaced by the closure of a hospital or a residency program. Under other circumstances where the exception does not apply, such as an increase in the number of podiatry or dentistry residents or a decrease in the number of beds (that is, the denominator of the resident-to-bed ratio), the ratio can increase after a 1-year delay. The law requires a hospital's IME payment to be

determined based on the lower of the two ratios (see section 1886(d)(5)(B)(vi)(I) of the Act and regulations at 42 CFR 412.105(a)(1)(i)). An increase in the current cost reporting period's ratio (subject to the FTE cap on the overall number of allopathic and osteopathic residents) thereby establishes a higher cap for the following cost reporting period.

Sections 1886(h)(4)(F) and 1886(d)(5)(B)(v) of the Act established limits on the number of allopathic and osteopathic residents that hospitals may count for purposes of calculating direct GME payments and the IME adjustment, respectively, thereby establishing hospital specific direct GME and IME full-time equivalent (FTE) resident caps. However, under the authority granted by section 1886(h)(4)(H)(ii) of the Act, the Secretary may issue rules to allow institutions that are members of the same affiliated group to apply their direct GME and IME FTE resident caps on an aggregate basis through a Medicare GME affiliation agreement. The Secretary's regulations permit hospitals, through a Medicare GME affiliation agreement, to increase or decrease their IME and direct GME FTE resident caps to reflect the rotation of residents among affiliated hospitals for agreed-upon academic years. Consistent with the broad authority conferred by the statute, we established criteria for defining an ''affiliated group'' and an ''affiliation agreement'' in both the August 29, 1997, final rule (62 FR 45966, 46006) and the May 12, 1998, final rule (63 FR 26318). In the August 1, 2002, IPPS final rule (67 FR 50069), we amended our regulations to require that each Medicare GME affiliation agreement must have a shared rotational arrangement. The regulations for ''Medicare GME affiliation agreements'' are at 42 CFR 413.75(b) and (f). In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49075, August 10, 2022), we expanded the regulations regarding Medicare GME affiliation agreements to permit urban and rural hospitals that participate in the same separately accredited family medicine Rural Track Program (RTP) and have rural track FTE limitations to enter into ''Rural Track Medicare GME Affiliation Agreements''.

As previously mentioned, as described in existing § 412.105(a)(1)(i), the numerator of the prior year resident-to bed ratio may be adjusted to reflect an increase in the current cost reporting period's resident-to-bed ratio due to residents in a Medicare GME affiliation agreement (among other limited reasons). As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27016), we have occasionally received inquiries related to adjusting the prior year numerator when the hospital is training more residents in the current year as a result of an IME FTE cap increase under the terms of a Medicare GME affiliation agreement. A hospital can train more residents in the current year versus the prior year under the terms of a Medicare GME affiliation agreement as a result of several scenarios. As an example, Hospital A and Hospital B participate in a Medicare GME affiliation agreement over a period of several years, and generally, under the terms of the agreement, Hospital A is giving IME FTE cap slots to Hospital B:

Example of Medicare GME Affiliations:

	HOSPITAL A IME CAP	HOSPITAL B IME CAP
2020	-5 (decrease of 5)	+5 (increase of 5)
2021	-6 (net decrease of 1 compared to prior year)	+6 (net increase of 1 compared to prior year)
2022	-5 (net increase of 1, as Hospital A is giving away 1 less FTE this year compared to prior year)	+5 (net decrease of 1, as Hospital B is receiving 1 less FTE this year compared to prior year)

In this example, we see that Hospital B's IME cap increases from 2019 to 2020 and again from 2020 to 2021 because it receives cap slots from Hospital A. However, we also see that Hospital A experiences a net increase in its FTE cap from 2021 to 2022, even though it continues to loan IME slots to Hospital B. This is because, under the terms of the Medicare GME affiliation agreement, Hospital A loans one less IME FTE to Hospital B in 2022 than it did in 2021. In the FY 2024 IPPS/LTCH PPS proposed rule, we proposed to clarify how to determine the net increase in FTEs in the current year numerator as compared to the prior year numerator as a result of the terms of a Medicare GME affiliation agreement. We explained that to determine this change accurately, we need to isolate only changes resulting from the Medicare GME affiliation agreement, and not, for example, an increase in the resident-bed-ratio due to participation in new programs, or due to a change in the number of beds in the denominator. Under the current cost report instructions (Transmittal 20) on Form CMS–2552–10, Worksheet E, Part A line 20, regarding the determination the prior year IRB ratio, states:

Line 20—In general, enter from the prior year cost report the intern and resident to bed ratio by dividing line 12 by line 4 (divide line 3.14 by line 3 if the prior year cost report was the Form CMS–2552–96). However, if the provider is participating in training residents in a new medical residency training program(s) under 42 CFR 413.79(e) for a new program started prior to October 1, 2012, add to the numerator of the prior year intern and resident to bed ratio (that is, line 12 of the prior cost report, which might be zero), if applicable, the number of FTE residents in the current cost reporting period that are in the initial period of years of a new program (line 16) (that is, the period of years is the minimum accredited length of the program). For a new program started prior to October 1, 2012, contact your contractor for instructions on how to complete this line if you have a new program for which the period of years is less than or more than three years. For urban hospitals that began participating in training residents in a new program for the first time on or after October 1, 2012, under 42 CFR 413.79(e)(1), if this cost reporting period is prior to the cost reporting period that coincides with or follows the start of the sixth program year of the first new program started, then divide line 16 of this cost report by line 4 of the prior year cost report (see 79 FR 50110 (August 22, 2014)). For rural hospitals participating in a new program on or after October 1, 2012, under 42 CFR 413.79(e)(3), for each new program started, if this cost reporting period is prior to the cost reporting period that coincides with or follows the start of the sixth program year of each particular new program, then add the amount from line 12 of the prior year (if greater than zero) and line 16 of this cost report, and divide the sum by line 4 of the prior year's cost report (see 79 FR 50110 (August 22, 2014)). *If the provider is participating in a Medicare GME affiliation agreement or rural track Medicare GME affiliation agreement under 42 CFR 413.79(f), and the provider increased its current year FTE cap and current year FTE count due to this affiliation agreement, identify the lower of: (a) the difference between the current year numerator and the prior year numerator, and*

(b) the number by which the FTE cap increased per the affiliation agreement, and add the lower of these two numbers to the prior year's numerator (see 42 CFR 412.105(a)(1)(i)). If the hospital is participating in a valid emergency Medicare GME affiliation agreement under a § 1135 waiver, and a portion of this cost report falls within the time frame covered by that emergency affiliation agreement, then, effective on and after October 1, 2008, enter the current year resident-to-bed ratio from line 19 (see 73 FR 48649 (August 19, 2008) and 42 CFR 412.105(f)(1)(vi)). Effective for cost reporting periods beginning on or after October 1, 2002, if the hospital is training FTE residents in the current year that were displaced by the closure of another hospital or program, also adjust the numerator of the prior year ratio for the number of current year FTE residents that were displaced by hospital or program closure (see 42 CFR 412.105(a)(1)(iii)). The amount added to the prior year's numerator is the displaced resident FTE amount that you would not be able to count without a temporary cap adjustment. This is the same amount of displaced resident FTEs entered on line 17. For cost reporting periods beginning on or after October 1, 2022, for urban and rural hospitals participating in a rural track program(s), adjust the numerator by adding to the amount on Worksheet E, Part A, line 12, of the prior year cost report (if greater than zero) the FTEs in the rural track program(s) on line 16 of this worksheet, if this cost report is still prior to the cost reporting period that coincides with or follows the start of the sixth program year of that rural track program (italics emphasis added).

Our proposed clarification focused on the italicized text as previously detailed:

If the provider is participating in a Medicare GME affiliation agreement or rural track Medicare GME affiliation agreement under 42 CFR 413.79(f), and the provider increased its current year FTE cap and current year FTE count due to this affiliation agreement, identify the lower of: (a) the difference between the current year numerator and the prior year numerator, and (b) the number by which the FTE cap increased per the affiliation agreement, and add the lower of these two numbers to the prior year's numerator (emphasis added).

We have been asked by teaching hospitals to clarify what lines on the cost report to use to determine that the provider ''increased its current year FTE cap,'' and that the provider increased its ''current year FTE count'' due to the affiliation agreement. We have also been asked to clarify what line on the cost report represents the ''current year numerator,'' specifically, whether this value refers to current year line 12, or line 15, or line 18.

Line 8 states: Enter the adjustment (increase or decrease) to the FTE count for allopathic and osteopathic programs for affiliated programs in accordance with 42 CFR 413.75(b), 413.79(c)(2)(iv) and 63 FR 26340 (May 12, 1998), and 67 FR 50069 (August 1, 2002).

Line 10 states: Enter the FTE count for allopathic and osteopathic programs in the current year from your records. Do not include residents in the initial years of the new program.

Line 12 states: Enter the result of the lesser of line 9, or line 10 added to line 11.

Line 15 states: Enter the sum of lines 12 through 14 divided by three.

Line 18 states: Enter the sum of lines 15, 16 and 17.

Line 19 states: Enter the current year resident to bed ratio by dividing line 18 by line 4 [beds].

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27017 through 27018), if the provider is participating in a Medicare GME affiliation agreement (or rural track Medicare GME affiliation agreement under 42 CFR 413.75(b)), the provider first has to make sure that in fact, it increased its current year FTE cap, *and second,* that it increased its current year allowable FTE count. We proposed to clarify that, to determine if there is an increase in the current year FTE cap ''due to this affiliation agreement,'' the provider would check if the difference of current year line 8 minus prior year line 8 is positive. If yes, next the provider would determine if the difference of current year allowable allopathic and osteopathic FTE count line 12 minus prior year allowable allopathic and osteopathic FTE count line 12 is positive. The provider would determine the difference between current year line 12 and prior year line 12 by first excluding any dental and podiatry FTEs on line 11 of both years, if applicable. If negative, then the provider did not increase its current year allowable allopathic and osteopathic FTE count due to the affiliation agreement, and there is no adjustment made to the prior year IRB ratio. If positive, the provider would proceed with the next part of the determination to ''*identify the lower of: (a) the difference between the current year numerator and the prior year numerator, and (b) the number by which the FTE cap increased per the affiliation agreement, and add the lower of these two numbers to the prior year's numerator.*''

We further proposed to clarify that the ''current year numerator'' referred to in the excerpt from Worksheet E, Part A line 20 is line 15; that is, the current year numerator before making any adjustments for new programs, new RTPs, or displaced residents, but including residents counted under the terms of a Medicare GME affiliation agreement, and subject to the three-year rolling average. We explained the reasons for this in detail and restate the explanation in this section of this final rule. We also acknowledged that the phrase ''current year numerator'' in the context of line 20 must refer to a different value than the numerator of the ''current year resident to bed ratio'' in line 19, which states, ''Enter the current year resident to bed ratio by dividing line 18 by line 4.'' In the context of Medicare GME affiliation agreements in line 20, the current year numerator cannot refer to line 18, as line 18 represents the current year IRB ratio with various adjustments, including the FTEs in new programs from line 16, and FTEs displaced by hospital or program closure on line 17. As previously stated, we need to isolate only changes associated with the Medicare GME affiliation agreement, and including FTEs associated with new programs or closed programs on line 18 would introduce extraneous variables into the equation.

Next, we noted that the ''current year numerator'' is not line 12. Line 12 is the current year allowable FTE count; that is, the lower of the current year FTE count or the adjusted FTE cap, which reflects the FTE adjustment under the terms of the Medicare GME affiliation agreement. The current year allowable FTE count on line 12 is used in the 3-year rolling average calculation on line 15, which sums the current year allowable FTE count, the prior year allowable FTE count, and the penultimate year FTE count, and divides the result by 3. While it may seem that averaging the current year FTEs with FTEs from prior years interferes with determining only changes to the current year FTEs under an affiliation agreement, the law and regulations require that additional FTEs added due to a Medicare GME affiliation agreement are subject to the 3-year rolling average (see section 1886(d)(5)(B)(viii) of the Act and 42 CFR 413.79(f), regarding a Medicare GME affiliated group, which provides that a hospital may receive a temporary adjustment to its FTE cap, which is subject to the averaging rules under § 413.79(d), to reflect residents added or subtracted because the hospital is participating in a Medicare GME affiliated group (as defined under § 413.75(b)). Because any additional FTEs due to participation in a Medicare GME affiliation agreement must be included in the rolling average on line 15, we stated that we believe that the ''current year numerator'' referred to on Worksheet E, Part A line 20 is line 15,

not line 12. This contrasts with the ''prior year numerator,'' which we note is line 12, as the instructions for line 20 state: ''In general, enter from the prior year cost report the intern and resident to bed ratio by dividing line 12 by line 4.'' (See 42 CFR 412.105(a)(1)(i), which states ''this ratio may not exceed the ratio for the hospital's most recent prior cost reporting period after accounting for the cap on the number of allopathic and osteopathic full-time equivalent residents as described in paragraph (f)(1)(iv) of this section.'' This regulation does not require accounting for the 3-year rolling average.) Therefore, we proposed to clarify the instructions on Worksheet E, Part A line 20 as follows, in italics:

If the provider is participating in a Medicare GME affiliation agreement or rural track Medicare GME affiliation agreement under 42 CFR 413.79(f), and the provider increased its current year FTE cap *(difference of current year line 8 and prior year line 8 is positive) and increased its* current year allowable FTE count *(difference of current year line 12 (excluding current year dental and podiatry from line 11) and prior year line 12 (excluding prior year dental and podiatry from line 11) is positive)* due to this affiliation agreement, identify the lower of: a) the difference between the current year numerator *line 15* and the prior year numerator *line 12 of the prior year cost report,* and b) the number by which the FTE cap increased per the affiliation agreement *(difference of current year line 8 and prior year line 8),* and add the lower of these two numbers to the prior year's numerator *line 12 of the prior year cost report.*

Comment: Several commenters appreciated CMS's proposed clarification to the IME worksheet on the Medicare cost report when hospitals enter into a Medicare GME affiliation agreement, stating it will assist hospitals in ensuring that they complete the worksheet and report FTE counts in the proper manner. A commenter supported CMS's clarification efforts and another asked CMS to continue listening to teaching hospitals when specific policies are unclear.

Other commenters disagreed with aspects of CMS's proposed clarification. Another commenter noted that CMS's proposed clarification involves a comparison of the total allowable FTEs from the prior year and the current year as reported on line 12 (''. . . the provider . . . increased its current year allowable FTE count (difference of *current year line 12* (excluding current year dental and podiatry from line 11) and *prior year line 12* (excluding prior year dental and podiatry from line 11) is positive) due to this affiliation agreement . . .'' (88 FR 27017–27018, emphasis added). The commenter noted that the total allowable FTE count on line 12 is subject to the FTE cap, and since there are many hospitals that have IME FTE counts limited by their FTE caps, utilizing this line may not be the most accurate reflection of an actual increase or decrease in FTEs between years. The commenter suggested that a better reflection of an increase/decrease between years would be to compare the actual current year FTEs from line 10 between years before any FTE cap limits are applied.

Two commenters that opposed CMS's proposed clarification focused on another part of the clarification, where CMS proposed to compare current year line 15 and prior year line 12 (''. . . identify the lower of: (a) the difference between the current year numerator line 15 and the prior year numerator line 12 of the prior year cost report . . .'') (88 FR 27018). The commenters provided two examples where they believed the prior year numerator would not be sufficiently increased as a result of this proposed clarification. In the first example, a hospital experiences a decrease in its three-year rolling average FTE count in the current year as a result of a decrease in its number of dental and podiatric FTEs, even though its allopathic and osteopathic FTE count and its FTE cap increase under the terms of a Medicare GME affiliation agreement. In the second example, a hospital's allopathic and osteopathic FTE count and cap similarly increase in the current year as a result of a Medicare GME affiliation agreement, but the hospital's three-year rolling average FTE count is nevertheless lower than the prior-year allowable FTE count as a result of a significantly lower FTE count in the penultimate year. Furthermore, the commenters noted that in these examples CMS's proposed clarification would result in an inappropriate *reduction* to the numerator of the prior-year IRB ratio, since subtracting prior year line 12 from current year line 15 would result in a negative number. In addition, these commenters argued that CMS's proposed language does not account for rural track FTE affiliation agreements.

Response: We appreciate commenters' support of our proposed clarification and the careful review from those who raised concerns about it. Specifically, we proposed to add the following italicized language to Worksheet E, Part A, line 20 of CMS-Form-2552–10:

If the provider is participating in a Medicare GME affiliation agreement or rural track Medicare GME affiliation agreement under 42 CFR 413.79(f), and the provider increased its current year FTE cap *(difference of current year line 8 and prior year line 8 is positive) and* increased its current year allowable FTE count *(difference of current year line 12 (excluding current year dental and podiatry from line 11) and prior year line 12 (excluding prior year dental and podiatry from line 11) is positive)* due to this affiliation agreement, identify the lower of: (a) the difference between the current year numerator *line 15* and the prior year numerator *line 12* of *the prior year cost report,* and (b) the number by which the FTE cap increased per the affiliation agreement *(difference of current year line 8 and prior year line 8),* and add the lower of these two numbers to the prior year's numerator *line 12 of the prior year cost report* (88 FR 27018).

We do not concur with the commenters who disagreed with certain aspects of the proposed clarification, because we believe the commenters overlooked key portions of the law and regulations in drawing their conclusions. First, we reiterate that the point of permitting the numerator of the prior year IRB ratio to be adjusted due to the exceptions listed at 42 CFR 412.105(a)(1)(i) (for example, a new GME program or new Rural Track Program, a Medicare GME affiliation agreement, or due to residents displaced by the closure of a hospital or a residency program) is to more equitably compute a hospital's IME payment in certain situations where the IME cap increases year-over-year, so that the hospital is not held to a lower IME payment based on the prior year's FTE cap. Second, once the appropriate adjustments are made to the numerator of the prior year IRB ratio, the law at section 1886(d)(5)(B)(vi) of the Act requires that for actual payment, we take the *lower* of the current year IRB ratio or the prior year IRB ratio. That is, line 21 on Worksheet E, Part A states, ''Enter the lesser of line 19 or 20.'' It appears that the commenters disregarded this key point.

In the examples the commenters provided, they argued that under CMS's proposed clarification, the prior year IRB ratio is not sufficiently increased, and that the comparison of current year line 15 to prior year line 12 distorts the calculation of the IRB ratio. However, we have reviewed the examples and the adjustments that commenters suggested, and the result is that even if the prior year numerator were increased in the manner requested by commenters, this would not increase a hospital's IME payment, since doing so would have no effect on the value of the *current* year numerator: in both examples, the current year IRB ratio on line 19 would still be *lower* than the prior year IRB ratio on line 20, so that the current year IRB ratio would be reported on line 21. This demonstrates that there is no need to increase the prior year numerator

above the current year numerator; it is only necessary to ensure that the prior year numerator is adjusted to accommodate the additional FTEs counted as a result of certain increases to a hospital's IME FTE cap.

In this way we also address the commenters' concern that the proposed clarification distorts the calculation of the IRB ratio, and their contention that a hospital is harmed if its current year three-year average FTE count is less than its prior year total allowable FTE count, either through a decrease in dental or podiatry FTEs or because of a low FTE count in the penultimate year. Since the law requires IME payment to be based on the lesser of the current year IRB ratio or the prior year IRB ratio, if a hospital's current year FTE count goes down, then payment would logically be made based on the current year's lower IRB ratio; payment based on last year's higher ratio would result in an overpayment in the current year. Thus, if a hospital increases its cap through a Medicare GME affiliation agreement, but, for whatever reason, its three-year average FTE count is *less than* the prior year total allowable FTE count, then an adjustment to the prior year numerator will make no difference, as the law requires that the hospital use the *lower* of the current year IRB ratio or prior year IRB ratio for IME payment.

Similarly, we do not believe it is appropriate to compare line 10 of the current year to line 10 of the prior year, as a commenter suggested. First, the FTEs used in the IRB ratio are subject to a hospital's IME FTE cap, which applies to line 12 but *not* to line 10. Second, the following fairly common scenario demonstrates how comparing line 10 to line 10 may lead to unfair results. Assume a hospital is training FTEs significantly over its FTE cap, and even though it has increased its FTE cap via a Medicare GME affiliation agreement, it is still training FTEs in excess of that affiliated cap. However, this hospital's current year FTE count on line 10 is somewhat less than the prior year FTE count on line 10. Specifically, assume that in 2020, Hospital A has an FTE cap of 100 (line 9 = 100) and trains 200 allopathic and osteopathic FTE residents (line 10 = 200); further assume that Hospital A does not train any dental or podiatry residents (line 11 = 0; line 12 = 100). In 2021, Hospital A has difficulty filling positions in a certain program, and therefore, it experiences a reduction in its FTE count and trains 190 allopathic and osteopathic residents (line 10 = 190). However, under the terms of a Medicare GME affiliation agreement, Hospital A increases its FTE cap by 10 to 110 (line 8 = 10; line 9 = 110; line 12 = 110). Thus, the hospital's *total* FTE count decreased from 200 to 190, but because its FTE cap increased from 100 to 110 under the Medicare GME affiliation agreement, its *allowable* FTE count actually increased by 10, from 100 to 110. If we were to take the difference between the current year line 10 (190 FTEs) and prior year line 10 (200 FTEs), the result would be a negative number (−10), and there would be no adjustment to the prior year numerator, since the FTE count decreased in the current year. But under CMS's proposed clarification, the hospital *increased its allowable FTE count,* and when we determine the difference between current year line 12 (110) and prior year line 12 (100), the result is a positive difference of 10, allowing the hospital to adjust the prior year numerator by +10. In this manner, the hospital's IME payment will reflect the fact that its current year allowable FTE count increased by 10 relative to the prior year allowable FTE count. That is also why we proposed to clarify the language on line 20 to require that the hospital increase its *allowable* FTE count, as follows:

If the provider is participating in a Medicare GME affiliation agreement or rural track Medicare GME affiliation agreement under 42 CFR 413.79(f), and the provider increased its current year FTE cap *(difference of current year line 8 and prior year line 8 is positive) and increased its* current year **allowable** FTE count *(difference of current year line 12 (excluding current year dental and podiatry from line 11) and prior year line 12 (excluding prior year dental and podiatry from line 11) is positive)* due to this affiliation agreement . . . (88 FR 27018, bolded emphasis added).

As noted previously, commenters pointed out that under certain circumstances, instead of making a positive adjustment to the prior year numerator, CMS's proposed instructions would direct the hospital to make an improper negative adjustment to the prior year numerator. In one of the commenters' examples, even though a hospital's current year line 8 increased by 8 FTEs due to an affiliation agreement, and the current year FTE count also increased by 8 FTEs, the hospital would receive a negative adjustment to its IRB ratio under CMS's proposed clarification because the difference between the current year numerator line 15 (that is, 90.67) and the prior-year numerator line 12 of the prior year cost report (that is, 92) is -1.33. Since CMS's proposed instructions say to "add the lower of these two numbers to the prior year's numerator line 12 of the prior year cost report," the result would be that the hospital would have to subtract 1.33 from prior year line 12 amount of 92 (92 - 1.33 = 90.67). The commenters believe it would be inappropriate to decrease the prior year numerator in the case where the current year FTE cap and FTE counts both increased. We agree with the commenters that the hospital should not "add" the lower of the two amounts to the prior year numerator if the lower amount is a negative number, as that would be a reduction to the prior year numerator. In this final rule, we are revising that portion of the instructions to line 20 to state: ". . . add the lower of these two numbers to the prior year's numerator *line 12 of the prior year cost report.* ***If the lower of these two numbers is a negative number, do not adjust the prior year numerator line 12"*** *(bolded language is new).*

In addition, the commenters correctly pointed out that the instructions should specifically reference line 7.02 to allow consideration of a cap increase under the terms of a rural track Medicare GME affiliation agreement. Therefore, in this final rule we are revising the instructions on line 20 to include this reference to line 7.02 of Worksheet E, Part A. We are finalizing our proposed clarification to the instructions on line 20 of Worksheet E, Part A of the Medicare cost report, in addition to adding the bolded changes stated later

in this section in response to comments, as follows:

> If the provider is participating in a Medicare GME affiliation agreement or rural track Medicare GME affiliation agreement under 42 CFR 413.79(f), and the provider increased its current year FTE cap *(difference of* ***the sum of*** *current year line 8* ***and line 7.02,*** *and* ***sum of*** *prior year line 8* ***and line 7.02*** *is positive) and increased its* current year allowable FTE count *(difference of current year line 12 (excluding current year dental and podiatry from line 11) and prior year line 12 (excluding prior year dental and podiatry from line 11) is positive)* due to this affiliation agreement, identify the lower of: (a) the difference between the current year numerator *line 15* and the prior year numerator *line 12 of the prior year cost report,* and (b) the number by which the FTE cap increased per the affiliation agreement *(difference of* ***sum of*** *current year line 8* ***and line 7.02,*** *and* ***sum of*** *prior year line 8* ***and line 7.02****),* and add the lower of these two numbers to the prior year's numerator *line 12 of the prior year cost report.* ***If the lower of these two numbers is a negative number, do not adjust the prior year numerator line 12.***

We did not propose any changes to the regulation text at 42 CFR 412.105, as we believe the appropriate regulations text already exists at 42 CFR 412.105(a)(1)(i) and 413.79(f), indicating that an adjustment may be made to the prior year numerator due to an increase in the Medicare GME affiliated cap, that the lower of the current or prior year IRB ratio is used for payment, and that FTE residents added under a Medicare GME affiliation agreement are subject to the rolling average. Rather, as we stated, we proposed to clarify the Medicare cost report instructions Form CMS–2552–10 Worksheet E, Part A, line 20 to more clearly indicate how these calculations are performed. We intend to insert the finalized clarification into the next update of the Medicare cost report instructions Form CMS–2552–10 Worksheet E, Part A, line 20.

3. Training in New REH Facility Type

In the Hospital Outpatient Prospective Payment System CY 2023 final rule with comment (87 FR 71748) CMS finalized certain payment policies and conditions of participation (CoPs) with respect to rural emergency hospitals (REHs). Section 125 of Division CC of the Consolidated Appropriations Act, 2021 (CAA) added a new section 1861(kkk) of the Act to establish REHs as a new Medicare provider type, effective January 1, 2023. REHs are facilities that convert from either a critical access hospital (CAH) or a rural hospital (or one treated as such under section 1886(d)(8)(E) of the Act) with not more than 50 beds, and that do not provide acute care inpatient services with the exception of post-hospital extended care services furnished in a unit of the facility that is a distinct part licensed as a skilled nursing facility. By statute, REH services include emergency department services and observation care and, at the election of the REH, other outpatient medical and health services furnished on an outpatient basis, as specified by the Secretary through rulemaking. REHs are a new provider type established by the CAA, 2021 to address the growing concern over closures of rural hospitals. Similar to CAHs, REHs are intended to provide much needed healthcare services, often times as the initial and only accessible point of care for individuals living in rural underserved areas.

As part of the comments received in response to the CY 2023 Outpatient Prospective Payment System (OPPS) proposed rule (87 FR 44502) and the proposed rule establishing REH CoPs (87 FR 40350), CMS received the request to designate REHs as graduate medical education (GME) eligible facilities similar to the GME designation for CAHs (87 FR 72164). CMS' current policy with respect to CAHs and GME is discussed in the August 16, 2019 **Federal Register** (84 FR 42411). In that rule we finalized the policy that effective with portions of cost reporting periods beginning on or after October 1, 2019, a hospital may include FTE residents training at a CAH in its direct GME and IME FTE counts as long as it meets the nonprovider setting requirements currently included at 42 CFR 412.105(f)(1)(ii)(E) and 413.78(g). We stated that while a CAH is considered a ''provider of services'' under section 1861(u) of the Act, the term ''nonprovider'' is not explicitly defined in the statute. Furthermore, section 1861(e) of the Act, which states in part that the term ''hospital'' does not include, unless the context otherwise requires, a critical access hospital (as defined in section 1861(mm)(1) of the Act), underscores the sometimes ambiguous status of CAHs. We stated that we believe that the lack of both an explicit statutory definition of ''nonprovider'' and a definitive determination as to whether a CAH is considered a hospital along with the fact that a CAH is a facility primarily engaged in patient care (we referred readers to section 1886(h)(5)(K) of the Act which states that the term ''nonprovider setting that is primarily engaged in furnishing patient care'' means a nonprovider setting in which the primary activity is the care and treatment of patients, as defined by the Secretary), provides flexibility within the current statutory language to consider a CAH as a ''nonprovider'' setting for direct GME and IME payment purposes.

Section 125(a)(1)(A) of the CAA, 2021, amended section 1861(e) of the Social Security Act by inserting the phrase ''or a rural emergency hospital (as defined in subsection (kkk)(2))'', such that the language now states that the term ''hospital'' does not include, unless the context otherwise requires, a critical access hospital (as defined in section 1861(mm)(1) of the Act) or a rural emergency hospital (as defined in subsection (kkk)(2)). Given the inclusion of REHs in the last sentence of section 1861(e) and the fact that an REH is a facility primarily engaged in patient care (see the previous discussion of 1886(h)(5)(K)), we believe that statutory flexibility also exists for REHs to be considered nonprovider settings for GME payment purposes. In addition, facilities currently designated as CAHs, which serve as nonprovider sites, may choose to convert to REH status to be able to continue to provide healthcare

services within their communities. We believe that increasing access to physicians in rural areas can be supported by a flexible policy which would allow for residency training to continue at these former CAHs and begin at other newly designated REHs, which may have not previously trained residents. Therefore, we proposed to add a new paragraph (d) at 42 CFR 419.92 to state that effective for portions of cost reporting periods beginning on or after October 1, 2023, a hospital may include FTE residents training at an REH in its direct GME and IME FTE counts as long as it meets the nonprovider setting requirements included at 42 CFR 412.105(f)(1)(ii)(E) and 413.78(g) and any succeeding regulations. Consistent with our policy regarding residency training at CAHs during a hospital's cap building period (84 FR 42415), if a hospital is at some point in its 5-year cap-building period as of October 1, 2023, and as of that date is sending residents in a new program to train at a REH, assuming the regulations governing nonprovider site training are met, the time spent by FTE residents training at the REH on or after October 1, 2023, will be included in the hospital's FTE cap calculation.

As an alternative to being considered a nonprovider site, we stated in the August 16, 2019 **Federal Register** (84 FR 42415), that a CAH may decide to continue to incur the costs of training residents in an approved residency training program(s) and receive payment based on 101 percent of the reasonable costs for those training costs. In this situation no hospital can include the residents training at the CAH in its direct GME and IME FTE counts. We believe REHs may make a similar decision to incur residency training costs directly consistent with the statutory language at section 1886(k)(2)(D) of the Act, which refers to nonhospital providers, and the aforementioned flexibility provided under 1861(e) of the Act. Specifically, we proposed under the authority of section 1886(k)(2)(D) of the Act to add a new paragraph (d) at 42 CFR 419.92 indicating that effective for portions of cost reporting periods beginning on or after October 1, 2023, REHs may decide to incur the costs of training residents in an approved residency training program(s) and receive payment based on 100 percent of the reasonable costs for those training costs, consistent with the reasonable cost principles at section 1861(v)(1)(A) of the Act. As is the case when CAHs incur GME costs directly, no hospital can include the residents training at the REH in its direct GME and IME FTE counts when the REH chooses to be paid for direct GME costs instead of functioning as a nonprovider site and as such, residency training in this instance is not limited by FTE resident caps.

In summary, we proposed that effective for portions of cost reporting periods beginning on or after October 1, 2023, an REH may decide to be a nonprovider site such that if the requirements at 42 CFR 412.105(f)(1)(ii)(E) and 413.78(g) are met, a hospital can include the FTE residents training at the REH in its direct GME and IME FTE counts for Medicare payment purposes, or, the REH may decide to incur direct GME costs and be paid based on reasonable costs for those training costs. We proposed to add a new paragraph (d) at 42 CFR 419.92 to implement these provisions.

Comment: Commenters supported the proposal to treat REHs similar to CAHs for Medicare GME payment purposes such that an REH may choose to function as a nonprovider setting consistent with 42 CFR 412.105(f)(1)(ii)(E) and 413.78(g) or choose to be paid based on reasonable costs for the GME training costs that it incurs.

Many commenters stated that allowing REHs to be GME eligible facilities will help promote greater physician participation in rural healthcare thereby improving workforce shortages in rural areas and in turn improve patient access to care in underserved areas. Commenters noted the correlation between where residents train and where they practice such that increasing residency training in rural areas has a positive impact on physician supply and interest in serving in rural areas. A commenter noted that while the proposal is not a complete solution to oncology workforce challenges in rural areas, they support it as an initial step toward improving access to cancer care in rural communities. The commenter encouraged CMS to consider future policies to retain practitioners of various specialties, including oncology, in rural and underserved settings. A few commenters stated that family physicians are an essential source of emergency care in rural areas and are uniquely suited to work in REHs. The commenters stated that multiple studies have demonstrated that, while many family physicians provide emergency care in urban and suburban communities, rural family physicians are more likely to work in emergency departments. The commenters stated that The Accreditation Council for Graduate Medical Education (ACGME) requirements for family medicine residents include several proficiencies important for providing emergency care and that in addition to emergency services, REHs can offer other outpatient services like pregnancy and delivery care, behavioral health services, and primary care, all of which are within family physicians' scope of training. The commenters therefore believe that REHs would be a valuable training site for family medicine residents. A commenter stated that it is critically important that REHs be adequately staffed, considering the important role that they play in rural communities. The commenter stated that as long as the rotations at REHs meet the requirements set out by the ACGME, thereby ensuring that residents are still receiving the high-quality education they deserve, they support the expansion of considering REHs as nonprovider sites for purposes of GME training and payment. A commenter expressed support for the proposal and noted that a large part of their state is designated as a Health Professional Shortage Area and reimbursement for GME training programs is an important piece to sustain and hopefully grow healthcare in these areas. Another commenter stated that allowing REHs to attract, educate, and be reimbursed for training additional healthcare workforce will help sustain these critical healthcare access points across rural parts of their state. A commenter stated they anticipate the proposed policy will be favorable to rural communities and REHs as it would provide for continued training of residents in rural areas for converting CAHs and offer the opportunity for additional rural training of residents that might not otherwise be viable in the absence of the proposal.

Response: We appreciate the commenters' support. After consideration of the public comments received, we are finalizing our proposal that effective for portions of cost reporting periods beginning on or after October 1, 2023, an REH may decide to be a non-provider site. If the requirements at 42 CFR 412.105(f)(1)(ii)(E) and 413.78(g) and any succeeding regulations are met, a hospital can include the FTE residents training at the REH in its direct GME and IME FTE counts for Medicare payment purposes. In the alternative, the REH may decide to incur direct GME costs and be paid based on reasonable costs for those training costs. We are finalizing our proposed regulation text to include these provisions at 42 CFR 419.92(d).

Comment: A commenter stated that the designation of REHs as GME-eligible

facilities is a perfect example of how a flexible policy can increase access to physicians in rural areas. The commenter stated that the proposed policy reduces barriers to Tribal facilities that may be considering redesignation to an REH by eliminating one of the cons from the equation, that is, deciding whether it can cut its training program and continue providing adequate care to its patient populations. The commenter stated as this new provider type rolls out, CMS must continue to address the concerns that come up from Tribal facilities to ensure that the REH program operates as intended, to best serve folks in rural areas. One of these identified concerns is that the REH payment structure does not include the all-inclusive encounter rate, so the new provider type is not as attractive as it could be to Indian Health Care Providers (IHCPs). These are the kinds of issues that come up and can be addressed when CMS engages with Tribes.

Response: We appreciate hearing that the proposed policy may help alleviate concerns related to REH designation for Tribal facilities. Regarding the REH payment structure, while the proposed policy discussed in this section is not related to general REH payment policies, we appreciate hearing the concerns brought up by Tribal facilities regarding the REH program and look forward to continued discussions with Tribes to address these concerns.

Comment: Several commenters stated that the proposed policy to consider REHs as GME eligible training sites will allow small rural teaching hospitals and CAHs that convert to REHs to minimize unnecessary financial burdens when they convert and choose to continue their educational mission. The commenters stated that the REH program should provide stability in health care delivery systems for communities that would otherwise experience the closure of a hospital and that the proposal helps limit the financial barriers for any REH with the capacity to operate as a rural training site. Another commenter stated that their concern lies principally in the financial viability of the REH model, given the prohibition on providing inpatient services, and therefore the commenter's advocacy focuses on ensuring that REHs retain every opportunity to participate fully in Medicare as permitted by Congress in the CAA, 2021. The commenters thanked CMS for the proposal to incorporate REHs into the GME program via the ''nonprovider'' designation and permit REHs the same opportunities as CAHs to receive reimbursement for the costs incurred in training residents.

However, some commenters expressed concern over the proposed payment methodology should an REH choose to be reimbursed directly for training costs. Several commenters asked that CMS adopt cost-based reimbursement at 101 percent for REHs that choose to incur direct GME costs since CAHs currently receive reimbursement at 101 percent of reasonable costs for residency training and therefore CMS should maintain consistency for CAHs that convert to REHs. The commenters stated that hospitals that choose to convert to REHs do not make the decision lightly and are more likely to be independent CAHs, have a three-year negative operating margin, and have a relatively low average daily census. The commenters stated that hospitals that convert to REHs and decide to train residents are doing so while in a precarious financial position and thus should receive higher reimbursement. The commenters stated that aligning the REH GME policy with the policy applicable to CAHs is consistent with CMS' approach in other areas of law for REHs, such as mirroring many CAH conditions of participation for REHs. A few commenters stated that the REH provider type was created with the express goal of enabling CAHs to transition into REHs to keep their doors open amid financial challenges. The commenters stated that they do not believe REHs should be penalized in their GME payments when transitioning from a CAH to an REH. Another commenter requested that CMS pay for residency training at CAHs at 101 percent of the reasonable cost under section 1861(v) of the Social Security Act, which would align with CAH payments based on reasonable cost principals.

Response: We appreciate the comments indicating that allowing REHs to be GME eligible facilities will reduce financial barriers to REH conversion and aid in supporting the financial viability of REHs. We understand the commenters' request to reimburse REHs based on 101 percent of reasonable costs when they choose to be paid for the direct costs of training residents as is the case for CAHs. However, there is no statutory basis for reimbursing REHs for the direct costs of GME at 101 percent of reasonable costs. Whereas the statutory language for CAH inpatient and outpatient reimbursement at sections 1814(l) and 1834(g) of the Act specifically refers to 101 percent of reasonable costs, payments made to REHs for outpatient services under section 1834(x) of the Act are generally made under the Outpatient Prospective Payment System plus 5 percent. Furthermore, sections 1886(k)(2)(D) of the Act (Payment to Nonhospital Providers) and 1861(v)(1)(A) of the Act (Reasonable Cost) do not specify reimbursement at 101 percent of reasonable costs. Therefore, as noted previously, we are finalizing the proposed policy that if an REH chooses to be reimbursed for its direct GME costs, it will be reimbursed based on 100 percent of reasonable costs. As stated in the proposed rule (88 FR 27019), if an REH chooses to be reimbursed for the direct costs of residency training, it is not limited by FTE residency caps. Therefore, training at REHs that choose to be reimbursed directly are Medicare GME payments that are made above the statutorily mandated caps and thus provide for additional funding supporting training in rural areas despite payment at 100 percent of reasonable costs as opposed to 101 percent of reasonable costs.

Comment: Several commenters submitted comments specific to REHs and rural track programs (RTPs). Commenters stated that the size of REH facilities and training requirements from the ACGME will likely limit the number of residents who train at these sites, but with new opportunities for hospitals to expand training through RTPs, REH GME has the potential to create training partnerships in rural areas with larger academic medical centers. The commenters stated that the learning experience provided to trainees in rural areas is unique and additional resources like REH GME may have positive patient care outcomes in these underserved areas. A commenter stated that as evidenced by their strong advocacy for RTPs (formerly rural training tracks) and the inclusion of hospitals located in rural areas among the beneficiaries of resident cap relief legislation, they support innovative strategies that will incentivize bringing physician services to those living in rural areas. Another commenter stated they expect the proposed policy will enable REHs to serve as rotator sites for RTPs, which would enhance resident training in rural areas and potentially improve timely access to care in areas with an REH. The commenter specifically requested CMS clarify in the final rule that REHs will be able to serve as rotator sites in RTPs.

Response: We appreciate the comments noting that training at REHs may help to expand RTPs. Since we are finalizing a policy to treat REHs similar to CAHs for Medicare GME payment purposes, REHs can serve as a rural training site in an RTP in the same

manner as a CAH would. Note that if an REH has reclassified as rural under 42 CFR 412.103 (section 1886(d)(8)(E) of the Act), it would only be considered rural for IME payment purposes in the event it is serving as a non-provider site. We refer readers to the current policies concerning RTPs as discussed in the December 27, 2021 **Federal Register**, which implements section 127 of the CAA, 2021 (86 FR 73445).

Comment: A commenter stated that as the REH model evolves, it would be helpful for CMS to evaluate and request feedback from participating facilities to help guide future policy. The commenter encouraged CMS to continue working collaboratively to provide support for facilities converting, or considering converting, to the new REH status, as well as provide clarity and support for those considering participating as a GME training facility.

Response: We appreciate the commenter's recommendation to continue collaborative efforts that will support facilities interested in REH status. We encourage individuals to contact CMS or their Medicare Administrative Contractor (MAC) should they have any questions on specific policies concerning REHs and Medicare GME payments.

Comment: A commenter stated that to further alleviate workforce shortages and address the needs of rural and medically underserved communities, they urge CMS to work with members of the United States Senate Committee on Health, Education, Labor, and Pensions (HELP). The commenter stated that the Senate HELP Committee recently sought feedback from the public on healthcare workforce shortages, and provided several recommendations to reduce barriers to care, diversify the healthcare workforce, increase funding for GME programs specifically designated for mental health and substance use disorder providers, and advance technology solutions to reduce administrative friction and workforce burnout. The commenter stated by working together, CMS and the Senate HELP Committee can effectively address workforce shortages, increase community resources, and mitigate closures of rural hospitals. The commenter stated they welcome the opportunity to discuss their investments and recommendations with CMS and also encouraged CMS to work with Congress on additional policy changes and investments that support the healthcare workforce and rural and medically underserved communities.

A commenter stated that they support other initiatives to transform physician training programs from urban settings, currently representing the majority of programs, and having more robust training options in rural communities. The commenter recommended that the financial support and resources for such training programs be sustainable and allow residents to fully complete their training without the concern of funding gaps. The commenter stated that they aim to ensure continuous financial support for training programs, avoiding any interruptions or breaks in funding. The commenter noted that since most rural hospitals are unable to financially support residency training positions independently, they rely on federally funded GME resources.

A commenter requested that similar to the GME designation for CAHs, REHs also include advanced practice nursing education. The commenter stated that this designation is essential, especially since 221 clinical sites for nurse anesthesia have been designated as having CAH status and are eligible to convert to REH status. The commenter stated that certified registered nurse anesthetists (CRNAs) predominate in rural hospitals, and it is critical that these educational opportunities are available for CRNAs and other advanced practice registered nurses. The commenter stated that in some states, CRNAs are the sole anesthesia providers in nearly100 percent of rural hospitals, affording these medical facilities obstetrical, surgical, trauma stabilization, and pain management capabilities. The commenter stated that the importance of CRNA services in rural areas was highlighted in a recent study which examined the relationship between socioeconomic factors related to geography, insurance type, and the distribution of anesthesia provider type. The study correlated CRNAs with lower income populations and correlated anesthesiologist services with higher-income populations. The commenter stated that of particular importance to the implementation of public benefit programs in the U.S., the study showed that compared with anesthesiologists, CRNAs are more likely to work in areas with lower median incomes and larger populations of citizens who are unemployed, uninsured, and/or Medicaid beneficiaries.

Response: The policy finalized in this rule relates specifically to Medicare GME payments made to REH facilities. These payments are made only for the training of medical, dental, and podiatry residents. Because Medicare GME payments do not include payments for training CRNAs and because the policy finalized in this rule is limited in scope to residency training at REHs, we consider these comments to be out of scope and are not responding to them in this final rule.

H. Reasonable Cost Payment for Nursing and Allied Health Education Programs (§§ 413.85 and 413.87)

1. General

Under section 1861(v) of the Act, Medicare has historically paid providers for Medicare's share of the costs that providers incur in connection with approved educational activities. Approved nursing and allied health (NAH) education programs are those that are, in part, operated by a provider, and meet State licensure requirements, or are recognized by a national accrediting body. The costs of these programs are excluded from the definition of ''inpatient hospital operating costs'' and are not included in the calculation of payment rates for hospitals or hospital units paid under the IPPS, IRF PPS, or IPF PPS, and are excluded from the rate-of-increase ceiling for certain facilities not paid on a PPS. These costs are separately identified and ''passed through'' (that is, paid separately on a reasonable cost basis). Existing regulations on NAH education program costs are located at 42 CFR 413.85. The most recent substantive rulemakings on these regulations were in the January 12, 2001 final rule (66 FR 3358 through 3374), and in the August 1, 2003 final rule (68 FR 45423 and 45434).

b. Medicare Advantage Nursing and Allied Health Education Payments

Section 541 of the Balanced Budget Refinement Act (BBRA) of 1999 provides for additional payments to hospitals for costs of nursing and allied health education associated with services to Medicare+Choice (now called Medicare Advantage (MA)) enrollees. Hospitals that operate approved nursing or allied health education programs and receive Medicare reasonable cost reimbursement for these programs would receive additional payments from MA organizations. Section 541 of the BBRA limits total spending under the provision to no more than $60 million in any calendar year (CY). (In this document, we refer to the total amount of $60 million or less as the payment ''pool''.) Section 541 of the BBRA also provides that direct graduate medical education (GME) payments for Medicare+Choice utilization are reduced to the extent that these additional payments are made for nursing and allied health education programs. This provision was effective for portions of cost reporting periods

occurring in a CY, on or after January 1, 2000.

Section 512 of the Benefits Improvement and Protection Act (BIPA) of 2000 changed the formula for determining the additional amounts to be paid to hospitals for MA nursing and allied health costs. Under section 541 of the BBRA, the additional payment amount was determined based on the proportion of each individual hospital's nursing and allied health education payment to total nursing and allied health education payments made to all hospitals. However, this formula did not account for a hospital's specific MA utilization. Section 512 of the BIPA revised this payment formula to specifically account for each hospital's MA utilization. This provision was effective for portions of cost reporting periods occurring in a calendar year, beginning with CY 2001, and was implemented in the August 1, 2001 IPPS final rule (66 FR 39909 and 39910).

The regulations at 42 CFR 413.87 codified both statutory provisions. We first implemented the BBRA NAH MA provision in the August 1, 2000 IPPS interim final rule with comment period (IFC) (65 FR 47036 through 47039). In that IFC, we outlined the qualifying conditions for a hospital to receive the NAH MA payment, how we would calculate the NAH MA payment pool, and how a qualifying hospital would calculate its ''share'' of payment from that pool. Determining a hospital's NAH MA payment essentially involves applying a ratio of the hospital-specific NAH Part A payments, total inpatient days, and MA inpatient days, to national totals of those same amounts, from cost reporting periods ending in the fiscal year that is 2 years prior to the current calendar year. The formula is as follows:

(((Hospital NAH pass-through payment/ Hospital Part A Inpatient Days) * Hospital MA Inpatient Days)/ ((National NAH pass-through payment/National Part A Inpatient Days) * National MA Inpatient Days)) * Current Year Payment Pool.

With regard to determining the total national amounts for NAH pass-through payment, Part A inpatient days, and MA inpatient days, we note that section 1886(l) of the Act, as added by section 541 of the BBRA, gives the Secretary the discretion to ''estimate'' the national components of the formula noted previously. For example, section 1886(l)(2)(A) of the Act states that the Secretary would estimate the ratio of payments for all hospitals for portions of cost reporting periods occurring in the year under subsection 1886(h)(3)(D) to total direct GME payments estimated for the same portions of periods under section 1886(h)(3) of the Act. Accordingly, we stated in the August 1, 2000 IFC (65 FR 47038) that each year, we would determine and publish in a final rule the total amount of nursing and allied health education payments made across all hospitals during the fiscal year 2 years prior to the current calendar year We would use the best available cost reporting data for the applicable hospitals from the Hospital Cost Report Information System (HCRIS) for cost reporting periods in the fiscal year that is 2 years prior to the current calendar year (65 FR 47038).

To calculate the pool, in accordance with section 1886(l) of the Act, we would ''estimate'' a total amount for each calendar year, not to exceed $60 million (65 FR 47038).

To calculate the proportional reduction to Medicare+Choice (now MA) Direct GME payments, we stated that the percentage is estimated by calculating the ratio of the Medicare+Choice nursing and allied health payment ''pool'' for the current calendar year to the projected total Medicare+Choice direct GME payments made across all hospitals for the current calendar year. We stated that the projections of Medicare+Choice direct GME and Part A direct GME are based on the best available cost report data from the HCRIS (for example, for calendar year 2000, the projections are based on the best available cost report data from HCRIS 1998), and these payment amounts were increased using the increases allowed by section 1886(h) of the Act for these services (using the percentage applicable for the current calendar year for Medicare+Choice direct GME and the Consumer Price Index (CPI–U) increases for Part A direct GME). We also stated that we would publish the applicable percentage reduction each year in the IPPS proposed and final rules (65 FR 47038).

Thus, in the August 1, 2000 IFC, we described our policy regarding the timing and source of the national data components for the NAH MA add-on payment and the percent reduction to the direct GME MA payments, and we stated that we would publish the rates for each calendar year in the IPPS proposed and final rules. While the rates for CY 2000 were published in the August 1, 2000, IFC (see 65 FR 47038 and 47039), the rates for subsequent CYs were only issued through Change Requests (CRs) (CR 2692, CR 11642, CR 12407). After recent issuance of the CY 2019 rates in CR 12407 on August 19, 2021, we reviewed our update procedures, and were reminded that the August 1, 2000 IFC states that we would publish the NAH MA rates and direct GME percent reduction every year in the IPPS rules. Accordingly, for CY 2020 and CY 2021, we proposed and finalized the NAH MA add-on rates in the FY 2023 IPPS/LTCH PPS proposed and final rules. We stated that for CYs 2022 and after, we would similarly propose and finalize their respective NAH MA rates and direct GME percent reductions in subsequent IPPS/LTCH PPS rulemakings (see 87 FR 49073, August 10, 2022).

In the FY 2024 IPPS/LTCH PPS proposed rule, we proposed the rates for CY 2022. Consistent with the use of HCRIS data for past calendar years, we proposed to use data from cost reports ending in FY 2020 HCRIS (the fiscal year that is 2 years prior to CY 2022) to compile these national amounts: NAH pass-through payment, Part A Inpatient Days, MA Inpatient Days.

For the proposed rule, we accessed the FY 2020 HCRIS data from the fourth quarterly HCRIS update of 2022. However, to calculate the ''pool'' and the direct GME MA percent reduction, we ''project'' Part A direct GME payments and MA direct GME payments for the current calendar year, which in the proposed rule and in this final rule, is CY 2022, based on the ''best available cost report data from the HCRIS'' (65 FR 47038). Next, consistent with the method we described previously from the August 1, 2000 IFC, we increased these payment amounts from midpoint to midpoint of the appropriate calendar year using the increases allowed by section 1886(h) of the Act for these services (using the percentage applicable for the current calendar year for MA direct GME, and the Consumer Price Index-Urban (CPI–U) increases for Part A direct GME). For CY 2022, the direct GME projections are based on the fourth quarterly update of CY 2020 HCRIS, adjusted for the CPI–U and for increasing MA enrollment.

For CY 2022, the proposed national rates and percentages, and their data sources are set forth in this table. We stated in the proposed rule that we intend to update these numbers in the FY 2024 final rule based on the latest available cost report data.

CY 2022 NAH MA Rates	CY 2022	SOURCE
NAH Pass-Through	$289,890,999	Cost reports ending in FY 2020 HCRIS
Part A Inpatient Days	67,427,704	Cost reports ending in FY 2020 HCRIS
MA Inpatient Days	11,865,080	Cost reports ending in FY 2020 HCRIS
Part A Direct GME	$2,673,355,222	CY 2020 HCRIS + CPI-U
MA Direct GME	$1,836,860,771	CY 2020 HCRIS + CPI-U
Pool (not to exceed $60 million)	$60,000,000	((MA DGME /Part A DGME) * (NAH Pass-through))
Percent Reduction to MA DGME Payments	3.27%	Pool/MA direct GME

We did not receive any comments on the proposed national NAH MA rates and percentages.

For this final rule, consistent with the use of HCRIS data for past calendar years, for CY 2022, we use data from cost reports ending in FY 2020 HCRIS (the fiscal year that is 2 years prior to CY 2022) to compile these national amounts: NAH pass-through payment, Part A Inpatient Days, MA Inpatient Days. For this final rule, we accessed the HCRIS data from the first quarterly HCRIS update of 2023. However, to calculate the ''pool'' and the direct GME MA percent reduction, we project Part A direct GME payments and MA direct GME payments for the current calendar year, which in this final rule, is CY 2022 as the best available cost report data. Next, consistent with the method we described previously from the August 1, 2000 IFC, we increased these payment amounts from midpoint to midpoint of the appropriate calendar year using the increases allowed by section 1886(h) of the Act for these services (using the percentage applicable for the current calendar year for MA direct GME, and the Consumer Price Index—Urban (CPI–U) increases for Part A direct GME). For CY 2022, the direct GME projections are based on FY 2020 HCRIS, and the final national rates and percentages, and their data sources are set forth in this table.

Final CY 2022 NAH MA Rates	Final CY 2022	FINAL SOURCE
NAH Pass-Through	$289,284,244	Cost reports ending in FY 2020 HCRIS
Part A Inpatient Days	67,407,803	Cost reports ending in FY 2020 HCRIS
MA Inpatient Days	11,859,978	Cost reports ending in FY 2020 HCRIS
Part A Direct GME	$2,678,717,287	CY 2020 HCRIS + CPI-U
MA Direct GME	$1,834,761,073	CY 2020 HCRIS + CPI-U
Pool (not to exceed $60 million)	$60,000,000	((MA DGME /Part A DGME) * (NAH Pass-through))
Percent Reduction to MA DGME Payments	3.27%	Pool/MA direct GME

In summary, we are finalizing our proposal to use NAH MA add-on rates as well as the direct GME MA percent reductions for CY 2022, based on sufficient HCRIS data to develop the rates for these years. We expect to propose to issue the rates for CY 2023 in the FY 2025 IPPS/LTCH PPS proposed rule, when sufficient HCRIS data is available to develop the rates for CY 2023.

Section 4143 of the CAA 2023 (enacted December 29, 2022), called ''Waiver of Cap on Annual Payments for Nursing and Allied Health Education Payments,'' amends section 1886(l)(2)(B) of the Act to state that for portions of cost reporting periods occurring in each of CYs 2010 through 2019, the $60 million payment limit, or payment ''pool,'' *shall not apply* to the total amount of additional payments for nursing and allied health education to be distributed to hospitals that, as of the date of enactment of this clause, are operating a school of nursing, a school of allied health, or a school of nursing and allied health. As noted previously, section 541 of the BBRA limited total spending under the NAH MA provision to no more than $60 million in any calendar year. Under CR 11642 issued on November 19, 2020, CMS instructed MACs to recalculate historical payments to hospitals consistent with the $60 million limit per calendar year, and make applicable adjustments to NAH MA payments. In the FY 2023 IPPS/LTCH PPS proposed rule (88 FR 27022), we proposed a method for the MACs to implement section 4143 in the absence of the $60 million limit on the pool.

In addition, section 541 of the BBRA 1999 also provides that direct GME payments for MA utilization will be reduced to the extent that these additional payments are made for nursing and allied health education programs. However, section 4143 of the CAA 2023 also provides that in not applying the $60 million limit for each of 2010 through 2019, the Secretary shall not take into account any increase in the total amount of such additional payment amounts for such nursing and allied health education for portions of cost reporting periods occurring in the year. In the proposed rule, we proposed to interpret this to mean that, pursuant to the requirement set out at section 4143(b) of CAA 2023, MACs shall not change the DGME MA percent reduction amounts specified in CR 11642 for CYs 2010 through 2018, and CR 12407 for CY 2019 (and CR 12596 which corrected the DGME MA percent reduction related to CY 2018 specified in CR 11642).

The following table shows the recalculated pool amounts for CYs 2010 through 2019. We proposed that MACs would first determine whether hospitals that received revised payments under CR 11642 were still receiving NAH MA payments on an interim basis as of December 29, 2022. For example, if a hospital's payments for a NAH program(s) were adjusted under CR 11642, but that hospital since closed all of its NAH programs, that hospital would not be eligible under section 4143 to receive adjusted payments for CYs 2010 through 2019, even if the hospital itself has remained operational.

Second, we proposed that MACs would use the table in this section of this rule to recalculate an eligible hospital's NAH MA payment for portions of cost reporting periods occurring in CY 2010 through CY 2019 that are still within the 3-year reopening period. The formula is specified previously in this section.

Third, we proposed that the MACs would subtract the payment amount determined under CR 11642 (or CR 12596 or CR 12407 as applicable) for a

CY from the recalculated amount in the second step, as previously detailed.

Fourth, we proposed that the MACs would determine the amount owed to a hospital in a CY as the amount calculated in the third step plus the difference, if any, between that amount and the amount previously recouped under CR 11642 (or CR 12596 or CR 12407 as applicable) or the amount that would have been recouped under CR 11642 (or CR 12596 or CR 12407 as applicable) if not for the enactment of section 4143 of the CAA 2023, if such difference for a CY is greater than $0. We noted that by adding this difference to the amount calculated in the third step, the amounts previously recouped under CR 11642 (or CR 12596 or CR 12407 as applicable) would be returned to hospitals, and recoupments that would have occurred under CR 11642 (or CR 12596 or CR 12407 as applicable) if not for the enactment of section 4143 of the CAA 2023 would not occur.

CALCULATION TABLE FOR SECTION 4143 OF CAA OF 2023

	Section 4143 CAA POOL	FFS NAH PAYMENTS	FFS INPATIENT DAYS	MA INPATIENT DAYS	(FFS NAH/FFS INPT DAYS) X MA INPT DAYS	PERCENT REDUCTION TO MA DGME PAYMENTS
CY 2010	$62,997,033	$213,862,393	45,409,814	3,114,194	$14,666,631	9.77%
CY 2011	$66,438,422	$226,645,225	49,217,935	3,825,354	$17,615,494	7.85%
CY 2012	$76,035,672	$240,958,503	55,551,047	4,376,532	$18,983,667	7.16%
CY 2013	$84,753,118	$245,304,017	54,965,956	4,945,724	$22,071,952	6.41%
CY 2014	$93,598,893	$248,506,989	54,405,730	5,360,315	$24,484,107	5.86%
CY 2015	$102,448,386	$247,076,161	55,223,064	5,907,933	$26,432,967	5.32%
CY 2016	$110,412,962	$253,272,740	55,717,901	6,376,818	$28,986,630	4.99%
CY 2017	$119,165,456	$249,546,528	58,599,068	7,241,576	$30,838,548	4.44%
CY 2018	$130,335,289	$267,714,849	61,066,487	7,888,809	$34,584,457	4.12%
CY 2019	$140,589,366	$262,043,840	62,649,285	8,481,459	$35,475,490	4.07%

We did not propose any changes to the regulations text at 42 CFR 413.87.

Comment: Multiple commenters stated that they support the steps outlined in the proposed rule as the method of returning the full amount of NAH MA recoupments to hospitals. Commenters also stated that they support the process outlined in previously issued CR 13122 as a first step towards returning a portion of the recoupments to hospitals while we engaged in rulemaking to implement section 4143 in full. One commenter asked that CMS provide guidance to the MACs instructing them to use the same variables that were in place prior to the release of Change Request 11642, to help ensure that the payments returned are accurate. Another commenter that expressed support for CMS's proposal urged CMS to direct MACs to expeditiously recalculate and reconcile NAH payments before the final rule goes into effect on October 1, 2023.

Response: We appreciate the supportive comments, and we are finalizing the proposed methodology, such that the amounts previously recouped under CR 11642 (or CR 12596 or CR 12407 as applicable) will be returned to hospitals, and recoupments that would have occurred under CR 11642 (or CR 12596 or CR 12407 as applicable) if not for the enactment of section 4143 of the CAA 2023 will not occur. By returning the amounts previously recouped, the amounts would be consistent with the amounts calculated with variables in place prior to the release of CR 11642. After issuance of this final rule, we will issue another CR to reflect this finalized methodology. The exact timeframe and details of the implementation process will be specified in the CR.

Comment: A commenter stated that under CMS's proposal, many hospitals will not have full payment restored as required by section 4143 of the CAA. Specifically, several commenters added that CMS's proposed approach to not allow reopening after the 3-year reopening period is inconsistent with the language in section 4143(c), which states, ''The amendments made by this section shall apply to payments made for portions of cost reporting periods occurring in 2010 through 2019.'' Another commenter stated that the ''reopening regulations at 42 CFR 405.1885 do not require the three-year reopening limitation when related to reimbursement changes mandated by law.'' One commenter expressed concern that the proposal that would only permit corrections to cost reports within the three-year reopening time period as of 12/29/2022 (that is, cost reports finalized prior to 12/29/2019 will not be reopened). A different commenter stated that Congress eliminated the cap for all years between 2010 and 2019, and it ''was clearly Congress' intent that nursing and allied health programs be made whole for past underpayments so long as they were still functioning at the time CAA, 2023 was passed.''

Response: As commenters are aware, in the proposed rule, we noted that the provision applies to ''each of 2010 through 2019,'' and included a table called CALCULATION TABLE FOR SECTION 4143 OF CAA OF 2023 that includes revised Section 4143 Pool amounts for each of CYs 2010 through 2019. That is, we provided revised payment rates for as far back as 2010, thereby conforming with the retroactive aspect of this provision. However, we proposed that MACs would use the table to recalculate an eligible hospital's NAH MA payment only for portions of cost reporting periods occurring in CY 2010 through CY 2019 that are still within the 3-year reopening period. We have reviewed the comments and the language in section 4143, subsection (c) regarding ''Retroactive Application,'' and we do not believe that language overrides CMS's existing reopening regulations. Rather, we believe the statute indicates that Congress instructed us to ensure that necessary payments ''apply'' retroactively. We note that any recoupments under CR 11642 (or CR 12596 or CR 12407 as applicable) occurred during the last three years, and thus we can reverse the recoupments by reopening cost reports affected by those CRs consistent with the reopening regulations. Further, because those CRs and the recoupments conducted under them are the source of the underpayments corrected by Section 4143 and this implementing rule, we do not believe it is necessary to reopen other cost reports to ''apply'' ''the

amendments made under Section 4143.'' In addition, we do not understand the commenter's concern that the proposal would only permit corrections to cost reports within the three-year reopening time period ''as of 12/29/2022''; nowhere in the proposal did we specify such a requirement. On the contrary, we point out that generally, there should be no concern that a cost report reopening timeframe would expire since the time that the cost report was adjusted under CR 11642. We note that CR 11642 states that ''MACs shall not make recalculations or reconciliations for MA nursing and allied health education payments or MA direct GME payments for cost reports that are already beyond the 3-year reopening period as of the implementation date of this CR.'' CR 11642 further instructed MACs to complete their work between approximately December 14, 2020, and March 2022. This means that during that implementation timeframe, MACs would only have made adjustments to cost reports from 2010 and 2019 that were still open or reopenable. Thus, for example, a 2010 cost report would likely not have been reopenable as of December 14, 2020, and therefore would not have been subject to any recoupment under CR 11642. (If such a cost report were reopenable as of December 14, 2020, and was in fact reopened pursuant to CR 11642, it would be reopenable again for three years from the date of the reopening to implement CR 11642, meaning that it remains reopenable until December 14, 2023, at the earliest). Accordingly, there would either be no need to reverse a recoupment to that 2010 cost report, or that cost report would have been adjusted and would be subject to a reversal of that adjustment under Section 4143. Furthermore, if, after applying CR 11642 to a still open or reopenable cost report, the MAC subsequently settled that cost report, then that cost report should still fall within a new 3-year reopening period because the earliest possible reopening to implement CR 11642 would have occurred on December 14, 2020. Accordingly, since applicable cost reports would either still be open or would fall within a recently restarted 3-year reopening period, it is not obvious to us that there is any conflict between Congress's instructions to apply section 4143 retroactively and our reopening regulations. In the absence of such conflict, we decline to create an exception to our reopening regulations.

In addition, some commenters refer to restoration of ''past underpayments'' or being ''made whole for past underpayments'' under section 4143. We disagree with this position and point out that hospitals were generally being overpaid. Specifically, prior to issuance of CR 11642 on November 19, 2020, the MACs were relying on the instructions contained in CR 2692, which CMS had issued in 2003. Under these instructions, NAH MA payments were calculated on the basis of aggregate data that had not been updated since CY 2001, when total MA patient days were still relatively low, and the size of the NAH MA payment pool was $43,663,043 (refer to CR 2692, Transmittal A–03–043, *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/a03043.pdf*). Over the course of those years from 2003 through 2020, MACs were calculating NAH MA payments to individual hospitals using contemporaneous hospital-specific data, which, as the years passed, reflected the significant increase in MA patient days during this period. Because hospital-specific MA patient days are one of the factors used in the calculation of a hospital's NAH MA payments in a calendar year (see § 413.87(e)(1)(iii)), the interaction of the aggregate data that had not been updated since 2001 and the contemporaneous hospital-specific data for each calendar year resulted in significant empirical overpayments to hospitals.

Under CR 11642, CMS instructed MACs to recalculate historical payments to hospitals consistent with the $60 million limit per calendar year (applicable as of CY 2010 and after), and use updated national data and make applicable adjustments to NAH MA payments. Under our proposal for the implementation of section 4143, the amounts previously recouped under CR 11642 (or CR 12596 or CR 12407 as applicable) will be returned to hospitals, and recoupments that would have occurred under CR 11642 (or CR 12596 or CR 12407 as applicable) if not for the enactment of section 4143 of the CAA 2023 will not occur. In other words, CMS only imposed the $60 million cap that section 4143(a)(2)(ii) stated ''shall not apply [for 2010–2019] to those hospitals that, as of [December 29, 2022], are operating a school of nursing, a school of allied health, or a school of nursing and allied health'' via the previously described CRs, and all cost reports affected by those CRs are within the three-year reopening window. We believe we can fulfill Congress's instructions to apply section 4143 retroactively without creating an exception to our reopening regulations. For the reasons stated previously, we do not believe an override or exception to the reopening regulations is required, and we are finalizing our proposal to recalculate an eligible hospital's NAH MA payment only for portions of cost reporting periods occurring in CY 2010 through CY 2019 that are still within the 3-year reopening period.

Comment: Some commenters disagreed with CMS's proposal that MACs would first determine whether hospitals that received revised payments under CR 11642 were still receiving NAH MA payments on an interim basis as of December 29, 2022. One commenter stated that there is nothing in the statute that suggests a hospital must receive payments on an interim basis, only that a nursing and allied health program ''was operating'' on December 29, 2022. This commenter asked that CMS eliminate the reference to payments on an interim basis and indicate that all hospitals operating a nursing and allied health program as of December 29, 2022, are eligible under section 4143 to receive adjusted nursing and allied health MA payments for CYs 2010 through 2019. Other commenters recommended that instead of interim rates, the MACs should apply Section 4143 to hospitals that file pass-through costs for NAH programs on their cost reports, because these hospitals still have their NAH programs even though the MAC disallowed their pass-through costs as a result of audits. Another commenter stated that some hospitals may have closed their NAH programs because the MACs disallowed payment. This commenter asserted that regardless of why a NAH program may have closed prior to December 29, 2022, it seems unfair not to provide the same relief for underpayments they received in the past when they were operating those programs. In cases where the MACs disallowed payment, and the hospitals are appealing those determinations, the commenters argued that, even though the hospitals were not receiving interim payments as of December 29, 2022, they were still operating their programs, and they expect their NAH payments to be recognized after a successful appeal.

Response: We understand that there may be a few possible reasons why a hospital may not have been receiving NAH MA payments on an interim basis as of December 29, 2022, even though the hospital had not formally closed its NAH program(s). For example, the hospital's NAH pass-through amount may be too small to qualify for interim payments. Also, as the commenters describe, the MAC may have disallowed the hospital's pass-through payments, and the hospital might currently be in

the process of appealing that determination. Alternatively, a hospital may have several years of cost reports that it filed with NAH costs, but those cost reports may not yet be settled, and thus, the MAC has not yet made a determination as to the allowability of the NAH pass-through costs with regard to interim payments. In the first case, where the NAH pass-through amount is too small to qualify for interim payments, if the hospital's NAH pass-through would otherwise qualify for interim payments as of December 29, 2022, if the amount had been large enough, then for the purpose of implementing Section 4143, we would treat the hospital as though it was receiving interim payments as of December 29, 2022. With regard to multiple cost reporting years that have not yet been settled, it may be that CR 11642 was not yet applied to those cost reports, in which case there would be no need for reversal of a recoupment upon eventual settlement of those cost reports. However, regarding the situation where the MAC has disallowed the NAH payment, we understand that in many cases the MACs have found that hospitals are not ''operating'' the NAH program(s) consistent with the regulations at 42 CFR 413.85, although hospitals may believe that ''as of the date of enactment'' of section 4143, the hospitals ''are operating'' a school or nursing and/or allied health. Where the MACs have disallowed the NAH payment, settled the cost report(s), and the hospitals are appealing the disallowance, then we believe the normal appeals process should be followed, and NAH payments, under section 4143 or otherwise, are held in abeyance pending the outcome of the appeals. Thus, we proposed to use receipt of interim payments as of December 29, 2022 as an indicator of eligibility of NAH pass-through payments; lack of such pass-through payment could indicate a MAC disallowance, which should be adjudicated through the normal appeals process. If the hospitals should be successful in their appeals to restore NAH pass-through payment, then for the purpose of implementing section 4143, we would treat the hospitals as though they were receiving interim payments as of December 29, 2022. If, on the other hand, a hospital closed its NAH program(s), whether the closure was allegedly a result of MAC disallowances or due to some other reason, we do not believe that section 4143 applies in those cases, because section 4143 clearly states that payments should only be made to ''those hospitals that, as of the date of enactment, are operating a school of nursing, a school of allied health, or a school of nursing and allied health (emphasis added).'' Thus, in this final rule, we are still requiring that MACs first determine whether hospitals that received revised payments under CR 11642 were still receiving NAH MA payments on an interim basis as of December 29, 2022, with the exception of hospitals whose NAH pass-through payment would otherwise qualify for interim payments as of December 29, 2022, if the amount had been large enough, and hospitals that will be successful in their appeals to restore NAH pass-through payment.

Comment: One commenter believed that no money should be siphoned away from DGME funding to pay for nonphysician training. Though the commenter appreciates the role that nonphysician providers play, the commenter believed that there should be a funding source separate from GME funding. This commenter also expressed concern that the rule does not contain proposals to ensure that in the future, too much MA DGME would not be removed from GME funding, and recommended that CMS put robust guardrails in place to ensure that GME funding updates are made accurately every year moving forward.

Response: This comment is generally out of the scope of the proposals made in the FY 2024 IPPS/LTCH PPS proposed rule; therefore, we are not responding to it directly at this time. However, with regard to ensuring accurate (and timely) payment rate updates, we note that starting with the rates for CY 2020 and CY 2021, we proposed and finalized the NAH MA add-on rates in the FY 2023 IPPS/LTCH PPS proposed and final rules. We stated that for CYs 2022 and after, we would similarly propose and finalize their respective NAH MA rates and direct GME percent reductions in subsequent IPPS/LTCH PPS rulemakings (see 87 FR 49073 August 10, 2022). In the FY 2024 IPPS/LTCH PPS proposed rule, we proposed the rates for CY 2022, and we are finalizing the CY 2022 rates in this final rule. Accordingly, we have established an annual process to ensure issuance of updated NAH MA and DGME MA rates that are as updated and accurate as possible.

In summary, after consideration of the public comments received, we are finalizing the proposed methodology for the implementation of section 4143, such that the amounts previously recouped under CR 11642 (or CR 12596 or CR 12407 as applicable) will be returned to hospitals, and recoupments that would have occurred under CR 11642 (or CR 12596 or CR 12407 as applicable) if not for the enactment of section 4143 of the CAA 2023 will not occur. After issuance of this final rule, we will issue another CR to reflect this finalized methodology.

I. Payment Adjustment for Certain Clinical Trial and Expanded Access Use Immunotherapy Cases (§§ 412.85 and 412.312)

Effective for FY 2021, we created MS–DRG 018 for cases that include procedures describing CAR T-cell therapies, which were reported using ICD–10–PCS procedure codes XW033C3 or XW043C3 (85 FR 58599 through 58600). Effective for FY 2022, we revised MS–DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 448106).

Effective for FY 2021, we modified our relative weight methodology for MS–DRG 018 to develop a relative weight that is reflective of the typical costs of providing CAR T-cell therapies relative to other IPPS services. Specifically, under our finalized policy we do not include claims determined to be clinical trial claims that group to MS–DRG 018 when calculating the average cost for MS–DRG 018 that is used to calculate the relative weight for this MS–DRG, with the additional refinements that: (a) when the CAR T-cell therapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the claim will be included when calculating the average cost for MS–DRG 018 to the extent such claims can be identified in the historical data; and (b) when there is expanded access use of immunotherapy, these cases will not be included when calculating the average cost for MS–DRG 018 to the extent such claims can be identified in the historical data (85 FR 58600). The term ''expanded access'' (sometimes called ''compassionate use'') is a potential pathway for a patient with a serious or immediately life-threatening disease or condition to gain access to an investigational medical product (drug, biologic, or medical device) for treatment outside of clinical trials when, among other criteria, there is no comparable or satisfactory alternative therapy to diagnose, monitor, or treat

the disease or condition (21 CFR 312.305).[218]

Effective FY 2021, we also finalized an adjustment to the payment amount for applicable clinical trial and expanded access immunotherapy cases that group to MS–DRG 018 using the same methodology that we used to adjust the case count for purposes of the relative weight calculations (85 FR 58842 through 58844). (As previously noted, effective beginning FY 2022, we revised MS–DRG 018 to include cases that report the procedure codes for CAR T-cell and non-CAR T-cell therapies and other immunotherapies (86 FR 44798 through 448106).) Specifically, under our finalized policy we apply a payment adjustment to claims that group to MS–DRG 018 and include ICD–10–CM diagnosis code Z00.6, with the modification that when the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product, the payment adjustment will not be applied in calculating the payment for the case. We also finalized that when there is expanded access use of immunotherapy, the payment adjustment will be applied in calculating the payment for the case. This payment adjustment is codified at 42 CFR 412.85 (for operating IPPS payments) and 412.312 (for capital IPPS payments), for claims appropriately containing Z00.6, as described previously, and reflects that the adjustment is also applied for cases involving expanded access use immunotherapy, and that the payment adjustment only applies to applicable clinical trial cases; that is, the adjustment is not applicable to cases where the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product. The regulations at 42 CFR 412.85(c) also specify that the adjustment factor will reflect the average cost for cases to be assigned to MS–DRG 018 that involve expanded access use of immunotherapy or are part of an applicable clinical trial to the average cost for cases to be assigned to MS–DRG 018 that do not involve expanded access use of immunotherapy and are not part of a clinical trial (85 FR 58844).

For FY 2024, we proposed to continue to apply an adjustment to the payment amount for expanded access use of immunotherapy and applicable clinical trial cases that would group to MS–DRG 018, as calculated using the same proposed modifications to our existing methodology, as adopted in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58842), that we proposed to use to adjust the case count for purposes of the relative weight calculations, as described in section II.D. of the preamble of the proposed rule and this final rule. As discussed in that section, the December update of the FY 2022 MedPAR claims data now includes a field that identifies whether or not the claim includes expanded access use of immunotherapy. For the FY 2022 MedPAR claims data, this field identifies whether or not the claim includes condition code ZB. For the FY 2023 MedPAR data and for subsequent years, this field will identify whether or not the claim includes condition code 90. The MedPAR files now also include information for claims with the payer-only condition code ''ZC'', which is used by the IPPS Pricer to identify a case where the CAR T-cell, non-CAR T-cell, or other immunotherapy product is purchased in the usual manner, but the case involves a clinical trial of a different product so that the payment adjustment is not applied in calculating the payment for the case (for example, see Change Request 11879, available at *https://www.cms.gov/files/document/r10571cp.pdf*). We refer the readers to section II.D. of the preamble of the proposed rule and this final rule for further discussion of our proposed changes to our methodology for identifying clinical trial claims and expanded access use claims in MS–DRG 018 and our proposed modifications to the methodology used to adjust the case count for purposes of the relative weight calculations.

Consistent with these proposals, and using the same methodology that we proposed to use to adjust the case count for purposes of the relative weight calculations, we proposed to calculate the adjustment to the payment amount for expanded access use of immunotherapy and applicable clinical trial cases as follows:

- Calculate the average cost for cases assigned to MS–DRG 018 that either (a) contain ICD–10–CM diagnosis code Z00.6 and do not contain condition code ''ZC'' or (b) contain condition code 90 (or, for FY 2024 ratesetting, which is based on the FY 2022 MedPAR data, condition code ''ZB'').
- Calculate the average cost for all other cases assigned to MS–DRG 018.
- Calculate an adjustor by dividing the average cost calculated in step 1 by the average cost calculated in step 2.
- Apply this adjustor when calculating payments for expanded access use of immunotherapy and applicable clinical trial cases that group to MS–DRG 018 by multiplying the relative weight for MS–DRG 018 by the adjustor.

We refer the readers to section II.D. of the preamble of the proposed rule and this final rule for further discussion of these proposed methodology changes.

Consistent with our calculation of the proposed adjustor for the relative weight calculations, for the proposed rule we proposed to calculate this adjustor based on the December 2022 update of the FY 2022 MedPAR file for purposes of establishing the FY 2024 payment amount. Specifically, in accordance with 42 CFR 412.85 (for operating IPPS payments) and 412.312 (for capital IPPS payments), we proposed to multiply the FY 2024 relative weight for MS–DRG 018 by a proposed adjustor of 0.28 as part of the calculation of the payment for claims determined to be applicable clinical trial or expanded use access immunotherapy claims that group to MS–DRG 018, which includes CAR T-cell and non-CAR T-cell therapies and other immunotherapies. We also proposed to update the value of the adjustor based on more recent data for the final rule.

We did not receive any comments specifically relating to the proposed payment adjustment for applicable clinical trial and expanded access use immunotherapy cases and are therefore finalizing our proposal without modification. We are also finalizing our proposal to update the value of this adjustor based on more recent data for this final rule. Therefore, using the March 2023 update of the FY 2022 MedPAR data, we are finalizing an adjustor of 0.27 for FY 2024, which will be multiplied by the final FY 2024 relative weight for MS–DRG 018 as part of the calculation of the payment for claims determined to be applicable clinical trial or expanded use access immunotherapy claims that group to MS–DRG 018.

J. Hospital Readmissions Reduction Program

1. Statutory Basis for the Hospital Readmissions Reduction Program

Section 1886(q) of the Act established the Hospital Readmissions Reduction Program. We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49531) and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240) for a detailed discussion of and additional information on the statutory history of the Hospital Readmissions Reduction Program.

[218] *https://www.fda.gov/news-events/expanded-access/expanded-access-keywords-definitions-and-resources.*

2. Regulatory Background

We refer readers to the following final rules for detailed discussions of the regulatory background and descriptions of the current policies for the Hospital Readmissions Reduction Program:

- FY 2012 IPPS/LTCH PPS final rule (76 FR 51660 through 51676);
- FY 2013 IPPS/LTCH PPS final rule (77 FR 53374 through 53401);
- FY 2014 IPPS/LTCH PPS final rule (78 FR 50649 through 50676);
- FY 2015 IPPS/LTCH PPS final rule (79 FR 50024 through 50048);
- FY 2016 IPPS/LTCH PPS final rule (80 FR 49530 through 49543);
- FY 2017 IPPS/LTCH PPS final rule (81 FR 56973 through 56979);
- FY 2018 IPPS/LTCH PPS final rule (82 FR 38221 through 38240);
- FY 2019 IPPS/LTCH PPS final rule (83 FR 41431 through 41439);
- FY 2020 IPPS/LTCH PPS final rule (84 FR 42380 through 42390);
- FY 2021 IPPS/LTCH PPS final rule (85 FR 58844 through 58847);
- FY 2022 IPPS/LTCH PPS final rule (86 FR 45249 through 45266); and
- FY 2023 IPPS/LTCH PPS final rule (87 FR 49081 through 49094).

We have also codified certain requirements of the Hospital Readmissions Reduction Program at 42 CFR 412.152 through 412.154.

3. Current Measures

The Hospital Readmissions Reduction Program currently includes six applicable conditions/procedures: Acute myocardial infarction (AMI); heart failure (HF); pneumonia (PN); elective primary total hip arthroplasty/total knee arthroplasty (THA/TKA); chronic obstructive pulmonary disease (COPD); and coronary artery bypass graft (CABG) surgery.

We did not make any proposals or updates in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27024) for the Hospital Readmissions Reduction Program. We refer readers to section V.G.5. of the preamble for an updated estimate of the financial impact of using the proportion of dually eligible beneficiaries, Excess Readmission Ratios, and aggregate payments for each condition/procedure and all discharges for applicable hospitals from the FY 2024 Hospital Readmissions Reduction Program applicable period (that is, July 1, 2019, through June 30, 2022).

While we did not make any proposals or updates to the Hospital Readmissions Reduction Program, we did receive comments noting additional opportunities for addressing health equity. Suggestions included expanding social risk adjustments, particularly to include homelessness Z codes in risk adjustments, a comment not to use dual eligibility status, and a comment to expand social risk adjustments to decrease annual readmissions penalties. A few commenters urged CMS to find more ways to support safety net hospitals including by incorporating an essential hospital definition in the peer grouping methodology. We thank the commenters for their input, and we will consider these comments for future rulemaking.

K. Hospital Value-Based Purchasing (VBP) Program: Policy Changes

1. Background

a. Overview

Section 1886(o) of the Act requires the Secretary to establish a hospital value-based purchasing program (the Hospital VBP Program) under which value-based incentive payments are made in a fiscal year (FY) to hospitals that meet performance standards established for a performance period for such fiscal year. Both the performance standards and the performance period for a fiscal year are to be established by the Secretary.

For descriptions of our current policies for the Hospital VBP Program, we refer readers to our codified requirements for the Hospital VBP Program at 42 CFR 412.160 through 412.168.

b. FY 2024 Program Year Payment Details

Section 1886(o)(7)(B) of the Act instructs the Secretary to reduce the base operating DRG payment amount for a hospital for each discharge in a fiscal year by an applicable percent. Under section 1886(o)(7)(A) of the Act, the sum of these reductions in a fiscal year must equal the total amount available for value-based incentive payments for all eligible hospitals for the fiscal year, as estimated by the Secretary. We finalized details on how we would implement these provisions in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), and we refer readers to that rule for further details.

Under section 1886(o)(7)(C)(v) of the Act, the applicable percent for the FY 2024 program year is 2.00 percent. Using the methodology we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53571 through 53573), we estimate that the total amount available for value-based incentive payments for FY 2024 is approximately $1.7 billion, based on the March 2023 update of the FY 2022 MedPAR file.

As finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53573 through 53576), we will utilize a linear exchange function to translate this estimated amount available into a value-based incentive payment percentage for each hospital, based on its Total Performance Score (TPS). We published proxy value-based incentive payment adjustment factors in Table 16 associated with the proposed rule (which is available via CMS website). We are publishing updated proxy value-based incentive payment adjustment factors in Table 16A associated with this final rule (which is available via the CMS website). We note that these proxy adjustment factors will not be used to adjust hospital payments for FY 2024 as they were calculated using the historical baseline and performance periods for the FY 2023 Hospital VBP Program. These updated proxy factors were calculated using the March 2023 update to the FY 2022 MedPAR file. The updated slope of the linear exchange function used to calculate these proxy factors was 2.6517299103, and the estimated amount available for value-based incentive payments to hospitals for FY 2024 is approximately $1.7 billion. We will add Table 16B to display the actual value-based incentive payment adjustment factors, exchange function slope, and estimated amount available for the FY 2024 Hospital VBP Program. We expect that Table 16B will be posted in Fall 2023.

2. Retention and Removal of Quality Measures

a. Retention of Previously Adopted Hospital VBP Program Measures and Relationship Between the Hospital IQR and Hospital VBP Program Measure Sets

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53592), we finalized a policy to retain measures from prior program years for each successive program year, unless otherwise proposed and finalized. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41440 through 41441), we finalized a revision to our regulations at 42 CFR 412.164(a) to clarify that once we have complied with the statutory prerequisites for adopting a measure for the Hospital VBP Program (that is, we have selected the measure from the Hospital IQR Program measure set and included data on that measure on Hospital Compare for at least one year prior to its inclusion in a Hospital VBP Program performance period), the Hospital VBP Program statute does not require that the measure continue to remain in the Hospital IQR Program.

We did not propose any changes to these policies in the FY 2024 IPPS/LTCH PPS proposed rule.

b. Codification of the Current Hospital VBP Program Measure Removal Factors

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41441 through 41446), we finalized eight measure removal factors for the Hospital VBP Program, and we refer readers to that final rule for details. In the FY 2024 IPPS/LTCH PPS proposed rule, we proposed to codify at 42 CFR 412.164(c) of our regulations these eight measure removal factors as well as the policies for updating measure specifications and retaining measures (88 FR 27025). We believe that this codification will make it easier for interested parties to find these policies and will further align the Hospital VBP Program regulations with the regulations we have codified for other quality reporting programs.

We invited public comment on this proposal.

We did not receive any comments on this proposal and are finalizing this proposal as proposed with minor technical modifications to regulation text at 42 CFR 412.164(c).

c. Substantive Measure Modifications

(1) Adoption of Substantive Measure Updates to the Medicare Spending per Beneficiary (MSPB)—Hospital Measure (CBE #2158) Beginning With the FY 2028 Program Year

In the FY 2024 IPPS/LTCH PPS proposed rule, we proposed to adopt substantive measure updates to the MSPB Hospital measure (CBE #2158) in the Hospital VBP Program beginning with the FY 2028 program year (88 FR 27025 through 27026). We adopted the MSPB Hospital measure in the Hospital VBP Program in the FY 2012 IPPS/LTCH PPS final rule beginning with the FY 2014 program year (76 FR 51654 through 51658). We continue to believe that the MSPB Hospital measure provides important data on resource use (addressing the Meaningful Measures Framework priority of making care affordable), which is why we proposed substantive updates to the MSPB Hospital measure in the Hospital VBP Program under the Efficiency/Cost Domain. We refer readers to the FY 2019 IPPS/LTCH PPS final rule for a broader discussion of the Meaningful Measures Framework (83 FR 41147).

We previously adopted the same substantive updates to the MSPB Hospital measure for use in the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49257 through 49263). The substantive updates to the MSPB Hospital measure are three refinements which ensure a more comprehensive and consistent assessment of hospital performance by capturing more episodes and adjusting the measure calculation:

- An update to allow readmissions to trigger new episodes to account for episodes and costs that are currently not included in the measure but that could be within the hospital's reasonable influence;
- A new indicator variable in the risk adjustment model for whether there was an inpatient stay in the 30 days prior to episode start date; and
- An updated MSPB amount calculation methodology to change one step in the measure calculation from the sum of observed costs divided by the sum of expected costs (ratio of sums) to the mean of observed costs divided by expected costs (mean of ratios).

These refinements also appear in a summary of the measure re-evaluation on the CMS QualityNet website posted in July 2020.[219]

We presented the three substantive updates to the MSPB Hospital measure (CBE #2158) to the consensus-based entity (CBE) [220] in the Fall 2020 cycle for measure re-endorsement. During the Fall 2020 11-month endorsement cycle, the re-evaluated MSPB Hospital measure was reviewed by the Scientific Methods Panel (SMP), Cost and Efficiency Standing Committee, and Consensus Standards Approval Committee (CSAC).[221] The re-evaluated measure passed on the reliability and validity criteria when reviewed by the SMP. The Cost and Efficiency Standing Committee reviewed each aspect of the re-evaluated measure in detail across three meetings. The CSAC approved the Standing Committee's endorsement recommendation unanimously and re-endorsed the MSPB Hospital measure (CBE #2158) in June 2021 with the three refinements.[222] Following re-endorsement, we included the updated measure in CMS's ''List of Measures Under Consideration (MUC) for December 1, 2021.'' [223] The re-evaluated MSPB Hospital measure (MUC2021–131) underwent Measure Applications Partnership (MAP) [224] review during the 2021–2022 cycle. On December 15, 2021, the MAP Hospital Workgroup supported the re-evaluated measure for rulemaking. On January 19, 2022, the MAP Coordinating Committee upheld the MAP Hospital Workgroup's preliminary recommendation to support the re-evaluated measure for rulemaking. More detail on the discussion is available in the MAP's final report.[225]

For the purpose of continuing to assess hospitals' efficiency and resource use and to meet statutory requirements under section 1886(o)(2)(B)(ii) of the Act, we proposed to adopt the substantive updates to the MSPB Hospital measure in the Hospital VBP Program under the Efficiency and Cost Reduction Domain. As previously stated, we previously adopted the same substantive updates to the measure in the Hospital IQR Program (87 FR 49257 through 49263), and we intend to begin posting the updated measure data on *Care Compare* beginning in January 2024, which will enable us to post data on the substantive updates to the measure for at least one year before the proposed beginning of the performance period for the FY 2028 program year (discharges beginning January 1, 2026).

We proposed to adopt the substantive updates to the MSPB Hospital measure (CBE #2158) in the Hospital VBP Program beginning with the FY 2028 program year. We refer readers to section V.K.4.c of the preamble of this final rule where we discuss our defined baseline and performance periods for this updated measure under the Hospital VBP Program. We also proposed that the performance standards calculation methodology for the updated MSPB Hospital measure will be the same as that which we currently use for the measure. The performance standards for the updated measure for the FY 2028 program year are not yet available.

We invited public comment on this proposal.

[219] Medicare Spending Per Beneficiary (MSPB) Measure Methodology. Available at: *https://qualitynet.cms.gov/inpatient/measures/mspb/methodology*.

[220] In previous years, we referred to the consensus-based entity by corporate name. We have updated this language to refer to the consensus-based entity more generally.

[221] The submission materials, including the testing results, are available at: *https://mmshub.cms.gov/sites/default/files/cost-and-efficiency-final-report-fall-2020.pdf*.

[222] Centers for Medicare & Medicaid Services. (2020) Cost and Efficiency Final Report—Fall 2020 Cycle. Available at: *https://mmshub.cms.gov/sites/default/files/cost-and-efficiency-final-report-fall-2020.pdf*.

[223] Centers for Medicare & Medicaid Services. (2021) List of Measures Under Consideration for December 1, 2021. Available at: *https://mmshub.cms.gov/sites/default/files/Overview-of-the-2021-MUC-List-20220308-508.pdf*.

[224] Interested parties convened by the consensus-based entity will provide input and recommendations on the Measures under Consideration (MUC) list as part of the pre-rulemaking process required by section 1890A of the Act. We refer readers to *https://p4qm.org/PRMR-MSR* for more information.

[225] Centers for Medicare & Medicaid Services. (2022) Measure Applications Partnership 2021–2022 Considerations for Implementing Measures in Federal Programs: Clinician, Hospital, and Post-Acute Care Long-Term Care. Available at: *https://mmshub.cms.gov/sites/default/files/map_2021-2022_considerations_for_implementing_measures_in_federal_programs_final_report.pdf*.

Comment: Many commenters supported the proposal to implement the substantive updates to the MSPB Hospital measure in Hospital VBP Program. Several commenters commended CMS for its alignment with the Hospital IQR Program. A commenter cited the updates to readmission terminology as a significant factor in their support.

Response: We thank commenters for their support, and we aim to maintain alignment with the Hospital IQR Program in line with our statutory requirements and to update our existing measures when possible.

Comment: A few commenters did not support the proposal and expressed concern that allowing readmissions to trigger new episodes could lead to the same costs being attributed to hospitals twice and provide a misleading portrayal of hospital performance.

Response: As previously stated in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49257 through 49263) where we adopted the MSPB re-evaluated measure in the Hospital IQR Program, the refinement allows readmissions to trigger new episodes which will result in some services being assigned to multiple episodes. These services, however, will only be counted once per episode, so the cost of these services will not be counted twice within the same episode. Additionally, the presence of an inpatient admission within 30 days before the start date of an episode based on a readmission is controlled for in the risk adjustment model to account for the additional complexity that readmissions may entail.[226] Further, the inclusion of episodes triggered by readmissions does not necessarily result in a worse measure score for the provider. Such episodes still use the observed over expected cost ratios, where it is possible for the observed cost to be lower than expected cost, if the hospital performed better on the episode than expected.

Comment: A few commenters did not support the proposal to adopt the re-evaluated MSPB Hospital measure citing concern that hospitals have not had enough time to understand how these measure refinements will impact hospital performance. A few commenters recommended allowing hospitals to have a better understanding of the impact the measure updates will have on performance. Specifically, commenters recommended delaying implementation in the Hospital VBP Program so that hospitals have a better understanding of how the updates impacted hospital performance in the Hospital IQR Program, including allowing hospitals to see performance metrics, prior to implementation in the Hospital VBP Program. A commenter requested to see the calculations and impact changes before being able to appropriately comment, and a commenter recommended delaying adoption for one year to allow for more robust feedback. Additionally, a few commenters expressed concern that the measure will increase the burden on hospitals because they will have to monitor and validate two different performance rates using two different measure specifications. A few commenters also expressed concern that the policy will result in two slightly different measure specifications being used simultaneously in the two different programs which they believe could yield different results and make it more difficult to interpret results.

Response: We appreciate the commenters' concerns. As we have previously stated in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27025 through 27026), we adopted the re-evaluated version of the MSPB Hospital measure into the Hospital IQR Program to accommodate the statutory and regulatory requirements as well as to provide interested parties with an opportunity to become familiar with the new version of the measure and provide feedback. We staged our proposals across the Hospital IQR Program and Hospital VBP Program to accommodate statutory and regulatory requirements, as further discussed later in this section. We refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49257 through 49263) for more information on the policy to adopt the substantive updates to MSPB Hospital measure in the Hospital IQR Program, which provided interested parties with an opportunity to become familiar with the new version of the measure and provide feedback prior to our proposal to adopt the measure updates in the Hospital VBP Program. Hospital-specific reports for the re-evaluated MSPB Hospital measure in the Hospital IQR Program will be available for review in October 2023. Further, hospitals will be able to see their performance in the Hospital IQR Program for four years prior to measure implementation in the Hospital VBP Program beginning with the FY 2028 program year.

We acknowledge the commenters' concerns that two slightly different versions of the measure will be in use across the Hospital IQR and Hospital VBP Programs simultaneously until the measure is removed from the Hospital IQR Program with the FY 2028 payment determination. Section 1886(o)(2)(C)(i) of the Act and 42 CFR 412.164(b) state that measures must be publicly reported for one year in the Hospital IQR Program prior to the beginning of the performance period in the Hospital VBP Program. Additionally, section 1886(o)(2)(B)(ii) of the Act outlines that the Hospital VBP Program must contain an efficiency measure. As part of routine measure maintenance, we will continue to monitor the measure's impact on hospitals.

Comment: A commenter recommended suppressing one set of measures from public reporting to reduce confusion caused by two different publicly reported rates.

Response: Results for the MSPB Hospital measure currently implemented in the Hospital VBP Program will continue to be available on *data.medicare.gov* along with other Hospital VBP Program data until the re-evaluated measure is implemented under the finalized policy outlined in section V.K.2.a of this rule. We intend to continue publishing re-evaluated MSPB Hospital measure data on *Care Compare* for the period of time in which hospitals report on two versions of the measure to provide important cost measure information to the public. In addition, we will make sure it is clear which version of the measure is being displayed in which location through outreach and education efforts.

Comment: A few commenters did not support the re-evaluated MSPB Hospital measure proposal because they believed that the measure was not adequately tested and adjusted for social risk factors. A commenter believed that measure scores shifted when social risk factors were applied within the risk model. A commenter recommended implementing a social risk factor adjustment in calculating measure performance because they believed that it will improve measure reliability. A commenter specifically stated that they believed that the endorsement review suggested low reliability and validity. Another commenter expressed concern about the scientific acceptability of the measure, and a commenter believed that there would be a potential inverse relationship between outcomes, adjustment for social risk factors, and medical complexities due to vulnerable patient groups driving performance differences.

Response: We respectfully disagree with the commenters that the re-evaluated MSPB Hospital measure has low reliability and validity. The CBE rated the measure's reliability as high

[226] Medicare Spending Per Beneficiary (MSPB) Measure Methodology. Available at: *https://qualitynet.cms.gov/inpatient/measures/mspb/methodology*.

when endorsing the measure. The average reliability score of hospitals with at least 25 episodes was .92,[227] which far exceeds the standard generally considered as 'high' reliability. The CBE rated the measure's validity as moderate when endorsing the measure.[228] Further, as part of the CBE endorsement submission we assessed the impact of social risk factors on the measure, conducting testing based on CBE precedents, as well as supplemented with novel testing and in response to specific stakeholder feedback. Specifically, we tested whether the inclusion of sex, dual eligibility status, race/ethnicity, the AHRQ socioeconomic status (SES) index, components of the AHRQ SES index, and the Area Deprivation Index could meaningfully be incorporated into the measure's risk adjustment model so as not to penalize the hospital for the patients they treat, while also not setting a lower standard of care for hospitals with patients who have social risk factors. Results showed that the inclusion of these social risk factors in the risk model had a limited and inconsistent effect on measure scores, and some of the variation that was captured by tested covariates was attributable to the hospital in which the episodes were initiated. The CBE's Scientific Methods Panel carefully reviewed the testing results on the impacts of social risk factors on the measure and our recommendation to continue not including them in the measure's risk adjustment model and passed the measure on the validity criterion. While social risk factors continue to not be included in the measure's risk adjustment model, we plan to continue to conduct testing and monitoring of the impact of social risk factors on the measure as part of normal measure maintenance.

Comment: Several commenters expressed concerns about the re-evaluated MSPB Hospital measure, including their beliefs that the measure does not inform performance by condition, there could be an increased number of episodes included in the measure that could impact performance, and the explanation of how services are allocated to an episode is unclear on how this would not penalize a hospital twice.

Response: Regarding the commenter's concern about hospitals being penalized twice, this refinement will not result in hospitals being penalized twice because the re-evaluated MSPB Hospital measure, whether used in the Hospital IQR Program or Hospital VBP Program, and the condition- and procedure-specific readmission measures used in the Hospital Readmissions Reduction Program assess readmissions for different purposes. The re-evaluated MSPB Hospital measure assesses hospitals' cost efficiency on readmissions and other costs for both the hospital and patient, while the condition- and procedure- specific measures in the Hospital Readmissions Reduction Program are intended to reduce avoidable readmissions.

We respectfully disagree that there could be an increased number of episodes included in the measure and thus impact performance due to readmissions triggering new episodes. The inclusion of episodes triggered by readmissions does not necessarily result in a worse measure score for the provider. Such episodes still use the observed over expected cost ratios, where it is possible for the observed cost to be lower than expected cost, if the hospital performed better on the episode than expected. Additionally, allowing readmissions to trigger new MSPB Hospital episodes does not impact a hospital's readmissions rates, given that it merely captures episodes that are based on existing readmissions so that those episodes can be used to assess hospital performance.

Comment: A commenter requested additional clarification around what is a hospital's reasonable influence for a readmission. They expressed concern that it may be difficult for hospitals to track readmissions without understanding what CMS considers to be reasonable influence and recommended providing additional information on *Care Compare* prior to FY 2028.

Response: We interpret ''reasonable influence'' in the comment to mean the appropriateness to hold the hospital accountable for the costs associated with the readmissions if they are influenced not only by the hospital's care decisions but also other factors that the hospital may not have influence over (for example, a patient's age, comorbidities, or other risk factors). The Technical Expert Panel (TEP) that provided feedback to the measure developer on the re-evaluated MSPB Hospital measure agreed that readmissions should trigger MSPB episodes to capture costs in the subsequent 30 days post-discharge for the readmissions because they believed that it is clinically appropriate to hold a hospital responsible for these costs.[229] Allowing readmissions to trigger new episodes (i) encourages hospitals to provide cost efficient care and improve care coordination not only during initial hospitalizations, but also during readmissions, (ii) increases the number of episodes for which a clinician can be scored, and (iii) captures potentially high-cost services that are otherwise excluded. Additionally, allowing readmissions to trigger new MSPB Hospital episodes does not impact a hospital's readmissions rates, given that it merely captures episodes that are based on existing readmissions so that those episodes can be used to assess hospital performance. Furthermore, readmissions trigger an episode similarly to how initial admissions trigger in an episode, in that the episode window starts three days prior to the inpatient stay (whether it's an initial admission or readmission) and ends 30 days after discharge—thus, this refinement to measure construction will not result in any additional burden for hospitals to track.

We provide clarification on (i) how readmissions trigger an episode, and (ii) the impact of the re-evaluated MSPB Hospital measure as follows. An episode is opened, or triggered, by an initial admission to an inpatient hospital, and the episode window starts three days prior to this index admission and ends 30 days after discharge. If a readmission for the same patient occurs within the 30-day post-discharge of the first episode, then the readmission triggers a new episode. This new episode's window starts three days prior to the readmission and ends 30 days after discharge from the readmission. The hospital managing the readmission is now being measured under similar cost efficiency incentives by the new episode. Specifically, the new episode includes the costs in the post-discharge period of the readmission not previously captured. The refinement to allow readmissions to trigger a new episode will result in some services being assigned to multiple episodes. These services, however, are counted only once per episode (that is, cost will not be double-counted). The revised measure calculation compares each hospital's observed episode costs to predicted episode costs among their peers for patients with the same

[227] The submission materials, including the testing results, are available at: *https://mmshub.cms.gov/sites/default/files/cost-and-efficiency-final-report-fall-2020.pdf*.

[228] The submission materials, including the testing results, are available at: *https://mmshub.cms.gov/sites/default/files/cost-and-efficiency-final-report-fall-2020.pdf*.

[229] Physician Cost Measures and Patient Relationship Codes TEP Summary Report. (2020). Available at: *https://www.cms.gov/files/zip/physician-cost-measures-and-patient-relationship-codes-pcmp.zip*.

observable characteristics, rather than to a pre-defined standard. By comparing hospitals to other hospitals that are all attributed in the same way, we expect this comparison to be fair. This helps maintain care coordination incentives of the re-evaluated MSPB Hospital measure. Further, the inclusion of episodes triggered by readmissions does not necessarily result in a worse measure score for the provider—such episodes still use the observed over expected cost ratios, where it is possible for the observed cost to be lower than expected cost if the hospital performed better on the episode than expected. Additionally, the prior inpatient admission characteristic is controlled for in the risk adjustment model to avoid unfairly penalizing the hospital attributed to the newly triggered episode. An illustration of this refinement is available in Appendix B of the Measure Information Form (MIF) document available at: *https://qualitynet.cms.gov/files/647f8ba16f7752001c37e302?filename=2023_HIQR_Re-eval_MSPB_%20MIF.pdf*.

We also wish to note that because the updated version of this measure was adopted in the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49257 through 49263), hospitals will receive hospital-specific reports for the re-evaluated MSPB Hospital measure on an annual basis, which include patient-level episode information, prior to public display on the *Compare* tool. In addition, hospitals receive hospital-specific reports for seven readmission measures used in the Hospital IQR and Hospital Readmissions Reduction Programs that provide patient-level readmissions information.

Comment: A few commenters had recommendations for the re-evaluated MSPB Hospital measure including ensuring that the re-evaluated MSPB Hospital measure is reliable and valid for efficiency and cost reduction and exploring whether adding a new variable indicating a patient had an inpatient stay in the 30 days prior to an episode may unfairly disadvantage hospitals that frequently provide care to patients with a high case mix index.

Response: As discussed earlier, the re-evaluated MSPB Hospital measure rated high for reliability and moderate for validity during the CBE endorsement process. As part of the CBE endorsement submission, we undertook three approaches to empirically examine the extent to which the re-evaluated MSPB Hospital measure captures what it intends to capture. Firstly, we examined the relationship between risk adjusted episode cost ratios and episodes with and without post-admission events that are known indicators of high cost or intensive care. Secondly, we examined the relationship between a hospital's average expected episode cost and average episode rates of several service use categories, to test whether the risk adjustment model can predict patient need for certain services. Thirdly, we examined the relationship between the re-evaluated MSPB Hospital measure and other cost-specific measures, efficiency-related measures, and measures in other Hospital VBP Program domains. For all three types of validity testing, we observed results that were in line with our expectations, demonstrating that the measure is functioning as intended.

We thank the commenter for their feedback regarding performance of hospitals with high case mix index. There has been extensive testing done on the measure to demonstrate the validity of its risk adjustment model. In general, the re-evaluated MSPB Hospital measure's risk adjustment methodology accounts for patient case-mix and other factors by adjustment for patient age and severity of illness. Specifically, the risk adjustment methodology includes 12 age categorical variables, 79 hierarchical condition category (HCC) indicators, status indicator variables for whether the beneficiary qualifies for Medicare through disability or age and End-Stage Renal Disease (ESRD), indicators to account for disease interactions, an indicator of whether the beneficiary recently required long-term care, and the Medicare Severity-Diagnosis Related Group (MS–DRG) of the index hospitalization. We believe that this provides adequate adjustment for patient acuity. For the re-evaluated MSPB Hospital measure specifically, a variable indicator showing whether there was an inpatient stay in the 30 days prior to an episode start date is added to the risk adjustment model to account for differences in expected cost for episodes that are triggered by readmissions. This prior inpatient admission characteristic is controlled for in the risk adjustment model to ensure that the hospital attributed to the newly triggered episode from a readmission is not unfairly penalized for providing care to the patient during the episode that could be higher cost due to the readmission status. This refinement was supported by the TEP. As part of routine measure maintenance, we plan to continue to conduct testing and monitor the impact of risk factors on the measure.

After consideration of the public comments we received, we are finalizing this policy as proposed.

(2) Adoption of Substantive Measure Updates to the Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (CBE #1550) Measure Beginning With the FY 2030 Program Year

In the FY 2024 IPPS/LTCH PPS proposed rule, we proposed to adopt substantive measure updates to the Hospital-level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) (CBE #1550) (hereinafter referred to as the THA/TKA Complication measure), beginning with the FY 2030 program year (88 FR 27026). We adopted the THA/TKA Complication measure in the FY 2015 IPPS/LTCH PPS final rule beginning with the FY 2019 program year for use in the Hospital VBP Program (79 FR 50062 through 50063). We continue to consider the clinical outcomes of the THA/TKA Complication measure a high priority, and we believe that this measure provides important data on resource use (addressing the Meaningful Measures Framework priority of making care affordable), which is why we proposed to adopt substantive updates to the THA/TKA Complication measure in the Hospital VBP Program under the Clinical Outcomes Domain.

We previously adopted the same substantive updates to the THA/TKA Complication measure for use in the Hospital IQR Program as a re-evaluated measure in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49257 through 49263). We also listed the re-evaluated THA/TKA Complication measure in the publicly available document entitled ''List of Measures Under Consideration for December 1, 2021,'' [230] with identification number MUC2021–118. The MAP reviewed the re-evaluated the measure and voted to conditionally support the measure for rulemaking for use pending CBE review and endorsement of the measure update. The MAP Rural Health Advisory Group reviewed this re-evaluated measure on December 8, 2021, and agreed that the measure was suitable for use with rural providers given that there would be no undue consequences for rural hospitals.[231] The CBE re-endorsed the

[230] Centers for Medicare & Medicaid Services. (2021) List of measures under consideration for December 1, 2021. Available at: *https://www.cms.gov/files/document/measures-under-consideration-list-2021-report.pdf*.

[231] Centers for Medicare & Medicaid Services. (2022) MAP 2021-2022 Considerations for Implementing Measures Final Report—Clinicians,

Continued

original measure in July of 2021,[232] and we intend to submit the re-evaluated measure to the CBE for endorsement in Fall 2024.

The substantive updates to the THA/TKA Complication measure are the inclusion of index admission diagnoses and in-hospital comorbidity data from Medicare Part A claims. Additional comorbidities prior to the index admission are assessed using Part A inpatient, outpatient, and Part B office visit Medicare claims in the 12 months prior to index (initial) admission. As a claims-based measure, hospitals will not be required to submit additional data for calculating the updated measure. We refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49263 through 49267), which describes the same updates we proposed to apply to the THA/TKA Complication measure in the Hospital VBP Program, including updates to the risk adjustment and measure calculations.

Adopting these substantive measure updates into the Hospital VBP Program will expand the measure outcome to include 26 additional mechanical complication ICD–10 codes. The additional ICD–10 codes capture the following diagnoses: fracture following insertion of orthopedic implant, joint prosthesis, or bone plate of the pelvis, femur, tibia or fibula, and periprosthetic fracture around internal prosthetic hip, hip joint, knee, knee joint, and other or unspecified internal prosthetic joint. We refer readers to FY 2023 IPPS/LTCH PPS final rule (87 FR 49264) for further information on these additional included ICD–10 codes that are included in the updated measure as adopted for the Hospital IQR Program.

Section 1886(o)(2)(A) of the Act requires the Hospital VBP Program to select measures that have been specified for the Hospital IQR Program. We note that although section 1886(b)(3)(B)(viii)(IX)(aa) of the Act generally requires measures specified by the Secretary in the Hospital IQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, section 1886(b)(3)(B)(viii)(IX)(bb) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and, therefore, we believe that the exception in section 1886 6(b)(3)(B)(viii)(IX)(bb) of the Act applies. We note that we intend to submit the re-evaluated measure to the CBE for endorsement in Fall 2024.

For the purpose of continuing to assess clinical outcomes, we proposed to adopt the substantive measure updates to the THA/TKA Complication measure (CBE #1550) in the Hospital VBP Program under the Clinical Domain beginning with the FY 2030 program year. As previously stated, we previously adopted the same substantive updates to the measure in the Hospital IQR Program (87 49257 through 49263), and we intend to begin posting the updated measure data on *Care Compare* beginning in July 2023, which will enable us to post data on the substantive updates to the measure for at least one year before the proposed beginning of the FY 2030 performance period, April 1, 2025, through March 31, 2028.

We proposed to adopt the substantive updates to THA/TKA Complications measure (CBE #1550) in the Hospital VBP Program beginning with the FY 2030 program year. We refer readers to section V.K.4.c of the preamble of this final rule where we discuss our defined baseline and performance periods for this updated measure under the Hospital VBP Program. We also proposed that the performance standards calculation methodology for the updated THA/TKA Complications measure will be the same as that which we currently use for the measure. The performance standards for the updated measure for FY 2030 are not yet available.

We invited public comment on this proposal.

Comment: Many commenters supported the proposal to implement the re-evaluated THA/TKA Complications measure in Hospital VBP Program, with a commenter noting they believed that it is important to ensure measure specifications align across programs. A commenter believed the measure updates will reduce duplicative reporting requirements for hospitals participating in both programs, increase accountability for hospitals by rewarding hospitals with lower complication rates, and provide patients with information to guide their choices regarding where to seek care. The commenter also believed that the measure updates have the potential to lower healthcare costs by decreasing the likelihood of costly readmissions. A commenter noted that they believed that the expansion of the numerator events for this measure provides a more comprehensive picture of hospital performance for hip and knee arthroplasty procedures. A few commenters indicated their support of the inclusion of the 26 additional mechanical complication ICD–10 codes because the codes are clinically appropriate to be paired with arthroplasty and will improve the measure's accuracy. A commenter specifically mentioned the measure cohort expansion to include admission diagnoses and in-hospital comorbidity data in their support because they believed that it enables the inclusion of the 26 additional mechanical complication ICD–10 codes.

Response: We thank commenters for their support. We agree that it is important to align measures across programs where possible and that the 26 additional mechanical complication ICD–10 codes are clinically appropriate.

Comment: A few commenters did not support the substantive updates to the THA/TKA Complications measure citing concerns with the length of the delay in implementation, the inability to assess impact prior to implementation and ability to appropriately comment, and public confusion with the measure currently in the Hospital IQR Program. A commenter noted that they believe that the proposal does not provide enough information to demonstrate the anticipated improvements once implemented.

Response: Section 1886(o)(2)(C)(i) of the Act and 42 CFR 412.164(b) state that measures must be publicly reported for one year in the Hospital IQR Program prior to the beginning of the performance period in the Hospital VBP Program. As we stated in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27026), we previously adopted the re-evaluated THA/TKA Complication measure into the Hospital IQR Program to accommodate these statutory and regulatory requirements. We staged our proposals across the Hospital IQR Program and Hospital VBP Program to accommodate the statutory requirement. Therefore, we do not want to alter the public reporting timeline of the measures. Hospital-specific reports for the re-evaluated THA/TKA Complications measure in the Hospital IQR Program were released to hospitals

---

Hospitals, and PAC–LTC. Available at: *https://mmshub.cms.gov/sites/default/files/map_2021-2022_considerations_for_implementing_measures_in_federal_programs_final_report.pdf.*

[232] CMS Measure Inventory Tool. (2023) Hospital-level risk-standardized complication rate (RSCR) following elective primary total hip arthroplasty (THA) and/or total knee arthroplasty (TKA) Measure Specifications. Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=11547&sectionNumber=1.*

in May 2023. Additionally, hospitals will be able to see their performance in the Hospital IQR Program for 6 years prior to measure implementation in the Hospital VBP Program beginning with the FY 2030 program year. Further, like the re-evaluated MSPB Hospital measure, we will make sure it is clear which version of the measure is being publicly displayed in which location through outreach and education efforts.

Comment: A few commenters expressed concern that the measure will increase burden on hospitals because they will have to monitor and validate two different performance rates, with a commenter expressing concern regarding the number of hospitals that participate in the Hospital VBP Program versus the Hospital IQR Program. The commenter recommended monitoring reporting rates to make sure no reporting gaps occur when the measure is removed from the Hospital IQR Program.

Response: We acknowledge the commenters' concerns regarding burden of reporting two slightly different versions of the measure in the Hospital IQR and Hospital VBP Programs simultaneously. However, we respectfully disagree that the proposed transition of the re-evaluated THA/TKA Complication measure from the Hospital IQR Program to the Hospital VBP Program will cause significant data collection burden. Hospitals will not be required to submit additional data for calculating the measure as it is a claims-based measure. Section 1886(o) of the Act and at 42 CFR 412.164(b) of our regulations state that measures must be publicly reported for one year in the Hospital IQR Program prior to the beginning of the performance period in the Hospital VBP Program. As we have previously stated in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27026 through 27027), we adopted the revised version of the THA/TKA Complication measure into the Hospital IQR Program first to accommodate the statutory and regulatory requirements. The benefits of keeping the original THA/TKA Complications measure until the statutory timeframe for the updated measure has been met outweighs the burden of reporting two measures. We refer readers to FY 2023 IPPS/LTCH PPS final rule (87 FR 49263 through 49267), which provided interested parties with an opportunity to become familiar with the new version of the measure and provide feedback prior to our proposed adoption of that revised measure in the Hospital VBP Program.

Comment: Several commenters recommended that CMS consider modifying the measure to capture both inpatient and outpatient procedures in the case that the shift of procedures from an inpatient setting to an outpatient setting alters the measure validity and reliability or impacts performance.

Response: We thank the commenters for their feedback. We are monitoring the shifts of THA/TKA from the inpatient to outpatient setting as well as the potential impacts on this inpatient only measure. The proposed re-evaluated THA/TKA Complication measure is case mix adjusted for patient comorbidities and is a relative performance measure for hospitals performing these elective THA/TKA procedures.[233] As such, we believe that this measure accurately reflects hospital performance even if patients receiving these procedures in the inpatient setting tend to be sicker, on average, than those treated in an outpatient setting. We also refer readers to section XIV.B.3.b of the CY 2024 OPPS proposed rule for a proposal to adopt the THA/TKA Patient-Reported Outcome-based Performance Measure (PRO–PM) in the Hospital Outpatient Quality Reporting (OQR) Program.

Comment: A few commenters expressed concerns about the inclusion of the additional ICD–10 codes, including that the feedback from subject matter experts have not been reviewed or endorsed by the CBE and that the additional codes will negatively impact patients and clinicians in small community hospitals.

Response: As stated in the proposed rule (88 FR 27026), the re-evaluated measure was conditionally supported by the MAP in December of 2021. The CBE re-endorsed the original measure in July of 2021, and we intend to submit the re-evaluated measure to the CBE for endorsement in the fall of 2024. Additionally, the MAP Rural Health Advisory Group reviewed this re-evaluated measure on December 8, 2021, and agreed that the measure was suitable for use with rural providers given that there would be no undue consequences for rural hospitals.[234] We also note while conducting internal analyses, orthopedic surgeons and clinical coding experts vetted the additional 26 mechanical complication ICD–10 codes and agreed they should be included.

Comment: A commenter recommended suppressing one set of measure results from public reporting to reduce potential confusion, while another commenter recommended reviewing the changes to makes sure reliability and validity of the measure were not impacted. Additional recommendations included allowing hospitals to have the ability to see the performance metrics to have a better understanding of the impacts of the modifications and publicly reporting the risk-adjusted, one-year mortality and revision rates on the *Care Compare* website.

Response: We thank the commenters for their feedback on the re-evaluated THA/TKA measure. We will work to clearly identify the version of the measure when publicly reporting the re-evaluated THA/TKA Complications measure and help address any potential confusion. Data for this measure will continue to be posted to the *Care Compare* website.

Comment: A few commenters made recommendations about including adjustments around socioeconomic and SDOH considerations, including expanding the claims lines from 25 to a number that allows for the capture of mechanical complication codes along with SDOH diagnosis codes that could also impact the outcome of an elective THA or TKA, and creating a socioeconomic status risk-adjustment that stratifies by dual eligibility populations. A few commenters stated that they believe hospitals taking care of the most complex patients may be unfairly penalized and recommend exploring an alternative risk adjustment.

Response: We are committed to measuring and improving health equity and addressing social risk factors in quality measurement. During the last CBE endorsement maintenance submission for the THA/TKA Complication measure prior to 2022, comprehensive testing was completed which included an assessment of the impact of social risk as captured by dual eligibility and the AHRQ SES Index. The AHRQ SES index score considers aspects of socioeconomic status and is computed using US census data and considers factors including median household income, percentage of persons below the Federal poverty line, unemployment, education, property value, and percentage of persons in crowded households at the 9-digit zip

[233] For more detailed measure specifications, we refer readers to the ''2022 Procedure-Specific Complication Measure Updates and Specifications: THA/TKA'' at the *CMS.gov* QualityNet website at: *https://qualitynet.cms.gov/inpatient/measures/complication/methodology*.

[234] Centers for Medicare & Medicaid Services. (2022) MAP 2021–2022 Considerations for Implementing Measures Final Report—Clinicians, Hospitals, and PAC–LTC. Available at: *https://mmshub.cms.gov/sites/default/files/map_2021-2022_considerations_for_implementing_measures_in_federal_programs_final_report.pdf*.

code level.[235] We found wide variation in the prevalence of the two social risk factors we examined, with a large proportion of hospitals treating zero patients with these risk factors. We also found that both had some association with complication risk. However, adjustment for these factors did not have a material impact on hospital RSCRs.[236] [237] Our decisions about which risk factors should be included in each measure's risk-adjustment model are based on whether inclusion of such variables is likely to make the measures more successful at illuminating quality differences and motivating quality improvement. Given these empiric findings and program considerations, we chose not to include these two social risk factors in the final risk model. In presenting these results and interpretation, the CBE re-endorsed the original measure (CBE #1550) in June of 2021 without adjustment for patient-level social risk factors.[238] We acknowledge the importance of balancing these competing considerations and we plan to continue to reevaluate the risk adjustment model and available risk factors on an ongoing basis as part of routine measure maintenance, with the goal of producing the most accurate and fair risk adjustment models for assessing provider performance. Further details related to social risk testing for this measure can be found from downloading the measure specifications from the National Quality Forum (NQF)'s Surgery Fall Cycle 2020 project here: *https://nqfappservicesstorage.blob.core.windows.net/proddocs/22/Fall/2020/measures/1550/shared/1550.zip*.

After consideration of the public comments we received, we are finalizing our policy as proposed.

3. New Measure for the Hospital VBP Program Set

We consider measures for adoption based on the statutory requirements, including specification under the Hospital IQR Program, posting dates on the *Care Compare* website, and our priorities for quality improvement as outlined in the CMS National Quality Strategy, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*. We also refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41147 through 41148), in which we describe the Meaningful Measures Framework, our objectives under this Framework for quality measurement, and the quality topics that we have identified as high-impact measurement areas that are relevant and meaningful to both patients and providers. Due to the time necessary to adopt measures, we often adopt policies for the Hospital VBP Program well in advance of the program year for which they will be applicable.

a. New Measure Adoption Beginning With the FY 2026 Program Year: Severe Sepsis and Septic Shock: Management Bundle (CBE #0500)

(1) Background

Sepsis, severe sepsis, and septic shock can arise from simple infections, such as a pneumonia or urinary tract infection. Although it can affect anyone at any age, sepsis is more common in infants, the elderly, and patients with chronic health conditions such as diabetes and immunosuppressive disorders.[239] A 2021 report by the Healthcare Cost and Utilization Project on the most frequent principal diagnoses among non-maternal, non-neonatal inpatient stays using the 2018 National Inpatient Sample revealed septicemia as the most frequent principal diagnosis with over 2.2 million hospital stays.[240] The CDC estimates there are approximately 1.7 million adults diagnosed with sepsis annually with approximately 270,000 resulting deaths. An analysis of over 2.5 million patients with sepsis discharged from January 1, 2010, to September 30, 2016, revealed average mortality rates of 14.9 percent for patients with severe sepsis and 34.3 percent for patients with septic shock.[241] Another analysis using CMS claims data for services provided to approximately 6.9 million patients admitted to inpatient with sepsis from January 1, 2012, to December 31, 2018, showed that while the number of patients admitted to the hospital with sepsis increased over this time period, mortality rates decreased, however they remained high with mortality rates at one week post discharge of approximately 15 percent for severe sepsis and approximately 40 percent for patients with septic shock. For this same population mortality rates increased at six months post discharge to approximately 36 percent for severe sepsis and 60 percent for septic shock.[242]

In a 2001 study by Rivers et al.,[243] it was shown that an absolute and relative reduction in mortality from sepsis can be reduced 16 percent and 30 percent, respectively, when aggressive care is provided within six hours of hospital arrival. In a more recent study that utilized chart-abstracted data for the Severe Sepsis and Septic Shock: Management Bundle measure (CBE #0500) from October 1, 2015, to March 31, 2017, submitted to CMS for over 1.3 million patients, Townsend et al. found that compliance with the measure was associated with a reduction in 30-day mortality.[244]

(2) Overview of Measure and MAP Feedback

We previously adopted the Severe Sepsis and Septic Shock: Management Bundle measure (CBE #0500) into the Hospital IQR Program beginning with the FY 2017 payment determination in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50236 through 50241). Hospital submission of patient level data for reporting on the measure began with qualifying patient discharges starting

[235] Bonito A, Bann C, Eicheldinger C, Carpenter L. Creation of new race-ethnicity codes and socioeconomic status (SES) indicators for Medicare beneficiaries. Final Report, Sub-Task. 2008;2.

[236] National Quality Forum. Surgery Fall Cycle 2020. Measure Testing (subcriteria 2a2, 2b1–2b6) Document. November 3, 2020. Available at: *https://nqfappservicesstorage.blob.core.windows.net/proddocs/22/Fall/2020/measures/1550/shared/1550.zip*.

[237] Health and Human Services. (2016) 2016 Procedure-Specific Measure Updates and Specifications Report Hospital-Level Risk-Standardized Complication Measure. Available at: *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/elective%20primary%20tha%20and-or%20tka%20complications%20measure%20specifications_0.pdf*.

[238] National Quality Forum. Consensus Standards Approval Committee—Measure Evaluation Web Meeting, June 2021. Available at: *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=95862*.

[239] National Institute of General Medical Sciences. (2021). Bethesda, MD: U.S. Department of Health and Human Services. Available at: *https://nigms.nih.gov/education/fact-sheets/Pages/sepsis.aspx*.

[240] McDermott KW, Roemer M. (2021) Most Frequent Principal Diagnoses for Inpatient Stays in U.S. Hospitals, 2018. Healthcare Cost and Utilization Project (HCUP) Statistical Brief #277. Available at: *https://www.hcup-us.ahrq.gov/reports/statbriefs/sb277-Top-Reasons-Hospital-Stays-2018.pdf*.

[241] Paoli CJ, Reynolds MA, Sinha M, Gitlin M, Crouser E. (2018). Epidemiology and Costs of Sepsis in the United States—An Analysis Based on Timing of Diagnosis and Severity Level. Critical Care Medicine.46(12):1889–1897.–doi: 10.1097/CCM.0000000000003342.

[242] Buchman TG, Simpson SQ, Sciarretta KL, et al. (2020). Sepsis Among Medicare Beneficiaries: 1. The Burdens of Sepsis, 2012–2018. Crit Care Med. 48(3):276–288. doi: 10.1097/CCM.0000000000004224. PMID: 32058366; PMCID: PMC7017943.

[243] Rivers E, Nguyen B, Havstad S et al. (2001) Early goal directed therapy in the treatment of severe sepsis and septic shock. N Engl J Med. 345: 1368–77.

[244] Townsend SR, Phillips GS, Duseja R, et al. (2021) Effects of compliance with the early management bundle (SEP–1) on mortality changes among Medicare beneficiaries with sepsis: a propensity score matched cohort study. Chest. doi:10.1016/j.chest.2021.07.2167.

October 1, 2015. We began public reporting of the Severe Sepsis and Septic Shock: Management Bundle measure (CBE #0500) performance results on the *Care Compare* website with the July 2018 refresh at which time the national average performance for the measure was 49 percent. Performance rates have increased with each subsequent *Care Compare* refresh reaching 60 percent for results reported from October 1, 2019, through September 30, 2020. During the COVID–19 public health emergency (PHE), performance rates decreased slightly to 57 percent for the results reported from January 1, 2021, through December 31, 2021. Performance rates for the top 10 percent of hospitals have averaged 80 percent since we began public reporting with performance data from October 1, 2017, through September 30, 2018. We believe that additional incentives will support continued improvement in measure performance. The Severe Sepsis and Septic Shock: Management Bundle measure (CBE #0500) was initially endorsed by the CBE in 2008 for the hospital/acute care facility setting, and underwent maintenance review and endorsement renewal in June 2013, November 2014, July 2017, and December 2021.

The Severe Sepsis and Septic Shock: Management Bundle measure supports the efficient, effective, and timely delivery of high-quality sepsis care. The Severe Sepsis and Septic Shock: Management Bundle provides a standard operating procedure for the early risk stratification and management of a patient with severe infection. When the care interventions in the Severe Sepsis and Septic Shock: Management Bundle measure are provided as a composite, there have been significant reductions observed in hospital length of stay, re-admission rates and mortality.[245] [246] Additional information about this measure is available on the CMS Measures Inventory Tool (CMIT) website.[247]

We believe that the adoption of this measure aligns with the core principles outlined in the HHS National Healthcare System Action Alliance to Advance Patient Safety, including the focus on demonstrating and fostering commitments to safety as a core value and the promotion of the development of safety cultures.[248] We also believe that the adoption of the Sepsis and Septic Shock: Management Bundle measure will contribute toward CMS' goal of advancing health equity, as outlined in the CMS National Quality Strategy.[249] Research on in-hospital sepsis mortality between 2004–2013 showed that there is a higher rate of sepsis mortality for Black and Hispanic patients, compared with White patients.[250] Further, this research showed that disparities in outcomes disappeared when results were adjusted for hospital characteristics which highlights the need for improved septic management in hospitals that are treating a high proportion of Black and Hispanic patients.[251] Another study of 249 academic medical centers found that for patients with a diagnosis of sepsis, Black patients exhibited lower adjusted sepsis mortality than White patients.[252] While the results of research in the field are varied, we believe that this measure, which outlines standardized protocols, could mitigate potential biases held by individuals and systems that lead to such variation in outcomes.

The measure was submitted to the MAP for the Hospital VBP Program for the 2022–2023 pre-rulemaking cycle and received conditional support for rulemaking pending the measure developer providing clarity about the differences between the measure specifications submitted to the MUC list in May 2022 and reviewed by MAP and the current measure specifications published in December 2022 which include abstraction guidance updates related to crystalloid fluid administration volumes. During the public comment period for the MUC list, we received comments that were both supportive and not supportive of the inclusion of the measure in the Hospital VBP Program. Public comments supportive of including the measure in the Hospital VBP Program noted the measure is CBE endorsed and that it encourages hospitals to follow published international guidelines for the early identification and management of severe sepsis and septic shock.

Public comments not supportive of including the measure in the Hospital VBP Program centered around two main themes. The first group of commenters were concerned that the adoption of the Severe Sepsis and Septic Shock: Management Bundle measure could result in the overuse of antibiotics, more specifically, that adherence to the Severe Sepsis and Septic Shock: Management Bundle measure includes administering antibiotic therapy to all patients with possible sepsis, regardless of severity-of-illness, which commenters believed could risk excessive and unwarranted antibiotic administration. The antibiotic requirements and timing for the measure are consistent with antimicrobial recommendations Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock: 2021.[253] We believe that there is enough flexibility to incorporate clinician judgment in the measure as there are several opportunities for abstractors to disregard Systemic Inflammatory Response Syndrome (SIRS) criteria or signs of organ dysfunction if there is physician, advance practice nurse, or physician assistant documentation that SIRS criteria or signs of organ dysfunction are due to a chronic condition, medication, or a non-infectious source.

Second, some commenters had concerns around the burden associated with the data abstraction of the measure and staying up to date with changes to the data abstraction. We note that adding the measure to the Hospital VBP Program will not create a new burden for hospitals because they are already required to report data on the measure under the Hospital IQR Program. With regard to concerns about the overall burden of collecting these data in the Hospital IQR Program, we note that we are currently developing a sepsis outcome electronic clinical quality measure (eCQM) that, if adopted for that program, would not be as burdensome

[245] Levy MM, Gesten FC, Phillips GS, et al. (2018). Mortality Changes Associated with Mandated Public Reporting for Sepsis. The Results of the New York State Initiative. Am J Respir Crit Care Med. 198(11):1406–1412. doi: 10.1164/rccm.201712–2545OC. PMID: 30189749; PMCID: PMC6290949.

[246] Bauer SR, Han X, Wang XF, Blonsky H, Reddy AJ. (2020) Association Between Compliance With the Sepsis Quality Measure (SEP–1) and Hospital Readmission. Chest. 158(2):608–611. doi: 10.1016/j.chest.2020.02.042. Epub 2020 Mar 10. PMID: 32169628.

[247] Severe Sepsis and Septic Shock: Management Bundle (Composite Measure) *https://cmit.cms.gov/cmit/#/MeasureView?variantId=778&sectionNumber=1.*

[248] The National Healthcare System Action Alliance To Advance Patient Safety. HHS. Available at: *ahrq.gov/cpi/about/otherwebsites/action-alliance.html.*

[249] Centers for Medicare & Medicaid Services. (2022) CMS National Quality Strategy. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS/Quality-Strategy.*

[250] Jones JM, Fingar KR, Miller MA, et al. (2017). Racial Disparities in Sepsis-Related In-Hospital Mortality: Using a Broad Case Capture Method and Multivariate Controls for Clinical and Hospital Variables, 2004–2013. Crit Care Med. 45(12):e1209–e1217. doi: 10.1097/CCM.0000000000002699. PMID: 28906287.

[251] Ibid.

[252] Chaudhary N, Donnelly, J, Wang H (2018). Critical Care Medicine 46(6):p 878–883, June 2018. | DOI: 10.1097/CCM.0000000000003020.

[253] Evans L, Rhodes A, Alhazzani W, et al. (2021) Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock 2021. Crit Care Med. 49(11):e1063–e1143. doi: 10.1097/CCM.0000000000005337. PMID: 34605781.

for hospitals to report. However, in light of our high priority to address patient safety, in the FY 2024 IPPS/LTCH PPS proposed rule, we proceeded with the proposal to adopt the Severe Sepsis and Septic Shock: Management Bundle measure (88 FR 27027 through 27029). The specifications for the proposed measure are listed in v5.14 of the CMS Specifications Manual for National Hospital Inpatient Quality Measures, and those specifications apply to patients discharged from July 1, 2023, through December 31, 2023.[254] The proposed measure specifications for v5.14 include minor technical updates to the data abstraction guidance and review for consistency with recent published literature. The minor technical updates were made to address hospital abstractor and clinician feedback received via the QualityNet Question and Answer Tool from hospital medical record abstractors and clinicians about the documentation required for fluid resuscitation within three hours of tissue hypoperfusion presentation. We routinely make these minor, technical updates based on feedback we receive from abstractors and clinicians to improve the data abstraction of the measure. The measure is in alignment with the Surviving Sepsis Campaign: International Guidelines for Management of Severe Sepsis and Septic Shock: 2021 which suggest administering at least 30 mL/kg of intravenous (IV) crystalloid fluids within the first three hours of resuscitation noting that timely, effective fluid resuscitation is critical to stabilize patients with sepsis-induced tissue hypoperfusion. The guidelines noted that there are no prospective interventional studies comparing various crystalloid fluid volumes for initial resuscitation but reference observational studies and a retrospective study that demonstrated not administering 30 mL/kg of crystalloid fluids within three hours of sepsis identification was associated with higher mortality regardless of comorbidities such as end-stage renal disease and heart failure. With this in mind, the guidelines suggest that fluid administration should be guided by careful assessment of responsiveness to avoid over- and under-resuscitation. The measure requires starting crystalloid fluids within three hours of recognition of tissue hypoperfusion but does not require fluids for resuscitation be completely infused within three hours. This is in part due to recognition of various factors that can contribute to complete fluid infusion potentially taking longer. The measure establishes 30 mL/kg of crystalloid fluids as the default volume for fluid resuscitation but does allow for lesser volumes ordered by a clinician and accompanied by documentation of a reason for administering a lesser volume in recognition that some patients may not tolerate 30 mL/kg and that others may respond adequately to a lesser volume.

We have made technical updates to the measure specifications since we adopted this measure in the Hospital IQR Program, and we proposed to adopt the measure, as updated, for the Hospital VBP Program. The data submission requirements, Specifications Manual, and submission deadlines are posted on the QualityNet website at: *https://qualitynet.cms.gov* (or other successor CMS designated websites).

(3) Overview of the Measure Specifications

a. Numerator

Patients who received all of the following interventions for which they qualify:

Time frame	Intervention
Within 3 hours of presentation of severe sepsis	• Initial lactate level measurement • Broad spectrum or other antibiotics administered • Blood cultures drawn prior to antibiotics
AND	
Within 6 hours of presentation of severe sepsis, ONLY if the initial lactate is elevated	• Repeat lactate level measurement
AND	
Within 3 hours of initial hypotension, OR Within 3 hours of septic shock	• Resuscitation with 30 mL/kg crystalloid fluids
AND	
Within 6 hours of septic shock presentation, ONLY if hypotension persists after fluid administration	• Vasopressors are administered
AND	
Within 6 hours of septic shock presentation, if hypotension persists after fluid administration, or initial lactate >= 4 mmol/L	• Repeat volume status and tissue perfusion assessment is performed

[254] Hospital IQR Program, Inpatient Specifications Manual v5.14. *https://qualitynet.cms.gov/files/6391eabf76962e0016ad91ba?filename=HIQR_SpecsMan_v5.14.zip.*

b. Denominator

The denominator is patients 18 years of age and older with an ICD–10–CM Principal or Other Diagnosis Code for sepsis, severe sepsis without septic shock, or severe sepsis with septic shock, and without an ICD–10–CM Principal or Other Diagnosis Code of U07.1 (COVID–19).

Patients who are admitted as a transfer from an inpatient, outpatient, or emergency/observation department of another hospital or an ambulatory surgical center, or who are enrolled in a clinical trial associated with treatment of patients with sepsis, are excluded from the denominator. The denominator is further refined as the number of patients confirmed with severe sepsis or septic shock through medical record review for the presence of a suspected infection, two or more SIRS criteria, and a sign of organ dysfunction that are all documented within 6 hours of each other. Additional exclusions are for patients:

- With advanced directives for comfort care or palliative care;
- Who or for whom a surrogate decision maker declines or is unwilling to consent to interventions required to meet the numerator;
- With severe sepsis or septic shock who are discharged within six hours of presentation; or
- Who received IV antibiotics for more than 24 hours prior to severe sepsis presentation.

We proposed to adopt the Severe Sepsis and Septic Shock: Management Bundle measure in the Hospital VBP Program under the Safety Domain beginning with the FY 2026 program year. The proposed measure fulfills all the statutory requirements for the Hospital VBP Program based on our adoption of the measure in the Hospital IQR Program. We refer readers to section V.K.4.c of the preamble of this final rule where we discussed our proposed baseline periods and performance periods for this measure if adopted for the Hospital VBP Program.

We invited public comment on this proposal.

Comment: Many commenters supported the Severe Sepsis and Septic Shock Management Bundle measure proposal, agreeing that the severity of the diagnoses warrants the implementation of the measure, that the measure will not create additional burden, and that the measure is in alignment with the Surviving Sepsis Campaign International Guidelines for Management of Severe Sepsis and Septic Shock. A commenter supported that the measure is kept up to date by incorporating Version 5.14 and that the review period includes updates between May 2022 and December 2022. A commenter supported the measure proposal but recommended delaying implementation until streamlining and standardization of the severe sepsis and septic shock definition is completed by the Federal Sepsis Task Force.

Several commenters supported the Severe Sepsis and Septic Shock: Management Bundle proposal because they believed that it will benefit clinicians and patients, including allowing flexibilities for clinician judgment in prescribing therapies and driving enhanced quality of care for the Medicare patient population. A commenter noted the clinician benefit of initial and serial procalcitonin monitoring that complements and enhances compliance with Severe Sepsis and Septic Shock: Management Bundle. A commenter recommended future modifications to better tailor individual patients' care.

Response: We thank the commenters for their support of our proposal to adopt the Severe Sepsis and Septic Shock: Management Bundle (CBE #0500) measure for the Hospital VBP Program beginning with the FY 2026 program year. We appreciate the commenters' recognition that the measure is in alignment with the most recent Surviving Sepsis Campaign International Guidelines for Management of Severe Sepsis and Septic Shock. We recognize the importance of making sure the measure is maintained and consistent with the most recent guidelines and best practice published evidence. We understand and respect the need to harmonize with sepsis definitions and measures used by other Federal agencies, such as the Centers for Disease Control and Prevention (CDC) Adult Sepsis Event (ASE) definition.[255] We will apply the severe sepsis and septic shock screening criteria that the measure currently uses because those criteria are consistent with previous iterations of the measure and are an established, tested method for early identification of sepsis. We will reevaluate this as newer methods and definitions are finalized.

We believe that recent updates to the measure that incorporate options that acknowledge clinician judgment and enable greater assessment and prescribing flexibility consistent with clinical practice guidelines and recent literature will be beneficial. We thank commenters for their feedback on the use of serial procalcitonin and recommendation for future modifications to better account for individual patient care needs. We will take these into consideration for future program years.

Comment: Several commenters supported the Severe Sepsis and Septic Shock: Management Bundle proposal in the Hospital VBP Program because they believed that it incentivizes hospitals to increase the quality and timeliness of care which result in better patient outcomes.

A few commenters supported the Severe Sepsis and Septic Shock: Management Bundle measure proposal and commended CMS for taking steps to improve sepsis outcomes, particularly through the development of an eCQM in the future that could replace the Severe Sepsis and Septic Shock: Management Bundle in a less burdensome manner.

A commenter supported the Severe Sepsis and Septic Shock: Management Bundle measure proposal because they believed in the importance of evidence-based correlation to outcomes. A commenter also supported the Severe Sepsis and Septic Shock: Management Bundle measure proposal because it promotes health equity.

Response: We agree that additional incentivization will lead to continued improvements in the quality and timeliness of care leading to better patient outcomes. We thank commenters for their support of our proposal to adopt the Severe Sepsis and Septic Shock: Management Bundle measure for the Hospital VBP Program and continue to strive to develop measures that support improving outcomes for patients with severe sepsis and septic while minimizing reporting burden. We also continue to take updated published guidelines and evidence-based literature that demonstrates correlations between processes of care and improved outcomes into consideration for measures.

We agree that efforts to support equity in the provision of health care are important to improving outcomes for all patients with severe sepsis and septic shock. As noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27028), and in section V.K.3(2) of this final rule, we believe that the adoption of the Sepsis and Septic Shock: Management Bundle measure will contribute toward CMS' goal of advancing health equity, as outlined in the CMS National Quality

[255] Centers for Disease Control and Prevention. (2018) Hospital Toolkit for Adult Sepsis Surveillance. Available at: *https://www.cdc.gov/sepsis/pdfs/sepsis-surveillance-toolkit-mar-2018_508.pdf.*

Strategy.[256] Research on in-hospital sepsis mortality between 2004–2013 showed that there is a higher rate of sepsis mortality for Black and Hispanic patients, compared with White patients.[257] Further, this research showed that disparities in outcomes disappeared when results were adjusted for hospital characteristics which highlights the need for improved septic management in hospitals that are treating a high proportion of Black and Hispanic patients.[258] Another study of 249 academic medical centers found that for patients with a diagnosis of sepsis, Black patients exhibited lower adjusted sepsis mortality than White patients.[259] While the results of research in the field are varied, we believe that this measure, which outlines standardized protocols, could mitigate potential biases held by individuals and systems that lead to such variation in outcomes.

Comment: Many commenters did not support Severe Sepsis and Septic Shock: Management Bundle measure because they believed that there are unrealistic documentation and data collection expectations that burden providers. A few commenters cited that the measure is time consuming, and many hospitals have difficulty meeting the measure requirements and implementing the measure. A commenter expressed concerns that the documentation requirements place a heavy burden on rural hospitals. A commenter noted that limitations of documentation tools make it difficult to measure compliance fairly. A commenter expressed concern that a piece of the documentation is missing for the IV fluid documentation requirements.

Response: We acknowledge the commenters' concerns. However, the Severe Sepsis and Septic Shock: Management Bundle measure has been in the Hospital IQR Program since October 1, 2015, and eligible hospitals, including community and rural hospitals have successfully reported data on the measure. Additionally, the Rural Health Advisory Group expressed the importance of the measure for rural health.[260] As we noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27028), adopting the measure into the Hospital VBP Program will not result in a change to measure data collection requirements and burden because hospitals are already required to report data on the measure under the Hospital IQR Program. We acknowledge that this measure has been subject to updates in response to changes in the published evidence and feedback from medical record abstractors and clinicians; however, we believe these are minor technical updates. Additionally, the level of documentation required for this measure is commensurate with the complexity of sepsis and septic shock and with the severity of the consequences for patients if sepsis and septic shock are not detected and managed in a timely manner. We have also initiated an effort in collaboration with the CDC to develop a sepsis outcome eCQM that is a less burdensome and could potentially replace the Severe Sepsis and Septic Shock: Management Bundle measure in the future. However, until that measure is fully developed and available for use in our programs, the severity of the diagnoses and the significant impact on patients warrants using the Severe Sepsis and Septic Shock: Management Bundle measure. CMS continues to work in collaboration with CDC and stakeholders and welcomes public comment and engagement in improving sepsis outcomes and mortality.

With regard to the commenter's concern about the documentation requirements for IV fluids, the Crystalloid Fluid Administration data elements provide guidance with examples for abstractors to determine the volume of fluid ordered, the start time, end time, and volume of fluid administered based upon various scenarios provided by abstractors. At a minimum, there must be an order for the crystalloid fluids that includes the type of fluid, volume of fluid, and a rate or time over which the fluids are to be given. There must also be clear documentation in the medical record of the date and time the crystalloid fluids were started. We note that often the fluid administration end time is not clearly documented and the manual provides guidance to help abstractors determine the end time based upon a combination of the start time, fluid volume and infusion rate. If there is not sufficient documentation in the medical record to determine the volume ordered, the start, end time, and volume administered, then the case will not meet the requirements for the Crystalloid Fluid Administration data elements.

Comment: Many commenters did not support the adoption of the Severe Sepsis and Septic Shock: Management Bundle measure because they believed that there will continue to be frequent updates to the measure that make it more difficult to implement the measure and educate staff. A few commenters cited concerns around the baseline periods noting that given the frequent updates, it is unclear how CMS will establish accurate baselines for evaluating hospitals' performance over time and that the comparison of the baseline period to the performance period would not be equal because of the measure updates every 6 months. A few commenters expressed that the continual shifts in the measure specifications have led to inconsistent interpretation across facilities. A commenter expressed concern that the measure is still not stable if it is undergoing changes with each manual release every 6 months. A commenter noted that frequent updates to the measure leads to increased documentation burden.

Response: We acknowledge the commenters' concerns that the Severe Sepsis and Septic Shock: Management Bundle measure has been subject to frequent updates in response to changes in the published evidence and feedback from medical record abstractors and clinicians. However, we respectfully disagree that the updates will impact performance. We wish to emphasize that, as noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27028), the updates made to Severe Sepsis and Septic Shock: Management Bundle are minor technical updates that are incorporated for consistency with recent published literature and to address hospital abstractor and clinician feedback received via the QualityNet Question and Answer Tool from hospital medical record abstractors and clinicians that do not impact performance. For example, in v5.13 of the Hospital IQR measure specifications manual, we added guidance about the use of documentation of severe sepsis and septic shock with a footnote in the EHR identifying the time based on question and comments from abstractors. We also added examples to the *Crystalloid Fluid Administration* data element based upon documentation scenarios provided by abstractors, and

[256] Centers for Medicare & Medicaid Services. (2022) CMS National Quality Strategy. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*.

[257] Jones JM, Fingar KR, Miller MA, et al. (2017). Racial Disparities in Sepsis-Related In-Hospital Mortality: Using a Broad Case Capture Method and Multivariate Controls for Clinical and Hospital Variables, 2004–2013. Crit Care Med. 45(12):e1209-e1217. doi: 10.1097/CCM.0000000000002699. PMID: 28906287.

[258] Ibid.

[259] Chaudhary N, Donnelly, J, Wang H (2018). Critical Care Medicine 46(6):p 878–883, June 2018. | DOI: 10.1097/CCM.0000000000003020.

[260] Centers for Medicare & Medicaid Services. (2022) Measure Applications Partnership (MAP) Hospital Workgroup Preliminary Analyses. Available at: *https://mmshub.cms.gov/sites/default/files/2022-preliminary-analysis-hospital-workgroup.pdf* .

we added guidance in the *Initial Hypotension* data element to clarify the time frame for abstraction of hypotension to count toward this data element which ends when the ordered crystalloid fluid volume is completely given. In v5.14 of the Hospital IQR measure specifications manual, we added guidance to allow documentation that no fluids were ordered because the patient was not volume or fluid responsive by clinical evidence. This is based upon newer technology that is becoming more widely used to assess a patient's fluid responsiveness. This noninvasive technology allows clinicians to identify whether a patient responds positively to crystalloid fluids without administering fluids or with administration of only a nominal amount. The guidance requires documentation that invasive or noninvasive measurements of cardiac output (CO), cardiac index (CI), stroke volume (SV), or stroke volume index (SVI) were used to determine the patient was not volume or fluid responsive. This impacts a small proportion of patients with sepsis-induced hypotension and takes into consideration shifts in the availability and use of new technology. These minor technical updates to the measure ensure the measure is up to data and providing the most accurate data. The updates also help hospitals drive local quality improvement in patient care. We, therefore, believe that the baseline and performance periods are appropriate as proposed because the updates to the measure specifications are not substantive.

Comment: Many commenters did not support the Severe Sepsis and Septic Shock: Management Bundle measure because they believed that the measure creates incentives to increase antibiotic use and potentially overuse antibiotics with a few commenters expressing their belief that overuse will be magnified if the Severe Sepsis and Septic Shock: Management Bundle measure shifts to pay-for-performance. A few commenters noted that the measure requires all patients to receive antibiotics within one hour of presentation but that not all patients with sepsis or septic shock need antibiotics. A few commenters noted that the measure does not allow exceptions for providers to treat patients in the manner they feel is clinically appropriate, which leads to non-discriminatory antibiotic administration. A commenter did not support the Severe Sepsis and Septic Shock: Management Bundle measure because of the requirement of parenteral antibacterial medications given that are not necessary for the management of some patients with sepsis and oral therapy is quicker. A few commenters recommended minimizing the potential for antibiotic overuse. A commenter recommended excluding patients with unconfirmed sepsis who do not have shock from the bundle, as the data supporting immediate antibiotics are weak, and a commenter recommended that Severe Sepsis and Septic Shock: Management Bundle be modified so that there is additional time permitted to confirm an infection prior to providing antibiotics.

Response: We appreciate the commenters' concern and will continue to monitor the literature for signs of antibiotic overuse associated with the measure. While we agree with the importance of antimicrobial stewardship, we are not aware of published literature that demonstrates an association between the implementation of the measure and antibiotic overutilization. In the largest study to address sepsis and antibiotic use to date which includes 701,055 patients, Anderson et al. found that among the subgroup of ten hospitals with complete microbiology data and specifically assessing patients with suspected sepsis (31,013 patients), antibiotic utilization was unchanged during the 12 months prior to measure implementation on October 1, 2015, and declined one percent each month during the 12 months after implementation of the measure in the Hospital IQR Program period from November 1, 2015, through October 31, 2016.[261] We are not aware of any published information that reports a non-discriminatory increase in antibiotic administration associated with implementation of the Severe Sepsis and Septic Shock: Management Bundle measure. The measure screening criteria and construct focuses on patients with a high likelihood for sepsis or septic shock which is consistent with the Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock 2021 recommendation for the immediate administration of antibiotics to patients with septic shock or a high likelihood for sepsis. We wish to clarify that the Severe Sepsis and Septic Shock: Management Bundle measure does not require that patients receive antibiotics within one hour of presentation. The measure requirements are for antibiotic administration within three hours of severe sepsis presentation time. We are not aware of any evidence that oral antimicrobial therapy is quicker or more effective than parenteral therapy. We refer to the Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock 2021 recommendations for further information on recommendations for the delivery of antibiotics. We also wish to clarify that the measure does allow for exclusion of patients if there is clinician documentation indicating the patient does not have severe sepsis or an infection within six hours following clinical criteria being met thereby preserving clinical judgement and clinical decision making. In addition, patients presenting with sepsis of a viral etiology are excluded from the measure because antibiotics are typically not warranted. We also wish to note that the measure is meant to complement clinical judgement in the best interest of the patient.

Comment: Several commenters did not support the Severe Sepsis and Septic Shock: Management Bundle measure because of the level of detail required of the measure, noting that the measure is too nuanced which makes it challenging to determine whether a hospital is providing quality care because the measure is all-or-nothing. A few commenters also noted that the Severe Sepsis and Septic Shock: Management Bundle measure is very complex in terms of data elements, calculations, and measurements.

Response: We appreciate the commenters' concern about the complexity of the measure. However, the complexity of this measure is commensurate with the complexity of sepsis and septic shock and with the severity of the consequences for patients if sepsis and septic shock are not detected and managed in a timely manner. All components of this measure ensure that timely and optimal care is delivered for patients with sepsis and septic shock. We are assuming that by ''all-or-nothing'' the commenter is referring to the fact that hospitals do not get partial credit for completing some of the protocols laid out in the Severe Sepsis and Septic Shock Management Bundle measure. In regards to the commenter's concern that the all-or-nothing nature of the measure makes it challenging to determine whether a hospital is providing quality care, we note that performance data for the Severe Sepsis and Septic Shock: Management Bundle measure is reported at a more granular level on a CMS-designated website, currently *Care*

[261] Anderson DJ, Moehring RW, Parish A, et al. (2022) The Impact of Centers for Medicare & Medicaid Services SEP–1 Core Measure Implementation on Antibacterial Utilization: A Retrospective Multicenter Longitudinal Cohort Study With Interrupted Time-Series Analysis. *Clin Infect Dis.*75(3):503–511. doi: 10.1093/cid/ciab937. PMID: 34739080.

Compare, at the national, state, and hospital level for measure performance overall and by the four measure bundles, severe sepsis 3-hour, severe sepsis 6-hour, septic shock 3-hour, and septic shock 6-hour bundles at *https://data.cms.gov/provider-data/search?fulltext=timely%20and%20effective%20care&theme=Hospitals*. This enables hospitals to view their performance for each bundle as well as their results overall and compare them to other hospitals, their state, and national average and top performing hospital results. We will take these comments into consideration as we evaluate updates for future program years.

Comment: Many commenters did not support the adoption of Severe Sepsis and Septic Shock: Management Bundle measure due to concerns around the burden of chart abstraction, citing that the measure is time and resource intensive and that the value of the measure is not worth the challenges. A few commenters noted that chart abstraction is labor intensive, given that determining eligibility for the measure can take upwards of 45 minutes, which they did not believe is in line with the CMS Burden Reduction efforts, and that even highly experienced teams spend 1–4 hours reviewing each sepsis core measure chart which is challenging and costly. A few commenters believed that adding a manual chart abstracted measure is not in line with CMS' focus on transitioning to digital quality measures. A few commenters noted that the nuances of the measure make it challenging to develop a standard approach to abstraction, and that the complicated abstraction guidance leads to incorrect measure outcomes which affects performance. Many commenters recommended delaying adoption of a sepsis measure in the Hospital VBP Program until the development of sepsis outcome eCQM is available because they believed that an outcome eCQM measure is in alignment with the focus to reduce reporting burden, promotes unity in Federal measures, and emphasizes outcome measures. A commenter believed that the measure does not measure quality of care but rather quality of documentation. A commenter also recommended developing a risk standardized sepsis mortality measure, and another commenter recommended that the development of an eCQM include removing the SIRS criteria and diagnosis codes to simplify implementation and decrease variability between hospitals.

Response: We respectfully disagree with commenters who believe the burden of the Severe Sepsis and Septic Shock: Management Bundle measure outweighs the benefits. We believe that the impact of this measure on patient care and improved outcomes for patients with severe sepsis and septic shock outweighs the abstraction burden. In a recent study that used chart-abstracted data for the Severe Sepsis and Septic Shock: Management Bundle measure submitted to CMS for over 1.3 million patients, Townsend et al. found that compliance with the measure was associated with a reduction in 30-day mortality.[262] In that same study, Townsend et al. note that based on published average medical record abstraction times of 30 to 120 minutes per case and assuming that a hospital had 300 sepsis cases per quarter, less than one-quarter of a full-time employee would be required to perform medical record abstraction. In a study by Buchman et al., the costs of sepsis inpatient admissions and subsequent skilled nursing facility care to Medicare were estimated to exceed $41.5 billion annually with 6-month mortality rates for Medicare fee-for service beneficiaries of approximately 60 percent for septic shock and 36 percent for severe sepsis.[263] Adding the measure to the Hospital VBP Program will not create a new burden for hospitals because they are already required to report data on the measure under the Hospital IQR Program. We will continue with plans for transitioning to digital quality measures and are currently developing a sepsis outcome eCQM that will reduce unnecessary burden for hospitals to report. However, until that measure is fully developed, we remain committed to patient safety as a high priority and believe that the adoption of the Severe Sepsis and Septic Shock: Management Bundle measure aligns with the core principles outlined in the HHS National Healthcare System Action Alliance to Advance Patient Safety and is consistent with this commitment.

Comment: Several commenters did not support the adoption of Severe Sepsis and Septic Shock: Management Bundle because of concerns that the measure will interfere with physicians' judgment, feeling pressure to meet the measure specifications as opposed to using clinician discretion. A few commenters believed that the measure disadvantages facilities that have large subsets of patients where elements of the Severe Sepsis and Septic Shock: Management Bundle measure may be contraindicated but are not excluded. A commenter stated that the measure does not allow exceptions for providers to treat patients using their discretion specifically regarding crystalloid fluids and vasopressors. A commenter noted that the bundled nature of the measure does not help hospitals target specific areas for improvement.

Response: The measure includes flexibility for clinician judgment by providing multiple opportunities for exclusion of patients from the measure based on clinician documentation such as notations within six hours following clinical criteria being met that severe sepsis or an infection is not present or that SIRS criteria or signs of organ dysfunction are due to a chronic condition, medication, or a non-infectious source. This measure is meant to complement clinical judgement in the best interest of the patient. We wish to clarify that the measure does include allowances for fluid volumes less than 30 mL/kg with documentation of a reason for a lesser volume. We appreciate the commenter's concern about the bundled nature of the measure. With respect to the concern that the bundled nature of the measure does not help hospitals target specific areas for improvement, we note that performance data for the Severe Sepsis and Septic Shock: Management Bundle measure is reported at a more granular level on a CMS-designated website, currently Care Compare, at the national, state, and hospital level for measure performance overall and by the four measure bundles, severe sepsis 3-hour, severe sepsis 6-hour, septic shock 3-hour, and septic shock 6-hour bundles at *https://data.cms.gov/provider-data/search?fulltext=timely%20and%20effective%20care&theme=Hospitals*. This enables hospitals to view their performance for each bundle as well as their results overall, identify areas for improvement, and compare them to other hospitals, their state, and national average and top performing hospital results. Additionally, there are categories by bundle that providers can use for quality improvement information beyond seeing their performance rates.

Comment: Many commenters did not support the adoption of the Severe Sepsis and Septic Shock: Management Bundle measure because they believed that the measure lacks evidence for improving patient outcomes and does

[262] Townsend SR, Phillips GS, Duseja R, et al. (2021) Effects of compliance with the early management bundle (SEP–1) on mortality changes among Medicare beneficiaries with sepsis: a propensity score matched cohort study. *Chest.* doi:10.1016/j.chest.2021.07.2167.

[263] Buchman TG, Simpson SQ, Sciarretta KL, et al. (2020). Sepsis Among Medicare Beneficiaries: 1. The Burdens of Sepsis, 2012–2018. *Crit Care Med.* 48(3):276–288. doi: 10.1097/CCM.0000000000004224. PMID: 32058366; PMCID: PMC7017943.

not provide any benefit to patient care. Several commenters cited that compliance with the measure does not reflect the care provided to sepsis patients. Several commenters noted that survival rates were not significantly improved, and sepsis mortality rates have not lowered under the measure. A few commenters believed that the measure incorrectly assumes all patients have similar characteristics and does not consider significant clinical variation. A few commenters cited potential harms and worsened outcomes in patients from the measure and noted that the risks of the measure outweigh the benefits. A few commenters recommended that CMS focus on evidence-based measures that improve outcomes for patients with sepsis. A commenter expressed concern that the measure may create unintended threats to the health of those with sepsis or other conditions that can mimic sepsis. A commenter believed that the measure lumps together septic shock and non-shock patients and it may not be appropriate for all patients to receive each of the bundle elements. A commenter noted that the requirement of universal blood cultures prior to antimicrobial therapy worsens outcomes by adding to episode cost and length of stay.

Response: As referenced in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27028), there is evidence of an association between the elements of the Severe Sepsis and Septic Shock: Management Bundle measure and improved patient outcomes. A study by Townsend et al of over 1.3 million patients that used chart-abstracted data for the Severe Sepsis and Septic Shock: Management Bundle measure found that compliance with the measure was associated with a reduction in 30-day mortality.[264] The Severe Sepsis and Septic Shock: Management Bundle measure was designed based on evidence based relevant literature and clinical practice guidelines and is intended to measure appropriate care as it applies to the majority of the patient population represented in the measure. As noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27027 through 27029), the measure is CBE-endorsed and follows published international guidelines for the early identification and management of severe sepsis and septic shock, which reflects that the measure is evidence-based and has undergone rigorous processes in measure development and maintenance. We appreciate and recognize that some patients may present with clinical characteristics and response to care that varies from the majority of patients with the same condition. We agree that in some cases the best outcome for the patient may be dependent upon clinician judgement that varies from guideline recommendations for care. We wish to emphasize that the measure is not intended to replace clinician judgement or to treat every patient identically; rather, complement clinical judgement in the best interest of the individual patient. With this in mind, we do not expect 100 percent performance for the measure with every patient. Recent data indicates that mean performance on this measure is less than 60% and thus there is still substantial room for improvement on sepsis care. Measure design and recent updates to the measure allow for some variations in care by allowing flexibility in crystalloid fluid administration volumes and exclusions for some groups of patients based on clinician documentation. We are not aware of published literature that makes an association between the measure and patient harm. We agree that all patients will not qualify for all of the bundle elements in the measure. While the measure performance results are reported as an overall score, the measure incorporates exclusion criteria for those patients who do qualify for specific elements of care. As referenced in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27027 through 27029), there is evidence of an association between the elements of the Severe Sepsis and Septic Shock: Management Bundle measure and improved patient outcomes. A 2022 study by Townsend et al. of over 1.3 million patients that used chart-abstracted data for the Severe Sepsis and Septic Shock: Management Bundle measure found that compliance with the measure was associated with a reduction in 30-day mortality.[265] In 2019, Kahn et al. published the results of a study of over 325,786 sepsis admissions to 163 hospitals in New York State and the impact that mandated public reporting of sepsis had on mortality.[266] The requirement for protocolized sepsis care, consistent with the Severe Sepsis and Septic Shock: Management Bundle measure, was associated with a statistically significant reduction in risk-adjusted mortality. To address concerns about potential unintended consequences of protocol administration the authors also studied intensive care unit (ICU) admission rates, as an indicator of intensity of health care; hospital length of stay, as a reflection of resource utilization; central venous catheter use, to measure impact on invasive monitoring; and *Clostridium difficile* infection rates, as sign of potential antibiotic overuse. The study found no change in ICU admission, minimal impact on length of stay, a trend toward lower use of central venous catheters and a significant reduction in *Clostridium difficile* infection rates. With regard to the commenter's concern about other conditions that can mimic sepsis, the Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock 2021 recommends that clinicians perform a rapid assessment for the possibility of infectious versus non-infectious causes and recommend this assessment be completed, whenever possible, within three hours of symptom presentation to expedite clinical decision making. The Severe Sepsis and Septic Shock: Management Bundle measure requirements are consistent with these guideline recommendations in that the time frame for antibiotic administration is within three hours of severe sepsis presentation. The guidelines note that it is best practice to continually reassess patients to determine whether diagnoses other than sepsis are possible to facilitate treatment adjustments as needed. The measure allows for exclusion of patients from the measure if there is clinician documentation indicating that severe sepsis or septic shock is not present within six hours after severe sepsis or septic shock presentation. Additionally, in regard to the commenter's concern about universal blood cultures, we are not aware of any published information demonstrating a significant increase in costs or hospital length of stay directly associated with obtaining blood cultures. The measure's requirement for obtaining blood cultures prior to antibiotic administration is consistent with the guideline recommendation to obtain routine microbiologic cultures (including blood) before starting antibiotic treatment in patients with

[264] Townsend SR, Phillips GS, Duseja R, et al. (2021) Effects of compliance with the early management bundle (SEP–1) on mortality changes among Medicare beneficiaries with sepsis: a propensity score matched cohort study. *Chest.* doi:10.1016/j.chest.2021.07.2167.

[265] Townsend SR, Phillips GS, Duseja R, et al. (2021) Effects of compliance with the early management bundle (SEP–1) on mortality changes among Medicare beneficiaries with sepsis: a propensity score matched cohort study. *Chest.* doi:10.1016/j.chest.2021.07.2167.

[266] Kahn JM, Davis BS, Yabes JG, et al. (2019) Association Between State-Mandated Protocolized Sepsis Care and In-hospital Mortality Among Adults With Sepsis. *JAMA.* 322(3):240–250. doi: 10.1001/jama.2019.9021. PMID: 31310298; PMCID: PMC6635905.

suspected sepsis and septic shock. Blood cultures are important to help optimize antibiotic coverage and assist with antibiotic de-escalation.

Comment: A few commenters did not support the adoption of Severe Sepsis and Septic Shock: Management Bundle measure because the measure does not include any risk stratification or stratification by race or other patient risk factors. A commenter noted that stratification would help advance health equity and is more appropriate for a claims-based measure.

Response: We appreciate the commenters' feedback and recommendations regarding risk stratification and stratification by race or other patient factors. The Severe Sepsis and Septic Shock: Management Bundle measure provides a standard operating procedure for early risk stratification and management of a patient with severe infection by identifying patient risk levels relating to sepsis care needs. As we take these recommendations into consideration, we will carefully weigh the potential extra burden that collection of additional clinical information necessary for risk stratification of chart abstracted measures may impose upon hospitals. We are in the process of developing a methodology for stratifying measures by sex, race, ethnicity, and other social determinants of health.

Comment: Several commenters did not support the adoption of this measure because they believed the difficulty of capturing a diagnostic start time creates challenges for all components of the bundle and creates challenges for clinicians. A few commenters noted that the criteria in the sepsis bundle are different from care teams' diagnostic criteria. A commenter believed that the complexity of the current time zero definition contributes to variability in abstraction and undermines the measure. A commenter believed that the measure is flawed because it is based on discharge diagnoses and retrospectively identifies a start time based on abnormal vital signs. A commenter recommended defining the inconsistent definition of time zero. A commenter noted that the Severe Sepsis and Septic Shock: Management Bundle measure's focus is only on the initial 6 hours of care which the commenter believed oversimplifies the complexity of comprehensive sepsis care.

Response: We appreciate the commenters' concerns about the challenges with identifying the severe sepsis presentation time and will take this under consideration as future methods and tools for early identification of severe sepsis and septic shock become available and are tested. We recognize there is variation in screening tools and criteria used at the bedside for identification of severe sepsis and septic shock and wish to clarify that the measure does not dictate nor limit the severe sepsis and septic shock screening criteria that clinicians use at the bedside. While the measure uses ICD–10–CM diagnosis codes to identify the initial patient population, clinical criteria are used to confirm the presence of severe sepsis and septic shock and allow for exclusion of patients who do not meet the clinical criteria. The intent of the measure is to confirm care and interventions provided upon early identification of the presence of severe sepsis and septic shock. The clinical criteria used by the measure provides a well-established common set of criteria, identified by Waligora et al. as having high sensitivity for early identification of sepsis (72%–94.5%), that abstractors from all hospitals across the U.S. use to determine which patients from their initial populations remain in the measure.[267] We agree that focusing on early therapies is not the only strategy important for sepsis care and improved outcomes but suggest that it is the predominate opportunity in the largest number of cases. The Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock 2021, note that early identification of sepsis and timely appropriate management in the initial hours is associated with improved outcomes. The guidelines specifically note early administration of antibiotics as is one of the most effective interventions associated with reducing mortality and that fluid therapy is a crucial part of sepsis and septic shock resuscitation.

Comment: Many commenters did not support the adoption of this measure because of concerns around tying the Severe Sepsis and Septic Shock: Management Bundle measure to hospital performance and payment given that high performance is not related to improving sepsis outcomes and bundle scoring makes it difficult for hospitals to achieve high scores. A few commenters expressed concern that there will be a disproportionate impact to safety-net healthcare systems if the measure is included in a pay-for-performance program and that financially strapped organizations will struggle to implement the full-scale interventions of the Severe Sepsis and Septic Shock: Management Bundle measure. A commenter conducted their own calculations that showed that 66% of the hospitals that were scored on improvement under the Severe Sepsis and Septic Shock: Management Bundle measure had a score of zero, meaning that the hospital did not improve or improved minimally.

Response: We appreciate the commenters' concern regarding the association between measure performance and patient outcomes. In a study by Townsend et al of over 1.3 million patients that used chart-abstracted data for the Severe Sepsis and Septic Shock: Management Bundle measure the authors found that compliance with the measure was associated with a reduction in 30-day mortality. We recognize that achieving high scores on a bundled measure is challenging since all bundle elements for which a patient is eligible must be met for the patient case to meet the measure. However, we believe that all the bundle elements are needed because the complete bundle impacts patient outcomes. As we noted in the proposed rule, performance rates for the top 10 percent of hospitals have averaged 80 percent since we began public reporting with performance data from October 1, 2017, through September 30, 2018. We wish to emphasize that under the Hospital VBP Program's scoring methodology, the highest performing hospitals will receive achievement points, even if the highest performing hospitals are not performing at 100%. Additionally, we note that this measure will be added to the Safety domain which currently has 5 other measures and is weighted at 25% of the TPS.

We acknowledge commenters' concern about potential impact on safety-net healthcare systems. We note eligible hospitals have successfully reported on the measure in the Hospital IQR Program since October 1, 2015, including smaller community and rural hospitals. Additionally, we wish to note that smaller hospitals have performed better than large hospitals, on average, for the Severe Sepsis and Septic Shock: Management Bundle measure. Regarding a commenter's concern about sampling, sampling is a statistically valid method to estimate a hospital's performance, and we have allowed sampling for many chart-abstracted measures including the Severe Sepsis and Septic Shock: Management Bundle measure to help reduce the abstraction burden. We refer commenters to the Population and Sampling Specifications

[267] Waligora G, Gaddis G, Church A, Mills L (2020). Rapid Systematic Review: The Appropriate Use of Quick Sequential Organ Failure Assessment (qSOFA) in the Emergency Department. *J Emerg Med.* 59(6):977–983. doi: 10.1016/j.jemermed.2020.06.043. Epub 2020 Aug 20. PMID: 32829969.

in the Hospital Inpatient Specifications Manual located on QualityNet at *https://qualitynet.cms.gov/inpatient/specifications-manuals* for more information about case sampling for this measure.

Comment: Several commenters did not support the adoption of this measure over concerns that the Severe Sepsis and Septic Shock: Management Bundle measure is not aligned with other standards and reimbursement criteria, which they believed results in confusion around definitions and inconsistency in diagnosing sepsis. A few commenters noted that because many commercial payers endorse SEP–3 definitions, organizations have difficulty determining which criteria to adopt and that some Medicare managed care organizations do not recognize or reimburse for Severe Sepsis and Septic Shock: Management Bundle. A few commenters believed that the measure does not align with the Surviving Sepsis Campaign or SEP–3. A commenter believed that sepsis management is misaligned with value-based purchasing but should be encouraged in other quality programs. A few commenters recommended that CMS ensure that the measure aligns with national standards for sepsis care. A commenter noted that the Severe Sepsis and Septic Shock: Management Bundle measure has not kept up with the shifting evidence of which interventions are most effective. A commenter recommended that the measure finalization be postponed until aspects of the Severe Sepsis and Septic Shock: Management Bundle measure are brought into alignment with scientific literature.

Response: The measure does not dictate or limit the severe sepsis and septic shock screening criteria that clinicians use at the bedside. In Waligora et al., the clinical criteria used by the measure were identified as having a high sensitivity for early identification of sepsis (72%–94.5%) and as providing abstractors with a standard tool for confirmation of the presence of severe sepsis and septic shock.[268] This aligns with the measure intent of early identification of patients with severe sepsis and septic shock and helps ensure the same criteria are used for all hospitals to determine which patients remain in the measure and which ones are excluded. We recognize there is variation in screening tools and criteria used at the bedside for identification of severe sepsis and septic shock and for other purposes.

We emphasize the Severe Sepsis and Septic Shock: Management Bundle measure is in alignment with the Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock 2021 that recommended against using quick sequential organ failure assessment (qSOFA) compared with SIRS or other screening tools.[269] In addition, antibiotic requirements and timing, measurement of lactate, administration of crystalloid fluids, monitoring response to fluid administration, and use of vasopressors for the measure are consistent with recommendations in the guidelines. We will continue to monitor the evidence and standards for sepsis care as they evolve and consider revisions as warranted for future program years. We also wish to clarify the concerns around the SEP–3 definitions. The SEP–3 definition, introduced in The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis–3) published in February 2016, uses the Sequential Organ Failure Assessment (SOFA), which has been well-validated association with mortality risk and the simplified quick SOFA (qSOFA).[270] The SIRS based criteria used in the Severe Sepsis and Septic Shock: Management Bundle measure, were identified in a structured literature review by Waligora et al. as having a high sensitivity for early identification of sepsis (72%–94.5%) compared to the qSOFA (32%–58.3%).[271] Use of the SIRS-based criteria aligns with the measure intent of early identification of patients with severe sepsis and septic shock. We wish to note that the criteria used by the measure is intended to provide abstractors with a standard tool for confirmation of the presence of severe sepsis and septic shock to help ensure the same criteria are used for all hospitals to determine which patients remain in the measure and which ones are excluded. The measure does not dictate nor limit the severe sepsis and septic shock screening criteria that clinicians use at the bedside.

Comment: A few commenters did not support the adoption of this measure because of concerns around the sampling methodology. A commenter noted that the results in a data set might not be representative of the sepsis population and therefore not compliant with valid statistical analysis. A commenter stated that the burden of abstraction will make hospitals reevaluate increasing their sampling size because the Severe Sepsis and Septic Shock: Management Bundle measure casts a wide population net with the initial population, then uses chart abstraction to determine if the patient has severe sepsis or septic shock. A commenter stated that because many cases are ultimately excluded for not meeting the criteria for severe sepsis, most hospitals end up oversampling to ensure they present a more accurate representation of their compliance with the measure. A commenter believed that because hospitals are allowed to sample the measure, it does not represent a complete picture of the hospital's performance.

Response: Sampling is a statistically valid method to estimate a hospital's performance and we have allowed sampling for many chart-abstracted measures including the Severe Sepsis and Septic Shock: Management Bundle measure to help reduce the abstraction burden. We refer commenters to the Population and Sampling Specifications in the Hospital Inpatient Specifications Manual located on QualityNet at *https://qualitynet.cms.gov/inpatient/specifications-manuals* for more information about case sampling for this measure. The Severe Sepsis and Septic Shock: Management Bundle measure has been in the Hospital IQR Program since October 1, 2015, and eligible hospitals, including smaller community and rural hospitals, have successfully reported on the measure. We are aware that many hospitals already choose to oversample due to the relatively high case exclusion rate associated with the measure. Sepsis is associated with patient deaths, hospital readmissions, and increased length of hospital stays. This measure fills an important measure gap and will positively impact patient care. We believe that these benefits outweigh data collection burdens. We also do not believe this measure will be more burdensome than other measures for hospitals, because the measure data may be collected concurrently, retrospectively, or a combination of both. As we noted in the proposed rule,

[268] Waligora G, Gaddis G, Church A, Mills L (2020). Rapid Systematic Review: The Appropriate Use of Quick Sequential Organ Failure Assessment (qSOFA) in the Emergency Department. *J Emerg Med.* 59(6):977–983. doi: 10.1016/j.jemermed.2020.06.043. Epub 2020 Aug 20. PMID: 32829969.

[269] Evans L, Rhodes A, Alhazzani W, et al. (2021). Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock 2021. *Crit Care Med*. 49(11):e1063–e1143. doi: 10.1097/CCM.0000000000005337. PMID: 34605781.

[270] Singer M, Deutschman CS, Seymour CW, et al. The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis–3). JAMA. 2016;315(8):801–810. doi:10.1001/jama.2016.0287.

[271] Waligora G, Gaddis G, Church A, Mills L (2020). Rapid Systematic Review: The Appropriate Use of Quick Sequential Organ Failure Assessment (qSOFA) in the Emergency Department. J Emerg Med. 2020 Dec;59(6):977–983. doi: 10.1016/j.jemermed.2020.06.043. Epub 2020 Aug 20. PMID: 32829969.

adopting the measure into the Hospital VBP Program does not result in a change to measure data collection requirements and burden since hospitals are already required to report data on the measure under the Hospital IQR Program.

Comment: Several commenters recommended changes to the documentation requirements associated with the Severe Sepsis and Septic Shock: Management Bundle measure, including a commenter who recommended removing some of the documentation rules because they believed that it would make the measure less cumbersome, and a commenter who recommended making changes to allow providers to document rationale for why fluid bolus was not indicated.

Response: We note the measure specifications do allow providers to document rationale for why fluid bolus was not indicated; specifically, recent updates to crystalloid fluid administration guidance allow for the administration of fluid volumes of less than 30 mL/kg, and in specific situations, no fluid administration with supporting documentation. We will take other recommendations regarding documentation into consideration for refinements to the measure.

Comment: Several commenters recommended focusing solely on septic shock. A few commenters believed that focusing on septic shock would simplify data abstraction and a few commenters cited evidence supporting the benefits of immediate intervention with the subset of patients experiencing septic shock. A commenter believed that focusing on septic shock would minimize antibiotic overuse and eliminate bundle elements that do not contribute to improved patient outcomes. A commenter expressed concern that the measure is not supported by compelling evidence.

Response: We respectfully disagree with the commenters' recommendations regarding focusing the measure only on septic shock. Early identification and treatment of patients with severe sepsis is essential and, in many cases, can prevent further clinical progression to septic shock. The Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock 2021 includes a strong recommendation for the immediate administration of antibiotics to patients with septic shock or a high likelihood for sepsis. The measure is consistent with these guidelines since the measure screening criteria focus on patients with a high likelihood for sepsis or septic shock. We are not aware of published literature that demonstrates an association between the implementation of the measure and antibiotic overutilization. We appreciate the commenter's concerns about measure alignment with published evidence; however, we disagree. The Severe Sepsis and Septic Shock: Management Bundle measure is in alignment with the Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock 2021 recommendations about use of screening tools, antibiotic requirements and timing, measurement of lactate, administration of crystalloid fluids, monitoring response to fluid administration, and use of vasopressors. We will continue to monitor the evidence and standards for sepsis care as the evolve and consider revisions as warranted for future program years.

Comment: Several commenters recommended that the focus should be on improving patient outcomes with a commenter recommending elimination of bundle elements that do not contribute to improved patient outcomes, such as lactate testing. A few commenters expressed concern that the time-zero definition does not reflect excellent care and that the focus on the initial hours of care takes away incentive to optimize subsequent care for patients. A commenter expressed their belief that shifting to this measure amidst clinical disagreement on measure specifications and abstraction issues will bring no additional benefit to patients.

Response: We appreciate the commenters' recommendations regarding measure focus. We note that providing patients with evidence-based care such as that included in the Severe Sepsis and Septic Shock: Management Bundle measure has been associated with improved outcomes. We refer commenters to the results of the study of over 1.3 million patients by Townsend et al that utilized chart-abstracted data for the Severe Sepsis and Septic Shock: Management Bundle measure from October 1, 2015, to March 31, 2017, in which the authors found that compliance with the measure was associated with a reduction in 30-day mortality.[272] We recognize that some elements of care may have a greater impact on outcomes and will take the commenter's recommendations into consideration for future program years. We also wish to note that while focusing on early therapies is not the only area of opportunity for sepsis care improvement, it is the predominate opportunity in the majority of cases as subsequent care needs are often dependent on the early care that is provided. We also emphasize that the measure is in alignment with the Surviving Sepsis Campaign: International Guidelines for Management of Sepsis and Septic Shock 2021 recommendations about use of screening tools, antibiotic requirements and timing, measurement of lactate, administration of crystalloid fluids, monitoring response to fluid administration, and use of vasopressors. The guidelines note that the presence of an elevated lactate level in patients with suspected sepsis is associated with an increased likelihood of a final diagnosis of sepsis and that there is a well-established association between lactate levels and mortality in patients with suspected infection and sepsis. In a recent study that used chart-abstracted data for the Severe Sepsis and Septic Shock: Management Bundle measure submitted to CMS for over 1.3 million patients, Townsend et al. found that compliance with obtaining an initial lactate level was associated with decreased adjusted mortality.[273]

Comment: Several commenters expressed concerns about the flexibility of the measure or recommended that the measure be made more flexible. A commenter cited the challenge of a one-size-fits-all measure given the continuously evolving definition and best practices of sepsis. A commenter recommended that physicians should be able to opt out of blood cultures and parenteral therapy. A commenter also expressed concern that the all-or-nothing measure does not allow credit for timely and appropriate resuscitation efforts. A commenter recommended that the measure provide flexibility in a way that hospitals can receive support from CMS for quality improvement efforts to improve performance on the measure.

Response: The measure includes flexibility for clinician judgment by providing multiple opportunities for exclusion of patients from the measure based on clinician documentation such as notations within six hours following clinical criteria being met that severe sepsis or an infection is not present or that SIRS criteria or signs of organ dysfunction are due to a chronic condition, medication, or a non-infectious source. The measure also includes allowances for fluid volumes less than 30 mL/kg with documentation of a reason for a lesser volume. The measure is in alignment with the Surviving Sepsis Campaign: International Guidelines for

[272] Townsend SR, Phillips GS, Duseja R, et al. (2021). Effects of compliance with the early management bundle (SEP–1) on mortality changes among Medicare beneficiaries with sepsis: a propensity score matched cohort study. *Chest.* doi:10.1016/j.chest.2021.07.2167.

[273] *Ibid.*

Management of Sepsis and Septic Shock 2021 recommendations about use of screening tools, antibiotic requirements and timing, measurement of lactate, administration of crystalloid fluids, monitoring response to fluid administration, and use of vasopressors. We appreciate the commenter's recommendations about opting out of blood cultures and parenteral therapy. The Surviving Sepsis Campaign guidelines upon which this measure is based recommend as a best practice obtaining routine microbiologic cultures (including blood) before starting antimicrobial therapy in patients with suspected sepsis and septic shock if it does not result in a substantial delay to starting the antimicrobials. The measure includes allowances for obtaining blood cultures after starting antimicrobials in specific situations such as when there is clear documentation that obtaining the culture prior to starting antibiotics will result in a delay that will be detrimental to the patient. We appreciate the commenter's concern about the bundled nature of the measure and recommendation for additional flexibility. We will take these recommendations into consideration for future refinements of the measure.

Comment: A commenter expressed concern that the achievement threshold and benchmark should be reversed.

Response: We thank the commenters for the notice and note that the achievement threshold and benchmark have been correctly updated in Table V.K–09 of this final rule.

Comment: A commenter did not support converting the Severe Sepsis and Septic Shock: Management Bundle measure to an eCQM in the future.

Response: We thank the commenter for their feedback and note that the sepsis eCQM we are currently developing in collaboration with the CDC is an outcome measure and not a direct conversion of the current measure to an eCQM.

Comment: A commenter recommended removing the exclusion of COVID–19 from the Severe Sepsis and Septic Shock: Management Bundle measure as done in the measurement and reporting of other respiratory diseases.

Response: We interpret the commenter's recommendation as suggesting to remove the exclusion of patients with suspected or confirmed COVID–19 from the measure. We added this exclusion because COVID–19 is viral, and the measure excludes cases of severe sepsis and septic shock with a viral etiology since antibiotics are generally not required unless there is also an underlying bacterial infection. In addition, early evidence suggested a conservative fluid resuscitation approach for patients with COVID–19 associated septic shock. As a result, patients with COVID–19 will have a higher likelihood of not meeting the measure numerator requirements.

Comment: A few commenters recommended that CMS obtain input and support from all interested parties for intended changes and recommended that CMS work with interested parties to develop digital quality measurement that is outcome-based and a true metric of sepsis care.

Response: We appreciate the commenters' recommendations. We consider input from multiple interested parties and resources when determining whether to implement measure updates and will continue to do so. For example, we have previously collaborated with clinician representatives from organizations such as the California Maternal Quality Care Collaborative (CMQCC), Infectious Disease Society of America (IDSA), and Society for Healthcare Epidemiology of America (SHEA), and from clinical specialties such as emergency medicine, critical care medicine, internal medicine, and infectious disease. We also convene an Expert Work Group (EWG) with critical care medicine, emergency care medicine, infectious disease, pharmacy, performance improvement and patient representation as needed to provide feedback on the clinical aspects of measure maintenance. We also wish to note that the Sepsis Technical Expert Panel (TEP) which provides guidance on the development of the sepsis outcome electronic clinical quality measure (eCQM) includes clinicians representing emergency medicine, critical care medicine, internal medicine, infectious disease, as well as patients and caregivers.

Comment: A commenter did not support including year three of the COVID–19 public health emergency as baseline data because of concerns about the use of data from the COVID–19 public health emergency.

Response: We thank the commenter for their concern regarding the use of CY 2022 data for the baseline period. This baseline period is in alignment with the previously finalized baseline periods for the Safety, Patient and Community Engagement, and Cost and Efficiency Domains for the FY 2026 program year (87 FR 49114). As discussed in the FY 2023 IPPS/LTCH PPS final rule we believe that using CY 2022 data is appropriate given the widespread availability of COVID–19 vaccines in CY 2022 and subsequent years (87 FR 49105 through 49106).

Comment: A few commenters recommended providing additional clarity on how CMS will establish an appropriate baseline and account for changes in measurement between the baseline and performance periods given frequent updates to the measure.

Response: We thank the commenters for their feedback. As we noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27028), the updates made to Severe Sepsis and Septic Shock: Management Bundle measure, as reflected in the specification's manual, are minor technical updates that do not impact performance. We, therefore, believe that the baseline and performance periods are appropriate as proposed because the updates to the measure specifications are not substantive and therefore do not require modifications to the baseline and performance periods.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

b. Summary of Previously Adopted Measures for the FY 2024 and FY 2025 Program Years, and Previously Adopted Measures and Newly Adopted Measures Beginning With the FY 2026 Program Year

We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45281 through 45284) for summaries of previously adopted measures for the FY 2024 and FY 2025 program years, and to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49110 through 49111) for summaries of previously adopted measures for the FY 2024, FY 2025, and FY 2026 program years. In the FY 2024 IPPS/LTCH PPS proposed rule, we did not propose any changes to the FY 2024 and FY 2025 measure sets (88 FR 27029 through 27030). The Hospital VBP Program measure set for the FY 2024 and FY 2025 years will contain the following measures:

TABLE V.K.-01: SUMMARY OF PREVIOUSLY ADOPTED MEASURES FOR THE FY 2024 AND FY 2025 PROGRAM YEARS

Measure Short Name	Domain/Measure Name	CBE #
Person and Community Engagement Domain		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition measure)	0166 (0228)
Safety Domain		
CAUTI	National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure	1716
CDI	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital onset *Clostridioides difficile* Infection (CDI) Outcome Measure	1717
Clinical Outcomes Domain		
MORT-30-AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization	0230
MORT-30-HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization	0229
MORT-30-PN (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization	0468
MORT-30-COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization	1893
MORT-30-CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery	2558
COMP-HIP-KNEE	Hospital Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550
Efficiency and Cost Reduction Domain		
MSPB	Medicare Spending Per Beneficiary (MSPB) Hospital	2158

In the FY 2024 IPPS/LTCH PPS proposed rule, we proposed substantive measure updates to the MSPB and THA/TKA Complication measures (88 FR 27030 through 27031). We also proposed to adopt the Severe Sepsis and Septic Shock: Management Bundle. Table V.K.–02 summarizes the previously adopted and newly adopted Hospital VBP Program measures for the FY 2026 through FY 2030 program years:

TABLE V.K.-02: SUMMARY OF PREVIOUSLY ADOPTED MEASURES AND NEWLY ADOPTED MEASURES FOR THE FY 2026 THROUGH FY 2030 PROGRAM YEARS

Measure Short Name	Domain/Measure Name	CBE #
Person and Community Engagement Domain		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) (including Care Transition measure)	0166 (0228)
Safety Domain		
CAUTI	National Healthcare Safety Network (NHSN) Catheter Associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CLABSI	National Healthcare Safety Network (NHSN) Central Line Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons Centers for Disease Control and Prevention (ACSCDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital onset Methicillin-resistant resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure	1716
CDI	National Healthcare Safety Network (NHSN) Facility wide Inpatient Hospital onset *Clostridioides difficile* Infection (CDI) Outcome Measure	1717
SEP-1*	Severe Sepsis and Septic Shock: Management Bundle	0500
Clinical Outcomes Domain		
MORT-30-AMI	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Acute Myocardial Infarction (AMI) Hospitalization	0230
MORT-30-HF	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Heart Failure (HF) Hospitalization	0229
MORT-30-PN (updated cohort)	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Pneumonia Hospitalization	0468
MORT-30-COPD	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Chronic Obstructive Pulmonary Disease (COPD) Hospitalization	1893
MORT-30-CABG	Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate Following Coronary Artery Bypass Graft (CABG) Surgery	2558
COMP-HIP-KNEE**	Hospital Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA)	1550
Efficiency and Cost Reduction Domain		
MSPB***	Medicare Spending Per Beneficiary (MSPB) Hospital	2158

* In section V.K.3.a of the preamble of this final rule, we finalized the adoption of the Severe Sepsis and Septic Shock: Management Bundle beginning with the FY 2026 program year.
**In section V.K.2.c.(2) of the preamble of this final rule, we finalized the adoption of substantive updates to the THA/TKA Complications measure beginning with the FY 2030 program year.
*** In section V.K.2.c.(1) of the preamble of this final rule, we finalized the adoption of substantive updates to the MSPB Hospital measure beginning with the FY 2028 program year.

c. Updates to the Data Collection and Submission Requirements for the HCAHPS Survey Measure (CBE #0166) Beginning With the FY 2027 Program Year

We refer readers to section IX.C.10.h of this final rule where the Hospital IQR Program proposed to make updates to the administration and submission requirements of the HCAHPS Survey measure beginning with the FY 2027 payment determination. We also proposed to make the same updates to the form and manner of the administration of the HCAHPS Survey measure under the Hospital VBP Program. These changes are—

- Adding three new modes of survey administration (Web-Mail mode, Web-Phone mode, and Web-Mail-Phone mode) in addition to the current Mail Only, Telephone Only, and Mail-Phone modes, beginning with January 2025 discharges, because in the 2021 HCAHPS mode experiment, adding an initial web component to the three current HCAHPS modes of survey administration resulted in increased response rates;
- Removing the requirement that only the patient may respond to the survey to thus allow a patient's proxy to

respond to the survey, beginning with January 2025 discharges;

- Extending the data collection period for the HCAHPS Survey from 42 to 49 days, beginning with January 2025 discharges;
- Limiting the number of supplemental items to 12 to align with other CMS CAHPS surveys;
- Requiring hospitals to collect information about the language that the patient speaks while in the hospital (whether English, Spanish, or another language) and requiring the official CMS Spanish translation of the HCAHPS Survey be administered to all patients who prefer Spanish, beginning with January 2025 discharges; and
- Removing two currently available options for administration of the HCAHPS Survey that are not used by participating hospitals, beginning in January 2025:

++ The Active Interactive Voice Response (IVR) survey mode, also known as touch-tone IVR, which has not been employed by any hospital since 2016 and has never been widely used for the HCAHPS Survey, and

++ The ''Hospitals Administering HCAHPS for Multiple Sites'' option for HCAHPS Survey administration which has not been utilized by any hospitals since 2019 and has never been widely used.

We stated in the proposed rule that data collection and administration of the HCAHPS Survey measure would remain the same, except for the proposed changes described in section V.K.3.c of this final rule. We also stated that there would be no changes to the HCAHPS Survey measure patient eligibility or exclusion criteria. We noted that adopting these changes in the Hospital VBP Program would not create a new burden for hospitals because they are already required to report the measure under the Hospital VBP Program. Therefore, we stated that this proposal to adopt technical changes would not require hospitals to submit any additional information.

Detailed information on the HCAHPS Survey measure data collection protocols can be found in the current HCAHPS Quality Assurance Guidelines, located at: *https://www.hcahpsonline.org/en/quality-assurance/.*

We invited public comment on this proposal.

Comment: Many commenters stated their support of the proposed HCAHPS changes because they increase response rates, modernize and improve accessibility of the survey, advance health equity, and improve representation of different populations. A commenter recommended testing the impact on performance measures derived from HCAHPS data before publicly reporting results or using results for payment purposes.

Response: We thank the commenters for their support. We refer the commenter who recommended testing changes to the Hospital IQR Program's section of the FY 2024 IPPS/LTCH PPS proposed rule, where we discussed a large-scale mode experiment that we conducted to test adding the web mode and other updates to the form, manner, and timing of HCAHPS Survey data collection and reporting (88 FR 27112 through 27113). We also note that because these changes are only being made to the form and manner of the administration of the survey, we do not believe that there will be substantive impacts to hospitals' performance.

Comment: Many commenters supported allowing the survey to be administered in Spanish because they believed that it will improve response rates and advance health equity by ensuring that language does not hinder the quality or experience of care. A few commenters made recommendations to expand the requirement to other languages in the future, specifically the seven other languages that the survey is available in.

Response: We appreciate the commenters support and agree that these changes will encourage improved response rates from a wider pool of patients in HCAHPS responses. We thank the commenters for their recommendations regarding future translations of HCAHPS for the seven other languages that the survey is available in (Chinese, Russian, Vietnamese, Portuguese, German, Tagalog, and Arabic) and further validation of existing translated versions, and we will take these recommendations into consideration for future program years. We also believe that the removing the requirement that only the patient may respond to the survey will improve response rates and address language barriers.

Comment: Many commenters supported the expansion to electronic modes of administration because they will improve the volume and timeliness of survey response rates, particularly from the younger patient population, they are easier to administer, and they align with the Modernizing the HCAHPS Survey report.

Response: We thank the commenters for their support and agree that the addition of these new modes of survey implementation will likely increase response rates and modernize the survey. We also agree that these new modes of survey implementation have the potential to reduce the burden of administering the survey.

Comment: Several commenters supported removing the requirement that only the patient may respond to the survey because they believed that it improves the inclusivity of the survey, and it is a positive way for family and caregivers to contribute to patient-centered care.

Response: We thank the commenters for their support and agree that removing the prohibition of proxy respondents will likely inclusivity and engage a more diverse pool of respondents.

Comment: Several commenters supported the extension of the data collection period to 49 days. A commenter also recommends not exceeding the 49-day period because a longer extension may risk compromising the reliability and validity of the data.

Response: We thank the commenters for their support of the extended collection period. We will also take the recommendation to not exceed the 49-day period into consideration for future program years.

Comment: A commenter recommended using a separate patient experience survey that addresses psychiatric care rather than the traditional HCAHPS survey.

Response: We thank the commenter for the recommendation and we refer the commenter to the FY 2024 IPPS/LTCH PPS (88 FR 27114) proposed rule in which the Hospital IQR Program solicited feedback on the potential addition of patients with a primary psychiatric diagnosis to the HCAHPS Survey measure.

After consideration of the public comments we received, we are finalizing this policy as proposed.

4. Previously Adopted and Newly Adopted Baseline and Performance Periods

a. Background

Section 1886(o)(4) of the Act requires the Secretary to establish a performance period for the Hospital VBP Program that begins and ends prior to the beginning of such fiscal year. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 56998 through 57003) for a previously finalized schedule for all future baseline and performance periods for previously adopted measures. We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38256 through 38261), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41466 through 41469), the FY 2020 IPPS/LTCH

PPS final rule (84 FR 42393 through 42395), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58850 through 58854), the FY 2022 IPPS/LTCH PPS final rule (86 FR 45284 through 45290), and the FY 2023 IPPS/LTCH PPS final rule (87 FR 49111 through 49115) for additional previously adopted baseline and performance periods for the FY 2025 and subsequent program years.

b. Baseline and Performance Period for the Severe Sepsis and Septic Shock: Management Bundle Beginning With the FY 2026 Program Year

As discussed in section V.K.3.a of this final rule, we are finalizing the Severe and Septic Shock: Management Bundle measure beginning with the FY 2026 program year. In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27032), we proposed to adopt a 12-month baseline period and a 12-month performance period for that measure. Therefore, for the FY 2026 program year, we proposed to adopt a 12-month performance period that runs from January 1, 2024 to December 31, 2024 and a baseline period that runs from January 1, 2022 to December 31, 2022. We also proposed to use 12-month baseline and performance periods in subsequent program years, beginning with January 1st and ending with December 31st of a given year. Section V.K.3.a of this final rule describes the comments we received regarding the baseline and performance periods and our responses. We display these finalized baseline and performance periods in Table V.K.–04.

c. Summary of Previously Adopted Baseline and Performance Periods for the FY 2025 Program Year and Previously Adopted and Newly Adopted Baseline and Performance Periods Beginning With the FY 2026 Program Year

Tables V.K.–03, V.K.–04, V.K.–05, V.K.–06, and V.K.–07 summarize the baseline and performance periods that we have previously adopted and those that we are newly adopting in this final rule.

TABLE V.K.-03: PREVIOUSLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2025 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS	January 1, 2019 – December 31, 2019*	January 1, 2023 – December 31, 2023
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort))	July 1, 2015 – June 30, 2018	July 1, 2020 – June 30, 2023
COMP-HIP-KNEE	April 1, 2015 – March 31, 2018	July 1, 2020 – March 31, 2023**
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2019 – December 31, 2019*	January 1, 2023 – December 31, 2023
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2021 – December 31, 2021	January 1, 2023 – December 31, 2023

*In the FY 2023 IPPS/LTCH PPS final rule, we finalized that these baseline periods would be January 1, 2019, through

TABLE V.K.-04: PREVIOUSLY ADOPTED AND NEWLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2026 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS	January 1, 2022 – December 31, 2022	January 1, 2024 – December 31, 2024
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort))	July 1, 2016 – June 30, 2019	July 1, 2021 – June 30, 2024
COMP-HIP-KNEE	April 1, 2016 – March 31, 2019	April 1, 2021 – March 31, 2024
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2022 – December 31, 2022	January 1, 2024 – December 31, 2024
SEP-1*	January 1, 2022 – December 31, 2022	January 1, 2024 – December 31, 2024
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2022 – December 31, 2022	January 1, 2024 – December 31, 2024

* We are finalizing adoption of the Severe Sepsis and Septic Shock: Management Bundle measure beginning with the FY 2026 program year, as discussed in section XXX of this final rule.

TABLE V.K.-05: PREVIOUSLY ADOPTED AND NEWLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2027 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS	January 1, 2023 – December 31 2023	January 1, 2025 – December 31 2025
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort))	July 1, 2017 – June 30, 2020*	July 1, 2022 – June 30, 2025
COMP-HIP-KNEE	April 1, 2017 – March 31, 2020*	April 1, 2022 – March 31, 2025
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2023 – December 31, 2023	January 1, 2025 – December 31, 2025
SEP-1	January 1, 2023 – December 31, 2023	January 1, 2025 – December 31, 2025
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2023 – December 31, 2023	January 1, 2025 – December 31, 2025

*These baseline periods are impacted by the ECE granted by CMS on March 22, 2020. Qualifying claims will be excluded from the measure calculations for January 1, 2020–March 31, 2020 (Q1 2020), and April 1, 2020–June 30, 2020 (Q2 2020), from the claims-based complication and mortality measures. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).

TABLE V.K.-06: PREVIOUSLY ADOPTED AND NEWLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2028 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS	January 1, 2024 – December 31, 2024	January 1, 2026 – December 31, 2026
Clinical Outcomes Domain		
Mortality measures (MORT-30-AMI, MORT-30-HF, MORT3-0-COPD, MORT-30-CABG, MORT-30-PN (updated cohort))	July 1, 2018 – June 30, 2021**	July 1, 2023 – June 30, 2026
COMP-HIP-KNEE	April 1, 2018 – March 31, 2021**	April 1, 2023 – March 31, 2026
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2024 – December 31, 2024	January 1, 2026 – December 31, 2026
SEP-1	January 1, 2024 – December 31, 2024	January 1, 2026 – December 31, 2026
Efficiency and Cost Reduction Domain		
MSPB *	January 1, 2024 – December 31, 2024	January 1, 2026 – December 31, 2026

* We are finalizing substantive updates to the MSPB measure beginning with the FY 2028 program year, as discussed in section XXX of this final rule.

**These baseline periods are impacted by the ECE granted by CMS on March 22, 2020. Qualifying claims will be excluded from the measure calculations for January 1, 2020–March 31, 2020 (Q1 2020), and April 1, 2020–June 30, 2020 (Q2 2020), from the claims-based complication and mortality measures. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).

TABLE V.K.-07: NEWLY ADOPTED BASELINE AND PERFORMANCE PERIODS FOR THE FY 2029 PROGRAM YEAR

Measures	Baseline Period	Performance Period
Person and Community Engagement Domain		
HCAHPS	January 1, 2025 – December 31, 2025	January 1, 2027 – December 31, 2027
Clinical Outcomes Domain		
Mortality measures (MOR-T30-AMI, MORT-30-HF, MORT-30-COPD, MORT-30-CABG, MORT-30-PN (updated cohort))	July 1, 2019 – June 30, 2022*	July 1, 2024 – June 30, 2027
COMP-HIP-KNEE**	April 1, 2019 – March 31, 2022*	April 1, 2024 – March 31, 2027
Safety Domain		
NHSN measures (CAUTI, CLABSI, Colon and Abdominal Hysterectomy SSI, CDI, MRSA Bacteremia)	January 1, 2025 – December 31, 2025	January 1, 2027 – December 31, 2027
SEP-1	January 1, 2025 – December 31, 2025	January 1, 2027 – December 31, 2027
Efficiency and Cost Reduction Domain		
MSPB	January 1, 2025 – December 31, 2025	January 1, 2027 – December 31, 2027

*These baseline periods are impacted by the ECE granted by CMS on March 22, 2020. Qualifying claims will be excluded from the measure calculations for January 1, 2020–March 31, 2020 (Q1 2020), and April 1, 2020–June 30, 2020 (Q2 2020), from the claims-based complication and mortality measures. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).

** We are finalizing substantive updates to the THA/TKA Complications measure beginning with the FY 2030 program year, as discussed in section XXX of this final rule.

5. Performance Standards for the Hospital VBP Program

a. Background

We refer readers to sections 1886(o)(3)(A) through 1886(o)(3)(D) of the Act for the statutory provisions governing performance standards under the Hospital VBP Program. We refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513) for further discussion of achievement and improvement standards under the Hospital VBP Program. We refer readers to the FY 2013 IPPS/LTCH PPS final rule, the FY 2014 IPPS/LTCH PPS final rule, and the FY 2015 IPPS/LTCH PPS final rule (77 FR 53599 through 53605; 78 FR 50694 through 50699; and 79 FR 50077 through 50081, respectively) for a more detailed discussion of the general scoring methodology used in the Hospital VBP Program.

We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45290 through 45292) for previously established performance standards for the FY 2024 program year. We also refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49115 through 49118) for the previously established performance standards for the FY 2025 program year. We refer readers to the FY 2021 IPPS/LTCH PPS final rule for further discussion on performance standards for which the measures are calculated with lower values representing better performance (85 FR 58855).

b. Technical Corrections

(1) Background

After publication of the FY 2023 IPPS/LTCH PPS final rule, we determined there was a display error in the performance standards for the FY 2025 program year and an incorrectly labeled title for the FY 2028 program year. In the FY 2024 IPPS/LTCH PPS proposed rule, (88 FR 27035 through 27036), we announced technical corrections in accordance with 42 CFR 412.160 of our regulations that allows for updates to a performance standard if making a single correction for calculation errors or other problems that would significantly change the performance standards. Technical corrections were issued for these performance standards tables to ensure that hospitals have the correct performance standards for the applicable performance periods. The corrected performance standards are displayed in sections V.K.5.b.(2) and V.K.5.b.(3) of this final rule.

(2) Technical Correction to the Performance Standards for the FY 2025 Program Year

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49115 through 49116), we established performance standards for the measures in the FY 2025 program year in Table V.I.–09. In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27035), we issued a correction to display the correct performance standards for the Safety domain measures using CY 2019 data for the FY 2025 program year. The previously established and newly corrected performance standards for the measures in the FY 2025 program year have been updated and are set out in Table V.K–08. All other performance standards for the FY 2025 program year, including the HCAHPS Performance Standards for the Person and Community Engagement domain, were correctly displayed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49115 through 49117).

TABLE V.K.-08: PREVIOUSLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2025 PROGRAM YEAR

Measure Short Name	Achievement Threshold	Benchmark
Safety Domain ♦		
CAUTI*	0.650	0
CLABSI*	0.589	0
CDI*	0.520	0.014
MRSA Bacteremia*	0.726	0
Colon and Abdominal Hysterectomy SSI*	0.717 0.738	0 0
Clinical Outcomes Domain		
MORT-30-AMI#	0.872624	0.889994
MORT-30-HF#	0.883990	0.910344
MORT-30-PN (updated cohort)#	0.841475	0.874425
MORT-30-COPD#	0.915127	0.932236
MORT-30-CABG#	0.970100	0.979775
COMP-HIP-KNEE*#	0.025332	0.017946
Efficiency and Cost Reduction Domain		
MSPB*#	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

♦As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 49111 through 49112), we finalized updates to the FY 2025 baseline periods for measures included in the Person and Community Engagement and Safety domains to use CY 2019 data instead of CY 2021 data due to the impacts of the COVID-19 public health emergency. Therefore, the performance standards displayed in this table for the Safety domain measures were calculated using CY 2019 data.

* Lower values represent better performance.

Previously established performance standards.

(3) Technical Correction to the Performance Standards for Certain Measures for the FY 2028 Program Year

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49118), we established the performance standards for certain measures for the FY 2028 program in Table V.I.–13. The title of Table V.I.–13 incorrectly labeled the program year as FY 2027. In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27036), we issued a correction to display the title of the table as, Newly Established Performance Standards for the FY 2028 Program Year. The performance standards for the measures in the FY 2028 program year were correctly displayed and remain as finalized in the FY 2023 IPPS/LTCH PPS final rule and are set out in section V.K.5.e and Table V.K.–12 of this final rule.

c. Previously and Newly Established Performance Standards for the FY 2026 Program Year

In the FY 2021 IPPS/LTCH PPS final rule (84 FR 42398 through 42399), we established performance standards for the FY 2026 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and for the Efficiency and Cost Reduction domain measure (MSPB Hospital). We note that the performance standards for the MSPB Hospital measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. As discussed in section V.K.3.a of this final rule, we are finalizing the Severe and Septic Shock: Management Bundle measure beginning with the FY 2026 program year. The previously established and newly established performance standards for the measures in the FY 2026 program year are set out in Tables V.K.–09 and V.K.–10.

TABLE V.K.-09: PREVIOUSLY ESTABLISHED AND NEWLY ESTIMATED PERFORMANCE STANDARDS FOR THE FY 2026 PROGRAM YEAR

Measure Short Name	Achievement Threshold	Benchmark
Safety Domain♦		
CAUTI**	0.615	0
CLABSI**	0.76	0
CDI*	0.423	0
MRSA Bacteremia*	0.793	0
Colon and Abdominal Hysterectomy SSI*	0.747 0.763	0
SEP-1*** #	0.597482	0.843620
Clinical Outcomes Domain		
MORT-30-AMI	0.874426	0.890687
MORT-30-HF	0.885949	0.912874
MORT-30-PN (updated cohort)	0.843369	0.877097
MORT-30-COPD	0.914691	0.932157
MORT-30-CABG	0.970568	0.980473
COMP-HIP-KNEE*	0.024019	0.016873
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

** We note that the numerical values for the performance standards for the HAI measures in this final rule represent estimates based on the most recently available data. These estimates are based on CY 2022 data.

*** We note that the numerical values for the performance standards for the SEP-1 measure displayed in this final rule represent estimates based on the most recently available data. These estimates are based on CY 2022 data.

After publication of the FY 2024 IPPS/LTCH PPS proposed rule, we determined there was a display error in the performance standards for this measure. Specifically, the Achievement Threshold and Benchmark values, accurate, were presented in the wrong categories. We corrected this issue in the FY 2024 IPPS/LTCH PPS final rule and the correct performance standards are displayed in the table.

The HCAHPS Base Score is calculated using the eight dimensions of the HCAHPS measure. For each of the eight dimensions, Achievement Points (0–10 points) and Improvement Points (0–9 points) are calculated, the larger of which is then summed across the eight dimensions to create the HCAHPS Base Score (0–80 points). Each of the eight dimensions is of equal weight; therefore, the HCAHPS Base Score ranges from 0 to 80 points. HCAHPS Consistency Points are then calculated, which range from 0 to 20 points. The Consistency Points take into consideration the scores of all eight Person and Community Engagement dimensions. The final element of the scoring formula is the summation of the HCAHPS Base Score and the HCAHPS Consistency Points, which results in the Person and Community Engagement domain score that ranges from 0 to 100 points.

TABLE V.K.-10: ESTIMATED PERFORMANCE STANDARDS FOR THE FY 2026 PROGRAM YEAR: PERSON AND COMMUNITY ENGAGEMENT DOMAIN

HCAHPS Survey Dimension*	Floor (minimum)	Achievement Threshold (50th percentile)	Benchmark (mean of top decile)
Communication with Nurses	55.23	76.41	85.57
Communication with Doctors	58.04	76.83	85.93
Responsiveness of Hospital Staff	36.52	59.56	77.19
Communication about Medicines	39.27	58.06	70.11
Hospital Cleanliness & Quietness	38.59	62.61	77.49
Discharge Information	63.22	85.54	91.10
Care Transition	19.98	48.55	60.85
Overall Rating of Hospital	31.58	67.59	83.16

* The newly established performance standards displayed in this table were calculated using CY 2022 data. Data includes IPPS hospitals with 100+ completed surveys from patients discharged between January 2022 and December 2022.

d. Previously Established Performance Standards for Certain Measures for the FY 2027 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and the Efficiency and Cost Reduction domain for future program years to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45294 through 45295), we established performance standards for the FY 2027 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB). We note that the performance standards for the MSPB measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. We also note that the performance standard calculation methodology for the substantive updates to the MSPB Hospital measure, discussed in section XXX of this final rule, will not change with the adoption of the substantive measure updates. The updated performance standards for the substantive measure updates to the MSPB measure are not yet available for FY 2028. The previously established performance standards for these measures are set out in Table V.K.–11.

TABLE V.K.-11: PREVIOUSLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2027 PROGRAM YEAR

Measure Short Name	Achievement Threshold	Benchmark
Clinical Outcomes Domain**		
MORT-30-AMI	0.877824	0.893133
MORT-30-HF	0.887571	0.913388
MORT-30-PN (updated cohort)	0.844826	0.877204
MORT-30-COPD	0.917395	0.932640
MORT-30-CABG	0.971149	0.980752
COMP-HIP-KNEE*	0.023322	0.017018
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

** As discussed in the FY 2022 IPPS/LTCH PPS final rule (86 FR 5297 through 45299), we did not include data from Q1 and Q2 of CY 2020 in the calculation of these performance standards.

e. Previously Established Performance Standards for Certain Measures for the FY 2028 Program Year

We have adopted certain measures for the Safety domain, Clinical Outcomes domain, and the Efficiency and Cost Reduction domain for future program years to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In the FY 2023 IPPS/LTCH PPS final rule (86 FR 49118), we established performance standards for the FY 2028 program year for the Clinical Outcomes domain measures (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30– CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain measure (MSPB Hospital). As discussed in section V.K.5.b.(3) of this final rule, in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27038), we issued a technical correction with respect to the title of Table V.I.–13 in the FY 2023 IPPS/LTCH PPS final rule. We note that the performance standards for the MSPB Hospital measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The previously established performance standards for these measures are set out in Table V.K.–12.

TABLE V.K.12: PREVIOUSLY AND NEWLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2028 PROGRAM YEAR		
Measure Short Name	**Achievement Threshold**	**Benchmark**
Clinical Outcomes Domain**		
MORT-30-AMI	0.877260	0.893229
MORT-30-HF	0.885427	0.910649
MORT-30-PN (updated cohort)	0.831776	0.866166
MORT-30-COPD	0.913752	0.929652
MORT-30-CABG	0.971052	0.980570
COMP-HIP-KNEE*	0.029758	0.022002
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

** We note that these performance standards are calculated using some data from CY 2020 and CY 2021, which are included in the COVID-19 PHE. However, these performance standards have been calculated using the updated technical specifications described in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49106 through 49110), which excludes patients diagnosed with COVID-19 and risk-adjusts for history of COVID-19 for these measures.

f. Newly Established Performance Standards for Certain Measures for the FY 2029 Program Year

As discussed previously, we have adopted certain measures for the Clinical Outcomes domain (MORT–30–AMI, MORT–30–HF, MORT–30–PN (updated cohort), MORT–30–COPD, MORT–30–CABG, and COMP–HIP–KNEE) and the Efficiency and Cost Reduction domain (MSPB Hospital) for future program years to ensure that we can adopt baseline and performance periods of sufficient length for performance scoring purposes. In accordance with our methodology for calculating performance standards discussed more fully in the Hospital Inpatient VBP Program final rule (76 FR 26511 through 26513), which is codified at 42 CFR 412.160, we are establishing the following performance standards for the FY 2029 program year for the Clinical Outcomes domain and the Efficiency and Cost Reduction domain. We note that the performance standards for the MSPB Hospital measure are based on performance period data. Therefore, we are unable to provide numerical equivalents for the standards at this time. The newly established performance standards for these measures are set out in Table V.K.–13.

TABLE V.K.13: NEWLY ESTABLISHED PERFORMANCE STANDARDS FOR THE FY 2029 PROGRAM YEAR		
Measure Short Name	**Achievement Threshold**	**Benchmark**
Clinical Outcomes Domain**		
MORT-30-AMI	0.874856	0.893101
MORT-30-HF	0.880089	0.9072
MORT-30-PN (updated cohort)	0.814736	0.853996
MORT-30-COPD	0.905916	0.924829
MORT-30-CABG	0.971027	0.979822
COMP-HIP-KNEE*	0.025024	0.018708
Efficiency and Cost Reduction Domain		
MSPB*	Median Medicare Spending per Beneficiary ratio across all hospitals during the performance period.	Mean of the lowest decile Medicare Spending per Beneficiary ratios across all hospitals during the performance period.

* Lower values represent better performance.

** We note that these performance standards are calculated using some data from CY 2020 and CY 2021, which are included the COVID-19 PHE. However, these performance standards have been calculated using the updated technical specifications described in sections V.1.3.c. and V.1.3.d. of this final rule, which excludes patients diagnosed with COVID-19 and risk adjusts for history of COVID-19 for these measures.

6. Change to the Scoring Methodology

a. Background

In the Hospital Inpatient VBP Program final rule, we adopted a methodology for scoring clinical process of care, patient experience of care, and outcome measures (76 FR 26513 through 26531). We also refer readers to our codified requirements for performance scoring under the Hospital VBP Program at 42 CFR 412.165. In the FY 2024 IPPS/LTCH PPS proposed rule, we proposed modifications to the existing scoring methodology to reward excellent care in underserved populations.

b. Revision of the Hospital VBP Program Scoring Methodology To Add a New Adjustment That Rewards Hospitals Based on Their Performance and the Proportion of Their Patients Who Are Dually Eligible for Medicare and Medicaid

(1) Background and Overview

Healthcare disparities exist among patients throughout the United States, and certain patient characteristics such as socioeconomic status are associated with worse health outcomes.[274] [275] Research shows that patients experiencing worse health outcomes often face barriers to accessing health care services and have access to fewer healthcare providers.[276] [277] In leveraging our VBP programs to improve the quality of care and access to that care, we are interested in utilizing health equity-focused scoring modifications to create better health outcomes for all populations in these programs. The Office of the Assistant Secretary for Planning and Education's (ASPE) March 2020 Report to Congress: Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program, provides insight into whether and how value-based programs should account for social risk factors such as income, housing, transportation, and nutrition, that might adversely affect access to health care services or health outcomes.[278] A key finding was that dual enrollment status (that is, enrollment in both Medicare and Medicaid) is a strong predictor of poorer healthcare outcomes in Medicare's VBP programs, even when accounting for other social and functional risk factors. Dual enrollment status, an indicator at the individual level, also represents one way to capture common socioeconomic challenges that could affect an individual's ability to access care.

In the 2016 Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program, ASPE reported that beneficiaries with social risk factors, including dual enrollment in Medicare and Medicaid as a marker for low income, residence in a low-income area, Black race, Hispanic ethnicity, disability, and residence in a rural area, had worse outcomes and were more likely to be cared for by lower quality providers.[279] Patients with dual

[274] Hill, L., Artiga, S., and Haldar, S. (2022) Key Facts on Health and Health Care by Race and Ethnicity. Kaiser Family Foundation. Available at: *https://www.kff.org/report-section/key-facts-on-health-and-health-care-by-race-and-ethnicity-health-status-outcomes-and-behaviors/#:~:text=Health%20Status%2C%20Outcomes%2C%20and%20Behaviors%20Black%20people%20fared,than%20White%20people%20for%20most%20examined%20health%20measures.*

[275] National Academies of Sciences, Engineering, and Medicine. (2017) Accounting for Social Risk Factors in Medicare Payment, Washington, DC: National Academies Press. 47–84. Available at: *https://nap.nationalacademies.org/21858.*

[276] Kaiser Family Foundation. (2020) Disparities in Health and Health Care: Five Key Questions and Answers. Available at: *https://files.kff.org/attachment/Issue-Brief-Disparities-in-Health-and-Health-Care-Five-Key-Questions-and-Answers.*

[277] Thompson, T., McQueen, A., Croston, M., Luke, A., Caito, N., Quinn, K., Funaro, J., & Kreuter, MW (2019). Social needs and health-related outcomes among Medicaid beneficiaries. *Health Education & Behavior: The Official Publication of the Society for Public Health Education, 46*(3), 436–444. *https://doi.org/10.1177/1090198118822724.*

[278] U.S. Department of Health & Human Services. (2020) Executive Summary Report to Congress: Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. Office of the Assistant Secretary for Planning and Evaluation. Available at: *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195046/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report-Executive-Summary.pdf.*

[279] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. First Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2016. Available at:

eligibility status (DES), those who qualify for both Medicare and Medicaid coverage, are particularly vulnerable and experience significant disparities. Patients with DES are more likely to be disabled or functionally impaired, more likely to be medically complex, and have greater social needs compared to other beneficiaries.[280] Patients with DES are one of the most vulnerable populations.[281] [282] Despite the multitude of indicators available for assessing vulnerability and health risks, dual eligibility remains the strongest predictor of negative health outcomes.[283]

Executive Order 13985 of January 20, 2021 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, defines ''equity'' as the consistent and systematic fair, just, and impartial treatment of all individuals, including individuals who belong to underserved communities that have been denied such treatment, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ[I]A+) [284] persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality) (86 FR 7009).

CMS defines ''health equity'' as the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.[285] To achieve this vision, we are working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all individuals served by our programs, reducing avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our enrollees need to thrive.

Achieving health equity, addressing health disparities, and closing the performance gap in the quality of care provided to populations that have been disadvantaged, marginalized, and/or underserved by the healthcare system continue to be priorities for CMS as outlined in the CMS National Quality Strategy.[286] The Hospital IQR Program adopted three new health-equity focused quality measures in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49220). To further align with our goals to achieve health equity, address health disparities, and close the performance gap on the quality of care, in the FY 2024 IPPS/LTCH PPS proposed rule, we proposed to add Health Equity Adjustment bonus points to a hospital's Total Performance Score (TPS) that will be calculated using a methodology that incorporates a hospital's performance across all four domains for the program year and its proportion of patients with DES (88 FR 27039 through 27049).

We proposed to define the points that a hospital can earn based on its performance and proportion of patients with DES as the Health Equity Adjustment (HEA) bonus points. We believe that the awarding of these HEA bonus points is consistent with our strategy to advance health equity and will incentivize high-quality care across all hospitals.[287]

We proposed to define the term ''measure performance scaler'' as the sum of the points awarded to a hospital for each domain based on the hospital's performance on the measures in that domain. The number of points that we award to a hospital for each domain will be 4, 2, or 0, based on whether the hospital's performance is in the top third, middle third, and bottom third of performance, respectively, of all hospitals for the domain. Specifically, a hospital will receive 4 points if its performance falls in the top third, 2 points if its performance falls in the middle third, or 0 points if its performance falls in the bottom third of performance of all hospitals for the domain. Hospitals could thus receive a maximum of 16 measure performance scaler points for being a top performer across all four domains.

We proposed to define the term ''underserved multiplier'' as the number of inpatient stays for patients with DES out of the total number of inpatient Medicare stays during the calendar year two years before the start of the respective program year. For example, for the FY 2026 program year, we will use the total number of inpatient stays from January 1, 2024 through December 31, 2024. A logistic exchange function will be then applied to the number of patients with DES. Data on DES is sourced from the State Medicare Modernization Act (MMA) file of dual eligible beneficiaries, which each of the 50 States and the District of Columbia submit to CMS at least monthly. This file is utilized to deem individuals with DES automatically eligible for the Medicare Part D Low Income Subsidy, as well as other CMS program needs and thus can be considered the gold standard for determining DES. We note that this is the same file used for determining DES in the Hospital Readmissions Reduction Program. More detail on this file can be found on the CMS website at *https://www.cms.gov/Medicare-Medicaid-Coordination/Medicare-and-Medicaid-Coordination/Medicare-Medicaid-Coordination-Office/DataStatisticalResources/StateMMAFile* and at the Research Data Assistance Center website at *https://resdac.org/cms-data/variables/monthly-medicare-medicaid-dual-eligibility-code-january*.

We proposed that the HEA bonus points will be calculated as the product of the measure performance scaler and the underserved multiplier. The HEA bonus points are designed to award higher points for hospitals that (1) serve

https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf.

[280] Johnston, KJ, & Joynt Maddox, KE (2019). The Role of Social, Cognitive, and Functional Risk Factors In Medicare Spending for Dual and Nondual Enrollees. *Health Affairs (Project Hope), 38*(4), 569–576. *https://doi.org/10.1377/hlthaff.2018.05032*.

[281] Johnston, KJ, & Joynt Maddox, KE (2019). The Role of Social, Cognitive, and Functional Risk Factors in Medicare Spending for Dual and Nondual Enrollees. *Health Affairs (Project Hope), 38*(4), 569–576. *https://doi.org/10.1377/hlthaff.2018.05032*.

[282] Wadhera, RK, Wang, Y., Figueroa, JF, Dominici, F., Yeh, R.W., & Joynt Maddox, KE (2020). Mortality and Hospitalizations for Dually Enrolled and Nondually Enrolled Medicare Beneficiaries Aged 65 Years or Older, 2004 to 2017. *JAMA, 323*(10), 961–969. *https://doi.org/10.1001/jama.2020.1021*.

[283] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. Second Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2020. Available at: *https://aspe.hhs.gov/reports/second-report-congress-social-risk-medicares-value-based-purchasing-programs*.

[284] We note that the original, cited definition only stipulates, ''LGBTQ+'', however, HHS and the White House now recognize individuals who are intersex/have intersex traits. Therefore, we have updated the term to reflect these changes.

[285] Health Equity Strategic Pillar. Centers for Medicare & Medicaid Services. *https://www.cms.gov/pillar/health-equity*.

[286] Centers for Medicare & Medicaid Services. (2022) CMS National Quality Strategy. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*.

[287] Centers for Medicare & Medicaid Services. (2022) CMS Outlines Strategy to Advance Health Equity, Challenges Industry Leaders to Address Systemic Inequities. Available at: *https://www.cms.gov/newsroom/press-releases/cms-outlines-strategy-advance-health-equity-challenges-industry-leaders-address-systemic-inequities#:~:text=In%20effort%20to%20address%20systemic%20inequities%20across%20the,Medicare%2C%20Medicaid%20or%20Marketplace%20coverage%2C%20need%20to%20thrive*.

greater percentages of underserved populations, which are defined here for the purpose of this proposal as hospital patients with DES who receive inpatient services, and (2) have higher quality performance.

The methodology for the calculation of the HEA bonus points is described in sections V.K.6.b.(3) and V.K.6.b.(4) of this final rule. By providing HEA bonus points to hospitals that serve higher proportions of patients with DES and perform well on quality measures, we believe that we can begin to bridge performance gaps and better address the social needs of patients, in alignment with our National Quality Strategy.[288] We are committed to achieving health equity for hospitalized patients by supporting hospitals in quality improvement activities to reduce health disparities, enabling patients and their family members and caregivers to make more informed decisions, and promoting provider accountability for health care disparities. We believe that this scoring methodology update will continue encouraging high quality performance and provide an incentive for hospitals to provide high quality care to all of the populations they serve. We also believe the scoring methodology update aligns with the broader CMS health equity goals to close gaps in health care quality and promote the highest quality outcomes for all people.[289]

We proposed to adopt this adjustment to the Hospital VBP Program scoring methodology beginning with the FY 2026 program year.

We note that the Shared Savings Program recently adopted a health equity adjustment for Accountable Care Organizations that report all-payer electronic clinical quality measures (eCQMs)/Merit-based Incentive Payment System CQMs, are high-performing on quality, and serve a large proportion of underserved beneficiaries, as defined by dual-eligibility, enrollment in the Medicare Part D low income subsidy (LIS) (meaning the individual is enrolled in a Part D plan and receives LIS) and an Area Deprivation Index (ADI) score of 85 or above, as detailed in the CY 2023 Physician Fee Schedule final rule (87 FR 69838 through 69857). The proposed definitions and calculations in this final rule are similar to the health equity adjustment finalized in the Shared Savings Program. Additionally, a similar health equity adjustment was proposed in the FY 2024 Skilled Nursing Facility (SNF) Prospective Payment System (PPS) proposed rule for the SNF Value-Based Purchasing (VBP) Program (88 FR 21383 through 21393).

(2) Determining the Underserved Multiplier and Measure Performance Scaler

At this time, for purposes of the Hospital VBP Program's health equity adjustment policy, we are unable to obtain patients' neighborhood-level data necessary to incorporate the ADI under all of the Hospital VBP Program measures as currently specified. We note that the use of both the LIS designation and DES could be preferable to using DES alone, as doing so reduces variability because of the differences in Medicaid eligibility across States; however, given that the DES data are readily available and already used in the Hospital Readmissions Reduction Program, we proposed to only use DES data at this time. As DES is a strong indicator of poorer healthcare outcomes in Medicare's VBP programs,[290] we believe that it can serve as an appropriate underserved multiplier on its own in the Hospital VBP Program. We will continue to consider whether to incorporate the LIS, ADI, and other indicators for underserved populations in future health equity adjustment proposals for the Hospital VBP Program. We sought comment on the use of these additional indicators in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27049) and summarized the comments we received in section V.K.6.b.(7) of this final rule.

The measure performance scaler points will be available to all hospitals that exhibit high quality care across the entire patient population. Each domain will be assessed independently such that a hospital that performs in the top or middle third of performance for one domain will be eligible for measure performance scaler points even if it does not perform in the top or middle third of performance for any other domain. Similarly, if a hospital performs in the top third of performance for all domains, they will receive measure performance scaler points for all domains. Alternatively, a hospital which is in the bottom third of performance for all four domains will not receive any performance scaler points. A hospital's performance is relative to the performance of all other hospitals in the Hospital VBP Program, and this measure performance scaler methodology is further defined in section V.K.6.b.(3). of this final rule.

The underserved multiplier will be calculated using a similar approach as the Hospital Readmissions Reduction Program's dual proportion calculation, which identifies patients with DES based on the dual-eligibility codes in the Medicare Beneficiary Summary File.[291] These data will provide us with the number of inpatient stays for patients with DES out of the total number of inpatient Medicare stays, which is all Medicare FFS and Medicare Advantage stays. A stay is identified as being dually eligible if it is for a patient with Medicare and full Medicaid benefits for the month the patient was discharged from the hospital, unless the patient died in the month of discharge, in which case DES is determined using the previous month. We proposed that the dual proportion is calculated with stays that occurred during the calendar year two years before the start of the respective program year. A logistic exchange function will then be applied to this dual proportion. We will then multiply this underserved multiplier by the aforementioned measure performance scaler to determine the hospital's HEA bonus points. This methodology is described further in section V.K.6.b.(3) of this final rule. Unlike the Shared Savings Program's policy, we note that we did not propose a minimum percent of patients with DES that a hospital must treat, such that a hospital serving one percent of patients with DES and a hospital serving 80 percent of patients with DES are both eligible for HEA bonus points to give every hospital an opportunity to participate in this final scoring change.

Through the availability of HEA bonus points, we seek to improve outcomes by providing incentives to hospitals to strive for high performance

[288] Centers for Medicare & Medicaid Services. (2022) What is the CMS National Quality Strategy? Available at: *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/cms-quality-strategy*.

[289] Centers for Medicare & Medicaid Services. (2022) CMS Outlines Strategy to Advance Health Equity, Challenges Industry Leaders to Address Systemic Inequities. Available at: *https://www.cms.gov/newsroom/press-releases/cms-outlines-strategy-advance-health-equity-challenges-industry-leaders-address-systemic-inequities#:~:text=CMS%20Health%20Equity%20Strategy%3A%20CMS%20Administrator%20Chiquita%20Brooks-LaSure,access%20to%20care.%20They%20include%20the%20following%20actions%3A*.

[290] Assistant Secretary for Planning and Evaluation. (2020) Social Risk and Performance in Medicare's Value-Based Purchasing Programs. Available at: *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195036/Social-Risk-in-Medicare%E2%80%99s-VBP–2nd-Report-3-Pager.pdf#:~:text=After%20accounting%20for%20additional%20social%20and%20functional%20risk,and%20resource%20use%20measures%20in%20Medicare%E2%80%99s%20VBP%20programs*.

[291] Research Data Assistance Center. (2023) Medicare-Medicaid Dual Eligibility Code—January. Available at: *https://resdac.org/cms-data/variables/medicare-medicaid-dual-eligibility-code-january*.

across the domains as well as to care for a high proportion of underserved populations, as defined by dual eligibility status for the purposes of this final rule. While we recognize and discuss in this final rule that there are many different indicators that could be used to measure underserved populations, we note that we are referring to patients with DES when we use the term ''underserved population'' throughout this final rule. As noted in section V.K.6.b.(1), DES is a good indicator of socioeconomic disadvantage, as dual eligibility is associated with a patient's inability to access care.[292]

The HEA bonus point calculation is purposefully designed to not reward poor quality. Likewise, if the underserved population represents only a small proportion of a hospital's total population, such as a hospital only serving five percent of patients with DES, then the health equity adjustment will be lower because the bonus points are not designed to reward hospitals that serve a low number of underserved patients. Instead, the health equity adjustment is intended to incentivize hospitals to improve their overall quality of care across the entire hospital's population by bridging performance gaps and improving overall health outcomes for patients while reducing the unintended risk of decreased access to care for underserved patients. As described more fully in this section of this final rule, the combination of the measure performance scaler and the underserved multiplier will result in a range of possible HEA bonus points that is designed to give the highest rewards to hospitals caring for a larger percentage of underserved individuals and delivering high quality care.

We also proposed to codify at 42 CFR 412.160 of our regulations the definitions of these new scoring methodology terms, and we proposed to codify at 42 CFR 412.165(b) of our regulations the updates to the steps for performance scoring with the incorporated health equity scoring adjustments.

(3) Application of Health Equity Adjustment

After considering how to modify the existing quality performance scoring in the Hospital VBP Program to more fully assess the quality of care provided by hospitals that serve a high proportion of underserved patients, we proposed to adjust the sum of an individual hospital's domain scores based on their overall performance within each domain, with a maximum potential of 16 measure performance scaler points across the four domains. For hospitals that only get three domain scores because they do not meet measure minimums for all four domains, the maximum number of measure performance scaler points that a hospital could earn will be 12.

We proposed to calculate a hospital's HEA bonus points by multiplying the measure performance scaler by the hospital's underserved multiplier. As explained more fully in this section, the number of HEA bonus points that could then be added to a hospital's TPS for a program year will be capped at 10. We believe that capping the total number of potential HEA bonus points at 10 recognizes the effort hospitals put forth to serve large populations of patients with DES, while not overly inflating TPSs. We believe that limiting the number of HEA bonus points that a hospital is eligible to receive to a maximum of 10 points creates a balanced incentive that increases a hospital's TPS without dominating the score and creating unintended incentives. Additionally, the maximum of 10 HEA bonus points aligns with the magnitude of points we award for a given measure in the existing Hospital VBP Program's scoring methodology. Therefore, the maximum number of HEA bonus points that could be added to the TPS would be 10 points. In the FY 2024 IPPS/LTCH PPS proposed rule, we proposed that no hospital could earn more than a 110 maximum final TPS that includes the HEA bonus points (88 FR 27049). We refer readers to section V.K.6.b.(6) of this final rule where we have finalized this proposal as proposed and our newly-adopted regulations at 42 CFR 412.160 where we modify the TPS maximum to 110. This final maximum at 110 will ensure that the application of the health equity adjustment allows for a hospital that receives the maximum number of points in weighted domain scores to still have the opportunity to receive the additional 10 HEA bonus points.

(4) Calculation Steps and Examples

In this section and in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27042 through 27045), we outline the calculation steps and provide examples of the determination of health equity adjustment bonus points and the application of these bonus points to a hospital's TPS. These example calculations illustrate possible health equity adjustment bonus points resulting from the proposed approach, which accounts for both a hospital's quality performance and a logistic exchange function applied to its proportion of patients with DES. For each hospital, the bonus will be calculated according to the following formula:

Health Equity Adjustment (HEA) bonus points = measure performance scaler × underserved multiplier

The proposed calculation of the HEA bonus points will be as follows:

Step One—Calculate the Number of Measure Performance Scaler Points for Each Hospital

We proposed to first assign a measure performance scaler to each domain based on a hospital's domain level scores. We will assign point values to hospitals for each domain based on their performance on the measures in that domain. A hospital will receive 4, 2, or 0 points for top third, middle third, or bottom third of performance, respectively, on each domain such that a hospital could receive a maximum of 16 measure performance scaler points for being in the top third of performance for all of the four domains, as depicted in this sample equation and in Table V.K.–13. We note that if a hospital performs in the bottom third of performance in all four domains, that hospital would receive a total of 0 out of 16 measure performance scaler points. Additionally, hospitals that can be scored in only three domains could receive a maximum of 12 measure performance scaler points for being in the top third of performance for each domain.

Hospital 1 (High Performance):
4 pts in Clinical Domain + 4 pts in Cost & Efficiency Domain + 4 pts Safety Domain + 4 pts in Person and Community Engagement = 16 total performance scaler points for Hospital 1

Hospital 2 (Medium Performance):
4 pts in Clinical Domain + 2 pts in Cost & Efficiency Domain + 2 pts in Safety Domain + 0 in Person & Community Engagement Domain = 8 total performance scaler points for Hospital 2

Hospital 3 (Low Performance):
0 pts in Clinical Domain + 0 pts in Cost & Efficiency Domain + 2 pts in Safety Domain + 0 pts in Person & Community Engagement Domain = 2 total performance scaler points for Hospital 3

[292] U.S. Department of Health & Human Services. (2020) Executive Summary: Report to Congress: Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. Available at: *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195046/Social-Risk-in-Medicare%E2%80%99s-VBP/2nd-Report-Executive-Summary.pdf.*

Table V.K.–13 displays the measure performance scaler that three example hospitals will receive for each domain based on their performance.

TABLE V.K.-13: EXAMPLE OF THE MEASURE PERFORMANCE SCALER ASSIGNED TO HOSPITAL BASED ON PERFORMANCE BY DOMAIN

Domain	Hospital 1 – High Performance		Hospital 2 - Middle performance		Hospital 3 - Low performance	
	Performance Group	Value	Performance Group	Value	Performance Group	Value
Clinical	Top third	4	Top Third	4	Bottom Third	0
Cost & Efficiency	Top third	4	Middle Third	2	Bottom Third	0
Safety	Top third	4	Middle Third	2	Middle Third	2
Person and Community Engagement	Top third	4	Bottom Third	0	Bottom Third	0
	Total Measure Performance Scaler Value	16	Total Measure Performance Scaler Value	8	Total Measure Performance Scaler Value	2

Step Two—Calculate the Underserved Multiplier

Second, we proposed to calculate an underserved multiplier for each hospital, which we proposed to define as the logistic function applied to the proportion of inpatient stays for patients with DES during the calendar year two years before the applicable program year divided by the total number of inpatient Medicare stays, which is all Medicare FFS and Medicare Advantage stays, at each hospital. For example, for the FY 2026 program year, we will use the total number of inpatient stays from January 1, 2024, through December 31, 2024. The primary goal of the underserved multiplier is to appropriately reward hospitals that are able to overcome the challenges of caring for high proportions of patients with DES. By utilizing a logistic exchange function to calculate the underserved multiplier, hospitals who care for the highest proportions of patients with DES will have the opportunity for the most HEA bonus points. Thus, we proposed to utilize a logistic exchange function to calculate the underserved multiplier for scoring hospitals such that there will be a lower rate of increase at the beginning and the end of the curve.

The underserved multiplier calculation will thus be:

Underserved Multiplier = Logistic Function (Number of Inpatient Stays for Patients with DES/Total Medicare Inpatient Stays)

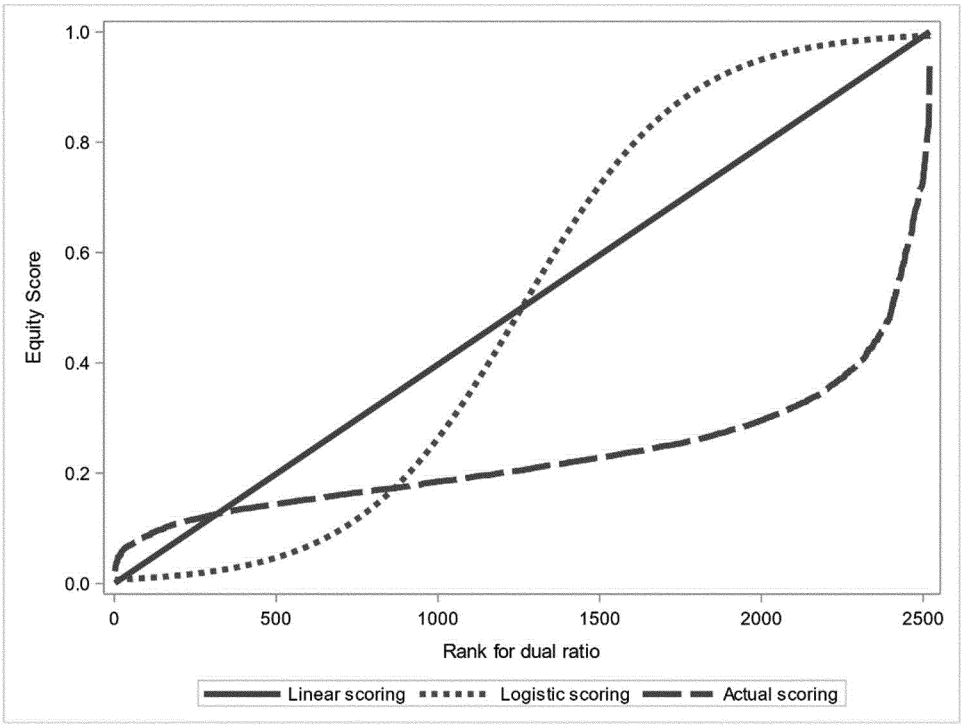
$$Underserved\ Multiplier = \frac{1}{1 + e^{-(-5+10*\frac{Dual\ Rank}{Max\ Dual\ Rank})}}$$

To determine the proportion of the number of inpatient stays for patients with DES, we proposed to use patient level data on the proportion of all Medicare FFS and Medicare Advantage inpatient stays in a hospital in which the patient was dually eligible for Medicare and full Medicaid benefits. For the HEA adjustment, the dual proportion is calculated with stays that occurred during the calendar year two years before the applicable the program year, and then a logistic exchange function is applied to that proportion. For example, for the FY 2026 program year, the dual proportion data will be calculated using stays from January 1, 2024, through December 31, 2024. In alignment with the Hospital Readmissions Reduction Program approach to determine the dual proportion, a stay is identified as being dually eligible if it is for a patient with Medicare and full Medicaid benefits for the month the patient was discharged from the hospital, unless the patient died in the month of discharge, in which case DES is determined using the previous month. Using the proportion of DES patients calculated among both Medicare FFS and Medicare Advantage patients more accurately represents the proportion of patients with DES served by the hospital compared to only using the proportion of Medicare FFS stays as well as that DES data for Medicare Advantage patients are readily available. This is the approach finalized by the Hospital Readmissions Reduction Program to determine the dual proportion in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38228 through 38229).

We proposed to utilize a logistic exchange function to calculate the underserved multiplier for scoring hospitals such that there will be a lower rate of increase at the beginning and the end of the curve. A logistic exchange function assumes a large difference between hospitals treating the most and fewest patients with DES and produces a large score difference between the groups, but less difference within the groups. This will ensure that there will be very few differences in the points awarded between hospitals with similar proportions of patients served. For example, there will be little difference in the points awarded to a hospital serving 59 percent of individuals with DES and a hospital serving 61 percent of individuals with DES. Utilizing a logistic function allows for hospitals in the middle third of performance to have a strong association between an increase in HEA bonus points based on proportion of patients with DES served. We note that there is no minimum or maximum threshold on the percentage of individuals with DES that a hospital serves for the calculation of HEA bonus

points. We believe that this gives all hospitals an opportunity and incentive to serve a percentage of patients with DES. We also considered linear and actual scoring alternatives to calculate the underserved multiplier, as displayed in Figure V.K.–01, but we believe that the logistic function scoring applied to the proportion of patients with DES (dotted line in Figure V.K.–01) provides the best opportunity for hospitals serving large proportions of patients with DES to receive HEA bonus points. We note that a scoring approach using actual proportion of patients with DES, as depicted by the dashed line in Figure V.K.–01, assumes that the hospitals' treatment of patients with DES is reflected simply in their actual share in the patient population. A linear scoring approach, as depicted by the solid line in Figure V.K.–01, assumes that a hospital's treatment of patients with DES is correlated by rank.

Figure V.K.-01



Step Three—Calculate the Health Equity Adjustment Bonus Points

We proposed to calculate the HEA bonus points that apply to a hospital for a program year by multiplying the measure performance scaler total by the underserved multiplier. We believe that combining the measure performance scaler and the underserved multiplier to calculate the HEA bonus points allows for us to reward those hospitals with high quality performance across the four domains that are also serving high populations of patients with DES. This approach also incentivizes other hospitals to improve their performance (by a higher measure performance scaler) and serve more patients with DES (by a higher underserved multiplier) to earn greater HEA bonus points. The product of the measure performance scaler points and the underserved multiplier proportion results is the HEA bonus point total capped at 10 points. Table V.K.–14 displays the HEA bonus points that six example hospitals would receive based on their measure performance scaler and underserved multiplier, with the cap of 10 total possible HEA bonus points. For example, Hospital 1 in Table V.K.–14 that has performed in the top third of performance in all four of the domains and whose population of patients with DES is 80 percent after applying the logistic function will earn 16 measure performance scaler points, which will then be multiplied by an underserved multiplier of 0.8, resulting in 12.8 HEA bonus points that would then be reduced to 10 HEA bonus points per the 10 HEA bonus point cap.

Step Four—Add Health Equity Adjustment Bonus Points to the Total of the Weighted Domain Scores To Calculate the TPS

Health Equity Adjustment (HEA) bonus points = Performance Scaler × Underserved Multiplier

TABLE V.K.-14: EXAMPLE OF THE HEALTH EQUITY ADJUSTMENT BONUS POINTS CALCULATION

Hospital	Measure Performance Scaler	Underserved Multiplier	Health Equity Adjustment bonus points
Hospital 1	16	0.8	10
Hospital 2	16	0.2	3.2
Hospital 3	8	0.3	2.4
Hospital 4	8	0.1	0.8
Hospital 5	2	0.8	1.6
Hospital 6	2	0.2	0.4

Finally, we proposed that we will add a hospital's HEA bonus points as calculated in Step Three of this section to the total of the four weighted domain scores that we sum to calculate the hospital's TPS. The sum of the weighted domain scores, which will remain as outlined in our regulations at 42 CFR 412.165(b)(4), and the HEA bonus points will be the hospital's TPS for the program year. We did not propose to revise the process for converting the TPS into the incentive payment adjustment percentage. As established in our regulations at 42 CFR 412.162(b)(3), the value-based incentive payment percentage is calculated as the product of: the applicable percent as defined in 42 CFR 412.160, the hospital's TPS, and the linear exchange function slope. We proposed to modify the definition of TPS in our regulations at 42 CFR 412.160 to align with the proposal to modify the TPS range to be 0–110 beginning with the FY 2026 program year as discussed in section V.K.6.b.5 of this final rule. Table V.K.–15 displays the HEA bonus points and TPSs awarded to the six example hospitals from Table V.K.–14.

Health equity adjustment bonus points + Total of Weighted Domain Scores = Total Performance Score

TABLE V.K.-15: EXAMPLE OF THE HEALTH EQUITY ADJUSTMENT BONUS POINTS CALCULATION

Hospital	Total of Weighted Domain Scores	Health Equity Adjustment bonus points	TPS
Hospital 1	100	10	110
Hospital 2	90	3.2	93.2
Hospital 3	48	2.4	50.4
Hospital 4	47.2	0.8	48.8
Hospital 5	20	1.6	21.6
Hospital 6	20	0.4	20.4

By adding these HEA bonus points to the total of each hospital's weighted domain scores, hospitals can be rewarded for delivering excellent care to large proportions of underserved populations. We believe that a scoring adjustment designed to advance health equity through the Hospital VBP Program is consistent with CMS's goal to advance health equity by providing an incentive for hospitals to care for underserved populations and to provide high quality care to all of the populations they serve.

We invited public comment on this scoring change, which we also proposed to codify in our regulations at 42 CFR 412.160 and 412.165(b).

Comment: Many commenters supported the adoption of a Health Equity Adjustment for the Hospital VBP Program. Many commenters supported the Health Equity Adjustment because they believed that it would promote high quality care for underserved populations and incentivize hospitals to focus on reducing disparities. A commenter believed that it would encourage hospitals to reach additional underserved patients in the healthcare system. Many commenters supported the Health Equity Adjustment because they believed that the scoring would in turn support providers treating greater proportions of patients in underserved communities with higher payments. A

commenter stated that the scoring revision would account for the additional challenges hospitals overcome to achieve high standards for all their patients. Several commenters supported the Health Equity Adjustment because they believed that the revision aligns with goals, initiatives, and programs across CMS, such as the goal to advance health equity and CMS's Health Equity Strategy and Roadmap. A few commenters stated how the proposal creates similarities in health equity adjustment policies across payment programs of CMS. A few commenters also supported the Health Equity Adjustment because it aligns with the health equity goals of their programs. A few commenters believed that this would allow for hospitals that care for patients from underserved communities with fewer resources to be fairly assessed and not heavily penalized. A few commenters supported the Health Equity Adjustment because it recognizes challenges that patients face and factors beyond a hospital's control that may impact performance. In addition to the support, a few commenters recommended improvements to the methodology such as considering alternative approaches to identifying hospitals that disproportionately serve marginalized patient populations.

Response: We thank the commenters for their support of our proposal to adopt a Health Equity Adjustment. We agree that this adjustment will promote high quality care for underserved populations, incentivize addressing disparities, and recognize challenges hospitals overcome to achieve high standards for all their patients. We also agree that the adjustment recognizes structural challenges that patients with DES face and hospitals have to overcome to provide excellent care. We will take into consideration for future years the recommendations of assessing alternative approaches to identifying hospitals that disproportionately serve marginalized patient populations.

Comment: Several commenters supported the initial use of DES with a few commenters noting the alignment with the Hospital Readmissions Reduction Program. A few commenters recommended considering alternate indicators and sources of social risk factor data in the future as Medicaid eligibility varies by state.

Response: We thank commenters for their support of the initial use of DES and their recommendations to consider alternate approaches for capturing social risk. We will take this into consideration in future years. We also refer readers to section V.K.6.b.(7) of this final rule where we summarized additional comments we received in response to a request for information on additional indicators besides DES for the health equity adjustment. We remain committed to refining this health equity scoring methodology, as determined appropriate, in the future.

Comment: A few commenters supported the use of the logistic exchange function for calculating the underserved multiplier.

Response: We thank commenters for their support of using the logistic exchange function for calculating the underserved multiplier.

Comment: A few commenters supported structuring the Health Equity Adjustment as a form of bonus points as opposed to an addition to the base TPS because the financial incentive would help offset costs associated with addressing the social needs of underserved patient populations. A few commenters supported that the bonus points from the Health Equity Adjustment would be available to those in the top two thirds of each domain performance rather than only those in the top third. A commenter also supported the threshold methodology of three levels because it is consistent with health equity calculations in other payment programs.

Response: We thank the commenters for their support of the threshold methodology and how the Health Equity Adjustment is available as bonus points to the top two thirds of each domain performance.

Comment: A commenter supported beginning the adjustment in the FY 2026 program year to allow for an evaluation and adjustment period before it impacts hospital payments.

Response: We appreciate the commenter's support. We note that for the FY 2026 program year, the dual proportion data will be calculated using stays from January 1, 2024, through December 31, 2024. We also refer readers to Table V.K.–04 in section V.K.4.c of this final rule that displays the baseline and performance periods for the FY 2026 program year. We anticipate hospitals will receive their confidential Percentage Payment Summary Reports with their FY 2026 program year results to review by no later than August 1, 2025.

Comment: A commenter did not support the alternate methodology in which hospitals must be in the top third of all performers in the measure domain to receive bonus points because it would create performance cliffs.

Response: We appreciate the commenter's feedback and agree that awarding measure performance scaler points to the top two thirds of all performers instead of the top third of all performers for each domain would lessen the potential impact of performance cliffs. We are finalizing the proposed methodology as opposed to the alternate methodology.

Comment: Several commenters did not support the use of DES as an indicator for the Health Equity Adjustment. Several commenters expressed concern around the challenges of using DES because dual eligible beneficiary percentages vary across states and that the proportion of patients with DES varies over time within a hospital. A few commenters believed that DES provides an incomplete picture of health equity. A commenter recommended replacing the underserved multiplier with direct billing for case management. A few commenters did not support the use of ADI because they believe it is highly correlated across domains which may lead to the overstating of aspects of social risk, and it is incapable of accurately reflecting neighborhood deprivation in high-cost areas. A commenter also did not support the use of Part D LIS alone because it is not a reasonable proxy for social risk. A commenter also expressed concern over the inconsistent definition of ''underserved'' across CMS programs. The commenter cited the Medicare Shared Savings Program (MSSP), which uses DES along with ADI and the Part D LIS, and the Center for Medicare & Medicaid Innovation (CMMI) ACO REACH model, which uses DES and ADI.

Response: We appreciate the commenters' concern regarding the use of DES and agree that by itself DES does not capture all aspects of social risk for health inequities. However, we believe that use of DES data is an important first step to introducing a health equity adjustment in the Hospital VBP Program, as well as being a readily available data source. As ASPE noted in its 2020 report to Congress, DES is a strong indicator of poorer healthcare

outcomes in Medicare's VBP programs.[293] Regarding its availability, as mentioned in the FY 2024 IPPS/LTCH PPS proposed rule, we are able to capture the proportion of patients with DES served by a hospital by using patient level data on the proportion of Medicare FFS and Medicare Advantage stays within the defined performance period of two years prior to the program year (88 FR 27043). We will consider alternative approaches in future years and will take the concerns around the ADI into consideration at that time. We appreciate the feedback on the use of the ADI, and we note that we did not propose using ADI at this time. We also refer readers to section V.K.6.b.(7) of this final rule where we summarized additional comments we received in response to a request for information on additional indicators besides DES for the health equity adjustment.

With regard to our use of the term ''underserved'' across CMS programs, we reference Executive Order 13985 of January 20, 2021 on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, which provides examples of individuals who belong to underserved communities, such as Black, Latino, and Indigenous and Native American persons, Asian Americans and Pacific Islanders and other persons of color; members of religious minorities; lesbian, gay, bisexual, transgender, and queer (LGBTQ[I]A+)[294] persons; persons with disabilities; persons who live in rural areas; and persons otherwise adversely affected by persistent poverty or inequality (86 FR 7009). We believe that our definition of underserved, as defined by patients with DES for the purposes of this health equity adjustment, is in line with this definition, particularly with regards to persons otherwise adversely affected by persistent poverty or inequality. Additionally, we specified in the FY 2024 IPPS/LTCH PPS proposed rule that the term ''underserved'' for purposes of discussing the health equity adjustment in the Hospital VBP Program refers to hospital patients with DES who receive inpatient services (88 FR 27040).

Comment: A few commenters recommended focusing exclusively on rewards as opposed to rewards and penalties. A commenter recommended guaranteeing that non-participation or poor performance does not result in negative repercussions.

Response: We wish to clarify that the program is statutorily structured to withhold 2% from all hospitals and then distribute value-based incentive payments based on performance. However, all hospitals are still eligible to earn HEA bonus points. As noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27045 through 27046), under the health equity adjustment, even if a hospital receives a penalty, that hospital can still gain from the health equity adjustment, if the penalty is smaller after the health equity adjustment. The health equity adjustment thus offers every hospital an opportunity to earn HEA bonus points regardless of whether they receive a bonus or penalty under the Hospital VBP Program. In addition, we reiterate the budget neutral structure of the Hospital Value-Based Purchasing (HVBP) Program, as the HEA bonus points are added before the TPS is calculated. This would only result in changes to the hospital's relative position to other hospitals as opposed to the distribution of bonuses and penalties. With regard to the concern of non-participation, we note that subsection (d) hospitals cannot opt-out of this program.

Comment: Several commenters recommended working with the hospital community to fine-tune the methodology for identifying underserved populations and to determine how they may impact hospitals across a diverse set of marginalized communities. A few commenters recommended working with relevant interested parties to create a standard framework and to implement consistent methodologies and risk factors for health equity adjustments across programs. A few commenters recommended that the HEA be utilized as a pilot before full implementation as it would allow for understanding potential impacts and identifying potential issues or challenges before going into full effect. A commenter recommended continuing to work to further optimize the use of reporting requirements and incentives to promote health equity.

Response: We thank commenters for their feedback. We note that the Hospital VBP Program's proposed methodology is similar to the Shared Savings Program's health equity adjustment and to the SNF VBP Program's health equity adjustment proposal. While some differences exist between these programs' methodologies due to the data available to each program and the structure of each program as dictated by their respective statutes, across all of these programs we have aimed to apply the same conceptual framework of rewarding excellent care in underserved populations, with an upside-only incentive approach to the greatest extent feasible for the applicable program, be it in terms of bonus points like the Hospital VBP Program or both bonus points and additional payments like the Shared Savings Program and proposal for the SNF VBP Program.

In regards to comments suggesting the health equity adjustment be implemented as a pilot, we refer readers to the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27045 through 27046) and section V.K.6.b.(5) of this final rule, where we presented the results of an impact analysis that simulated the proposed scoring methodology and provided an understanding of how hospitals will be impacted by the scoring change, as well as to show that the scoring change is feasible to implement across all hospitals participating in the Hospital VBP Program. Additionally, as noted in the proposed rule, this is a first step, and we expect the early years of this policy to effectively serve the purpose of piloting future health equity efforts in the program. We also note that we will monitor the impact of the adjustment and may, as necessary, consider modifications to the design of the adjustment through future notice and comment rulemaking. We agree with the commenter who recommended continuing to leverage reporting requirements and incentives to promote health equity. For example, in the FY 2023 IPPS/LTCH PPS final rule, we adopted the Screening for Social Drivers of Health measure in the Hospital IQR Program (87 FR 49202 through 49215). We welcome continued engagement with all interested parties on these efforts.

Comment: A commenter recommended focusing on a specific population for the performance evaluation in the future because evaluating performance only across dual eligible beneficiaries ensures that improvement efforts are focused on the population with the greatest risk factors.

Response: We thank the commenter for the feedback and will consider additional indicators for the underserved population in the future.

[293] Assistant Secretary for Planning and Evaluation. (2020) Social Risk and Performance in Medicare's Value-Based Purchasing Programs. Available at: *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195036/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report-3-Pager.pdf#:~:text=After%20accounting%20for%20additional%20social%20and%20functional%20risk,and%20resource%20use%20measures%20in%20Medicare%E2%80%99s%20VBP%20programs.*

[294] We note that the original, cited definition only stipulates, ''LGBTQ+'', however, HHS and the White House now recognize individuals who are intersex/have intersex traits. Therefore, we have updated the term to reflect these changes.

We believe that as a first step to incorporating a health equity adjustment in the Hospital VBP Program, the underserved multiplier adequately accounts for the patients with DES while the measure performance scaler accounts for overall quality such that if a large proportion of a hospital's patients with DES population is receiving low quality of care, then the health equity adjustment bonus points will appropriately decrease. The health equity adjustment was purposefully designed to not reward poor quality. Likewise, if the quality of care received by a hospital's underserved population is high, but the patients with DES represent only a small proportion of a hospital's total population, then the health equity adjustment will be lower.

Comment: A commenter recommended incentivizing primary care or ambulatory services as an equity lever as they believed that those settings would be better for prevention and management of chronic conditions.

Response: We agree on the importance of incentivizing health equity in not only the acute care setting, but also primary care and other ambulatory care settings. For example, the Shared Savings Program's Accountable Care Organizations are groups of doctors, hospitals, and other health care providers who collaborate to give coordinated high-quality care to people with Medicare. The Shared Savings Program recently adopted a health equity adjustment for Accountable Care Organizations that report all-payer electronic clinical quality measures (eCQMs)/Merit-based Incentive Payment System CQMs, are high-performing on quality, and serve a large proportion of underserved beneficiaries, as defined by dual-eligibility, enrollment in the Medicare Part D low income subsidy (LIS) (meaning the individual is enrolled in a Part D plan and receives LIS) and an ADI score of 85 or above, as detailed in the CY 2023 Physician Fee Schedule final rule (87 FR 69838 through 69857). In addition, in the CY 2023 Physician Fee Schedule final rule, the Merit-Based Incentive Payment System (MIPS) included four new health equity-related improvement activities (87 FR 70059 through 70060), expanded the definition of ''high priority measure'' in the Quality category to include health equity measures (87 FR 70047 through 70048), and added a new Quality measure called Screening for Social Drivers of Health (87 FR 70054 through 70055). We note that as outlined in section 1886(o)(1)(C)(i) of the Act, the Hospital VBP Program only applies to acute care hospitals that are paid under the IPPS.

Comment: A few commenters expressed concern around potential negative impacts including that a commenter believed that the proposed logistic multiplier will inadvertently negatively affect safety net and rural hospitals while inadvertently rewarding urban and non-safety net hospitals that were not receiving an incentive prior to the adjustment. A commenter expressed concern that the HEA may result in harm through reduced incentive payments to high-performing hospitals that do not serve high proportions of underserved patient populations.

Response: We do not believe that the logistic multiplier will negatively affect safety-net and rural hospitals given the results of the simulated impact analyses in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27045 through 27046) and in this final rule, which demonstrates that the increase in the number of hospitals receiving a bonus occurs primarily among safety net hospitals compared to non-safety net and resulted in the greatest gains among safety net hospitals and rural hospitals. Lastly, we do not believe that the scoring adjustment will result in harm to high-performing hospitals. The intent of the HEA is to incentivize high quality care among all patients in the hospital and to recognize the additional resources required to care for patients with DES.

Comment: A commenter expressed concern with utilizing overly complex scoring methods because they have been a challenge in getting hospitals to embrace data quality measurements in the past.

Response: We recognize that there is some inherent complexity in developing a new health equity scoring adjustment, however, we believe that hospitals will have time to adapt to the methodology given that the scoring change will not go into effect until the FY 2026 program year. As stated in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27042 through 27045) and this final rule, if a hospital, relative to other hospitals, is in the top or middle third of performance for any domain, they are eligible for measure performance scaler points. Additionally, if a hospital serves any proportion of patients with DES, they are eligible for the underserved multiplier. The HEA bonus points are then the product of the measure performance scaler and the underserved multiplier. The HEA bonus points are added to the total of hospital's four weighted domain scores before the TPS is calculated. A hospital that knows that they provide care for high proportions of patients with DES and performs well on any domains may anticipate a higher adjustment due to this addition to the program. We also reiterate that the HEA is intended to reward high quality performance and not solely adjust for a greater underserved patient population, which may leave lower performing hospitals with high proportions of patients with DES without any HEA bonus points. We do not intend to reward lower quality performance, and we believe that the current HEA incentivizes lower performing facilities to improve their quality scores. We will continue to provide regular outreach and education on the QualityNet website about this scoring methodology.

Comment: A commenter expressed concern that the Health Equity Adjustment points will not be true bonus points as they will be added to the existing points and contribute to how the pool is distributed.

Response: We disagree that the HEA points are not a true bonus because, as noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27045) and this final rule, we proposed to add the HEA bonus points before the TPS is calculated. Therefore, the bonus points can change the relative position of the hospital compared to other hospitals.

Comment: A commenter did not support the proposed HEA as they believed that it may result in having to calculate a new linear exchange function to determine the minimum TPS at which a hospital begins to earn a bonus. A few commenters requested clarification around the linear exchange function slope and whether it would be adjusted by the HEA bonus points. A commenter expressed concern that the program would no longer be budget neutral.

Response: As noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27045) and this final rule, we proposed to add the HEA bonus points before the TPS is calculated. Therefore, the linear exchange function slope remains unchanged and the Hospital VBP Program remains budget neutral because the bonus points are added to the total of the four weighted domain scores that we then sum to calculate the hospital's TPS.

Comment: Many commenters provided recommendations around the scoring methodology. Many commenters recommended sharing information on potential new indicators, such as geographic or socioeconomic indicators, and moving away from DES. A commenter recommended exploring the interaction between DES, ADI, and LIS variables as CMS continues to refine the HEA. Several commenters

recommended that CMS provide the logistic exchange function for the underserved multiplier. Several commenters recommended that CMS convene a technical expert panel from the hospital community to fine-tune the health equity adjustment methodology.

Response: We thank commenters for their recommendation. At this time, we believe that using DES data is an important first step for the health equity adjustment in the Hospital VBP Program, but we will consider these alternative indicators in future years. We have added the logistic exchange function used for calculating the underserved multiplier to this final rule in section V.K.6.b.(4). We appreciate this feedback from commenters, and we will explore convening a technical expert panel in future years.

Comment: Several commenters recommended that CMS provide additional information such as detailed specifications for proposed HEA bonus points, how payments will be redistributed once the HEA is accounted for, and how hospitals would perform on the HEA through confidential reports.

Response: We thank the commenters for their recommendations. We wish to clarify that the methodology for distributing payments will remain the same. As noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27045) and in this final rule, the HEA bonus points will be added before the TPS is calculated, and the linear exchange function slope remains unchanged.

Comment: A commenter recommended that the HEA be applied across the care delivery spectrum to ensure continuity of high-quality care. A commenter also recommended being consistent in the application of the HEA term and methodology, particularly for the use of indicators for underserved.

Response: We thank the commenters for their feedback, and we will explore avenues to increase consistency across programs in future years. We also wish to note that the Hospital VBP Program's proposed methodology is similar to the Shared Savings Program's health equity adjustment and to the SNF VBP Program's health equity adjustment proposal. The differences that exist between these programs' methodologies are due to the data available to each program and the structure of each program, which prevents further consistency across programs at this time.

Comment: A few commenters recommended accounting for differences that hospitals experience such as in budget and location, considering the realities that smaller health systems in rural areas face. A commenter expressed concern that the HEA may result in harm to high performing hospitals that do not serve a high proportion of the underserved patient population.

Response: We thank commenters for their recommendations. We reiterate that, on average, the HEA would not negatively impact safety net and rural hospitals. As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27045 through 27046) and in this final rule, the impact analysis demonstrates that the increase in the number of hospitals receiving a bonus occurs primarily among safety net hospitals compared to non-safety net and that the greatest gains resulted among safety net hospitals and rural hospitals. We will consider additional ways to support smaller hospitals in rural areas, but we believe that this policy is a crucial first step in providing more opportunities to smaller and rural hospitals. With regard to high performance, on average, the HEA would similarly not negatively impact high-performing hospitals. The intent of the HEA is to incentivize high quality care among all patients in the hospital and to recognize the additional resources required to care for patients with DES. Additionally, hospitals that are high performing have other opportunities to be rewarded for their quality care under the Hospital VBP Program's existing scoring methodology.

Comment: A commenter also recommended that CMS consider a peer grouping approach with regards to impacts on payments for providers with different shares of DES patients.

Response: We will take a peer grouping approach into consideration in future program years.

Comment: A commenter recommended that the measure performance scaler should exclude the Cost and Effectiveness Domain since the domain is further removed from quality of care.

Response: In our impact analyses, we assessed the impact of excluding the Cost and Effectiveness Domain, however, the results were negligible. While the impact is negligible for excluding the Cost and Effectiveness Domain as the domain exists at this time with the one MSPB Hospital measure, we will take the commenter's suggestion into consideration with regard to any future potential changes to the HEA methodology.

Comment: A few commenters recommended that CMS require standard practices for collecting and analyzing patient demographic data.

Response: We thank commenters for their response. We may consider the requirement of standard practices for demographic data collection and analysis in future program years. We would like to note ongoing effort to develop the United States Core Data for Interoperability (USCDI) and we look to align with developed electronic standards in the future.

After consideration of the public comments we received, we are finalizing this proposal as proposed with minor technical modifications to regulation text at 42 CFR 412.160 and 412.165(b).

(5) Impact Analysis of Scoring Methodology Change

In the FY 2024 IPPS/LTCH PPS proposed rule, we included a discussion of the analyses we conducted to simulate the proposed scoring methodology change for HEA bonus points in the Hospital VBP Program to assess the potential impact on hospitals and payments using FY 2023 program year data (88 FR 27045 through 27049). We also compared these impacts to the impacts of the existing scoring methodology, as well as a similar alternative that simulates only awarding 4 measure performance scaler points to the hospitals in the top third of performance for each domain, while hospitals in the middle and bottom third of performance received 0 measure performance scaler points. We modeled this alternative methodology to contextualize the request for additional information in section V.K.6.b.(7) of this final rule. The proposal and alternative method both included HEA bonus points comprised of the measure performance scaler and the underserved multiplier based on the hospital's proportion of patients who are dually eligible and their performance on existing Hospital VBP Program measures. For purposes of this simulation, we used the dual proportion data that were calculated using Medicare inpatient stays for the Hospital Readmissions Reduction Program FY 2023 performance period which included stays between June 1, 2018, to December 1, 2019, and July 1, 2020, to June 30, 2021.[295] A logistic

[295] We note that this calculation excludes Q1 and Q2 2020 data based on the ECE granted in response to the COVID–19 PHE and the policies finalized in the September 2, 2020 interim final rule with comment 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), we will exclude qualifying claims data from measure calculations for the following quarters: January 1, 2020, through March 31, 2020 (Q1 2020), and April 1, 2020, through June 30, 2020 (Q2 2020), that was

exchange function was then applied to the dual proportion. This analysis also used one-year base operating DRG payments for FY 2021 from October 1, 2020, to September 30, 2021, to calculate the bonus payments and penalties. Additionally, the TPS and quality domain scores data used in this analysis were calculated for the FY 2023 Hospital VBP Program. The proposal and alternative method both include a cap of 10 possible HEA bonus points. We note that while this simulation uses multi-year Hospital Readmissions Reduction Program data for the calculation of the dual proportion, we proposed to use dual proportion data from the calendar year two years ahead of the program year, as discussed in section V.K.6.b(2) of this final rule. The results of these analyses are outlined in this section and described further in Tables V.K.–16 and V.K.–17. Based on this initial modeling, the average TPS will increase with the addition of the HEA bonus points.

Our analysis finds that both the proposed and alternative HEA scoring options increase the number of hospitals getting a bonus compared to the existing scoring methodology. We note that these analyses show the percentage of hospitals gaining from the proposed health equity scoring change. Through these analyses, we found that the hospital-weighted average payment adjustment is positive even though the Hospital VBP Program remains budget neutral. The increase in the number of hospitals receiving a bonus occurs primarily among safety net hospitals compared to non-safety net. A hospital was considered a safety net hospital if it was in the top Disproportionate Share Hospital (DSH) quintile.

Table V.K.–16 provides the number of hospitals that received a bonus or penalty, respectively, along with the size of these bonuses and penalties. The third column in Table V.K.–16 shows the estimated impact of our proposed scoring methodology changes. Based on the analyses, the proposed methodology resulted in the greatest gains among safety net hospitals and rural hospitals, on average. The proposed methodology resulted in the largest percent of hospitals gaining from the HEA bonus overall, where gains are indicated by both greater bonus payments and smaller penalty payments, compared to the existing methodology. The mean payment adjustment was 0.20 percent compared to 0.18 percent.

The fourth column in Table V.K.–16 shows the estimated impact of an alternative method in which we only award 4 measure performance scaler points to the hospitals in the top third of performance for each domain, while hospitals in the middle and bottom third of performance received 0 measure performance scaler points. This produced the smallest number of hospitals gaining from the alternative health equity scoring adjustment among rural hospitals and among safety net hospitals. This produced a smaller number of hospitals gaining from the alternative health equity scoring adjustment among rural hospitals, among large hospitals, and among safety net hospitals relative to the proposed approach. This alternative method resulted in a similar mean payment adjustment of 0.20 percent as the proposed approach, while the program remains revenue neutral. For both the proposed and alternative approaches, the mean payment adjustment, as shown in Table V.K.–16, is larger than the mean payment adjustment for the existing scoring methodology.

Table V.K.–17 shows the percentage of hospitals who gained under the proposed and alternative methodologies. For purposes of discussion in this final rule and Table V.K.–17, ''Gaining'' is defined as receiving a larger bonus or smaller penalty under the proposed health equity adjustment compared to their bonus or penalty under the original methodology. In Table V.K.–17, we note that the percentage of hospitals that gain may be different than the percentage of hospitals that receive a bonus. This is because hospitals, even if they receive a penalty, can still gain from the health equity adjustment, if the penalty is smaller after the health equity adjustment.

We sought feedback on the alternative scoring method in section V.K.6.b.(7) of this final rule for future consideration.

voluntarily submitted for scoring purposes under the Hospital VBP Program.

TABLE V.K.-16 ESTIMATED BONUSES AND PENALTIES PER YEAR RESULTING FROM SCORING OPTIONS

Performance scoring methodology features	Existing scoring methodology	Proposal: HEA bonus points with performance scaler (0,2,4) and underserved multiplier	Alternative: HEA bonus points with performance scaler (0,0,4) and underserved multiplier*
Underserved multiplier	N/A	Logistic	Logistic
Capped	NA	Yes	Yes
Average Bonus	$3,738	$3,724	$3,886
Average Penalty	($3,980)	($4,246)	($4,424)
Bonus Hospitals (Count)	1,299	1,342	1,341
Safety net hospitals	195	241	232
Non-safety net	1,104	1,101	1,109
Urban	956	977	985
Rural	343	365	356
Penalty Hospitals (Count)	1,220	1,177	1,178
Safety net hospitals	285	239	248
Non-safety net	935	938	930
Urban	1,016	995	987
Rural	204	182	191
Average Payment Adjustment %	0.18%	0.20%	0.20%

* We are requesting feedback on the alternative scoring method in section V.K.6.b.(7) of this final rule.

TABLE V.K.-17 ESTIMATED HOSPITALS GAINING FROM THE HEA BONUS POINTS

Performance scoring features	Proposal: HEA bonus points with performance scaler (0,2,4) and underserved multiplier	Alternative: HEA bonus points with performance scaler (0,0,4) and underserved multiplier
Underserved multiplier	Logistic	Logistic
Capped	Yes	Yes
All hospitals	50.18%	41.37%
Location		
Urban	45.59%	36.00%
Rural	66.73%	60.69%
Bed size		
Bed size< 100	47.71%	49.36%
Bed size 100 – 499	51.72%	40.75%
Bed size 500+	46.76%	31.47%
Safety net status		
Safety net hospitals	86.88%	64.58%
Non-safety net	41.54%	35.90%

Based on the results of these analyses, we proposed to change the scoring methodology to award HEA bonus points (with a measure performance scaler of 0, 2, and 4 points) because this option allows more hospitals treating a large share of patients with DES to gain from the HEA bonus, particularly safety net hospitals. We believe that these bonuses offer an important first step in addressing health equity within the Hospital VBP Program. Safety net hospitals serve large proportions of patients with DES, and patients living in rural areas tend to experience worse health outcomes.[296] [297] Therefore, we believe that our proposal ensures that we are addressing performance gaps and incentivizing high-quality care in underserved populations compared to the existing scoring methodology.

In developing this scoring methodology change, we also explored alternative indicators for the underserved variable, such as an Area Deprivation Index (ADI) of 85 or greater, and enrollment in LIS. Identifying and prioritizing social risk or demographic variables to consider for measuring equity can be challenging. This is due to the high number of variables that have been identified in the literature as risk factors for poorer health outcomes and the limited availability of much of

[296] Sarkar, R.R., Courtney, P.T., Bachand, K., et al. (2020) Quality of care at safety-net hospitals and the impact on pay-for-performance reimbursement. *Cancer.* 126(20):4584–4592. doi: 10.1002/cncr.33137. PMID: 32780469.

[297] Health Resources and Services Administration. (2020) Rural Health Disparities. Available at: *https://www.hrsa.gov/sites/default/files/hrsa/advisory-committees/graduate-medical-edu/publications/cogme-rural-health-policy-brief.pdf.*

this data. Each source of data has advantages and disadvantages for identifying the most vulnerable populations to assess disparities. Income-based indicators are the most frequently used measures of vulnerability, but other indicators such as neighborhood level indicators can also provide important insights and are becoming more common in quality programs. There is research to support that geographic, neighborhood-level factors are associated with worse health outcomes for affected residents. The ADI is a demonstrated tool for assessing socioeconomic conditions based on geographic, neighborhood-level disadvantage.[298] [299] Specifically, living in an area with an ADI score of 85 or above is shown to be a predictor of 30-day readmission rates, lower rates of cancer survival, poor end-of-life care for patients with heart failure, and longer lengths of stay and fewer home discharges post-knee surgery even after accounting for individual social and economic risk factors.[300] [301] [302] [303] [304] Many rural areas also have relatively high levels of neighborhood disadvantage and high ADI levels. We believe that dual Medicare and Medicaid eligibility and ADI scores are both good indicators of patients with high needs. *Dual eligibility,* an indicator at the beneficiary level, is intended to capture socioeconomic challenges that could affect a patient's ability to access care, while ADI, a neighborhood-level indicator, is intended to capture local socioeconomic factors correlated with medical disparities and underservice. However, the ADI data are updated infrequently.[305] Additionally, to date, the ADI has not been extensively studied or widely used in value-based purchasing programs, and we do not collect patient level demographic level data for all measures that would allow us to use a neighborhood-level factors such as ADI in the Hospital VBP Program. However, we are considering using the ADI in the Hospital VBP Program in future years as data becomes more readily available through new measures in the Program to better align with other CMS programs such as the Shared Savings Program. ASPE recently conducted an environmental scan and concluded that while area-level indices can be beneficial, none of the existing area-level indices are ideal and should only be implemented in very specific circumstances.[306] Finally, as compared to DES, use of the proportion of patients that receive LIS under the Medicare Part D prescription drug program may capture a more consistent group of low-income patients as the eligibility criteria for LIS do not vary by state. However, we note that the Part D LIS has certain limitations as well. For example, individuals with DES or who receive Supplemental Security Income (SSI) automatically receive the LIS designation in CMS data systems. LIS designation means that the individual is enrolled in a Medicare Part D plan and receives the low-income subsidy. Individuals without DES or SSI status, but whose income is lower than 150 percent of the Federal poverty level and whose resources are limited, can qualify for LIS, but must apply. Additionally, LIS is not available in the U.S. territories. Most Medicare beneficiaries with the LIS designation are those who automatically receive this designation, rather than those who applied for the benefit and were approved. Nonetheless, despite this limitation, we agree that the use of the LIS designation, in addition to DES, is preferable to using DES alone, as doing so reduces variability across States. However, LIS is not available in the U.S. territories. Ultimately, we believe that using DES data is an important first step to introducing health equity adjustment bonus points in the Hospital VBP Program and will consider other indicators for the underserved multiplier in the future.

Comment: A commenter expressed concern that the impact analysis does not make a compelling case to indicate that the alternative methodology would be superior to what is proposed and recommended finalizing a methodology that is not overly complex and allows hospitals to have every opportunity to receive the maximum number of points.

Response: We thank the commenter for the feedback. We will not be finalizing the alternative methodology, and we believe that the proposed methodology that we are finalizing allows every hospital an opportunity to receive HEA bonus points. We recognize a level complexity with the methodology being adopted in this final rule and we will address this with education and outreach.

Comment: A commenter recommended that the average bonus under the proposed methodology should be higher than the stated amount because it is lower than the average under the existing methodology.

Response: We appreciate the commenter's concern. As noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27045 through 27048), the proposed methodology that we are finalizing resulted in the largest percent of hospitals gaining from the HEA bonus overall, where gains are indicated by both greater bonus payments and smaller penalty payments, compared to the existing methodology. We wish to clarify that although the percent of hospitals gaining is higher under the proposed methodology, the average bonus under the proposed methodology is lower than the average under the existing methodology because the hospitals that are not benefitting from the bonus are larger and are fewer in number, and thus have a greater impact on the average payments. The change in average bonuses and penalties is based on the changes in how many hospitals receive a bonus or penalty, the size of the bonus or penalty, and the size of the hospital. The impact analysis showed that the proposed methodology spreads

[298] Center for Health Disparities Research University of Wisconsin. (2022). Neighborhood Atlas. Available at: *https://www.neighborhoodatlas.medicine.wisc.edu/.*

[299] Maroko, A.R., Doan, T.M., Arno, P.S., Hubel, M., Yi, S., Viola, D. Integrating Social Determinants of Health With Treatment and Prevention: A New Tool to Assess Local Area Deprivation. Prev Chronic Dis 2016;13:160221. DOI: *https://dx.doi.org/10.5888/pcd13.160221.*

[300] Kind, A.J., Jenks, S., Brock, J., et al. (2014). Neighborhood socioeconomic disadvantage and 30-day rehospitalization: a retrospective cohort study. Annals of Internal Medicine. No. 161(11), pp 765–74, doi: 10.7326/M13-2946. Available at: *https://www.acpjournals.org/doi/epdf/10.7326/M13-2946.*

[301] Jencks, S.F., Schuster, A., Dougherty, G.B., et al. (2019). Safety-Net Hospitals, Neighborhood Disadvantage, and Readmissions Under Maryland's All-Payer Program. Annals of Internal Medicine. No. 171, pp 91–98, doi:10.7326/M16-2671. Available at: *https://www.acpjournals.org/doi/epdf/10.7326/M16-2671.*

[302] Cheng, E., Soulos, P.R., Irwin, M.L., et al. (2021). Neighborhood and Individual Socioeconomic Disadvantage and Survival Among Patients With Nonmetastatic Common Cancers.JAMA Network Open Oncology. No. 4(12), pp 1–17, doi: 10.1001/jamanetworkopen.2021.39593 Available at: *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2787244.*

[303] Hutchinson, R.N., Han, P.K.J, Lucas, F.L., Black, A., Sawyer, D., and Fairfield, K. (2022). Rural disparities in end-of-life care for patients with heart failure: Are they due to geography or socioeconomic disparity? The Journal of Rural Health. No. 38, pp 457–463, doi: 10.1111/jrh.12597 Available at: *https://onlinelibrary.wiley.com/doi/epdf/10.1111/jrh.12597.*

[304] Khlopas, A., Grits, D., Sax, O., et al. (2022). Neighborhood Socioeconomic Disadvantages Associated With Prolonged Lengths of Stay, Nonhome Discharges, and 90-Day Readmissions After Total Knee Arthroplasty. The Journal of Arthroplasty. No. 37(6), pp S37–S43, doi: 10.1016/j.arth.2022.01.032 Available at: *https://www.sciencedirect.com/science/article/pii/S0883540322000493.*

[305] Office of the Assistant Secretary for Planning and Evaluation, U.S. Department of Health & Human Services. First Report to Congress on Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program. 2016. *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf.*

[306] ASPE. (2022) Addressing Social Drivers of Health: Evaluating Area-level indices. Available at: *https://aspe.hhs.gov/sites/default/files/documents/474a62378abf941f20b3eaa74ca5721c/Area-level-Indices-ASPE-Reflections.pdf.*

the bonuses among more hospitals, with the largest hospitals having the lowest proportion of gaining compared to medium- and smaller-sized hospitals. The result is thus a lower average bonus under the proposed methodology despite that the percent of hospitals gaining is higher.

(6) Modification of the Total Performance Score (TPS) Maximum

The Hospital Inpatient VBP Program final rule finalized a methodology for assessing the total performance of each hospital based on its performance under the Hospital VBP Program with respect to a fiscal year (76 FR 26493 through 26494). Additionally, section 1886(o)(5)(A) of the Act provides the Secretary with the discretion to adopt a performance scoring methodology. Currently, the TPS is defined in our regulations as a numeric score ranging from 0 to 100. In the FY 2024 IPPS/LTCH PPS proposed rule, we proposed to modify the Total Performance Score (TPS) maximum to be 110, resulting in numeric score range of 0 to 110, beginning with the FY 2026 program year (FR 88 27049). A TPS maximum of 110 will allow for hospitals that have achieved top performance across all four domains to still be eligible to earn HEA bonus points. For example, if a hospital obtains a summed total of 100 weighted domain score points, that hospital could still receive up to 10 HEA bonus points, resulting in a maximum TPS of 110. We believe that modifying the TPS range will afford even top-performing hospitals the opportunity to receive up to an additional 10 HEA bonus points.

We also proposed to codify at 42 CFR 412.160, 412.162(b)(3), and 412.165(b)(6) of our regulations the new TPS numeric score range of 0 to 110. We believe that this policy will make it easier for interested parties to find these updated policies.

We invited public comment on this proposal.

Comment: Several commenters expressed their support for the proposal to modify the TPS numeric score range to be 0 to 110 because it allows for high performing hospitals to be eligible to earn HEA bonus points.

Response: We thank the commenters for their support and agree that the modification of the TPS range will allow high performing hospitals to be eligible to earn the HEA bonus points.

After consideration of the public comments we received, we are finalizing our policy as proposed with minor technical modifications at 42 CFR 412.160, 412.162(b)(3), and 412.165(b)(6).

(7) Request for Information on Potential Additional Changes to the Hospital VBP Program That Would Address Health Equity

As noted in the CMS National Quality Strategy, we are committed to addressing the disparities that underlie our health system, both within and across settings, to ensure equitable access and care for all.[307] We believe that the proposed scoring methodology embodies this commitment, but recognize it is only a first step.

Therefore, we welcomed public comment on the following:

- Should we consider using any of the previously detailed variables, ADI of greater than or equal to 85 and Medicare Part D LIS, in combination with or instead of DES? For example, should we use the higher of a few selected factors based on a hospital's inpatient population in a given program year, including: (1) the proportion of the hospital's patient population residing in a census block group with an ADI national percentile rank of at least 85 (or another threshold); (2) the proportion of the hospital's patients that are dually eligible for Medicare and Medicaid; or (3) the proportion of the hospital's patients receiving LIS? Should we consider patients with partial-dual eligibility in addition to full-dual eligibility? Are there additional variables we should consider using to identify populations that have been disadvantaged, marginalized, and/or underserved by the healthcare system?
- Should we consider other thresholds for scoring, such as using a quintile-based scoring approach whereby hospitals are awarded measure performance scaler points based on 5 levels of performance rather than 3? This would include awarding 0, 1, 2, 3, and 4, measure performance scaler points across the 5 levels from bottom to top performance, respectively, to allow for more nuance in the distribution of performance across each of the current four domains.
- In the future, we are considering further refining this scoring methodology change to only look at a hospital's quality performance on patients in the focus population (for example, patients with DES). We believe that this future potential refinement would more specifically address disparities in performance, and in turn, close equity gaps which would ultimately result in greater overall improvement for the entire hospital patient population. At this time, we collect patient-level data on the claims measures in the clinical domain and the MSPB measure, but not on all other measures in the Hospital VBP Program. Because we do not collect patient level demographic level data for all measures, it is difficult to use neighborhood-level indicators, such as the ADI, the measure level at this time. Therefore, we are instead proposing to use performance on existing measures for all eligible patients and thus welcome stakeholder feedback on for the Hospital VBP Program to assess patient-level data in the future.
- Should we use a linear scoring function or actual scoring for calculating the underserved multiplier instead of the proposed logistic exchange function as depicted in Figure V.K.–01 instead?
- Are there other approaches that the Hospital VBP Program could propose to adopt to effectively address healthcare disparities and advance health equity, such as the alternative methodology simulated in the analysis displayed in Tables V.K.–16 and V.K.–17? For example, should we only award measure performance scaler points to the top third of performance whereby a hospital in the middle and bottom thirds of performance would receive 0 performance scaler points, as simulated in the analysis? Alternatively, should we only provide measure performance scaler points to the Clinical, Safety, and Patient and Community Engagement Domains, excluding the Cost and Effectiveness Domain from performance scaler points?

We received many comments on this request for information, which are summarized in this section of this document:

Comment: Many commenters provided feedback on alternative underserved multiplier variables. Several commenters recommended incorporating the ADI or LIS alongside the proposed use of patients with DES because there are multiple ways to recognize the structural challenges that patients and hospitals face and a combination of these will be the most sensitive to capturing at-risk beneficiaries. A commenter noted that the concerns of administrative complexity relating to using more than one variable are outweighed by the potential to draw on multiple sources of information. Another commenter also recommended incorporating partial-dual eligible patients. Another commenter recommended that CMS ensure that underserved variables are not double counted and redundancies within social risk indices as the ADI are

[307] Centers for Medicare & Medicaid Services. (2022) CMS National Quality Strategy. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.*

accounted for. A commenter recommended considering the impact of states' decisions for Medicaid expansion versus non-expansion because states without expansion will have higher rates of uninsured individuals, anticipated delays in access to care, and higher healthcare costs over time.

A few commenters expressed concerns around the underserved multiplier alternatives including concerns that ignoring race or ethnicity underestimates adverse local factors and that only focusing on DES is problematic because of the differential expansion of Medicaid. A few commenters expressed concern around the ADI including that it is unclear how CMS would ensure a patient residence on file is accurate if incorporating the ADI into the calculation and that the ADI is heavily weighted towards income and home values with little contribution from other variables which masks inequities and underestimates vulnerabilities of neighborhoods. A commenter expressed concern that CMS is not considering other potential indices that would be better indicators of social needs.

Several commenters recommended underserved multiplier variables beyond ADI, DES, and LIS, including such alternatives as, a socioeconomic index, a formal designation for essential hospitals that could be applied to the HEA adjustment to more accurately identify hospitals serving marginalized populations, a stratification by patients' HRSN, an index using regression that is tuned for predictive strength, the social screening measure results from IQR, and a more tailored individual level health related social needs predictor that assesses the availability of ICD–10 Z-codes and may document individual social need factors. A commenter recommended that any social risk indices be weighted appropriately given that social risk has varying degrees of association with adverse events, and a commenter recommended aligning SDOH data items across care settings when future health equity quality measures are developed.

A few commenters also provided feedback on alternative thresholds for scoring including a few commenters recommending using quartiles or quintiles for performance scaler points to allow for greater diversity in the bonus points awarded to facilities. A commenter recommended considering whether institutions make improvement relative to where they started rather than which quintile or quartile, they are in by giving greater weight for improvement starting from a lower quintile than a similar improvement starting from a higher quintile.

Many commenters offered recommendations for alternative scoring methodologies. A commenter recommended excluding the Cost and Effectiveness Domain from the measure performance scaler because the data is not actionable. A few commenters made recommended stratification including stratifying results and prioritizing disparities in treatment rendered and stratifying results in a way that reflects both ''within-provider'' and ''across-provider'' assessments of the level of disparities in clinical processes and outcomes. Several commenters made additional recommendations including measuring performance of different measures within a domain as separate scores rather than a composite score for the domain, incorporating measure performance scaler points that incentivize hospitals to initiate service connections when a patient screens positive for HRSN, assigning greater weight to a local socioeconomic index and amount of uncompensated care, capturing indicators among beneficiaries for which there are currently limited person-level data available, and considering the portion of behavioral health patients treated because Medicare patients suffering from behavioral health issues represent some of the most vulnerable beneficiaries.

Several commenters made recommendations around improving data collection including creating a robust data collection system that identifies the social risk factors faced by patient populations, collecting demographic data, investing in strategies to improve more robust self-reporting of race and ethnicity data at point of service, working with the Office of the National Coordinator for Health Information Technology (ONC) to establish data exchange policies and infrastructure that allows access to electronic health record (EHR) data because private sector EHRs are successfully collecting demographic data with high volume and high levels of accuracy, and leveraging race and ethnicity data collected by NHIS, MEPS, and the 2020 Census to address gaps in the current data pool.

Several commenters made other recommendations including adopting health equity standards that could be used across medicine, aligning with the Hospital IQR Program's health equity measure, working with hospital stakeholders to better understand how hospitals are identifying health inequities in their communities to better inform agency's approach, prioritizing existing quality measures with identified disparity in treatment or outcomes, providing more staff education to increase awareness and understanding of social risk factors including better documentation of Z-codes, and continuously evaluating and adapting to reduce disparities and improve health equity. Several commenters recommended other considerations such as exploring if social risk factors should be added to the measures used in HVBP, including public reporting of stratified measure alongside overall measures in a meaningful and transparent way, considering hospital characteristics for equity in hospital scoring, considering various dimensions that influence inequities, and exploring new incentives to encourage providers to work with non-traditional healthcare workers to help address SDOH.

A few commenters made recommendations around the clarity of the scoring calculations, recommending transparent and interpretable definitions and algorithms with an opportunity for patients and communities to understand how it is impacting their care.

Response: We appreciate the comments and suggestions we have received. While we will not be responding to specific comments submitted in response to this request for information, we believe that this input is valuable in our efforts to continue to promote health equity in the Hospital VBP Program. We may consider these suggestions in future rulemaking.

c. Domain Weighting for Hospitals That Receive a Score on All Domains

In the FY 2018 IPPS/LTCH PPS final rule (82 FR 38265 through 38266), we finalized our proposal to retain the equal weight of 25 percent for each of the four domains in the Hospital VBP Program for the FY 2020 program year and subsequent years for hospitals that receive a score in all domains.

In the FY 2024 IPPS/LTCH PPS proposed rule, we did not propose any changes to these domain weights (88 FR 27050).

d. Domain Weighting for Hospitals Receiving Scores on Fewer Than Four Domains

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50084 through 50085), we adopted a policy that hospitals must receive domain scores on at least three of four quality domains to receive a TPS, for the FY 2017 program year and subsequent years. Hospitals with sufficient data on only three domains will have their TPSs proportionately

reweighted (79 FR 50084 through 50085).

In the FY 2024 IPPS/LTCH PPS proposed rule, we did not propose any changes to these domain weights (88 FR 27050).

e. Minimum Numbers of Measures for Hospital VBP Program Domains

We refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266) for our previously finalized requirements for the minimum numbers of measures for hospitals to receive domain scores.

In the FY 2024 IPPS/LTCH PPS proposed rule, we did not propose any changes to these policies (88 FR 27050).

f. Minimum Numbers of Cases for Hospital VBP Program Measures

(1) Background

Section 1886(o)(1)(C)(ii)(IV) of the Act requires the Secretary to exclude for the fiscal year hospitals that do not report a minimum number (as determined by the Secretary) of cases for the measures that apply to the hospital for the performance period for the fiscal year. For additional discussion of the previously finalized minimum numbers of cases for measures under the Hospital VBP Program, we refer readers to the Hospital Inpatient VBP Program final rule (76 FR 26527 through 26531); the CY 2012 OPPS/ASC final rule (76 FR 74532 through 74534); the FY 2013 IPPS/LTCH PPS final rule (77 FR 53608 through 53610); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50085 through 50086); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49570); and the FY 2018 IPPS/LTCH PPS final rule (82 FR 38266 through 38267).

(2) Summary of Previously Adopted and Newly Established Minimum Numbers of Cases

The previously adopted minimum numbers of cases for the Hospital VBP Program measures are set forth in Table V.K.–18. Table V.K.–18 also sets forth the proposed minimum number of cases for the proposed Severe Sepsis and Septic Shock: Management Bundle measure beginning with the FY 2026 program year. For the proposed updates to MSPB Hospital measure and the proposed THA/TKA Complications measure, we proposed to maintain the same minimum number of cases as the current measures.

We proposed to codify at 42 CFR 412.165(a)(1)(i) these minimum numbers of cases. We believe that this proposal will make it easier for interested parties to find these policies.

TABLE V.K.-18: PREVIOUSLY ADOPTED AND NEWLY ESTABLISHED MINIMUM CASE NUMBER REQUIREMENTS FOR HOSPITAL VBP PROGRAM

Measure Short Name	Minimum Number of Cases
Person and Community Engagement Domain	
HCAHPS	Hospitals must report a minimum number of 100 completed HCAHPS surveys.
Clinical Outcomes Domain	
MORT-30-AMI	Hospitals must report a minimum number of 25 cases.
MORT-30-HF	Hospitals must report a minimum number of 25 cases.
MORT-30-PN (updated cohort)	Hospitals must report a minimum number of 25 cases.
MORT-30-COPD	Hospitals must report a minimum number of 25 cases.
MORT-30-CABG	Hospitals must report a minimum number of 25 cases.
COMP-HIP-KNEE	Hospitals must report a minimum number of 25 cases.
Safety Domain	
CAUTI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CLABSI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
Colon and Abdominal Hysterectomy SSI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
MRSA Bacteremia	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CDI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
SEP-1*	Hospitals must report a minimum number of 25 cases.
Efficiency and Cost Reduction Domain	
MSPB	Hospitals must report a minimum number of 25 cases.

*In section V.K.3.a of the preamble of this final rule, we proposed to adopt the Severe Sepsis and Septic Shock: Management Bundle measure beginning with the FY 2026 program year.

We invited comment on these proposals.

We received no comments on this proposal and are finalizing this provision without modification.

7. Extraordinary Circumstance Exception (ECE) Policy for the Hospital VBP Program

We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45298 through 45299) and 42 CFR 412.165(c) for additional details related to the Hospital VBP Program ECE policy.

In the FY 2024 IPPS/LTCH PPS proposed rule, we did not propose any changes to the Hospital VBP Program ECE policy (88 FR 27051).

L. Hospital-Acquired Condition (HAC) Reduction Program

1. Regulatory Background

We refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50708) for a general overview of the HAC Reduction Program and to the same final rule (78 FR 50708 through 50709) for a detailed discussion of the statutory basis for the Program. For additional descriptions of our previously finalized policies for the HAC Reduction Program, we also refer readers to the following final rules:

- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50707 through 50729).
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50087 through 50104).
- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49570 through 49581).
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57011 through 57026).
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38269 through 38278).
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41472 through 41492).
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42402 through 42411).

- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58860 through 58865).
- The FY 2022 IPPS/LTCH PPS final rule (86 FR 45300 through 45310).
- The FY 2023 IPPS/LTCH PPS final rule (87 FR 49120 through 49138).

We have also codified certain requirements of the HAC Reduction Program at 42 CFR 412.170 through 412.172.

2. Measures for FY 2024 and Subsequent Years in the HAC Reduction Program

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41472 through 41474) for more information about how the HAC Reduction Program supports our goal of bringing quality measurement, transparency, and improvement together with value-based purchasing to the hospital inpatient care setting through the Meaningful Measures Framework and Meaningful Measures 2.0.[308]

a. Current Measures

The HAC Reduction Program has adopted six measures to date. In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50717), we finalized the use of five Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) hospital-associated infection (HAI) measures: (1) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure; (2) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure; (3) Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure; (4) Colon and Abdominal Hysterectomy Surgical Site Infection (SSI) Outcome Measure; and (5) Facility-wide Inpatient Hospital-onset Methicillin-resistant F;*Staphylococcus aureus* (MRSA) bacteremia Outcome Measure. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57014), we finalized the use of the CMS PSI 90 measure. These previously finalized measures are shown in table IX.L.–01.[309]

TABLE IX.L.-01: HAC REDUCTION PROGRAM MEASURES FOR FY 2024 AND SUBSEQUENT YEARS

HAC Reduction Program Measures for FY 2024 and Subsequent Years		
Short Name	**Measure Name**	**CBE[309] #**
CMS PSI 90	CMS Patient Safety and Adverse Events Composite (CMS PSI 90)	0531
CAUTI	CDC NHSN Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure	0138
CDI	CDC NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure	1717
CLABSI	CDC NHSN Central Line-Associated Bloodstream Infection (CLABSI) Outcome Measure	0139
Colon and Abdominal Hysterectomy SSI	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure	0753
MRSA Bacteremia	CDC NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure	1716

Technical specifications for the CMS PSI 90 measure can be found on the QualityNet website available at: *https://qualitynet.cms.gov/inpatient/measures/psi/resources*. Technical specifications for the CDC NHSN HAI measures can be found at the CDC's NHSN website at *https://www.cdc.gov/nhsn/acute-care-hospital/index.html* and on the QualityNet website available at: *https://qualitynet.cms.gov/inpatient/measures/hai/resources*. These three web pages provide measure updates and other information necessary to guide hospitals participating in the collection of HAC Reduction Program data.

We did not propose to add or remove any measures from the HAC Reduction Program.

b. Measure Removal Factors Policy

We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42404 through 42406) for information about our measure removal and retention factors for the HAC Reduction Program. We did not propose any measure removal and retention factor policy changes.

3. Maintenance of Technical Specifications for Quality Measures in the HAC Reduction Program

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50100 through 50101), we adopted a process that allows us to expeditiously incorporate technical measure specification updates while preserving the public's ability to comment upon updates that fundamentally change a measure. In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49133 through 49134), we adjusted the minimum threshold criteria for the CMS PSI 90 measure beginning in the FY 2023 program year, requiring hospitals to have one or more component PSI measures with at least 25 eligible discharges and seven or more component PSI measures with at least three eligible discharges to receive a CMS PSI 90 composite score. We also announced a technical measure specification update to the CMS PSI 90 software to include COVID–19 diagnosis as a risk adjustment parameter beginning with the FY 2024 program year, to address the impact of COVID–19 hospitalized individuals on the CMS PSI 90 measure. We note the COVID–19 public health emergency ended on May 11, 2023.[310]

We did not propose any changes to these policies.

4. Advancing Patient Safety in the HAC Reduction Program—Request for Comment

As discussed in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50708), the intent of the HAC Reduction Program is to encourage all hospitals to reduce the incidence of hospital-acquired conditions. According to the CDC 2021 National and State Healthcare-Associated Infection Progress Report, rates of CLABSI, CAUTI, and MRSA bacteremia increased between 2020 and

[308] Centers for Medicare & Medicaid Services. (2022) Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization*.

[309] In previous years, we referred to the consensus-based entity by corporate name. We have updated this language to refer to the consensus-based entity more generally.

[310] The White House. (2023) Notice of the Continuation of the National Emergency Concerning the Coronavirus Disease 2019 (COVID–19) Pandemic. Available at: *https://www.whitehouse.gov/briefing-room/presidential-actions/2023/02/10/notice-on-the-continuation-of-the-national-emergency-concerning-the-coronavirus-disease-2019-covid-19-pandemic-3/*.

2021, by 7 percent, 5 percent, and 14 percent respectively.[311] HAI standard infection ratios for these three measures were notably higher than pre-COVID–19 pandemic levels, indicating continued room for improvement to reduce the incidence of hospital-acquired conditions nationwide.[312] The HAC Reduction Program's efforts to reduce hospital-acquired conditions are vital to improving patients' quality of care and reducing complications and mortality, while simultaneously decreasing costs. The reduction of hospital-acquired conditions is an important marker of quality of care and has a positive impact on both patient outcomes and cost of care. Moreover, the HAC Reduction Program has an opportunity to advance both healthcare safety and equity by encouraging participating hospitals to further focus their improvement efforts on eliminating disparities that exist in the rate and severity of hospital-acquired conditions among different patient populations. According to a 2021 study conducted by the Urban Institute, Black patients experienced worse quality of care in 6 out of 11 patient safety indicators relative to White patients in 2017 across 26 states.[313] We aim to have the HAC Reduction Program advance the CMS National Quality Strategy goals of improving health equity by addressing underlying disparities in our health system and promoting safety by preventing harm or death from health care errors.[314] Further, we also seek to align with the HHS-led National Healthcare System Action Alliance to Advance Patient Safety and its priority of establishing and sustaining a strong culture of safety in a way that is equitable and engaging of patients, families, care partners, and the health care workforce.[315] [316]

We are conducting a review of the patient safety and healthcare-associated infection measures and the scoring and weighting methodology, as part of our ongoing efforts to evaluate and strengthen the HAC Reduction Program. As we did in the FY 2018 IPPS/LTCH PPS proposed rule (82 FR 19986 through 19990), the FY 2019 IPPS/LTCH PPS proposed rule (83 FR 20437), and the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28452), we sought input from interested parties on the addition of new program measures. We seek to adopt patient safety focused electronic clinical quality measures (eCQMs) to strengthen the growing portfolio of eCQMs and promote further alignment across quality reporting and value-based purchasing programs.

Adoption of eCQMs in the HAC Reduction Program supports the CMS Meaningful Measures 2.0 priority to move fully to digital quality measurement. In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49136), we described the Request for Comment (RFC) on the potential future adoption of the digital NHSN Healthcare-associated *Clostridioides difficile* Infection Outcome measure and the digital NHSN Hospital-Onset Bacteremia (HOB) & Fungemia Outcome measure. We received public input in support of the adoption of these two eCQMs. However, a few commenters stated concern regarding baseline data testing, measure definitions, and the risk adjustment methodology for both eCQMs. In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27052), we sought feedback on potentially adopting patient safety related eCQMs which are currently used in the Hospital Inpatient Quality Reporting (IQR) Program, including: Hospital Harm—Opioid-Related Adverse Events eCQM, Hospital Harm-Severe Hypoglycemia eCQM, and Hospital Harm-Severe Hyperglycemia eCQM. In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49233), the Hospital IQR Program adopted the Hospital Harm—Opioid-Related Adverse Events eCQM and in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45382), the Hospital IQR Program adopted the Hospital Harm-Severe Hypoglycemia eCQM and Hospital Harm-Severe Hyperglycemia eCQM. In sections IX.C.5.a and IX.C.5.b of this final rule, the Hospital IQR Program is finalizing the adoption of three additional eCQMs, which we sought input on for inclusion in the HAC Reduction Program, including: Hospital Harm-Acute Kidney Injury eCQM, Hospital Harm-Pressure Injury eCQM, and Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computer Tomography in Adults eCQM. We believe adoption of hospital harm eCQMs would address two high priority areas including safety and adopting outcome eCQMs. In addition, as part of our commitment to patient safety, we are developing new digital quality measures that use data from hospital electronic health records that would assess various aspects of patient safety in the inpatient care setting. We invited public comment on the adoption of these six eCQMs in the HAC Reduction Program.

Our longstanding policy is that, to the extent practicable, HAC Reduction Program measures should be nationally endorsed by a multi-stakeholder organization. Measures should be aligned with best practices among other payers and the needs of the end users of the measures. Measures should consider widely accepted criteria established in medical literature.

We invited public comment on potential future measures as well as on how the HAC Reduction Program can further promote patient safety. Specifically, we invited comment on:

- What measures should be introduced in the HAC Reduction Program to address emerging high priority patient harm events and healthcare-associated infections?
- What measures should be introduced in the HAC Reduction Program to address equity gaps in the rate and severity of patient harm events and healthcare-associated infections?
- How can weighting and scoring methods be improved to better assess hospital performance and promote equity in the HAC Reduction Program payment assessments?
- How can the HAC Reduction Program be strengthened to encourage patient safety best practices, which also prioritize the delivery of equitable care, in inpatient facilities?

Comment: Several commenters recommended that new measures be introduced in the HAC Reduction Program that address medication safety related adverse events, procedure or surgery related adverse events, and SSIs. Many commenters suggested the adoption of a hospital-onset COVID–19 measure in the HAC Reduction Program,

[311] Centers for Disease Control and Prevention. (2022) Current HAI Progress Report. Available at: *https://www.cdc.gov/hai/data/portal/progress-report.html#2018*.

[312] Lastinger, L., Alvarez, C., Kofman, A., Konnor, R., Kuhar, D., Nkwata, A., . . . Dudeck, M. (2022). Continued increases in the incidence of healthcare-associated infection (HAI) during the second year of the coronavirus disease 2019 (COVID–19) pandemic. Infection Control & Hospital Epidemiology, 1–5. doi:10.1017/ice.2022.116.

[313] Gangopadhyaya, Anuj. (2021) Black patients are more likely than white patients to be in hospitals with worse patient safety conditions. Urban Institute. Available at: *https://www.urban.org/sites/default/files/publication/103925/black-patients-are-more-likely-than-white-patients-to-be-in-hospitals-with-worse-patient-safety-conditions.pdf*.

[314] Centers for Medicare & Medicaid Services. (2022) What is the CMS National Quality Strategy? Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*.

[315] Agency for Healthcare Research and Quality. (2022) The National Healthcare System Action Alliance to Advance Patient Safety. Available at: *https://www.ahrq.gov/cpi/about/otherwebsites/action-alliance.html*.

[316] National Steering Committee for Patient Safety. (2020) Safer Together: A National Action Plan to Advance Patient Safety. Boston, Massachusetts: Institute for Healthcare Improvement. Available at: *www.ihi.org/SafetyActionPlan*.

defined as infections diagnosed after five days of admission or greater. Several commenters also recommended the adoption of a HOB measure with a blood culture contamination benchmark of less than one percent. Many commenters expressed support for the potential future adoption in the HAC Reduction Program of the three hospital harm and patient safety eCQMs that are currently in the Hospital IQR Program—Opioid-Related Adverse Events, Severe Hypoglycemia, and Severe Hyperglycemia eCQMs—and the three patient safety related eCQMs that were proposed in the Hospital IQR Program in the FY 2024 IPPS/LTCH PPS proposed rule—Acute Kidney Injury, Pressure Injury, and Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computer Tomography in Adults eCQMs—for the HAC Reduction Program.

Many commenters did not support the future adoption of the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computer Tomography in Adults eCQM expressing concern about the metrics, calculation methods, and software used for the measure. Many commenters did not support the addition of new measures, specifically eCQMs, and expressed concern about receiving timely, actionable performance feedback and stated concern about the burden and cost associated with implementing eCQMs. Several commenters recommended CMS thoroughly review, test, and first adopt eCQMs in the Hospital IQR Program before adoption in the HAC Reduction Program. Several commenters recommended standardizing the health equity methods across quality reporting and value-based purchasing programs and to adjust measures for patients who are dually eligible for Medicare and Medicaid. A few commenters recommended peer grouping hospitals by size and hospital characteristics for better performance comparisons. Several commenters recommended stratifying measures by Medicaid eligibility and social risk factors for equitable comparisons and to mitigate overly penalizing hospitals that serve disproportionately impacted populations.

Response: We thank commenters for their feedback on the potential future measures to include in the HAC Reduction Program. We also appreciate commenters' feedback on potential program modifications to encourage equitable care, reduce administrative and provider burden, and promote patient safety. We will consider all input and note that any future proposal to implement a new measure or program modification would be announced through future notice-and comment rulemaking.

5. HAC Reduction Program Scoring Methodology and Scoring Review and Corrections Period

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41484), we clarified the Scoring Calculations Review and Correction Period for the HAC Reduction Program. Hospitals must register and submit quality data through the Hospital Quality Reporting (HQR) System (previously referred to as the QualityNet Secure Portal) in order to access their annual hospital-specific reports. The HQR System is safeguarded in accordance with the HIPAA Privacy and Security Rules to protect submitted patient information. See 45 CFR parts 160 and 164, subparts A, C, and E.

We did not propose any changes to the Scoring Calculations Review and Correction Period process.

6. Validation of HAC Reduction Program Data

We previously adopted data validation policies for the CDC NHSN HAI measures in the HAC Reduction Program in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41478 through 41484). Since then, we have continued to update the validation policies. We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42406 through 42410), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58862 through 58865), and the FY 2023 IPPS/LTCH PPS final rule (87 FR 49137 through 49138) for detailed information on the HAC Reduction Program data validation processes.

a. Validation Reconsideration Beginning With the FY 2025 Program Year

(1) Background

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41480) and FY 2020 IPPS/LTCH final rule (84 FR 42407), we finalized annual random selection of up to 200 hospitals for inpatient validation, and the annual targeted selection of up to 200 hospitals using the following targeting criteria:

- Any hospital that failed validation the previous year;
- Any hospital that submits data to NHSN after the HAC Reduction Program data submission deadline has passed;
- Any hospital that has not been randomly selected for validation in the past 3 years;
- Any hospital that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent; and
- Any hospital which failed to report to NHSN at least half of actual HAI events detected as determined during the previous year's validation effort.

As discussed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41480), under the current policies, once we validate all quarters of the relevant fiscal year, we calculate a total score reflecting a hospital's reporting accuracy for the HAI measures used within the HAC Reduction Program. The calculated total score is then utilized to compute a confidence interval with the consideration of the results from the educational review process. If the estimated reliability upper bound (ERUB) of the confidence interval is 75 percent or higher, the hospital will pass the HAC Reduction Program validation requirement; if the ERUB is below 75 percent, the hospital will fail the HAC Reduction Program validation requirement.

As described in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41481 through 41482), a hospital that fails validation (that is, their ERUB is below the 75 percent threshold) is assigned the maximum Winsorized *z*-scores only for the set of measures validated. For example, if a hospital were selected on CLABSI, CAUTI, and SSI, and failed validation, that hospital would receive the maximum Winsorized *z*-scores (that is, the worst score) for CLABSI, CAUTI, and SSI. We did not propose any changes to these processes.

(2) Adopt a Validation Reconsideration Process

In the FY 2024 IPPS/LTCH PPS proposed rule, we proposed to add a validation reconsideration process to the HAC Reduction Program, giving hospitals the opportunity to request reconsideration of their final validation scores (88 FR 27054 through 27055). Prior to establishing administrative policies for the HAC Reduction Program to collect, validate, and publicly report quality measure data independently instead of conducting these activities through the Hospital IQR Program, as finalized in FY 2019 IPPS/LTCH PPS final rule (83 FR 41475 through 41484), hospitals that failed their Annual Payment Update (APU) requirement related to validation of certain Hospital IQR Program measures, which included but was not limited to HAI measures, had the opportunity to request reconsideration of their final validation scores for the HAI measures. We intend for the HAC Reduction Program's reconsideration processes to be similar to the current validation reconsideration processes of the Hospital IQR Program, which hospitals are familiar with. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 through

51651) for further detail on the Hospital IQR Program validation reconsideration process. Beginning with the FY 2025 program year (affecting calendar year 2022 discharges), we proposed to allow hospitals that fail validation to request reconsideration of their validation results before use in HAC Reduction Program scoring calculations. The validation reconsideration process will be conducted once per program fiscal year after the validation of HAIs for all four quarters of the relevant fiscal year's data period and after the confidence interval has been calculated.[317]

The process will complement the quarterly educational reviews that are currently available to hospitals. The adoption of a reconsideration process for the HAC Reduction Program aligns data validation processes with the Hospital IQR Program reconsideration process, which hospitals are familiar with. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41480 through 41481) for more details on the HAC Reduction Program educational review process.

(a) Notification of Validation Results and Request for Reconsideration Process

Once we calculate the confidence intervals for validation total scores, we proposed to notify a hospital that failed the HAC Reduction Program validation requirement for the CDC NHSN HAI measures via a notification letter sent by certified mail. The letter will instruct a hospital on how to submit a request for reconsideration to CMS. A hospital requesting validation reconsideration must submit a reconsideration request form within 30 days from the date stated on the notification letter. The form for submitting a reconsideration request and a detailed description of the reconsideration process will be available on the QualityNet website. A hospital's request for validation reconsideration must include, among other things:

- Basis for requesting reconsideration—identifying specific reason(s) for why the hospital believes it met the HAC Reduction Program validation requirements.
- All documentation and evidence that supports the hospital's request for reconsideration.

We will provide hospitals an email acknowledgement, following receipt of a request for validation reconsideration, using the contact information provided in the validation reconsideration request. We will also provide written notification of the formal decision regarding the reconsideration request to the hospital contact(s) listed on the validation reconsideration form. We anticipate that the reconsideration process may take approximately 90 days from the receipt of the reconsideration request.

Only hospitals that fail to meet the passing threshold for the end-of-year confidence interval calculation will receive an opportunity to request reconsideration of their validation results. The scope of the proposed reconsideration parallels the scope used within the Hospital IQR Program reconsideration process:

- If the hospital requests reconsideration for CMS contractor-abstracted data elements classified as mismatches affecting validation scores, hospitals must submit a copy of the entire requested medical record to CMS during the initial validation process (not during reconsideration) by the 30-day deadline date indicated on the notification letter for the requested case to be eligible to be reconsidered on the basis of mismatched data elements.
- On occasion, a hospital requests reconsideration for medical record copies submitted during the initial validation process and classified as invalid record selections. Such invalid record selections are defined as medical records submitted by hospitals during the initial validation process that do not match the patient's episode of care information as determined by CMS (in other words, CMS determines that the hospital returned a medical record that is different from that which was requested). For more information about inpatient validation case statuses, we refer readers to the CMS Inpatient Data Validation Case Status Details for Validated Results on the QualityNet website available at *https://qualitynet.cms.gov/inpatient/data-management/data-validation/resources*. If we determine that the hospital has submitted an invalid record selection case, it will be awarded a zero validation score for the case because the hospital did not submit the entire copy of the medical record for that requested case. During the reconsideration process, our review of invalid record selections would be limited to determining whether the record submitted was actually an entire copy of the requested medical record. If we determine during reconsideration that the hospital did submit the entire copy of the requested medical record, then we would re-abstract data elements from the medical record submitted by the hospital.
- If the hospital requests reconsideration for medical records not submitted within the 30-day deadline of the initial validation process, our review would initially be limited to determining whether we received the requested record within 30 calendar days of the initial validation process. If we determined during reconsideration that we did receive a copy of the requested medical record within 30 calendar days, then we will abstract data elements from the medical record submitted by the hospital. This proposed policy is also designed to address those instances where the hospital's request is based on invalid record selections, which are defined as medical records submitted during the initial validation process that do not match the patient's episode of care information as determined by CMS, as previously discussed.

In summary, similar to the validation reconsideration process under the Hospital IQR Program, we will limit the scope of our HAC Reduction Program data validation reconsideration reviews to information already submitted by the hospital during the initial validation process, and we will not abstract medical records that were not submitted during the initial validation process. We will expand the scope of our review only if we found during the review that the hospital correctly and timely submitted the requested medical records. In that case, we will abstract data elements from the medical record submitted by the hospital as part of our review of its reconsideration request. After the reconsideration process is complete, we will re-calculate a hospital's confidence interval based on the results of the reconsideration of the hospital's cases and determine whether the hospital passed or failed validation requirements for the HAC Reduction Program. Those results will then be used for HAC Reduction Program scoring, as detailed in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41485 through 41489). The updated validation results could impact a hospital's payment adjustments. If a hospital still fails validation after receiving updated validation results, we will assign the maximum Winsorized *z*-score for the three measures CMS validated. If a hospital passes validation after the reconsideration process, their SIRs for the measures validated will be their measure results in the HAC Reduction Program scoring calculations process. As described in § 412.172(b) and (e)(2), hospitals in the worst performing quartile, that is the 25 percent of hospitals with the highest Total HAC

[317] To clarify, the validation reconsideration process would be conducted after validation of HAIs for all four quarters of the first year of the program's performance period and after the confidence interval has been calculated.

Scores, are subject to a 1-percent payment reduction under the HAC Reduction Program. We noted in the proposed rule that the HAC Reduction Program reconsideration process would be limited to reconsideration as to the data validation requirements of the program. We did not propose a reconsideration process as to any other program requirements, including measure calculations, scoring, or determination of payment reductions not related to data validation. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41484) where we discuss our policies related to the Scoring Review and Corrections Period for hospitals that may have questions about their Total HAC Score calculations.

We invited public comment on this proposal.

Comment: Several commenters supported the proposal to establish a reconsideration process for data validation. A few commenters supported the proposal because it would provide hospitals an opportunity to request further review of mismatches between reported data and medical record information that were identified during the validation process and that may result in failing data validation and receiving the worst possible scores for the measures validated.

Response: We thank the commenters for their support.

Comment: A commenter questioned whether a hospital could file an appeal with the Provider Reimbursement Review Board (PRRB) and the potential options if it is dissatisfied with the reconsideration determination.

Response: We appreciate the commenter's question on the options for hospitals to appeal their validation results. Hospitals will not have the option to file an appeal with the PRRB if it is dissatisfied with the reconsideration determination. We refer the commenter to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41480) where we finalized the Educational Review Process in which hospitals selected for validation would have a 30-day period following the receipt of quarterly validation results to seek educational review. During this 30-day period, hospitals may review, seek clarification, and potentially identify a CMS validation error. Additionally, hospitals may request reconsideration of their validation results as described in section X.X. of this final rule. We believe that both the educational review and the reconsideration processes provide hospitals with multiple avenues to request review of their validation results.

After consideration of the public comments we received, we are finalizing our proposal to establish a validation reconsideration process in the HAC Reduction Program beginning with the FY 2025 program year as proposed.

(3) Update the Targeting Criteria for Hospitals Granted an Extraordinary Circumstances Exception (ECE)

As proposed in the Hospital IQR Program as discussed in section IX.C.11.b of this final rule, we proposed to update our targeting criteria for validation of hospitals granted an extraordinary circumstances exception (ECE) in the HAC Reduction Program (88 FR 27055). Specifically, we proposed to modify the validation targeting criteria to include any hospital with a ERUB of the two-tailed confidence interval that is less than 75 percent and received an extraordinary circumstances exception (ECE) for one or more quarters beginning with the FY 2027 program year, affecting validation of calendar year 2024 discharges.

We proposed to add a new criterion to the five established targeting criteria used to select the up to 200 additional hospitals. We proposed that a hospital subject to validation that received an extraordinary circumstance exception (ECE) for one or more quarters for the data period validated and has a ERUB of the two-tailed confidence interval that is less than 75 percent would be targeted for validation in the subsequent validation year and would not fail data validation in the HAC Reduction Program. The hospital will not receive the penalty of the maximum Winsorized *z*-scores, the worst scores, for measures validated. This exception will not except a hospital from participation in the HAC Reduction Program, and the hospital will still receive a Total HAC Score. We refer readers to the previously established program scoring methodology in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41485). We believe this additional criterion will promote alignment with the Hospital IQR Program. Hospitals that meet this criterion will be required to submit medical records to CMS within 30 days of the date identified on the written request as finalized in the Hospital IQR Program in FY 2017 IPPS/LTCH PPS final rule (81 FR 57179 and 57180) and in the HAC Reduction Program in FY 2019 Rule IPPS/LTCH PPS final rule (83 FR 41482).

It is important to clarify that, consistent with our previously finalized policy, a hospital is subject to both the maximum Winsorized *z*-scores penalty and targeting for validation in the subsequent year if it does not have an ECE for one or more quarters and does not meet the 75 percent threshold.

Specifically, we proposed to add the following criterion for targeting up to 200 additional hospitals for validation: any hospital with a two-tailed confidence interval that is less than 75 percent, and received an ECE for one or more quarters for the data period validated.

This modification to the targeting criteria aligns across the HAC Reduction, Hospital IQR and Hospital OQR Programs. In the CY 2023 OPPS/ASC final rule, we finalized the addition of this criterion to the Hospital OQR Program's targeting criteria for validation selection beginning with validations affecting the CY 2023 reporting period/CY 2025 payment determination (87 FR 72115 and 72116). We discussed in the proposed rule that this policy would also allow us to appropriately address instances in which hospitals, with an ECE for one or more quarters for the data period validated, will receive the maximum Winsorized *z*-scores penalty and thus be more likely to be subject to the payment reduction under the current validation policies.

We invited public comment on this proposal.

Comment: A few commenters supported the modification to the data validation targeting criteria. A commenter expressed support for the proposal because it would align with other quality reporting programs and ensure hospitals granted an ECE are not penalized for failing to meet the validation requirement during an unforeseen circumstances.

Response: We appreciate the commenters for their support of the proposal. We agree that the modification of the targeting criteria will further align the HAC Reduction Program with the Hospital IQR and Hospital OQR Programs. We agree that the addition of the criterion will appropriately address instances in which hospitals with an ECE for one or more quarters for the data period validated fail validation, and will prevent a hospital from receiving the maximum Winsorized *z*-scores based on data representing a period during an extraordinary event.

After consideration of the public comments we received, we are finalizing, as proposed, to modify the HAC Reduction Program data validation targeting criteria to include any hospital with a two-tailed confidence interval that is less than 75 percent, and received an ECE for one or more quarters for the data period validated beginning with the FY 2027 program

year, affecting validation of calendar year 2024 discharges.

K. Rural Community Hospital Demonstration Program

1. Introduction

The Rural Community Hospital Demonstration was originally authorized by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173). The demonstration has been extended three times since the original 5-year period mandated by the MMA, each time for an additional 5 years. These extensions were authorized by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148), section 15003 of the 21st Century Cures Act (Pub. L. 114–255) (Cures Act) enacted in 2016, and most recently, by section 128 of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260). In this final rule, we summarize the status of the demonstration program, and the current methodologies for implementation and calculating budget neutrality.

We are finalizing the amount to be applied to the national IPPS payment rates to account for the costs of the demonstration in FY 2024, and, in addition, we are including the reconciled amount of demonstration costs for FY 2018 in the FY 2024 IPPS/LTCH final rule, based on the finalized cost reports for this earlier year.

2. Background

Section 410A(a) of Public Law 108–173 required the Secretary to establish a demonstration program to test the feasibility and advisability of establishing rural community hospitals to furnish covered inpatient hospital services to Medicare beneficiaries. The demonstration pays rural community hospitals under a reasonable cost-based methodology for Medicare payment purposes for covered inpatient hospital services furnished to Medicare beneficiaries. A rural community hospital, as defined in section 410A(f)(1), is a hospital that—

- Is located in a rural area (as defined in section 1886(d)(2)(D) of the Act) or is treated as being located in a rural area under section 1886(d)(8)(E) of the Act;
- Has fewer than 51 beds (excluding beds in a distinct part psychiatric or rehabilitation unit) as reported in its most recent cost report;
- Provides 24-hour emergency care services; and
- Is not designated or eligible for designation as a CAH under section 1820 of the Act.

Our policy for implementing the 5-year extension period authorized by Public Law 116–260 (the Consolidated Appropriations Act, 2021) follows upon the previous extensions under the ACA (Pub. L. 111–148) and the Cures Act (Pub. L. 114–255). Section 410A of Pub L. 108–173 (MMA) initially required a 5-year period of performance. Subsequently, sections 3123 and 10313 of Public Law 111–148 required the Secretary to conduct the demonstration program for an additional 5-year period, to begin on the date immediately following the last day of the initial 5-year period. In addition, Public Law 111–148 limited the number of hospitals participating to no more than 30. Section 15003 of the Cures Act required a 10-year extension period in place of the 5-year extension period under the ACA, thereby extending the demonstration for another 5 years. Section 128 of Public Law 116–260, in turn, revised the statute to indicate a 15-year extension period, instead of the 10-year extension period mandated by the Public Law 114–159 (Cures Act). Please refer to the FY 2023 IPPS proposed and final rules (87 FR 28454 through 28458 and 87 FR 49138 through 49142, respectively) for an account of hospitals entering into and withdrawing from the demonstration with these re-authorizations. There are currently 26 hospitals participating in the demonstration.

2. Budget Neutrality

a. Statutory Budget Neutrality Requirement

Section 410A(c)(2) of Public Law 108–173 requires that, in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount that the Secretary would have paid if the demonstration program under this section was not implemented. This requirement is commonly referred to as ''budget neutrality.'' Generally, when we implement a demonstration program on a budget neutral basis, the demonstration program is budget neutral on its own terms; in other words, the aggregate payments to the participating hospitals do not exceed the amount that would be paid to those same hospitals in the absence of the demonstration program. We note that the payment methodology for this demonstration, that is, cost-based payments to participating small rural hospitals, makes it unlikely that increased Medicare outlays will produce an offsetting reduction to Medicare expenditures elsewhere. Therefore, in the IPPS final rules spanning the period from FY 2005 through FY 2016, we adjusted the national inpatient PPS rates by an amount sufficient to account for the added costs of this demonstration program, thus applying budget neutrality across the payment system as a whole rather than merely across the participants in the demonstration program. (We applied a different methodology for FY 2017, with the demonstration expected to end prior to the Cures Act extension). As we discussed in the FYs 2005 through 2017 IPPS/LTCH PPS final rules (69 FR 49183; 70 FR 47462; 71 FR 48100; 72 FR 47392; 73 FR 48670; 74 FR 43922, 75 FR 50343, 76 FR 51698, 77 FR 53449, 78 FR 50740, 77 FR 50145; 80 FR 49585; and 81 FR 57034, respectively), we believe that the statutory language of the budget neutrality requirements permits the agency to implement the budget neutrality provision in this manner.

We resumed this methodology of offsetting demonstration costs against the national payment rates in the IPPS final rules from FY 2018 through FY 2023. Please see the FY 2023 IPPS final rule for an account of how we applied the budget neutrality requirement for these fiscal years (87 FR 49140 through 49142).

b. General Budget Neutrality Methodology

We have generally incorporated two components into the budget neutrality offset amounts identified in the final IPPS rules in previous years. First, we have estimated the costs of the demonstration for the upcoming fiscal year, generally determined from historical, ''as submitted'' cost reports for the hospitals participating in that year. Update factors representing nationwide trends in cost and volume increases have been incorporated into these estimates, as specified in the methodology described in the final rule for each fiscal year. Second, as finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. If the actual costs for the demonstration for the earlier fiscal year exceeded the estimated costs of the demonstration identified in the final rule for that year, this difference was added to the estimated costs of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year. Conversely, if the estimated

costs of the demonstration set forth in the final rule for a prior fiscal year exceeded the actual costs of the demonstration for that year, this difference was subtracted from the estimated cost of the demonstration for the upcoming fiscal year when determining the budget neutrality adjustment for the upcoming fiscal year.

We note that we have calculated this difference for FYs 2005 through 2017 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

c. Budget Neutrality Methodology for the Extension Period Authorized by Public Law 116–159

For the most recently enacted extension period, under the Consolidated Appropriations Act, 2021, we have continued upon the general budget neutrality methodology used in previous years, as described above in the citations to earlier IPPS final rules. In this final rule, we outline the methodology for determining the offset to the national IPPS payment rates for FY 2024.

(1) Methodology for Estimating Demonstration Costs for FY 2024

Consistent with the general methodology from previous years, we estimate the costs of the demonstration for the upcoming fiscal year, and incorporate this estimate into the budget neutrality offset amount to be applied to the national IPPS rates for the upcoming fiscal year, that is, FY 2024. We are conducting this estimate for FY 2024 based on the 26 currently participating hospitals. The methodology for calculating this amount for FY 2024 proceeds according to the following steps:

Step 1: For each of these 26 hospitals, we identify the reasonable cost amount calculated under the reasonable cost-based methodology for covered inpatient hospital services, including swing beds, as indicated on the ''as submitted'' cost report for the most recent cost reporting period available. For each of these hospitals, the ''as submitted'' cost report is that with cost report period end date in CY 2021. We sum these hospital-specific amounts to arrive at a total general amount representing the costs for covered inpatient hospital services, including swing beds, across the total 26 hospitals eligible to participate during FY 2024.

Then, we multiply this amount by the FYs 2022, 2023, and 2024 IPPS market basket percentage increases, which are calculated by the CMS Office of the Actuary. (We are using the market basket percentage increase for FY 2024 IPPS final rule, which can be found at section V.B. of the preamble to this final rule.) The result for the 26 hospitals is the general estimated reasonable cost amount for covered inpatient hospital services for FY 2024.

Consistent with our methods in previous years for formulating this estimate, we are applying the IPPS market basket percentage increases for FYs 2022 through 2024 to the applicable estimated reasonable cost amount (previously described) to model the estimated FY 2024 reasonable cost amount under the demonstration. We believe that the IPPS market basket percentage increases appropriately indicate the trend of increase in inpatient hospital operating costs under the reasonable cost methodology for the years involved.

Step 2: For each of the participating hospitals, we identify the estimated amount that would otherwise be paid in FY 2024 under applicable Medicare payment methodologies for covered inpatient hospital services, including swing beds (as indicated on the same set of ''as submitted'' cost reports as in Step 1), if the demonstration were not implemented. We sum these hospital-specific amounts, and, in turn, multiply this sum by the FYs 2022, 2023, and 2024 IPPS applicable percentage increases. (For FY 2024, we are using the applicable percentage increase amount identified in section V.B. of the preamble of this final rule.) This methodology differs from Step 1, in which we apply the market basket percentage increases to the hospitals' applicable estimated reasonable cost amount for covered inpatient hospital services. We believe that the IPPS applicable percentage increases are appropriate factors to update the estimated amounts that generally would otherwise be paid without the demonstration. This is because IPPS payments constitute the majority of payments that would otherwise be made without the demonstration and the applicable percentage increase is the factor used under the IPPS to update the inpatient hospital payment rates.

Step 3: We subtract the amount derived in Step 2 from the amount derived in Step 1. According to our methodology, the resulting amount indicates the total difference for the 26 hospitals (for covered inpatient hospital services, including swing beds), which will be the general estimated amount of the costs of the demonstration for FY 2024.

For this final rule, the resulting amount is $37,766,716, to be incorporated into the budget neutrality offset adjustment for FY 2024. This estimated amount is based on the specific assumptions regarding the data sources used, that is, recently available ''as submitted'' cost reports and historical update factors for cost and payment. We note that in this final rule we are using revised update factors as compared to the proposed rule, to estimate the costs for the demonstration program for FY 2024 in accordance with our methodology for determining the budget neutrality estimate.

(2) Reconciling Actual and Estimated Costs of the Demonstration for Previous Years

As described earlier, we have calculated the difference for FYs 2005 through 2017 between the actual costs of the demonstration, as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

At this time, for the FY 2024 final rule, all of the finalized cost reports have become available for the 29 hospitals that completed cost report periods beginning in FY 2018 under the demonstration payment methodology. Thus, as we described in the proposed rule, we are including the difference between the actual cost of the demonstration for FY 2018 as determined from finalized cost reports and the estimated amount for the fiscal year within the budget neutrality offset amount in the FY 2024 final rule.

The actual costs of the demonstration for FY 2018, as determined from the finalized cost reports for the 29 hospitals that completed cost report periods beginning in FY 2018 under the demonstration payment methodology, is $46,745,899. This amount exceeds the amount that was estimated for FY 2018 in the FY 2019 IPPS final rule ($31,070,880) by $15,675,019. (Following upon the selection of new hospitals for the demonstration in 2017, the estimated costs of the demonstration for FYs 2018 and 2019 were included in the FY 2019 IPPS final rule). (83 FR 41054). Thus, keeping with past practice, we are adding this difference to the estimated cost for FY 2024 in determining the budget neutrality offset amount for the FY 2024 IPPS final rule.

(3) Total Budget Neutrality Offset Amount for FY 2024

Therefore, for this FY 2024 IPPS/LTCH PPS final rule, the budget

neutrality offset amount for FY 2024 is the sum of two amounts:

(i) the amount determined under section X.2.c.(1). of the preamble of this final rule, representing the difference applicable to FY 2024 between the sum of the estimated reasonable cost amounts that would be paid under the demonstration for covered inpatient services to the 26 hospitals eligible to participate in the fiscal year and the sum of the estimated amounts that would generally be paid if the demonstration had not been implemented. This estimated amount is $37,766,716.

(ii) the amount determined under section X.2.c.(2), which represents the difference between the actual costs of the demonstration for FY 2018, as determined from the finalized cost reports for the 29 hospitals with cost reporting periods under the demonstration payment methodology that began in that fiscal year, and the earlier estimated cost of the demonstration for the fiscal year. This amount is $15,675,019.

Thus, the total budget neutrality offset amount for the FY 2024 IPPS final rule is $53,441,735. This amount will be subtracted from the national IPPS payment rates for FY 2024.

Comment: The parent company for two of the participating hospitals expressed support for the continuation of the of the Rural Community Hospital Demonstration program, but noted that it does not offer long-term financial stability needed to maintain health care access in rural areas. The commenter requests that the demonstration be made a permanent program, and, in addition, that CMS institute an application process to ensure the demonstration meets program capacity. Furthermore, the commenter requests several technical adjustments to the administration of the demonstration that may enhance stability in the payment to the participating hospitals.

Response: We appreciate the comments. We have conducted the demonstration program in accordance with Congressional mandates. Title XVIII does not extend authority to make the demonstration a permanent program. With regard to any further actions, we intend to work with the commenter and other rural stakeholders to examine the issues involved.

VI. Changes to the IPPS for Capital Related Costs

A. Overview

Section 1886(g) of the Act requires the Secretary to pay for the capital-related costs of inpatient acute hospital services in accordance with a prospective payment system established by the Secretary. Under the statute, the Secretary has broad authority in establishing and implementing the IPPS for acute care hospital inpatient capital-related costs. We initially implemented the IPPS for capital-related costs in the FY 1992 IPPS final rule (56 FR 43358). In that final rule, we established a 10-year transition period to change the payment methodology for Medicare hospital inpatient capital-related costs from a reasonable cost-based payment methodology to a prospective payment methodology (based fully on the Federal rate).

FY 2001 was the last year of the 10-year transition period that was established to phase in the IPPS for hospital inpatient capital-related costs. For cost reporting periods beginning in FY 2002, capital IPPS payments are based solely on the Federal rate for almost all acute care hospitals (other than hospitals receiving certain exception payments and certain new hospitals). (We refer readers to the FY 2002 IPPS final rule (66 FR 39910 through 39914) for additional information on the methodology used to determine capital IPPS payments to hospitals both during and after the transition period.)

The basic methodology for determining capital prospective payments using the Federal rate is set forth in the regulations at 42 CFR 412.312. For the purpose of calculating capital payments for each discharge, the standard Federal rate is adjusted as follows:

(Standard Federal Rate) x (DRG Weight) × (Geographic Adjustment Factor (GAF) ×(COLA for hospitals located in Alaska and Hawaii) × (1 + Capital DSH Adjustment Factor + Capital IME Adjustment Factor, if applicable).

In addition, under § 412.312(c), hospitals also may receive outlier payments under the capital IPPS for extraordinarily high-cost cases that qualify under the thresholds established for each fiscal year.

B. Additional Provisions

1. Exception Payments

The regulations at 42 CFR 412.348 provide for certain exception payments under the capital IPPS. The regular exception payments provided under § 412.348(b) through (e) were available only during the 10-year transition period. For a certain period after the transition period, eligible hospitals may have received additional payments under the special exceptions provisions at § 412.348(g). However, FY 2012 was the final year hospitals could receive special exceptions payments. For additional details regarding these exceptions policies, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725).

Under § 412.348(f), a hospital may request an additional payment if the hospital incurs unanticipated capital expenditures in excess of $5 million due to extraordinary circumstances beyond the hospital's control. Additional information on the exception payment for extraordinary circumstances in § 412.348(f) can be found in the FY 2005 IPPS final rule (69 FR 49185 and 49186).

2. New Hospitals

Under the capital IPPS, the regulations at 42 CFR 412.300(b) define a new hospital as a hospital that has operated (under previous or current ownership) for less than 2 years and lists examples of hospitals that are not considered new hospitals. In accordance with § 412.304(c)(2), under the capital IPPS, a new hospital is paid 85 percent of its allowable Medicare inpatient hospital capital related costs through its first 2 years of operation, unless the new hospital elects to receive full prospective payment based on 100 percent of the Federal rate. We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51725) for additional information on payments to new hospitals under the capital IPPS.

3. Payments for Hospitals Located in Puerto Rico

In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57061), we revised the regulations at 42 CFR 412.374 relating to the calculation of capital IPPS payments to hospitals located in Puerto Rico beginning in FY 2017 to parallel the change in the statutory calculation of operating IPPS payments to hospitals located in Puerto Rico, for discharges occurring on or after January 1, 2016, made by section 601 of the Consolidated Appropriations Act, 2016 (Pub. L. 114–113). Section 601 of Public Law 114–113 increased the applicable Federal percentage of the operating IPPS payment for hospitals located in Puerto Rico from 75 percent to 100 percent and decreased the applicable Puerto Rico percentage of the operating IPPS payments for hospitals located in Puerto Rico from 25 percent to zero percent, applicable to discharges occurring on or after January 1, 2016. As such, under revised § 412.374, for discharges occurring on or after October 1, 2016, capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the capital Federal rate.

C. Annual Update for FY 2024

The annual update to the national capital Federal rate, as provided for in 42 CFR 412.308(c), for FY 2024 is discussed in section III. of the Addendum to this FY 2024 IPPS/LTCH PPS final rule.

D. Treatment of Rural Reclassifications for Capital DSH Payments

Section 1886(d)(8)(E)(i) of the Act, implemented at § 412.103, specifies for a hospital that meets certain requirements and criteria, the Secretary shall treat the hospital as being located in the rural area of the State in which the hospital is located for purposes of section 1886(d) of the Act. In the FY 2007 IPPS/LTCH PPS final rule (71 FR 48104), we codified at § 412.320(a)(1)(iii) that hospitals reclassified as rural under § 412.103 also are considered rural under the capital IPPS for purposes of determining eligibility for capital DSH payments. Under the capital IPPS, as set forth in § 412.320(a), only urban hospitals with 100 or more beds are eligible for capital DSH payments. Therefore, under the current regulations, hospitals reclassified as rural under § 412.103 are not eligible to receive capital DSH payments. On September 30, 2021, in Toledo Hospital v. Becerra, the U.S. District Court for the District of Columbia issued a decision that the FY 2007 final rule codifying CMS's policy of not providing capital DSH payments to urban hospitals that are reclassified as rural under § 412.103 was arbitrary and capricious because, the court concluded, the record did not demonstrate that CMS took relative costs into account when considering the rule and the policy at issue.

We do not necessarily agree with the court's conclusions but nevertheless in light of the decision, in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27058 through 27059), we proposed to revise the capital DSH regulations in response to this court ruling. Specifically, we proposed that effective for discharges occurring on or after October 1, 2023, hospitals reclassified as rural under § 412.103 will no longer be considered rural for purposes of determining eligibility for capital DSH payments. We proposed to codify this change by amending existing § 412.320(a)(1)(iii) to specify that the exception for an urban hospital that is reclassified as rural as set forth in § 412.103 is effective for discharges occurring on or after October 1, 2006, and before October 1, 2023. That is, for discharges occurring on or after October 1, 2023, for purposes of § 412.320, the geographic classifications specified under § 412.64 would apply with no exceptions.

Comment: Commenters were generally supportive of our proposal to no longer consider hospitals reclassified as rural under § 412.103 as rural for purposes of determining eligibility for capital DSH payments and some emphasized their belief that capital costs of reclassified rural providers under § 412.103 are more equivalent to other urban providers as opposed to geographically rural providers. Some commenters expressed concern that CMS did not propose to apply this change in policy retroactively. These commenters disagree that the exception codified at § 412.320(a)(1)(iii) should remain effective for discharges occurring on or after October 1, 2006, and before October 1, 2023. These commenters believe that this exception remaining effective for this period is inconsistent with the court's decision and also inconsistent with the proposal that the exception will no longer apply for discharges on or after October 1, 2023. Some of these commenters believe at a minimum CMS should allow hospitals reclassified as rural under § 412.103 to receive capital DSH payments for any open or reopenable cost reports between FY 2007 and FY 2023.

Response: We thank commenters for their support of our proposal. We do not agree with commenters that believe our proposal should be applied retroactively. The IPPS is a prospective system, and therefore we generally make changes to IPPS regulations effective prospectively based on the date of discharge or the start of a cost reporting period within a certain Federal fiscal year.

Comment: A commenter encouraged CMS to also expand capital DSH eligibility to geographically rural hospitals. The commenter believes this would bolster the rural health care safety net. The commenter cited negative capital margins at geographically rural hospitals, low occupancy rates in geographically rural hospitals, as well as recent closure of geographically rural hospitals as reasons why expanding capital DSH eligibility to geographically rural hospitals would be justified.

Response: We believe this comment is out of scope of this rulemaking. We thank the commenter for this suggestion and may consider it in future rulemaking. We note that the capital DSH payment adjustments were finalized in the FY 1992 IPPS final rule (56 FR 43377 through 43379) based on a cost regression analysis.

After consideration of the public comments we received, we are finalizing as proposed, that effective for discharges occurring on or after October 1, 2023, hospitals reclassified as rural under § 412.103 will no longer be considered rural for purposes of determining eligibility for capital DSH payments. We also are finalizing our proposal to amend existing § 412.320(a)(1)(iii) to specify that the exception for an urban hospital that is reclassified as rural as set forth in § 412.103 is effective for discharges occurring on or after October 1, 2006, and before October 1, 2023. That is, for discharges occurring on or after October 1, 2023, for purposes of § 412.320, the geographic classifications specified under § 412.64 will apply with no exceptions.

VII. Changes for Hospitals Excluded From the IPPS

A. Rate-of-Increase in Payments to Excluded Hospitals for FY 2024

Certain hospitals excluded from a prospective payment system, including children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage. For each cost reporting period, the updated target amount is multiplied by total Medicare discharges during that period and applied as an aggregate upper limit (the ceiling as defined in § 413.40(a)) of Medicare reimbursement for total inpatient operating costs for a hospital's cost reporting period. In accordance with § 403.752(a) of the regulations, religious nonmedical health care institutions (RNHCIs) also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously. Furthermore, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals also are subject to the rate-of-increase limits established under § 413.40 of the regulations discussed previously.

As explained in the FY 2006 IPPS final rule (70 FR 47396 through 47398), beginning with FY 2006, we have used

the percentage increase in the IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, and RNHCIs. Consistent with the regulations at §§ 412.23(g) and 413.40(a)(2)(ii)(A) and (c)(3)(viii), we also have used the percentage increase in the IPPS operating market basket to update target amounts for short–term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. In the FY 2018 IPPS/LTCH PPS final rule, we rebased and revised the IPPS operating market basket to a 2014 base year, effective for FY 2018 and subsequent fiscal years (82 FR 38158 through 38175), and finalized the use of the percentage increase in the 2014-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2018 and subsequent fiscal years. As discussed in section IV. of the preamble of the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45207), we rebased and revised the IPPS operating market basket to a 2018 base year. Therefore, we used the percentage increase in the 2018-based IPPS operating market basket to update the target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for FY 2022 and subsequent fiscal years.

For the FY 2024 IPPS/LTCH PPS proposed rule, based on IGI's 2022 fourth quarter forecast, we estimated that the 2018-based IPPS operating market basket percentage increase for FY 2024 would be 3.0 percent (that is, the estimate of the market basket rate-of-increase). However, we proposed that if more recent data became available for the FY 2024 IPPS/LTCH PPS final rule, we would use such data, if appropriate, to calculate the final IPPS operating market basket update for FY 2024. As proposed, we used more recent data for this FY 2024 IPPS/LTCH PPS final rule, based on IGI's 2023 second quarter forecast, we estimate that the 2018-based IPPS operating market basket update for FY 2024 is 3.3 percent. Based on this estimate, the FY 2024 rate-of-increase percentage that will be applied to the FY 2023 target amounts in order to calculate the FY 2024 target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa will be 3.3 percent, in accordance with the applicable regulations at 42 CFR 413.40.

In addition, payment for inpatient operating costs for hospitals classified under section 1886(d)(1)(B)(vi) of the Act (which we refer to as ''extended neoplastic disease care hospitals'') for cost reporting periods beginning on or after January 1, 2015, is to be made as described in 42 CFR 412.526(c)(3), and payment for capital costs for these hospitals is to be made as described in 42 CFR 412.526(c)(4). For additional information on these payment regulations, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38321 through 38322). Section 412.526(c)(3) provides that the hospital's Medicare allowable net inpatient operating costs for that period are paid on a reasonable cost basis, subject to that hospital's ceiling, as determined under § 412.526(c)(1), for that period. Under § 412.526(c)(1), for each cost reporting period, the ceiling was determined by multiplying the updated target amount, as defined in § 412.526(c)(2), for that period by the number of Medicare discharges paid during that period. Section 412.526(c)(2)(i) describes the method for determining the target amount for cost reporting periods beginning during FY 2015. Section 412.526(c)(2)(ii) specifies that, for cost reporting periods beginning during fiscal years after FY 2015, the target amount will equal the hospital's target amount for the previous cost reporting period updated by the applicable annual rate-of-increase percentage specified in § 413.40(c)(3) for the subject cost reporting period (79 FR 50197).

For FY 2024, in accordance with §§ 412.22(i) and 412.526(c)(2)(ii) of the regulations, for cost reporting periods beginning during FY 2024, the proposed update to the target amount for extended neoplastic disease care hospitals (that is, hospitals described under § 412.22(i)) is the applicable annual rate-of-increase percentage specified in § 413.40(c)(3), which is estimated to be the percentage increase in the 2018-based IPPS operating market basket (that is, the estimate of the market basket rate-of-increase). Accordingly, the proposed update to an extended neoplastic disease care hospital's target amount for FY 2024 was 3.0 percent, which was based on IGI's fourth quarter 2022 forecast. Furthermore, we proposed that if more recent data became available for the FY 2024 IPPS/LTCH PPS final rule, we would use such data, if appropriate, to calculate the IPPS operating market basket rate of increase for FY 2024. For this FY 2024 IPPS/LTCH PPS final rule, based on IGI's 2023 second quarter forecast, we estimate that the 2018-based IPPS operating market basket update for FY 2024 is 3.3 percent.

We received no comments on this proposal and therefore are finalizing this provision without modification. Incorporating more recent data available for this final rule, as we proposed, we are adopting a 3.3 percent update for FY 2024.

B. Report on Adjustment (Exception) Payments

Section 4419(b) of Public Law 105–33 requires the Secretary to publish annually in the **Federal Register** a report describing the total amount of adjustment payments made to excluded hospitals and hospital units by reason of section 1886(b)(4) of the Act during the previous fiscal year.

The process of requesting, reviewing, and awarding an adjustment payment is likely to occur over a 2-year period or longer. First, generally, an excluded hospital must file its cost report for the fiscal year in accordance with § 413.24(f)(2) of the regulations. The MAC reviews the cost report and issues a notice of provider reimbursement (NPR). Once the hospital receives the NPR, if its operating costs are in excess of the ceiling, the hospital may file a request for an adjustment payment. After the MAC receives the hospital's request in accordance with applicable regulations, the MAC or CMS, depending on the type of adjustment requested, reviews the request, and determines if an adjustment payment is warranted. This determination is sometimes not made until more than 180 days after the date the request is filed because there are times when the request applications are incomplete and additional information must be requested to have a completed request application. However, in an attempt to provide interested parties with data on the most recent adjustment payments for which we have data, we are publishing data on adjustment payments that were processed by the MAC or CMS during FY 2022.

The table that follows includes the most recent data available from the MACs and CMS on adjustment payments that were adjudicated during FY 2022. As indicated previously, the adjustments made during FY 2022 only pertain to cost reporting periods ending in years prior to FY 2022. Total adjustment payments made to IPPS-excluded hospitals during FY 2022 are $4,338,890. The table depicts for each

class of hospitals, in the aggregate, the number of adjustment requests adjudicated, the excess operating costs over the ceiling, and the amount of the adjustment payments.

Class of Hospital	Number	Excess Cost Over Ceiling	Adjustment Payments
Cancer Hospitals	2	$11,974,166	$3,645,981
Children's Hospitals	5	$1,038,797	$625,277
RNHCIs	1	$160,881	$67,632
Total	**8**	**$13,173,844**	**$4,338,890**

B. Critical Access Hospitals (CAHs)

1. Background

Section 1820 of the Act provides for the establishment of Medicare Rural Hospital Flexibility Programs (MRHFPs), under which individual States may designate certain facilities as critical access hospitals (CAHs). Facilities that are so designated and meet the CAH conditions of participation under 42 CFR part 485, subpart F, will be certified as CAHs by CMS. Regulations governing payments to CAHs for services to Medicare beneficiaries are located in 42 CFR part 413.

2. Frontier Community Health Integration Project Demonstration

a. Introduction

The Frontier Community Health Integration Project Demonstration was originally authorized by section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L. 110–275). The demonstration has been extended by section 129 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) for an additional 5 years. In this final rule, we are summarizing the status of the demonstration program, and the ongoing methodologies for implementation and budget neutrality for the demonstration extension period.

b. Background and Overview

As discussed in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49144 through 49147), section 123 of the Medicare Improvements for Patients and Providers Act of 2008, as amended by section 3126 of the Affordable Care Act, authorized a demonstration project to allow eligible entities to develop and test new models for the delivery of health care services in eligible counties in order to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries. The demonstration was titled ''Demonstration Project on Community Health Integration Models in Certain Rural Counties,'' and commonly known as the Frontier Community Health Integration Project (FCHIP) Demonstration.

The authorizing statute stated the eligibility criteria for entities to be able to participate in the demonstration. An eligible entity, as defined in section 123(d)(1)(B) of Public Law 110–275, as amended, is a Medicare Rural Hospital Flexibility Program (MRHFP) grantee under section 1820(g) of the Act (that is, a CAH); and is located in a state in which at least 65 percent of the counties in the state are counties that have 6 or less residents per square mile.

The authorizing statute stipulated several other requirements for the demonstration. In addition, section 123(g)(1)(B) of Public Law 110–275 required that the demonstration be budget neutral. Specifically, this provision stated that, in conducting the demonstration project, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project under the section were not implemented. Furthermore, section 123(i) of Public Law 110–275 stated that the Secretary may waive such requirements of titles XVIII and XIX of the Act as may be necessary and appropriate for the purpose of carrying out the demonstration project, thus allowing the waiver of Medicare payment rules encompassed in the demonstration. CMS selected CAHs to participate in four interventions, under which specific waivers of Medicare payment rules would allow for enhanced payment for telehealth, skilled nursing facility/nursing facility beds, ambulance services, and home health services. These waivers were formulated with the goal of increasing access to care with no net increase in costs.

Section 123 of Public Law 110–275 initially required a 3-year period of performance. The FCHIP Demonstration began on August 1, 2016, and concluded on July 31, 2019 (referred to in this section of the final rule as the ''initial period''). Subsequently, section 129 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260) extended the demonstration by 5 years (referred to in this section of the final rule as the ''extension period''). The Secretary is required to conduct the demonstration for an additional 5-year period. CAHs participating in the demonstration project during the extension period began such participation in their cost reporting year that began on or after January 1, 2022.

As described in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49144 through 49147), 10 CAHs were selected for participation in the demonstration initial period. The selected CAHs were located in three states—Montana, Nevada, and North Dakota—and participated in three of the four interventions identified in the FY 2023 IPPS/LTCH PPS final rule. Each CAH was allowed to participate in more than one of the interventions. None of the selected CAHs were participants in the home health intervention, which was the fourth intervention.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), CMS concluded that the initial period of the FCHIP Demonstration (covering the performance period of August 1, 2016, to July 31, 2019) had satisfied the budget neutrality requirement described in section 123(g)(1)(B) of Public Law 110–275. Therefore, CMS did not apply a budget neutrality payment offset policy for the initial period of the demonstration.

Section 129 of Public Law 116–260, stipulates that only the 10 CAHs that participated in the initial period of the FCHIP Demonstration are eligible to participate during the extension period. Among the eligible CAHs, five have elected to participate in the extension period. The selected CAHs are located in two states—Montana and North Dakota—and are implementing three of the four interventions. The eligible CAH participants elected to change the number of interventions and payment waivers they would participate in during the extension period. CMS accepted and approved the CAHs intervention and payment waiver updates. For the extension period, four

CAHs are participants in the telehealth intervention, three CAHs are participants in the skilled nursing facility/nursing facility bed intervention, and three CAHs are participants in the ambulance services intervention. As with the initial period, each CAH was allowed to participate in more than one of the interventions during the extension period. None of the selected CAHs are participants in the home health intervention, which was the fourth intervention.

c. Intervention Payment and Payment Waivers

As described in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49144 through 49147), CMS waived certain Medicare rules for CAHs participating in the demonstration initial period to allow for alternative reasonable cost-based payment methods in the three distinct intervention service areas: telehealth services, ambulance services, and skilled nursing facility/nursing facility (SNF/NF) beds expansion. The payments and payment waiver provisions only apply if the CAH is a participant in the associated intervention. CMS Intervention Payment and Payment Waivers for the demonstration extension period consist of the following:

(1) Telehealth Services Intervention Payments

CMS waives section 1834(m)(2)(B) of the Act, which specifies the facility fee to the originating site for Medicare telehealth services. CMS modifies the facility fee payment specified under section 1834(m)(2)(B) of the Act to make reasonable cost-based reimbursement to the participating CAH where the participating CAH serves as the originating site for a telehealth service furnished to an eligible telehealth individual, as defined in section 1834(m)(4)(B) of the Act. CMS reimburses the participating CAH serving as the originating site at 101 percent of its reasonable costs for overhead, salaries and fringe benefits associated with telehealth services at the participating CAH. CMS does not fund or provide reimbursement to the participating CAH for the purchase of new telehealth equipment.

CMS waives section 1834(m)(2)(A) of the Act, which specifies that the payment for a telehealth service furnished by a distant site practitioner is the same as it would be if the service had been furnished in-person. CMS modifies the payment amount specified for telehealth services under section 1834(m)(2)(A) of the Act to make reasonable cost-based reimbursement to the participating CAH for telehealth services furnished by a physician or practitioner located at distant site that is a participating CAH that is billing for the physician or practitioner professional services. Whether the participating CAH has or has not elected Optional Payment Method II for outpatient services, CMS would pay the participating CAH 101 percent of reasonable costs for telehealth services when a physician or practitioner has reassigned their billing rights to the participating CAH and furnishes telehealth services from the participating CAH as a distant site practitioner. This means that participating CAHs that are billing under the Standard Method on behalf of employees who are physicians or practitioners (as defined in section 1834(m)(4)(D) and (E) of the Act, respectively) would be eligible to bill for distant site telehealth services furnished by these physicians and practitioners. Additionally, CAHs billing under the Optional Method would be reimbursed based on 101 percent of reasonable costs, rather than paid based on the Medicare physician fee schedule, for the distant site telehealth services furnished by physicians and practitioners who have reassigned their billing rights to the CAH. For distant site telehealth services furnished by physicians or practitioners who have not reassigned billing rights to a participating CAH, payment to the distant site physician or practitioner would continue to be made as usual under the Medicare physician fee schedule. Except as described herein, CMS does not waive any other provisions of section 1834(m) of the Act for purposes of the telehealth services intervention payments, including the scope of Medicare telehealth services as established under section 1834(m)(4)(F) of the Act.

(2) Ambulance Services Intervention Payments

CMS waives 42 CFR 413.70(b)(5)(i)(D) and section 1834(l)(8) of the Act, which provides that payment for ambulance services furnished by a CAH, or an entity owned and operated by a CAH, is 101 percent of the reasonable costs of the CAH or the entity in furnishing the ambulance services, but only if the CAH or the entity is the only provider or supplier of ambulance services located within a 35-mile drive of the CAH, excluding ambulance providers or suppliers that are not legally authorized to furnish ambulance services to transport individuals to or from the CAH. The participating CAH would be paid 101 percent of reasonable costs for its ambulance services regardless of whether there is any provider or supplier of ambulance services located within a 35-mile drive of the participating CAH or participating CAH-owned and operated entity. CMS would not make cost-based payment to the participating CAH for any new capital (for example, vehicles) associated with ambulance services. This waiver does not modify any other Medicare rules regarding or affecting the provision of ambulance services.

(3) SNF/NF Beds Expansion Intervention Payments

CMS waives 42 CFR 485.620(a) and 485.645(a)(2) and section 1820(c)(2)(B)(iii) of the Act which limit CAHs to maintaining no more than 25 inpatient beds, including beds available for acute inpatient or swing bed services. CMS waives 1820(f) of the Act permitting designating or certifying a facility as a critical access hospital for which the facility at any time is furnishing inpatient beds which exceed more than 25 beds. Under this waiver, if the participating CAH has received swing bed approval from CMS, the participating CAH may maintain up to ten additional beds (for a total of 35 beds) available for acute inpatient or swing bed services; however, the participating CAH may only use these 10 additional beds for nursing facility or skilled nursing facility level of care. CMS would pay the participating CAH 101 percent of reasonable costs for its SNF/NF services furnished in the 10 additional beds.

d. Budget Neutrality

(1) Budget Neutrality Requirement

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), we finalized a policy to address the budget neutrality requirement for the demonstration initial period. As explained in the FY 2022 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation in the demonstration with the goal of maintaining the budget neutrality of the demonstration on its own terms meaning that the demonstration would produce savings from reduced transfers and admissions to other health care providers, offsetting any increase in Medicare payments as a result of the demonstration. However, because of the small size of the demonstration and uncertainty associated with the projected Medicare utilization and costs, the policy we finalized for the demonstration initial period of performance in the FY 2022 IPPS/LTCH PPS final rule provides a contingency plan to ensure that the budget neutrality

requirement in section 123 of Public Law 110–275 is met.

In the FY 2023 IPPS/LTCH PPS final rule, we adopted the same budget neutrality policy contingency plan used during the demonstration initial period to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met during the demonstration extension period. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as from other data sources, including cost reports for the participating CAHs, shows that increases in Medicare payments under the demonstration during the 5-year extension period are not sufficiently offset by reductions elsewhere, we would recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide.

As explained in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49144 through 49147), because of the small scale of the demonstration, we indicated that we did not believe it would be feasible to implement budget neutrality for the demonstration extension period by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration extension period is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration extension period were not implemented, CMS policy is to comply with the budget neutrality requirement finalized in the FY 2023 IPPS/LTCH PPS final rule, by reducing payments to all CAHs, not just those participating in the demonstration extension period.

In the FY 2023 IPPS/LTCH PPS final rule, we stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP Demonstration was specifically designed to test innovations that affect delivery of services by the CAH provider category. We explained our belief that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

In the FY 2023 IPPS/LTCH PPS final rule, we finalized a policy that in the event the demonstration extension period is found not to have been budget neutral, any excess costs would be recouped within one fiscal year. We explained our belief that this policy is a more efficient timeframe for the government to conclude the demonstration operational requirements (such as analyzing claims data, cost report data or other data sources) to adjudicate the budget neutrality payment recoupment process due to any excess cost that occurred as result of the demonstration extension period.

(2) FCHIP Budget Neutrality Methodology and Analytical Approach

As explained in the FY 2022 IPPS/LTCH PPS final rule, we finalized a policy to address the demonstration budget neutrality methodology and analytical approach for the initial period of the demonstration. In the FY 2023 IPPS/LTCH PPS final rule, we finalized a policy to adopt the budget neutrality methodology and analytical approach used during the demonstration initial period to ensure budget neutrality for the extension period. The analysis of budget neutrality during the initial period of the demonstration identified both the costs related to providing the intervention services under the FCHIP Demonstration and any potential downstream effects of the intervention-related services, including any savings that may have accrued.

The budget neutrality analytical approach for the demonstration initial period incorporated two major data components: (1) Medicare cost reports; and (2) Medicare administrative claims. As described in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), CMS computed the cost of the demonstration for each fiscal year of the demonstration initial period using Medicare cost reports for the participating CAHs, and Medicare administrative claims and enrollment data for beneficiaries who received demonstration intervention services.

In addition, in order to capture the full impact of the interventions, CMS developed a statistical modeling, Difference-in-Difference (DiD) regression analysis to estimate demonstration expenditures and compute the impact of expenditures on the intervention services by comparing cost data for the demonstration and non-demonstration groups using Medicare administrative claims across the demonstration period of performance under the initial period of the demonstration. The DiD regression analysis would compare the direct cost and potential downstream effects of intervention services, including any savings that may have accrued, during the baseline and performance period for both the demonstration and comparison groups.

Second, the Medicare administrative claims analysis would be reconciled using data obtained from auditing the participating CAHs' Medicare cost reports. We would estimate the costs of the demonstration using ''as submitted'' cost reports for each hospital's financial fiscal year participation within each of the demonstration extension period performance years. Each CAH has its own Medicare cost report end date applicable to the 5-year period of performance for the demonstration extension period. The cost report is structured to gather costs, revenues and statistical data on the provider's financial fiscal period. As a result, we finalized a policy in the FY 2023 IPPS/LTCH PPS final rule that we would determine the final budget neutrality results for the demonstration extension once complete data is available for each CAH for the demonstration extension period.

e. Policies for Implementing the 5-Year Extension and Provisions Authorized by Section 129 of the Consolidated Appropriations Act, 2021 (Pub. L. 116–260)

As stated in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49144 through 49147), our policy for implementing the 5-year extension period for section 129 of Public Law 116–260 follows same budget neutrality methodology and analytical approach as the demonstration initial period methodology. While we expect to use the same methodology that was used to assess the budget neutrality of the FCHIP Demonstration during initial period of the demonstration to assess the financial impact of the demonstration during this extension period, upon receiving data for the extension period, we may update and/or modify the FCHIP budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured.

f. Total Budget Neutrality Offset Amount for FY 2024

At this time, for the FY 2024 IPPS/LTCH PPS final rule, while this discussion represents our anticipated approach to assessing the financial impact of the demonstration extension period based on upon receiving data for the full demonstration extension period, we may update and/or modify the FCHIP Demonstration budget neutrality methodology and analytical approach to ensure that the full impact of the

demonstration is appropriately captured.

We received no comments on our proposal not to apply a budget neutrality payment offset to payments to CAHs in FY 2024. Therefore, we are finalizing this provision without modification. This policy will have no impact for any national payment system for FY 2024.

VIII. Changes to the Long-Term Care Hospital Prospective Payment System (LTCH PPS) for FY 2024

A. Background of the LTCH PPS

1. Legislative and Regulatory Authority

Section 123 of the Medicare, Medicaid, and SCHIP (State Children's Health Insurance Program) Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106–113), as amended by section 307(b) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106–554), provides for payment for both the operating and capital-related costs of hospital inpatient stays in long-term care hospitals (LTCHs) under Medicare Part A based on prospectively set rates. The Medicare prospective payment system (PPS) for LTCHs applies to hospitals that are described in section 1886(d)(1)(B)(iv) of the Act, effective for cost reporting periods beginning on or after October 1, 2002.

Section 1886(d)(1)(B)(iv)(I) of the Act originally defined an LTCH as a hospital that has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days. Section 1886(d)(1)(B)(iv)(II) of the Act also provided an alternative definition of LTCHs (''subclause II'' LTCHs). However, section 15008 of the 21st Century Cures Act (Pub. L. 114–255) amended section 1886 of the Act to exclude former ''subclause II'' LTCHs from being paid under the LTCH PPS and created a new category of IPPS-excluded hospitals, which we refer to as ''extended neoplastic disease care hospitals,'' to be paid as hospitals that were formally classified as ''subclause (II)'' LTCHs (82 FR 38298).

Section 123 of the BBRA requires the PPS for LTCHs to be a ''per discharge'' system with a diagnosis-related group (DRG) based patient classification system that reflects the differences in patient resource use and costs in LTCHs.

Section 307(b)(1) of the BIPA, among other things, mandates that the Secretary shall examine, and may provide for, adjustments to payments under the LTCH PPS, including adjustments to DRG weights, area wage adjustments, geographic reclassification, outliers, updates, and a disproportionate share adjustment.

In the August 30, 2002 **Federal Register**, we issued a final rule that implemented the LTCH PPS authorized under the BBRA and BIPA (67 FR 55954). For the initial implementation of the LTCH PPS (FYs 2003 through 2007), the system used information from LTCH patient records to classify patients into distinct long-term care-diagnosis-related groups (LTCDRGs) based on clinical characteristics and expected resource needs. Beginning in FY 2008, we adopted the Medicare severity-long-term care-diagnosis related groups (MS–LTC–DRGs) as the patient classification system used under the LTCH PPS. Payments are calculated for each MS–LTC–DRG and provisions are made for appropriate payment adjustments. Payment rates under the LTCH PPS are updated annually and published in the **Federal Register**.

The LTCH PPS replaced the reasonable cost-based payment system under the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97248) for payments for inpatient services provided by an LTCH with a cost reporting period beginning on or after October 1, 2002. (The regulations implementing the TEFRA reasonable-cost-based payment provisions are located at 42 CFR part 413.) With the implementation of the PPS for acute care hospitals authorized by the Social Security Amendments of 1983 (Pub. L. 98–21), which added section 1886(d) to the Act, certain hospitals, including LTCHs, were excluded from the PPS for acute care hospitals and paid their reasonable costs for inpatient services subject to a per discharge limitation or target amount under the TEFRA system. For each cost reporting period, a hospital specific ceiling on payments was determined by multiplying the hospital's updated target amount by the number of total current year Medicare discharges. (Generally, in this section of the preamble of this final rule, when we refer to discharges, we describe Medicare discharges.) The August 30, 2002 final rule further details the payment policy under the TEFRA system (67 FR 55954).

In the August 30, 2002 final rule, we provided for a 5-year transition period from payments under the TEFRA system to payments under the LTCH PPS. During this 5-year transition period, an LTCH's total payment under the PPS was based on an increasing percentage of the Federal rate with a corresponding decrease in the percentage of the LTCH PPS payment that is based on reasonable cost concepts, unless an LTCH made a one-time election to be paid based on 100 percent of the Federal rate. Beginning with LTCHs' cost reporting periods beginning on or after October 1, 2006, total LTCH PPS payments are based on 100 percent of the Federal rate.

In addition, in the August 30, 2002 final rule, we presented an in-depth discussion of the LTCH PPS, including the patient classification system, relative weights, payment rates, additional payments, and the budget neutrality requirements mandated by section 123 of the BBRA. The same final rule that established regulations for the LTCH PPS under 42 CFR part 412, subpart O, also contained LTCH provisions related to covered inpatient services, limitation on charges to beneficiaries, medical review requirements, furnishing of inpatient hospital services directly or under arrangement, and reporting and recordkeeping requirements. We refer readers to the August 30, 2002 final rule for a comprehensive discussion of the research and data that supported the establishment of the LTCH PPS (67 FR 55954).

In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623), we implemented the provisions of the Pathway for Sustainable Growth Rate (SGR) Reform Act of 2013 (Pub. L. 113–67), which mandated the application of the ''site neutral'' payment rate under the LTCH PPS for discharges that do not meet the statutory criteria for exclusion beginning in FY 2016. For cost reporting periods beginning on or after October 1, 2015, discharges that do not meet certain statutory criteria for exclusion are paid based on the site neutral payment rate. Discharges that do meet the statutory criteria continue to receive payment based on the LTCH PPS standard Federal payment rate. For more information on the statutory requirements of the Pathway for SGR Reform Act of 2013, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57068 through 57075).

In the FY 2018 IPPS/LTCH PPS final rule, we implemented several provisions of the 21st Century Cures Act (''the Cures Act'') (Pub. L. 114–255) that affected the LTCH PPS. (For more information on these provisions, we refer readers to 82 FR 38299.)

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41529), we made conforming changes to our regulations to implement the provisions of section 51005 of the Bipartisan Budget Act of 2018 (Pub. L. 115–123), which extended

the transitional blended payment rate for site neutral payment rate cases for an additional 2 years. We refer readers to section VII.C. of the preamble of the FY 2019 IPPS/LTCH PPS final rule for a discussion of our final policy. In addition, in the FY 2019 IPPS/LTCH PPS final rule, we removed the 25-percent threshold policy under 42 CFR 412.538, which was a payment adjustment that was applied to payments for Medicare patient LTCH discharges when the number of such patients originating from any single referring hospital was in excess of the applicable threshold for given cost reporting period.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42439), we further revised our regulations to implement the provisions of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67) that relate to the payment adjustment for discharges from LTCHs that do not maintain the requisite discharge payment percentage and the process by which such LTCHs may have the payment adjustment discontinued.

2. Criteria for Classification as an LTCH

a. Classification as an LTCH

Under the regulations at § 412.23(e)(1), to qualify to be paid under the LTCH PPS, a hospital must have a provider agreement with Medicare. Furthermore, § 412.23(e)(2)(i), which implements section 1886(d)(1)(B)(iv) of the Act, requires that a hospital have an average Medicare inpatient length of stay of greater than 25 days to be paid under the LTCH PPS. In accordance with section 1206(a)(3) of the Pathway for SGR Reform Act of 2013 (Pub. L. 113–67), as amended by section 15007 of Public Law 114–255, we amended our regulations to specify that Medicare Advantage plans' and site neutral payment rate discharges are excluded from the calculation of the average length of stay for all LTCHs, for discharges occurring in cost reporting period beginning on or after October 1, 2015.

b. Hospitals Excluded From the LTCH PPS

The following hospitals are paid under special payment provisions, as described in § 412.22(c) and, therefore, are not subject to the LTCH PPS rules:

- Veterans Administration hospitals.
- Hospitals that are reimbursed under State cost control systems approved under 42 CFR part 403.
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of the Social Security Amendments of 1967 (Pub. L. 90–248) (42 U.S.C. 1395b-1), section 222(a) of the Social Security Amendments of 1972 (Pub. L. 92–603) (42 U.S.C. 1395b1 (note)) (Statewide-all payer systems, subject to the rate-of increase test at section 1814(b) of the Act), or section 3201 of the Patient Protection and Affordable Care Act (Pub. L. 111–148) (42 U.S.C. 1315a).
- Nonparticipating hospitals furnishing emergency services to Medicare beneficiaries.

3. Limitation on Charges to Beneficiaries

In the August 30, 2002 final rule, we presented an in-depth discussion of beneficiary liability under the LTCH PPS (67 FR 55974 through 55975). This discussion was further clarified in the RY 2005 LTCH PPS final rule (69 FR 25676). In keeping with those discussions, if the Medicare payment to the LTCH is the full LTC–DRG payment amount, consistent with other established hospital prospective payment systems, § 412.507 currently provides that an LTCH may not bill a Medicare beneficiary for more than the deductible and coinsurance amounts as specified under §§ 409.82, 409.83, and 409.87, and for items and services specified under § 489.30(a). However, under the LTCH PPS, Medicare will only pay for services furnished during the days for which the beneficiary has coverage until the short-stay outlier (SSO) threshold is exceeded. If the Medicare payment was for a SSO case (in accordance with § 412.529), and that payment was less than the full LTC–DRG payment amount because the beneficiary had insufficient coverage as a result of the remaining Medicare days, the LTCH also is currently permitted to charge the beneficiary for services delivered on those uncovered days (in accordance with § 412.507). In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49623), we amended our regulations to expressly limit the charges that may be imposed upon beneficiaries whose LTCHs' discharges are paid at the site neutral payment rate under the LTCH PPS. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57102), we amended the regulations under § 412.507 to clarify our existing policy that blended payments made to an LTCH during its transitional period (that is, an LTCH's payment for discharges occurring in cost reporting periods beginning in FYs 2016 through 2019) are considered to be site neutral payment rate payments.

4. Best Available Data

We refer readers to section I.E. of the preamble of this final rule for our discussion on our use of the most recent data available for the FY 2024 LTCH PPS ratesetting, including the FY 2022 MedPAR claims and FY 2021 cost report data.

Comment: We received several comments unrelated to LTCH PPS proposals included in the proposed rule. For example, some commenters requested changes to the structure of the site neutral payment policy or the calculation of the average length of stay.

Response: We appreciate the commenters' feedback and will keep these comments in mind for future rulemaking.

B. Medicare Severity Long-Term Care Diagnosis-Related Group (MS–LTC–DRG) Classifications and Relative Weights for FY 2024

1. Background

Section 123 of the BBRA required that the Secretary implement a PPS for LTCHs to replace the cost-based payment system under TEFRA. Section 307(b)(1) of the BIPA modified the requirements of section 123 of the BBRA by requiring that the Secretary examine the feasibility and the impact of basing payment under the LTCH PPS on the use of existing (or refined) hospital DRGs that have been modified to account for different resource use of LTCH patients.

Under both the IPPS and the LTCH PPS, the DRG-based classification system uses information on the claims for inpatient discharges to classify patients into distinct groups (for example, DRGs) based on clinical characteristics and expected resource needs. When the LTCH PPS was implemented for cost reporting periods beginning on or after October 1, 2002, we adopted the same DRG patient classification system utilized at that time under the IPPS. We referred to this patient classification system as the ''long-term care diagnosis-related groups (LTC–DRGs).'' As part of our efforts to better recognize severity of illness among patients, in the FY 2008 IPPS final rule with comment period (72 FR 47130), we adopted the MS–DRGs and the Medicare severity long-term care diagnosis-related groups (MS–LTC–DRGs) under the IPPS and the LTCH PPS, respectively, effective beginning October 1, 2007 (FY 2008). For a full description of the development, implementation, and rationale for the use of the MS–DRGs and MS–LTC–DRGs, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47141 through 47175 and 47277 through 47299). (We note that, in that same final rule, we revised the regulations at § 412.503 to specify that for LTCH discharges occurring on or

after October 1, 2007, when applying the provisions of 42 CFR part 412, subpart O, applicable to LTCHs for policy descriptions and payment calculations, all references to LTC–DRGs would be considered a reference to MS–LTC–DRGs. For the remainder of this section, we present the discussion in terms of the current MS–LTC–DRG patient classification system unless specifically referring to the previous LTC–DRG patient classification system that was in effect before October 1, 2007.)

Consistent with section 123 of the BBRA, as amended by section 307(b)(1) of the BIPA, and § 412.515 of the regulations, we use information derived from LTCH PPS patient records to classify LTCH discharges into distinct MS–LTC–DRGs based on clinical characteristics and estimated resource needs. As noted previously, we adopted the same DRG patient classification system utilized at that time under the IPPS. The MS–DRG classifications are updated annually, which has resulted in the number of MS–DRGs changing over time. For FY 2024, there will be 766 MS–DRG, and by extension, MS–LTC–DRG, groupings based on the changes, as discussed in section II.E. of the preamble of this final rule.

Although the patient classification system used under both the LTCH PPS and the IPPS are the same, the relative weights are different. The established relative weight methodology and data used under the LTCH PPS result in relative weights under the LTCH PPS that reflect the differences in patient resource use of LTCH patients, consistent with section 123(a)(1) of the BBRA. That is, we assign an appropriate weight to the MS–LTC–DRGs to account for the differences in resource use by patients exhibiting the case complexity and multiple medical problems characteristic of LTCH patients.

2. Patient Classifications Into MS–LTC–DRGs

a. Background

The MS–DRGs (used under the IPPS) and the MS–LTC–DRGs (used under the LTCH PPS) are based on the CMS DRG structure. As noted previously in this section, we refer to the DRGs under the LTCH PPS as MS–LTC–DRGs although they are structurally identical to the MS–DRGs used under the IPPS.

The MS–DRGs are organized into 25 major diagnostic categories (MDCs), most of which are based on a particular organ system of the body; the remainder involve multiple organ systems (such as MDC 22, Burns). Within most MDCs, cases are then divided into surgical DRGs and medical DRGs. Surgical DRGs are assigned based on a surgical hierarchy that orders operating room (O.R.) procedures or groups of O.R. procedures by resource intensity. The GROUPER software program does not recognize all ICD–10–PCS procedure codes as procedures affecting DRG assignment. That is, procedures that are not surgical (for example, EKGs) or are minor surgical procedures (for example, a biopsy of skin and subcutaneous tissue (procedure code 0JBH3ZX)) do not affect the MS–LTC–DRG assignment based on their presence on the claim.

Generally, under the LTCH PPS, a Medicare payment is made at a predetermined specific rate for each discharge that varies based on the MS–LTC–DRG to which a beneficiary's discharge is assigned. Cases are classified into MS–LTC–DRGs for payment based on the following six data elements:

- Principal diagnosis.
- Additional or secondary diagnoses.
- Surgical procedures.
- Age.
- Sex.
- Discharge status of the patient.

Currently, for claims submitted using the version ASC X12 5010 standard, up to 25 diagnosis codes and 25 procedure codes are considered for an MS–DRG assignment. This includes one principal diagnosis and up to 24 secondary diagnoses for severity of illness determinations. (For additional information on the processing of up to 25 diagnosis codes and 25 procedure codes on hospital inpatient claims, we refer readers to section II.G.11.c. of the preamble of the FY 2011 IPPS/LTCH PPS final rule (75 FR 50127).)

Under the HIPAA transactions and code sets regulations at 45 CFR parts 160 and 162, covered entities must comply with the adopted transaction standards and operating rules specified in subparts I through S of part 162. Among other requirements, on or after January 1, 2012, covered entities are required to use the ASC X12 Standards for Electronic Data Interchange Technical Report Type 3—Health Care Claim: Institutional (837), May 2006, ASC X12N/005010X223, and Type 1 Errata to Health Care Claim: Institutional (837) ASC X12 Standards for Electronic Data Interchange Technical Report Type 3, October 2007, ASC X12N/005010X233A1 for the health care claims or equivalent encounter information transaction (45 CFR 162.1102(c)).

HIPAA requires covered entities to use the applicable medical data code sets when conducting HIPAA transactions (45 CFR 162.1000). Currently, upon the discharge of the patient, the LTCH must assign appropriate diagnosis and procedure codes from the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM) for diagnosis coding and the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) for inpatient hospital procedure coding, both of which were required to be implemented October 1, 2015 (45 CFR 162.1002(c)(2) and (3)). For additional information on the implementation of the ICD–10 coding system, we refer readers to section II.F.1. of the preamble of the FY 2017 IPPS/LTCH PPS final rule (81 FR 56787 through 56790) and section II.E.1. of the preamble of this final rule. Additional coding instructions and examples are published in the AHA's *Coding Clinic for ICD–10–CM/PCS.*

To create the MS–DRGs (and by extension, the MS–LTC–DRGs), base DRGs were subdivided according to the presence of specific secondary diagnoses designated as complications or comorbidities (CCs) into one, two, or three levels of severity, depending on the impact of the CCs on resources used for those cases. Specifically, there are sets of MS–DRGs that are split into 2 or 3 subgroups based on the presence or absence of a CC or a major complication or comorbidity (MCC). We refer readers to section II.D. of the preamble of the FY 2008 IPPS final rule with comment period for a detailed discussion about the creation of MS–DRGs based on severity of illness levels (72 FR 47141 through 47175).

Medicare Administrative Contractors (MACs) enter the clinical and demographic information submitted by LTCHs into their claims processing systems and subject this information to a series of automated screening processes called the Medicare Code Editor (MCE). These screens are designed to identify cases that require further review before assignment into a MS–LTC–DRG can be made. During this process, certain types of cases are selected for further explanation (74 FR 43949).

After screening through the MCE, each claim is classified into the appropriate MS–LTC–DRG by the Medicare LTCH GROUPER software on the basis of diagnosis and procedure codes and other demographic information (age, sex, and discharge status). The GROUPER software used under the LTCH PPS is the same GROUPER software program used under the IPPS. Following the MS–LTC–DRG assignment, the MAC determines the prospective payment amount by using

the Medicare PRICER program, which accounts for hospital-specific adjustments. Under the LTCH PPS, we provide an opportunity for LTCHs to review the MS–LTC–DRG assignments made by the MAC and to submit additional information within a specified timeframe as provided in § 412.513(c).

The GROUPER software is used both to classify past cases to measure relative hospital resource consumption to establish the MS–LTC–DRG relative weights and to classify current cases for purposes of determining payment. The records for all Medicare hospital inpatient discharges are maintained in the MedPAR file. The data in this file are used to evaluate possible MS–DRG and MS–LTC–DRG classification changes and to recalibrate the MS–DRG and MS–LTC–DRG relative weights during our annual update under both the IPPS (§ 412.60(e)) and the LTCH PPS (§ 412.517), respectively.

b. Changes to the MS–LTC–DRGs for FY 2024

As specified by our regulations at § 412.517(a), which require that the MS–LTC–DRG classifications and relative weights be updated annually, and consistent with our historical practice of using the same patient classification system under the LTCH PPS as is used under the IPPS, in this final rule, as proposed, we updated the MS–LTC–DRG classifications effective October 1, 2023 through September 30, 2024 (FY 2024) consistent with the changes to specific MS–DRG classifications presented in section II.F. of the preamble of this final rule. Accordingly, the MS–LTC–DRGs for FY 2024 are the same as the MS–DRGs being used under the IPPS for FY 2024. In addition, because the MS–LTC–DRGs for FY 2024 are the same as the MS–DRGs for FY 2024, the other changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under GROUPER Version 41, as discussed in section II.E. of the preamble of this final rule, including the changes to the MCE software and the ICD–10–CM/PCS coding system, are also applicable under the LTCH PPS for FY 2024.

3. Development of the FY 2024 MS–LTC–DRG Relative Weights

a. General Overview of the MS–LTC–DRG Relative Weights

One of the primary goals for the implementation of the LTCH PPS is to pay each LTCH an appropriate amount for the efficient delivery of medical care to Medicare patients. The system must be able to account adequately for each LTCH's case-mix to ensure both fair distribution of Medicare payments and access to adequate care for those Medicare patients whose care is costlier (67 FR 55984). To accomplish these goals, we have annually adjusted the LTCH PPS standard Federal prospective payment rate by the applicable relative weight in determining payment to LTCHs for each case. Under the LTCH PPS, relative weights for each MS–LTC–DRG are a primary element used to account for the variations in cost per discharge and resource utilization among the payment groups (§ 412.515). To ensure that Medicare patients classified to each MS–LTC–DRG have access to an appropriate level of services and to encourage efficiency, we calculate a relative weight for each MS–LTC–DRG that represents the resources needed by an average inpatient LTCH case in that MS–LTC–DRG. For example, cases in an MS–LTC–DRG with a relative weight of 2 would, on average, cost twice as much to treat as cases in an MS–LTC–DRG with a relative weight of 1.

The established methodology to develop the MS–LTC–DRG relative weights is generally consistent with the methodology established when the LTCH PPS was implemented in the August 30, 2002 LTCH PPS final rule (67 FR 55989 through 55991). However, there have been some modifications of our historical procedures for assigning relative weights in cases of zero volume or nonmonotonicity or both resulting from the adoption of the MS–LTC–DRGs. We also made a modification in conjunction with the implementation of the dual rate LTCH PPS payment structure beginning in FY 2016 to use LTCH claims data from only LTCH PPS standard Federal payment rate cases (or LTCH PPS cases that would have qualified for payment under the LTCH PPS standard Federal payment rate if the dual rate LTCH PPS payment structure had been in effect at the time of the discharge). We also adopted, beginning in FY 2023, a 10-percent cap policy on the reduction in a MS–LTC–DRG's relative weight in a given year. (For details on the modifications to our historical procedures for assigning relative weights in cases of zero volume and nonmonotonicity or both, we refer readers to the FY 2008 IPPS final rule with comment period (72 FR 47289 through 47295) and the FY 2009 IPPS final rule (73 FR 48542 through 48550). For details on the change in our historical methodology to use LTCH claims data only from LTCH PPS standard Federal payment rate cases (or cases that would have qualified for such payment had the LTCH PPS dual payment rate structure been in effect at the time) to determine the MS–LTC–DRG relative weights, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49614 through 49617). For details on our adoption of the 10-percent cap policy, we refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49152 through 49154).)

For purposes of determining the MS–LTC–DRG relative weights, under our historical methodology, there are three different categories of MS–LTC–DRGs based on volume of cases within specific MS–LTC–DRGs: (1) MS–LTC–DRGs with at least 25 applicable LTCH cases in the data used to calculate the relative weight, which are each assigned a unique relative weight; (2) low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases that are grouped into quintiles (as described later in this section in Step 3 of our methodology) and assigned the relative weight of the quintile); and (3) no-volume MS–LTC–DRGs that are cross-walked to other MS–LTC–DRGs based on the clinical similarities and assigned the relative weight of the cross-walked MS–LTC–DRG (as described later in this section in Step 8 of our methodology). For FY 2024, we are continuing to use applicable LTCH cases to establish the same volume-based categories to calculate the FY 2024 MS–LTC–DRG relative weights.

b. Development of the MS–LTC–DRG Relative Weights for FY 2024

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27064 through 27073), we presented our proposed methodology for determining the MS–LTC–DRG relative weights for FY 2024. In this section, we first respond to the public comments received regarding the proposed methodology and the proposed MS–LTC–DRG relative weights for FY 2024. As discussed in Section I.E., of the preamble to this final rule, we received several comments on our proposal to use FY 2022 data for purposes of the FY 2024 LTCH PPS ratesetting. While the comments were nearly all focused on the specific use of FY 2022 data when determining the FY 2024 outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases, some commenters did state that CMS should not use FY 2022 data to calculate the MS–LTC–DRG relative weights without also modifying our proposed MS–LTC–DRG relative weight methodology. The commenters did not provide specific suggestions on what modifications CMS should make to the FY 2024 MS–LTC–DRG relative weight

methodology, but did express that modifications are necessary due to the impact of the COVID–19 PHE on the FY 2022 data. Since these comments were nearly all focused on the specific use of FY 2022 data when determining the FY 2024 outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases, we have fully summarized and responded to all comments on the use of FY 2022 data for purposes of the FY 2024 LTCH PPS ratesetting in section V.D.3. of the Addendum to this final rule. For the reasons discussed in that section, we are finalizing our proposal to use FY 2022 data for purposes of the FY 2024 IPPS and LTCH PPS ratesetting. We also are finalizing, without modification, our proposed methodology for determining the FY 2024 MS–LTC–DRG relative weights.

Comment: A commenter stated that the proposed MS–LTC–DRG relative weights would have a negative impact on Virginia hospitals. The commenter asked that CMS readdress the proposed MS–LTC–DRG weight methodology, stating that it appears to be flawed due to the cases used in the calculations. The commenter did not specify what cases they believe make the methodology flawed or provide a specific suggestion on what modifications CMS should make to our proposed methodology.

Response: It is expected that the annual recalibration of the MS–LTC–DRG relative weights will increase the estimated case-mix index of some hospitals while decreasing the estimated case-mix index of other hospitals. For example, based on the relative weights calculated for this final rule, we estimate that the FY 2024 recalibration of the MS–LTC–DRG relative weights will result in the case-mix index for standard payment rate cases increasing for 3 Virginia LTCHs while decreasing for the other 3 Virginia LTCHs. We note that while the annual recalibration of the MS–LTC–DRG relative weights will have a positive impact for some LTCHs and a negative impact for other LTCHs, the MS–LTC–DRG weight methodology ensures that estimated aggregate payments under the LTCH PPS are not affected (that is, they are not decreased or increased) by the annual recalibration of the MS–LTC–DRG relative weights. For the reasons discussed in section V.D.3. of the Addendum to this final rule, we continue to believe that FY 2022 MedPAR claims are the best data available for calculating the FY 2024 MS–LTC–DRG relative weights and disagree that modifications to our proposed MS–LTC–DRG weight methodology are warranted for this final rule.

Comment: A commenter stated that the proposed relative weights for 18 of the top 25 MS–LTC–DRGs decreased, while the geometric length of stay for 6 of these 18 MS–LTC–DRGs increased. The commenter believes this is counterintuitive and that, by recognizing a MS–LTC–DRG will require longer care, the MS–LTC–DRG weight should innately increase. The commenter stated that the proposed decreases to the weights of these MS–LTC–DRGs will allocate less funding for patients who can only receive the level of care they need at LTCHs because other care settings cannot meet the medical needs of the patients.

Response: We were unable to replicate the commenter's calculations. Based on the proposed FY 2024 MS–LTC–DRG relative weights, we determined that 16 of the top 25 MS–LTC–DRGs (determined by number of applicable LTCH cases in the FY 2022 MedPAR file) would see their relative weights decrease relative to their FY 2023 relative weight. Of these 16 MS–LTC–DRGs, we determined that the proposed geometric length of stay would increase for 3 of these MS–LTC–DRGs. We note that it should not be expected that an MS–LTC–DRG with an increased geometric length of stay will always have a corresponding increased relative weight. Each MS–LTC–DRG relative weight represents the average resources required to treat an LTCH patient grouped to that MS–LTC–DRG compared to the average resources require to treat all LTCH patients. If the average resources required to treat all LTCH patients increases more than the average resources required to treat an LTCH patient grouped to a certain MS–LTC–DRG, then the relative weight for that MS–LTC–DRG will decrease.

Comment: A commenter expressed concern regarding the high concentration of LTCH discharges assigned to only two MS–LTC–DRGs: 189 (Pulmonary edema and respiratory failure) and 207 (Respiratory system diagnosis with ventilator support 96+ hours). The commenter stated that these two MS–LTC–DRGs alone account for more than 40 percent of LTCH stays. Due to this high concentration, the commenter encouraged CMS to study splitting and refining by complication or comorbidity (CC) and major complication or comorbidity (MCC) these MS–LTC–DRGs. The commenter believes this high concentration is one of the main factors causing annual increases in the fixed-loss amount for LTCH PPS standard Federal rate cases. The commenter stated that when there is significant concentration of cases in an MS–LTC–DRG, there is a wide range of costs among the cases assigned to the MS–LTC–DRG, making it more likely that there will be high cost outlier cases in the cases assigned to the MS–LTC–DRG.

Response: We thank the commenter for this suggestion to further study these MS–LTC–DRGs. We may consider this suggestion for future rulemaking.

Comment: A commenter objected to our proposal to continue to apply a budget neutrality adjustment to the MS–LTC–DRG relative weights so that the 10-percent cap on relative weight reductions is implemented in a budget neutral manner. This commenter urged CMS to fund this policy for FY 2024 with additional new funds rather than through a budget-neutrality reduction.

Response: We thank the commenter for this comment. However, we continue to believe it is appropriate to apply this policy in a budget neutral manner, consistent with the existing budget neutrality requirement for annual MS–LTC–DRG reclassification and recalibration, which we adopted to mitigate estimated fluctuations in estimated aggregate LTCH PPS payments (72 FR 26881 through 26882).

After consideration of the comments we received, we are finalizing, without modification, our proposed methodology for determining the MS–LTC–DRG relative weights for FY 2024. In the remainder of this section, we present our finalized methodology. We first list and provide a brief description of our steps for determining the FY 2024 MS–LTC–DRG relative weights. We then, later in this section, discuss in greater detail each step. (We note for FY 2023, to account for the impact of COVID–19 on the ratesetting data, we finalized a temporary modification to our relative weights methodology that established the FY 2023 MS–LTC–DRG relative weights as an average of the relative weights calculated both including and excluding COVID–19 cases. For FY 2024, as we proposed, we are returning to our historical relative weight methodology as described in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58898 through 58907), subject to a ten percent cap as described in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49162). For this reason, the steps presented in this section differ from those presented in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49155 through 49162).)

- *Step 1—Prepare data for MS–LTC–DRG relative weight calculation.* In this step, we select and group the applicable claims data used in the development of the MS–LTC–DRG relative weights.
- *Step 2—Remove cases with a length of stay of 7 days or less.* In this step, we

trim the applicable claims data to remove cases with a length of stay of 7 days or less.

• *Step 3—Establish low-volume MS–LTC–DRG quintiles.* In this step, we employ our established quintile methodology for low-volume MS–LTC–DRGs (that is, MS–LTC–DRGs with less than 25 cases).

• *Step 4—Remove statistical outliers.* In this step, we trim the applicable claims data to remove statistical outlier cases.

• *Step 5—Adjust charges for the effects of Short Stay Outliers (SSOs).* In this step, we adjust the number of applicable cases in each MS–LTC–DRG (or low-volume quintile) for the effect of SSO cases.

• *Step 6—Calculate the relative weights on an iterative basis using the hospital-specific relative weights methodology.* In this step, we use our established hospital-specific relative value (HSRV) methodology, which is an iterative process, to calculate the relative weights.

• *Step 7—Adjust the relative weights to account for nonmonotonically increasing relative weights.* In this step, we make adjustments that ensure that within each base MS–LTC–DRG, the relative weights increase by MS–LTC–DRG severity.

• *Step 8—Determine a relative weight for MS–LTC–DRGs with no applicable LTCH cases.* In this step, we cross-walk each no-volume MS–LTC–DRG to another MS–LTC–DRG for which we calculated a relative weight.

• *Step 9—Budget neutralize the uncapped relative weights.* In this step, to ensure budget neutrality in the annual update to the MS–LTC–DRG classifications and relative weights, we adjust the relative weights by a normalization factor and a budget neutrality factor that ensures estimated aggregate LTCH PPS payments will be unaffected by the updates to the MS–LTC–DRG classifications and relative weights.

• *Step 10—Apply the 10-percent cap to decreases in MS–LTC–DRG relative weights.* In this step we limit the reduction of the relative weight for a MS–LTC–DRG to 10 percent of its prior year value. This 10-percent cap does not apply to zero-volume MS–LTC–DRGs or low-volume MS–LTC–DRGs.

• *Step 11—Budget neutralize the application of the 10-percent cap policy.* In this step, to ensure budget neutrality in the application of the MS–LTC–DRG cap policy, we adjust the relative weights by a budget neutrality factor that ensures estimated aggregate LTCH PPS payments will be unaffected by our application of the cap to the MS–LTC–DRG relative weights.

We next describe each of the 11 proposed steps for calculating the proposed FY 2024 MS–LTC–DRG relative weights in greater detail.

Step 1—Prepare data for MS–LTC–DRG relative weight calculation.

For the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27067), consistent with our proposal in section I.E. of the preamble of the proposed rule to use FY 2022 data in the FY 2024 LTCH PPS ratesetting, we obtained total charges from FY 2022 Medicare LTCH claims data from the December 2022 update of the FY 2022 MedPAR file and used proposed Version 41 of the GROUPER to classify LTCH cases. Consistent with our historical practice, we proposed that if better data become available, we would use those data and the finalized Version 41 of the GROUPER in establishing the FY 2024 MS–LTC–DRG relative weights in the final rule. Accordingly, for this final rule, we are establishing the FY 2024 MS–LTC–DRG relative weights based on updated FY 2022 Medicare LTCH claims data from the March 2023 update of the FY 2022 MedPAR file, which is the best available data at the time of development of this final rule, and the finalized Version 41 of the GROUPER to classify LTCH cases.

To calculate the FY 2024 MS–LTC–DRG relative weights under the dual rate LTCH PPS payment structure, as we proposed, we continue to use applicable LTCH data, which includes our policy of only using cases that meet the criteria for exclusion from the site neutral payment rate (or would have met the criteria had they been in effect at the time of the discharge) (80 FR 49624). Specifically, we began by first evaluating the LTCH claims data in the March 2023 update of the FY 2022 MedPAR file to determine which LTCH cases would meet the criteria for exclusion from the site neutral payment rate under § 412.522(b) or had the dual rate LTCH PPS payment structure applied to those cases at the time of discharge. We identified the FY 2022 LTCH cases that were not assigned to MS–LTC–DRGs 876, 880, 881, 882, 883, 884, 885, 886, 887, 894, 895, 896, 897, 945, and 946, which identify LTCH cases that do not have a principal diagnosis relating to a psychiatric diagnosis or to rehabilitation; and that either—

• The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the immediately preceding stay in that subsection (d) hospital included at least 3 days in an ICU, as we define under the ICU criterion; or

• The admission to the LTCH was ''immediately preceded'' by discharge from a subsection (d) hospital and the claim for the LTCH discharge includes the applicable procedure code that indicates at least 96 hours of ventilator services were provided during the LTCH stay, as we define under the ventilator criterion. Claims data from the FY 2022 MedPAR file that reported ICD–10–PCS procedure code 5A1955Z were used to identify cases involving at least 96 hours of ventilator services in accordance with the ventilator criterion. (We note that section 3711(b)(2) of the CARES Act, which provided a waiver of the application of the site neutral payment rate for LTCH cases admitted during the COVID–19 PHE period, was in effect for the entirety of FY 2022. Therefore, all LTCH PPS cases in FY 2022 were paid the LTCH PPS standard Federal rate regardless of whether the discharge met the statutory patient criteria. However, for purposes of setting rates for LTCH PPS standard Federal rate cases for FY 2024 (including MS–LTC–DRG relative weights), we used FY 2022 cases that meet the statutory patient criteria without consideration to how those cases were paid in FY 2022.)

Furthermore, consistent with our historical methodology, we excluded any claims in the resulting data set that were submitted by LTCHs that were all-inclusive rate providers and LTCHs that are paid in accordance with demonstration projects authorized under section 402(a) of Public Law 90–248 or section 222(a) of Public Law 92–603. In addition, consistent with our historical practice and our policies, we excluded any Medicare Advantage (Part C) claims in the resulting data. Such claims were identified based on the presence of a GHO Paid indicator value of ''1'' in the MedPAR files.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49448), we discussed an LTCH (CCN 312024) whose abnormal charging practices in FY 2021 led to the LTCH receiving an excessive amount of high cost outlier payments. In that rule, we stated our belief, based on information we received from the provider, that these abnormal charging practices would not persist into FY 2023. Therefore, we did not include their cases in our model for determining the FY 2023 outlier fixed-loss amount. The FY 2022 MedPAR claims also reflect the abnormal charging practices of this LTCH. In the March 2023 update of the FY 2022 MedPAR file, we identified 166 LTCH PPS standard Federal payment rate cases for this LTCH. Of these 166 cases, 118 of the cases had charges that were exactly or

within ten dollars of $10 million. Since the majority of this LTCH's FY 2022 claims reflect very little variation in charges, we do not believe they are an accurate reflection of relative resources used and therefore it would not be appropriate to use these claims in determining the FY 2024 MS–LTC–DRG relative weights. Therefore, as we proposed, we removed claims from CCN 312024 when determining the FY 2024 MS–LTC–DRG relative weights. We note, as discussed in section V of the addendum to this final rule, we also are removing this LTCH from all other FY 2024 ratesetting calculations, including the calculation of the area wage level adjustment budget neutrality factor and the fixed-loss amount for LTCH PPS standard Federal payment rate cases.

In summary, in general, we identified the claims data used in the development of the FY 2024 MS–LTC–DRG relative weights in this final rule by trimming claims data that would have been paid the site neutral payment rate had the provisions of the CARES Act not been in effect. We trimmed the claims data of all-inclusive rate providers reported in the March 2023 update of the FY 2022 MedPAR file and any Medicare Advantage claims data. There were no data from any LTCHs that are paid in accordance with a demonstration project reported in the March 2023 update of the FY 2022 MedPAR file, but had there been any, we would have trimmed the claims data from those LTCHs as well, in accordance with our established policy. We also removed all claims from CCN 312024.

We used the remaining data (that is, the applicable LTCH data) in the subsequent steps to calculate the MS–LTC–DRG relative weights for FY 2024.

Step 2—Remove cases with a length of stay of 7 days or less.

The next step in our calculation of the FY 2024 MS–LTC–DRG relative weights is to remove cases with a length of stay of 7 days or less. The MS–LTC–DRG relative weights reflect the average of resources used on representative cases of a specific type. Generally, cases with a length of stay of 7 days or less do not belong in an LTCH because these stays do not fully receive or benefit from treatment that is typical in an LTCH stay, and full resources are often not used in the earlier stages of admission to an LTCH. If we were to include stays of 7 days or less in the computation of the FY 2024 MS–LTC–DRG relative weights, the value of many relative weights would decrease and, therefore, payments would decrease to a level that may no longer be appropriate. We do not believe that it would be appropriate to compromise the integrity of the payment determination for those LTCH cases that actually benefit from and receive a full course of treatment at an LTCH by including data from these very short stays. Therefore, as we proposed, consistent with our existing relative weight methodology, in determining the FY 2024 MS–LTC–DRG relative weights, we removed LTCH cases with a length of stay of 7 days or less from applicable LTCH cases. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 3—Establish low-volume MS–LTC–DRG quintiles.

To account for MS–LTC–DRGs with low-volume (that is, with fewer than 25 applicable LTCH cases), consistent with our existing methodology, as we proposed, we are continuing to employ the quintile methodology for low-volume MS–LTC–DRGs, such that we grouped the ''low-volume MS–LTC–DRGs'' (that is, MS–LTC–DRGs that contain between 1 and 24 applicable LTCH cases into one of five categories (quintiles) based on average charges (67 FR 55984 through 55995; 72 FR 47283 through 47288; and 81 FR 25148)).

In this final rule, based on the best available data (that is, the March 2023 update of the FY 2022 MedPAR file), we identified 236 MS–LTC–DRGs that contained between 1 and 24 applicable LTCH cases. This list of MS–LTC–DRGs was then divided into 1 of the 5 low-volume quintiles. We assigned the low-volume MS–LTC–DRGs to specific low-volume quintiles by sorting the low-volume MS–LTC–DRGs in ascending order by average charge in accordance with our established methodology. Based on the data available for this final rule, the number of MS–LTC–DRGs with less than 25 applicable LTCH cases was not evenly divisible by 5. The quintiles each contained at least 47 MS–LTC–DRGs (236/5 = 47 with a remainder of 1). As we proposed, we employed our historical methodology of assigning each remainder low-volume MS–LTC–DRG to the low-volume quintile that contains an MS–LTC–DRG with an average charge closest to that of the remainder low-volume MS–LTC–DRG. In cases where these initial assignments of low-volume MS–LTC–DRGs to quintiles results in nonmonotonicity within a base-DRG, as we proposed, we adjusted the resulting low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in Step 7 of our methodology.

To determine the FY 2024 relative weights for the low-volume MS–LTC–DRGs, consistent with our historical practice, we used the five low-volume quintiles described previously. We determined a relative weight and (geometric) average length of stay for each of the five low-volume quintiles using the methodology described in Step 6 of our methodology. We assigned the same relative weight and average length of stay to each of the low-volume MS–LTC–DRGs that make up an individual low-volume quintile. We note that, as this system is dynamic, it is possible that the number and specific type of MS–LTC–DRGs with a low-volume of applicable LTCH cases would vary in the future. Furthermore, we note that we continue to monitor the volume (that is, the number of applicable LTCH cases) in the low-volume quintiles to ensure that our quintile assignments used in determining the MS–LTC–DRG relative weights result in appropriate payment for LTCH cases grouped to low-volume MS–LTC–DRGs and do not result in an unintended financial incentive for LTCHs to inappropriately admit these types of cases.

For this final rule, we are providing the list of the composition of the low-volume quintiles for low-volume MS–LTC–DRGs in a supplemental data file for public use posted via the internet on the CMS website for this final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* to streamline the information made available to the public that is used in the annual development of Table 11.

Step 4—Remove statistical outliers.

The next step in our calculation of the FY 2024 MS–LTC–DRG relative weights is to remove statistical outlier cases from the LTCH cases with a length of stay of at least 8 days. Consistent with our existing relative weight methodology, as we proposed, we are continuing to define statistical outliers as cases that are outside of 3.0 standard deviations from the mean of the log distribution of both charges per case and the charges per day for each MS–LTC–DRG. These statistical outliers are removed prior to calculating the relative weights because we believe that they may represent aberrations in the data that distort the measure of average resource use. Including those LTCH cases in the calculation of the relative weights could result in an inaccurate relative weight that does not truly reflect relative resource use among those MS–LTC–DRGs. (For additional information on what is removed in this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.) After removing cases with a length of stay of 7 days or less and statistical outliers, in each set of claims, we were left with applicable LTCH cases that have a length of stay greater

than or equal to 8 days. In this final rule, we refer to these cases as ''trimmed applicable LTCH cases.''

Step 5—Adjust charges for the effects of Short Stay Outliers (SSOs).

As the next step in the calculation of the FY 2024 MS–LTC–DRG relative weights, consistent with our historical approach, as we proposed, we adjusted each LTCH's charges per discharge for those remaining cases (that is, trimmed applicable LTCH cases) for the effects of SSOs (as defined in § 412.529(a) in conjunction with § 412.503). Specifically, as we proposed, we made this adjustment by counting an SSO case as a fraction of a discharge based on the ratio of the length of stay of the case to the average length of stay of all cases grouped to the MS–LTC–DRG. This has the effect of proportionately reducing the impact of the lower charges for the SSO cases in calculating the average charge for the MS–LTC–DRG. This process produces the same result as if the actual charges per discharge of an SSO case were adjusted to what they would have been had the patient's length of stay been equal to the average length of stay of the MS–LTC–DRG.

Counting SSO cases as full LTCH cases with no adjustment in determining the FY 2024 MS–LTC–DRG relative weights would lower the relative weight for affected MS–LTC–DRGs because the relatively lower charges of the SSO cases would bring down the average charge for all cases within a MS–LTC–DRG. This would result in an ''underpayment'' for non-SSO cases and an ''overpayment'' for SSO cases. Therefore, we are continuing to adjust for SSO cases under § 412.529 in this manner because it would result in more appropriate payments for all LTCH PPS standard Federal payment rate cases. (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55989 and 74 FR 43959.)

Step 6—Calculate the relative weights on an iterative basis using the hospital-specific relative value methodology.

By nature, LTCHs often specialize in certain areas, such as ventilator-dependent patients. Some case types (MS–LTC–DRGs) may be treated, to a large extent, in hospitals that have, from a perspective of charges, relatively high (or low) charges. This nonrandom distribution of cases with relatively high (or low) charges in specific MS–LTC–DRGs has the potential to inappropriately distort the measure of average charges. To account for the fact that cases may not be randomly distributed across LTCHs, consistent with the methodology we have used since the implementation of the LTCH PPS, in this FY 2024 IPPS/LTCH PPS final rule, as we proposed, we are continuing to use a hospital-specific relative value (HSRV) methodology to calculate the MS–LTC–DRG relative weights for FY 2024. We believe that this method removes this hospital-specific source of bias in measuring LTCH average charges (67 FR 55985). Specifically, under this methodology, we reduced the impact of the variation in charges across providers on any particular MS–LTC–DRG relative weight by converting each LTCH's charge for an applicable LTCH case to a relative value based on that LTCH's average charge for such cases.

Under the HSRV methodology, we standardize charges for each LTCH by converting its charges for each applicable LTCH case to hospital-specific relative charge values and then adjusting those values for the LTCH's case-mix. The adjustment for case-mix is needed to rescale the hospital-specific relative charge values (which, by definition, average 1.0 for each LTCH). The average relative weight for an LTCH is its case-mix; therefore, it is reasonable to scale each LTCH's average relative charge value by its case-mix. In this way, each LTCH's relative charge value is adjusted by its case-mix to an average that reflects the complexity of the applicable LTCH cases it treats relative to the complexity of the applicable LTCH cases treated by all other LTCHs (the average LTCH PPS case-mix of all applicable LTCH cases across all LTCHs). In other words, by multiplying an LTCH's relative charge values by the LTCH's case-mix index, we account for the fact that the same relative charges are given greater weight at an LTCH with higher average costs than they would at an LTCH with low average costs, which is needed to adjust each LTCH's relative charge value to reflect its case-mix relative to the average case-mix for all LTCHs. By standardizing charges in this manner, we count charges for a Medicare patient at an LTCH with high average charges as less resource-intensive than they would be at an LTCH with low average charges. For example, a $10,000 charge for a case at an LTCH with an average adjusted charge of $17,500 reflects a higher level of relative resource use than a $10,000 charge for a case at an LTCH with the same case-mix, but an average adjusted charge of $35,000. We believe that the adjusted charge of an individual case more accurately reflects actual resource use for an individual LTCH because the variation in charges due to systematic differences in the markup of charges among LTCHs is taken into account.

Consistent with our historical relative weight methodology, as we proposed, we calculated the FY 2024 MS–LTC–DRG relative weights using the HSRV methodology, which is an iterative process. Therefore, in accordance with our established methodology, for FY 2024, we continued to standardize charges for each applicable LTCH case by first dividing the adjusted charge for the case (adjusted for SSOs under § 412.529 as described in Step 5 of our methodology) by the average adjusted charge for all applicable LTCH cases at the LTCH in which the case was treated. The average adjusted charge reflects the average intensity of the health care services delivered by a particular LTCH and the average cost level of that LTCH. The average adjusted charge is then multiplied by the LTCH's case-mix index to produce an adjusted hospital-specific relative charge value for the case. We used an initial case-mix index value of 1.0 for each LTCH.

For each MS–LTC–DRG, we calculated the FY 2024 relative weight by dividing the SSO-adjusted average of the hospital-specific relative charge values for applicable LTCH cases for the MS–LTC–DRG (that is, the sum of the hospital-specific relative charge value, as previously stated, divided by the sum of equivalent cases from Step 5 for each MS–LTC–DRG) by the overall SSO-adjusted average hospital-specific relative charge value across all applicable LTCH cases for all LTCHs (that is, the sum of the hospital-specific relative charge value, as previously stated, divided by the sum of equivalent applicable LTCH cases from Step 5 for each MS–LTC–DRG). Using these recalculated MS–LTC–DRG relative weights, each LTCH's average relative weight for all of its SSO-adjusted trimmed applicable LTCH cases (that is, it's case-mix) was calculated by dividing the sum of all the LTCH's MS–LTC–DRG relative weights by its total number of SSO-adjusted trimmed applicable LTCH cases. The LTCHs' hospital-specific relative charge values (from previous) are then multiplied by the hospital-specific case-mix indexes. The hospital-specific case-mix adjusted relative charge values are then used to calculate a new set of MS–LTC–DRG relative weights across all LTCHs. This iterative process continued until there was convergence between the relative weights produced at adjacent steps, for example, when the maximum difference was less than 0.0001.

Step 7—Adjust the relative weights to account for nonmonotonically increasing relative weights.

The MS–DRGs contain base DRGs that have been subdivided into one, two, or three severity of illness levels. Where there are three severity levels, the most severe level has at least one secondary diagnosis code that is referred to as an MCC (that is, major complication or comorbidity). The next lower severity level contains cases with at least one secondary diagnosis code that is a CC (that is, complication or comorbidity). Those cases without an MCC or a CC are referred to as ''without CC/MCC.'' When data do not support the creation of three severity levels, the base MS–DRG is subdivided into either two levels or the base MS–DRG is not subdivided. The two-level subdivisions may consist of the MS–DRG with CC/MCC and the MS–DRG without CC/MCC. Alternatively, the other type of two-level subdivision may consist of the MS–DRG with MCC and the MS–DRG without MCC.

In those base MS–LTC–DRGs that are split into either two or three severity levels, cases classified into the ''without CC/MCC'' MS–LTC–DRG are expected to have a lower resource use (and lower costs) than the ''with CC/MCC'' MS–LTC–DRG (in the case of a two-level split) or both the ''with CC'' and the ''with MCC'' MS–LTC–DRGs (in the case of a three-level split). That is, theoretically, cases that are more severe typically require greater expenditure of medical care resources and would result in higher average charges. Therefore, in the three severity levels, relative weights should increase by severity, from lowest to highest. If the relative weights decrease as severity increases (that is, if within a base MS–LTC–DRG, an MS–LTC–DRG with CC has a higher relative weight than one with MCC, or the MS–LTC–DRG ''without CC/MCC'' has a higher relative weight than either of the others), they are nonmonotonic. We continue to believe that utilizing nonmonotonic relative weights to adjust Medicare payments would result in inappropriate payments because the payment for the cases in the higher severity level in a base MS–LTC–DRG (which are generally expected to have higher resource use and costs) would be lower than the payment for cases in a lower severity level within the same base MS–LTC–DRG (which are generally expected to have lower resource use and costs). Therefore, in determining the FY 2024 MS–LTC–DRG relative weights, consistent with our historical methodology, as we proposed, we continued to combine MS–LTC–DRG severity levels within a base MS–LTC–DRG for the purpose of computing a relative weight when necessary to ensure that monotonicity is maintained. For a comprehensive description of our existing methodology to adjust for nonmonotonicity, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (74 FR 43964 through 43966). Any adjustments for nonmonotonicity that were made in determining the FY 2024 MS–LTC–DRG relative weights by applying this methodology are denoted in Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the internet on the CMS website.

Step 8—Determine a relative weight for MS–LTC–DRGs with no applicable LTCH cases.

Using the trimmed applicable LTCH cases, consistent with our historical methodology, we identified the MS–LTC–DRGs for which there were no claims in the March 2023 update of the FY 2022 MedPAR file and, therefore, for which no charge data was available for these MS–LTC–DRGs. Because patients with a number of the diagnoses under these MS–LTC–DRGs may be treated at LTCHs, consistent with our historical methodology, we generally assign a relative weight to each of the no-volume MS–LTC–DRGs based on clinical similarity and relative costliness (with the exception of ''transplant'' MS–LTC–DRGs, ''error'' MS–LTC–DRGs, and MS–LTC–DRGs that indicate a principal diagnosis related to a psychiatric diagnosis or rehabilitation (referred to as the ''psychiatric or rehabilitation'' MS–LTC–DRGs), as discussed later in this section of this final rule). (For additional information on this step of the relative weight methodology, we refer readers to 67 FR 55991 and 74 FR 43959 through 43960.)

Consistent with our existing methodology, as we proposed, we cross-walked each no-volume MS–LTC–DRG to another MS–LTC–DRG for which we calculated a relative weight (determined in accordance with the methodology as previously described). Then, the ''no-volume'' MS–LTC–DRG is assigned the same relative weight (and average length of stay) of the MS–LTC–DRG to which it was cross-walked (as described in greater detail in this section of this final rule).

Of the 766 MS–LTC–DRGs for FY 2024, we identified 429 MS–LTC–DRGs for which there were no trimmed applicable LTCH cases. The 429 MS LTC DRGs for which there were no trimmed applicable LTCH cases includes the 11 ''transplant'' MS–LTC–DRGs, the 2 ''error'' MS–LTC–DRGs, and the 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs, which are discussed in this section of this rule, such that we identified 401 MS–LTC–DRGs that for which, we assigned a relative weight using our existing ''no-volume'' MS–LTC–DRG methodology (that is, 429 − 11 − 2 − 15 = 401). As we proposed, we assigned relative weights to each of the 401 no-volume MS–LTC–DRGs based on clinical similarity and relative costliness to 1 of the remaining 337 (766 − 429 = 337) MS–LTC–DRGs for which we calculated relative weights based on the trimmed applicable LTCH cases in the FY 2022 MedPAR file data using the steps described previously. (For the remainder of this discussion, we refer to the ''cross-walked'' MS–LTC–DRGs as one of the 337 MS–LTC–DRGs to which we cross-walked each of the 401 ''no-volume'' MS–LTC–DRGs.) Then, in general, we assigned the 401 no-volume MS–LTC–DRGs the relative weight of the cross-walked MS–LTC–DRG (when necessary, we made adjustments to account for nonmonotonicity).

We cross-walked the no-volume MS–LTC–DRG to a MS–LTC–DRG for which we calculated relative weights based on the March 2023 update of the FY 2022 MedPAR file, and to which it is similar clinically in intensity of use of resources and relative costliness as determined by criteria such as care provided during the period of time surrounding surgery, surgical approach (if applicable), length of time of surgical procedure, postoperative care, and length of stay. (For more details on our process for evaluating relative costliness, we refer readers to the FY 2010 IPPS/RY 2010 LTCH PPS final rule (73 FR 48543).) We believe in the rare event that there would be a few LTCH cases grouped to one of the no-volume MS–LTC–DRGs in FY 2024, the relative weights assigned based on the cross-walked MS–LTC–DRGs would result in an appropriate LTCH PPS payment because the crosswalks, which are based on clinical similarity and relative costliness, would be expected to generally require equivalent relative resource use.

Then we assigned the relative weight of the cross-walked MS–LTC–DRG as the relative weight for the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight (and average length of stay) for FY 2024. We note that, if the cross-walked MS–LTC–DRG had 25 applicable LTCH cases or more, its relative weight (calculated using the methodology as previously described in Steps 1 through 4) is assigned to the no-volume MS–LTC–DRG as well. Similarly, if the MS–LTC–DRG to which the no-volume MS–LTC–DRG was cross-walked had 24 or less cases and,

therefore, was designated to 1 of the low-volume quintiles for purposes of determining the relative weights, we assigned the relative weight of the applicable low-volume quintile to the no-volume MS–LTC–DRG such that both of these MS–LTC–DRGs (that is, the no-volume MS–LTC–DRG and the cross-walked MS–LTC–DRG) have the same relative weight for FY 2024. (As we noted previously, in the infrequent case where nonmonotonicity involving a no-volume MS–LTC–DRG resulted, additional adjustments are required to maintain monotonically increasing relative weights.)

For this final rule, we are providing the list of the no-volume MS–LTC–DRGs and the MS–LTC–DRGs to which each was cross-walked (that is, the cross-walked MS–LTC–DRGs) for FY 2024 in a supplemental data file for public use posted via the internet on the CMS website for this final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html* to streamline the information made available to the public that is used in the annual development of Table 11.

To illustrate this methodology for determining the relative weights for the FY 2024 MS–LTC–DRGs with no applicable LTCH cases, we are providing the following example.

Example: There were no trimmed applicable LTCH cases in the FY 2022 MedPAR file that we are using for this final rule for MS–LTC–DRG 061 (Ischemic stroke, precerebral occlusion or transient ischemia with thrombolytic agent with MCC). We determined that MS–LTC–DRG 064 (Intracranial hemorrhage or cerebral infarction with MCC) is similar clinically and based on resource use to MS–LTC–DRG 061. Therefore, we assigned the same relative weight (and average length of stay) of MS–LTC–DRG 064 of 1.4532 for FY 2024 to MS–LTC–DRG 061 (we refer readers to Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the internet on the CMS website).

Again, we note that, as this system is dynamic, it is entirely possible that the number of MS–LTC–DRGs with no volume would vary in the future. Consistent with our historical practice, as we proposed, we used the best available claims data to identify the trimmed applicable LTCH cases from which we determined the relative weights in the final rule.

For FY 2024, consistent with our historical relative weight methodology, as we proposed, we are establishing a relative weight of 0.0000 for the following transplant MS–LTC–DRGs: Heart Transplant or Implant of Heart Assist System with MCC (MS–LTC–DRG 001); Heart Transplant or Implant of Heart Assist System without MCC (MS–LTC–DRG 002); Liver Transplant with MCC or Intestinal Transplant (MS–LTC–DRG 005); Liver Transplant without MCC (MS–LTC–DRG 006); Lung Transplant (MS–LTC–DRG 007); Simultaneous Pancreas/Kidney Transplant (MS–LTC–DRG 008); Simultaneous Pancreas/Kidney Transplant with Hemodialysis (MS–LTC–DRG 019); Pancreas Transplant (MS–LTC–DRG 010); Kidney Transplant (MS–LTC–DRG 652); Kidney Transplant with Hemodialysis with MCC (MS–LTC–DRG 650), and Kidney Transplant with Hemodialysis without MCC (MS LTC DRG 651). This is because Medicare only covers these procedures if they are performed at a hospital that has been certified for the specific procedures by Medicare and presently no LTCH has been so certified. At the present time, we include these 11 transplant MS–LTC–DRGs in the GROUPER program for administrative purposes only. Because we use the same GROUPER program for LTCHs as is used under the IPPS, removing these MS–LTC–DRGs would be administratively burdensome. (For additional information regarding our treatment of transplant MS–LTC–DRGs, we refer readers to the RY 2010 LTCH PPS final rule (74 FR 43964).) In addition, consistent with our historical policy, we are establishing a relative weight of 0.0000 for the 2 ''error'' MS–LTC–DRGs (that is, MS–LTC–DRG 998 (Principal Diagnosis Invalid as Discharge Diagnosis) and MS–LTC–DRG 999 (Ungroupable)) because applicable LTCH cases grouped to these MS–LTC–DRGs cannot be properly assigned to an MS–LTC–DRG according to the grouping logic.

Additionally, we are establishing a relative weight of 0.0000 for the following ''psychiatric or rehabilitation'' MS–LTC–DRGs: MS–LTC–DRG 876 (O.R. Procedure with Principal Diagnoses of Mental Illness); MS–LTC–DRG 880 (Acute Adjustment Reaction & Psychosocial Dysfunction); MS–LTC–DRG 881 (Depressive Neuroses); MS–LTC–DRG 882 (Neuroses Except Depressive); MS–LTC–DRG 883 (Disorders of Personality & Impulse Control); MS–LTC–DRG 884 (Organic Disturbances & Mental Retardation); MS–LTC–DRG 885 (Psychoses); MS–LTC–DRG 886 (Behavioral & Developmental Disorders); MS–LTC–DRG 887 (Other Mental Disorder Diagnoses); MS–LTC–DRG 894 (Alcohol/Drug Abuse or Dependence, Left Ama); MS–LTC–DRG 895 (Alcohol/Drug Abuse or Dependence, with Rehabilitation Therapy); MS–LTC–DRG 896 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy with MCC); MS–LTC–DRG 897 (Alcohol/Drug Abuse or Dependence, without Rehabilitation Therapy without MCC); MS–LTC–DRG 945 (Rehabilitation with CC/MCC); and MS–LTC–DRG 946 (Rehabilitation without CC/MCC). We are establishing a relative weight of 0.0000 for these 15 ''psychiatric or rehabilitation'' MS–LTC–DRGs because the blended payment rate and temporary exceptions to the site neutral payment rate would not be applicable for any LTCH discharges occurring in FY 2024, and as such payment under the LTCH PPS would be no longer be made in part based on the LTCH PPS standard Federal payment rate for any discharges assigned to those MS–LTC–DRGs.

Step 9—Budget neutralize the uncapped relative weights.

In accordance with the regulations at § 412.517(b) (in conjunction with § 412.503), the annual update to the MS–LTC–DRG classifications and relative weights is done in a budget neutral manner such that estimated aggregate LTCH PPS payments would be unaffected, that is, would be neither greater than nor less than the estimated aggregate LTCH PPS payments that would have been made without the MS–LTC–DRG classification and relative weight changes. (For a detailed discussion on the establishment of the budget neutrality requirement for the annual update of the MS–LTC–DRG classifications and relative weights, we refer readers to the RY 2008 LTCH PPS final rule (72 FR 26881 and 26882).

To achieve budget neutrality under the requirement at § 412.517(b), under our established methodology, for each annual update the MS–LTC–DRG relative weights are uniformly adjusted to ensure that estimated aggregate payments under the LTCH PPS would not be affected (that is, decreased or increased). Consistent with that provision, as we proposed, we continued to apply budget neutrality adjustments in determining the FY 2024 MS–LTC–DRG relative weights so that our update of the MS–LTC–DRG classifications and relative weights for FY 2024 are made in a budget neutral manner. For FY 2024, as we proposed, we applied two budget neutrality factors to determine the MS–LTC–DRG relative weights. In this step, we describe the determination of the budget neutrality adjustment that accounts for the update of the MS–LTC–DRG classifications and relative weights prior to the application

of the ten-percent cap. In steps 10 and 11, we describe the application of the 10-percent cap policy (step 10) and the determination of the budget neutrality factor that accounts for the application of the 10-percent cap policy (step 11).

In this final rule, to ensure budget neutrality for the update to the MS–LTC–DRG classifications and relative weights prior to the application of the 10-percent cap (that is, uncapped relative weights), under § 412.517(b), we continued to use our established two-step budget neutrality methodology. Therefore, in the first step of our MS–LTC–DRG update budget neutrality methodology, for FY 2024, we calculated and applied a normalization factor to the recalibrated relative weights (the result of Steps 1 through 8 discussed previously) to ensure that estimated payments are not affected by changes in the composition of case types or the changes to the classification system. That is, the normalization adjustment is intended to ensure that the recalibration of the MS–LTC–DRG relative weights (that is, the process itself) neither increases nor decreases the average case-mix index.

To calculate the normalization factor for FY 2024, we used the following three steps: (1.a.) use the applicable LTCH cases from the best available data (that is, LTCH discharges from the FY 2022 MedPAR file) and group them using the FY 2024 GROUPER (that is, Version 41 for FY 2024) and the recalibrated FY 2024 MS–LTC–DRG uncapped relative weights (determined in Steps 1 through 8 discussed previously) to calculate the average case-mix index; (1.b.) group the same applicable LTCH cases (as are used in Step 1.a.) using the FY 2023 GROUPER (Version 40) and FY 2023 MS–LTC–DRG relative weights and calculate the average case-mix index; and (1.c.) compute the ratio of these average case-mix indexes by dividing the average case-mix index for FY 2023 (determined in Step 1.b.) by the average case-mix index for FY 2024 (determined in Step 1.a.). As a result, in determining the MS–LTC–DRG relative weights for FY 2024, each recalibrated MS–LTC–DRG uncapped relative weight is multiplied by the normalization factor of 1.31064 (determined in Step 1.c.) in the first step of the budget neutrality methodology, which produces ''normalized relative weights.''

In the second step of our MS–LTC–DRG update budget neutrality methodology, we calculated a budget neutrality adjustment factor consisting of the ratio of estimated aggregate FY 2024 LTCH PPS standard Federal payment rate payments for applicable LTCH cases before reclassification and recalibration to estimated aggregate payments for FY 2024 LTCH PPS standard Federal payment rate payments for applicable LTCH cases after reclassification and recalibration. That is, for this final rule, for FY 2024, we determined the budget neutrality adjustment factor using the following three steps: (2.a.) simulate estimated total FY 2024 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the uncapped normalized relative weights for FY 2024 and GROUPER Version 41; (2.b.) simulate estimated total FY 2024 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the FY 2023 GROUPER (Version 40) and the FY 2023 MS–LTC–DRG relative weights in Table 11 of the FY 2023 IPPS/LTCH PPS final rule; and (2.c.) calculate the ratio of these estimated total payments by dividing the value determined in Step 2.b. by the value determined in Step 2.a. In determining the FY 2024 MS–LTC–DRG relative weights, each uncapped normalized relative weight is then multiplied by a budget neutrality factor of 0.9964763 (the value determined in Step 2.c.) in the second step of the budget neutrality methodology.

Step 10—Apply the 10-percent cap to decreases in MS–LTC–DRG relative weights.

To mitigate the financial impacts of significant year-to-year reductions in MS–LTC–DRGs relative weights, beginning in FY 2023, we adopted a policy that applies, in a budget neutral manner, a 10-percent cap on annual relative weight decreases for MS–LTC–DRGs with at least 25 applicable LTCH cases (§ 412.515(b)). Under this policy, in cases where CMS creates new MS–LTC–DRGs or modifies the MS–LTC–DRGs as part of its annual reclassifications resulting in renumbering of one or more MS–LTC–DRGs, the 10-percent cap does not apply to the relative weight for any new or renumbered MS–LTC–DRGs for the fiscal year. We refer readers to section VIII.B.3.b. of the preamble of the FY 2023 IPPS/LTCH PPS final rule with comment period for a detailed discussion on the adoption of the 10-percent cap policy (87 FR 49152 through 49154).

Applying the 10-percent cap to MS–LTC–DRGs with 25 or more cases results in more predictable and stable MS–LTC–DRG relative weights from year to year, especially for high-volume MS–LTC–DRGs that generally have the largest financial impact on an LTCH's operations. For this final rule, in cases where the relative weight for a MS–LTC–DRG with 25 or more applicable LTCH cases would decrease by more than 10-percent in FY 2024 relative to FY 2023, as we proposed, we limited the reduction to 10-percent. Under this policy, we do not apply the 10 percent cap to the low-volume MS–LTC–DRGs identified in Step 3 or the no-volume MS–LTC–DRGs identified in Step 8.

Therefore, in this step, for each FY 2024 MS–LTC–DRG with 25 or more applicable LTCH cases (excludes low-volume and zero-volume MS–LTC–DRGs) we compared its FY 2024 relative weight (after application of the normalization and budget neutrality factors determined in Step 9), to its FY 2023 MS–LTC–DRG relative weight. For any MS–LTC–DRG where the FY 2024 relative weight would otherwise have declined more than 10 percent, we established a capped FY 2024 MS–LTC–DRG relative weight that is equal to 90 percent of that MS–LTC–DRG's FY 2023 relative weight (that is, we set the FY 2024 relative weight equal to the FY 2023 weight × 0.90).

In section II.E. of the preamble of this final rule, we discuss our changes to the MS–DRGs, and by extension the MS–LTC–DRGs, for FY 2024. As discussed previously, under our current policy, the 10-percent cap does not apply to the relative weight for any new or renumbered MS–LTC–DRGs. We did not propose any changes to this policy for FY 2024, and as such any new or renumbered MS–LTC–DRGs for FY 2024 were not eligible for the 10-percent cap.

Step 11—Budget neutralize application of the 10-percent cap policy.

Under the requirement at existing § 412.517(b) that aggregate LTCH PPS payments will be unaffected by annual changes to the MS–LTC–DRG classifications and relative weights, consistent with our established methodology, we continued to apply a budget neutrality adjustment to the MS–LTC–DRG relative weights so that the 10-percent cap on relative weight reductions (step 10) is implemented in a budget neutral manner. Therefore, we determined the budget neutrality adjustment factor for the 10-percent cap on relative weight reductions using the following three steps: (a) simulate estimated total FY 2024 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the capped relative weights for FY 2024 (determined in Step 10) and GROUPER Version 41; (b) simulate estimated total FY 2024 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the uncapped relative weights for FY 2024 (determined in Step 9) and GROUPER Version 41; and (c) calculate

the ratio of these estimated total payments by dividing the value determined in step (b) by the value determined in step (a). In determining the FY 2024 MS–LTC–DRG relative weights, each capped relative weight is then multiplied by a budget neutrality factor of 0.9984221 (the value determined in step (c)) to achieve the budget neutrality requirement.

Table 11, which is listed in section VI. of the Addendum to this final rule and is available via the internet on the CMS website, lists the MS–LTC–DRGs and their respective relative weights, geometric mean length of stay, and five-sixths of the geometric mean length of stay (used to identify SSO cases under § 412.529(a)) for FY 2024. We also are making available on the website the MS–LTC–DRG relative weights prior to the application of the 10 percent cap on MS–LTC–DRG relative weight reductions and corresponding cap budget neutrality factor.

C. Changes to the LTCH PPS Payment Rates and Other Changes to the LTCH PPS for FY 2024

1. Overview of Development of the LTCH PPS Standard Federal Payment Rates

The basic methodology for determining LTCH PPS standard Federal payment rates is currently set forth at 42 CFR 412.515 through 412.533 and 412.535. In this section, we discuss the factors that we use to update the LTCH PPS standard Federal payment rate for FY 2024, that is, effective for LTCH discharges occurring on or after October 1, 2023, through September 30, 2024. Under the dual rate LTCH PPS payment structure required by statute, beginning with discharges in cost reporting periods beginning in FY 2016, only LTCH discharges that meet the criteria for exclusion from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate specified at 42 CFR 412.523. (For additional details on our finalized policies related to the dual rate LTCH PPS payment structure required by statute, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49601 through 49623).)

Prior to the implementation of the dual payment rate system in FY 2016, all LTCH discharges were paid similarly to those now exempt from the site neutral payment rate. That legacy payment rate was called the standard Federal rate. For details on the development of the initial standard Federal rate for FY 2003, we refer readers to the August 30, 2002 LTCH PPS final rule (67 FR 56027 through 56037). For subsequent updates to the standard Federal rate from FYs 2003 through 2015, and LTCH PPS standard Federal payment rate from FY 2016 through present, as implemented under 42 CFR 412.523(c)(3), we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42445 through 42446).

In this FY 2024 IPPS/LTCH PPS final rule, we present our policies related to the annual update to the LTCH PPS standard Federal payment rate for FY 2024.

The update to the LTCH PPS standard Federal payment rate for FY 2024 is presented in section V.A. of the Addendum to this final rule. The components of the annual update to the LTCH PPS standard Federal payment rate for FY 2024 are discussed in this section, including the statutory reduction to the annual update for LTCHs that fail to submit quality reporting data for FY 2024 as required by the statute (as discussed in section VIII.C.2.c. of the preamble of this final rule). As we proposed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27073), we also made an adjustment to the LTCH PPS standard Federal payment rate to account for the estimated effect of the changes to the area wage level for FY 2024 on estimated aggregate LTCH PPS payments, in accordance with 42 CFR 412.523(d)(4) (as discussed in section V.B. of the Addendum to this final rule).

2. FY 2024 LTCH PPS Standard Federal Payment Rate Annual Market Basket Update

a. Overview

Historically, the Medicare program has used a market basket to account for input price increases in the services furnished by providers. The market basket used for the LTCH PPS includes both operating and capital-related costs of LTCHs because the LTCH PPS uses a single payment rate for both operating and capital-related costs. We adopted the 2017-based LTCH market basket for use under the LTCH PPS beginning in FY 2021 (85 FR 58907 through 58909). For additional details on the historical development of the market basket used under the LTCH PPS, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53467 through 53476), and for a complete discussion of the LTCH market basket and a description of the methodologies used to determine the operating and capital-related portions of the 2017-based LTCH market basket, we refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58909 through 58926).

Section 3401(c) of the Affordable Care Act provides for certain adjustments to any annual update to the LTCH PPS standard Federal payment rate and refers to the timeframes associated with such adjustments as a ''rate year.'' We note that, because the annual update to the LTCH PPS policies, rates, and factors now occurs on October 1, we adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010, to conform with the standard definition of the Federal fiscal year (October 1 through September 30) used by other PPSs, such as the IPPS (75 FR 50396 through 50397). Although the language of sections 3004(a), 3401(c), 10319, and 1105(b) of the Affordable Care Act refers to years 2010 and thereafter under the LTCH PPS as ''rate year,'' consistent with our change in the terminology used under the LTCH PPS from ''rate year'' to ''fiscal year,'' for purposes of clarity, when discussing the annual update for the LTCH PPS standard Federal payment rate, including the provisions of the Affordable Care Act, we use ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.

b. Annual Update to the LTCH PPS Standard Federal Payment Rate for FY 2024

As previously noted, we adopted the 2017-based LTCH market basket for use under the LTCH PPS beginning in FY 2021. The 2017-based LTCH market basket is primarily based on the Medicare cost report data submitted by LTCHs and, therefore, specifically reflects the cost structures of only LTCHs. For additional details on the development of the 2017-based LTCH market basket, we refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58909 through 58926). We continue to believe that the 2017-based LTCH market basket appropriately reflects the cost structure of LTCHs for the reasons discussed when we adopted its use in the FY 2021 IPPS/LTCH PPS final rule. Therefore, in this final rule, as we proposed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27073), we use the 2017-based LTCH market basket to update the LTCH PPS standard Federal payment rate for FY 2024.

Section 1886(m)(3)(A) of the Act provides that, beginning in FY 2010, any annual update to the LTCH PPS standard Federal payment rate is reduced by the adjustments specified in clauses (i) and (ii) of subparagraph (A), as applicable. Clause (i) of section 1886(m)(3)(A) of the Act provides for a reduction, for FY 2012 and each subsequent rate year, by ''the productivity adjustment'' described in

section 1886(b)(3)(B)(xi)(II) of the Act. Clause (ii) of section 1886(m)(3)(A) of the Act provided for a reduction, for each of FYs 2010 through 2019, by the ''other adjustment'' described in section 1886(m)(4)(F) of the Act; therefore, it is not applicable for FY 2024.

Section 1886(m)(3)(B) of the Act provides that the application of paragraph (3) of section 1886(m) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year.

c. Adjustment to the LTCH PPS Standard Federal Payment Rate Under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In accordance with section 1886(m)(5) of the Act, the Secretary established the Long-Term Care Hospital Quality Reporting Program (LTCH QRP). The reduction in the annual update to the LTCH PPS standard Federal payment rate for failure to report quality data under the LTCH QRP for FY 2014 and subsequent fiscal years is codified under 42 CFR 412.523(c)(4). The LTCH QRP, as required for FY 2014 and subsequent fiscal years by section 1886(m)(5)(A)(i) of the Act, requires that a 2.0 percentage points reduction be applied to any update under 42 CFR 412.523(c)(3) for an LTCH that does not submit quality reporting data to the Secretary in accordance with section 1886(m)(5)(C) of the Act with respect to such a year (that is, in the form and manner and at the time specified by the Secretary under the LTCH QRP) (42 CFR 412.523(c)(4)(i)). Section 1886(m)(5)(A)(ii) of the Act provides that the application of the 2.0 percentage points reduction may result in an annual update that is less than 0.0 for a year, and may result in LTCH PPS payment rates for a year being less than such LTCH PPS payment rates for the preceding year. Furthermore, section 1886(m)(5)(B) of the Act specifies that the 2.0 percentage points reduction is applied in a noncumulative manner, such that any reduction made under section 1886(m)(5)(A) of the Act shall apply only with respect to the year involved, and shall not be taken into account in computing the LTCH PPS payment amount for a subsequent year. These requirements are codified in the regulations at 42 CFR 412.523(c)(4). (For additional information on the history of the LTCH QRP, including the statutory authority and the selected measures, we refer readers to section VIII.C. of the preamble of this final rule.)

d. Annual Market Basket Update Under the LTCH PPS for FY 2024

Consistent with our historical practice, we estimate the market basket percentage increase and the productivity adjustment based on IHS Global Inc.'s (IGI's) forecast using the most recent available data. Based on IGI's fourth quarter 2022 forecast, the proposed FY 2024 market basket percentage increase for the LTCH PPS using the 2017-based LTCH market basket was 3.1 percent. The proposed productivity adjustment for FY 2024 based on IGI's fourth quarter 2022 forecast was 0.2 percentage point.

For FY 2024, section 1886(m)(3)(A)(i) of the Act requires that any annual update to the LTCH PPS standard Federal payment rate be reduced by the productivity adjustment, described in section 1886(b)(3)(B)(xi)(II) of the Act. Consistent with the statute, we proposed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27074) to reduce the FY 2024 market basket percentage increase by the FY 2024 productivity adjustment. To determine the proposed market basket update for LTCHs for FY 2024 we subtracted the proposed FY 2024 productivity adjustment from the proposed FY 2024 market basket percentage increase. (For additional details on our established methodology for adjusting the market basket percentage increase by the productivity adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771).) In addition, for FY 2024, section 1886(m)(5) of the Act requires that, for LTCHs that do not submit quality reporting data as required under the LTCH QRP, any annual update to an LTCH PPS standard Federal payment rate, after application of the adjustments required by section 1886(m)(3) of the Act, shall be further reduced by 2.0 percentage points.

In the FY 2024 IPPS/LTCH PPS proposed rule, in accordance with the statute, we proposed to reduce the proposed FY 2024 market basket percentage increase of 3.1 percent (based on IGI's fourth quarter 2022 forecast of the 2017-based LTCH market basket) by the proposed FY 2024 productivity adjustment of 0.2 percentage point (based on IGI's fourth quarter 2022 forecast). Therefore, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, consistent with 42 CFR 412.523(c)(3)(xvii), we proposed to establish an annual market basket update to the LTCH PPS standard Federal payment rate for FY 2024 of 2.9 percent (that is, the LTCH PPS market basket increase of 3.1 percent less the productivity adjustment of 0.2 percentage point). For LTCHs that fail to submit quality reporting data under the LTCH QRP, under 42 CFR 412.523(c)(3)(xvii) in conjunction with 42 CFR 412.523(c)(4), we proposed to further reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points, in accordance with section 1886(m)(5) of the Act. Accordingly, we proposed to establish an annual update to the LTCH PPS standard Federal payment rate of 0.9 percent (that is, 2.9 percent minus 2.0 percentage points) for FY 2024 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP. Consistent with our historical practice, we proposed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27074) to use a more recent estimate of the market basket and the productivity adjustment, if appropriate, in the final rule to establish an annual update to the LTCH PPS standard Federal payment rate for FY 2024. We note that, consistent with historical practice, we also proposed to adjust the FY 2024 LTCH PPS standard Federal payment rate by an area wage level budget neutrality factor in accordance with 42 CFR 412.523(d)(4) (as discussed in section V.B.5. of the Addendum to the proposed rule).

Comment: Many commenters expressed concern that the proposed 3.1 percent market basket update and the 0.4 percentage point increase to the labor-related share do not sufficiently account for the dramatic increases in labor costs that LTCHs are incurring. They stated labor costs, especially for clinicians, are increasing faster than what CMS factored into the market basket for this FY 2024 update. Some of the commenters cited their own analysis of labor costs and many referenced the analysis from the American Hospital Association (AHA). Commenters also noted that medical supply costs had also increased significantly in recent years and are expected to continue to rise in FY 2024. Commenters stated that the rising labor and supply costs have resulted in nearly half of hospitals having negative profit margins for 2022, according to a Kauffman Hall analysis. Several commenters also stated that the proposed increase is inadequate noting the unprecedented inflationary environment that LTCHs are experiencing. Several commenters further stated that it is incorrect for CMS to argue that the market basket update appropriately accounts for provider costs when the projection used in the final rule has severely underestimated

LTCH costs in the recent annual updates.

Commenters requested that CMS implement a temporary payment adjustment increase or add-on payment to increase LTCH payments to account for higher labor and supply costs. A commenter requested that the Secretary consider using his ''special adjustment authority'' to increase the market basket update to 10 percent to reflect the actual increases in costs over the last year. A few commenters requested that CMS modify the market basket update to provide an additional payment increase to help offset the unprecedented inflation currently faced by LTCHs and other providers.

Several of the commenters indicated that a temporary payment adjustment should be applied to Medicare payments to LTCHs at least until CMS rebases the LTCH PPS market basket. A commenter noted that CMS did not propose to rebase and revise the 2017-based LTCH market basket despite CMS proposing to rebase the IRF and IPF market baskets for FY 2024. The commenter noted that CMS stated in the FY 2024 IRF PPS proposed rule that commenters in prior years reported significantly higher IRF labor and other costs due to the COVID–19 PHE and inflation and therefore, CMS determined that it was appropriate to rebase and revise the IRF PPS market basket using a 2021 base year. The commenter stated that LTCHs are similarly affected by increased costs attributable to COVID–19 and inflation, including labor and supply costs yet, CMS did not propose to rebase and revise the LTCH PPS market basket.

A commenter stated that CMS clearly has the authority to implement this type of payment adjustment for the LTCH PPS in FY 2024 using its ''broad authority under section 123 of the BBRA as amended by section 307(b)(1) of the BIPA to determine appropriate adjustments under the LTCH PPS, including whether (and how) to provide for adjustments to reflect variations in the necessary costs of treatment among LTCHs,'' noting CMS has used this authority to establish other payment adjustment policies in the LTCH PPS. The commenter requested that if CMS does not apply a temporary payment increase or add-on payment then it should rebase and revise the 2017-based LTCH market basket for FY 2024 using the most recent LTCH cost report data available to account for the drastic increase in labor costs.

Response: CMS has historically used a market basket to account for input price increases in the services furnished by fee-for-service providers. Since the inception of the LTCH PPS, the LTCH PPS standard Federal payment rates (with the exception of statutorily mandated updates) have been updated based on a projection of a market basket percentage increase. The LTCH market basket (as well as other CMS market baskets) is a fixed-weight, Laspeyres-type index that measures price changes over time and would not reflect increases in costs associated with changes in the volume or intensity of input goods and services. As such, the LTCH market basket update would reflect the prospective price pressures described by the commenters as increasing during a high inflation period (such as faster wage growth or higher energy prices), but would inherently not reflect other factors that might increase the level of costs, such as the quantity of labor used. Changes in quantity or use of services would be captured when the market basket is rebased.

While we did not propose to rebase the LTCH market basket in the FY 2024 IPPS/LTCH proposed rule, we did review the most recent Medicare cost report data available for LTCHs. At the time of the FY 2024 proposed rulemaking, the latest complete Medicare cost report data for LTCHs was for 2020. The latest 2020 Medicare cost report data showed a compensation cost weight of 52.1 percent compared to the 2017-based LTCH market basket compensation cost weight of 53.2 percent. As part of our review of the latest available Medicare cost report data, we found that about 50 percent of LTCHs have a Medicare cost reporting period that begins on or after July 1st of the current year and therefore complete 2021 Medicare cost report data for LTCHs was not available in time to analyze for the FY 2024 rulemaking cycle. Over the next year, we plan to analyze the submitted Medicare cost report data for LTCHs and assess whether a proposal to rebase and revise the LTCH market basket would be appropriate for FY 2025.

We appreciate the commenters' concern regarding inflationary pressure, including labor and supply costs, encountered by LTCHs. We note that the market basket percentage increase is a forecast of the price pressures that LTCHs are expected to face in FY 2024, and the final FY 2024 LTCH market basket percentage increase reflects IGI's (a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the price proxies of the market baskets) projected inflation and overall economic outlook. As projected by IGI and other independent forecasters, compensation growth and upward price pressures are expected to slow in FY 2024 relative to FY 2022 and FY 2023. As is our general practice, we proposed that if more recent data became available, we would use such data, if appropriate, to derive the final FY 2024 LTCH market basket update for the final rule. For this final rule, we now have an updated forecast of the price proxies underlying the market basket that incorporates more recent historical data. Based on IGI's second quarter 2023 forecast with historical data through the first quarter of 2023, the projected 2017-based LTCH market basket percentage increase factor for FY 2024 is 3.5 percent, which is 0.4 percentage point higher than the projected FY 2024 LTCH market basket percentage increase factor in the proposed rule, and reflects a projected increase in compensation prices of 4.3 percent. We note that the 10-year historical average (2013–2022) growth rate of the 2017-based LTCH market basket is 2.4 percent with the historical average growth rate of compensation prices equal to 2.5 percent.

As discussed earlier, we believe the LTCH market basket percentage increase appropriately reflects the input price growth (including compensation price growth) that LTCHs incur in providing medical services. As also described earlier, we are using an updated forecast of the price proxies underlying the market basket that incorporates more recent historical data. For these reasons, as discussed previously, we believe the LTCH market basket is methodologically sound and is using the best available data for FY 2024. Therefore, we disagree with the commenters that CMS should apply a temporary payment adjustment, add-on payment or additional payment increase to the LTCH PPS to account for or offset higher labor and supply costs or unprecedented inflation.

Comment: Many commenters stated the existing market basket methodology has failed to properly account for inflation in recent annual updates, particularly in FY 2021 and FY 2022. They stated that in FY 2022, CMS implemented a 2.6 percent LTCH market basket update, and in contrast, the actual increase according to IGI data was 5.5 percent. Many commenters urged CMS to use its authority to implement an adjustment for FY 2024 to account for the difference between the market basket update that was implemented for FY 2022 and what the market basket is currently projected to be for FY 2022.

Commenters pointed out that there are bipartisan coalitions in both the Senate and House of Representatives sending letters to CMS, calling on the agency to use its broad authority to

reevaluate the hospital market basket update and implement a retrospective payment adjustment to account for the difference between the projected market basket update for FY 2022 and the actual market basket in FY 2022. These commenters stated that although these letters specify the IPPS, LTCH PPS payments are based on the same DRGs and LTCH site neutral payments are equivalent to IPPS payments; therefore, the commenters requested that CMS make the same types of changes to the LTCH PPS.

Response: In responding to similar comments in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49165), we explained that under the law, the LTCH PPS is a per-discharge prospective payment system that uses a market basket percentage increase to set the annual update prospectively. This means that the update relies on a mix of both historical data for part of the period for which the update is calculated and forecasted data for the remainder. (For instance, the 2017-based LTCH market basket growth rate for FY 2024 in this final rule is based on IGI's second quarter 2023 forecast with historical data through the first quarter of 2023.) While there is currently no mechanism to adjust for market basket forecast error in the LTCH payment update, the forecast error for a market basket update is equal to the actual market basket percentage increase for a given year less the forecasted market basket percentage increase. Due to the uncertainty regarding future price trends, forecast errors can be both positive and negative.

While the projected LTCH market basket updates for FY 2021 and FY 2022 were underforecast (actual increases less forecasted increases were positive), this was largely due to unanticipated inflation and labor market pressures as the economy emerged from the COVID–19 pandemic. However, an analysis of the forecast error of the LTCH market basket over a longer period of time shows the forecast error has been both positive and negative. For example, for each fiscal year from 2012 through 2020, the forecasted LTCH market basket update implemented in the final rule was shown to be higher than the actual LTCH market basket update once historical data were available. Only considering the forecast error for years when the final LTCH market basket update is lower than the actual LTCH market basket update addresses only one direction of a forecast error that can be either positive or negative. For these reasons, we are not adopting the commenters' request to implement an adjustment for FY 2024 to account for the difference between the actual and forecasted FY 2022 LTCH market basket update.

Comment: A commenter believes that the IGI data does not conform with CMS's assumption about COVID–19 related costs. The commenter stated that the reduction in the proposed FY 2024 market basket update relative to the FY 2023 market basket update is likely due to the IGI projecting a decrease in COVID–19 cases, hospitalizations, and costs for providers. The commenter further states that CMS proposed to establish the outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2024 using FY 2022 claims because CMS expects LTCH hospitalization rates and cases to be similar in these two fiscal years. The commenter therefore believes that CMS has taken inconsistent positions with respect to projected costs in FY 2024, and that this highlights the need for CMS to provide an adjustment to the FY 2024 market basket update.

Response: The forecast of the LTCH market basket update is derived using IGI's independent projections of price, wage, and economic expectations. These projections are not based on similar considerations as those used to derive the outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases. However, we note that after consideration of comments received, as discussed in section V.D.3. of the addendum to this final rule, we are modifying our proposed methodology for establishing the FY 2024 outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases. These modifications include changes to the proposed charge inflation factor and cost-to-charge ratio adjustment factor, which when used to estimate the cost of each claim reflects a projected increase in the cost of FY 2024 LTCH PPS standard Federal payment rate cases that more closely aligns with the FY 2024 market basket update.

Comment: Several commenters expressed concerns about the proposed productivity adjustment and requested that CMS use its existing authority to eliminate the adjustment for FY 2024. Several commenters requested that CMS at least temporarily (if not permanently) suspend the productivity adjustment due to recent declines in hospital productivity. A commenter noted that the private nonfarm business economy experienced a rapid increase in output and productivity gains when communities began emerging from COVID–19 lockdowns in late 2021, but that the same has not been true for hospital services. The commenter stated that generally, hospital services have not recovered to pre-pandemic levels, and it is highly unlikely that hospitals have achieved the significant productivity gains incorporated into the proposed FY 2024 payment update. The commenter stated that CMS research indicates that hospitals can only achieve a productivity gain that is one-third of the gains seen in the private nonfarm business sector and using the private nonfarm business sector total factor productivity to adjust the market basket exacerbates Medicare underpayments to hospitals.

Response: As required by statute and as discussed in greater detail in section V.B.1. of this preamble, the FY 2024 productivity adjustment is derived based on the 10-year moving average growth in economy-wide productivity for the period ending in FY 2024. We recognize the concerns of the commenters regarding the appropriateness of the productivity adjustment; however, as we explained in response to similar comments in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49165), we are required pursuant to section 1886(m)(3)(A)(i) of the Act to apply the specific productivity adjustment described in section 1886(b)(3)(B)(xi) of the Act; therefore, we do not have the authority to eliminate the productivity adjustment. For this final rule, based on IGI's second quarter 2023 forecast, we are updating the productivity adjustment to reflect more recent historical data as published by BLS for 2022 as well as a revised economic outlook for FY 2023 and FY 2024. Using this more recent forecast, the FY 2024 productivity adjustment based on the 10-year moving average growth in economy-wide total factor productivity for the period ending FY 2024 is 0.2 percentage point, which is lower than the productivity adjustments applied for FY 2022 and FY 2023.

Comment: A commenter cited a 2022 AHA report that stated that contract nurses continue to account for an outsized portion of hospitals' labor costs. The commenter noted that this is important for two reasons: first, because of the increased expense and second, because the Employment Cost Index (ECI) used by CMS to calculate the market basket update includes only hospital-employed staff and not the contract staffing that hospitals have been forced to rely on more than ever in recent years. The commenter urged CMS to use its broad authority to provide a more accurate payment update. The commenter recognized that CMS has an established methodology for calculating rate increases and that CMS relies on a specific source of data for those calculations, however, in the

commenter's view, that data source is failing to produce an appropriate update that reflects actual increases in health care costs. The commenter stated that CMS has the authority to change its methodology and encouraged CMS to do so.

Response: As previously discussed, the 2017-based LTCH market basket is a fixed-weight, Laspeyres-type price index that measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time relative to a base period are not measured.

For the compensation cost weight in the 2017-based LTCH market basket (which includes salaried and contract labor employees), we use the ECI for wages and salaries and benefits for all civilian workers in hospitals to proxy the price increases of labor for LTCHs (there is not a publicly available data source for LTCH workers only). We note that the 2017-based LTCH market basket cost weights show that contract labor costs account for about 8 percent of total compensation costs (reflecting employed and contract labor staff) for LTCHs in 2017 and we found a similar proportion based on 2020 Medicare cost report data. As mentioned previously, we will analyze more recent Medicare cost report data as they become available. The ECI (published by the BLS) measures the change in the hourly labor cost to employers, independent of the influence of employment shifts among occupations and industry categories. An analysis of Medicare cost report data for LTCHs that reported contract labor hours on Worksheet S–3 part II shows that contract labor hours accounted for about 4 percent of total compensation hours (reflecting employed and contract labor staff) in 2020. The proportion found for IPPS hospitals was similar. Therefore, while we acknowledge that the ECI measures only reflect price changes for employed staff, we believe that the ECI for hospital workers is accurately reflecting the price change associated with the labor used to provide hospital care (as employed workers' hours account for 96 percent of hospital compensation hours). For these reasons, we believe it continues to be an appropriate measure to use in the LTCH market basket. Therefore, we are not adopting commenters' request to make an adjustment to the FY 2024 payment update. As discussed earlier, we plan to analyze the Medicare cost report data for LTCHs and assess whether a proposal to rebase and revise the LTCH market basket is appropriate for FY 2025.

After consideration of public comments, we are finalizing the LTCH payment update using the most recent forecast of the 2017-based LTCH market basket percentage increase and productivity adjustment. As such, based on IGI's second quarter 2023 forecast, the FY 2024 market basket update for the LTCH PPS using the 2017-based LTCH market basket is 3.5 percent. The current estimate of the productivity adjustment for FY 2024 based on IGI's second quarter 2023 forecast is 0.2 percentage point. Therefore, under the authority of section 123 of the BBRA as amended by section 307(b) of the BIPA, consistent with 42 CFR 412.523(c)(3)(xvii), we are establishing an annual market basket update to the LTCH PPS standard Federal payment rate for FY 2024 of 3.3 percent (that is, the most recent estimate of the LTCH PPS market basket percentage increase of 3.5 percent less the productivity adjustment of 0.2 percentage point).

For LTCHs that fail to submit quality reporting data under the LTCH QRP, under § 412.523(c)(3)(xvii) in conjunction with 42 CFR 412.523(c)(4), as we proposed, we further reduced the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points, in accordance with section 1886(m)(5) of the Act. Accordingly, we are establishing an annual update to the LTCH PPS standard Federal payment rate of 1.3 percent (that is, 3.3 percent minus 2.0 percentage points) for FY 2024 for LTCHs that fail to submit quality reporting data as required under the LTCH QRP.

IX. Quality Data Reporting Requirements for Specific Providers

A. Overview

In section IX. of the preamble of the proposed rule (88 FR 27074 through 27173), we sought comment on and proposed changes to the following Medicare quality reporting programs:

- In section IX.B., Proposal to Modify the COVID–19 Vaccination Coverage Among Healthcare Personnel Measure in the Hospital IQR Program, PCHQR Program, and LTCH QRP.
- In section IX.C., the Hospital IQR Program.
- In section IX.F., the PCHQR Program.
- In section IX.G., the LTCH QRP.
- In section IX.H. the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs) (previously known as the Medicare EHR Incentive Program).

We respond to public comments on each of these sections below.

B. Modification of the COVID–19 Vaccination Coverage Among Healthcare Personnel Measure for the Hospital Inpatient Quality Reporting, Long-Term Care Hospital Quality Reporting, and PPS-Exempt Cancer Hospital Quality Reporting Programs

(1) Background

On January 31, 2020, the Secretary of the Department of Health and Human Services declared a public health emergency (PHE) for the United States in response to the global outbreak of SARS–CoV–2, a novel (new) coronavirus that causes a disease named ''coronavirus disease 2019'' (COVID–19).[318] Subsequently, the measure was adopted across multiple quality reporting programs including the Hospital Inpatient Quality Reporting Program (86 FR 45374), the Inpatient Psychiatric Facility Quality Reporting Program (86 FR 42633 through 42640), the Hospital Outpatient Quality Reporting Program (86 FR 63824 through 63833), the PPS-Exempt Cancer Hospital Quality Reporting Program (86 FR 45428 through 45434), the Ambulatory Surgical Center Quality Reporting Program (86 FR 63875 through 63883), the Long-Term Care Hospital Quality Reporting Program (86 FR 45438 through 45446), the Skilled Nursing Facility Quality Reporting Program (86 FR 42480 through 42489), the End-Stage Renal Disease Quality Incentive Program (87 FR 67244 through 67248), and the Inpatient Rehabilitation Facility Quality Reporting Program (86 FR 42385 through 42396). COVID–19 has continued to spread domestically and around the world with more than 103.9 million cases and 1.13 million deaths in the United States as of June 19, 2023.[319] In recognition of the ongoing significance and complexity of COVID–19, the Secretary renewed the PHE on April 21, 2020, July 23, 2020, October 2, 2020, January 7, 2021, April 15, 2021, July 19, 2021, October 15, 2021, January 14, 2022, April 12, 2022, July 15, 2022, October 13, 2022, January 11, 2023, and February 9, 2023.[320]

[318] U.S. Dept of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. (2020). Determination that a Public Health Emergency Exists. Available at: *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx*.

[319] Centers for Disease Control and Prevention. COVID Data Tracker. Accessed June 19, 2023. Available at: *https://covid.cdc.gov/covid-data-tracker/#datatracker-home*.

[320] U.S. Dept. of Health and Human Services. Office of the Assistant Secretary for Preparedness and Response. (2023). Renewal of Determination that a Public Health Emergency Exists. Available at: *https://aspr.hhs.gov/legal/PHE/Pages/COVID19-9Feb2023.aspx*.

While the PHE status expired on May 11, 2023, HHS stated that the public health response to COVID–19 remains a public health priority with a whole of government approach to combatting the virus, including through vaccination efforts.[321]

As we stated in the FY 2022 IPPS/LTCH PPS final rule (Hospital IQR Program (86 FR 45375), PCHQR Program (86 FR 45428), and LTCH QRP (86 FR 45438)) and in our Revised Guidance for Staff Vaccination Requirements,[322] vaccination is a critical part of the nation's strategy to effectively counter the spread of COVID–19. We continue to believe it is important to incentivize and track HCP vaccination through quality measurement across care settings, including the inpatient, long-term care, and cancer hospital settings to protect healthcare workers, patients, and caregivers, and to help sustain the ability of HCP in each of these care settings to continue serving their communities throughout the PHE and beyond. At the time we issued the FY 2022 IPPS/LTCH PPS final rule, the Food and Drug Administration (FDA) had issued emergency use authorizations (EUAs) COVID–19 vaccines for adults manufactured by Pfizer-BioNTech,[323] Moderna,[324] and Janssen.[325] The populations for which all three vaccines were authorized at that time included individuals 18 years of age and older, and the Pfizer-BioNTech vaccine was authorized for ages 12 and older. Shortly following the publication of that final rule, on August 23, 2021, the FDA issued an approval for the Pfizer-BioNTech vaccine, marketed as Comirnaty.[326] The FDA issued approval for the Moderna vaccine, marketed as Spikevax, on January 31, 2022,[327] and an EUA for the Novavax adjuvanted vaccine on July 13, 2022.[328] The FDA also issued EUAs for single booster doses of the then authorized COVID–19 vaccines. As of November 19, 2021,[329] [330] [331] a single booster dose of each COVID–19 vaccine was authorized for all eligible individuals 18 years of age and older. EUAs were subsequently issued for a second booster dose of the Pfizer-BioNTech and Moderna vaccines in certain populations in March 2022.[332] FDA first authorized the use of a booster dose of bivalent or ''updated'' COVID–19 vaccines from Pfizer-BioNTech and Moderna in August 2022.[333]

We stated at the time of publication of the FY 2022 IPPS/LTCH PPS final rule that data on the effectiveness of COVID–19 vaccines to prevent asymptomatic infection or transmission of SARS–CoV–2 were limited (Hospital IQR Program (86 FR 45375) and PCHQR Program (86 FR 45430)). While the impact of COVID–19 vaccines on asymptomatic infection and transmission is not yet fully known, there is now robust data available on COVID–19 vaccine effectiveness across multiple populations against symptomatic infection, hospitalization, and death. Two-dose COVID–19 vaccines from Pfizer-BioNTech and Moderna were found to be 88 percent and 93 percent effective against hospitalization for COVID–19, respectively, over six months for adults over age 18 without immunocompromising conditions.[334] During a SARS–CoV–2 surge in the spring and summer of 2021, 92 percent of COVID–19 hospitalizations and 91 percent of COVID–19-associated deaths were reported among persons not fully vaccinated.[335] Real-world studies of population-level vaccine effectiveness indicated similarly high rates of effectiveness in preventing SARS–CoV–2 infection among frontline workers in multiple industries, with a 90 percent effectiveness in preventing symptomatic and asymptomatic infection from December 2020 through August 2021.[336] Vaccines have also been highly effective in real-world conditions preventing COVID–19 in HCP with up to 96 percent effectiveness for fully vaccinated HCP, including those at risk for severe infection and those in racial and ethnic groups disproportionately affected by COVID–19.[337] In the presence of high

[321] U.S. Dept. of Health and Human Services. Fact Sheet: COVID–19 Public Health Emergency Transition Roadmap. February 9, 2023. Available at: *https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html*.

[322] Centers for Medicare & Medicaid Services. Revised Guidance for Staff Vaccination Requirements QSO–23–02–ALL. October 26, 2022. Available at: *https://www.cms.gov/files/document/qs0-23-02-all.pdf*.

[323] Food and Drug Administration. (December 2020). FDA Takes Key Action in Fight Against COVID–19 By Issuing Emergency Use Authorization for First COVID–19 Vaccine. Available at: *https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19*.

[324] Food and Drug Administration. (December 2020) FDA Takes Additional Action in Fight Against COVID–19 By Issuing Emergency Use Authorization for Second COVID–19 Vaccine. Available at: *https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid*.

[325] Food and Drug Administration. (February 2021) FDA Issues Emergency Use Authorization for Third COVID–19 Vaccine. Available at: *https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine*.

[326] Food and Drug Administration. (August 2021) FDA Approves First COVID–19 Vaccine. Available at: *https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine*.

[327] Food and Drug Administration. (January 2022) Coronavirus (COVID–19) Update: FDA Takes Key Action by Approving Second COVID–19 Vaccine. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine*.

[328] Food and Drug Administration. (July 2022) Coronavirus (COVID–19) Update: FDA Authorizes Emergency Use of Novavax COVID–19 Vaccine, Adjuvanted. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-emergency-use-novavax-covid-19-vaccine-adjuvanted*.

[329] Food and Drug Administration. (September 2021) FDA Authorizes Booster Dose of Pfizer-BioNTech COVID–19 Vaccine for Certain Populations. Available at: *https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations*.

[330] Food and Drug Administration. (October 2021) Coronavirus (COVID–19) Update: FDA Takes Additional Actions on the Use of a Booster Dose for COVID–19 Vaccines. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines*.

[331] Food and Drug Administration. (November 2021) Coronavirus (COVID–19) Update: FDA Expands Eligibility for COVID–19 Vaccine Boosters. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-covid-19-vaccine-boosters*.

[332] Food and Drug Administration. (March 2022) Coronavirus (COVID–19) Update: FDA Authorizes Second Booster Dose of Two COVID–19 Vaccines for Older and Immunocompromised Individuals. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-second-booster-dose-two-covid-19-vaccines-older-and*.

[333] Food and Drug Administration. (August 2022) Coronavirus (COVID–19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID–19 Vaccines for Use as a Booster Dose. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use*.

[334] Centers for Disease Control and Prevention. (September 24, 2021) Morbidity and Mortality Weekly Report (MMWR). Comparative Effectiveness of Moderna, Pfizer-BioNTech, and Janssen (Johnson & Johnson) Vaccines in Preventing COVID–19 Hospitalizations Among Adults Without Immunocompromising Conditions—United States, March-August 2021. Available at: *https://cdc.gov/mmwr/volumes/70/wr/mm7038e1.htm?s_cid=mm7038e1_w*.

[335] Centers for Disease Control and Prevention. (September 10, 2021) Morbidity and Mortality Weekly Report (MMWR). Monitoring Incidence of COVID–19 Cases, Hospitalizations, and Deaths, by Vaccination Status—13 U.S. Jurisdictions, April 4–July 17, 2021. Available at: *https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e1.htm*.

[336] Centers for Disease Control and Prevention. (August 27, 2021) Morbidity and Mortality Weekly Report (MMWR). Effectiveness of COVID–19 Vaccines in Preventing SARS–COV–2 Infection Among Frontline Workers Before and During B.1.617.2 (Delta) Variant Predominance—Eight U.S. Locations, December 2020–August 2021. Available at: *https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm*.

[337] Pilishivi, T. et al. (December 2022). Effectiveness of mRNA Covid-19 Vaccine among U.S. Health Care Personnel. New England Journal of Medicine. 2021 Dec 16;385(25):e90. Available

community prevalence of COVID–19, residents of nursing homes with low staff vaccination coverage had cases of COVID–19 related deaths 195 percent higher than those among residents of nursing homes with high staff vaccination coverage.[338] Overall, data demonstrate that COVID–19 vaccines are effective and prevent severe disease, including hospitalization and death.

As SARS–CoV–2 persists and evolves, our COVID–19 vaccination strategy must remain responsive. When we finalized adoption of the COVID–19 Vaccination Coverage among HCP measure in the FY 2022 IPPS/LTCH PPS final rule, we stated that the need for booster doses of COVID–19 vaccines had not been established and no additional doses had been recommended (Hospital IQR Program (86 FR 45378), PCHQR Program (86 FR 45432), and LTCH QRP (86 FR 45444)). We also stated that we believed the numerator was sufficiently broad to include potential future boosters as part of a ''complete vaccination course'' and that the measure was sufficiently specified to address boosters (Hospital IQR Program (86 FR 45378), PCHQR Program (86 FR 45432), and LTCH QRP (86 FR 45444)). Since we finalized the COVID–19 Vaccination Coverage among HCP measure in the FY 2022 IPPS/LTCH PPS final rule, new variants of SARS–CoV–2 have emerged around the world and within the United States. Specifically, the Omicron variant (and its related subvariants) is listed as a variant of concern by the CDC because it spreads more easily than earlier variants.[339] Vaccine manufacturers have responded to the Omicron variant by developing bivalent COVID–19 vaccines, which include a component of the original virus strain to provide broad protection against COVID–19 and a component of the Omicron variant to provide better protection against COVID–19 caused by the Omicron variant.[340] These booster doses of the bivalent COVID–19 vaccines have been shown to increase immune response to SARS–CoV–2 variants, including Omicron, particularly in individuals who are more than six months removed from receipt of their primary series.[341] The FDA issued EUAs for booster doses of two bivalent COVID–19 vaccines, one from Pfizer-BioNTech [342] and one from Moderna,[343] and strongly encourages anyone who is eligible to consider receiving a booster dose with a bivalent COVID–19 vaccine to provide better protection against currently circulating variants.[344] COVID–19 booster doses are associated with a greater reduction in infections among HCP and their patients relative to those who only received primary series vaccination, with a rate of breakthrough infections among HCP who received only a two-dose regimen of 21.4 percent compared to a rate of 0.7 percent among boosted HCP.[345] [346] Data from the existing COVID–19 Vaccination Coverage among HCP measure demonstrate significant variation in booster dose vaccination rates across facilities. During the first quarter of 2022, acute care hospitals reported a median coverage rate of booster/additional doses of 22.5 percent, with an interquartile range of 9.1 percent to 38.7 percent, a difference of 29.6 percentage points.[347] LTCHs reported a median coverage rate of booster/additional dose of 22.6 percent, with an interquartile range of 10.8 percent to 36.9 percent, a difference of 26.1 percentage points which is indicative of a substantial variation among LTCHs.[348]

We believe that vaccination remains the most effective means to prevent the worst consequences of COVID–19, including severe illness, hospitalization, and death. Given the availability of vaccine efficacy data, EUAs issued by the FDA for bivalent boosters, the continued presence of SARS–CoV–2 in the United States, and variance among rates of booster dose vaccination, it is important to modify the COVID–19 Vaccination Coverage among HCP measure to reflect recent updates that explicitly specify for HCP to remain up to date in a timely manner. As the COVID–19 pandemic persists, we continue to believe that monitoring and surveillance is important and provides patients, beneficiaries, and their caregivers with information to support informed decision making. We proposed to modify the COVID–19 Vaccination Coverage among HCP measure to replace the term ''complete vaccination course'' with the term ''up to date'' in the HCP vaccination definition. We also proposed to update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID–19 vaccines, beginning with the Quarter 4 2023 reporting period/FY 2025 payment determination for the Hospital IQR Program and the FY 2025 program year for both the LTCH QRP and the PCHQR Program. As we stated in the FY 2022 IPPS/LTCH PPS final rule (Hospital IQR Program (86 FR 45378), PCHQR Program (86 FR 45432), and LTCH QRP (86 FR 45445)), the COVID–19 Vaccination Coverage among HCP measure is a process measure that assesses HCP vaccination coverage rates. Unlike outcome measures, process measures do not assess a particular outcome.

(2) Overview of Measure

The COVID–19 Vaccination Coverage among HCP measure is a process measure developed by the CDC to track COVID–19 vaccination coverage among HCP in settings such as acute care and post-acute care (PAC) facilities and is reported via the CDC's National Healthcare Safety Network (NHSN).

We refer readers to the FY 2022 IPPS/LTCH PPS final rule (Hospital IQR

online at: *https://pubmed.ncbi.nlm.nih.gov/34551224/*.

[338] McGarry BE et al. (January 2022). Nursing Home Staff Vaccination and Covid–19 Outcomes. New England Journal of Medicine. 2022 Jan 27;386(4):397–398. Available online at: *https://pubmed.ncbi.nlm.nih.gov/34879189/*.

[339] Centers for Disease Control and Prevention. (August 2021) Variants of the Virus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html*.

[340] Food and Drug Administration. (November 2022) COVID–19 Bivalent Vaccine Boosters. Available at: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines*.

[341] Chalkias, S et al. (October 2022). A Bivalent Omicron-Containing Booster Vaccine against Covid-19. N Engl J Med 2022; 387:1279–1291. Available online at: *https://www.nejm.org/doi/full/10.1056/NEJMoa2208343*.

[342] Food and Drug Administration. (November 2022) Pfizer-BioNTech COVID–19 Vaccines. Available at: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines*.

[343] Food and Drug Administration. (November 2022) Moderna COVID–19 Vaccines. Available at: *https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines*.

[344] Food and Drug Administration. (August 2022) Coronavirus (COVID–19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID–19 Vaccines for Use as a Booster Dose. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use*.

[345] Prasad N et al. (May 2022). Effectiveness of a COVID–19 Additional Primary or Booster Vaccine Dose in Preventing SARS-CoV–2 Infection Among Nursing Home Residents During Widespread Circulation of the Omicron Variant—United States, February 14–March 27, 2022. Morbidity and Mortality Weekly Report (MMWR). 2022 May 6;71(18):633–637. Available online at: *https://pubmed.ncbi.nlm.nih.gov/35511708/*.

[346] Oster Y et al. (May 2022). The effect of a third BNT162b2 vaccine on breakthrough infections in health care workers: a cohort analysis. Clin Microbiol Infect. 2022 May;28(5):735.e1–735.e3. Available online at: *https://pubmed.ncbi.nlm.nih.gov/35143997/*.

[347] Centers for Medicare & Medicaid Services. (December 2022) Measure Applications Partnership (MAP) Hospital Workgroup Preliminary Analyses. Available at: *https://mmshub.cms.gov/sites/default/files/2022-preliminary-analysis-hospital-workgroup.pdf*.

[348] Centers for Medicare & Medicaid Services. (December 2022) Measure Applications Partnership (MAP) PAC/LTC workgroup Preliminary Analyses. Available at: *https://mmshub.cms.gov/sites/default/files/2022-prliminary-analysis-pacltc-workgroup.pdf*.

Program (86 FR 45376 through 45377), PCHQR Program (86 FR 45430 through 45431), and LTCH QRP (86 FR 45440 through 45441)) for more information on the initial review of the measure by the Measure Applications Partnership (MAP).[349] We included an updated version of the measure on the Measures Under Consideration (MUC) list for the 2022–2023 pre-rulemaking cycle for consideration by the MAP.[350] In December 2022, the MAP's Hospital Workgroup and Post-Acute Care/Long-Term Care (PAC/LTC) Workgroup discussed the modified measure. The Hospital Workgroup stated that the revision of the current measure captures up to date vaccination information in accordance with CDC recommendations updated since its initial development. Additionally, the Hospital Workgroup appreciated that the respecified measure of the target population is broader and simplified from seven categories of healthcare personnel to four.[351] The PAC/LTC Workgroup voted to support the staff recommendation of conditional support for rulemaking. During review, the Health Equity Advisory Group highlighted the importance of COVID–19 measures and asked whether the measure excludes individuals with contraindications to Food and Drug Administration (FDA) authorized or approved COVID–19 vaccines, and whether the measure will be stratified by demographic factors. The measure developer confirmed that HCP with contraindications to the vaccines are excluded from the measure denominator, but the measure will not be stratified since the data are submitted at an aggregate rather than an individual level. The Rural Health Advisory Group expressed concerns about data collection burden, citing that collection is performed manually and that small rural hospitals may not have employee health software.[352] The measure developer acknowledged the challenge of getting adequate documentation and emphasized the goal to ensure the measure does not present a burden on the provider. The developer also noted that the model used for this measure is based on the Influenza Vaccination Coverage among HCP measure (CBE #0431), and it intends to utilize a similar approach to the modified COVID–19 Vaccination Coverage among HCP measure if vaccination strategy becomes seasonal. The revised measure received conditional support for rulemaking from both MAP workgroups pending testing indicating the measure is reliable and valid, and endorsement by the consensus-based entity (CBE). The MAP noted that the previous version of the measure received endorsement from the CBE (CBE #3636) [353] and that the CDC intends to submit the updated measure for endorsement.

(a) Measure Specifications

This measure includes at least one week of data collection a month for each of the three months in a quarter. The denominator is the number of HCP eligible to work in the facility for at least one day during the reporting period, excluding persons with contraindications to COVID–19 vaccination that are described by the CDC. Facilities report the following four categories of HCP to NHSN: [354]

1. *Employees*: includes all persons who receive a direct paycheck from the reporting facility (that is, on the facility's payroll), regardless of clinical responsibility or patient contact.

2. *Licensed independent practitioners (LIPs)*: This includes physicians (MD, DO), advanced practice nurses, and physician assistants only who are affiliated with the reporting facility, but are not directly employed by it (that is, they do not receive a direct paycheck from the reporting facility), regardless of clinical responsibility or patient contact. Post-residency fellows are also included in this category if they are not on the facility's payroll.

3. *Adult students/trainees and volunteers:* This includes all medical, nursing, or other health professional students, interns, medical residents, and volunteers aged 18 or over who are affiliated with the healthcare facility but are not directly employed by it (that is, they do not receive a direct paycheck from the facility), regardless of clinical responsibility or patient contact.

4. *Other contract personnel:* Contract personnel are defined as persons providing care, treatment, or services at the facility through contract who do not fall into any of the previously discussed denominator categories. This also includes vendors providing care, treatment, or services at the facility who may or may not be paid through a contract. Facilities are required to enter data on other contract personnel for submission in the NHSN application, but data for this category are not included in the COVID–19 Vaccination Coverage among HCP measure.

The denominator excludes denominator-eligible individuals with contraindications as defined by the CDC.[355] There are no changes to the denominator exclusions.

The numerator will be the cumulative number of HCP in the denominator population who are considered up to date with CDC recommended COVID–19 vaccines. Providers should refer to the definition of up to date as of the first day of the applicable reporting quarter, which can be found at: *https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf*. In the proposed rule we provided the example that HCP would have been considered up to date during the Quarter 4 CY 2022 reporting period for the Hospital IQR Program, PCHQR Program, and the LTCH QRP if they met one of the following criteria:

1. Individuals who received an updated bivalent [356] booster dose, or

2a. Individuals who received their last booster dose less than 2 months ago, or

2b. Individuals who completed their primary series[357] less than 2 months ago.

We note that since publication of the proposed rule, CDC's definition for up to date vaccination has evolved. HCP would be considered up to date in the Quarter 3 CY 2023 reporting period for the Hospital IQR Program, PCHQR Program, and the LTCH QRP if they met the following criteria:

[349] Interested parties convened by the consensus-based entity (CBE) will provide input and recommendations on the Measures Under Consideration (MUC) list as part of the pre-rulemaking process required by section 1890A of the SSA. We refer readers to *https://p4qm.org/PRMR-MSR* for more information.

[350] Centers for Medicare & Medicaid Services. (2023) Pre-Rulemaking MUC Lists and MAP Reports. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[351] Centers for Medicare & Medicaid Services. MAP 2022–2023 Preliminary Analysis Worksheet. 2022. Available at: *https://mmshub.cms.gov/sites/default/files/map-preliminary-recommendations-2022-2023.xlsx.*

[352] Centers for Medicare & Medicaid Services. MAP 2022–2023 Final Recommendations. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[353] Centers for Medicare & Medicaid Services. Measure Specifications for Hospital Workgroup for the 2022 MUC List. Available at: *https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf.*

[354] Centers for Disease Control and Prevention. (2023) Measure Specification: NHSN COVID–19 Vaccination Coverage among Healthcare Personnel. Available at: *https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-rev-2023-508.pdf.*

[355] Centers for Disease Control and Prevention. (2022) Contraindications and precautions. Available at: *https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications.*

[356] The updated (bivalent) Moderna and Pfizer-BioNTech boosters target the most recent Omicron subvariants. The updated (bivalent) boosters were recommended by the CDC on 9/2/2022. As of this date, the original, monovalent mRNA vaccines are no longer authorized as a booster dose for people ages 12 years and older.

[357] Completing a primary series means receiving a two-dose series of a COVID–19 vaccine or a single dose of Janssen/J&J COVID–19 vaccine.

1. Individuals who received an updated bivalent [358] booster dose.

We refer readers to *https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpcoverage-rev-2023-508.pdf* for more details on the measure specifications.

We proposed that public reporting of the modified version of the COVID–19 Vaccination Coverage among HCP measure will begin with the October 2024 Care Compare refresh or as soon as technically feasible after then, for the Hospital IQR Program, PCHQR Program, and LTCH QRP.

(b) CBE Endorsement

The current version of the measure in the Hospital IQR Program, PCHQR Program, and LTCH QRP received CBE endorsement (CBE #3636, ''Quarterly Reporting of COVID–19 Vaccination Coverage among Healthcare Personnel'') on July 26, 2022.[359] The applicable authorities of the Hospital IQR Program,[360] PCHQR Program,[361] and LTCH QRP[362] generally require that measures specified by the Secretary for use in these programs be endorsed by the CBE with a contract under section 1890(a) of the Act. However, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.[363] In developing the FY 2024 IPPS/LTCH PPS proposed rule, we reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic; therefore, we believe the exception for non CBE-endorsed measures applies. The CDC, as the measure developer, is pursuing endorsement for the modified version of the measure.

(3) Data Submission and Reporting

We refer readers to the FY 2022 IPPS/LTCH PPS final rule (Hospital IQR Program (86 FR 45377), PCHQR Program (86 FR 45431), and LTCH QRP (86 FR 45441 through 45442)) for information on data submission and reporting of the measure. While we did not propose any changes to the data submission or reporting process in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27074 through 27078), we proposed that reporting of the updated measure will begin with the Quarter 4 CY 2023 reporting period for the Hospital IQR Program, PCHQR Program, and LTCH QRP. Under the data submission and reporting process, providers will collect the numerator and denominator for the COVID–19 Vaccine Coverage among HCP measure for at least one self-selected week during each month of the reporting quarter and submit the data to the NHSN Healthcare Personal Safety (HPS) Component before the quarterly deadline. If a provider submits more than one week of data in a month, the most recent week's data will be used to calculate the measure. Each quarter, the CDC will calculate a single quarterly COVID–19 HCP vaccination coverage rate for each provider, which will be calculated by taking the average of the data from the three weekly rates submitted by the provider for that quarter. We will publicly report each quarterly COVID–19 HCP vaccination coverage rate as calculated by the CDC (Hospital IQR Program (86 FR 45377), PCHQR Program (86 FR 45431), and LTCH QRP (86 FR 45441 through 45442). Following the ending of the PHE, which occurred on May 11, 2023,[364] reporting requirements under the Hospital Conditions of Participation (CoP) have been revised.[365] We plan to communicate any future changes to the CoP through Quality Safety & Oversight memoranda and other communications materials when new policies are finalized.

We invited public comment on this proposal.

Comment: Many commenters supported the proposed modification to the COVID–19 Vaccination Coverage among HCP measure. A few commenters noted the importance of vaccination in preventing greater spread of COVID–19 and the potential for continued vaccination to prevent future large-scale outbreaks.

Response: We thank the commenters for their support. We agree that vaccination plays a critical part of the Nation's strategy to effectively counter the spread of COVID–19. We continue to believe it is important to incentivize and track HCP vaccination through quality measurement across care settings, including the inpatient, long-term care, and cancer hospital settings to protect healthcare workers, patients, and caregivers, and to help sustain the ability of HCP in each of these care settings to continue serving their communities.

Comment: Many commenters did not support updating the specifications for the COVID–19 Vaccination Coverage among HCP measure because the PHE has expired and the CoPs for hospitals have been revised [366] to no longer require reporting of these data. Several commenters expressed concern that retaining measurement of COVID–19 vaccination coverage among HCP after the vaccination requirement has been removed from CoPs sends an inconsistent message regarding CMS's priorities and increases the burden required to continue to collect and report these data. A commenter observed that the end of other Federal vaccination requirements creates challenges for justifying continued data collection for this measure, particularly in states where vaccination requirements have been contentious.

Response: Since publication of the FY 2024 IPPS/LTCH PPS proposed rule, the COVID–19 PHE expired on May 11, 2023.[367] We acknowledge that some state and Federal requirements regarding COVID–19 vaccination have since changed. CMS requirements for Medicare and Medicaid-certified providers and suppliers to ensure that their staff were fully vaccinated for COVID–19 have ended with the expiration of the COVID–19 PHE (88 FR 36488). Nevertheless, we revised the hospital and critical access hospitals (CAHs) infection prevention and control CoP so that hospitals and CAHs will continue to report on a reduced number of COVID–19 data elements after the conclusion of the COVID–19 PHE until April 30, 2024, unless the Secretary

[358] The updated (bivalent) Moderna and Pfizer-BioNTech boosters target the most recent Omicron subvariants. The updated (bivalent) boosters were recommended by the CDC on 9/2/2022. As of April 13, 2023, the original, monovalent mRNA vaccines are no longer authorized as a booster dose for people ages 12 years and older. More details are available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-changes-simplify-use-bivalent-mrna-covid-19-vaccines*.

[359] Centers for Medicare & Medicaid Services. Measure Specifications for Hospital Workgroup for the 2022 MUC List. Available at: *https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf*.

[360] Sec. 1886(b)(3)(B)(viii)(IX)(aa) of the Act.

[361] Sec. 1866(k)(3)(A) of the Act.

[362] Sec. 1886(m)(5)(D)(i) of the Act.

[363] *See* sec. 1886(b)(3)(B)(viii)(IX)(bb) of the Act for the Hospital IQR Program; sec. 1866(k)(3)(B) of the Act for the PCHQR Program; sec. 1886(m)(5)(D)(ii) of the Act for the LTCH QRP.

[364] Office of Management and Budget. (2023) Statement of Administration Policy H.R. 382 and H.J. Res. 7. Available at: *https://www.whitehouse.gov/wp-content/uploads/2023/01/SAP-H.R.-382-H.J.-Res.-7.pdf*.

[365] 88 FR 36485.

[366] 88 FR 36485.

[367] U.S. Dept. of Health and Human Services. Fact Sheet: COVID–19 Public Health Emergency Transition Roadmap. February 9, 2023. Available at: *https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html*.

establishes an earlier end date.[368] While these changes may impact certain aspects of facility reporting on COVID–19 data, we note that the reporting requirements of the Hospital IQR, PCHQR, and LTCH QRPs are distinct from those related to the expiration of the PHE and facilities participating in these programs are required to report the COVID–19 Vaccination Coverage among HCP measure. We further note that in our final rule removing staff vaccination requirements, we clarified that we were aligning our approach with that for other infectious diseases, specifically influenza, and that we would encourage ongoing COVID–19 vaccination through our quality reporting and value-based incentive programs (88 FR 38486).

This measure continues to align with our goals to promote wellness and disease prevention. Under CMS' Meaningful Measures Framework 2.0, the COVID–19 Vaccination Coverage among HCP measure addresses the quality priorities of ''Immunizations'' and ''Public Health'' through the Meaningful Measures Area of ''Wellness and Prevention.'' [369] Under the National Quality Strategy, the measure addresses the goal of Safety under the priority area Safety and Resiliency.[370] Our continued response to COVID–19 is not fully dependent on the emergency declaration for the COVID–19 PHE and, beyond the end of the COVID–19 PHE, we continue to work to protect individuals and communities from the virus and its worst impacts by supporting access to COVID–19 vaccines, treatments, and tests.[371]

Comment: Many commenters did not support updating the COVID–19 Vaccination Coverage among HCP measure because of concerns that the frequency of changes to the CDC's definition of up to date combined with the uncertainty around future vaccination schedules creates unnecessary burden for facilities. Many commenters expressed concern that changing definitions and guidance exacerbates staffing and resource challenges and requires updates to facility or system-level vaccination policies, adding burden and confusion. Some of these commenters recommended maintaining current measure requirements to collect only primary vaccination series to reduce this burden or to remove the measure entirely.

Response: Since the adoption of the current version of the COVID–19 Vaccination Coverage among HCP measure, the public health response to COVID–19 has necessarily adapted to respond to the changing nature of the virus's transmission and community spread. When we finalized the adoption of the COVID–19 Vaccination Coverage among HCP measure in the FY 2022 IPPS/LTCH PPS final rule (Hospital IQR Program, 86 FR 45374; PCHQR Program, 86 FR 45428; LTCH QRP, 86 FR 45438), we received several comments encouraging us to continue to update the measure as new evidence on COVID–19 continues to arise and we stated our intention to continue to work with partners including the FDA and CDC to consider any updates to the measure in future rulemaking as appropriate. We recognize commenters' recommendations to limit reporting to primary series or remove the measure to reduce burden but disagree with these suggestions given the ongoing circulation of SARS–CoV–19. The measure modification aligns with the CDC's responsive approach to COVID–19 and will continue to support vaccination as the most effective means to prevent the worst consequences of COVID–19, including severe illness, hospitalization, and death.

Comment: Many commenters did not support the measure modification and recommended that we reduce the required reporting frequency to quarterly or annually to reduce reporting burden for facilities. Some of these commenters observed that annual reporting would mirror the reporting schedule for the Influenza Vaccination Coverage among HCP measure, which is in some quality reporting programs. A couple of commenters observed that the COVID–19 Vaccination Coverage among HCP measure is significantly more burdensome than the Influenza Vaccination Coverage among HCP measure, which is a ''yes'' or ''no'' attestation. Others believed that annual reporting would not improve patient understanding of publicly reported measure data, which they considered as out of date at the time of display and therefore not accurately reflective of facility HCP vaccination levels. A couple of commenters stated that there is variation between states and facilities in what information can be requested of staff and under which conditions of employment, which may also impact the accuracy of public reporting and could increase the burden of reporting depending on a facility's location. A few commenters believed that the requirements to report vaccination status for all personnel, including contract personnel, students, volunteers, and independent contractors, is particularly burdensome and requires multiple applications and processes. Several commenters believed that, in addition to reducing reporting frequency, any future reporting of the measure should be voluntary. A commenter recommended collecting data only for HCP who have been vaccinated within the prior six months to reduce burden and increase data accuracy. Another commenter observed that, in addition to reduced reporting frequency, an alternate data collection option, such as collection of information at the location where the vaccinations occurred, would be less burdensome for small, rural, and underserved facilities.

Response: As we stated in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27077), the measure developer noted that the model used for this measure is based on the Influenza Vaccination Coverage among HCP measure (CBE #0431), which is reported annually, and it intends to utilize a similar approach to the modified COVID–19 Vaccination Coverage among HCP measure if vaccination strategy becomes seasonal. While monitoring and surveillance are ongoing, we do not currently have data demonstrating seasonal trends in the circulation of SARS–CoV–2 and therefore at this time, reporting at least one self-selected week during each month of the reporting quarter remains appropriate. Additionally, while the measure developer noted that the model used for this measure is based on the Influenza Vaccination Coverage among HCP measure (CBE #0431), these are different public health initiatives, and different vaccines, and therefore the measure specifications are not in complete alignment (86 FR 45379). Furthermore, given the continued circulation of the SARS–CoV–2 virus in the United States, we do not believe it

[368] Centers for Medicare & Medicaid Services Center for Clinical Standards and Quality/Quality, Safety & Oversight Group. May 1, 2023. Guidance for the Expiration of the COVID–19 Public Health Emergency (PHE) QSO 23–13–ALL. Accessed May 22, 2023. Available at: *https://www.cms.gov/files/document/qso-23-13-all.pdf*.

[369] Centers for Medicare & Medicaid Services. June 17, 2022. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Accessed May 26, 2023. Available at: *https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization*.

[370] Centers for Medicare & Medicaid Services. May 1, 2023. CMS National Quality Strategy. Accessed May 26, 2023. Available at: *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/cms-quality-strategy*.

[371] U.S. Department of Health and Human Services. May 9, 2023. Fact Sheet: End of the COVID–19 Public Health Emergency. Accessed May 22, 2023. Available at: *https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html#:~:text=That%20means%20with%20the%20COVID,the%20expiration%20of%20the%20PHE*.

is appropriate to propose voluntary reporting or reduce the population of HCP reported for the measure at this time.

We agree with commenters who observe that there is a delay between data collection and public reporting for this measure and note that such a delay exists for all measures in the Hospital IQR, PCHQR, and LTCH Quality Reporting Programs. However, the data will provide meaningful information to consumers in making healthcare decisions because the data will be able to reflect differences between facilities in COVID–19 vaccination coverage of their workforce even if the data do not reflect immediate vaccination rates. While we recognize the commenter suggestion to limit data collection to those HCP vaccinated in the prior six months, we disagree that this would reduce burden for reporting facilities and would not improve data accuracy as reporting facilities may be required to revise reporting processes.

Regarding commenter concerns about reporting burden, we note that for purposes of NHSN surveillance, the CDC began using the same definition of up to date reflected in the measure modification beginning with the Quarter 3 2023 surveillance period (June 26, 2023–September 24, 2023). Additionally, facilities have been reporting the COVID–19 Vaccination Coverage among HCP measure since October 1, 2021 and there has been sufficient time to allocate the necessary resources required to report the measure. We recognize the unique challenges of small and rural facilities but note that NHSN reporting does not permit data collection from the site of vaccination at this time. We continue to monitor COVID–19 as part of our public health response and will consider data as well as commenters' feedback to inform any future rulemaking.

Comment: Several commenters expressed concern that the COVID–19 Vaccination Coverage among HCP measure has not been endorsed by the CBE.

Response: The current version of the measure received CBE endorsement (CBE #3636, ''Quarterly Reporting of COVID–19 Vaccination Coverage among Healthcare Personnel'') on July 26, 2022. As we stated in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27078), in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. For this FY 2024 IPPS/LTCH PPS rule cycle, we reviewed CBE-endorsed measures. While the current, CBE-endorsed version of the measure is available, the modified version of the measure more completely accounts for the availability of booster and bivalent doses which were not yet developed when the current version of the measure was adopted. Because the modified version of the measure is more comprehensive than the current version, the exception for non-CBE-endorsed measures applies. The measure steward, CDC, has submitted the modified measure to the CBE for endorsement and it is currently under review.[372]

Comment: Some commenters recommended that we include an exclusion for sincerely held religious beliefs to adhere to HHS Office of Civil Rights Guidance. Some of these commenters also requested the measure be updated to track the number of HCP who decline vaccination. Several commenters observed that there are many factors beyond a facility's control (such as weather, holidays, state or local regulations, etc.) that may affect performance on this measure.

Response: We recognize that there are many reasons, including religious objections or concerns regarding an individual HCP's specific health status that may lead individual HCP to decline vaccination. The CDC's NHSN tool allows facilities to report on the number of HCP who were offered a vaccination but declined for religious or philosophical objections.[373] We understand the commenters' concern that there are many factors outside of a facility's control which could affect vaccination coverage; however, all facilities face such concerns. Nonetheless, public reporting of this measure can help patients and their caregivers identify which facilities have better vaccination coverage among their HCP. Furthermore, reporting of the measure based on one week per month over three months will allow some seasonal or other effects to be mitigated. We wish to emphasize that neither the modified measure nor the current version of the measure mandate vaccines. The COVID–19 Vaccination Coverage among HCP measure only requires reporting of vaccination rates for successful program participation.

Comment: A commenter observed that removing the measure would be appropriate because vaccination percentage has been incorporated into the Overall Star Rating program, thereby penalizing hospitals with lower vaccine rates.

Response: We note that the purpose of the Overall Hospital Quality Star Ratings is to summarize hospital quality information using measures posted on Care Compare in a way that is simple and easy to understand by patients. Although Overall Hospital Quality Star Ratings are reported through CMS programs, which are tied to payment, hospital performance on the Overall Hospital Quality Star Ratings is not used by CMS for any hospital payment or reimbursement purposes.

Comment: A commenter stated that the bivalent boosters are currently approved under an EUA and believed it inappropriate to base the measure modification on bivalent boosters given the expiration of the PHE.

Response: We note that on August 31, 2022, the FDA amended the EUAs for the Moderna COVID–19 vaccine and the Pfizer-BioNTech COVID–19 vaccine to authorize bivalent formulations of the vaccines for use as a single booster dose at least two months following primary or booster vaccination.[374] The bivalent boosters are appropriate for inclusion in the measure modification.

Comment: A couple of commenters requested clarification regarding NHSN reporting challenges. A commenter described issues that arise when a facility selects to report on a week that crosses between two months, whereafter the reporting is not properly received and the facility appears non-compliant. Another commenter requested clarification whether NHSN data submission for the measure meets all requirements for the measure under the Hospital IQR Program.

Response: We thank the commenters for their questions. We are aware that some facilities may have experienced issues with reporting weeks that crossed between two months. CDC has clarified that a week is designated as belonging to the month of the week-end date. For example, reporting data for the week of September 27 through October 3 is

[372] Partnership for Quality Measurement. Quarterly Reporting of COVID–19 Vaccination Coverage among Healthcare Personnel (3636). Accessed July 13, 2023. Available at: *https://p4qm.org/endorsements/measure/6041*.

[373] Weekly Healthcare Personnel Influenza Vaccination Summary for Non-Long-Term Care Facilities-HCP (*cdc.gov*).

[374] Food and Drug Administration. August 31, 2022. Coronavirus (COVID–19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID–19 Vaccines for Use as a Booster Dose. Accessed June 29, 2023. Available at: *https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use*.

considered as submitting data for a week in October. More information is available in the NHSN Manual for COVID–19 Vaccination Reporting [375] and through CDC Frequently Asked Questions on COVID–19 Hospital Data Reporting.[376] We also wish to clarify that NHSN data submission for the measure does meet requirements under the Hospital IQR Program for participating facilities.

After consideration of the public comments we received, we are finalizing the proposal as proposed.

C. Changes to the Hospital Inpatient Quality Reporting (IQR) Program

1. Background and History of the Hospital IQR Program

Through the Hospital IQR Program, we strive to ensure that patients, along with their clinicians, can use information from meaningful quality measures to make better decisions about their health care. We support technology that reduces burden and allows clinicians to focus on providing high-quality healthcare for their patients. We also support innovative approaches to improve quality, accessibility, affordability, and equity of care while paying particular attention to improving clinicians' and beneficiaries' experiences when interacting with CMS programs. In combination with other efforts across HHS, we believe the Hospital IQR Program incentivizes hospitals to improve healthcare quality and value, while giving patients the tools and information needed to make the best decisions for themselves.

We seek to promote higher quality, equitable, and more efficient healthcare for Medicare beneficiaries. The adoption of widely agreed upon quality and cost measures supports this effort. We work with relevant interested parties to define measures in almost every care setting and currently measure many aspects of care for almost all Medicare beneficiaries. These measures assess clinical processes and outcomes, patient safety and adverse events, patient experiences with care, care coordination, and cost of care. We have implemented quality measure reporting programs for multiple settings of care. To measure the quality of hospital inpatient services, we implemented the Hospital IQR Program. We refer readers to the following final rules for detailed discussions of the history of the Hospital IQR Program, including statutory history, and for the measures we have previously adopted for the Hospital IQR Program measure set:

- The FY 2010 IPPS/LTCH PPS final rule (74 FR 43860 through 43861);
- The FY 2011 IPPS/LTCH PPS final rule (75 FR 50180 through 50181);
- The FY 2012 IPPS/LTCH PPS final rule (76 FR 51605 through 61653);
- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53503 through 53555);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50775 through 50837);
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50217 through 50249);
- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49660 through 49692);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57148 through 57150);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38326 through 38328 and 38348);
- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 through 41609);
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42448 through 42509);
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58926 through 58959);
- The FY 2022 IPPS/LTCH PPS final rule (86 FR 45360 through 45426); and
- The FY 2023 IPPS/LTCH PPS final rule (87 FR 49190 through 49310).

We also refer readers to 42 CFR 412.140 for Hospital IQR Program regulations.

2. Retention of Previously Adopted Hospital IQR Program Measures for Subsequent Payment Determinations

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53512 and 53513) for our finalized measure retention policy. Pursuant to this policy, when we adopt measures for the Hospital IQR Program beginning with a particular payment determination, we automatically readopt these measures for all subsequent payment determinations unless a different or more limited period is proposed and finalized. Measures are also retained unless we propose to remove, suspend, or replace the measures. We did not propose any changes to these policies in the proposed rule.

3. Removal Factors for Hospital IQR Program Measures

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544) for a summary of the Hospital IQR Program's removal factors. We did not propose any changes to these policies in the proposed rule. However, as discussed in section IX.C.7.d. of this final rule, we are codifying our measure retention and removal policies in our regulations at § 412.140.

4. Considerations in Expanding and Updating Quality Measures

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53510 through 53512) for a discussion of the previous considerations we have used to expand and update quality measures under the Hospital IQR Program. We also refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41147 and 41148), in which we describe the Meaningful Measures Framework. In 2021, we launched Meaningful Measures 2.0 to promote innovation and modernization of all aspects of quality, and to address a wide variety of settings, interested parties, and measure requirements.[377] We also refer readers to the CMS National Quality Strategy that we launched on April 12, 2022, with the aims of promoting the highest quality outcomes and safest care for all individuals.[378]

We did not propose any changes to these policies in the proposed rule.

5. Proposed New Measures for the Hospital IQR Program Measure Set

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27079 through 27084), we proposed to adopt three new measures, all of which are electronic clinical quality measures (eCQMs): (1) Hospital Harm—Pressure Injury eCQM, with inclusion in the eCQM measure set beginning with the CY 2025 reporting period/FY 2027 payment determination and for subsequent years; (2) Hospital Harm—Acute Kidney Injury eCQM, with inclusion in the eCQM measure set beginning with the CY 2025 reporting period/FY 2027 payment determination and for subsequent years; and (3) Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Inpatient) eCQM, with inclusion in the eCQM measure set beginning with the CY 2025 reporting period/FY 2027 payment determination and for subsequent years.

We discuss each of these measures, along with the public comments that we received on them, in subsequent sections.

[375] Centers for Disease Control and Prevention. August 2022. NHSN Manual for COVID–19 Vaccination Reporting. Accessed June 26, 2023. Available at: *https://www.cdc.gov/nhsn/pdfs/ltc/covidvax/protocol-resident-patient-508.pdf.*

[376] Centers for Disease Control and Prevention. April 13, 2023. CDC FAQs: COVID–19 Hospital Data Reporting. Accessed June 26, 2023. Available at: *https://www.cdc.gov/nhsn/covid19/hospital-reporting-faqs.html.*

[377] Centers for Medicare & Medicaid Services. (2021) Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

[378] Centers for Medicare & Medicaid Services. (2022) What is the National Quality Strategy? Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.*

a. Adoption of Hospital Harm—Pressure Injury eCQM, Beginning With the CY 2025 Reporting Period/FY 2027 Payment Determination and for Subsequent Years

(1) Background

Hospital-acquired pressure injuries are serious events and one of the most common patient harms. The incidence of pressure injuries in hospitalized patients has been estimated at 5.4 per 10,000 patient-days and the rate of hospital-acquired pressure injuries has been estimated at 8.4 percent for inpatients.[379] Pressure injuries commonly lead to further patient harm, including local infection, osteomyelitis, anemia, and sepsis,[380] in addition to causing pain and discomfort to patients.[381] Development of a pressure injury can increase the length of a patient's hospital stay by an average of four days.[382] Hospital-acquired pressure injuries are associated with 1.5 to 2.0 times greater risk of 30, 60, and 90-day readmissions.[383] Any stage 3, stage 4, or unstageable pressure ulcer acquired after admission/presentation to a healthcare setting is considered a serious reportable event by the Agency for Healthcare Research and Quality (AHRQ).[384]

The risk of developing a pressure injury can be reduced through best practices including risk assessment, assessment of skin and tissue, preventive skin care, and reducing progression through treatment of pressure injuries, including nutrition.[385] Prior studies also confirm that significant variation in rates of hospital-acquired pressure injuries exists between hospitals and show a higher prevalence of pressure injuries in patients with darker skin tones. [386] [387] These findings suggest that current skin assessment protocols could be less effective at assessing lower stage pressure injuries for people with darker skin tones and indicate an opportunity for improvement.

(2) Overview of Measure

The Hospital Harm-Pressure Injury measure is an outcome eCQM that assesses the proportion of inpatient hospitalizations for patients 18 years and older who suffer the harm of developing a new stage 2, stage 3, stage 4, deep tissue, or unstageable pressure injury. The intent of this measure is to incentivize greater achievements in reducing harms and to enhance hospital performance on patient safety outcomes. Systematically assessing patients who develop new pressure injuries while in the hospital setting will provide hospitals with a reliable and timely measurement of harm reduction efforts and the ability to modify their improvement efforts in near real-time.

This measure was previously described in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19489 through 19491) to solicit public comment on potential future inclusion in the Hospital IQR Program. The measure developer has since revised the measure specifications in response to public comments and feedback. Specifically, the measure developer:

- Expanded the value set to improve capture of pressure injuries;
- Incorporated a present on admission indicator for ICD–10–CM diagnoses;
- Incorporated a denominator exclusion for pressure injuries present on admission;
- Incorporated a 24-hour time window for accurate and timely identification of stage 2, 3, 4, or unstageable pressure injury present on admission; and
- Incorporated a 72-hour time window for accurate and timely identification of deep tissue pressure injury (DTPI) because early diagnosis of DTPI allows prompt identification of possible causes, initiation of treatment, and implementation of preventive strategies. Up to 72 hours can lapse between the precipitating pressure event and the onset of purple or maroon skin, so a longer time window is needed to exclude cases when the precipitating event occurred before the patient's admission.[388]

The measure was re-tested in 18 hospitals (test sites) with two different electronic health record (EHR) vendors (Epic and Cerner) with varying bed size, geographic location, teaching status, and urban/rural status. Test results indicated strong measure reliability (0.97 signal-to-noise ratio and 0.916 intra-class correlation coefficient using the split-half sample) and validity (strong concordance and inter-rater agreement between data exported from the EHR and data in the patient chart).[389]

An older version of this measure was reviewed by the consensus-based entity (CBE) convened Measure Applications Partnership (MAP) [390] for the Hospital IQR Program and Medicare Promoting Interoperability Program during the 2017–2018 pre-rulemaking cycle. The measure received a recommendation of conditional support for rulemaking pending review and endorsement by the CBE once the measure was fully tested. This measure was subsequently reviewed by the CBE during the Spring 2019 cycle but withdrawn due to anticipated substantive changes in measure specifications, described in the Measure Overview section of the proposed rule and this final rule. The revised measure was re-submitted to the MAP for the 2022–2023 pre-rulemaking cycle and received conditional support for rulemaking pending endorsement by the CBE.[391] During its review, the MAP expressed concern about the measure specifications and cautioned about potential bias against facilities that do not have the expertise needed to accurately stage pressure injuries (for example, certified wound care nurses).

[379] Li, Z., Lin, F., Thalib, L., & Chaboyer, W. (2020). Global prevalence and incidence of pressure injuries in hospitalized adult patients: A systematic review and meta-analysis. International Journal of Nursing Studies, Vol. 105. *https://doi.org/10.1016/j.ijnurstu.2020.103546*.

[380] Brem, H., Maggi, J., Nierman, D., Rolnitzky, L., Bell, D., Rennert, R., Golinko, M., Yan, A., Lyder, C., Vladeck, B. (2010). High cost of stage IV pressure ulcers. The American Journal of Surgery, 200: 473–477.

[381] Gunningberg, L., Donaldson, N., Aydin, C., Idvall, E. (2011). Exploring variation in pressure ulcer prevalence in Sweden and the USA: Benchmarking in action. 18. Journal of evaluation in clinical practice., 904–910.

[382] Bauer K, Rock K, Nazzal M, Jones O, Qu W. Pressure Ulcers in the United States' Inpatient Population From 2008 to 2012: Results of a Retrospective Nationwide Study. Ostomy Wound Manage. 2016;62(11):30–38.

[383] Wassel, C.L., Delhougne, G., Gayle, J.A., Dreyfus, J., & Larson, B. (2020). Risk of readmissions, mortality, and hospital-acquired conditions across hospital-acquired pressure injury (HAPI) stages in a US National Hospital Discharge database. Int Wound J., 17, 1924–1934. *https://doi.org/10.1111/iwj.13482*.

[384] AHRQ. (2019). Never Events. *https://psnet.ahrq.gov/primer/never-events*.

[385] Berlowitz, D.; VanDeusen Lukas, C.; Parker, V.; Niederhauser, A.; & Silver, J.L.C.; Ayello, E.; Zulkowski, K. (2012). Preventing Pressure Ulcers in Hospitals—A Toolkit for Improving Quality of Care.

[386] Rondinelli, J., Zuniga, S., Kipnis, P., Kawar, L.N., Liu, V., & Escobar, G.J. (2018). Hospital-Acquired Pressure Injury: Risk-Adjusted Comparisons in an Integrated Healthcare Delivery System. Nurs Res, 67(1), 16–25.

[387] Oozageer Gunowa, N, Hutchinson, M, Brooke, J, Jackson, D. Pressure injuries in people with darker skin tones: A literature review. J Clin Nurs. 2018; 27: 3266–3275. *https://doi.org/10.1111/jocn.14062*.

[388] Wound Management & Prevention: Volume 64—Issue 11—November 2018 ISSN 1943–2720 Index: Ostomy Wound Manage. 2018;64(11):30–41' Definition Inpatient hospitalizations.

[389] Centers for Medicare & Medicaid Services. 2022–2023 Measures Under Consideration (MUC) Cycle Measure Specifications. Available at: *https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf*.

[390] Interested parties convened by the consensus-based entity provide input and recommendations on the Measures under Consideration (MUC) list as part of the pre-rulemaking process required by section 1890A of the Act. We refer readers to *https://p4qm.org/PRMR* for more information.

[391] Centers for Medicare and Medicaid Services. MAP 2022–2023 Final Recommendations. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports*.

The MAP noted that risk adjustment may be necessary to ensure the measure does not disproportionately penalize facilities that may treat more complex patients (for example, academic medical centers or safety net providers). The MAP stated that the measure has several benefits as an eCQM in the Hospital IQR Program, including that hospitals can receive reliable and timely information on pressure injury rates and noted that hospital-acquired pressure injuries are one of the most common patient harms. Weighing these factors, the MAP ultimately offered its conditional support for rulemaking.[392]

The Hospital Harm-Pressure Injury measure was submitted to the CBE for endorsement review in the Fall 2022 cycle (CBE #3498e). Although section 1886(b)(3)(B)(viii)(IX)(aa) of the Act generally requires that measures specified by the Secretary for use in the Hospital IQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, section 1886(b)(3)(B)(viii)(IX)(bb) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and, therefore, we believe the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

(3) Measure Specifications

The numerator is inpatient hospitalizations for patients with a new DTPI or stage 2, 3, 4, or unstageable pressure injury, as evidenced by any of the following: (1) a diagnosis of DTPI with the DTPI not present on admission; (2) a diagnosis of stage 2, 3, 4 or unstageable pressure injury with the pressure injury diagnosis not present on admission; (3) a DTPI found on exam greater than 72 hours after the start of the encounter; (4) a stage 2, 3, 4 or unstageable pressure injury found on exam greater than 24 hours after the start of the encounter. The denominator is inpatient hospitalizations for patients 18 years and older. The following are excluded from the denominator: (1) Inpatient hospitalizations for patients with a DTPI or stage 2, 3, 4 or unstageable pressure injury diagnosis present on admission, (2) inpatient hospitalizations for patients with a DTPI found on exam within 72 hours of the encounter start, (3) inpatient hospitalizations for patients with a stage 2, 3, 4, or unstageable pressure injury found on exam within 24 hours of the encounter start, or (4) inpatient hospitalizations for patients with diagnosis of a COVID–19 infection during the encounter. Importantly, at the time of development and testing, the literature highlights a wide variety of skin manifestations of COVID–19 which hospitals have been confusing with pressure injury and sometimes report as pressure injury in the absence of clear coding guidance and clear evidence regarding the pathophysiology of COVID–19-related lesions.[393] [394] [395] [396] [397] Based on recommendations from the Technical Expert Panel (TEP), the exclusion for COVID–19 is included as transitional with the intention to be removed in the future (during the routine eCQM Annual Update process) when the field develops a better consensus about what is COVID–19-related tissue breakdown versus what is pressure injury. We refer readers to the eCQI Resource Center (*https://ecqi.healthit.gov/eh-cah?qt-tabs_eh=1*) for more details on the measure specifications.

(4) Data Source and Reporting

This eCQM uses data collected through hospitals' EHRs. The measure is designed to be calculated by the hospitals' certified electronic health record technology (CEHRT) using the patient-level data and then submitted by hospitals to CMS. As with all quality measures we develop, testing was performed to confirm the feasibility of the measure, data elements, and validity of the numerator, using clinical adjudicators who validated the EHR data compared with medical chart-abstracted data. Testing demonstrated that all critical data elements were reliably and consistently captured in patient EHRs and measure implementation is feasible.

We proposed the adoption of the Hospital Harm-Pressure Injury eCQM as part of the eCQM measure set, from which hospitals can self-select measures to report to meet the eCQM requirement, beginning with the CY 2025 reporting period/FY 2027 payment determination and for subsequent years. We refer readers to section IX.C.10.e. of the preamble of this final rule for a discussion of our previously finalized eCQM reporting and submission policies. Additionally, we refer readers to section IX.F. of the preamble of this final rule for a discussion of a similar policy to adopt this measure in the Medicare Promoting Interoperability Program.

We invited public comment on this proposal.

Comment: Many commenters supported the proposal to add the Hospital Harm-Pressure Injury eCQM (CBE #3498e) in the Hospital IQR Program. Many commenters noted that adoption of the measure would create valuable public transparency for hospitals and patients on the prevalence of pressure injuries and drive care improvements by encouraging the adoption of patient safety best practices, thereby reducing the risk for patient harm. A few commenters noted their appreciation for CMS expanding the list of available eCQMs within the Hospital IQR Program. A commenter suggested that the measure trigger an automatic mandatory submission of the Global Malnutrition Composite Score eCQM to strengthen the HAC Reduction Program by encouraging best practices for patient safety in inpatient facilities. A few commenters believed the measure should be incorporated into a value-based payment program to incentivize hospitals to adopt best practices. A few commenters appreciated the measure updates that exclude pressure injuries present on admission or that develop in a time window where the cause is unlikely to be tied to quality of care at the admitting hospital.

Response: We thank commenters for their support and input on the inclusion of Hospital Harm-Pressure Injury eCQM (CBE #3498e) in the Hospital IQR Program measure set beginning with the CY 2025 reporting period/FY 2027 payment determination. Regarding

[392] *Ibid.*

[393] Unavoidable Pressure Injury during COVID–19 Pandemic: A Position Paper from the National Pressure Injury Advisory Panel (2020). Available at: *https://npiap.com/page/COVID-19Resources.*

[394] Genovese, G., Moltrasio, C., Berti, E., Marzano, A.V. (2020). Skin Manifestations Associated with COVID–19: Current Knowledge and Future Perspectives, *Dermatology.* U.S. National Library of Medicine. Available at: *https://pubmed.ncbi.nlm.nih.gov/33232965/.*

[395] Perrillat, A., Foletti, J.M., Lacagne, A.S., Guyot, L., & Graillon, N. (2020). Facial pressure ulcers in COVID–19 patients undergoing prone positioning: How to prevent an underestimated epidemic? *Journal of Stomatology, Oral and Maxillofacial Surgery, 121*(4), 442–444.

[396] Jiang, S.T., Fang, C.H., Chen, J.T., & Smith, R.V. (2020). The Face of COVID–19: Facial Pressure Wounds Related to Prone Positioning in Patients Undergoing Ventilation in the Intensive Care Unit. *Otolaryngology—Head and Neck Surgery, 164*(2), 300–301.

[397] Johnson, C., Giordano, N.A., Patel, L., Book, K.A., Mac, J., Viscomi, J., Em, A., Westrick, A., Koganti, M., Tanpiengco, M., Sylvester, K., & Mastro, K.A. (2022). Pressure Injury Outcomes of a Prone-Positioning Protocol in Patients With COVID and ARDS. *American Journal of Critical Care, 31*(1), 34–41.

commenters' suggestion on mandatory reporting and use in a value-based payment program, we highlight that the Hospital Harm-Pressure Injury eCQM was proposed for the Hospital IQR Program and CMS separately makes decisions about inclusion of measures in value-based payment programs such as the HAC Reduction Program. However, in alignment with our goal of transitioning to a fully digital quality measurement landscape, we envision the potential future use of patient safety eCQMs in pay-for-performance programs such as the HAC Reduction Program.

Comment: A few commenters questioned whether 0.00 percent to 2.02 percent variation in performance rates among 18 hospital test sites is a sufficient performance gap to allow users to distinguish meaningful differences in performance. A commenter requested CMS weigh the performance gap of this measure against its other existing and potential new measures of patient safety to ensure this measure merits use in a CMS program. Others were supportive of addressing important patient safety concerns with the measure, but requested additional testing in a broader set of EHRs and hospitals.

Response: We acknowledge that some commenters have expressed concern regarding the magnitude of the performance gap, which they perceive to be small. We highlight that this measure was tested in 18 hospital test sites with varying bed size, geographic location, teaching status, urbanicity, and two different EHR systems. While it is true that measure scores among the hospitals tested ranged from 0.00 percent to 2.02 percent, regression results demonstrated that the measure detects clinically meaningful differences in pressure injuries across hospitals.[398] During testing, several hospitals' performance rates were consistently below the system-wide average while a few others were above that mean, indicating room for quality improvement in the inpatient setting.[399] We will monitor the performance gap as hospitals begin to report this measure.

Comment: Several commenters requested CMS delay adoption of the measure until it was reviewed and endorsed by the CBE.

Response: We thank commenters for their feedback. As mentioned previously, although section 1886(b)(3)(B)(viii)(IX)(aa) of the Act generally requires that measures specified by the Secretary for use in the Hospital IQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, section 1886(b)(3)(B)(viii)(IX)(bb) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. The Hospital Harm-Pressure Injury measure was submitted to the CBE for endorsement review in the Fall 2022 cycle (CBE #3498e). The Patient Safety Standing Committee reviewed the measure at the measure evaluation meeting on February 9, 2023. The measure received high passing scores on all measure criterion (100% pass for evidence, reliability, validity, feasibility, usability and 92.9% pass for performance gap and use) and the committee passed the measure unanimously (14/14) on suitability for endorsement.[400] CMS expects final measure endorsement when the Consensus Standards Approval Committee (CSAC) meets on July 24, 2023.

Comment: Several commenters did not support the adoption of the measure, raising concerns about implementation burden. A commenter requested that CMS allow hospitals two years to implement measures after they are finalized as there is significant technology and information technology (IT) systems work required to get hospital systems up to speed. Another commenter requested to delay measure adoption to the CY 2026 reporting period as pressure injuries are not currently documented in discrete fields at their facility but rather through provider notes. A few commenters had concerns with competing Federal quality reporting and EHR-related mandates given limited hospital quality and health IT resources.

Response: We thank commenters for their input. We highlight that the addition of this eCQM further advances CMS' goal of transitioning to a fully digital quality measurement landscape, promoting interoperability that will help decrease burden. Feasibility testing in 34 hospital inpatient acute care facilities (17 using Meditech EHRs and 17 using Cerner EHRs) showed that all data elements for this measure are in defined fields in electronic sources.[401] Further, this measure is able to capture the occurrence of pressure injuries through either clinical documentation or ICD–10–CM diagnosis codes, providing an alternative option for hospitals that do not yet use discrete fields for pressure injuries. This measure was proposed for inclusion beginning in the CY 2025 reporting period, which means it would first be reported to CMS in early March 2026. As hospitals will not be required to report on this eCQM, the selection of this measure in the Hospital IQR Program need not compete with other Federal quality reporting and EHR-related mandates for limited hospital quality and health IT resources. Rather, the measure will be included as one of the eCQMs that hospitals can self-select for reporting beginning with the CY 2025 reporting period/FY 2027 payment determination.

Comment: Several commenters did not support measure adoption, citing that there is already a claims-based pressure injury measure in the Hospital-Acquired Condition (HAC) Reduction Program (CMS PSI–03 within the CMS PSI–90 composite). Commenters noted that this measure is duplicative and does not reduce reporting requirements or align measures across programs. A few commenters asked for a single measure to streamline data tracking and avoid duplication and redundancies. A few commenters asked clarifying questions on measure implementation. A commenter asked if the intent is to retire PSI–03 when the Hospital Harm-Pressure Injury eCQM is added to the Hospital IQR Program. Another commenter asked if a single submission of the Hospital Harm-Pressure Injury eCQM would meet requirements for the Hospital IQR, Promoting Interoperability, and HAC Reduction Programs.

[398] Measures Management System Hub. (December 1, 2022) Measure Applications Partnership (MAP) Hospital Workgroup: 2022–2023 Measures Under Consideration (MUC) Cycle Measure Specifications Manual. Available at: *https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf.*

[399] Measures Management System Hub. (December 1, 2022) Measure Applications Partnership (MAP) Hospital Workgroup: 2022–2023 Measures Under Consideration (MUC) Cycle Measure Specifications Manual. Available at: *https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf.*

[400] Patient Safety Standing Committee—Measure Evaluation Web Meeting Summary (February 9, 2023). Available at: *https://www.p4qm.org/sites/default/files/2023-04/patient_safety_fall_2022_measure_evaluation_summary_final-508.pdf.*

[401] Measures Management System Hub. (December 1, 2022) Measure Applications Partnership (MAP) Hospital Workgroup: 2022–2023 Measures Under Consideration (MUC) Cycle Measure Specifications Manual. Available at: *https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf.*

Response: We appreciate commenters' feedback regarding duplicative measures. Hospital-acquired pressure injuries are currently measured and publicly reported in the HAC Reduction Program as Patient Safety Indicator (PSI) 03, a component of the Patient Safety PSI 90 measure. However, PSI–03 does not include stage 2 pressure injuries in the outcome, uses claims as its sole data source, and is focused only on Medicare fee-for-service beneficiaries aged 18 years and older. The Hospital Harm-Pressure Injury eCQM is the only EHR-based measure intended for use in acute care hospitals related to pressure injuries. By comparison with PSI 03, this measure utilizes EHR clinical documentation to identify pressure injuries more accurately, allowing hospitals to track pressure injury events and enabling other interested parties to understand the incidence of these events in a broader adult, all-payer population.

In alignment with our goal of transitioning to a fully digital quality measurement landscape, we envision the potential future use of patient safety eCQMs not only in the Hospital IQR Program, but also pay-for-performance programs such as the HAC Reduction Program, including as a potential replacement for the claims-based PSI 90 measure. As discussed in section V.L.2.b.(4) of the proposed rule, we seek to adopt patient safety focused eCQMs to promote further alignment across quality reporting and value-based purchasing programs However, until that time we intend to retain PSI 03 (within the PSI 90 composite) in the HAC Reduction Program as well as finalizing the Hospital Harm-Pressure Injury eCQM in the Hospital IQR Program. We also clarify that meeting the Hospital IQR Program eCQM requirement also satisfies the eCQM reporting requirement for the Medicare Promoting Interoperability Program for eligible hospitals and critical access hospitals (CAHs). However, HAC Reduction Program reporting requirements for PSI 90 are separate.

Comment: A commenter did not support the measure stating that it does not account for patients with complex comorbidities like acute skin failure, which may appear like a DTPI but is not and may lead to inaccurate reporting.

Response: We appreciate the commenter's concern but reiterate that the measure specification allows a 72-hour time window for accurate identification of DTPI due to the lapse between a precipitating event and the onset of skin discoloration. These records with documented DTPI within 72 hours after the start of the encounter are excluded from the measure denominator. Although evidence surrounding the causes and prevention of hospital-acquired pressure injuries continues to progress, it is well-established that the risk of hospital-acquired pressure injuries, including DTPI, can be reduced.[402] [403] [404]

Comment: Several commenters provided feedback on the measure specifications and opportunities for improvement. A few commenters asked for additional population exclusions for patients in hospice, obstetrics, and behavioral health units. A commenter suggested exclusions for pressure injuries that reopen over scar tissue or are hypotensive at admission. Another commenter expressed concern that the two different time courses in the numerator and denominator (stage 2, 3, or 4 or unstageable pressure injury greater than 24 hours after the start of the encounter and DTPI greater than 72 hours after the start of the encounter) adds to the complexity of the measure. A commenter had significant concerns about the inclusion of stage 2 pressure injuries, stating their experience that wounds related to incontinence-associated dermatitis are often misidentified as stage 2 pressure injuries, resulting in inaccurate reporting and reimbursement. Another commenter recommended that the 'encounter start' begin when the patient is admitted to inpatient, as patients may unfortunately have long hold times in the emergency room, where the usual inpatient protocols for skin care cannot reliably be implemented. Another commenter advised CMS to consider any changes to measure exclusion criteria as substantive, requiring use of the rulemaking process.

Response: We thank commenters for their feedback on the measure specification. We clarify this measure captures the number of patients who experience a pressure injury of stage 2 or higher during an acute care hospitalization. Therefore, hospice and behavioral health encounters are indirectly excluded from the measure. With regards to obstetrical patients, although the incidence is rare (<1%), patients receiving care in hospital labor and delivery units are still at risk of developing pressure injuries.[405] Some reported risk factors including: immobility and unsuitable positions (especially with epidural use), excessive humidity (particularly after rupture of membranes), excess weight, dehydration, prolonged labor, lack of risk assessment and planning, and lack of bariatric and pressure-relieving equipment.[406] [407] The target population for this measure is inpatient hospital encounters, inclusive of obstetrical encounters, and does not apply to hospice encounters or behavioral health encounters.

In response to commenter feedback regarding the two different time courses in the numerator and denominator, the use of a 24-hour time window for accurate and timely identification of stage 2, 3, 4, or unstageable pressure injury present on admission aligns with National Pressure Injury Advisory Panel (NPIAP) Clinical Practice Guidelines. The 72-hour time window for accurate and timely identification of DTPI was chosen because a longer time window is needed to exclude cases when the precipitating event occurred before the patient's admission. The use of two different time windows is determined by the complexity of the clinical condition and current practice guidelines.

Regarding the inclusion of stage 2 pressure injuries, we highlight that over 50% of reported pressure injuries in hospitals are stage 2 or higher and new-onset pressure injuries of stage 2 or greater are widely considered to be potentially avoidable with best practices.[408] The inclusion of stage 2 pressure injuries also harmonizes this measure with other National Database of Nursing Quality Indicators (NDNQI) measures, and CMS pressure injury measures used in the long-term care hospital, inpatient rehabilitation

[402] Tayyib, N., Coyer, F., & Lewis, P. (2016). Saudi Arabian adult intensive care unit pressure ulcer incidence and risk factors: A prospective cohort study. International Wound Journal, 13(5), 912–919. *https://doi.org/10.1111/iwj.12406.*

[403] Bly, D., Schallom, M., Sona, C., & Klinkenberg, D. (2016). A model of pressure, oxygenation, and perfusion risk factors for pressure ulcers in the intensive care unit. American Journal of Critical Care, 25(2), 156–154. *https://doi.org/10.4037/ajcc2016840.*

[404] Rondinelli, J., Zuniga, S., Kipnis, P., Kawar, L.N., Liu, V., & Escobar, G.J. (2018). Hospital-Acquired Pressure Injury: Risk-Adjusted Comparisons in an Integrated Healthcare Delivery System. Nurs Res, 67(1), 16–25. *https://doi.org/10.1097/NNR.0000000000000258.*

[405] Newton H, Butcher M. Investigating the risk of pressure damage during childbirth. Br J Nurs. 2000 Mar 23–Apr 12;9(6 Suppl):S20–2, S24, S26. doi: 10.12968/bjon.2000.9.Sup1.6347.

[406] Alfirevic, A., Argalious, M., & Tetzlaff, J.E. (2004). Pressure sore as a complication of labor epidural analgesia. *Anesthesia and analgesia, 98*(6), 1783–1784. *https://doi.org/10.1213/01.ANE.0000116928.80605.D6.*

[407] Newton, H., & Mitchell, M.D. (2000). Pressure ulcers during labour: the effect of epidural analgesia. *Anaesthesia, 55*(11), 1140–1141. *https://doi.org/10.1046/j.1365-2044.2000.01766-17.x.*

[408] Li, Z., Lin, F., Thalib, L., & Chaboyer, W. (2020). Global prevalence and incidence of pressure injuries in hospitalised adult patients: A systematic review and meta-analysis. International Journal of Nursing Studies, Vol. 105. *https://doi.org/10.1016/j.ijnurstu.2020.103546.*

facility, and home health care programs. CMS encourages hospitals to continue robust educational efforts to address knowledge gaps among health professionals, strengthen processes to avoid misidentification of pressure injuries, and ensure consistency in clinical documentation.

Regarding other recommendations to modify denominator exclusion criteria, CMS will continue to consider refinements as new information becomes available. Any proposed specification changes will be evaluated against CMS' existing criteria for technical measure specifications changes to determine whether the rulemaking process or a sub-regulatory process for review is most appropriate. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538) for more details on previously finalized policies regarding substantive vs. non-substantive changes.

As described in § 412.164(c)(1), CMS announces technical measure specification updates through the QualityNet website (*https://qualitynet.cms.gov*) and listserv announcements.

Finally, we appreciate the commenters' recommendation to begin 'encounter start' upon admission to the acute unit (due to potentially long wait times and varying skin assessment protocols in the ED). However, as up to 40% of hospitalized patients are admitted through the emergency department annually,[409] it is critical that pressure injury prevention begin at that point of entry to protect patients from avoidable harm.

Comment: A few commenters thought the measure would benefit from risk adjustment to ensure facilities treating patients with complex health conditions (such as safety net hospitals) or patient with higher illness acuity are not inadvertently penalized.

Response: We appreciate commenters' feedback to consider risk adjusting this measure. New-onset pressure injuries of stage 2 or greater are widely considered to be potentially avoidable with appropriate identification and mitigation of risk factors. There are many actions hospitals can take to reduce risk, such as conducting a structured risk assessment to identify individuals at risk for pressure injury (as soon as possible upon arrival and at regular intervals thereafter), as well as proper skin care, nutrition, and careful repositioning of patients. Although higher risk patients require more intervention to prevent pressure injuries, there is no empirically observed association between pre-existing risk and perceived avoidability.[410] For these reasons, none of the existing CMS measures of pressure injury (for example, home health care, skilled nursing facilities, rehabilitation facilities, long-term acute care) are risk-adjusted.

Comment: A commenter requested clarification on whether diagnosis of a pressure ulcer as a numerator case will be determined based on physician or advanced practice provider documentation (for example, diagnoses in problem lists or discharge documentation).

Response: We thank the commenter for their feedback. The numerator is determined through either ICD–10 CM coded diagnoses or structured clinical documentation to support variances in hospital documentation workflows and practices.

Comment: A few commenters supported the inclusion of the measure and requested that CMS post the pressure injury rates for each hospital on a yearly basis, to allow the public to see improvements soon, and so that hospitals can assess their performance over time as they adopt new protocols and various innovative technologies to reduce pressure injuries.

Response: We thank commenters for their suggestion of annual reporting and overall support for the measure. Based on our previously finalized policy in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58954 through 58959), eCQM performance information is publicly displayed on a CMS-specified website (currently, *data.cms.gov*). For example, if a hospital chooses to self-select the Hospital Harm-Pressure Injury eCQM as one of their self-selected eCQMs to meet the eCQM requirement in the CY 2025 reporting period, results would be posted in the October 2026 release on *data.cms.gov*. During a 30-day preview period, hospitals can review their data before the data are displayed. We will announce the public display of eCQM data on Care Compare on a later date.[411]

Comment: A few commenters stated the measure should be kept as optional, as there are several operational challenges hospitals would need to work through if the measure were to be made mandatory.

Response: As finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49299 through 49302), hospitals must report on six total eCQMs beginning with the CY 2024 reporting period and subsequent years. Hospitals must report on three eCQMs chosen by CMS and then three additional eCQMs that are self-selected from the list of remaining eCQMs. We reiterate this measure will be included as one of the eCQMs hospitals have the option to self-select for reporting beginning with the CY 2025 reporting period/FY 2027 payment determination. Future changes to the eCQM reporting requirements, including any additional eCQMs for mandatory reporting, would go through notice-and-comment rulemaking.

After consideration of the public comments we received, we are finalizing our proposal as proposed. We also refer readers to section IX.H.10.a.2. of this final rule where we are finalizing the same eCQM for the Medicare Promoting Interoperability Program.

b. Adoption of Hospital Harm—Acute Kidney Injury eCQM, Beginning With the CY 2025 Reporting Period/FY 2027 Payment Determination and for Subsequent Years

(1) Background

Acute kidney injury (AKI) is a group of conditions characterized by a sudden decrease in glomerular filtration rate, as evidenced by an increase in serum creatinine concentration or oliguria, and classified by stage and cause.[412] Published literature suggests that the incidence of AKI is 10–20 percent in general hospitalized patients and up to 45–50 percent among critically ill patients.[413] Up to two thirds of intensive care patients will develop AKI, which may result in the need for dialysis and is associated with an increased risk of mortality.[414] Both worsening renal function and injury requiring dialysis have lasting negative

[409] Santamaria N, Creehan S, Fletcher J, Alves P, Gefen A. Preventing pressure injuries in the emergency department: Current evidence and practice considerations. Int Wound J. 2019 Jun;16(3):746–752. doi: 10.1111/iwj.13092. Epub 2019 Feb 27. PMID: 30815991; PMCID: PMC7948891.

[410] Pittman J, Beeson T, Dillon J, Yang Z, Mravec M, Malloy C, Cuddigan J. Hospital-Acquired Pressure Injuries and Acute Skin Failure in Critical Care: A Case-Control Study. J Wound Ostomy Continence Nurs. 2021 Jan–Feb 01;48(1):20–30. doi: 10.1097/WON.0000000000000734.

[411] *https://www.qualityreportingcenter.com/globalassets/iqr2022events/ecqm121922/ecqm-webinar_cy-2022-ecqm-reporting-tools-and-faqs_12.19.22_vfinal508.pdf.*

[412] Levey, A.S., & James, M.T. (2017). Acute Kidney Injury. *Annals of internal medicine, 167*(9), ITC66–ITC80.

[413] Thongprayoon, C., Hansrivijit, P., Kovvuru, K., Kanduri, S.R., Torres-Ortiz, A., Acharya, P., Gonzalez-Suarez, M.L., Kaewput, W., Bathini, T., & Cheungpasitporn, W. (2020). Diagnostics, Risk Factors, Treatment and Outcomes of Acute Kidney Injury in a New Paradigm. Journal of clinical medicine, 9(4), 1104.

[414] Hoste, E.A., & Schurgers, M. (2008). Epidemiology of acute kidney injury: how big is the problem? Critical care medicine, 36(4 Suppl), S146–S151.

impacts.[415] [416] [417] AKI has also been associated with longer term harmful outcomes, such as increased odds of death, increased length of hospital stay, and an average of approximately $7,500 in excess hospital costs.[418] Several studies have demonstrated the association of chronic kidney disease (CKD) development following AKI, and development of ESRD, which increase hospital admissions and long-term mortality.[419] About 30 percent of patients with AKI may require ongoing dialysis in the outpatient setting after hospital discharge.[420] Survivors of AKI also have significantly lower health-related quality of life (HRQOL) compared to the general population.[421] HRQOL is a predictor of mortality among AKI survivors after adjusting for clinical risk variables.[422] Not all AKI is avoidable, but a substantial proportion of AKI cases are preventable and/or treatable at an early stage to improve outcomes. The Kidney Disease: Improving Global Outcomes (KDIGO) guidelines suggest careful management of hemodynamic status, fluids, and vasoactive medications for the prevention of AKI.[423] Literature suggests early AKI treatment such as nephrotoxic avoidance, drug dose adjustment, and attention to fluid balance are also effective preventive measures.[424] [425] Using EHR data from 20 hospitals in 2020, the measure developer found that hospital-level measure performance rates ranged from 0.76 percent to 4.43 percent, with a system-wide, weighted average rate equal to 1.52 percent.[426] The wide variability indicates room for quality improvement in hospital inpatient settings, with several hospitals' performance rates consistently below the overall mean.

(2) Overview of Measure

The Hospital Harm-Acute Kidney Injury measure is an outcome eCQM that assesses the proportion of inpatient hospitalizations for patients 18 years and older who have an AKI (stage 2 or greater) that occurred during the encounter. An AKI stage 2 or greater is defined as a substantial increase in serum creatinine value, or by the initiation of kidney dialysis (continuous renal replacement therapy (CRRT), hemodialysis or peritoneal dialysis). The goal of this measure is to improve patient safety and prevent patients from developing moderate-to-severe AKI (that is, stage 2 or greater) during their hospitalization. Early identification and management of at-risk patients is critical, as there is no specific treatment to reverse AKI.[427] Accurately monitoring the rate at which AKI occurs in the hospital setting will allow hospitals to improve quality and reduce AKI harm rates.

This measure was tested in 20 hospitals (test sites) with two different EHR vendors (Meditech and Cerner) with varying bed size, geographic location, teaching status, and urban/rural status. Testing results indicated strong measure reliability (0.91 for the signal-to-noise ratio and 0.79 for intra-class correlation coefficient using the split-half sample) and validity (strong concordance and inter-rater agreement between data exported from the EHR and data in the patient chart).[428]

The Hospital Harm-Acute Kidney Injury measure was submitted to the CBE-convened MAP for the 2022–2023 pre-rulemaking cycle and received conditional support for rulemaking pending endorsement by the CBE.[429] During its review, MAP noted that the measure fills a gap in quality measurement and provides incentives for improvement since there is currently no AKI measure in the Hospital IQR Program. The MAP also acknowledged that the measure aligns with CMS's goals for high-impact and outcome-based measures, as well as two high-priority areas for the Hospital IQR Program in safety and outcome eCQMs.

This measure was submitted to the CBE for endorsement review in the Fall 2022 cycle (CBE #3713e). Although section 1886(b)(3)(B)(viii)(IX)(aa) of the Act requires that measures specified by the Secretary for use in the Hospital IQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, section 1886(b)(3)(B)(viii)(IX)(bb) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and, therefore, we believe the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

(3) Measure Specifications

The numerator is inpatient hospitalizations for patients 18 years and older who develop AKI (stage 2 or greater) during the encounter, as evidenced by: (1) a subsequent increase in the serum creatinine value at least 2

[415] Hoste, E., & De Corte, W. (2011). Clinical consequences of acute kidney injury. *Contributions to nephrology, 174*, 56–64.

[416] Levey, A.S., & James, M.T. (2017). Acute Kidney Injury. *Annals of internal medicine, 167*(9), ITC66–ITC80.

[417] Libório, A.B., Leite, T.T., Neves, F.M., Teles, F., & Bezerra, C.T. (2015). AKI complications in critically ill patients: association with mortality rates and RRT. *Clinical journal of the American Society of Nephrology: CJASN, 10*(1), 21–28.

[418] Chertow, G.M., Burdick, E., Honour, M., Bonventre, J.V., & Bates, D.W. (2005). Acute kidney injury, mortality, length of stay, and costs in hospitalized patients. Journal of the American Society of Nephrology: JASN, 16(11), 3365–3370.

[419] Gameiro, J., Marques, F., Lopes, J.A. (2021). Long-term consequences of acute kidney injury: a narrative review, *Clinical Kidney Journal,* 14(3) 789–804.

[420] Dahlerus, C., Segal, J.H., He K, et al. (2021). Acute Kidney Injury Requiring Dialysis and Incident Dialysis Patient Outcomes in US Outpatient Dialysis Facilities. *Clin J Am Soc Nephrol,* 16(6), 853–861.

[421] Wang AY, Bellomo R, Cass A, Finfer S, Gattas D, Myburgh J, Chadban S, Hirakawa Y, Ninomiya T, Li Q, Lo S, Barzi F, Sukkar L, Jardine M, Gallagher MP; POST-RENAL Study Investigators and the ANZICS Clinical Trials Group. Health-related quality of life in survivors of acute kidney injury: The Prolonged Outcomes Study of the Randomized Evaluation of Normal versus Augmented Level Replacement Therapy study outcomes. Nephrology (Carlton). 2015 Jul;20(7):492–8. doi: 10.1111/nep.12488. PMID: 25891297.

[422] Joyce VR, Smith MW, Johansen KL, Unruh ML, Siroka AM, O'Connor TZ, Palevsky PM; Veteran Affairs/National Institutes of Health Acute Renal Failure Trial Network. Health-related quality of life as a predictor of mortality among survivors of AKI. Clin J Am Soc Nephrol. 2012 Jul;7(7):1063–70. doi: 10.2215/CJN.00450112. Epub 2012 May 17. PMID: 22595826; PMCID: PMC3386668.

[423] Kidney Disease: Improving Global Outcomes (KDIGO). (2012) KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. *Kidney international,* Suppl. 2, 1–138.

[424] Perazella M.A. (2012). Drug use and nephrotoxicity in the intensive care unit. *Kidney international, 81*(12), 1172–1178.

[425] Onuigbo, M.A., Samuel, E., & Agbasi, N. (2017). Hospital-acquired nephrotoxic exposures in the precipitation of acute kidney injury—A case series analysis and a call for more preventative nephrology practices. *J Nephropharmacol, 6*(2), 90–97.

[426] CMS. 2022–2023 Measures Under Consideration (MUC) Cycle Measure Specifications. Available at: *https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf.*

[427] Kidney Disease: Improving Global Outcomes (KDIGO). (2012) KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. *Kidney international,* Suppl. 2, 1–138.

[428] Centers for Medicare & Medicaid Services. 2022–2023 Measures Under Consideration (MUC) Cycle Measure Specifications. Available at: *https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf.*

[429] Centers for Medicare and Medicaid Services. MAP 2022–2023 Final Recommendations. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

times higher than the lowest serum creatinine value, and the increased value is greater than the highest sex-specific normal value for serum creatinine or (2) kidney dialysis (hemodialysis or peritoneal dialysis) initiated 48 hours or more after the start of the encounter. The denominator is inpatient hospitalizations for patients 18 years and older without a diagnosis of obstetrics, with a length of stay of 48 hours or longer, and who had at least one serum creatinine value after 48 hours from the start of the encounter. The denominator excludes inpatient hospitalizations for patients who (1) are already in AKI at the start of the encounter, (2) have CKD stage 3A or greater, (3) have less than two serum creatinine results within 48 hours of the encounter start, (4) have kidney dialysis initiated within 48 hours of the encounter start, (5) have at least one specified diagnosis present on admission that puts them at extremely high risk for AKI, or (6) have at least one specified procedure during the encounter that puts them at extremely high risk for AKI. We refer readers to the eCQI Resource Center (*https://ecqi.healthit.gov/eh-cah?qt-tabs_eh=1*) for more details on the measure specifications.

(4) Data Source and Reporting

The Hospital Harm-Acute Kidney Injury eCQM uses data collected through hospitals' EHRs. The measure is designed to be calculated by the hospitals' CEHRT using the patient-level data and then submitted by hospitals to CMS. With patient data available from hospitals' EHRs, we believe that hospitals could use confidential feedback reports for this measure to identify disparities in outcomes across different patient demographics, and potentially use that information to inform targeted quality improvement efforts. As with all quality measures we develop, testing was performed to confirm the feasibility of the measure, data elements, and validity of the numerator, using clinical adjudicators who validated the EHR data compared with medical chart-abstracted data. Feasibility testing in 34 inpatient acute care facilities showed that all critical data elements for this measure are defined in electronic fields.

We proposed the adoption of the Hospital Harm-Acute Kidney Injury eCQM as part of the eCQM measure set, from which hospitals can self-select measures to report to meet the eCQM requirement, beginning with the CY 2025 reporting period/FY 2027 payment determination and for subsequent years. We refer readers to section IX.C.10.e. of the preamble of this final rule for a discussion of our previously finalized eCQM reporting and submission policies. Additionally, we refer readers to section IX.F. of the preamble of this final rule for a discussion of a similar proposal to adopt this measure in the Medicare Promoting Interoperability Program.

We invited public comment on this proposal.

Comment: Many commenters supported the adoption of the Hospital Harm-Acute Kidney Injury eCQM into the Hospital IQR Program. A few commenters noted that expanding the list of available eCQMs within the Hospital IQR Program is helpful for quality improvement and this is an important area of patient safety not currently addressed in the program. Another commenter made a general request that CMS include this measure as a pre-rulemaking publication measure on the eCQI Resource Center.

Response: We thank the commenters for their support of our proposal to include Hospital Harm-Acute Kidney Injury eCQM (CBE #3713e) in the Hospital IQR Program measure set beginning with the CY 2025 reporting period/FY 2027 payment determination. We agree that accurately monitoring the rate at which AKI occurs in the hospital setting will allow hospitals to refine quality improvement programs and adopt best practices to identify AKI at an early stage, and intervene to prevent progression. We note that measure details including the electronic specifications were posted on the eCQI Resource Center pre-rulemaking page at the time of publication of the proposed rule at: *https://ecqi.healthit.gov/ecqm/eh/pre-rulemaking/2024/cms0832v1.*

Comment: A few commenters questioned whether a 0.76 percent to 4.43 percent variation in performance rates among the 20 hospital test sites is a sufficient performance gap to allow users to distinguish meaningful differences in performance. For this reason, a commenter was not supportive of adopting the measure, while others were supportive but requested additional testing in a broader set of EHRs and hospitals.

Response: We acknowledge that some commenters have expressed concern regarding the magnitude of the performance gap, which they perceive to be small. We highlight that this measure was tested in 20 hospital test sites with varying bed size, geographic location, teaching status, urbanicity, and two different EHR systems. While it is true that measure scores among the hospitals tested ranged from 0.76 percent to 4.43 percent, regression results demonstrated that the measure detects clinically meaningful differences in AKI across hospitals.[430] During testing, several hospitals' performance rates were consistently below the system-wide average while a few others were above that mean, indicating room for quality improvement in the inpatient setting.[431] We will monitor the performance gap as hospitals begin to report this measure.

Comment: Several commenters urged CMS to delay adoption of the measure until it was reviewed and endorsed by the CBE.

Response: We thank commenters for their feedback to consider delaying adoption of Hospital Harm-Acute Kidney Injury measure until it has been endorsed by a CBE. This measure was submitted to the CBE for endorsement review in the Fall 2022 cycle (CBE #3498e). The Patient Safety Standing Committee reviewed the measure at the measure evaluation meeting on February 9, 2023. The measure received high passing scores on all measure criteria (100% pass for reliability, validity and performance gap, 92.9% pass for evidence, feasibility, and use, and 85.7% pass on usability) and the committee passed the measure almost unanimously (13/14) on suitability for endorsement.[432] CMS expects final measure endorsement when the CSAC meets on July 24, 2023.

Comment: A few commenters were concerned that this measure is duplicative, citing that there is already a claims-based measure of Acute Kidney Injury in the HAC Reduction Program (PSI–10 Postoperative Acute Kidney Injury Requiring Dialysis Rate within the CMS PSI 90 composite). A few commenters were opposed to measure adoption as it would create instances of ''double jeopardy'' for the same patients or cases.

Response: We appreciate commenters' feedback regarding duplicative measures. Patient Safety Indicator (PSI) 10: Postoperative Acute Kidney Injury

[430] Measures Management System Hub. (December 1, 2022) Measure Applications Partnership (MAP) Hospital Workgroup: 2022–2023 Measures Under Consideration (MUC) Cycle Measure Specifications Manual. Available at: *https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf.*

[431] Measures Management System Hub. (December 1, 2022) Measure Applications Partnership (MAP) Hospital Workgroup: 2022–2023 Measures Under Consideration (MUC) Cycle Measure Specifications Manual. Available at: *https://mmshub.cms.gov/sites/default/files/map-hospital-measure-specifications-manual-2022.pdf.*

[432] National Quality Forum (NQF). Patient Safety Fall 2022 Measure Evaluation Summary Final. (2023) Retrieved from *https://www.p4qm.org/sites/default/files/2023-04/patient_safety_fall_2022_measure_evaluation_summary_final-508.pdf.*

Requiring Dialysis Rate, a component of the CMS PSI 90 composite measure, only captures patients who develop postoperative kidney failure requiring renal replacement therapy, uses claims as its sole data source, and is focused only on Medicare fee-for-service beneficiaries aged 18 years and older. In comparison, the Hospital Harm-Acute Kidney Injury eCQM measures how often stage 2 or greater AKI occurs in the inpatient hospital setting, whether or not the patient received dialysis, and whether or not the patient had surgery before developing AKI. The new measure is developed as an eCQM for adult inpatients, regardless of payer, so it is the only EHR-based measure intended for use in acute care hospitals related to AKI.

We wish to clarify that we intend to retain PSI–10 (within the PSI 90 composite) in the HAC Reduction Program when this measure is implemented into the Hospital IQR Program. In alignment with our goal of transitioning to a fully digital quality measurement landscape, we envision the potential future use of patient safety eCQMs not only in the Hospital IQR Program, but also pay-for-performance programs such as the HAC Reduction Program, including as a potential replacement for the claims-based PSI 90 measure. As discussed in section V.L.2.b.(4) of the proposed rule, we seek to adopt patient safety focused eCQMs to promote further alignment across quality reporting and value-based purchasing programs. However, until that time we intend to retain PSI 10 (within the PSI 90 composite) in the HAC Reduction Program as well as finalizing the Hospital Harm-Acute Kidney Injury eCQM in the Hospital IQR Program.

Comment: Several commenters raised concerns about implementation burden. A few commenters highlighted that there is a substantial cost and time burden faced by hospitals when adopting new eCQMs. A few commenters stated the measure should be kept as optional and a commenter requested that CMS delay until the CY 2026 reporting period. A commenter requested that new eCQMs be delayed until formats are changed to Fast Healthcare Interoperability Resources (FHIR) standard to avoid unnecessary duplication of work.

Response: We thank commenters for their input. We reiterate this measure will be included as one of the eCQMs hospitals can self-select for reporting beginning with the CY 2025 reporting period/FY 2027 payment determination.

We highlight that the addition of this eCQM further advances CMS' goal of transitioning to a fully digital quality measurement landscape, promoting interoperability that will help decrease burden. As the field transitions to FHIR, eCQMs specified using the Quality Data Model (QDM) may be used as a validation tool to assess the outcomes between the QDM and FHIR-based specification.

Comment: A few commenters expressed concern that the measure is not risk-adjusted or that the risk-adjustment model is not fully developed.

Response: The AKI measure is risk-adjusted using a fully developed and validated model. Specifically, the risk-adjustment model accounts for patient sex and age, vital signs at the encounter start, index estimated glomerular filtration rate (eGFR) based on the index serum creatinine (patient sex and age; race neutral), comorbidities present on admission (cancer, diabetes, heart failure, hypertension, and obesity), and hospital length of stay.[433] The risk-adjustment model has strong performance (C-statistic >0.8), ensuring that hospitals that care for sicker and more complex patients (for example, academic centers or hospitals that care for disadvantaged populations) are evaluated fairly.[434]

Comment: Several commenters suggested alternative approaches to defining AKI, including measures of urine output or other biomarkers.

Response: This eCQM uses a seven-day rolling window to examine a rise in serum creatinine by 2.0 times or greater, based on the KDIGO stage 2 definition established in the 2012 KDIGO AKI clinical practice guidelines.[435] CMS will continue to monitor developments in the field and incorporate professional consensus into future refinements.

Additionally, this measure excludes encounters that do not have at least two serum creatine values within 48 hours of arrival. Two values are needed within this timeframe to determine if the patient has AKI or moderate-to-severe kidney dysfunction on arrival. Encounters for patients with an increase in serum creatinine value of at least 0.3 mg/dL between the index serum creatinine and any subsequent serum creatinine taken within 48 hours of the encounter start are excluded. Due to the variability of decimal precision within programming languages and calculation tools, the value of >=0.3 is expressed in the logic as >0.299.

Comment: A few commenters provided feedback on measure exclusions. A commenter recommended excluding patients who have a co-diagnosis of volume overload as their lowest creatinine level may be a result of not being at their dry weight or euvolemic state. Another commenter suggested expanding the list of patients ''at extremely high risk for AKI'' to include sepsis, cardiac arrest, and acute myocardial infarction requiring urgent/emergent cardiac catheterization. Another commenter expressed that the current set of exclusions may not adequately address the delay in kidney injury seen in the setting of complicated medical conditions that require complex interventions or those receiving palliative care.

Response: We thank the commenters for their feedback on the measure denominator exclusions. Most of the suggested exclusions are already covered in the current measure specification, including:

- Inpatient hospitalizations for patients with an increase in serum creatinine value of at least 0.3 mg/dL between the index serum creatinine and a subsequent serum creatinine taken within 48 hours of the index serum creatinine. (This criterion excludes patients with AKI at presentation, including patients with sepsis, cardiogenic or traumatic shock, and other conditions that cause early-onset AKI.)
- Inpatient hospitalizations for patients with an eGFR value of <60 mL/min within 48 hours of the encounter start. (This criterion excludes patients with CKD stage 3a or greater at presentation as well as those with end stage kidney disease on dialysis.)
- Inpatient hospitalizations for patients who have kidney dialysis (CRRT, hemodialysis or peritoneal dialysis) initiated within 48 hours of the encounter start. (This criterion excludes patients who require early dialysis due to complete renal failure, acute volume overload, or toxic exposures at presentation.)
- Encounters that do not have at least two serum creatine values within 48 hours of arrival. Two values are needed within this timeframe to determine if the patient has AKI or moderate-to-severe renal dysfunction on arrival.

All of these denominator exclusions have been validated by manual review of medical records to ensure that

[433] Risk Adjustment Methodology Report: Hospital Harm-Acute Kidney Injury (April 2022). Available at: *https://ecqi.healthit.gov/sites/default/files/AKI-Risk-Adjust-Method-Rpt-508.pdf.*

[434] Risk Adjustment Methodology Report: Hospital Harm-Acute Kidney Injury (April 2022). Available at: *https://ecqi.healthit.gov/sites/default/files/AKI-Risk-Adjust-Method-Rpt-508.pdf.*

[435] Kidney Disease: Improving Global Outcomes (KDIGO). (2012) KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. *Kidney international,* Suppl. 2, 1–138.

patients with conditions causing AKI at presentation to the hospital have been excluded. Regarding other recommendations to modify denominator exclusion criteria, we will continue to consider refinements as new information becomes available. Any proposed specification changes will be evaluated against our existing criteria for technical measure specifications changes to determine whether the rulemaking process or a sub-regulatory process for review is most appropriate. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538) for more details on previously finalized policies regarding substantive vs. non-substantive changes. As described in § 412.164(c)(1), CMS announces technical measure specification updates through the QualityNet website (*https://qualitynet.cms.gov*) and listserv announcements.

Comment: A few commenters acknowledged that because there are different methods of calculating eGFR values, the measure should use a standard calculation and utilize a non-racially based formula to calculate eGFR.

Response: The eGFR values are calculated using the CKD–EPI Creatinine Equation (2021), recommended by the National Kidney Foundation (NKF) and American Society of Nephrology (ASN).[436] This is a gender-specific, race-neutral formula. This eCQM applies this formula to all reporting entities to eliminate variation in eGFR calculation methods across clinical laboratories.

Comment: A few commenters indicated concerns with the capture of acute dialysis treatment and that dialysis treatment can be used for non-AKI reasons.

Response: The measure has been carefully designed to exclude patients on chronic dialysis, including hospitalizations for patients who have kidney dialysis (CRRT, hemodialysis or peritoneal dialysis) initiated within 48 hours of the encounter start, hospitalizations for patients with stage 3a or greater CKD within 48 hours of the encounter start, and hospitalizations for patients whose serum creatinine rises by 0.3 mg/dL or more between the index serum creatinine and a subsequent serum creatinine taken within 48 hours of the index serum creatinine. The measure does not use diagnosis codes to identify patients on chronic dialysis; however, those patients would be captured by the previously noted exclusions. Although dialysis may be used for reasons other than AKI, these treatments are generally provided within 48 hours of the encounter start (for example, salicylate toxicity), or they employ other modalities such as isolated ultrafiltration (for example, heart failure with anasarca), which are not captured by the proposed measure.[437] [438]

Comment: Several commenters did not support the measure due to concerns about false positives; they stated that serum creatinine levels can be influenced by various factors such as medications and underlying medical conditions such as sepsis. A commenter noted that aminoglycosides, cisplatin, and cyclosporin may cause reversible kidney injury, but are necessary for patient care and another commenter mentioned that trimethoprim-sulfamethoxazole (TMP–SMX), angiotensin-converting enzyme (ACE) inhibitors, and sodium-glucose cotransporter-2 (SGLT2) inhibitors cause an elevation in creatinine without kidney injury. A commenter noted that radiographic contrast can cause AKI, but may be essential for accurate diagnosis of a patient's condition.

Response: We thank the commenters for their feedback on the use of serum creatinine as a marker for kidney function and diagnosis of AKI. We reiterate that KDIGO clinical practice guidelines for AKI cite serum creatinine as an acceptable and widely available proxy for defining and monitoring AKI and have provided detailed clinical guidelines to evaluate and monitor patients at-risk of kidney damage.[439] While some instances of AKI may be due to natural progression of underlying illness or complication of a necessary treatment, a substantial proportion of AKI cases are preventable and treatable if detected at stage 1, with improved outcomes.[440] [441] Further, KDIGO guidelines suggest careful management of hemodynamic status, fluids, and vasoactive medications, along with avoidance of nephrotoxic exposure and drug dose adjustment, for the prevention of AKI and the progression of AKI once identified.[442] [443]

We clarify that patients with an underlying medical condition such as sepsis are ''designed out'' of the measure specification in two ways. First, patients are excluded from the denominator if they have AKI when they present to the hospital or develop AKI (based on even the smallest meaningful bump in the serum creatinine, 0.3 mg/dl) within the first 48 hours of the encounter. Second, risk adjustment includes patient's vital signs at presentation, thus accounting for patients presenting with systemic inflammatory response syndrome (SIRS), including sepsis. Validation testing confirmed that the first criterion excludes nearly all patients admitted with community-acquired sepsis.

The medications to which the commenters refer (for example, aminoglycosides, ACE inhibitors, SGL–2 inhibitors) generally cause modest increases in the serum creatinine, within the range of what is classified as stage 1 AKI (for example, 1.5–2.0 fold increase in serum creatinine).[444] This measure's numerator is restricted to stage 2 AKI, or ''a subsequent increase in serum creatinine value at least 2 times higher than the lowest serum creatinine value, and the increased value is greater than the highest sex-specific normal value for serum creatinine.'' Recognizing stage 1 AKI will provide an opportunity for the clinician to discontinue or adjust the offending medication without penalty. Most of the drugs specified are not

[436] NKF and ASN Release New Way to Diagnose Kidney Diseases (Sept. 23, 2021). Available at: *https://www.kidney.org/news/nkf-and-asn-release-new-way-to-diagnose-kidney-diseases*.

[437] American College of Medical Toxicology (2015). Guidance document: management priorities in salicylate toxicity. *Journal of medical toxicology: official journal of the American College of Medical Toxicology, 11*(1), 149–152. *https://doi.org/10.1007/s13181-013-0362-3*.

[438] Kabach M, Alkhawam H, Shah S, Joseph G, Donath EM, Moss N, Rosenstein RS, Chait R. Ultrafiltration versus intravenous loop diuretics in patients with acute decompensated heart failure: a meta-analysis of clinical trials. Acta Cardiol. 2017 Apr;72(2):132–141. doi: 10.1080/00015385.2017.1291195.

[439] Kidney Disease: Improving Global Outcomes (KDIGO). (2012) KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. *Kidney international,* Suppl. 2, 1–138.

[440] Kidney Disease: Improving Global Outcomes (KDIGO). (2012) KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. *Kidney international,* Suppl. 2, 1–138.

[441] Wilson, F.P., Shashaty, M., Testani, J., Aqeel, I., Borovskiy, Y., Ellenberg, S.S., Fuchs, B. (2015). Automated, electronic alerts for acute kidney injury: a single-blind, parallel-group, randomised controlled trial. Lancet, 385(9981), 1966–1974.

[442] Kidney Disease: Improving Global Outcomes (KDIGO). (2012) KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease. *Kidney international,* Suppl. 2, 1–138.

[443] Ostermann, M., Bellomo, R., Burdmann, E.A., Doi, K., Endre, Z.H., Goldstein, S.L., Kane-Gill, S.L., Liu, K.D., Prowle, J.R., Shaw, A.D., Srisawat, N., Cheung, M., Jadoul, M., Winkelmayer, W.C., Kellum, J.A., & Conference Participants (2020). Controversies in acute kidney injury: conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) Conference. *Kidney international, 98*(2), 294–309.

[444] Rey, A., Gras-Champel, V., Choukroun, G., Masmoudi, K., & Liabeuf, S. (2022). Risk factors for and characteristics of community- and hospital-acquired drug-induced acute kidney injuries. *Fundamental & clinical pharmacology, 36*(4), 750–761. *https://doi.org/10.1111/fcp.12758*.

nephrotoxic at the doses that are typically used, and with appropriate monitoring, significant increases in serum creatinine levels can be avoided.[445] Risk-adjustment provides additional assurance that providers will not be penalized for appropriate care. Based on the risk-adjustment model, for example, patients with heart failure have about 70% higher odds of AKI than patients without heart failure. The risk model also includes pre-existing diabetes, hypertension, cancer, and obesity.[446]

There has been extensive debate about whether contrast-induced nephropathy is a meaningful clinical entity.[447] [448] [449] For example, a recent systematic review and meta-analysis of 13 nonrandomized controlled studies involving over 25,000 patients found no increased AKI risk among patients who received intravenous contrast.[450] Additionally, the risk of contrast-induced AKI is extremely low among patients with normal or minimally impaired kidney function at baseline, to which this measure is restricted [451] [452] [453] Finally, the 2020 KDIGO conference directly addressed this question as follows: ''recent evidence suggests that the risks associated with IV contrast are far fewer with modern agents and practice patterns, and significant kidney injury is unusual in patients with normal or mildly reduced baseline kidney function. IV contrast should not be withheld owing to concern for AKI in life-threatening conditions in which the information gained from the contrast study could have important therapeutic implications.'' [454] It is generally within the provider's control to determine if the benefits of the contrast study outweigh the risks, and to effectively mitigate those risks.[455] [456]

After consideration of the public comments we received, we are finalizing our proposal as proposed. We also refer readers to section IX.H.10.a.2. of this final rule where we are finalizing the same eCQM for the Medicare Promoting Interoperability Program.

c. Adoption of Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography in Adults (Hospital Level—Inpatient) eCQM Beginning With the CY 2025 Reporting Period/FY 2027 Payment Determination and for Subsequent Years

(1) Background

Over 80 million computed tomography (CT) scans are performed each year in the United States, compared to only three million in 1980.[457] The increased use of CT scans has also increased patients' exposure to x-rays, a type of ionizing radiation that contributes to the development of cancer.[458] The use of CT scans accounts for 24 percent of all radiation exposure for people in the U.S., but has greatly improved the diagnosis and treatment of many conditions.[459]

CT scans deliver higher doses of radiation than conventional x-rays, with a chest x-ray emitting about 0.1 millisieverts (mSv) of radiation, while a regular-dose CT chest scan exposes a patient to seven mSv.[460] In comparison, on average a person in the U.S. is exposed to three mSv of radiation per year from naturally occurring radioactive materials, making a regular-dose CT chest scan equivalent to receiving about two years of background radiation.[461]

A large body of research links CT scans to a higher risk of developing cancer.[462] [463] [464] [465] [466] One study found that patients who received CT scans had a 0.7 percent higher risk of developing cancer in their lifetime compared to the general U.S. population. The risk increased for patients who underwent multiple CT scans, ranging from 2.7 to 12 percent higher.[467] While the

---

[445] Rey, A., Gras-Champel, V., Choukroun, G., Masmoudi, K., & Liabeuf, S. (2022). Risk factors for and characteristics of community- and hospital-acquired drug-induced acute kidney injuries. *Fundamental & clinical pharmacology, 36*(4), 750–761. *https://doi.org/10.1111/fcp.12758*.

[446] American Institutes for Research. Risk Adjustment Methodology Report: Hospital Harm-Acute Kidney Injury (April 2022). Available at: *https://ecqi.healthit.gov/sites/default/files/AKI-Risk-Adjust-Method-Rpt-508.pdf*.

[447] Ehrmann, S., Aronson, D. & Hinson, J.S. Contrast-associated acute kidney injury is a myth: Yes. *Intensive Care Med* 44, 104–106 (2018). *https://doi.org/10.1007/s00134-017-4950-6*.

[448] Kashani, K., Levin, A. & Schetz, M. Contrast-associated acute kidney injury is a myth: We are not sure. *Intensive Care Med* 44, 110–114 (2018). *https://doi.org/10.1007/s00134-017-4970-2*.

[449] Weisbord, S.D., du Cheryon, D. Contrast-associated acute kidney injury is a myth: No. *Intensive Care Med* 44, 107–109 (2018). *https://doi.org/10.1007/s00134-017-5015-6*.

[450] McDonald, J., McDonald, R., Comin, J., Williamson, E., Katzberg, R, Hassan Murad, H., & Kallmes, D. Frequency of Acute Kidney Injury Following Intravenous Contrast Medium Administration: A Systematic Review and Meta-Analysis. *Radiology* 267:1, 119–128 (2013).

[451] Hitinder S. Gurm, M.S., Kooiman, J., & Share, D. A Novel Tool for Reliable and Accurate Prediction of Renal Complications in Patients Undergoing Percutaneous Coronary Intervention. *Journal of the American College of Cardiology,* 61, 2242–2248 (2013). *https://doi.org/10.1016/j.jacc.2013.03.026*.

[452] Mehran, R., Aymong, E., Nikolsky, E., Lasic, Z., Iakovou, I., Fahy, M., Mintz, G., Lansky, A., Moses, J., Stone, G., Leon, M., & Dangas, G. A simple risk score for prediction of contrast-induced nephropathy after percutaneous coronary intervention: Development and initial validation. *Journal of the American College of Cardiology,* 44:7, 1393–1399 (2004). *https://doi.org/10.1016/j.jacc.2004.06.068*.

[453] Tsai, T., Patel, U., Chang, T., Kennedy, K., Masoudi, F., Matheny, M., Kosiborod, M., Amin, A., Messenger, J., Rumsfeld, J., & Spertus, J. Contemporary Incidence, Predictors, and Outcomes of Acute Kidney Injury in Patients Undergoing Percutaneous Coronary Interventions: Insights From the NCDR Cath-PCI Registry. *JACC: Cardiovascular Interventions.* 7:1. 1–9 (2014). *https://doi.org/10.1016/j.jcin.2013.06.016*.

[454] Ostermann, M., Bellomo, R., Burdmann, E.A., Doi, K., Endre, Z.H., Goldstein, S.L., Kane-Gill, S.L., Liu, K. D., Prowle, J.R., Shaw, A.D., Srisawat, N., Cheung, M., Jadoul, M., Winkelmayer, W.C., Kellum, J.A., & Conference Participants (2020). Controversies in acute kidney injury: conclusions from a Kidney Disease: Improving Global Outcomes (KDIGO) Conference. *Kidney international, 98*(2), 294–309.

[455] Weisbord SD, Mor MK, Resnick AL, et al. Prevention, Incidence, and Outcomes of Contrast-Induced Acute Kidney Injury. *Arch Intern Med.* 2008;168(12):1325–1332. doi:10.1001/archinte.168.12.1325

[456] Cho, A., Lee, J.E., Yoon, J.Y., Jang. H.R., Huh., W., Kim, Y.G., Kim, D., & Oh, H. Effect of an Electronic Alert on Risk of Contrast-Induced Acute Kidney Injury in Hospitalized Patients Undergoing Computed Tomography. *AJKD: National Kidney Foundation.* 60:1, P74–81 (July 2012). *https://doi.org/10.1053/j.ajkd.2012.02.331*.

[457] Harvard Health Publishing. (2021) Radiation Risk from Medical Imaging. Available at: *https://www.health.harvard.edu/cancer/radiation-risk-from-medical-imaging*.

[458] *Ibid.*

[459] *Ibid.*

[460] *Ibid.*

[461] National Cancer Institute. (2019) Computed Tomography (CT) Scans and Cancer. Available at: *https://www.cancer.gov/about-cancer/diagnosis-staging/ct-scans-fact-sheet#is-the-radiation-from-ct-harmful*.

[462] Berrington de González, A., Mahesh, M., Kim, K. P., Bhargavan, M., Lewis, R., Mettler, F., & Land, C. (2009). Projected cancer risks from computed tomographic scans performed in the United States in 2007. *Archives of Internal Medicine,* 169(22), 2071–2077. *https://doi.org/10.1001/archinternmed.2009.440*.

[463] Pearce MS, Salotti JA, Little MP, McHugh K, Lee C, Kim KP, Howe NL, Ronckers CM, Rajaraman P, Sir Craft AW, Parker L, Berrington de González A. Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: a retrospective cohort study. *Lancet.* 2012 Aug 4;380(9840):499–505. Doi: 10.1016/S0140–6736(12)60815–0. Epub 2012 Jun 7. PMID: 22681860; PMCID: PMC3418594.

[464] Mathews JD, Forsythe AV, Brady Z, Butler MW, Goergen SK, Byrnes GB, Giles GG, Wallace AB, Anderson PR, Guiver TA, McGale P, Cain TM, Dowty JG, Bickerstaffe AC, Darby SC. Cancer risk in 680,000 people exposed to computed tomography scans in childhood or adolescence: data linkage study of 11 million Australians. *BMJ.* 2013 May 21;346:f2360. Doi: 10.1136/bmj.f2360. PMID: 23694687; PMCID: PMC3660619.

[465] Albert JM. Radiation risk from CT: implications for cancer screening. *AJR Am J Roentgenol.* 2013 Jul;201(1):W81–7. Doi: 10.2214/AJR.12.9226. PMID: 23789701.

[466] Hong JY, Han K, Jung JH, Kim JS. Association of Exposure to Diagnostic Low-Dose Ionizing Radiation With Risk of Cancer Among Youths in South Korea. *JAMA Netw Open.* 2019 Sep 4;2(9):e1910584. Doi: 10.1001/jamanetworkopen.2019.10584. PMID: 31483470; PMCID: PMC6727680.

[467] Harvard Health Publishing. (2021) Radiation Risk from Medical Imaging. Available at: *https://www.health.harvard.edu/cancer/radiation-risk-from-medical-imaging*.

likelihood of developing cancer from a CT scan is small on an individual level, on a population level it can lead to many more cancer cases given the number of CT scans performed every year.[468] One study estimated that the percentage of cancers in the U.S. attributable to CT scans may be as high as two percent.[469] Therefore, it is critically important to ensure that patients are exposed to the lowest possible level of radiation while preserving image quality.

(2) Overview of Measure

The Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Inpatient) eCQM (hereinafter referred to as the Excessive Radiation eCQM) provides a standardized method for monitoring the performance of diagnostic CT to discourage unnecessarily high radiation doses while preserving image quality. It is expressed as a percentage of eligible CT scans that are out-of-range based on having either excessive radiation dose or inadequate image quality, relative to evidence-based thresholds based on the clinical indication for the exam.[470] This measure is not currently risk-adjusted. The purpose of this measure is to reduce unintentional harm to patients. Setting a standard for diagnostic CT scans to prevent unnecessarily high radiation doses while preserving image quality will provide hospitals with a reliable method to assess harm reduction efforts and modify their improvement efforts. This measure also addresses high priority areas as stated in our Meaningful Measures Framework, including the transition to digital quality measures and the adoption of high-quality measures that improve patient outcomes and safety.[471] We also proposed to adopt the Excessive Radiation eCQM to support the National Quality Strategy goal of promoting safety by reducing preventable harm to patients.[472] The measure was developed according to evidence and consensus-based clinical guidelines for optimizing CT radiation doses. These include guidelines created by the American College of Radiology,[473] The Society of Interventional Radiology,[474] The Society of Cardiovascular CT,[475] cardiovascular imaging societies,[476] Image Wisely 2020,[477] and the FDA.[478]

The measure was tested across 16 inpatient and outpatient hospitals and a large system of outpatient radiology practices. Measure testing revealed that availability, accuracy, validity and reproducibility were high for all of the measure's required data elements and the variables that were calculated by the translation software. The measure developer further assessed the reporting burden by administering surveys to each of the participating hospitals and outpatient groups. They found that the burden was small to moderate, comparable to the burden of measure reporting for other measures and fell to information technology (IT) personnel rather than physicians.

Measure testing found that assessing radiation doses and providing audit feedback to radiologists resulted in significant reductions in excessive and unsafe dose levels. The testing sites also noted that the assessment of their doses as specified in the measure was helpful for identifying areas for quality improvement. Over 40 letters were submitted in support of the measure, including several from radiologists and medical physicists who serve as leaders of the testing sites, that confirmed it was feasible and data assembly would not pose a large burden.

The measure was submitted to the CBE for endorsement review in the Fall 2021 cycle (CBE #3663e) and was endorsed on August 2, 2022. The Excessive Radiation eCQM (MUC2022–018) was submitted to the CBE-convened MAP for the 2022–2023 pre-rulemaking cycle and received support for rulemaking.[479] The MAP noted that the Hospital IQR Program currently does not have any measures assessing the risk of radiation exposure from CT scans, and this measure will encourage shared decision-making between providers and patients.[480]

(3) Data Sources

The Excessive Radiation eCQM uses hospitals' EHR data and radiology electronic clinical data systems, including the Radiology Information System (RIS) and the Picture Archiving and Communication System (PACS). Medical imaging information such as Radiation Dose Structured Reports and image pixel data are stored according to the universally adopted Digital Imaging and Communications in Medicine (DICOM) standard. Currently, eCQMs cannot access and process data elements in their original DICOM formats. The measure developer has created software, called the Alara Imaging Software for CMS Measure Compliance, to address this gap. This software links primary data elements, assesses CT scans for eligibility for inclusion in the measure, and generates three data elements mapped to a clinical terminology for eCQM consumption: CT Dose and Image Quality Category, Calculated CT Size-Adjusted Dose, and Calculated CT Global Noise.

The Alara Imaging Software for CMS Measure Compliance will be available to all reporting entities free of charge and will be accessible by creating a secure account through the measure developer's website. Education materials will provide step-by-step instructions on how hospitals can create an account and then link their EHR and PACS data to the software. Reporting entities and their vendors will be able to use the data elements created by this software to calculate the eCQM and to submit results to the Hospital IQR Program as they do for all other eCQMs.

(4) Measure Specifications

The measure numerator includes diagnostic CT scans that have a size-adjusted radiation dose greater than the

[468] Berrington de González, A., Mahesh, M., Kim, K. P., Bhargavan, M., Lewis, R., Mettler, F., & Land, C. (2009). Projected cancer risks from computed tomographic scans performed in the United States in 2007. *Archives of Internal Medicine,* 169(22), 2071–2077. *https://doi.org/10.1001/archinternmed.2009.440.*

[469] *Ibid.*

[470] Centers for Medicare & Medicaid Services. 2022 MUC List. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[471] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.*

[472] CMS Quality Strategy. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.*

[473] American College of Radiology. (2015). Development and Revision Handbook. *https://www.acr.org/-/media/ACR/Files/Practice-Parameters/DevelopmentHandbook.pdf.*

[474] Stecker, Michael S. et al. Guidelines for Patient Radiation Dose Management. Journal of Vascular and Interventional Radiology. 2009. Volume 20, Issue 7, S263–S273.

[475] Halliburton SS, Abbara S, Chen MY, Gentry R, Mahesh M, Raff GL, Shaw LJ, Hausleiter J; Society of Cardiovascular Computed Tomography. SCCT guidelines on radiation dose and dose-optimization strategies in cardiovascular CT. J Cardiovasc Comput Tomogr. 2011 Jul–Aug;5(4):198–224. doi: 10.1016/j.jcct.2011.06.001. PMID: 21723512; PMCID: PMC3391026.

[476] Hirshfeld, JW, Ferrari, VA, Bengel, FM, et al. 2018 ACC/HRS/NASCI/SCAI/SCCT Expert Consensus Document on Optimal Use of Ionizing Radiation in Cardiovascular Imaging: Best Practices for Safety and Effectiveness. Catheter Cardiovasc Interv. 2018; 92: E35– E97. *https://doi.org/10.1002/ccd.27659.*

[477] Image Wisely 2020. Available at: *https://www.imagewisely.org/.*

[478] FDA. (2019). Computed Tomography (CT). *https://www.fda.gov/radiation-emitting-products/medical-x-ray-imaging/computed-tomography-ct#6.*

[479] Centers for Medicare & Medicaid Services. MAP 2022–2023 Final Recommendations. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[480] *Ibid.*

threshold defined for the specific CT category. The threshold is determined by the body region being imaged and the reason for the exam, which affects the radiation dose and image quality required for that exam. The numerator also includes CT scans with a noise value greater than a threshold specific to the CT category.[481]

The measure denominator is the number of all diagnostic CT scans performed on patients 18 years and older during the one-year measurement period which have an assigned CT category, a size-adjusted radiation dose value, and a global noise value.[482]

The measure excludes CT scans that cannot be categorized by the area of the body being imaged or reason for imaging. These include scans that are simultaneous exams of multiple body regions outside of four commonly performed multiple region exams defined by the measure, or scans that cannot be classified based on diagnosis and procedure codes. Exams that cannot be classified are specified as Logical Observation Identifiers Names and Codes (LOINC) 96914–7, CT Dose and Image Quality Category, Full Body. The measure also has technical exclusions for CT scans missing information on the patient's age, Calculated CT Size-Adjusted Dose, or Calculated CT Global Noise. We refer readers to the eCQI Resource Center (*https://ecqi.healthit.gov/eh-cah?qttabs_eh=1&globalyearfilter=2024&global_measure_group=3726*) for more details on the measure specifications.

(5) Data Submission and Reporting

We proposed the adoption of the Excessive Radiation eCQM as part of the Hospital IQR Program measure set, from which hospitals can self-select to report it to meet the eCQM requirement, beginning with the CY 2025 reporting period/FY 2027 payment determination. We refer readers to section IX.C.10.e. of the preamble of this final rule for a discussion of our previously finalized eCQM reporting and submission policies. We also refer readers to section IX.F. of the preamble of this final rule for more information on our proposal to adopt the Excessive Radiation eCQM in the Medicare Promoting Interoperability Program.

We invited public comment on this proposal.

Comment: Many commenters supported our proposal to adopt the Excessive Radiation eCQM into the Hospital IQR Program. Many commenters expressed their belief that the measure would improve patient safety by reducing unnecessary radiation exposure and risk of developing cancer for patients. Several commenters appreciated that this measure could help address a lack of oversight of CT scans, which has led to wide variation in the radiation doses administered. Many commenters noted their belief that adopting the measure would not compromise diagnostic image quality. Several commenters supported the measure proposal, citing the rigorous testing that the measure went through, which demonstrated that implementation was highly feasible and would not place a large reporting burden on clinicians. Several commenters also expressed support because the measure was endorsed by the CBE. Several commenters supported the adoption of the eCQM as an optional measure that hospitals can select to meet eCQM reporting requirements.

Response: We thank the commenters for their support. We agree that this measure will help reduce unnecessary radiation exposure from CT scans and improve patient safety. We also appreciate the commenters' support for the measure as part of the pool of eCQMs from which hospitals can self-select to meet the eCQM requirements.

Comment: Many commenters recommended implementing this measure earlier than proposed, beginning as early as the CY 2024 reporting period. Many commenters urged CMS to make the measure mandatory to report for the Hospital IQR Program. Commenters expressed their belief that given the large number of exams performed annually, excessive radiation from CT scans is a major issue, and mandatory reporting of this measure would drive considerable improvements in safety.

Response: We appreciate commenters' support for an earlier adoption date and for requiring reporting on the Excessive Radiation eCQM. When proposing this measure for adoption, we sought to balance quickly addressing the patient safety concerns presented by exposure to excessive radiation while still providing hospitals with enough time to implement the measure. To ensure this balance remains, we are not accelerating the adoption timeline. We will consider requiring reporting of this measure for future rulemaking.

Comment: Many commenters did not support adoption of the Excessive Radiation eCQM and raised concerns with the measure's technical specifications. A few commenters stated their belief that the measure had not been adequately vetted by experts such as major radiology societies or standards organizations. Some commenters believed that some of the measure's data elements lack scientific and practical validity. A few commenters recommended that CMS find an alternate approach for optimizing radiation doses while preserving diagnostic image quality, whether through existing standards or by working with the medical imaging community to develop new approaches.

Response: We thank the commenters for their input and feedback on this measure. We respectfully disagree that the measure has not been adequately tested. The data elements are scientifically and practically valid. The measure's thresholds for noise and radiation dose were developed with close input from an experienced and diverse TEP, which included representation from radiologists and physicists in medicine and were informed by an image quality study.[483]

The measure also relies on evidence and consensus-based clinical guidelines for optimizing CT radiation doses. These include guidelines developed by the American College of Radiology,[484] The Society of Interventional Radiology,[485] The Society of Cardiovascular CT,[486] cardiovascular imaging societies,[487] Image Wisely 2020,[488] and the FDA.[489] Measure testing by the measure developer across 16 inpatient and outpatient hospitals

[481] Centers for Medicare & Medicaid Services. 2022 MUC List. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[482] *Ibid.*

[483] Smith-Bindman, R., Yu, S., Wang, Y., Kohli, M. D., Chu, P., Chung, R., Luong, J., Bos, D., Stewart, C., Bista, B., Alejandrez Cisneros, A., Delman, B., Einstein, A. J., Flynn, M., Romano, P., Seibert, J. A., Westphalen, A. C., & Bindman, A. (2022). An Image Quality-informed Framework for CT Characterization. Radiology, 302(2), 380–389. *https://doi.org/10.1148/radiol.2021210591.*

[484] American College of Radiology. (2015) Development and Revision Handbook. *https://www.acr.org/-/media/ACR/Files/Practice-Parameters/DevelopmentHandbook.pdf.*

[485] Stecker, Michael S. et al. Guidelines for Patient Radiation Dose Management. Journal of Vascular and Interventional Radiology. 2009. Volume 20, Issue 7, S263–S273.

[486] Halliburton SS, Abbara S, Chen MY, Gentry R, Mahesh M, Raff GL, Shaw LJ, Hausleiter J; Society of Cardiovascular Computed Tomography. SCCT guidelines on radiation dose and dose-optimization strategies in cardiovascular CT. J Cardiovasc Comput Tomogr. 2011 Jul–Aug;5(4):198–224. doi: 10.1016/j.jcct.2011.06.001. PMID: 21723512; PMCID: PMC3391026.

[487] Hirshfeld, JW, Ferrari, VA, Bengel, FM, et al. 2018 ACC/HRS/NASCI/SCAI/SCCT Expert Consensus Document on Optimal Use of Ionizing Radiation in Cardiovascular Imaging: Best Practices for Safety and Effectiveness. Catheter Cardiovasc Interv. 2018; 92: E35–E97. *https://doi.org/10.1002/ccd.27659.*

[488] Image Wisely 2020. Available at: *https://www.imagewisely.org/.*

[489] FDA. (2019) Computed Tomography (CT). *https://www.fda.gov/radiation-emitting-products/medical-x-ray-imaging/computed-tomography-ct#6.*

showed that availability, accuracy, validity and reproducibility were high for all of the measure's required data elements and the variables that were calculated by the translation software. The testing sites reported that the assessment of their radiation doses as specified in the measure was helpful for identifying areas for quality improvement, and the measure received support from radiologists and medical physicists who serve as leaders of the testing sites (88 FR 27084). We also reiterate that this measure was submitted to the CBE by the measure developer for endorsement review (CBE #3663e) and was endorsed on August 2, 2022. The Excessive Radiation eCQM (MUC2022–018) was submitted to the CBE-convened MAP for the 2022–2023 pre-rulemaking cycle and received support for rulemaking (88 FR 27083 and 27084).[490]

Comment: Some commenters stated their belief that the complex relationship between noise and radiation is oversimplified by the measure. Many commenters did not support the measure out of concern that the fixed limits for noise and dose may prevent CT scan operators from appropriately adjusting radiation doses when needed, resulting in incorrect radiation doses and potential misdiagnoses, particularly for patients of size.

Response: We thank the commenters for their feedback. We wish to clarify that the purpose of the Excessive Radiation eCQM is to ensure that radiation dose and image quality fall within thresholds that are safe and appropriate, and it is not intended to oversimplify the relationship between noise and radiation. The image quality component is included in the measure as a balancing component to the radiation dose thresholds, to ensure that CT image quality does not decrease as an unintended consequence of the measure.

We also acknowledge the commenters' concerns about the fixed limits for noise and radiation dose. We reiterate that the thresholds for radiation doses are size-adjusted to accommodate patients of all sizes. We would like to further emphasize that hospitals should use the measure as a guideline for conducting CT scans while also adjusting noise and radiation doses when necessary to provide quality patient care in special circumstances. The measure seeks to reduce harm from excessive radiation for the vast majority of patients and should not replace appropriate clinical judgement if adjustments need to be made in select circumstances.

Comment: A few commenters stated that CMS did not adequately consider references that express concern with the measure's benchmarking approach such as ''Benchmarking CT Radiation Doses Based on Clinical Indications: Is Subjective Image Quality Enough?'' by Mahadevappa Mahesh in Radiology (2022; 302:2, 390–391).

Response: We acknowledge the commenters' concern. We note that the measure developer reviewed the reference cited by the commenters and took its recommendations into account while developing the Excessive Radiation eCQM. The measure developer then rigorously tested the measure across 16 inpatient and outpatient hospitals and a large system of outpatient radiology practices (88 FR 27084).

Comment: Some commenters suggested that this measure is not suitable for eCQM reporting because the measure requires information from radiology data systems, as opposed to clinical information stored in an EHR system.

Response: This measure is suitable for eCQM reporting. As set forth in the eCQI Resource Center, we define an eCQM as a measure specified in a standard electronic format that uses data electronically extracted from EHRs and/or health IT systems to measure the quality of health care provided.[491] By using patients' radiology data that exist in a structured and standard electronic format that can be electronically extracted from radiology IT data systems, this measure meets the definition of an eCQM. And while radiology data are stored in health IT systems, we understand that for many hospitals the radiology data system may not be fully integrated or interoperable with the EHRs. To address this gap, the measure developer created the Alara Imaging Software for CMS Measure Compliance. This software links primary data elements, assesses CT scans for eligibility for inclusion in the measure, and generates three data elements mapped to a clinical terminology for eCQM consumption: CT Dose and Image Quality Category, Calculated CT Size-Adjusted Dose, and Calculated CT Global Noise (88 FR 27084).

Comment: Many commenters expressed concern that implementing this software may be additionally burdensome. Specifically, commenters were concerned that integrating proprietary software and securely deploying it within existing IT systems would place an administrative burden exceeding that of other measures. They stated this burden could include ensuring the compatibility of the software with their system IT networks. Commenters questioned how hospitals unable to use the software for any reason would be able to report this measure.

Other commenters believed that hospital staff would face additional burden in reporting the data. Commenters questioned how the software would integrate with certified EHR reporting technology. They believed that staff would need to manually enter data into the EHR and verify data accuracy across systems as part of the data submission processes. According to commenters, if the software integrates with the EHR, they believe staff time would also be required to build and maintain that integration.

Commenters believed that EHR developers would face a burden in developing and configuring new software to support measure reporting. Multiple interfaces and third-party applications might need to be reconfigured and mapped to process radiology data.

Response: We thank the commenters for sharing their concerns about the Alara Imaging Software for CMS Measure Compliance. The software accepts a wide range of FHIR, HL7 formats for EHR data, and DICOM CT radiation dose and image data to decrease burden. Similar to other eCQMs, the measure has also been developed using proven formats: Quality Data Model (QDM) for immediate implementation and FHIR when adopted in the future, in accordance with our aim of encouraging interoperability based on the FHIR Application Programming Interface (API). Thus, the overall burden is comparable to that of existing eCQMs.

While the Alara Imaging Software for CMS Measure Compliance is proprietary, it will be available to all reporting entities free of charge and accessible by creating a secure account through the measure steward's website. To clarify the reporting process, we note that a hospital can log in through the measure developer's secure portal and run the Alara Imaging Software for CMS Measure Compliance inside the firewall. The software runs automatically to create the three intermediate data elements needed for the measure: CT Dose and Image Quality Category, Calculated CT Size-Adjusted Dose, and

[490] Centers for Medicare & Medicaid Services. MAP 2022–2023 Final Recommendations. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[491] *https://ecqi.healthit.gov/glossary.*

Calculated CT Global Noise. Once the software finishes creating these intermediate variables, hospitals can send the data to its EHR for measure calculation and reporting. The software allows additional options such as the ability to send the data to other business associates of the hospital if needed. No manual data entry is required.

We anticipate that some EHR vendors may develop solutions to ingest these calculated variables and calculate the eCQM, as they have done for other eCQMs. This burden to EHR developers should be similar to any other new eCQM adopted into the Hospital IQR Program.

We additionally note that the adoption timeline and option to self-select reporting on this measure should provide sufficient flexibility for those hospitals that may need time to integrate the software and implement this measure.

Comment: A few commenters requested that we release the complete specifications and guidance on implementing the software at least one year before adopting this measure.

Response: We note that measure details including the electronic specifications were posted on the eCQI Resource Center pre-rulemaking page at the time of publication of the proposed rule: *https://ecqi.healthit.gov/ecqm/eh/pre-rulemaking/2024/cms1074v1*. Education materials will provide step-by-step instructions for the creation of secure accounts and linking hospital EHRs and PACS data to the Alara Imaging Software for CMS Measure Compliance (88 FR 27084). Additional outreach and education will be provided through routine communication channels. This includes but is not limited to issuing memos, emails, and notices on the QualityNet and eCQI Resource Center websites. Therefore, hospitals should have sufficient guidance for implementing the software.

Comment: Some commenters worried about relying on the measure developer as the sole vendor of the translation software. They believed that hospitals could be left unable to report data should the measure developer or its software experience problems. A few commenters raised the concern that hospitals would have to agree to onerous licensing and data use conditions to use the software. Commenters suggested that we allow other vendors to provide translation software to support reporting on this measure. Commenters expressed concern about potential data breaches and whether the measure developer and software have appropriate security protocols to safeguard sensitive patient information. Commenters also stated that hospitals would need to conduct a third-party risk management assessment prior to using the software. A commenter asked whether translation software is currently available for hospitals to integrate with their systems.

Response: We appreciate the commenters' concerns. Hospitals are not required to use the Alara Imaging Software for CMS Measure Compliance. They may choose to use any software that performs the necessary functions to generate the same standardized data elements necessary to calculate the measure consistent with the measure's specifications. The Alara Imaging Software for CMS Measure Compliance was created for this purpose under a CMS-funded grant. The software links primary data elements, assesses CT scans for eligibility for inclusion in the measure, and generates three data elements mapped to clinical terminology for EHR consumption (CT Dose and Image Quality Category, Calculated CT Size-Adjusted Dose, and Calculated CT Global Noise). These calculations all occur within the hospital's firewall to ensure data security. We also note that the measure has been extensively tested in a variety of inpatient and outpatient settings.

The Alara Imaging Software for CMS Measure Compliance has security protocols to safeguard sensitive patient information. It is installed and computes the measure within a hospital's firewall to be used for measure-related activities, including calculation, and reporting. The measure steward's security aligns with industry standards, including HIPAA and Systems and Organization Controls (SOC) 2 certification verified via ongoing third-party audits. As noted previously, while the Alara Imaging Software for CMS Measure Compliance is proprietary, it will be available to all reporting entities free of charge and accessible by creating a secure account through the measure steward's website.

Comment: Many commenters did not support the measure due to concerns about the measure developer's relevant expertise and for-profit status, as well as the potential for a conflict of interest due to the measure developer also being the only vendor for the translation software required for the measure.

Response: We respectfully disagree with the commenters' belief that the measure developer lacks the relevant expertise to steward the Excessive Radiation eCQM. The measure developer team includes radiologists and medical imaging informaticists experienced in developing, testing, publishing, and maintaining national quality measures. Additionally, this measure has undergone rigorous testing and received endorsement from the CBE.

We do not believe that Alara Imaging's corporate status by itself automatically poses a conflict of interest. The Alara Imaging Software for CMS Measure Compliance will be available to all reporting entities under the Hospital IQR and Medicare Promoting Interoperability Programs free of charge, as well as the Hospital Outpatient Quality Reporting (OQR) Program if the proposal to adopt the same measure is finalized.[492] If in the future access to the software is more limited, then we will reconsider retaining the measure in these CMS programs.

Comment: Many commenters questioned whether the risk of exposure to excessive radiation warranted adoption of this measure into the Hospital IQR Program. Many commenters suggested that this measure is not needed because existing regulations and accreditation programs already provide oversight. A few other commenters argued that there is not enough scientific evidence to link low-level radiation dose to cancer incidence and mortality.

Response: We appreciate the commenters' position. However, excessive radiation during CT scans is a major patient safety issue. Over 80 million CT scans are performed each year in the United States, compared to only three million in 1980. As a result of the increased use of CT scans, it accounts for 24 percent of all radiation exposure for people in the U.S.[493]

We reiterate that a large body of research links CT scans to a higher risk of developing cancer.[494] [495] [496] [497] [498] One

[492] CY 2024 Outpatient Prospective Payment System (OPPS)/Ambulatory Surgical Center (ASC) Payment System proposed rule, 88 FR 49552, July 31, 2023.

[493] Harvard Health Publishing. (2021) Radiation Risk from Medical Imaging. Available at: *https://www.health.harvard.edu/cancer/radiation-risk-from-medical-imaging.*

[494] Berrington de González, A., Mahesh, M., Kim, K.P., Bhargavan, M., Lewis, R., Mettler, F., & Land, C. (2009). Projected cancer risks from computed tomographic scans performed in the United States in 2007. *Archives of Internal Medicine,* 169(22), 2071–2077. *https://doi.org/10.1001/archinternmed.2009.440.*

[495] Pearce MS, Salotti JA, Little MP, McHugh K, Lee C, Kim KP, Howe NL, Ronckers CM, Rajaraman P, Sir Craft AW, Parker L, Berrington de González A. Radiation exposure from CT scans in childhood and subsequent risk of leukaemia and brain tumours: a retrospective cohort study. *Lancet.* 2012 Aug 4;380(9840):499–505. Doi: 10.1016/S0140–6736(12)60815–0. Epub 2012 Jun 7. PMID: 22681860; PMCID: PMC3418594.

[496] Mathews JD, Forsythe AV, Brady Z, Butler MW, Goergen SK, Byrnes GB, Giles GG, Wallace

study found that patients who received CT scans had a 0.7 percent higher risk of developing cancer in their lifetime compared to the general U.S. population. The risk increased for patients who underwent multiple CT scans, ranging from 2.7 to 12 percent higher.[499]

While the likelihood of developing cancer from a CT scan is small on an individual level, on a population level it can lead to many more cancer cases given the number of CT scans performed every year.[500] One study estimated that the percentage of cancers in the U.S. attributable to CT scans may be as high as two percent.[501] Ensuring that patients are exposed to the lowest possible level of radiation while preserving CT scan image quality therefore represents an opportunity to meaningfully reduce the incidence of cancer in the population (88 FR 27083).

While there are established regulations and programs to regulate radiation doses, radiation doses still vary greatly depending on where a patient goes for care.[502] This is concerning because the risk of developing cancer increases with the dose administered to patients.[503] The Excessive Radiation eCQM will address the problem by establishing a common standard for hospitals to follow and providing transparency in the public reporting of data.

Comment: Several commenters urged CMS not to require reporting of this measure. A few commenters recommended that CMS evaluate the feasibility and burden of measure implementation, as well as hospital performance, before considering requiring reporting or moving the measure to a pay-for-performance program.

Response: We appreciate the commenters' input. We note that at this time, the measure is being finalized for addition to the list of eCQMs from which hospitals can self-select in the Hospital IQR Program and in the Medicare Promoting Interoperability Program as discussed in section IX.F. As finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49299 through 49302), hospitals participating in the Hospital IQR Program must report on six total eCQMs beginning with the CY 2024 reporting period and subsequent years. Hospitals must report on three eCQMs chosen by CMS and then three additional eCQMs that are self-selected from the list of remaining eCQMs. We note that this eCQM is being added to the list of eCQMs from which a hospital can self-select to report and no hospital is required to select the Excessive Radiation eCQM to successfully meet the eCQM requirement in a given year.

There are also no plans to add this eCQM to a pay-for-performance program at this time and any future adoption of the measure in pay-for-performance programs would first be proposed in notice and comment rulemaking.

Comment: Several commenters recommended that the adoption timeline be delayed to allow for additional measure testing and implementation of the measure. Specifically, a commenter suggested that the measure be tested in hospitals serving small or rural communities. Another commenter requested additional opportunities for consultation with hospitals for more testing and input prior to adoption. A commenter recommended starting with a voluntary reporting period for testing and validation before requiring the measure.

Response: We thank the commenters for sharing these suggestions. When considering this measure for adoption, we sought to balance quickly addressing the patient safety concerns presented by exposure to excessive radiation while still providing hospitals with enough time to implement the measure. Indeed, as described earlier, many commenters requested that CMS adopt this measure earlier than proposed. The adoption timeline and option to self-select reporting on this measure provide sufficient flexibility for those hospitals that desire to report this measure but may need more time to integrate and implement this measure. Moreover, this measure is ready for adoption as proposed, as it has undergone rigorous testing and received endorsement from the CBE. The CBE endorsement process included review by the CBE-convened MAP Health Equity Advisory Group and Rural Health Advisory Group, which supported the measure.[504] Therefore, the measure has received input from a variety of relevant parties including hospitals serving small or rural communities.

Comment: A few commenters did not support the Excessive Radiation eCQM's adoption as proposed, citing the recent addition of many new measures to the Hospital IQR Program. They urged CMS to take a more gradual approach in changing reporting requirements, particularly noting the burden on hospitals to update their systems to report a new eCQM. One of these commenters further suggested that CMS delay adoption of new eCQMs until after hospitals have finished updating their systems to report in the FHIR-based format. A few commenters recommended that CMS instead consider adopting this measure as a dQM.

Response: We acknowledge the commenters' concern over the rate that the Hospital IQR Program has been adopting new eCQMs during recent rulemaking, and emphasize that we are not changing the total number of eCQMs that a hospital must report in this final rule. This eCQM is being added to the list of eCQMs from which a hospital can self-select to report, which should provide hospitals with enough time to implement the measure should they choose to report it.

We also appreciate the commenters' recommendation to adopt the measure as a dQM. An eCQM is a type of dQM. The addition of the Excessive Radiation eCQM further advances CMS' goal of transitioning to a fully digital quality measurement landscape, which promotes interoperability that will decrease the burden of reporting quality measures. While our goal is to eventually move to the FHIR API (87 FR 49181), it is important to address excessive radiation exposure from CT

AB, Anderson PR, Guiver TA, McGale P, Cain TM, Dowty JG, Bickerstaffe AC, Darby SC. Cancer risk in 680,000 people exposed to computed tomography scans in childhood or adolescence: data linkage study of 11 million Australians. *BMJ.* 2013 May 21;346:f2360. Doi: 10.1136/bmj.f2360. PMID: 23694687; PMCID: PMC3660619.

[497] Albert JM. Radiation risk from CT: implications for cancer screening. *AJR Am J Roentgenol.* 2013 Jul;201(1):W81–7. Doi: 10.2214/AJR.12.9226. PMID: 23789701.

[498] Hong JY, Han K, Jung JH, Kim JS. Association of Exposure to Diagnostic Low-Dose Ionizing Radiation With Risk of Cancer Among Youths in South Korea. *JAMA Netw Open.* 2019 Sep 4;2(9):e1910584. Doi: 10.1001/jamanetworkopen.2019.10584. PMID: 31483470; PMCID: PMC6727680.

[499] Harvard Health Publishing. (2021). Radiation Risk from Medical Imaging. Available at: *https://www.health.harvard.edu/cancer/radiation-risk-from-medical-imaging.*

[500] Berrington de González, A., Mahesh, M., Kim, K.P., Bhargavan, M., Lewis, R., Mettler, F., & Land, C. (2009). Projected cancer risks from computed tomographic scans performed in the United States in 2007. *Archives of Internal Medicine,* 169(22), 2071–2077. *https://doi.org/10.1001/archinternmed.2009.440.*

[501] *Ibid.*

[502] Jeukens C, Boere H, Wagemans B, et al. Probability of receiving a high cumulative radiation dose and primary clinical indication of CT examinations: a 5-year observational cohort study. BMJ Open 2021;11(1):e041883. DOI: 10.1136/bmjopen-2020–041883.

[503] Berrington de González, A., Mahesh, M., Kim, K.P., Bhargavan, M., Lewis, R., Mettler, F., & Land, C. (2009). Projected cancer risks from computed tomographic scans performed in the United States in 2007. *Archives of Internal Medicine,* 169(22), 2071–2077. *https://doi.org/10.1001/archinternmed.2009.440.*

[504] Centers for Medicare & Medicaid Services. MAP 2022–2023 Final Recommendations. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

scans as soon as feasible to protect patients.

Comment: A few commenters encouraged CMS to obtain endorsement from the CBE before adopting this measure.

Response: We thank the commenters for their input. As we stated in the proposed rule (88 FR 27084), this measure has received endorsement from the CBE.[505]

Comment: A commenter stated that using the term ''Excessive Radiation'' could deter patients from undergoing needed clinical care and suggested using more neutral terminology instead.

Response: We appreciate the commenter's recommendation. The measure name is nonetheless appropriate because excessive radiation doses are an outcome that the eCQM measures. We further expect that rather than deterring patients from needed care, reporting on this measure will reassure patients that the CT scans they undergo are safe and will use an appropriate amount of radiation.

Comment: A commenter requested clarification regarding whether a facility choosing to report this measure would be able to use a single submission to meet requirements for the Hospital IQR, Promoting Interoperability, and HAC Reduction Programs. Another commenter stated that if the measure is also proposed for adoption in the Hospital OQR Program, CMS should streamline reporting and allow hospitals to report one set of data for both the Hospital IQR and Hospital OQR Programs.

Response: We thank the commenters for their suggestions and feedback and will take it under consideration for future rulemaking. Regarding reporting a measure for multiple programs, hospitals can report the same Excessive Radiation eCQM for both the Hospital IQR and Medicare Promoting Interoperability Programs. This measure was not proposed in the HAC Reduction Program. We note that the HAC Reduction Program does not currently include eCQMs but has requested feedback on the possibility of adopting eCQMs (such as the Excessive Radiation eCQM) in the future, as discussed in section V.L.4. of this final rule. The Hospital OQR Program has also proposed to adopt the Excessive Radiation eCQM in the CY 2024 OPPS/ASC proposed rule,[506] which if adopted would require a separate submission to report. At this time, hospitals would not be able to report one set of data for both the Hospital IQR and Hospital OQR Programs because the two programs operate with respect to distinct patient populations. As we strive to increase electronic quality reporting, we will consider ways to improve cross-program reporting efficiencies.

Comment: A commenter stated that if the measure is adopted, CMS should develop a robust dissemination plan to inform patients and families of the measure's existence.

Response: We appreciate this recommendation and will continue to share outreach and education about the measure when it is publicly reported.

Comment: A commenter encouraged CMS to make specifications for the Excessive Radiation eCQM available for 2025 in the eCQI Resource Center, to allow the commenter to evaluate the measure's implementation.

Response: We appreciate the commenter's input and will take it into account. The measure specifications were posted on the eCQI Resource Center at *https://ecqi.healthit.gov/ecqm/eh/pre-rulemaking/2024/cms1074v1* at the time of the proposed rule. We will continue to update this page as more information becomes available. We will also provide information about the software's specifications as it becomes available through routine communication channels to hospitals, vendors, and other interested parties, including but not limited to, issuing memos, emails, and notices on QualityNet and the eCQI Resource Center websites.

Comment: A commenter requested clarification on several aspects of the measure. The commenter asked how ''good image quality'' would be determined beyond noise and stated that there are other elements that should be taken into consideration such as contrast resolution, lesion detection ability, and physician preference. The commenter also requested greater transparency around the data inputs, algorithm, and how the software would classify individual cases. The commenter recommended that CMS specifically identify the threshold values, particularly for image quality, and provide additional information about how these values were derived. The commenter further encouraged CMS to be as transparent as possible about the cost and burden associated with the measure, including costs associated with hardware, application support, and software maintenance. The commenter further requested clarification on whether the one-year measurement period measures the cumulative dose for all patients or individual patients. The commenter also asked CMS to identify specific requirements for maintaining the data over time, such as where to store the information.

Response: We appreciate the commenter's feedback. Regarding the commenter's question about how good image quality would be determined beyond noise, we wish to clarify that the image quality component, as measured by noise, was included to ensure that CT image quality does not decrease as an unintended consequence of lowering radiation doses. Noise was selected as the metric for measuring image quality because it is the most widely used measure of image quality for CT. Because the image quality component is not meant to be a comprehensive measure of image quality that can assess nuanced differences in quality across all CT scans, it does not take into account variables beyond noise.

We also wish to clarify the data inputs, algorithm, and how the software would classify individual cases. The measure specifications are listed in measure submission materials to the NQF[507] and on the eCQI Resource Center at *https://ecqi.healthit.gov/ecqm/eh/pre-rulemaking/2024/cms1074v1*. The framework for classifying CT scans into CT categories was published in ''An Image Quality-informed Framework for CT Characterization''.[508]

Regarding the measure's threshold values and approach for deriving them, this information can be found in the materials that the measure developer submitted to the NQF for endorsement review.[509] The thresholds were derived in part using data from the ACR Dose Index Registry and UCSF International CT Dose Registry.

We additionally thank the commenter for their encouragement to be as transparent as possible about the cost and burden associated with the measure. As discussed previously, to clarify the current reporting process, we note that a hospital would log in through the measure developer's secure portal and run the Alara Imaging

[505] Centers for Medicare & Medicaid Services. MAP 2022–2023 Final Recommendations. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[506] 88 FR 49552, July 31, 2023.

[507] Measure 3663e Information Form. Available at: *https://www.qualityforum.org/ProjectMeasures.aspx?projectID=86057&cycleNo=2&cycleYear=2021.*

[508] Smith-Bindman, R., Yu, S., Wang, Y., Kohli, M.D., Chu, P., Chung, R., Luong, J., Bos, D., Stewart, C., Bista, B., Alejandrez Cisneros, A., Delman, B., Einstein, A.J., Flynn, M., Romano, P., Seibert, J.A., Westphalen, A.C., & Bindman, A. (2022). An Image Quality-informed Framework for CT Characterization. Radiology, 302(2), 380–389. *https://doi.org/10.1148/radiol.2021210591.*

[509] Measure 3663e Information Form. Available at: *https://www.qualityforum.org/ProjectMeasures.aspx?projectID=86057&cycleNo=2&cycleYear=2021.*

Software for CMS Measure Compliance inside the firewall. The software runs automatically to create the three intermediate data elements needed for the measure: CT Dose and Image Quality Category, Calculated CT Size-Adjusted Dose, and Calculated CT Global Noise. Once the software finishes creating these intermediate variables, hospitals can send the data to its EHR for measure calculation and reporting. No additional hardware will be needed, nor any manual data entry.

With regard to the commenter's question about what the one-year measurement period is measuring, each CT scan in the one-year period is evaluated against size-adjusted dose and permissible image noise thresholds set for each CT category. There is no assessment that combines dose across time and there are no cumulative dose calculations.

Additionally, regarding the question about requirements for data maintenance, the Excessive Radiation eCQM uses data from radiology electronic clinical data systems, including the Radiology Information System (RIS) and the Picture Archiving and Communication System (PACS), and these medical imaging information such as Radiation Dose Structured Reports and image pixel data are stored according to the universally adopted DICOM standard, as described in the proposed rule (88 FR 27084). These data will need to be available at the time the hospital and/or its vendor calculates the eCQM for quality improvement and monitoring purposes as well reporting to CMS.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

6. Refinements to Current Measures in the Hospital IQR Program Measure Set

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27084 through 27088), we proposed refinements to three measures currently in the Hospital IQR Program measure set: (1) Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure beginning with the FY 2027 payment determination; (2) Hybrid Hospital-Wide All-Cause Readmission (HWR) measure beginning with the FY 2027 payment determination; and (3) COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with Quarter 4 CY 2023 reporting period/FY 2025 payment determination. We provide more details on these proposals in the subsequent sections and for the modification of the COVID–19 Vaccination Coverage among HCP measure, as previously discussed in section IX.B. of this final rule.

a. Modification of Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) Measure Beginning With the FY 2027 Payment Determination

(1) Background

Estimates suggest that more than 400,000 patients die each year from preventable harm in hospitals.[510] Existing condition-specific mortality measures support targeted quality improvement work and may have contributed to national declines in hospital mortality rates for measured conditions and/or procedures.[511] They do not, however, allow for measurement of a hospital's broader performance, nor do they meaningfully capture performance for smaller volume hospitals. While we do not ever expect mortality rates to be zero, studies have shown that, for selected conditions and diagnoses, mortality within 30 days of hospital admission is related to quality of care.[512]

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45365 through 45374), we adopted the Hybrid HWM measure into the Hospital IQR Program starting with one voluntary confidential reporting period beginning with performance data from July 1, 2022, through June 30, 2023, followed by mandatory data submission and public reporting in subsequent years. Specifically, hospitals are required to report the Hybrid HWM measure beginning with the performance data from July 1, 2023, through June 30, 2024, impacting the FY 2026 payment determination and subsequent years.[513]

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27085 through 27086), we proposed to modify the measure to expand the cohort of the Hybrid HWM measure from only Medicare fee-for-service (FFS) patients to a cohort which includes both FFS and Medicare Advantage (MA) patients 65 to 94 years old for the FY 2027 payment determination and subsequent years. The FY 2027 payment determination is associated with discharge data from July 1, 2024, through June 30, 2025. We proposed to expand the measure cohort to include MA patients because MA beneficiary enrollment has been rapidly increasing as a share of overall beneficiaries. In 2022, nearly half of Medicare beneficiaries—or over 28 million people—were enrolled in MA plans, and it is projected that enrollment will continue to grow.[514] The Congressional Budget Office estimates that by 2030, 62 percent of beneficiaries will be covered by MA plans.[515] MA coverage also varies across counties and states (ranging between one to 59 percent) with lower enrollment in rural states.[516] Including MA beneficiaries in hospital outcome measures will help ensure that hospital quality is measured across all Medicare beneficiaries. We further believe that the addition of MA beneficiaries to FFS will significantly increase the size of the measure's cohort, enhance the reliability of the measure scores, lead to more hospitals receiving results, and increase the chance of identifying meaningful differences in quality for some low-volume hospitals. Moreover, this update will address interested parties' concerns about differences in quality for MA and FFS beneficiaries by ensuring hospital outcomes are measured across all Medicare beneficiaries.[517] [518]

[510] James JT. A new, evidence-based estimate of patient harms associated with hospital care. Journal of patient safety. 2013;9(3):122–128. Accessed December 9, 2022. Available at: *https://psnet.ahrq.gov/issue/new-evidence-based-estimate-patient-harms-associated-hospital-care.*

[511] Suter LG, Li SX, Grady JN, et al. National patterns of risk-standardized mortality and readmission after hospitalization for acute myocardial infarction, heart failure, and pneumonia: update on publicly reported outcomes measures based on the 2013 release. Journal of general internal medicine. 2014;29(10):1333–1340. Accessed December 9, 2022. Available at: *https://pubmed.ncbi.nlm.nih.gov/24825244/.*

[512] Peterson ED, Roe MT, Mulgund J, et al. Association between hospital process performance and outcomes among patients with acute coronary syndromes. Jama. 2006;295(16):1912–1920. Accessed December 9, 2022. Available at: *https://jamanetwork.com/journals/jama/fullarticle/202753.*

[513] Subsequent reporting periods for the Hybrid HWM measure are from July 1, three years prior to the fiscal year in which the payment determination is applied and end on June 30, two years prior to the fiscal year in which the payment determination is applied.

[514] Freed M, Biniek JF, Damico A, Neuman T. Medicare Advantage in 2022: Enrollment Update and Key Trends. Kaiser Family Foundation. Accessed December 5, 2022. Available at: *https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-enrollment-update-and-key-trends/.*

[515] *Ibid.*

[516] *Ibid.*

[517] Ochieng N and Biniek JF. Beneficiary Experience, Affordability, Utilization, and Quality in Medicare Advantage and Traditional Medicare: A Review of the Literature. Accessed December 8, 2022. Available at: *https://www.kff.org/medicare/report/beneficiary-experience-affordability-utilization-and-quality-in-medicare-advantage-and-traditional-medicare-a-review-of-the-literature/.*

[518] Medicare Payment Advisory Commission. The Medicare Advantage program: Status Report and mandated report on dual-eligible special needs plans. Accessed December 8, 2022. Available at: *https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch12_SEC.pdf.*

(2) Overview of Measure

The Hybrid HWM measure is an outcome measure developed to capture the hospital-level, risk-standardized mortality within 30 days of hospital admission for most conditions or procedures. Hospitalizations are eligible for inclusion in the measure if the patient was hospitalized at a non-Federal, short-term acute care hospital. The measure is reported as a single summary score, derived from the results of risk-adjustment models for 15 mutually exclusive service-line divisions (categories of admissions grouped based on similar discharge diagnoses or procedures), with a separate risk model for each of the 15 service-line divisions. The 15 service-line divisions include nine non-surgical divisions and six surgical divisions. The non-surgical divisions are: cancer; cardiac; gastrointestinal; infectious disease; neurology; orthopedics; pulmonary; renal; and other. The surgical divisions are: cancer; cardiothoracic; general; neurosurgery; orthopedics; and other. The focus population is Medicare FFS and proposed MA beneficiaries who are 65 to 94 years old and hospitalized in non-Federal hospitals.

To compare mortality performance across hospitals, the measure accounts for differences in patient characteristics (patient case mix), as well as differences in the medical services provided and procedures performed by hospitals (hospital service mix). In addition, the Hybrid HWM measure employs a combination of administrative claims data and clinical EHR data to enhance clinical case mix adjustment with additional clinical data. As described previously, the measure is reported as a single summary score, derived from the results of risk-adjustment models for 15 mutually exclusive service-line divisions.

(3) Measure Calculation

The current Hybrid HWM measure cohort consists of Medicare FFS beneficiaries, between 65 and 94 years old, discharged from a non-Federal, short-term acute care hospital, within the one-year measurement period (July 1 to June 30). The cohort definition attempts to capture as many admissions as possible for which survival will be a reasonable indicator of quality and for which adequate risk adjustment is possible. The outcome for this measure is all-cause 30-day mortality. We define all-cause mortality as death from any cause within 30 days of the index hospital admission date.[519] The Hybrid HWM measure uses three main sources of data for the calculation of the measure: (1) Medicare Part A claims data; (2) a set of core clinical data elements from a hospital's EHR; and (3) mortality status obtained from the Medicare Enrollment Database.

The proposed inclusion of MA beneficiaries has several important benefits for the reliability and validity of this hospital outcome measure. Using data from July 1, 2018 through June 30, 2019, we calculated results from the MA claims to compare to the FFS-only results. We assessed 6,883,980 unique admissions (2,466,453 MA and 4,417,527 FFS) extracted from the CMS Integrated Data Repository for FFS claims, hospital-submitted MA claims, and Medicare Advantage Organization (MAO)-submitted MA inpatient encounter claims. Due to the lack of available EHR data, we conducted testing of the combined cohort (MA and FFS) in a claims-only version of the HWM measure. The Hybrid HWM measure is identical to the claims-only version of the measure except for the addition of the core clinical data elements. When the Hybrid HWM measure was initially developed, results using the Medicare Claims Re-Specification Dataset were compared with the hybrid measure results. The measure scores based on the claims-only model in the hybrid data are highly correlated to the measure scores based on the hybrid model (correlation coefficient = 0.96). C-statistics from logistic regression models comparing the hybrid and claims-only models were very similar, with improvement in the C- statistics with the addition of the core clinical data elements found in the EHR.[520]

With the inclusion of MA claims, 84 additional hospitals and 2,466,453 additional admissions were included in the Hybrid HWM measure cohort. When considering only hospitals with 25 or more eligible admissions, the cutoff used for public reporting of the HWM measure, the inclusion of MA data resulted in 62 additional hospitals in the measure. The observed (unadjusted) mortality rate was lower among MA admissions compared to FFS admissions (6.20 versus 6.36 percent). Additionally, the prevalence of comorbidities was generally lower among MA beneficiaries as compared to FFS. The mean hospital risk-standardized mortality rate was lower for the FFS and MA cohort compared to the FFS-only cohort (6.35 versus 6.39 percent for hospitals with 25 or more admissions). After the addition of MA admissions to the FFS-only HWM cohort and among hospitals with 25 or more FFS admissions, 70 percent of hospitals remained in the same risk standardized mortality rate (RSMR) quintile and 98 percent remained within one quintile. The correlation between hospital RSMRs was 0.90. Test-retest reliability for the combined FFS and MA cohort was higher than for the FFS-only cohort (0.736 versus 0.620 for hospitals with 25 or more admissions). The only change to the current Hybrid HWM measure that we proposed is the addition of MA admissions into the cohort; all other specifications will remain the same.

We refer readers to the Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Methodology Report (Version 2.1) revised March 2023 available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*.

The modified Hybrid HWM measure was re-submitted to the MAP for the 2022–2023 pre-rulemaking cycle and received conditional support for rulemaking, pending CBE endorsement. The Hybrid HWM measure received endorsement by the CBE on October 23, 2019.[521] The modified measure with expanded cohort is expected to be submitted for CBE re-endorsement in Fall 2024.

(4) Data Submission and Reporting

We proposed that hospitals will use Quality Reporting Data Architecture (QRDA) Category I files to report core clinical data elements for each Medicare FFS and MA beneficiary who is 65 to 94 years old for data submission (86 FR 45370 and 45371). Submission of data to CMS using QRDA I files is the current EHR data and measure reporting standard adopted for eCQMs implemented in the Hospital IQR Program (84 FR 42506, 85 FR 58940 through 58942). These core clinical data elements are data that hospitals

[519] *https://ecqi.healthit.gov/glossary*.

[520] Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Methodology Report—Version 2.0. Accessed December 9, 2022. Available at: *https://qualitynet.cms.gov/files/627d12f67c89c50016b442bd?filename=Hybrid_HWMort_Msr_Meth_032020.pdf*.

[521] Centers for Medicare & Medicaid Services Measures Inventory Tool (CMIT). Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure with Claims and Electronic Health Record Data. Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=5040&sectionNumber=3*.

routinely collect, that can be feasibly extracted from hospital EHRs, and that can be utilized as part of specific quality outcome measures.[522] The data elements are the values for a set of vital signs and common laboratory tests collected at the time the patient initially presents to the hospital. They are used, in addition to claims data, for risk adjustment of patients' severity of illness (for Medicare FFS beneficiaries who are between 65 and 94 years old).

To successfully submit the Hybrid HWM measure, hospitals will need to submit the core clinical data elements included in the Hybrid HWM measure, as described for measure calculation,[523] for all Medicare FFS and MA beneficiaries between 65 to 94 years old discharged from an acute care hospitalization in the one-year measurement period. Hospitals will also be required to successfully submit six linking variables that are necessary to merge the core clinical data elements with the CMS claims data to calculate the measure. For more details on Hybrid HWM measure data submission requirements, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45368 through 45374).

The cohort expansion of the Hybrid HWM measure to include MA admissions was the only change to the Hybrid HWM measure that was proposed. We proposed to include MA admissions in the Hybrid HWM beginning with the admissions data from July 1, 2024 through June 30, 2025, which affects the FY 2027 payment determination, and for subsequent years.

We invited public comment on this proposal.

Comment: Many commenters supported our proposal to modify the Hybrid Hospital-Wide Mortality (Hybrid HWM) measure to include Medicare Advantage (MA) beneficiaries. A few commenters noted that MA enrollment is expected to surpass the Fee-for Service (FFS) population by the time this modification is implemented, and therefore, will allow a more robust view of all Medicare beneficiaries. A few commenters stated that the inclusion of MA beneficiaries is aligned with CMS' goal of providing more comprehensive information on the quality of care for all Medicare beneficiaries.

Response: We agree and thank the commenters for their support.

Comment: A commenter shared a concern that some MA plans may manipulate risk scoring by selectively enrolling healthier patients, down coding diagnoses, or other risk-adjustment gaming behaviors, yet they applauded CMS for having implemented a number of programs and initiatives to address these practices, including risk adjustment data validation, medical record audits, and continued refinement of the Hierarchical Condition Categories (HCC model).

Response: We acknowledge the commenter's concerns related to the inclusion of MA data. In regard to the gaming behaviors, we thank the commenter for the recognition of the number of programs implemented by CMS to protect against impermissible practices. The Medicare Payment Advisory Commission (MedPAC) notes that the CMS–HCC risk-adjustment model, combined with requirements for MA plans to enroll all eligible Medicare beneficiaries who elect a plan, have generally reduced favorable selection of healthier or less costly beneficiaries by MA plans.[524] In addition, we note that prior research has found evidence of more intensive use of diagnosis codes leading to higher risk scores used for payment based on the HCCs for MA beneficiaries as compared to FFS.[525] In contrast, the risk variables we use in the Hybrid HWM measure do not apply the hierarchical methodology for the condition categories; rather, they are based on clinically relevant condition categories and Agency for Healthcare Research and Quality (AHRQ) clinical classification software (CCS) condition groups for principal diagnoses. Based on the Hybrid HWM measure's risk factors, we found the prevalence of comorbidities was slightly lower among MA beneficiaries. Additionally, as part of regular reevaluation efforts, we assess the need for measure modification annually. Modifications are informed by review of the most recent literature related to measure outcomes, feedback from interested parties, empirical analyses, and assessment of coding trends that reveal shifts in clinical practice or billing patterns.

Comment: A few commenters shared reliability concerns due to incomplete data for the MA population. A commenter recommended that CMS consider policies to ensure that MA plans provide complete encounter data that can be relied on for measurement, such as setting new data completeness requirements for plan payment and/or adopting sufficient penalties for plans that submit incomplete data. A commenter encouraged CMS to continue to explore different options to make data about MA beneficiary utilization and outcomes more available, particularly utility data at a procedure level across all care settings. A commenter suggested delaying the modification of the measure due to incomplete data for the MA population.

Response: We respectfully disagree that the level of completeness of the MA data presents a significant issue with regards to measure reliability. We have been evaluating the MA data for use in quality measurement since 2017 as discussed further in this section, and we note recent CMS policies have aimed to improve timeliness, completeness, and accuracy of MA data, thereby further enhancing its usability for hospital outcome measures.[526] [527] Hospital-submitted MA claims data are currently already in use for DSH and GME payment calculations and Medicare Advantage Organization (MAO)-submitted encounter data are currently already in use for calculating MA beneficiary risk scores.[528] In calculating the Hybrid HWM measure, we clarify that for each MA admission, we would use either the hospital-submitted MA claim or the MAO-submitted MA encounter claim, whichever is available. If the MA admission information for a patient is available in both sources, we would use the hospital-submitted MA

[522] 2013 Core Clinical Data Elements Technical Report (Version 1.1). 2015. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*.

[523] Centers for Medicare & Medicaid Services. Hybrid Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Methodology Report Version 2.0. Available at: *https://qualitynet.cms.gov/inpatient/measures/hybrid/methodology*.

[524] Medicare Payment Advisory Commission. March 2022 report to the Congress: Medicare Payment Policy: The Medicare Advantage program: Status Report and mandated report on dual-eligible special needs plans. May 30, 2022. Available from: *https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch12_SEC.pdf*.

[525] Kronick R, Welch WP. Measuring coding intensity in the Medicare Advantage program Medicare & Medicaid Research Review. 2014;4(2).

[526] Centers for Medicare & Medicaid Services. Encounter Data Submission and Processing Guide 2022. Accessed March 4, 2023. Available from:*https://www.csscoperations.com/internet/csscw3_files.nsf/F2/2022ED_Submission_Processing_Guide_20221130.pdf/$FILE/2022ED_Submission_Processing_Guide_20221130.pdf*.

[527] Centers for Medicare & Medicaid Services. Calendar Year (CY) 2024 Advance Notice of Methodological Changes for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies (the Advance Notice). Accessed March 5, 2023. Available from: *https://www.cms.gov/files/document/2024-advance-notice.pdf*.

[528] Medicare Payment Advisory Commission. March 2022 report to the Congress: Medicare Payment Policy: The Medicare Advantage program: Status Report and mandated report on dual-eligible special needs plans. May 30, 2022. Available from: *https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch12_SEC.pdf*.

claim because it is timelier and already associated with the applicable hospital's CCN.

More generally, we have found that incorporating data regarding MA patients into the Hybrid HWM measure improves reliability, narrows the confidence intervals of measure scores, and leads to more hospitals and beneficiaries being included in the measures. Based on internal analyses of MA data reported to CMS by hospitals and MAOs for the years 2017 through 2021, we determined that it is feasible to use MA admissions in CMS hospital outcome measures. Hospitals and MAOs submit the data on a schedule that allows for their use. National Provider Identifiers (NPIs) from inpatient MA claims in the Integrated Data Repository (IDR) can be matched to CMS Certification Numbers (CCNs) currently used to identify hospitals in the CMS outcome measures. A high percentage of MA claims were submitted within the three-month time frame needed for reporting hospital measures and has improved over time (90.3% in 2018 compared to 95.2% in 2021 for inpatient claims for acute care and critical access hospitals). Our internal analysis found a high rate of matching diagnoses between the MAO-submitted MA claims and the hospital-submitted MA claims, supporting the use of either data source for a given admission for measure calculation.

Comment: A commenter expressed that they believe MA plans are already requiring this reporting as part of the payer contracts, which they believe places duplicative reporting burdens on hospitals. A commenter suggested CMS coordinate efforts, so hospitals are not double penalized by CMS and MA plans, noting that many MA contracts already include quality metrics tied to readmissions, so it is important to ensure that the metrics are aligned and easily reportable.

Response: While we are not aware of MAOs specifically using this Hybrid HWM measure, particularly to assess quality of care for both Medicare FFS and MA beneficiaries, we acknowledge many MA contracts use a variety of quality metrics for many quality purposes including other mortality and readmissions measures. The Hybrid HWM measure was proposed for inclusion in the Hospital IQR Program, which is a pay-for-reporting program, and does not penalize hospitals based on measure results. Importantly, the use of this measure in the Hospital IQR Program offers transparency through public reporting of the Hybrid HWM measure, which is intended to provide a comprehensive and comparable picture of hospital quality, recognizing that numerous practices and policies within a hospital impact the quality of care and patient outcomes, including mortality. The inclusion of FFS and MA beneficiaries in the Hybrid HWM measure ensures performance on this measure is reflective of care provided to the majority of patients. We also note that there is no duplicative burden on MAOs or hospitals to report the claims-based portion of this measure. We plan to publicly report performance on the Hybrid HWM measure to ensure transparency for hospitals and patients.

Comment: Several commenters did not support the proposed inclusion of MA beneficiaries in the Hybrid HWM measure for the Hospital IQR Program. Some of these commenters expressed concern regarding the burden this modification would put on hospitals in regard to the collection and submission of linking variables and the difficulty of programming and implementing hybrid measures into hospital EHRs. These commenters suggested delaying mandatory reporting to allow hospitals or health systems time to make adjustments. A commenter suggested that it would be more efficient for CMS to use existing data sources, specifically MA plans, to incorporate MA enrollees into these measures, to avoid duplicate efforts and necessary changes to hospital reporting processes and systems.

Response: We disagree that reporting of the Hybrid HWM measure with the addition of MA beneficiaries creates significant burden for hospitals. This hybrid measure uses both claims-based data and EHR data, specifically, a set of core clinical data elements consisting of vital signs and laboratory test information and patient linking variables collected from hospitals' EHR systems. We note that hospitals are not responsible for combining the claims data with the EHR data to calculate the measure score as that is performed by CMS and the results are shared with hospitals in feedback reports. We refer readers to the Information Collection Requirements (ICR) section B.6.d within this final rule, for information regarding burden for the Hybrid HWM measure including MA beneficiaries.

The mandatory reporting requirement for the currently implemented version of the Hybrid HWM measure (with FFS beneficiaries only) was finalized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45365 through 45374). The implementation timeline started with one voluntary confidential reporting period beginning with performance data from July 1, 2022, through June 30, 2023, followed by mandatory data submission and public reporting in subsequent years. Specifically, hospitals are required to report the previously adopted version of the Hybrid HWM measure beginning with the performance data from July 1, 2023, through June 30, 2024, impacting the FY 2026 payment determination and subsequent years. The addition of the MA data to the cohort would not impact payment determinations until FY 2027 and subsequent years. The FY 2027 payment determination is associated with discharge data from July 1, 2024, through June 30, 2025. We proposed to expand the measure cohort to include MA patients because MA beneficiary enrollment has been rapidly increasing as a share of overall beneficiaries.[529] Thus, it is important to avoid further delay of incorporating MA patients within the cohort of the currently implemented Hybrid HWM measure. There will be sufficient time to allow hospitals and their health IT vendors to familiarize themselves with the measure reporting process. We strongly encouraged hospitals to participate in the voluntary reporting periods as an opportunity to obtain detailed feedback on their performance on the measure, to provide us with additional feedback on the measure specifications and their implementation experience, to confirm mapping and extraction of data elements, to perform quality assurance, and to troubleshoot any problems during data submissions.

Comment: A few commenters suggested delaying implementation until the measure is endorsed by a consensus-based entity (CBE).

Response: We acknowledge the commenters' concern regarding CBE endorsement of the measure. We note that the currently implemented version of the Hybrid HWM measure received CBE endorsement on October 23, 2019.[530] The modified measure with the addition of MA beneficiaries is expected to be submitted for CBE endorsement maintenance in Fall 2024. The re-endorsement process is expected to be completed prior to the FY 2027 payment determination. We believe the use of the updated measure is preferable to the existing, endorsed version of the

[529] Freed M, Biniek JF, Damico A, Neuman T. Medicare Advantage in 2022: Enrollment Update and Key Trends. Kaiser Family Foundation. Accessed December 5, 2022. Available at: *https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-enrollment-update-and-key-trends/*.

[530] Centers for Medicare & Medicaid Services Measures Inventory Tool (CMIT). Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure with Claims and Electronic Health Record Data. Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=5040&sectionNumber=3*.

measure as the addition of MA beneficiaries to the cohort enhances the reliability and validity of the measure and all other fundamental elements of the endorsed measure remain unchanged.

Comment: A commenter requested CMS make available the specifications for the new proposed eCQM. A few commenters requested CMS share information about how the incorporation of MA data has affected the validity, accuracy, and reliability of the hybrid measure.

Response: Measure specifications for the Hybrid HWM measure with the inclusion of MA patients were posted on the eCQI Resource Center on the FY 2024 Pre-Rulemaking page at the time of publication of the proposed rule: *https://ecqi.healthit.gov/eh-cah?qt-tabs_eh=1&globalyearfilter=2024&global_measure_group=3731*. Measure specifications for the previously adopted Hybrid HWM measure are located in the Annual Update and Specifications (AUS) reports found at *https://qualitynet.cms.gov/inpatient/measures/hybrid/methodology*.

According to the eCQI Resource Center, an eCQM is a measure specified in a standard electronic format that uses data electronically extracted from EHRs and/or health IT systems to measure the quality of health care provided.[531] Hybrid measures differ from eCQMs within the Hospital IQR Program because they merge EHR data elements, which are used for risk-adjustment, with claims data to calculate the risk-standardized mortality rates. We do consider this hybrid measure to be a digital quality measure (dQM), under our draft definition. The draft definition of dQM that we have published as part of strategic materials on the eCQI Resource Center states that in general, eCQMs are considered to be a subset of dQMs. This draft definition states that dQMs are quality measures that use standardized, digital data from one or more sources of health information that are captured and exchanged via interoperable systems; apply quality measure specifications that are standards-based and use code packages; and are computable in an integrated environment without additional effort. CMS' definition of a dQM is available on the eCQI Resource Center at: *https://ecqi.healthit.gov/dqm?qt-tabs_dqm=1*.[532]

With regards to how expanding the measure cohort has affected the measures' validity, reliability, and accuracy, as described in the proposed rule, the inclusion of MA beneficiaries has several important benefits for the reliability and validity of this hospital outcome measure. With the inclusion of MA claims, 84 additional hospitals and 2,466,453 additional admissions were included in the Hybrid HWM measure cohort. When considering only hospitals with 25 or more eligible admissions, the cutoff used for public reporting of the HWM measure, the inclusion of MA data resulted in 62 additional hospitals in the measure. The observed (unadjusted) mortality rate was lower among MA admissions compared to FFS admissions (6.20 versus 6.36 percent). Additionally, the prevalence of comorbidities was generally lower among MA beneficiaries as compared to FFS. The mean hospital risk-standardized mortality rate was lower for the FFS and MA cohort compared to the FFS-only cohort (6.35 versus 6.39 percent for hospitals with 25 or more admissions). After the addition of MA admissions to the FFS-only HWM cohort and among hospitals with 25 or more FFS admissions, 70 percent of hospitals remained in the same risk standardized mortality rate (RSMR) quintile and 98 percent remained within one quintile. The correlation between hospital RSMRs was 0.90. Test-retest reliability for the combined FFS and MA cohort was higher than for the FFS-only cohort (0.736 versus 0.620 for hospitals with 25 or more admissions). We also refer readers to Appendix G in the Hospital-Wide (All-Condition, All-Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Methodology Report (Version 2.1) revised March 2023 [533] for detailed rationale and testing results of integrating MA beneficiaries in the Hybrid Hospital-Wide Mortality (HWM) measure.

Comment: A few commenters recommended that CMS publicly report the Hybrid HWM measure in aggregate, as in not separately by Medicare FFS and MA or by insurance type, as they state the measure was developed and tested to provide information on hospital performance and has not been tested at the health plan level of analysis.

Response: We plan to publicly report the Hybrid HWM measure as an aggregate, single summary score by each hospital's CCN. The modification to the Hybrid HWM measure to add MA beneficiaries to the cohort will not affect the way this measure is publicly reported. The measure summary score is derived from the results of risk-adjustment models for 15 mutually exclusive service-line divisions (categories of admissions grouped based on similar discharge diagnoses or procedures), with a separate risk model for each of the 15 service-line divisions. In the future, we may consider public reporting of more granular measure performance information, and will take commenters' feedback into consideration.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

b. Modification of Hybrid Hospital-Wide All-Cause Readmission (HWR) Measure Beginning With the FY 2027 Payment Determination

(1) Background

Hospital readmission rates are affected by complex and critical aspects of care such as communication between providers or between providers and patients; prevention of, and response to, complications; patient safety; and coordinated transitions to the outpatient environment.[534] Some readmissions are unavoidable, for example, those that result from the inevitable progression of disease or worsening of chronic conditions. However, readmissions may also result from poor quality of care or inadequate transitional care.[535] [536] [537] [538]

[531] *https://ecqi.healthit.gov/glossary*.

[532] *Ibid.*

[533] Hospital-Wide (All-Condition, All- Procedure) Risk-Standardized Mortality Measure with Electronic Health Record Extracted Risk Factors Methodology Report. Updated March 2023. Available at: *https://www.cms.gov/files/document/hybrid-hospital-wide-all-condition-all-procedure-risk-standardized-mortality-measure-electronic.pdf*.

[534] Jencks SF, Williams MV, Coleman EA. Rehospitalizations among patients in the Medicare fee-for-service program. *N Engl J Med*. Apr 2, 2009;360(14):1418–1428. Accessed December 8, 2022. Available at: *https://www.nejm.org/doi/full/10.1056/nejmsa0803563*.

[535] Jack BW, Chetty VK, Anthony D, Greenwald JL, Sanchez GM, Johnson AE, et al. A reengineered hospital discharge program to decrease rehospitalization: a randomized trial. *Ann Intern Med*. 2009;150(3):178–87. Accessed December 8, 2022. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2738592/*.

[536] Courtney M, Edwards H, Chang A, Parker A, Finlayson K, Hamilton K. Fewer emergency readmissions and better quality of life for older adults at risk of hospital readmission: a randomized controlled trial to determine the effectiveness of a 24-week exercise and telephone follow-up program. *J Am Geriatr Soc*. 2009;57(3):395–402. Accessed December 8, 2022. Available at: *https://pubmed.ncbi.nlm.nih.gov/19245413/*.

[537] Garasen H, Windspoll R, Johnsen R. Intermediate care at a community hospital as an alternative to prolonged general hospital care for elderly patients: a randomized controlled trial. *BMCPublic Health*. 2007;7:68. Accessed December 8, 2022. Available at: *https://bmcpublichealth.biomedcentral.com/articles/10.1186/1471-2458-7-68*.

[538] Koehler BE, Richter KM, Youngblood L, Cohen BA, Prengler ID, Cheng D, et al. Reduction of 30-day post discharge hospital readmission or emergency department (ED) visit rates in high-risk elderly medical patients through delivery of a

Continued

For the July 1, 2020, through June 30, 2021, measurement period, the risk-standardized readmission rate from the hospital-wide population ranged from 9.9 to 22.5 percent, showing a performance gap across hospitals with wide variation and an opportunity to improve quality.[539]

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42465 through 42479), we adopted the Hybrid HWR measure into the Hospital IQR Program in a stepwise implementation timeline starting with two voluntary reporting periods, followed by mandatory data submission and public reporting. The first voluntary reporting period used performance period data from July 1, 2021, through June 30, 2022, and the second voluntary reporting period is July 1, 2022, through June 30, 2023. Hospitals are required to report the Hybrid HWR measure beginning with performance period data from July 1, 2023, through June 30, 2024, impacting the FY 2026 payment determination, and for subsequent years.[540]

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27086 through 27088), similar to our proposal for the Hybrid HWM measure, we proposed to expand the cohort of the Hybrid HWR measure from only Medicare FFS patients to a cohort which includes FFS and MA patients 65 years and older beginning with the FY 2027 payment determination.

We proposed to expand the measure cohort to include MA patients because MA beneficiary enrollment has been rapidly expanding as a share of Medicare beneficiaries. In 2022, nearly half of Medicare beneficiaries—or over 28 million people—were enrolled in MA plans, and it is projected that enrollment will continue to grow.[541] The Congressional Budget Office projects that by 2030, 62 percent of beneficiaries will be covered by MA plans.[542] MA coverage also varies across counties and states (ranging between one to 59 percent) with lower enrollment in rural states.[543] Including MA beneficiaries in CMS hospital outcome measures will help ensure that hospital quality is measured across all Medicare beneficiaries and not just the FFS population. We also believe that the addition of MA beneficiaries to FFS will significantly increase the size of the measure's cohort, enhance the reliability of the measure scores, lead to more hospitals receiving results, and increase the chance of identifying meaningful differences in quality for some low-volume hospitals. Moreover, this update will address stakeholder concerns about differences in quality for MA and FFS beneficiaries by ensuring hospital outcomes are measured across all Medicare beneficiaries.[544] [545]

(2) Overview of Measure

The Hybrid HWR measure is an outcome measure that captures the hospital-level, risk-standardized readmission rate (RSRR) of unplanned, all-cause readmissions within 30 days of hospital discharge for any eligible condition. The measure reports a single summary RSRR, derived from the volume-weighted results of five different models, one for each of the following specialty cohorts based on groups of discharge condition categories or procedure categories: (1) Surgery/gynecology; (2) general medicine; (3) cardiorespiratory; (4) cardiovascular; and (5) neurology. The measure also indicates the hospital-level standardized readmission ratios (SRR) for each of these five specialty cohorts. The outcome is defined as unplanned readmission for any cause within 30 days of the discharge date for the index admission (the admission included in the measure cohort). A specified set of readmissions are planned and do not count in the readmission outcome. The focus population is Medicare FFS and proposed MA beneficiaries who are 65 years or older and hospitalized in non-Federal hospitals.

(3) Measure Calculation

The outcome of this measure is 30-day unplanned readmissions. For this measure, we define readmission as an inpatient admission for any cause, except for certain planned readmissions, within 30 days from the date of discharge from an eligible index admission. If a patient has more than one unplanned admission (for any reason) within 30 days after discharge from the index admission, only one is counted as a readmission. The current measure includes admissions for beneficiaries enrolled in Medicare FFS for the 12 months prior to the date of index admission, on the date of the index admission, and the 30 days following discharge of the index admission; 65 years old or over; discharged alive from a non-Federal short-term acute care hospital; and not transferred to another acute care facility.

We proposed to add MA beneficiaries 65 years and older to the existing cohort of Medicare FFS beneficiaries for the Hybrid HWR measure. Using HWR claims-only data from July 1, 2018—June 30, 2019, we calculated measure results for the combined FFS and MA admissions and compared them to the results for FFS-only admissions. We assessed 11,029,470 unique admissions (4,077,633 MA and 6,951,837 FFS) extracted from the CMS Integrated Data Repository for FFS claims, hospital-submitted MA claims, and Medicare Advantage Organization (MAO)-submitted MA inpatient encounter claims. Based on the lack of availability of EHR data, we conducted testing of the combined cohort (MA and FFS) in the claims-only version of the HWR measure. The Hybrid HWR measure is identical to the claims-only measure except for the addition of the clinical data elements. When the Hybrid HWR measure was initially developed, the original claims-only HWR measure was compared with the hybrid measure results. The measure scores based on the claims-only model in the hybrid data were highly correlated to the measure scores based on the hybrid model (correlation coefficient = 0.99). C-statistics from logistic regression models comparing the hybrid and claims-only models were very similar, with some improvements in the C-statistics with the addition of the core clinical data elements found in the EHR.[546]

targeted care bundle. *J Hosp Med.* 2009;4(4):211–218. Accessed December 8, 2022. Available at: *https://pubmed.ncbi.nlm.nih.gov/19388074/.*

[539] DeBuhr J, Maffry C, Grady J, et al. 2022 Hospital-Wide Readmission Measure Updates and Specifications Report—Version 11.0. *https://qualitynet.cms.gov/files/6273c39a7c89c50016b44156?filename=2022_HWR_AUS_Report.pdf.*

[540] Subsequent reporting periods for the Hybrid HWR measure are from July 1, three years prior to the fiscal year in which the payment determination is applied and end on June 30, two years prior to the fiscal year in which the payment determination is applied.

[541] Freed M, Biniek JF, Damico A, Neuman T. Medicare Advantage in 2022: Enrollment Update and Key Trends. Kaiser Family Foundation. Accessed December 5, 2022. Available at: *https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2022-enrollment-update-and-key-trends/.*

[542] *Ibid.*

[543] *Ibid.*

[544] Ochieng N and Biniek JF. Beneficiary Experience, Affordability, Utilization, and Quality in Medicare Advantage and Traditional Medicare: A Review of the Literature. Accessed December 8, 2022. Available at: *https://www.kff.org/medicare/report/beneficiary-experience-affordability-utilization-and-quality-in-medicare-advantage-and-traditional-medicare-a-review-of-the-literature/.*

[545] Medicare Payment Advisory Commission. The Medicare Advantage program: Status Report and mandated report on dual-eligible special needs plans. Accessed December 8,2022. Available at: *https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch12_SEC.pdf.*

[546] Dorsey K, Wang Y, et al. Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors—Version 1.1. Accessed December 9, 2022. Available at: *https://qualitynet.cms.gov/files/5d0d36fc764be766b0100e6a?filename=Hybrd_HWRdmsn_Msr_Mth_020115.pdf.*

Inclusion of MA beneficiaries has several important benefits for the reliability and validity of the Hybrid HWR measure. The inclusion of MA admissions added 127 hospitals and more than four million admissions to the HWR cohort during the data period tested. When considering only hospitals with 25 or more eligible admissions, the cutoff used for public reporting of the HWR measure, the inclusion of MA data resulted in 63 additional hospitals in the measure. Observed (unadjusted) readmission within 30 days was higher for MA-only admissions than for FFS-only admissions (15.72 versus 15.35 percent), with comorbidities generally lower among MA beneficiaries. The mean risk-standardized readmission rate was slightly higher for the combined FFS and MA cohort compared to the FFS-only cohort (15.48 versus 15.35 percent for hospitals with 25 or more admissions in each cohort). This trend was seen across all specialty cohorts. After the addition of MA admissions to the FFS-only HWR measure and among hospitals with 25 or more FFS admissions, about two thirds (67 percent) of hospitals remained in their same performance quintile, and 95 percent remained within one quintile. The correlation between hospital RSRRs was 0.92. Test-retest reliability for the combined FFS and MA cohort was higher than for the FFS-only cohort (0.780 versus 0.725 among hospitals with 25 or more admissions). The only change to the existing Hybrid HWR measure was the addition of MA admissions into the cohort; all other specifications remained the same. We refer readers to the Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 2.1) revised March 2023 available at *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.html*. The modified Hybrid HWR measure was re-submitted to the MAP for the 2022–2023 pre-rulemaking cycle and received conditional support for rulemaking, pending CBE endorsement.

The currently implemented version of the Hybrid HWR measure was initially endorsed by the CBE on December 9, 2016, then endorsed again on September 1, 2020.[547] We intend to submit the modified measure with expanded cohort for CBE re-endorsement in Spring 2024. We note that section 1886(b)(3)(B)(viii)(IX)(aa) of the Act generally requires that measures specified by the Secretary for use in the Hospital IQR Program be endorsed by the entity with a contract under section 1890(a) of the Act. Under section 1886(b)(3)(B)(viii)(IX)(bb) of the Act, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and, therefore, we believe the exception in section 1886(b)(3)(B)(viii)(IX)(bb) of the Act applies.

(4) Data Submission and Reporting

Hospitals will use Quality Reporting Data Architecture (QRDA) Category I files for each Medicare FFS and MA beneficiary who is 65 years and older for data submission. Submission of data to CMS using QRDA I files is the current EHR data and measure reporting standard adopted for eCQMs implemented in the Hospital IQR Program (84 FR 42469 and 42470, 85 FR 58940).

To successfully submit the Hybrid HWR measure, hospitals will need to submit the core clinical data elements included in the Hybrid HWR measure, as described for measure calculation,[548] for all Medicare FFS and MA beneficiaries 65 years and older discharged from an acute care hospitalization in the one-year measurement period. These core clinical data elements are data that hospitals routinely collect, that can be feasibly extracted from hospital EHRs, and that can be utilized as part of specific quality outcome measures.[549] The data elements are the values for a set of vital signs and common laboratory tests collected at the time the patient initially presents to the hospital. They are used, in addition to claims data, for risk adjustment of patients' severity of illness (for Medicare FFS beneficiaries who are 65 years and older). Hospitals will also be required to successfully submit the six linking variables that are necessary to merge the core clinical data elements with the CMS claims data to calculate the measure. For more details on Hybrid HWR measure data submission requirements, we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42467 through 42470).

The cohort expansion of the Hybrid HWR measure to include MA admissions was the only proposed change to the Hybrid HWR measure. We proposed to include MA admissions in the Hybrid HWR cohort beginning with the discharge data from July 1, 2024 through June 30, 2025, which affects the FY 2027 payment determination, and for subsequent years.

We invited public comment on this proposal. Many commenters had the same comments about adding MA beneficiaries to the Hybrid HWR measure as they did for adding MA beneficiaries to the Hybrid HWM measure. We direct readers to section C.6.a. for the full discussion of these comments in the Hybrid HWM section. Comments specific to the Hybrid HWR measure are noted in the section.

Comment: Many commenters supported our proposal to modify the Hybrid Hospital-Wide Readmission (Hybrid HWR) measure to include MA beneficiaries. A few commenters noted that MA enrollment is expected to surpass the FFS population by the time this modification is implemented, and therefore will allow a more robust view of all Medicare beneficiaries. A few commenters stated that the inclusion of MA beneficiaries is aligned with CMS' goal of providing more comprehensive information on the quality of care for all Medicare beneficiaries.

Response: We agree and thank the commenters for their support.

Comment: A commenter questioned whether the Hybrid HWR measure may be a measure of care utilization instead of a measure of quality of care and suggested that smaller hospitals or health systems may be disadvantaged by this measure unless it is somehow adjusted to reflect the environment of care delivery.

Response: We acknowledge the commenters' concern that the Hybrid HWR measure may be a measure of care utilization rather than a measure of quality of care. We disagree that the Hybrid HWR measure is a measure of care utilization and assert that it is a measure of quality of care. The goal of the Hybrid HWR measure is to improve patient outcomes by providing patients, clinicians, and hospitals with

[547] Centers for Medicare & Medicaid Services Measures Inventory Tool (CMIT). Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=4597&sectionNumber=3.*

[548] Centers for Medicare & Medicaid Services. (2018) 2018 All-Cause Hospital-Wide Measure Updates and Specifications Report: Hospital-Wide Readmission. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.*

[549] 2013 Core Clinical Data Elements Technical Report (Version 1.1). 2015. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology.*

information about hospital level, risk standardized readmission rates of unplanned, all-cause readmission after admission for any eligible condition within 30 days of hospital discharge. The measure is adjusted to reflect the environment of care delivery as the risk model accounts for differences in patient characteristics (patient case mix), as well as differences in the medical services provided and procedures performed by hospitals (hospital service mix). Measurement of patient outcomes allows for a broad view of the quality of care that encompasses more than what can be captured by individual process of-care measures, such as a care utilization measure. Complex and critical aspects of care, such as communication between providers, prevention of, and response to, complications, patient safety and coordinated transitions to the outpatient environment, all contribute to patient outcomes but are difficult to measure by individual process measures. In general, randomized controlled trials have shown that improvement in the following areas can directly reduce readmission rates: quality of care during the initial admission; improvement in communication with patients, their caregivers, and their clinicians; patient education; predischarge assessment; and coordination of care after discharge. Evidence that hospitals have been able to reduce readmission rates through these quality of-care initiatives illustrates the degree to which hospital practices can affect readmission rates.[550] The Hybrid HWR measure provides an overall signal of quality for hospitals in contrast to condition specific measures which provide more narrowly focused quality information. Both types of readmission measures provide beneficiaries and providers with useful information that allows them to improve patient outcomes.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

7. Proposed Measure Removals for the Hospital IQR Program Measure Set and Proposed Codification of Measure Removal Factors

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27088 through 27093) we proposed to remove three measures: (1) Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure beginning with the April 1, 2025 through March 31, 2028 reporting period/FY 2030 payment determination; (2) Medicare Spending Per Beneficiary (MSPB)—Hospital measure beginning with the CY 2026 reporting period/FY 2028 payment determination; and (3) Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation (PC–01) measure beginning with the CY 2024 reporting period/FY 2026 payment determination.

We also proposed to codify the Measure Removal Factors that we have previously adopted for the Hospital IQR Program.

We provide more details on each of these proposals, as well as the public comments we received on them, in the subsequent sections.

a. Removal of Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty Measure Beginning With the FY 2030 Payment Determination

We adopted the original Hospital-Level Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty measure (hereinafter referred to as the THA/TKA Complication measure) for use in the Hospital IQR Program in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53516 through 53518). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50062 and 50063), we adopted the same measure for use in the Hospital Value-Based Purchasing (VBP) Program. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41558 and 41559), we finalized the removal of the measure from the Hospital IQR Program under measure removal factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. The measure's removal was part of agency-wide efforts to reduce provider burden since the measure is also being reported under the Hospital VBP Program.

After the measure was removed from the Hospital IQR Program, it was revised by the measure steward to include 26 additional mechanical complication ICD–10 codes, which were identified during measure maintenance. Our analyses showed the addition of these clinically relevant codes contributed to an increase in the THA/TKA national observed complication rate. Findings demonstrated an increase of approximately 0.5 percent (from 2.42 percent to 2.93 percent) in the THA/TKA national observed complication rate when evaluated for the FY 2021 performance period. These findings suggested that the expanded outcome will allow the updated THA/TKA Complication measure to capture a more complete outcome.

Therefore, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49263 through 49267), we adopted the re-evaluated THA/TKA Complication measure with an expanded measure outcome, beginning with claims data with admission dates from April 1, 2019 through March 31, 2022 (excluding data from the period covered by the extraordinary circumstances exception (ECE) granted by CMS related to the COVID–19 Public Health Emergency (PHE)) that is associated with the FY 2024 payment determination. For measure specification details on the updated measure, we refer readers to the Hip and Knee Arthroplasty

[550] We refer readers to the following sources for more detail on these issues: 1. Jack BW, Chetty VK, Anthony D, Greenwald JL, Sanchez GM, Johnson AE, et al. A reengineered hospital discharge program to decrease rehospitalization: A randomized trial. Ann Intern Med 2009;150(3):178–87; 2. Coleman EA, Smith JD, Frank JC, Min SJ, Parry C, Kramer AM. Preparing patients and caregivers to participate in care delivered across settings: The Care Transitions Intervention. J Am Geriatr Soc 2004;52(11):1817–25; 3. Courtney M, Edwards H, Chang A, Parker A, Finlayson K, Hamilton K. Fewer emergency readmissions and better quality of life for older adults at risk of hospital readmission: A randomized controlled trial to determine the effectiveness of a 24-week exercise and telephone follow-up program. J Am Geriatr Soc 2009;57(3):395–402; 4. Garasen H, Windspoll R, Johnsen R. Intermediate care at a community hospital as an alternative to prolonged general hospital care for elderly patients: A randomised controlled trial. BMC Public Health 2007;7:68; 5.Koehler BE, Richter KM, Youngblood L, Cohen BA, Prengler ID, Cheng D, et al. Reduction of 30-day postdischarge hospital readmission or emergency department (ED) visit rates in high-risk elderly medical patients through delivery of a targeted care bundle. J Hosp Med 2009;4(4):211–218; 6. Mistiaen P, Francke AL, Poot E. Interventions aimed at reducing problems in adult patients discharged from hospital to home: A systematic metareview. BMC Health Serv Res 2007;7:47; 7. Naylor M, Brooten D, Jones R, Lavizzo-Mourey R, Mezey M, Pauly M. Comprehensive discharge planning for the hospitalized elderly. A randomized clinical trial. Ann Intern Med 1994;120(12):999–1006; 8. Naylor MD, Brooten D, Campbell R, Jacobsen BS, Mezey MD, Pauly MV, et al. Comprehensive discharge planning and home follow-up of hospitalized elders: A randomized clinical trial. Jama 1999;281(7):613–20; 9. van Walraven C, Seth R, Austin PC, Laupacis A. Effect of discharge summary availability during post-discharge visits on hospital readmission. J Gen Intern Med 2002;17(3):186–92;10. Weiss M, Yakusheva O, Bobay K. Nurse and patient perceptions of discharge readiness in relation to postdischarge utilization. Med Care 2010;48(5):482–6; and 11. Krumholz HM, Amatruda J, Smith GL, et al. Randomized trial of an education and support intervention to prevent readmission of patients with heart failure. J Am Coll Cardiol. Jan 2 2022;39(1):8389.

Complications (ZIP) folder on the CMS.gov Measure Methodology website at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Measure-Methodology*.

As stated in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49263), we adopted this measure into the Hospital IQR Program with the intention to propose the updated measure into the Hospital VBP Program after the required year of public reporting in Hospital IQR Program. As noted at 42 CFR 412.164(b), measures in the Hospital VBP Program must be publicly reported for one year prior to the beginning of the performance period.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27089 through 27090), we proposed to remove the measure beginning with the April 1, 2025, through March 31, 2028, reporting period associated with the FY 2030 payment determination under measure removal factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. Concurrent to this proposal to remove the measure, the Hospital VBP Program proposed to adopt the re-evaluated measure to replace the original version of the measure that is in the Hospital VBP Program. Therefore, we proposed its removal from the Hospital IQR Program to prevent duplicative reporting of the measure in a quality reporting program and value-based program, and to simplify administration of both programs. This proposed removal is contingent on finalizing our proposal to adopt the re-evaluated measure in the Hospital VBP Program beginning with the FY 2030 program year. For example, we may modify the date on which we will remove the measure from the Hospital IQR Program to align with the date on which the Hospital VBP Program adopts the re-evaluated measure. We refer readers to section V.K. of this final rule for more information on the policy to adopt the re-evaluated THA/TKA Complication measure in the Hospital VBP Program.

We believe that removing this measure from the Hospital IQR Program will eliminate the costs associated with implementing and maintaining the measure for the program if and when the re-evaluated THA/TKA Complication measure with an expanded measure outcome begins to be used in the Hospital VBP Program. In particular, this will avoid the development and release of duplicative and potentially confusing confidential feedback reports to hospitals across multiple hospital quality and value-based purchasing programs. For example, it may be costly for health care providers to track the confidential feedback, preview reports, and publicly reported information on this measure across the Hospital IQR Program, Hospital VBP Program, and the Comprehensive Care for Joint Replacement (CJR) Model. We expect that health care providers would incur additional costs to monitor measure performance in multiple programs for internal quality improvement and financial planning purposes. Individuals may also find it confusing to see public reporting on the same measure in different programs. In addition, maintaining the specifications for the measure, as well as the tools we need to analyze and publicly report the measure data, results in costs to CMS. We believe the cost of maintaining the same measure in multiple programs, as previously discussed, outweigh the associated benefit to individuals of receiving the same information from multiple programs, because that information could be captured through inclusion of the re-evaluated version of this measure solely in the Hospital VBP Program if the re-evaluated form of the THA/TKA Complication measure is adopted in that program.

We seek to advance the Hospital IQR Program by maintaining a set of the most meaningful quality measures and recognizing the associated burden of reporting those measures. We believe the Hospital IQR Program continues to incentivize improvement in the quality of care provided to patients. We further believe that removing this measure from the Hospital IQR Program will help achieve that goal. We believe keeping this measure in both programs would be inconsistent with our goal of avoiding unnecessary complexity and cost with duplicative measures across programs. We continue to believe that this measure provides important data on patient outcomes following inpatient hospitalization (addressing Meaningful Measures 2.0's priority of driving outcome improvement),[551] which is why we proposed to adopt the updated measure in the Hospital VBP Program. Unlike the Hospital IQR Program, performance data on measures maintained in the Hospital VBP Program are used both to assess the quality and value of care provided at a hospital and to calculate incentive payment adjustments for a given year of the program based on performance. The Hospital VBP Program's incentive payment structure ties hospitals' payment adjustments on claims paid under the IPPS to their performance on selected quality measures, including the THA/TKA Complication measure, sufficiently incentivizing performance improvement on this measure among participating hospitals.

We proposed to remove the THA/TKA Complication measure from the Hospital IQR Program beginning with the FY 2030 payment determination. This proposal is contingent on finalizing our proposal to adopt the measure in the Hospital VBP Program beginning with the FY 2030 program year.

We invited public comment on this proposal.

Comment: Many commenters supported the proposal to remove the THA/TKA Complication measure from the Hospital IQR Program. Specifically, some commenters appreciated the removal of the THA/TKA Complication measure from the Hospital IQR Program as it will reduce duplication. A few commenters supported the removal of THA/TKA Complication measure from the Hospital IQR Program provided it will continue to be reported on the Care Compare website.

Response: We thank the commenters for their support. Results for the updated THA/TKA Complication measure being adopted into the Hospital VBP Program will continue to be publicly reported on Care Compare and *data.cms.gov* for the period of time in which hospitals report on the two versions of this measure.

Comment: A few commenters supported our proposal to remove the THA/TKA Complication measure but shared concerns about the transition of the measure from the Hospital IQR Program to the Hospital VBP Program. Specifically, a commenter expressed concern about the burden of reporting two slightly different measures prior to the transition of the revised measure from the Hospital IQR Program to the Hospital VBP Program. Another commenter expressed concern about the public's ability to interpret the data from the two versions of the measure and suggested that we suppress one set of results from public reporting.

Response: We acknowledge the commenters' concerns regarding burden of reporting two slightly different versions of the measure in the Hospital IQR and Hospital VBP Programs simultaneously. However, we respectfully disagree that the proposed transition of the THA/TKA Complication measure from the Hospital IQR Program to the Hospital VBP Program will cause significant data

[551] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy*.

collection burden. Hospitals will not be required to submit additional data for calculating the measure as it is a claims-based measure. Section 1886(o)(2)(C)(i) of the Act requires that a measure be publicly reported for one year in the Hospital IQR Program prior to the beginning of the applicable Hospital VBP Program performance period for the measure. As we have previously stated in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49263 through 49267), we adopted the revised version of the THA/TKA Complication measure into the Hospital IQR Program with the intention of eventually proposing the updated measure into the Hospital VBP Program with a performance period that starts after the required one year of public reporting in the Hospital IQR Program as well as to provide interested parties with an opportunity to become familiar with the new version of the measure and provide feedback. We refer readers to section V.K. of this final rule for more information on the policy to adopt the re-evaluated THA/TKA Complication measure in the Hospital VBP Program. We intend to continue publishing THA/TKA Complication measure data on the Care Compare site for the period of time in which this measure is reported in the Hospital IQR Program. In addition, we will make sure it is clear which version of the measure is being displayed in which location through outreach and education efforts.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

b. Removal of Medicare Spending Per Beneficiary (MSPB)—Hospital Measure Beginning With the CY 2026 Reporting Period/FY 2028 Payment Determination

We adopted the original Medicare Spending Per Beneficiary (MSPB)–Hospital measure (CBE# 2158) (hereinafter referred to as the MSPB Hospital measure) for use in the Hospital IQR Program in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51618 through 51627). In the FY 2012 IPPS/LTCH PPS final rule (76 FR 51654 through 51658) we adopted the same measure for use in the Hospital Value-Based Purchasing (VBP) Program. In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41559 and 41560), we removed the MSPB Hospital measure from the Hospital IQR Program beginning with the FY 2022 payment determination under measure removal factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. We believed that removing the measure from the Hospital IQR Program would eliminate costs associated with implementing and maintaining the measure, and in particular, development and release of duplicative and potentially confusing confidential feedback reports provided to hospitals across multiple hospital quality and value-based purchasing programs. The original version of the MSPB Hospital measure that was removed from the Hospital IQR Program was identical to the version that was concurrently and continues to be used in the Hospital VBP Program.

To continue assessing hospitals' efficiency and resource use and to meet statutory requirements under section 1886(o)(2)(B)(ii) of the Act, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49257 through 49263), we adopted the re-evaluated version of the MSPB Hospital measure in the Hospital IQR Program. We noted our plans to subsequently propose this version of the measure for the Hospital VBP Program measure set after the required year of public reporting in Hospital IQR Program. As required by 42 CFR 412.164(b), measures in the Hospital VBP Program must be publicly reported for at least one year prior to the beginning of the performance period.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27090 through 27091), we proposed to remove this measure beginning with the FY 2028 payment determination under measure removal factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program. This measure was proposed for adoption by the Hospital VBP Program in section V.K. of the proposed rule (88 FR 27025 through 27026), and we proposed its removal from the Hospital IQR Program to reduce the burden that would arise from duplicative reporting of the measure in a quality reporting program and value-based program, and to simplify administration of both programs. This proposed removal is contingent on finalizing our proposal to adopt the re-evaluated measure in the Hospital VBP Program beginning with the FY 2028 program year. For example, we may modify the date on which we will remove the measure from the Hospital IQR Program to align with the date on which the Hospital VBP Program adopts the re-evaluated measure. We refer readers to section V.K. of the preamble of this final for more information on the proposal to adopt the re-evaluated version of the MSPB Hospital measure in the Hospital VBP Program.

We believe that removing this measure from the Hospital IQR Program will eliminate the costs associated with implementing and maintaining the measure, and in particular, development and release of duplicative and potentially confusing confidential feedback reports provided to hospitals across multiple hospital quality and value-based purchasing programs. For example, it may be costly for health care providers to track confidential feedback, preview reports, and publicly reported information on this measure in both the Hospital IQR Program and in the Hospital VBP Program. We expect that health care providers would incur additional costs to monitor measure performance in multiple programs for internal quality improvement and financial planning purposes when measures are used across value-based purchasing programs. Individuals may also find it confusing to see public reporting on the same measure in different programs. In addition, maintaining the specifications for the measure, as well as the tools we need to analyze and publicly report the measure data, result in costs to CMS. We believe the cost of maintaining the same measure in multiple programs, as previously discussed, outweigh the associated benefit to individuals of receiving the same information from multiple programs, because that information could be captured through inclusion of the updated version of this measure solely in the Hospital VBP Program if the re-evaluated version of the MSPB Hospital measure is adopted in that program.

We sought to advance the Hospital IQR Program by maintaining a set of the most meaningful quality measures and recognizing the associated burden of reporting those measures. We believe the Hospital IQR Program continues to incentivize improvement in the quality of care provided to patients. We further believe that removing this measure from the Hospital IQR Program will help achieve that goal. As discussed in section V.K. of the preamble of this final rule, we believe keeping this measure in both programs would be inconsistent with our goal of avoiding unnecessary complexity or cost with duplicative measures across programs. We continue to believe this measure provides important data on resource use (addressing the Meaningful Measures Framework priority of making care affordable), which is why we proposed to adopt the updated measure in the Hospital VBP Program. Unlike the Hospital IQR Program, performance data on measures maintained in the Hospital VBP Program are used both to assess the quality and value of care provided at a hospital and to calculate incentive payment adjustments for a given year of the program based on performance. The

Hospital VBP Program's incentive payment structure ties hospitals' payment adjustments on claims paid under the IPPS to their performance on selected quality measures, including the MSPB Hospital measure, sufficiently incentivizing performance improvement on this measure among participating hospitals.

We proposed removal of the updated MSPB Hospital measure (CBE #2158) from the Hospital IQR Program beginning with the FY 2028 payment determination and for subsequent years, which is contingent on finalizing our proposal to adopt the updated MSPB Hospital measure in the Hospital VBP Program.

We invited public comment on this proposal.

Comment: Many commenters expressed their support of CMS' proposal to remove the MSPB Hospital measure from the Hospital IQR Program. Specifically, some commenters appreciated the removal of the MSPB Hospital measure from the Hospital IQR Program as it will reduce duplication. A few commenters supported the removal of MSPB Hospital measure from the Hospital IQR Program provided it will continue to be reported on the Care Compare website.

Response: We thank the commenters for their support. We intend to continue publicly reporting MSPB Hospital measure data on Care Compare for the period of time in which hospitals report on two version of the measure.

Comment: A few commenters supported our proposal to remove the MSPB Hospital measure but also shared concerns about the transition of the measure from the Hospital IQR Program to the Hospital VBP Program. Specifically, a few commenters identified concerns about reporting on two different versions of the measure for a single year and suggested that we adjust the removal and adoption timeline. Another commenter expressed concern about the public's ability to interpret the data from the two versions of the measure and suggested that we suppress one set of results from public reporting. A commenter suggested we wait to transition the updated MSPB Hospital measure into the Hospital VBP Program until after the data had been available to hospitals.

Response: We thank the commenters for their support and raising these concerns. We acknowledge the commenters' concerns that two slightly different versions of the measure would be in use across the Hospital IQR and Hospital VBP Programs simultaneously. Section 1886(o)(2)(C)(i) of the Act requires that a measure be publicly reported for one year in the Hospital IQR Program prior to the beginning of the applicable Hospital VBP Program performance period for the measure. As we have previously stated in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49257), we adopted the revised version of the MSPB Hospital measure into the Hospital IQR Program with the intention of eventually proposing the updated measure into the Hospital VBP Program after the required year of public reporting in the Hospital IQR Program as well as to provide interested parties with an opportunity to become familiar with the new version of the measure and provide feedback. We refer readers to section V.K. of this final rule for more information on the policy to adopt the re-evaluated MSPB Hospital measure in the Hospital VBP Program.

Additionally, by statute, the Hospital VBP Program must contain a cost measure. The MSPB Hospital measure, therefore, cannot be removed from the Hospital VBP Program, as it is the only cost measure under the Efficiency and Cost Reduction. Results for the MSPB Hospital measure currently implemented in the Hospital VBP Program will continue to be available on *data.medicare.gov* until it is removed under the finalized policy outlined in section X.k of the preamble this final rule. We intend to continue publishing MSPB Hospital measure data on Care Compare for the period of time in which this measure is reported in the Hospital IQR Program. In addition, we will make sure it is clear which version of the measure is being displayed in which location through outreach and education efforts.

Comment: A commenter requested clarification about whether removal of the MSPB Hospital measure in the Hospital IQR Program will impact the Merit-based Incentive Payment System (MIPS) and MIPS Value Pathways (MVPs) programs.

Response: We wish to clarify that the removal of MSPB Hospital measure from the Hospital IQR Program does not impact the MIPS and MVPs programs. MIPS eligible clinicians can continue to use their Hospital VBP Program Total Performance Score (TPS) for facility-based measurement. Facility-based measurement offers certain MIPS eligible clinicians and groups the opportunity to receive scores in traditional MIPS for the quality and cost performance categories based on their Hospital VBP Program TPS earned by their assigned facility.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

c. Removal of Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation (PC–01) Measure Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination

In the FY 2013 IPPS/LTCH PPS final rule (77 FR 53528 through 53530), we adopted the Elective Delivery Prior to 39 Completed Weeks Gestation: Percentage of Babies Electively Delivered Prior to 39 Completed Weeks Gestation measure (PC–01) (hereinafter referred to as the Elective Delivery measure) as a chart-abstracted measure beginning with the FY 2015 payment determination and subsequent years.

Over the six most recent reporting periods, hospital performance on PC–01 has met the criteria for removal under measure removal factor 1: Measure performance is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (that is, ''topped out'') with statistically indistinguishable performance at the 75th and 90th percentiles; and truncated coefficient of variation ≤0.10 (83 FR 41540 through 41544).

Table IX.C–01: PC–01 Data From Reporting Hospitals, Q1 2016 through Q4 2021

Payment Determination	Encounters	Number of Reporters	Mean	75th percentile	90th percentile	Truncated COV
FY 2018	Q1 2016 - Q4 2016	2,631	2.07	2.56	5.41	0.019
FY 2019	Q1 2017- Q4 2017	2,601	2.05	2.50	5.41	0.019
FY 2020	Q1 2018- Q4 2018	2,585	1.73	2.31	4.82	0.017
FY 2021	Q1 2019- Q4 2019	2,533	1.80	2.38	5.26	0.018
FY 2022	Q1 2020- Q4 2020	2,510	2.39	3.12	6.67	0.024
FY 2023	Q1 2021- Q4 2021	2,481	2.47	3.30	6.67	0.024

To address the ongoing maternal health crisis and reduce maternal morbidity and mortality, the Hospital IQR Program has continued to prioritize maternal health through quality measurement. In the FY 2022 IPPS/LTCH PPS final rule, we adopted the Maternal Morbidity Structural Measure beginning with the FY 2023 payment determination and for subsequent years (86 FR 45361 through 45365). In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49220 through 49233), we adopted the Severe Obstetric Complications eCQM and the Cesarean Birth eCQM as two of the eCQMs in the Hospital IQR Program measure set that hospitals can self-select to report for the CY 2023 reporting period/FY 2025 payment determination. We also finalized mandatory reporting of these two eCQMs beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. Additionally, in the FY 2023 IPPS/LTCH PPS final rule, we adopted a Birthing-Friendly Hospital designation to capture the quality and safety of maternal health care (87 FR 49282 through 49288). In December 2022, HHS convened maternal health leaders across government and industry to unveil the logo for the Birthing-Friendly Hospital designation, which will be posted on CMS' Care Compare website and on the websites of participating health plans, to indicate which facilities have received the Birthing-Friendly Hospital designation.[552] HHS further announced that more than 25 health plans have committed to displaying the ''Birthing-Friendly Hospital'' designation on their provider directories when the designation goes live in Fall 2023, providing more than 150 million Americans with the opportunity to make informed decisions about their birth options for care.[553]

We believe that the recent adoption of these measures highlights the importance of maternal health and provides hospitals with robust data to improve maternity care quality, safety, and equity, including through the reduction of early elective deliveries. Specifically, the Cesarean Birth eCQM is intended to facilitate safer patient care by assessing the rate of low-risk nulliparous, term, or singleton vertex (NTSV) C-sections to ultimately reduce the occurrence of non-medically indicated C-sections, promoting adherence to recommended clinical guidelines, and encouraging hospitals to track and improve their practices of appropriate monitoring and care management for pregnant and postpartum patients (87 FR 49222). While hospital performance on the Elective Delivery measure no longer provides meaningful distinctions and improvements to support its retention in the Hospital IQR Program measure set, we believe the prior adoption of the Cesarean Birth eCQM, along with the Maternal Morbidity Structural Measure, the Severe Obstetric Complications eCQM, and the Birthing-Friendly Hospital designation will provide hospitals with meaningful and actionable data to address rates of early elective delivery, among other factors that contribute to maternal morbidity and mortality as well as disparities in maternity care quality. We know that the Elective Delivery measure was used widely in quality measurement outside of CMS quality programs, and therefore we reached out to various other parts of the Department, including the Health Resources and Services Administration, National Institutes for Health, and the Centers for Disease Control and Prevention (CDC) in the development of this proposal. We reached consensus across these groups that while the measure is important, given the topped-out status and the availability of the two new eCQMs, it was appropriate to propose for removal at this time. We also refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49282 through 49288) in which we announced the Birthing-Friendly Hospital designation and remind readers that, while we proposed to remove the Elective Delivery measure, we continue to assess whether the Cesarean Birth and Severe Obstetric Complications eCQMs are appropriate for inclusion in the Birthing-Friendly Hospital designation as part of our continued commitment to improve maternity care quality, safety and equity.

Therefore, we proposed to remove the Elective Delivery (PC–01) measure beginning with the CY 2024 reporting period/FY 2026 payment determination.

We invited public comment on this proposal.

Comment: Many commenters supported the removal of the measure. Several commenters agreed that the topped-out measure is no longer meaningful for hospital quality improvement efforts, with a few noting that the opportunity for improvement is small. Several commenters stated their belief that the recent addition of more meaningful maternal health measures in the Hospital IQR Program will support maternal health outcomes and reduce redundancy. A few commenters recommended continued exploration and adoption of additional impactful maternity measures.

Response: We thank commenters for their support. We agree that the Elective

[552] U.S. Department of Health and Human Services. Readout: CMS Hosts Maternal Health Convening with Leaders Across Government, Industry. December 13, 2022. Available at: *https://www.hhs.gov/about/news/2022/12/13/readout-cms-hosts-maternal-health-convening-with-leaders-across-government-industry.html.*

[553] Centers for Medicare & Medicaid Services. Health Plans Committed to Using the Birthing-Friendly Designation. December 2022. Available at: *https://www.cms.gov/files/document/plans-using-birthing-friendly-designation.pdf.*

Delivery measure is no longer meaningful for hospital quality improvement efforts because it has been consistently topped-out for six years. We believe this demonstrates that the standard of care has improved to the point where other measurements are necessary to further drive improvements in maternal care. However, we recognize that the rates of Cesarean delivery have continued to rise and in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49220), we stated that there is a considerable amount of variation in the rates based on U.S. region, state, and healthcare institution as well as substantial variability across races and ethnicities.[554] [555] The Administration has prioritized the reduction of low-risk Cesarean deliveries as part of the HHS Initiative to Improve Maternal Health.[556] Because the Elective Delivery measure has been consistently topped out and rates of Cesarean deliveries have not meaningfully decreased, there is still room for improvement and a need for more robust quality measurement on this topic. Therefore, we also agree with commenters that the prior adoption of the Cesarean Birth eCQM, along with the Maternal Morbidity Structural measure, the Severe Obstetric Complications eCQM, and the Birthing-Friendly Hospital designation will provide hospitals with meaningful and actionable data and play a key role as part of our continued commitment to improve maternity care quality, safety, and equity.

Specifically, the Cesarean Birth eCQM expands our measurement and quality improvement opportunities for non-medically indicated Cesarean deliveries by measuring all NTSV Cesarean births after 37 weeks, not only those prior to 39 weeks as currently captured by the Elective Delivery measure. The Cesarean Birth eCQM seeks to focus attention on the most variable portion of Cesarean births, the term labor Cesarean birth in nulliparous women, as more than 60 percent of the variation among hospitals can be attributed to first birth labor induction rates and first birth early labor admission rates.[557] [558] A reduction in primary Cesarean births will reduce the number of women having repeat Cesarean births as almost 90 percent of mothers who have a primary cesarean birth will have subsequent cesarean birth.[559] As we stated in the FY 2023 IPPS/LTCH PPS final rule when we adopted the measure (87 FR 49221), Cesarean deliveries have higher morbidity and mortality than vaginal deliveries,[560] higher risk of subsequent miscarriage, placental abnormalities, and repeat Cesarean delivery for NTSV births, and higher rates of transfusions, ruptured uteri, unplanned hysterectomies, and intensive care unit (ICU) admissions for NTSV births across all races and ethnicities.[561] We recognize that Cesarean births are not a never event and the rate of Cesarean birth will never be zero as Cesarean delivery can be medically indicated. However, continued quality improvement efforts to reduce non-medically indicated Cesarean birth rates are important for improving patient safety, decreasing maternal and neonatal morbidity and mortality, and reducing health care costs.[562] [563] While the Elective Delivery measure has established the importance of measuring non-medically indicated Cesarean deliveries and labor inductions, its topped-out status limits the utility of the measure moving forward. The addition of the Cesarean Birth eCQM, the Maternal Morbidity Structural measure, the Severe Obstetric Complications eCQM, and the Birthing-Friendly Hospital designation offers hospitals greater opportunities for more comprehensive maternal health quality improvement, and reaffirms our commitment to and continued prioritization of maternal health quality measurement in the Hospital IQR Program. We also note that in the future we are planning to provide confidential reporting on the two new eCQMs that stratifies results by race and ethnicity.

Comment: Several commenters did not support measure removal because they did not believe the Hospital IQR Program measure set included a suitable alternative. A few commenters stated that maternal morbidity and mortality is an ongoing public health crisis and rates of maternal mortality have continued to rise despite topped-out performance of the measure. Some commenters expressed concern about unintended consequences from removing the measure, including neonatal and maternal complications resulting from increases in non-medically indicated labor inductions and Cesarean deliveries.

Response: We acknowledge commenters' concerns and agree that the improvement of maternity care quality and safety is critically important. When we adopted the Cesarean Birth eCQM in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49222), we stated that the measure is intended to facilitate safer patient care by assessing the rate of low-risk NTSV C-sections to ultimately reduce the occurrence of non-medically indicated C-sections, promoting adherence to recommended clinical guidelines, and encouraging hospitals to track and improve their practices of appropriate monitoring and care management for pregnant and postpartum patients. The Cesarean Birth eCQM measures the rate of NTSV patients delivered by Cesarean section after 37 weeks, with the exclusion of patients with abnormal presentation or placenta previa during the encounter. The measure will assist health care organizations to track all NTSV patients delivering by Cesarean section after 37 weeks and will support hospitals in their goals to reduce non-medically indicated labor inductions and Cesarean deliveries by going beyond those deliveries prior to 39 weeks currently measured by the Elective Delivery measure. We reiterate that this measure, in combination with the Severe Obstetric Complications eCQM finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49226 through 49233) and the Maternal Morbidity Structural measure finalized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45361 through 45365), will provide hospitals with robust data to monitor and improve maternal

[554] Kozhimannil, K.B., Law, M.R. & Virnig, B.A. (2013). Cesarean delivery rates vary tenfold among US hospitals; reducing variation may address quality and cost issues. Health Affairs, 32(3): 527–35.

[555] Hamilton, B.E., Martin, J.A., Osterman, M.J.K. (2020). Births: Provisional Data for 2020. National Vital Statistics Rapid Release, no 12. DOI: *https://doi.org/10.15620/cdc:104993.*

[556] Department of Health and Human Services. HHS Initiative to Improve Maternal Health. Available at: *https://aspe.hhs.gov/topics/public-health/hhs-initiative-improve-maternal-health.*

[557] ECQI Resource Center. Cesarean Birth. Accessed July 18, 2023. Available at: *https://ecqi.healthit.gov/sites/default/files/ecqm/measures/CMS334v4.html.*

[558] Main E.K., Morton, C.H., Melsop, K., Hopkins, D., Giuliani, G., & Gould, J.B. (2012). Creating a public agenda for maternity safety and quality in cesarean delivery. Obstetrics and gynecology, 120(5), 1194–1198. *https://doi.org/10.1097/aog.0b013e31826fc13d.*

[559] Centers for Disease Control and Prevention. 2020. Recent trends in vaginal birth after cesarean delivery: United States, 2016–2018. Retrieved from National Center for Health Statistics: *https://www.cdc.gov/nchs/products/databriefs/db359.htm.*

[560] Caughey AB, Cahill AG, Guise JM, Rouse DJ. (2014). Safe prevention of the primary cesarean delivery. Am J Obstet Gynecol, 210(3): 179–93. doi: 10.1016/j.ajog.2014.01.026.

[561] Keag, O.E., Norman, J.E. & Stock, S.J. (2018). Long-term risks and benefits associated with cesarean delivery for mother, baby, and subsequent pregnancies: Systematic review and meta-analysis. Plos Med, 15(1): e1002494.

[562] ECQI Resource Center. Cesarean Birth. Accessed July 18, 2023. Available at: *https://ecqi.healthit.gov/sites/default/files/ecqm/measures/CMS334v4.html.*

[563] American College of Obstetricians and Gynecologists. Safe prevention of the primary cesarean delivery. Obstetric Care Consensus No. 1. Obstet Gynecol 2014;123:693–711. Available at: *https://www.acog.org/clinical/clinical-guidance/obstetric-care-consensus/articles/2014/03/safe-prevention-of-the-primary-cesarean-delivery.*

morbidity and mortality, disparities in maternity care quality, and rates of early elective delivery to expand quality measurement within the Hospital IQR Program and reflect our commitment to maternal health. Regarding commenter concerns about unintended consequences of removing the Elective Delivery measure, we regularly monitor measure data and performance as part of the standard measure maintenance and will continue to do so with the Cesarean Birth and Severe Obstetrics Complication eCQMs and the Maternal Morbidity Structural Measure. Finally, because the Cesarean Birth and Severe Obstetric Complications eCQMs will begin mandatory reporting in the CY 2024 reporting period/FY 2026 payment determination, there will be no gap in reporting on Cesarean births following the removal of the Elective Delivery measure, which will also be effective beginning with the CY 2024 reporting period/FY 2026 payment determination.

Comment: A few commenters expressed concern about the impact of removal on Medicaid programs and commercial payers that are still observing variation in rates and find value in the measure.

Response: In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27092), we acknowledged that the Elective Delivery measure was used widely in quality measurement outside of CMS quality programs, and therefore we reached out to various other parts of the Department, including the Health Resources and Services Administration, National Institutes for Health, and the Centers for Disease Control and Prevention (CDC) in the development of this proposal. We reached consensus across these groups that while the measure is important, it was appropriate to propose for removal at this time given its topped-out status and the availability of two new eCQMs to further drive improvements in maternal care. We also stated our belief that the prior adoption of the Cesarean Birth eCQM, along with the Maternal Morbidity Structural measure, the Severe Obstetric Complications eCQM, and the Birthing-Friendly Hospital designation will provide hospitals with meaningful and actionable data to address rates of early elective delivery. Regarding information available to commercial payers, we note that more than 25 health plans have committed to displaying the Birthing-Friendly Hospital designation on their provider directories when the designation goes live, which will share important maternal health quality information with more than 150 million enrollees in commercial plans.[564] These additional maternal health measures will offer value to CMS quality reporting programs and other payers. While the Elective Delivery measure would no longer be included in the Hospital IQR Program, we expect that the improvements in reducing non-medically indicated labor inductions and Cesarean deliveries prior to 39 weeks that have been achieved outside of CMS quality reporting programs will remain because its removal would not prevent use of the measure outside of CMS quality programs and the measure continues to be maintained by The Joint Commission.[565] We also note that our topped out analysis included all-payer data.

Comment: A commenter requested the eCQM version of the Elective Delivery measure be restored in place of the chart-abstracted measure to continue to prioritize low rates of non-medically indicated elective Cesarean births and reduce reporting burden.

Response: We appreciate the commenter's suggestion. When we removed the eCQM version of the Elective Delivery measure in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41569), we stated if the chart-abstracted version of this measure were to be removed from the Hospital IQR Program, and hospitals could only elect to report the eCQM version of this measure, due to the low volume of patients relative to total adult hospital population, we would not receive enough data to produce meaningful analyses. Furthermore, the adoption of the Cesarean Birth eCQM, the Maternal Morbidity Structural measure, the Severe Obstetric Complications eCQM, and the Birthing-Friendly Hospital designation in the Hospital IQR Program continue to prioritize both a reduction of non-medically indicated elective Cesarean births and reporting burden for hospitals. Therefore, proposing to adopt the eCQM version of Elective Delivery for readoption would not be appropriate and would not reduce burden.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

[564] U.S. Department of Health and Human Services. December 13, 2022. Readout: CMS Hosts Maternal Health Convening with Leaders Across Government, Industry. Accessed July 18, 2023. Available at: *https://www.hhs.gov/about/news/2022/12/13/readout-cms-hosts-maternal-health-convening-with-leaders-across-government-industry.html#:~:text=Earlier%20this%20year%2C%20building%20on,and%20safety%20of%20maternity%20care.*

[565] The Joint Commission. 2023. Measure Information Form. Accessed June 28, 2023. Available at: *https://manual.jointcommissionorg/releases/TJC2023B/MIF0166.html.*

d. Codification of Measure Retention and Removal Policies

Under our current policies, when we adopt a measure for the Hospital IQR Program beginning with a particular payment determination, we automatically readopt the measure for all subsequent payment determinations unless we proposed to remove, suspend, or replace the measure (77 FR 53512 and 53513).

We have also adopted Measure Removal Factors as considerations when evaluating measures for removal from the Hospital IQR Program measure set. We most recently updated our measure removal factors in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41540 through 41544). In that final rule, we adopted measure removal factor 8, the costs associated with a measure outweigh the benefit of its continued use in the program.[566] The current list of Measure Removal Factors for the Hospital IQR Program is:

- *Factor 1.* Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measure). For the purpose of this paragraph, a measure is topped out when the performance of subsection (d) hospitals on the measure is statistically indistinguishable performance at the 75th and 90th percentiles and the measure's truncated coefficient of variation is less than or equal to 0.10;
- *Factor 2.* A measure does not align with current clinical guidelines or practice;
- *Factor 3.* The availability of a more broadly applicable measure (across settings or populations), or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic;
- *Factor 4.* Performance or improvement on a measure does not result in better patient outcomes;
- *Factor 5.* The availability of a measure that is more strongly associated

[566] In addition to the discussion in the FY 2019 IPPS/LTCH PPS final rule, we previously described the basis for the adoption of the other Measure Removal Factors in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49641 through 49643), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203 through 50204), and the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185). In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50203 through 50204), we clarified the criteria for determining when a measure is ''topped-out.'' We also adopted an immediate measure removal policy in cases where we believe that the continued use of a measure raises specific patient safety concerns in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43864 and 43865) and referenced this policy in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50185) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51609 through 51610). We incorporate these rationales by reference.

with desired patient outcomes for the particular topic;

- *Factor 6.* Collection or public reporting of a measure leads to negative unintended consequences other than patient harm;
- *Factor 7.* It is not feasible to implement the measure specifications; and
- *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

We proposed to codify our existing measure retention and removal policies in our regulations at 42 CFR 412.140(g)(1) through (3).

We invited public comment on this proposal.

Comment: A few commenters expressed support for our proposal to codify our measure retention and removal policies.

Response: We thank the commenters for their support.

Comment: A commenter opposed our proposal to codify our measure removal and retention factors, stating that we should consider more carefully whether measures are important to beneficiaries' or the public's interests. The commenter also suggested removing ''topped out'' status under Factor 1 from our measure removal criteria because some Hospital IQR Program measures quantify so-called never events, the methodology comparing performance between the 75th and 90th percentiles is ''problematic'' and does not adequately consider variation between higher and lower performing hospitals, and many Hospital IQR Program measures only include patients covered by FFS Medicare and exclude the large and growing population of MA beneficiaries, which makes the determination of whether a measure is topped out incomplete and inaccurate. The commenter also requested that we provide more details on the costs and benefits of a measure that we consider under Factor 8.

Response: We thank the commenter for this feedback. We consider in detail and on a case-by-case basis how each measure in the Program affects clinical care, and the quality of care delivered to patients is of paramount importance to Medicare beneficiaries and the public. We respectfully disagree with the commenter's suggestion of removing the topped out status as a removal criterion. Measures on which hospitals' performance is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made does not provide useful information to Medicare beneficiaries or the public about the quality of care that they receive. For this reason, topped out status is an important removal factor for the program. Regarding removal factor 8, we note that we estimate the information collection costs and other effects associated with each quality measure we adopt in each rule. For example, in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27194 through 27196), we discussed the estimated changes in reporting costs for participating hospitals associated with the rule's proposed changes to the Hospital IQR Program's measure set. We also discuss in detail the benefits of the measure to patients and to the health care system when we propose it. For example, in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27079 through 27080), we discussed the problems presented by hospital-acquired pressure injuries as well as the details of the Hospital Harm—Pressure Injury measure and how it assesses that clinical topic. We will, nonetheless, take the commenter's feedback into consideration for future potential refinements to the measure removal factors, as well as whether additional information on the costs and benefits beyond the discussion that we place in proposed rules would be helpful for the public.

After consideration of the public comments we received, we are finalizing the codification of this policy as proposed.

8. Summary of Previously Finalized and Newly Adopted Hospital IQR Program Measures

a. Summary of Previously Finalized and Newly Adopted Hospital IQR Program Measures for the FY 2025 Payment Determination

This table summarizes the previously finalized Hospital IQR Program measure set for the FY 2025 payment determination.

BILLING CODE 4120–01–P

TABLE IX.C–02. MEASURES FOR THE FY 2025 PAYMENT DETERMINATION

Short Name	Measure Name	CBE #
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage among Healthcare Personnel	0431
HCP COVID-19 Vaccination*	COVID-19 Vaccination Coverage among Healthcare Personnel	3636
Claims-Based Patient Safety Measures		
CMS PSI-04	Death Rate among Surgical Inpatients with Serious Treatable Complications (CMS Recalibrated Death Rate among Surgical Inpatients with Serious Treatable Complications)	0351
Claims-Based Mortality/Complications Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized Mortality- Rate Following Acute Ischemic Stroke	N/A
COMP-HIP-KNEE	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA	1550
Claims-Based Coordination of Care Measures		
READM-30-HWR**	Hospital-Wide All-Cause Unplanned Readmission Measure (HWR)	1789
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	3474
MSPB	Medicare Spending Per Beneficiary (MSPB)—Hospital	2158
Claims and Electronic Data Measures		

Short Name	Measure Name	CBE #
Hybrid HWR**	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879
Hybrid HWM***	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	3502
Chart-Abstracted Clinical Process of Care Measures		
PC-01	Elective Delivery	0469
SEP-1	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity	Maternal Morbidity Structural Measure	N/A
HCHE	Hospital Commitment to Health Equity	N/A
Electronic Clinical Quality Measures (eCQMs)		
ED-2	Admit Decision Time to Emergency Department (ED) Departure Time for Admitted Patients	0497
PC-05	Exclusive Breast Milk Feeding	0480
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
STK-06	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-01	Hospital Harm—Severe Hypoglycemia Measure	3503e
HH-02	Hospital Harm—Severe Hyperglycemia Measure	3533e
ePC-02	Cesarean Birth	0471e
ePC-07/SMM	Severe Obstetric Complications	N/A
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)
Process Measures		
SDOH-1****	Screening for Social Drivers of Health	N/A
SDOH-2****	Screen Positive Rate for Social Drivers of Health	N/A

* In this final rule, we are finalizing refinements to the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the FY 2025 payment determination and for subsequent years. We refer readers to section IX.B. for more detailed discussion.

** In the FY 2020 IPPS/LTCH PPS final rule, we finalized removal of the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (CBE #1789) and will replace it with the Hybrid HWR measure (CBE #2879), beginning with the FY 2026 payment determination (84 FR 42465 through 42481). In this final rule, we are finalizing refinements to these measures beginning with the FY 2027 payment determination. We refer readers to section IX.C.6.b. for more detailed discussion.

*** In the FY 2022 IPPS/LTCH PPS final rule, we finalized the adoption of the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure beginning with one voluntary reporting period (July 1, 2022-June 30, 2023), followed by mandatory reporting beginning with the July 1, 2023-June 30, 2024 reporting period, impacting the FY 2026 payment determination (86 FR 45365 through 45374). In this rule, we are finalizing refinements to this measure beginning with the FY 2027 payment determination. We refer readers to section IX.C.6.a. for more detailed discussion.

**** In the FY 2023 IPPS/LTCH PPS final rule, we finalized the adoption of the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure with voluntary data collection for the CY 2023 reporting period, and then mandatory reporting beginning with the CY 2024 reporting period/FY 2026 payment determination and subsequent years (87 FR 49201 through 49220).

b. Summary of Previously Finalized and Newly Adopted Hospital IQR Program Measures for the FY 2026 Payment Determinations

This table summarizes the previously finalized and newly finalized Hospital IQR Program measure set for the FY 2026 payment determination, including the removal of the Elective Delivery (PC–01) measure beginning with the FY 2026 payment determination:

TABLE IX.C–03. MEASURES FOR THE FY 2026 PAYMENT DETERMINATION

Short Name	Measure Name	CBE #
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage among Healthcare Personnel	0431
HCP COVID-19 Vaccination*	COVID-19 Vaccination Coverage among Healthcare Personnel	3636
Claims-Based Patient Safety Measures		
CMS PSI-04	Death Rate among Surgical Inpatients with Serious Treatable Complications (CMS Recalibrated Death Rate among Surgical Inpatients with Serious Treatable Complications)	0351
Claims-Based Mortality/Complications Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized Mortality- Rate Following Acute Ischemic Stroke	N/A
COMP-HIP-KNEE	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA	1550
Claims-Based Coordination of Care Measures		
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	3474
MSPB	Medicare Spending Per Beneficiary (MSPB)—Hospital	2158
Hybrid Measures		
Hybrid HWM**	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	3502

Short Name	Measure Name	CBE #
Hybrid HWR***	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879
Chart-Abstracted Clinical Process of Care Measures		
SEP-1	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity	Maternal Morbidity Structural Measure	N/A
HCHE	Hospital Commitment to Health Equity	N/A
Electronic Clinical Quality Measures (eCQMs)		
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
ePC-02	Cesarean Birth	0471e
ePC-07/SMM	Severe Obstetric Complications	N/A
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-01	Hospital Harm—Severe Hypoglycemia Measure	3503e
HH-02	Hospital Harm—Severe Hyperglycemia Measure	3533e
HH-ORAE	Hospital Harm—Opioid Related Adverse Events	3501e
GMCS	Global Malnutrition Composite Score	3592e
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)
Patient-Reported Outcome Performance Measures		
THA/TKA PRO-PM	Hospital-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure (PRO-PM)	3559
Process Measures		
SDOH-1	Screening for Social Drivers of Health	N/A
SDOH-2	Screen Positive Rate for Social Drivers of Health	N/A

* In this final rule, we are finalizing refinements to the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the FY 2025 payment determination and for subsequent years. We refer readers to section IX.B. for more detailed discussion.
** In the FY 2020 IPPS/LTCH PPS final rule, we finalized removal of the claims-only Hospital-Wide All-Cause Unplanned Readmission (HWR claims-only) measure (CBE #1789) and its replacement with the Hybrid HWR measure (CBE #2879), beginning with the FY 2026 payment determination (84 FR 42465 through 42481).
*** In the FY 2022 IPPS/LTCH PPS final rule, we finalized the adoption of the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality (HWM) measure beginning with one voluntary reporting period (July 1, 2022-June 30, 2023), followed by mandatory reporting beginning with the July 1, 2023-June 30, 2024 reporting period, impacting the FY 2026 payment determination (86 FR 45365 through 45374).

c. Summary of Previously Finalized and Proposed Hospital IQR Program Measures for the FY 2027 Payment Determination

This table summarizes the previously finalized and newly finalized Hospital IQR Program measure set for the FY 2027 payment determination including the adoption of three new eCQMs beginning with the CY 2025 reporting period/FY 2027 payment determination:

TABLE IX.C–04. MEASURES FOR THE FY 2027 PAYMENT DETERMINATION

Short Name	Measure Name	CBE #
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage among Healthcare Personnel	0431
HCP COVID-19 Vaccination*	COVID-19 Vaccination Coverage among Healthcare Personnel	3636
Claims-Based Patient Safety Measures		
CMS PSI-04	Death Rate among Surgical Inpatients with Serious Treatable Complications (CMS Recalibrated Death Rate among Surgical Inpatients with Serious Treatable Complications)	0351
Claims-Based Mortality/Complications Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized Mortality- Rate Following Acute Ischemic Stroke	N/A
COMP-HIP-KNEE	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA	1550
Claims-Based Coordination of Care Measures		
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	3474
MSPB	Medicare Spending Per Beneficiary (MSPB)—Hospital	2158
Hybrid Measures		
Hybrid HWM**	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	N/A
Hybrid HWR**	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879
Chart-Abstracted Clinical Process of Care Measures		
SEP-1	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500

Short Name	Measure Name	CBE #
Structural Measures		
Maternal Morbidity	Maternal Morbidity Structural Measure	N/A
HCHE	Hospital Commitment to Health Equity	N/A
Electronic Clinical Quality Measures (eCQMs)		
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
ePC-02	Cesarean Birth	N/A
ePC-07/SMM	Severe Obstetric Complications	N/A
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-01	Hospital Harm—Severe Hypoglycemia Measure	3503e
HH-02	Hospital Harm—Severe Hyperglycemia Measure	3533e
HH-ORAE	Hospital Harm—Opioid Related Adverse Events	3501e
HH-PI***	Hospital Harm—Pressure Injury	3498e
HH-AKI****	Hospital Harm—Acute Kidney Injury	3713e
GMCS	Global Malnutrition Composite Score	3592e
ExRad*****	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults	3663e
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)
Patient-Reported Outcome Performance Measures		
THA/TKA PRO-PM	Hospital-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure (PRO-PM)	3559
Process Measures		
SDOH-1	Screening for Social Drivers of Health	N/A
SDOH-2	Screen Positive Rate for Social Drivers of Health	N/A

* In this final rule, we are finalizing refinements to the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the FY 2025 payment determination and for subsequent years. We refer readers to section IX.B. for more detailed discussion.

** In this final rule, we are finalizing the refinements to two Hospital IQR Program measures-Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM) and Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)-beginning with the FY 2027 payment determination. We refer readers to sections IX.C.6.a. and IX.C.6.b., respectively, for more detailed discussion.

*** In this final rule, we are finalizing the adoption of the Hospital Harm—Pressure Injury eCQM beginning with the FY 2027 payment determination and for subsequent years. We refer readers to section IX.C.5.a. for more detailed discussion.

**** In this final rule, we are finalizing the adoption the Hospital Harm—Acute Kidney Injury eCQM beginning with the FY 2027 payment determination and for subsequent years. We refer readers to section IX.C.5.b. for more detailed discussion.

***** In this final rule, we proposed to adopt the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults eCQM beginning with the FY 2027 payment determination and for subsequent years. We refer readers to section IX.C.5.c. for more detailed discussion.

d. Summary of Previously Finalized and Proposed Hospital IQR Program Measures for the FY 2028 Payment Determination and Subsequent Years

This table summarizes the previously finalized and newly finalized Hospital IQR Program measure set for the FY 2028 payment determination, including the removal of the re-evaluated MSPB Hospital measure beginning with the CY 2026 reporting period/FY 2028 payment determination.

TABLE IX.C–05. MEASURES FOR THE FY 2028 PAYMENT DETERMINATION AND SUBSEQUENT YEARS

Short Name	Measure Name	CBE #
National Healthcare Safety Network Measures		
HCP Influenza Vaccination	Influenza Vaccination Coverage among Healthcare Personnel	0431
HCP COVID-19 Vaccination*	COVID-19 Vaccination Coverage among Healthcare Personnel	3636
Claims-Based Patient Safety Measures		
CMS PSI-04	Death Rate among Surgical Inpatients with Serious Treatable Complications (CMS Recalibrated Death Rate among Surgical Inpatients with Serious Treatable Complications)	0351
Claims-Based Mortality/Complications Measures		
MORT-30-STK	Hospital 30-Day, All-Cause, Risk Standardized Mortality- Rate Following Acute Ischemic Stroke	N/A
COMP-HIP-KNEE**	Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA	1550
Claims-Based Coordination of Care Measures		
AMI Excess Days	Excess Days in Acute Care after Hospitalization for Acute Myocardial Infarction	2881
HF Excess Days	Excess Days in Acute Care after Hospitalization for Heart Failure	2880
PN Excess Days	Excess Days in Acute Care after Hospitalization for Pneumonia	2882
Claims-Based Payment Measures		
AMI Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care for Acute Myocardial Infarction (AMI)	2431
HF Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-Day Episode-of-Care For Heart Failure (HF)	2436
PN Payment	Hospital-Level, Risk-Standardized Payment Associated with a 30-day Episode-of-Care For Pneumonia	2579
THA/TKA Payment	Hospital-Level, Risk-Standardized Payment Associated with an Episode-of-Care for Primary Elective Total Hip Arthroplasty and/or Total Knee Arthroplasty	3474
Hybrid Measures		
Hybrid HWM***	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	N/A
Hybrid HWR***	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879
Chart-Abstracted Clinical Process of Care Measures		
SEP-1	Severe Sepsis and Septic Shock: Management Bundle (Composite Measure)	0500
Structural Measures		
Maternal Morbidity	Maternal Morbidity Structural Measure	N/A
HCHE	Hospital Commitment to Health Equity	N/A
Electronic Clinical Quality Measures (eCQMs)		
Safe Use of Opioids	Safe Use of Opioids – Concurrent Prescribing	3316e
ePC-02	Cesarean Birth	N/A

Short Name	Measure Name	CBE #
ePC-07/SMM	Severe Obstetric Complications	N/A
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by the End of Hospital Day Two	0438
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
HH-01	Hospital Harm—Severe Hypoglycemia Measure	3503e
HH-02	Hospital Harm—Severe Hyperglycemia Measure	3533e
HH-ORAE	Hospital Harm—Opioid Related Adverse Events	3501e
HH-PI****	Hospital Harm—Pressure Injury	3498e
HH-AKI*****	Hospital Harm—Acute Kidney Injury	3713e
GMCS	Global Malnutrition Composite Score	3592e
ExRad******	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults	3663e
Patient Experience of Care Survey Measures		
HCAHPS	Hospital Consumer Assessment of Healthcare Providers and Systems Survey (including Care Transition Measure)	0166 (0228)
Patient-Reported Outcome Performance Measures		
THA/TKA PRO-PM	Hospital-Level Total Hip Arthroplasty and/or Total Knee Arthroplasty Patient-Reported Outcome-Based Performance Measure (PRO-PM)	3559
Process Measures		
SDOH-1	Screening for Social Drivers of Health	N/A
SDOH-2	Screen Positive Rate for Social Drivers of Health	N/A

* In this final rule, we are finalizing refinements to the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the FY 2025 payment determination and for subsequent years. We refer readers to section IX.B. for more detailed discussion.

**In this final rule, we are finalizing the proposal to remove the Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary THA and/or TKA measure beginning with the FY 2030 payment determination. We refer readers to section IX.C.7.a. for more detailed discussion.

***In this final rule, we are finalizing the refinements to two Hospital IQR Program measures-Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM) and Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)-beginning with the FY 2027 payment determination. We refer readers to sections IX.C.6.a. and IX.C.6.b., respectively, for more detailed discussion.

**** In this final rule, we are finalizing the adoption of the Hospital Harm—Pressure Injury eCQM beginning with the FY 2027 payment determination and for subsequent years. We refer readers to section IX.C.5.a. for more detailed discussion.

***** In this final rule, we are finalizing the adoption of the Hospital Harm—Acute Kidney Injury eCQM beginning with the FY 2027 payment determination and for subsequent years. We refer readers to section IX.C.5.b. for more detailed discussion.

****** In this final rule, we are finalizing adoption of the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults eCQM beginning with the FY 2027 payment determination and for subsequent years. We refer readers to section IX.C.5.c. for more detailed discussion.

4120–01–C

9. Future Considerations

We seek to develop a comprehensive set of quality measures to be available for widespread use for informed decision-making and quality and cost improvements focused on the inpatient hospital setting. We have identified potential future measures, which we believe address areas that are important to interested parties, but which are not currently included in the Hospital IQR Program's measure set. Therefore, in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27103 through 27109) we sought public feedback on these measures as we consider how best to develop the Hospital IQR Program's measure set. These are discussed in more detail in this section.

a. Potential Future Inclusion of Two Geriatric Care Measures

(1) Background

The U.S. population is aging rapidly, with one in five Americans estimated to be over 65 years old in the next 10 years. By the year 2030, all baby boomers will be older than 65.[567] The 65 and older population is expected to double in the U.S. by 2060, from an estimated 49 million in 2016 to an estimated 95 million people in 2060.[568] Similarly, the number of people 85 years and older is expected to grow from 6.5 million to 11.8 million in 2035, and to triple by 2060 to an estimated 19 million people.[569]

As the population ages, care can become more complex,[570] with patients often developing multiple chronic conditions. The CDC estimates that 68.4 percent of Medicare beneficiaries have two or more chronic conditions.[571] Research on Medicare fee-for-service beneficiaries with 15 prevalent chronic conditions showed that 62 percent for those between 65–74 years old and 81.5 percent for those 85 years and older experience multiple chronic conditions.[572]

Hospitals are increasingly faced with treating older patients who have complex medical, behavioral, and psychosocial needs that are often inadequately addressed by the current healthcare infrastructure.[573] Although existing Hospital IQR Program quality measures include patients who are 65 years and older, some of these measures may be narrow in scope and may not capture the full spectrum of geriatric care needs. Rather than addressing individual clinical issues in isolation, optimizing care for older patients with multiple co-morbidities will require a holistic approach that reimagines the entire care pathway to better serve the needs of this unique population. We believe an important part of what is needed in redesigning care for the older adult population is programmatic, facility-level geriatric assessment and management efforts.

Given these challenges, the American Geriatrics Society (AGS) developed guiding principles on the care of older adults with multiple chronic conditions using structured literature searches and consensus among clinicians.[574] To translate these principles into action steps, the AGS convened a workgroup of geriatricians, cardiologists, and generalists to identify a framework for decision-making for clinicians who provide care to older adults with multiple chronic conditions.[575] This workgroup recommended three actions: (1) identify and communicate patients' health priorities and health trajectory; (2) stop, start, or continue care based on health priorities, potential risks versus benefits, and health trajectory; and (3) align decisions and care among patients, caregivers, and other clinicians with patients' health priorities and trajectories.[576]

To address the challenges of delivering care to older adults with multiple chronic conditions from a health system perspective, multiple organizations including the American College of Surgeons (ACS), the Institute for Healthcare Improvement (IHI), and the American College of Emergency Physicians (ACEP) collaborated to identify clinical frameworks based on evidence-based best practices that provide goal-centered, clinically effective care for older patients. Together, these organizations have established an Age-Friendly Health System initiative. Age-friendly care is defined as: (1) following an essential set of evidence-based practices; (2) causing no harm; and (3) aligning with What Matters[577] to the older adult and their family or other caregivers.[578] The Age-Friendly Health System initiative has identified a framework comprised of a set of four evidence-based elements of high-quality care to older adults, called the ''4 Ms'': What Matters, Medication, Mentation, and Mobility.[579] These elements organize care for older adult wellness and apply regardless of the number of chronic conditions, a person's culture, or their racial, ethnic, or religious background.[580]

The collective evidence provided by these research efforts demonstrates that patient-centered care for aging patient populations with multiple chronic conditions should be prioritized by hospitals. Therefore, we are considering two attestation-based structural measures, the Geriatric Hospital measure and the Geriatric Surgical measure, for the Hospital IQR Program. We also requested public comment on the potential future proposal for a hospital designation focused on hospitals that participate in patient-centered geriatric care health system improvement initiatives.

These attestation-based structural measures apply evidence-based, concrete, actionable steps to improve patient-centered care in the hospital inpatient setting for older adults. The measures incentivize team-based care organized around the geriatric patient to meet their unique needs.[581] A major challenge presented in the geriatric population is that care is not a single structural element or process.[582] Within clinical domains of care such as geriatric care, there are crucial structures and processes of care to support high-quality patient-centered care, that reach across multiple interactions and link the care team's efforts together.[583] [584] Orchestrating all

[567] Vespa, J., Armstrong, D.M., & Medina, L. (Rev Feb 2020). Demographic turning points for the United States: Population projections for 2020 to 2060. Washington, DC: U.S. Department of Commerce, Economics and Statistics Administration, U.S. Census Bureau.

[568] *Ibid.*

[569] *Ibid.*

[570] Quiñones, A.R., Markwardt, S., & Botoseneanu, A. (2016). Multimorbidity combinations and disability in older adults. Journals of Gerontology Series A: Biomedical Sciences and Medical Sciences, 71(6), 823–830.

[571] Lochner KA, Cox CS. Prevalence of Multiple Chronic Conditions Among Medicare Beneficiaries, United States, 2010. Prev Chronic Dis 2013;10:120137. DOI: *https://dx.doi.org/10.5888/pcd10.120137.*

[572] Salive, M.E. (2013). Multimorbidity in older adults. Epidemiologic reviews, 35(1), 75–83.

[573] Boyd, C., Smith, C.D., Masoudi, F.A., Blaum, C.S., Dodson, J.A., Green, A.R., . . . & Tinetti, M.E. (2019). Decision making for older adults with multiple chronic conditions: executive summary for the American Geriatrics Society guiding principles on the care of older adults with multimorbidity. Journal of the American Geriatrics Society, 67(4), 665–673.

[574] American Geriatrics Society Expert Panel on the Care of Older Adults with Multimorbidity. (2012) Guiding principles for the care of older adults with multimorbidity: an approach for clinicians. *Journal of the American Geriatrics Society, 60*(10), E1–E25.

[575] Boyd, C., Smith, C.D., Masoudi, F.A., Blaum, C.S., Dodson, J.A., Green, A.R., . . . & Tinetti, M.E. (2019). Decision making for older adults with multiple chronic conditions: executive summary for the American Geriatrics Society guiding principles on the care of older adults with multimorbidity. Journal of the American Geriatrics Society, 67(4), 665–673.

[576] *Ibid.*

[577] Tinetti, M. (January 2019). [Blog] How focusing on What Matters simplifies complex care for older adults. Institute for Healthcare Improvement. Available at: *https://www.ihi.org/communities/blogs/how-focusing-on-what-matters-simplifies-complex-care-for-older-adult.*

[578] Institute for Healthcare Improvement. (2020). Age-friendly health systems: Guide to using the 4Ms in the care of older adults. Available at: *https://www.ihi.org/Engage/Initiatives/Age-Friendly-Health-Systems/Documents/IHIAgeFriendlyHealthSystems_GuidetoUsing4MsCare.pdf.*

[579] *Ibid.*

[580] *Ibid.*

[581] American Geriatrics Society Expert Panel on the Care of Older Adults with Multimorbidity. (2012). Guiding principles for the care of older adults with multimorbidity: an approach for clinicians. Journal of the American Geriatrics Society, 60(10), E1–E25. Available at: *https://pubmed.ncbi.nlm.nih.gov/22994865/.*

[582] *Ibid.*

[583] Institute for Healthcare Improvement. (2022) Age-Friendly Health Systems: Guide to Recognition for Geriatric Surgery Verification Hospitals. Available at: *https://forms.ihi.org/hubfs/Guide%20To%20Recognition%20for%20GSV%20Siteslowbar;FINAL.pdf.*

[584] Boyd, C., Smith, C.D., Masoudi, F.A., Blaum, C.S., Dodson, J.A., Green, A.R., . . . & Tinetti, M.E.

these elements results in better outcomes, and improving their implementation would be an essential first step to improve geriatric outcomes.[585]

Both structural measures are a collection of coordinated, team-based components across the continuum of care. Together, these represent patient-centered programs of care designed to improve surgical and general health outcomes for geriatric patients. When the components are properly tied together, complex care for this population is better coordinated and more reliably delivered, with harms minimized and outcomes optimized. The elements in these geriatric structural measures are focused on care delivery, coordination, data, and data-driven improvement activities.

The measure developer, ACS, designed these structural measures to assess geriatric care across various domains (see Table IX.C–06 and Table IX.C–07) using a suite of organizational competencies aimed at achieving patient-centered care for aging populations with multiple chronic conditions. We believe these measures would complement the current patient safety reporting, support hospitals in improving the quality of care for a complex patient population and could further our commitment to advancing health equity among the diverse communities served by participants in CMS programs.

These measures also align with our efforts under the Meaningful Measures Framework, which identifies high priority areas for quality measurement and improvement to assess core issues most critical to high-quality healthcare and improving patient outcomes.[586] More specifically, the measures align with the Meaningful Measures Framework priority focus on patient-centered care.[587] In 2021, we launched Meaningful Measures 2.0 to promote innovation and modernization of all aspects of quality and address a wide variety of settings, interested parties, and measure requirements. The Geriatric Hospital and Geriatric Surgical structural measures support the goal of ''leverage[ing] quality measures to promote health equity and close gaps in care.'' [588] In addition, these measures align with CMS's National Quality Strategy goal to ''embed quality into the care journey,'' by taking a person-centered approach to ensure a smoother care journey for a patient population that often has complex needs.[589]

The Geriatric Hospital (MUC2022–112) and Geriatric Surgical (MUC2022–032) measures were included in the publicly available ''2022 Measures Under Consideration Spreadsheet'' (MUC List), the list of measures under consideration for use in various Medicare programs.[590] The MAP Rural Health Advisory Group reviewed the MUC List and the Geriatric Hospital (MUC2022–112) and Geriatric Surgical (MUC2022–032) measures in detail on December 8–9, 2022.[591] The Rural Health Advisory Group agreed that both measures are important but had concerns regarding the limited resources that rural health providers face, including fewer clinicians and social services availability.[592] The Rural Health Advisory Workgroup also had concerns related to the potential for public trust to be negatively impacted if these measures are publicly reported.[593]

On December 6–7, 2022, the MAP Health Equity Advisory Group met to review the 2022 MUC list and Geriatric Hospital (MUC2022–112) and Geriatric Surgical (MUC2022–032) measures.[594] The MAP Health Equity Advisory Group was convened to provide input on the MUC list with the goal of reducing health disparities closely linked with social, economic, environmental and other systemic disadvantages. The Health Equity Advisory Group also requested that participants provide input on potential unintended consequences or measurement gap areas related to health disparities. The Health Equity Advisory Group agreed the geriatric measures are important measures, noting that geriatric patients are often more fragile and emphasized the importance of assessing their needs. The Health Equity Advisory Group had concerns related to implementation and to the limited evidence that attestation measures lead to improved health outcomes that further health equity.[595]

The MUC List, including Geriatric Hospital (MUC2022–112) and Geriatric Surgical (MUC2022–032) measures, were also reviewed by the MAP Hospital Workgroup on December 13–14, 2022.[596] The MAP Hospital Workgroup discussed the overlap between the Geriatric Hospital measure (MUC2022–112) and Geriatric Surgical measure (MUC2022–032), noting that hospitals, particularly ones in rural settings, may find it burdensome to report both measures. The MAP Hospital Workgroup did not support the Geriatric Hospital measure (MUC2022–112) for rulemaking, with the potential for mitigation. The potential mitigation for this measure (MUC2022–112) is consideration for combining the two geriatric care measures (MUC2022–112 and MUC2022–032) into a single measure that is less burdensome, or focusing on one of the two measures.[597] The MAP Hospital Workgroup conditionally supported the Geriatric Surgical measure (MUC2022–032) for rulemaking pending additional revisions to reduce the number of elements included in the attestation and present information about gaps for the components.

The MAP Coordinating Committee convened on January 23–24, 2023, to review the MUC List, including Geriatric Hospital (MUC2022–112) and Geriatric Surgical (MUC2022–032) measures.[598] The MAP Coordinating Committee similarly discussed the overlap between the Geriatric Hospital measure (MUC2022–112) and Geriatric Surgical measure (MUC2022–032), and agreed with the concerns noted by the MAP Hospital Workgroup that hospitals may find it burdensome to report both measures, particularly in rural settings. The MAP Coordinating Committee agreed with the decision to conditionally support the Geriatric Hospital measure (MUC2022–112) for rulemaking, pending CBE endorsement.

(2019). Decision making for older adults with multiple chronic conditions: executive summary for the American Geriatrics Society guiding principles on the care of older adults with multimorbidity. Journal of the American Geriatrics Society, 67(4), 665–673.

[585] *Ibid.*

[586] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.*

[587] *Ibid.*

[588] Centers for Medicare & Medicaid Services. (2022) Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization.*

[589] Centers for Medicare & Medicaid Services. (2022) What is the National Quality Strategy? Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy.*

[590] Centers for Medicare & Medicaid Services. 2022 MUC List. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[591] Centers for Medicare & Medicaid Services. MAP 2022–2023 Final Recommendations. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[592] *Ibid.*

[593] *Ibid.*

[594] *Ibid.*

[595] *Ibid.*

[596] *Ibid.*

[597] *Ibid.*

[598] *Ibid.*

The MAP Coordinating Committee agreed the potential for mitigation for this measure should be to consider combining the two geriatric care measures (MUC2022–112 and MUC2022–032) into a single measure that is less burdensome, or focus on one measure.[599] The MAP Coordinating Committee agreed with the MAP Hospital Workgroup's decision to conditionally support the Geriatric Surgical measure (MUC2022–032) for rulemaking, pending CBE endorsement, further paring down elements included in the attestations, and providing further information on the gaps in the measure components.[600] The MAP Coordinating Committee had concerns related to the subjectiveness of attestation based measures, noting a preference for outcome or process measures.[601] The MAP Coordinating Committee supported the focus of the measure and noted that attestation measures can help build infrastructure for important topics such as this and that these measures fill a gap in care management among a vulnerable population.[602]

(2) Potential Future Inclusion of a Geriatric Hospital Structural Measure

(i) Measure Overview

The Geriatric Hospital structural measure assesses hospital commitment to improving outcomes for patients 65 years or older through patient-centered competencies aimed at achieving quality of care and safety for all older patients. The measure includes 14 attestation-based questions across eight domains representing a comprehensive framework required for optimal care of older patients admitted to the hospital or being evaluated in the emergency department. Table IX.C–06 includes the eight attestation domains and 14 attestation statements which would be required to qualify for this measure.

BILLING CODE 4120–01–P

[599] *Ibid.*

[600] *Ibid.*

[601] *Ibid.*

[602] *Ibid.*

Table IX.C–06. The Geriatric Hospital Measure's Eight Domain Attestations

Attestation Domains	Attestation Statements: Select All That Apply (Note: Attestation of all statements would be required to qualify for the measure numerator)
Domain 1: Identifying Goals of Care	**(1) Advance Care Planning.** Please attest that your hospital provides education to patients and providers regarding advance care planning and ensures that advance care planning preferences are captured, updated, and available for review in the medical record. **(2) Patient Goals.** Please attest that your hospital provides education regarding goal concordant care and has established protocols for ensuring patient goals and decision making is documented in the medical record.
Domain 2: Medication Management	**(3) Inappropriate Medications.** Please attest that your hospital flags medications that may be inappropriate for older patients and has established protocols for reviewing drug and non-drug alternatives to identified substances. **(4) Pain Management.** Please attest that your hospital employs opioid sparing multimodal pain management strategies where possible and has protocols for capturing these regimens in the medical record.
Domain 3: Cognition and Delirium	**(5) Delirium and Cognition Screening.** Please attest that your hospital performs delirium and cognition screens and assessments and implements appropriate management plans for those with delirium.
Domain 4: Preventing Delirium Related Events	**(6) Delirium Prevention.** Please attest that your hospital establishes protocol for minimizing delirium for patients in the hospital through environment modifications, delirium screens, and timely discharge/transfer of patients.
Domain 5: Function and Mobility	**(7) Function and Mobility Screening.** Please attest that your hospital performs function and mobility assessments and implements appropriate management plans to promote mobility. **(8) Assistance with Activities of Daily Living (ADLs) / Instrumental Activities of Daily Living (IADLs).** Please attest that your hospital screens older patients for ADL/IADL needs and establishes protocols for management of patients with identified deficiencies.
Domain 6: Social Determinants of Health	**(9) Social Determinants of Health.** Please attest that your hospital assesses patients for psychosocial risk factors and employs appropriate management plans. **(10) Elder Abuse, Neglect, and Exploitation.** Please attest that your hospital assesses older patient for potential abuse and has protocols for intervention for positive assessments including appropriate reporting and involvement of social services.
Domain 7: Care Transitions	**(11) Identifying Needs at Hospital Discharge.** Please attest that your hospital elicits discussion between providers and patients regarding discharge care and establishes protocols to ensure that discharge summaries contain management plans for all identified post-discharge needs. **(12) Post-Acute Care.** Please attest that your hospital has protocols for establishing two-way communication between providers and post-acute care facilities and tracks the quality of care at post-acute care facilities upon discharge.

Attestation Domains	Attestation Statements: Select All That Apply (Note: Attestation of all statements would be required to qualify for the measure numerator)
Domain 8: Ensuring Quality Care for High-Risk Patients	**(13) Identification and Management of Seriously Ill Patients.** Please attest that your hospital employs multidisciplinary evaluation of older patients and provides appropriate management, including the early utilization of palliative care consultations, for those with serious illness. **(14) Geriatric Leader and Quality Framework.** Please attest that your hospital designates a geriatric champion to oversee all aspects of this measure and establishes a framework for ongoing quality improvement regarding the care for older patients.

BILLING CODE 4120–01–C

(ii) Measure Calculation

The Geriatric Hospital measure consists of eight domains, each representing a separate domain commitment. Hospitals would need to evaluate and determine whether they can affirmatively attest to each domain, some of which have multiple statements to which a hospital must attest.

To report on this measure, hospitals would respond to the eight domain attestations that encompass 14 corresponding statements (see Table IX.C–06.). A hospital would receive one point for each domain where they attest to each of the corresponding statements (for a total of zero to eight points). For domain questions with multiple statements, positive attestation to each statement would be required to qualify for the corresponding domain attestation.

The numerator is the number of complete domain attestations. Attestation of each statement within a domain would be required to qualify for the measure numerator. The denominator for each hospital is eight, which represents the total number of domain attestations. The measure would be calculated as the number of complete attestations divided by the total number of questions.

A hospital would not be able to receive partial credit for a domain. For example, for Domain 1 (''Identifying Goals of Care''), a hospital would evaluate and determine whether their hospital processes meet each of the attestation statements described in (1) and (2) (see Table IX.C–06.). If the hospital's processes meet both of these statements, the hospital would affirmatively attest to Domain 1 and would receive a point for that attestation domain.

We invited public comment on the potential future use of this measure in the Hospital IQR Program.

We thank readers for their comments and have summarized all responses to this potential future measure after the potential geriatric hospital designation RFI in section IX.C.9.b.

(3) Potential Future Inclusion of the Geriatric Surgical Structural Measure

(i) Measure Overview

The Geriatric Surgical structural measure assesses hospital commitment to improving surgical outcomes for patients 65 years or older through patient-centered competencies aimed at achieving quality of care and safety for all older patients. The measure includes 11 attestation-based questions across seven domains (see Table IX.C–07.), representing a comprehensive framework required for optimal care of the older surgical patient.

BILLING CODE 4120–01–P

Table IX.C–07. The Geriatric Surgical Measure's Seven Domain Attestations

Attestation Domains	Attestation Statements: Select All That Apply (Note: Attestation of all statements discussed in the chart would be required to qualify for the measure numerator)
Domain 1: Identifying Goals of Care	**(1) Advance Care Planning.** Please attest that your hospital provides education to patients and providers regarding advance care planning and ensures that advance care planning preferences are captured, updated, and available for review in the medical record. **(2) Patient Goals.** Please attest that your hospital provides education regarding goal concordant care and has established protocols for ensuring patient goals and decision making is documented in the medical record.
Domain 2: Medication Management	**(3) Inappropriate Medications.** Please attest that your hospital flags medications that may be inappropriate for older surgical patients and has established protocols for reviewing drug and non-drug alternatives to identified substances. **(4) Pain Management.** Please attest that your hospital employs opioid sparing multimodal pain management strategies where possible and has protocols for capturing these regimens in the medical record.
Domain 3: Cognition and Delirium	**(5) Delirium and Cognition Screening.** Please attest that your hospital performs delirium and cognition screens and implements protocols for flagging high risk patients and implementing appropriate management plans for those with positive screens.
Domain 4: Function and Mobility	**(6) Function and Mobility Screening.** Please attest that your hospital performs pre-operative function and mobility screens and implements protocols to flagging high risk patients and implementing appropriate management plans for those with positive screens.
Domain 5: Social Determinants of Health	**(7) Social Determinants of Health.** Please attest that your hospital performs preoperative screens for psychosocial risk factors and establishes protocols for identifying at risk patients and employing appropriate management plans.

Attestation Domains	Attestation Statements: Select All That Apply (Note: Attestation of all statements discussed in the chart would be required to qualify for the measure numerator)
Domain 6: Care Transitions	**(8) Identifying Needs at Hospital Discharge.** Please attest that your hospital elicits discussion between providers and patients regarding discharge care and establishes protocols to ensure that discharge summaries contain management plans for all identified post-discharge needs. **(9) Post-Acute Care.** Please attest that your hospital has protocols for establishing two-way communication between providers and post-acute care facilities and tracks the quality of care at post-acute care facilities upon discharge
Domain 7: Ensuring Quality Care for High-Risk Patients	**(10) Identification and Management of Seriously Ill Patients.** Please attest that your hospital employs multidisciplinary evaluation of older patients and provides appropriate management, including the early utilization of palliative care consultations, for those with serious illness. **(11) Geriatric Leader and Quality Framework.** Please attest that your hospital designates a geriatric surgery point person to oversee all aspects of this measure and establishes a framework for ongoing quality improvement regarding the care for patients.

BILLING CODE 4120–01–C

(ii) Measure Calculation

The Geriatric Surgical structural measure consists of seven domains. Each domain represents a separate domain commitment. A hospital would need to evaluate and determine whether it can affirmatively attest to each domain, some of which have multiple statements to which a hospital must attest.

To report on this measure, hospitals would respond to the seven domain attestations that encompass 11 corresponding statements. A hospital would receive one point for each domain where they attest to each of the corresponding statements (for a total of zero to seven points). For domain questions with multiple statements, positive attestation to each statement would be required to qualify for the corresponding domain attestation.

The numerator is the number of complete domain attestations. Attestation of each statement within a domain would be required to qualify for the measure numerator. The denominator for each hospital is seven, which represents the total number of domain attestations. The measure would be calculated as the number of complete attestation questions divided by the total number of domains.

A hospital would not be able to receive partial credit for a domain. For example, for Domain 1 (''Identifying Goals of Care''), a hospital would evaluate and determine whether their hospital processes meet each of the attestation statements described in (1) and (2) (see Table IX.C–07.). If the hospital's processes meet both of these statements, the hospital would affirmatively attest to Domain 1 and would receive a point for that attestation domain.

We invited public comment on the potential use of this measure in the Hospital IQR Program.

We thank readers for their comments and have summarized all responses to this potential future measure after the potential geriatric hospital designation RFI in section IX.C.9.b.

b. Potential Establishment of a Publicly Reported Hospital Designation To Capture the Quality and Safety of Patient-Centered Geriatric Care

In alignment with the Geriatric Hospital and Geriatric Surgical structural measures discussed in section IX.C.9.a., we are considering a geriatric care hospital designation to be publicly reported on a CMS website. This designation could initially be based on data from hospitals reporting on both Geriatric Hospital and Geriatric Surgical structural measures if they are proposed and finalized in the future. If proposed for future rulemaking, we could develop a scoring methodology for granting the designation, such as recognizing those hospitals that affirmatively attest to all domains in the Geriatric Hospital and Geriatric Surgical structural measures. This designation could be similar to the Birthing-Friendly designation that was finalized in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49282 through 49292).

We are considering whether to propose in future notice-and-comment rulemaking a more robust set of metrics for awarding the designation that may include other geriatric care-related measures that may be finalized for the Hospital IQR Program measure set in the future. We believe adding this designation to a consumer-facing CMS website would allow patients and families to choose hospitals that have demonstrated a commitment to improving patient-centered geriatric care through their implementation of best practices that support delivery of safe, high-quality, patient-centered geriatric care. Therefore, we are also soliciting comment on additional measures to consider for incorporation in the designation for future years.

We invited public comment on the potential future hospital designation for geriatric care in addition to the following questions:

- What are some of the key barriers and challenges faced by rural providers in reporting the attestation measures discussed in section IX.C.9.a. of the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27103 through 27109)?
- What are the best practices for hospitals to actively engage with post-

acute care facilities? What barriers do providers face, especially rural providers, in establishing protocols for bi-directional communication?

- What are the best practices that hospitals are implementing to provide education for and conduct outreach to patients in underserved communities to increase access to timely geriatric care?
- Among rural providers, do hospitals face barriers when identifying care goals between patients and providers, establishing protocols for ensuring patients' goals are met, and documenting the decision making process? Are there specific barriers to providing education regarding the coordination of care to meet the patient's goals?
- Are there barriers to implementing protocols for delirium and cognition screenings to flag high risk patients among geriatric populations? What challenges do providers face when implementing care management plans for high-risk patients?
- What barriers do hospitals face when implementing multidisciplinary evaluations of older adults? Are there challenges hospitals face with the early utilization of palliative care consultations for older populations with serious illness?
- Are any of the proposed elements of these measures potentially duplicative of existing measures in the Hospital IQR Program?
- Family caregivers play an important role in providing informal, often unpaid, care to help loved ones, including aging family members on Medicare. It is critical, particularly during care transitions, that hospital procedures focus on the patient's goals and preferences, and include family caregivers as active partners. How should the potential future hospital designation for geriatric care capture the role of family caregivers in hospital care delivery, care transitions and/or discharge planning?

We received comments on this topic.

Comment: Many commenters supported a combined geriatric measure that consolidates the attestation domains of the geriatric hospital and geriatric surgical measures, that could potentially be the foundation of a geriatric hospital designation. Commenters believed these measures and designation will help a rapidly aging, vulnerable population find the care they need.

Other commenters did not support the implementation of the geriatric attestation-based measures because they believed the measure burden would outweigh the potential benefits and would not add value to the patient or measure outcomes. Several commenters did not support adoption of either geriatric measure stating that there is no clear link between attestation and improving patient outcomes. A few commenters did not support geriatric measures due to concerns related to increased burden, particularly on rural hospitals, and concerns that the measures and potential hospital designation may not benefit hospitals and could confuse patients.

Commenters provided many recommendations for additional geriatric care considerations. These included recommendations regarding new attestations, the role of family caregivers, and clinical guidelines and screening tools. Additional recommendations focused on provider education regarding the specific needs of geriatric patients.

Commenters additionally recommended moving away from attestation measures and encouraging development of a more fulsome and streamlined set of measures that assess performance to support the geriatric hospital designation, including CBE-endorsed outcome-based measures for display on Care Compare. A few commenters recommended that the scoring methodology for a geriatric hospital designation be based on hospital performance and outcomes. Commenters recommended voluntary participation in a geriatric hospital designation and that only participating hospitals be impacted.

Response: We thank the commenters for their input and appreciate the many meaningful practices being utilized in hospitals across our nation and the commitment to improving geriatric care. We will consider these comments in any future rulemaking related to geriatric care in the Hospital IQR Program.

10. Form, Manner, and Timing of Quality Data Submission

a. Background

Section 1886(b)(3)(B)(viii)(I) and (II) of the Act states that the applicable percentage increase for FY 2015 and each subsequent year shall be reduced by one-quarter of such applicable percentage increase (determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act) for any subsection (d) hospital that does not submit data required to be submitted on measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. To successfully participate in the Hospital IQR Program, hospitals must meet specific procedural, data collection, submission, and validation requirements.

b. Maintenance of Technical Specifications for Quality Measures

For each Hospital IQR Program payment determination, we require that hospitals submit data on each specified measure in accordance with the measure's specifications for a particular period. We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538), in which we summarized how the Hospital IQR Program maintains the technical measure specifications for quality measures and the subregulatory process for incorporation of nonsubstantive updates to the measure specifications to ensure that measures remain up to date.

The data submission requirements, specifications manual, measure methodology reports, and submission deadlines are posted on the QualityNet website at: *https://qualitynet.cms.gov* (or other successor CMS designated websites). The CMS Annual Update for the Hospital Quality Reporting Programs (Annual Update) contains the technical specifications for eCQMs. The Annual Update contains updated measure specifications for the year prior to the reporting period. For example, for the CY 2023 reporting period/FY 2025 payment determination, hospitals are collecting and will submit eCQM data using the May 2022 Annual Update and any applicable addenda. The Annual Update and implementation guidance documents are available on the Electronic Clinical Quality Improvement (eCQI) Resource Center website at: *https://ecqi.healthit.gov/*.

Hospitals must register and submit quality data through the Hospital Quality Reporting (HQR) System (previously referred to as the QualityNet Secure Portal) (86 FR 45520). The HQR System is safeguarded in accordance with the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules to protect submitted patient information. See 45 CFR parts 160 and 164, subparts A, C, and E.

We did not propose any changes to these policies in the proposed rule.

c. Procedural Requirements

The Hospital IQR Program's procedural requirements are codified in regulation at 42 CFR 412.140. We refer readers to these codified regulations for participation requirements, as further explained by the FY 2014 IPPS/LTCH PPS final rule (78 FR 50810 through 50811) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57168). The previously finalized requirements, including setting up a HCQIS Access Roles and

Profile (HARP) account and the associated timelines, are described at 42 CFR 412.140(a)(2) and (e)(2)(iii) and in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51639 through 51640).

CMS may grant an exception with respect to quality data reporting requirements, including related validation requirements, in the event of extraordinary circumstances beyond the control of the hospital (42 CFR 412.140(c)(2)).

We did not propose any changes to these policies in the proposed rule.

d. Data Submission Requirements for Chart-Abstracted Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51640 through 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53536 through 53537), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50811) for details on the Hospital IQR Program data submission requirements for chart-abstracted measures.

We did not propose any changes to these policies in the proposed rule.

e. Data Submission and Reporting Requirements for eCQMs

For a discussion of our previously finalized eCQMs and policies, we refer readers to the FY 2014 IPPS/LTCH PPS final rule (78 FR 50807 through 50810; 50811 through 50819), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50241 through 50253; 50256 through 50259; and 50273 through 50276), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49692 through 49698; and 49704 through 49709), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57150 through 57161; and 57169 through 57172), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38355 through 38361; 38386 through 38394; 38474 through 38485; and 38487 through 38493), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41567 through 41575; 83 FR 41602 through 41607), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42501 through 42506), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58932 through 58940), the FY 2022 IPPS/LTCH PPS final rule (86 FR 45417 through 45421), and the FY 2023 IPPS/LTCH PPS final rule (87 FR 49298 through 49304).

In the FY 2018 IPPS/LTCH PPS final rule, we finalized eCQM reporting and submission requirements such that hospitals were required to report only one, self-selected, calendar quarter of data for four self-selected eCQMs for the CY 2018 reporting period/FY 2020 payment determination (82 FR 38358 through 38361). Those reporting requirements were extended to the CY 2019 reporting period/FY 2021 payment determination through the CY 2021 reporting period/FY 2023 payment determination (83 FR 41603 through 41604; 84 FR 42501 through 42503). In the FY 2020 IPPS/LTCH PPS final rule, we finalized that for the CY 2022 reporting period/FY 2024 payment determination, hospitals were required to report one, self-selected calendar quarter of data for: (a) Three self-selected eCQMs; and (b) the Safe Use of Opioids—Concurrent Prescribing eCQM, for a total of four eCQMs (84 FR 42503 through 42505).

In the FY 2021 IPPS/LTCH PPS final rule, we finalized a progressive increase in the number of required reported quarters of eCQM data, from one self-selected quarter of data to four quarters of data over a three-year period (85 FR 58932 through 58939). Specifically, for the CY 2021 reporting period/FY 2023 payment determination, hospitals were required to report two self-selected calendar quarters of data for each of the four self-selected eCQMs (85 FR 58939). For the CY 2022 reporting period/FY 2024 payment determination, hospitals were required to report three self-selected calendar quarters of data for each eCQM: (a) Three self-selected eCQMs, and (b) the Safe Use of Opioids—Concurrent Prescribing eCQM (85 FR 58939). We clarified in the FY 2021 IPPS/LTCH PPS final rule that until hospitals are required to report all four quarters of data beginning with the CY 2023 reporting period/FY 2025 payment determination, they may submit consecutive or non-consecutive self-selected quarters of data (85 FR 58939). In the FY 2022 IPPS/LTCH PPS final rule, we clarified that the self-selected eCQMs must be the same eCQMs across quarters in a given reporting year (86 FR 45418).

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49299 through 49302), we finalized a policy to increase eCQM reporting requirements from four to six eCQMs beginning with the CY 2024 reporting period/FY 2026 payment determination and for subsequent years. Specifically, hospitals will be required to report four calendar quarters of data for each required eCQM: (1) Three self-selected eCQMs; (2) the Safe Use of Opioids—Concurrent Prescribing eCQM; (3) the Cesarean Birth eCQM; and (4) the Severe Obstetric Complications eCQM; for a total of six eCQMs.

We did not propose any changes to these policies in the proposed rule.

The following Table IX.C–08 summarizes our finalized policies.

TABLE IX.C–08. eCQM REPORTING AND SUBMISSION REQUIREMENTS FOR THE CY 2022 REPORTING PERIOD/FY 2024 PAYMENT DETERMINATION AND FOR SUBSEQUENT YEARS

Reporting Period/ Payment Determination	eCQM Data Publicly Reported	Total Number of eCQMs Reported	eCQMs Required to be Reported
CY 2022/FY 2024	Three Quarters of Data	Four	• Three self-selected eCQMs; and • Safe Use of Opioids—Concurrent Prescribing eCQM
CY 2023/FY 2025	Four Quarters of Data	Four	• Three self-selected eCQMs; and • Safe Use of Opioids—Concurrent Prescribing eCQM
CY 2024/FY 2026 (and for subsequent years)	Four Quarters of Data	Six	• Three self-selected eCQMs; and • Safe Use of Opioids—Concurrent Prescribing eCQM; and • Cesarean Birth eCQM; and • Severe Obstetric Complications eCQM

(1) Continuation of Certification Requirements for eCQM Reporting

(a) Requiring Use of the 2015 Edition Cures Update Certification Criteria

In the FY 2022 IPPS/LTCH PPS final rule, beginning with the CY 2023 reporting period/FY 2025 payment determination and subsequent years, we finalized the requirement for hospitals to use only certified technology updated consistent with the 2015 Edition Cures Update to submit data for the Hospital IQR Program (86 FR 45418). We refer readers to the ONC 21st Century Cures Act final rule for additional information about the updates included in the 2015 Edition Cures Update (85 FR 25665).

We did not propose any changes to this policy in the proposed rule.

(b) Requiring EHR Technology to be Certified to all Available eCQMs

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42505 through 42506), we finalized the requirement that EHRs be certified to all available eCQMs used in the Hospital IQR Program for the CY 2020 reporting period/FY 2022 payment determination and subsequent years. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45418), we finalized the requirement for hospitals to use the 2015 Edition Cures Update beginning with the CY 2023 reporting period/FY 2025 payment determination; then all available eCQMs used in the Hospital IQR Program for the CY 2023 reporting period/FY 2025 payment determination and subsequent years would need to be reported using certified technology updated to the 2015 Edition Cures Update.

We did not propose any changes to this policy in the proposed rule.

(2) File Format for EHR Data, Zero Denominator Declarations, and Case Threshold Exemptions

We refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49708) and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57170) for our previously adopted eCQM file format requirements. Under these requirements, hospitals: (1) Must submit eCQM data via the Quality Reporting Document Architecture Category I (QRDA I) file format, (2) may use third parties to submit QRDA I files on their behalf, and (3) may either use abstraction or pull the data from non-certified sources to then input these data into certified EHR technology (CEHRT) for capture and reporting QRDA I. Hospitals can continue to meet the reporting requirements by submitting data via QRDA I files, zero denominator declaration, or case threshold exemption (82 FR 38387).

More specifically regarding the use of QRDA I files, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 and 57170) and the FY 2020 IPPS/LTCH PPS final rule (85 FR 58940), in which we specified QRDA I file requirements. We also refer readers to the CMS Implementation Guide for the data and file requirements, which is published on the eCQI Resource Center website at: *https://ecqi.healthit.gov/QRDA.*

We did not propose any changes to this policy in the proposed rule.

(3) Submission Deadlines for eCQM Data

We refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50256 through 50259), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49705 through 49709), and the FY 2017 IPPS/LTCH PPS final rule (81 FR 57169 through 57172) for our previously adopted policies to align eCQM data reporting periods and submission deadlines for both the Hospital IQR Program and the Medicare Promoting Interoperability Program. In the FY 2017 IPPS/LTCH PPS final rule (81 FR 57172), we finalized the alignment of the Hospital IQR Program eCQM submission deadline with that of the Medicare Promoting Interoperability Program—the end of two months following the close of the calendar year—for the CY 2017 reporting period/FY 2019 payment determination and subsequent years. We note the submission deadline will be moved to the next business day if it falls on a weekend or Federal holiday.

We did not propose any changes to this policy in the proposed rule.

f. Data Submission and Reporting Requirements for Hybrid Measures

In the FY 2020 IPPS/LTCH PPS final rule, we finalized the adoption of the Hybrid HWR measure for the Hospital IQR Program (84 FR 42465 through 42481) such that, beginning with the FY 2026 payment determination, hospitals are required to report on the Hybrid HWR measure (84 FR 42479). In the FY 2022 IPPS/LTCH PPS final rule, we also finalized the adoption of the Hybrid HWM measure in a stepwise fashion, beginning with a voluntary reporting

period from July 1, 2022, through June 30, 2023, and followed by mandatory reporting from July 1, 2023 through June 30, 2024, affecting the FY 2026 payment determination, and for subsequent years (86 FR 45365). We also finalized several requirements related to data submission and reporting requirements for hybrid measures under the Hospital IQR Program (84 FR 42506 through 42508).

We refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 19498 and 19499), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58941), the CY 2021 PFS final rule (85 FR 84472), and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45421) for our previously adopted policies regarding certification and file format requirements for hybrid measures in the Hospital IQR Program.

We refer readers to sections IX.C.6.a. and IX.C.6.b. of this final rule where we finalized refinements of the two hybrid measures in the Hospital IQR Program—the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality measure and the Hybrid Hospital-Wide All-Cause Risk Standardized Readmission measure.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49304), we finalized our proposal to remove zero denominator declarations and case threshold exemptions as an option for the reporting of hybrid measures beginning with the FY 2026 payment determination because we do not believe that these policies are applicable to hybrid measures due to the process of reporting the measure data since hybrid measures do not require that hospitals report a traditional denominator as is required for the submission of eCQMs (*Id.*). Instead, hybrid measures utilize the Initial Patient Population (IPP), as per their measure specifications, that identifies the patients for which hospitals need to extract the EHR data and annual claims data (*Id.*). We note that the FY 2026 payment determination is the first year for which hybrid measures, finalized as part of the Hospital IQR Program measure set, will become mandatory for reporting.

We did not propose any changes to these policies in the proposed rule.

g. Sampling and Case Thresholds for Chart-Abstracted Measures

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50221), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819), and the FY 2016 IPPS/LTCH PPS final rule (80 FR 49709) for details on our sampling and case thresholds for the FY 2016 payment determination and subsequent years.

We did not propose any changes to these policies in the proposed rule.

h. Data Submission and Reporting Requirements for the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey Measure

We refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 and 53538), and the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819 and 50820) for details on previously adopted HCAHPS submission requirements. We also refer hospitals and HCAHPS Survey vendors to the official HCAHPS website at *https://www.hcahpsonline.org* for new information and program updates regarding the HCAHPS Survey, its administration, oversight, and data adjustments.

(1) Updates to the HCAHPS Survey Measure (CBE #0166) Beginning With the FY 2027 Payment Determination

(a) Background

We partnered with the Agency for Healthcare Research and Quality (AHRQ) to develop the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) patient experience of care survey (CBE #0166) (hereinafter referred to as the HCAHPS Survey). We adopted the HCAHPS Survey in the Hospital IQR Program in the CY 2007 OPPS/ASC final rule with comment period (71 FR 68202 through 68204) beginning with the FY 2008 payment determination. We refer readers to the FY 2010 IPPS/LTCH PPS final rule (74 FY 43882), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50220 through 50222), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51641 through 51643), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53537 and 53538), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50819 and 50820), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38328 through 38342), and the CY 2019 OPPS/ASC final rule (83 FR 59140 through 59149) for details on previously adopted HCAHPS Survey requirements.

The HCAHPS Survey (OMB control number 0938–0981) is the first national, standardized, publicly reported survey of patients' experience of hospital care and asks eligible discharged patients 29 questions about their recent hospital stay. The HCAHPS Survey is administered to a random sample of adult patients who receive medical, surgical, or maternity care between 48 hours and six weeks (42 calendar days) after discharge and is not restricted to Medicare beneficiaries.[603] Hospitals must survey patients throughout each month of the year.[604] The HCAHPS Survey is available in official English, Spanish, Chinese, Russian, Vietnamese, Portuguese, German, Tagalog, and Arabic versions.

The HCAHPS Survey and its protocols for sampling, data collection and coding, and file submission can be found in the current HCAHPS Quality Assurance Guidelines, which is available on the official HCAHPS website at: *https://www.hcahpsonline.org/en/quality-assurance/*. AHRQ carried out a rigorous scientific process to develop and test the HCAHPS Survey instrument. This process entailed multiple steps, including: a public call for measures; literature reviews; cognitive interviews; consumer focus groups; multiple opportunities for additional stakeholder input; a three-state pilot test; small-scale field tests; and notice-and-comment rulemaking. The CBE first endorsed the HCAHPS Survey in 2005,[605] and re-endorsed the measure in 2010, 2015, and 2019.[606]

In 2021, we conducted a large-scale mode experiment to test adding the web mode and other updates to the form, manner, and timing of HCAHPS Survey data collection and reporting. The 2021 mode experiment employed a nationwide random sample of short-term acute care hospitals that participate in the HCAHPS Survey, including those from each of CMS's 10 geographic regions. Participating hospitals contributed patients discharged from April through September 2021. Within each hospital, patients were randomly assigned to each mode of survey administration. In total, we received responses to a revised version of the HCAHPS Survey from 36,001 patients in 46 hospitals. The design of the experiment was of sufficient scale to test survey items on new topics, revisions to existing survey items, and new and revised composite measures. It also enabled precise estimation of mode adjustments for current and new HCAHPS items for

[603] We refer readers to the CY 2019 OPPS/ASC final rule (83 FR 59140 through 59149), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38328 through 38342, 38398), and to the official HCAHPS website at: *https://www.hcahpsonline.org* for details on HCAHPS requirements.

[604] *Ibid.*

[605] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalHCAHPS.*

[606] CMS. Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS). Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=91&sectionNumber=1.*

three currently approved HCAHPS Survey mode protocols and an additional three web-based protocols. This mode experiment was designed to have the power and precision of adjustment estimates comparable to those that are used and have proven necessary for adjustment of previous HCAHPS data.

The 2021 HCAHPS mode experiment had four main goals: (1) test the large-scale feasibility of web-first sequential multimode survey administrations in an inpatient setting; (2) investigate whether mode effects significantly differ between individuals with email addresses available to the data collection vendor compared to individuals without email addresses available to the vendor; (3) develop mode adjustments to be used in future national implementation; and (4) test potential new survey items. This experiment included three currently approved mode protocols most commonly used by hospitals participating in HCAHPS: Mail Only, Phone Only, and Mail-Phone (mail with phone follow-up of non-responders). In this experiment, three additional mode protocols that added an initial Web phase to these current modes were considered: Web-Mail, Web-Phone, and Web-Mail-Phone. In addition, the mode experiment employed a 49-day data collection period for all six modes, which extended the standard HCAHPS data collection period by seven days. Doing so preserved the survey response period of the current survey while adding time for the Web phase. Unlike the current HCAHPS Survey, proxy respondents were not prohibited from completing the survey.

Another goal of the 2021 HCAHPS mode experiment was to test new survey content related to care coordination, discharge experience, communication with patients' families, emotional support, sleep, and summoning help. We are using the mode experiment results to inform decisions about potential changes to administration protocols and survey content. Potential measure changes will be submitted to the MUC List in 2023 and may be proposed in future rulemaking. We did not propose changes to the HCAHPS Survey's content in this rule.

(b) Addition of Three New Modes of Survey Implementation

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27113), we proposed to add three new modes of survey administration (Web-Mail mode, Web-Phone mode, and Web-Mail-Phone mode) in addition to the current Mail Only, Phone Only, and Mail-Phone modes, beginning with January 2025 discharges. We proposed this update because in the 2021 HCAHPS mode experiment, adding an initial web component to three current HCAHPS modes of survey administration resulted in increased response rates. Overall, 9,642 patients completed a survey, resulting in a 28 percent response rate. The response rate for Mail Only mode was 22 percent, compared to 29 percent for Web-Mail mode. The response rate for Phone Only mode was 23 percent, compared to 30 percent for Web-Phone mode. The response rate for Mail-Phone was 31 percent compared to 36 percent for Web-Mail-Phone mode.

Analysis of 2021 mode experiment data also revealed that patients who supplied an email address had a statistically significant higher response rate (31 percent) than patients without an email address (22 percent). The percentage of sampled patients with an email address varied by hospital, ranging from 11 percent to 94 percent. Overall 63 percent of patients supplied an email address. Evidence from this and previous HCAHPS mode experiments indicate that sequential mixed modes of survey administration (for example, web followed by mail, or phone, or both) result in overall higher response rates and better representation of younger, Spanish language-preferring, racial and ethnic minority, and maternity care patients.

We invited public comment on this proposed update.

Comment: Many commenters expressed their support for the addition of three new modes of survey implementation and stated their belief that the additional modes of survey implementation would likely increase survey response rates. A few commenters believed that new modes of survey implementation would increase participation from more diverse and underserved patient populations. A commenter believed that the additional modes of survey implementation would streamline data collection and reduce the data management burden. Another commenter believed that the new modes of survey implementation will be more cost effective in the long run. A commenter recommended considering sending a second email survey to non-respondents.

Response: We thank the commenters for their support and agree that the addition of these three new modes of survey implementation will likely increase response rates for all patient populations. We also agree that these new modes of survey implementation have the potential to reduce the data collection and management burden while reducing survey administration costs in the long run. We will send a second and third email invitation in the Web-Mail and Web-Phone modes, and a second email invitation in the Web-Mail-Phone mode, to patients who did not respond to earlier email invitations. We note that procedures for survey administration will be clearly defined in the HCAHPS Quality Assurance Guidelines for all survey administration modes.

Comment: A commenter recommended that CMS ensure comparability of results across modalities and determine if adjustments are needed to ensure accuracy of results.

Response: We thank the commenter for their feedback and remind the commenter that per HCAHPS Quality Assurance Guidelines, all HCAHPS Survey results are adjusted for survey mode and patient-mix prior to public reporting and note that only adjusted results are publicly reported and considered the official HCAHPS results.

Comment: A commenter requested clarification on whether the telephone mode of administration included a text message option and a few commenters recommended that CMS explore the inclusion of text message-based modes of HCAHPS administration.

Response: We thank the commenters for their feedback. While the current telephone administration mode does not include a text message option, we will take these recommendations into consideration for future program years, taking into consideration the Telephone Consumer Protection Act requirements.

Comment: A commenter recommended that non-English translations of HCAHPS be made available for use in the new web modes and that vendors be allowed and encouraged to develop an option within the web survey interface to allow respondents to select their preferred language and choose the survey version that aligns with their language preference.

Response: We thank the commenter for their feedback and would like to note that official HCAHPS Survey translations (English, Spanish, Chinese, Russian, Vietnamese, Portuguese, German, Tagalog, and Arabic) will be available for use in the new modes of implementation.

Comment: A commenter requested clarification on whether the sequence of mixed survey modes would be determined by CMS or whether hospitals would be permitted to choose the sequence of outreach.

Response: We appreciate the commenter's feedback and wish to clarify that much like the original mixed

mode survey which consisted of Mail combined with Telephone follow-up, the sequence for new modes of survey administration will be clearly defined in the HCAHPS Quality Assurance Guidelines which are updated regularly and can be found online at *https://www.hcahpsonline.org/en/quality-assurance/*.

After consideration of the public comments we received, we are finalizing this policy as proposed.

(c) Removal of Prohibition of Proxy Respondents to the HCAHPS Survey

In response to stakeholder feedback, and evidence that proxy response does occur in mail administration despite the current protocol that asks that only the patient complete the survey, the mode experiment assessed the impact of not excluding proxy respondents. We found that not excluding proxies did not impact HCAHPS measure scores and as such it is not necessary to control for completion of the survey by a proxy in patient-mix adjustment. Consequently, we proposed to remove the requirement that only the patient may respond to the survey and thus allow a patient's proxy to respond to the survey, beginning with January 2025 discharges. We will, however, still encourage patients to respond to the survey rather than proxies.

We invited public comment on this update.

Comment: Many commenters supported removing the prohibition of proxy respondents to the HCAHPS Survey. Many commenters expressed their belief that this change would increase the overall response rate and several commenters noted that they believed the change would widen the diversity of experiences in responses.

Response: We thank the commenters for their support.

Comment: A commenter recommended that the new survey modes be implemented for one to two years to measure changes in response rates prior to removing the prohibition on proxy respondents.

Response: We thank the commenter for this recommendation and would refer readers to the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27112 through 72113) which discusses the 2021 Mode Experiment upon which our proposed changes were based. This experiment included the addition of the new survey modes while simultaneously removing the prohibition on proxy respondents and found that not excluding proxies did not impact HCAHPS measure scores and as such it is not necessary to control for completion of the survey by a proxy.

Comment: A commenter suggested that we report the results of the changes and their effects on HCAHPS survey completion rates.

Response: We agree with the commenter suggesting that we continue reporting on HCAHPS completion rates and look forward to publishing additional information on the survey's details in the future.

After consideration of the public comments we received, we are finalizing this policy as proposed.

(d) Extension of the Data Collection Period

The 2021 mode experiment showed that extending the data collection period from 42 to 49 days allows time for respondents in the web-first modes to respond by email before contacting non-responders with the secondary mode of administration while still preserving adequate time for the secondary mode (either mail, phone, or mail followed by phone). Nearly 13 percent of respondents in the mode experiment completed the survey between days 43 and 49. Compared to the first 42 days, during days 43 to 49 there was a statistically significant increase in responses from patients who are typically under-represented in HCAHPS, including patients who speak Spanish at home, are Black, 25 to 34 years old, and with an 8th grade education or less. We therefore proposed to extend the data collection period for the HCAHPS Survey from 42 to 49 days, beginning with January 2025 discharges.

We invited public comment on the proposed change in the length of the data collection period.

Comment: Many commenters supported the proposed extension of the data collection period. Several commenters expressed their belief that the extension of the data collection period will likely increase overall response rates.

Response: We thank the commenters for their support and agree that the extended collection period will likely increase overall response rates.

Comment: A few commenters did not support our proposal to extend the data collection period, expressing concern that recall bias is already an issue with the current data collection period. A commenter suggested that we shorten the data collection period to address this challenge and expressed concern about the quality of responses that may be collected and whether those responses are fully reflective of patients' actual experience. Another commenter recommended CMS allow hospitals to administer surveys as soon as a patient is discharged.

Response: We understand and appreciate the commenters' concerns. Recall bias is a legitimate concern with survey responses, and we will continue to monitor results for potential recall bias effects, however, the benefits of extending the HCAHPS data collection period outweigh these concerns. Extending the data collection period will not delay the administration of the HCAHPS Survey, which may begin as soon as 48 hours after discharge. The proposed change will allow for more time for responses to be received. Through patient-mix adjustment we will continue to control for response percentile, which adjusts for when during the data collection period the respondent completes the survey. The 2021 Mode Experiment upon which our proposed changes were based demonstrated that within the extended period, there was a statistically significant increase in responses specifically in groups that are typically underrepresented in HCAHPS and the increased representation among these populations will improve the extent to which HCAHPS results are reflective of the entire patient population experience.

We thank the commenter for their recommendation to allow hospitals to immediately administer surveys upon patient discharge however we refer readers to the HCAHPS Quality Assurance Guidelines which outlines that the delay in allowing hospitals to administer the surveys is designed to ensure patients have time to return home and feel settled after a hospital stay prior to being contacted by the HCAHPS administrator.

Comment: A commenter recommended that we delay extension of data collection period until CMS can first measure success of the new collection modes.

Response: We thank the commenter for this recommendation and refer readers to the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27112 through 27113) which discusses the 2021 Mode Experiment upon which our proposed changes were based. This experiment included the addition of the new survey modes while simultaneously extending the data collection period and resulted in a statistically significant increase in responses from patients who are typically under-represented in HCAHPS.

Comment: A commenter expressed concern that the extended data collection period would impact timelines for preview and publication of stars data.

Response: We appreciate the commenter's concern, however we do not anticipate that the extension of the reporting period will result in a delay in the release of star ratings data.

After consideration of the public comments we received, we are finalizing this policy as proposed.

(e) Limit on the Number of Supplemental HCAHPS Survey Items

Currently, we do not place a limit on the number of supplemental items that may be added to the HCAHPS Survey for quality improvement purposes. We are concerned that this policy has contributed to decline in the survey's response rate. Other CMS CAHPS surveys limit the number of supplemental items that may be added to prevent the survey from becoming so long that the response rate is negatively impacted. For example, the Medicare Advantage and Prescription Drug Plan (MA & PDP) CAHPS Survey limits the number of supplemental items to a maximum of 12. Evidence from the 2016 HCAHPS mode experiment, as well as from the MA & PDP CAHPS Survey, strongly indicates that survey response rates decrease as the number of supplemental items increases. Analysis of the 2016 HCAHPS mode experiment data revealed that in the Mixed Mode (mail survey with phone follow-up of non-responders), 12 supplemental items would be expected to reduce HCAHPS response rates by 2.7 percentage points. An analysis of data from the MA & PDP CAHPS project found a 2.5 percentage point reduction in response rate associated with 12 supplemental items in Mixed Mode.[607] This is particularly relevant because it includes both mail and phone, the two most commonly used survey modes for HCAHPS. Declines of this magnitude represent a substantial loss in response rate. The proposed limit of 12 supplemental items aligns with other CMS CAHPS surveys.

We invited public comment on our proposal to limit the number of supplemental items. We welcomed suggestions for alternative limits below 12 supplemental items.

Comment: Many commenters supported limiting the number of supplemental survey items and several commenters noted they believe this would improve response rates.

Response: We thank the commenters for their support and agree that limiting supplemental items will likely increase response rates.

Comment: A few commenters did not support the proposal to limit the number supplemental HCAHPS survey items. A commenter requested clarification on the rationale for limiting the number of supplemental items at 12 and another commenter expressed their belief that capping the number of supplemental items at 12 was arbitrary and would not meaningfully affect response rates. A few commenters recommended setting the limit on supplemental items at 15.

Response: We acknowledge the commenters' concerns, and we refer readers to the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27113 through 27114) which outlines the data-based evidence that informed the proposal. This evidence demonstrates that additional supplemental questions reduce response rates and supports the decision to limit supplemental items to 12. Furthermore, the proposed limit of 12 supplemental items aligns with other CMS CAHPS surveys.

Comment: A few commenters expressed concern that specific hospital designations may require incorporation of specific supplemental HCAHPS questions, and a commenter noted that standardized CAHPS surveys include supplemental questions to address specific needs.

Response: We appreciate the commenters' concerns regarding required supplemental HCAHPS questions for hospital designation statuses, and we refer readers to the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27113 through 27114) which outlines the data-based evidence that informed the proposal. This evidence demonstrates that additional supplemental questions reduce response rates. Given the demonstrated decline in response rates as the number of supplemental questions increases, the benefits of limiting the number supplemental questions outweigh the benefits of unlimited supplemental questions. We would also remind readers that hospitals will still be able to select supplemental questions that best align with their hospital's unique needs.

After consideration of the public comments we received, we are finalizing this policy as proposed.

(f) Requirement to Use Official Spanish Translation for Spanish Language-Preferring Patients

We have created official translations of the HCAHPS Survey in eight languages in addition to English order to accommodate patient populations.[608] Hospitals' use of these translations, however, is voluntary. To ensure that all Spanish language-preferring patients, who constitute about four percent of HCAHPS respondents, have the opportunity to receive the Spanish translation of the HCAHPS Survey, we proposed that hospitals be required to collect information about the language that the patient speaks while in the hospital (whether English, Spanish, or another language), and that the official CMS Spanish translation of the HCAHPS Survey be administered to all patients who prefer Spanish, beginning with January 2025 discharges.

We invited public comment on the proposed requirement to administer the survey in Spanish. We also welcomed suggestions for additional translations beyond the existing translations in Spanish, Chinese, Russian, Vietnamese, Portuguese, German, Tagalog, and Arabic.

Comment: Many commenters expressed their support for the requirement to use official Spanish translation for Spanish Language-Preferring patients. Many commenters also expressed the belief that these requirements would improve health equity by allowing more patients an opportunity to provide feedback.

Response: We appreciate the commenters support and agree that these changes will encourage representation from a wider pool of patients in HCAHPS responses.

Comment: Several commenters recommended expanding the number of translations available in the survey. On commenter specifically recommended including the following languages in future HCAHPS language translations: Armenian, Cambodian, Simplified Chinese, Farsi, Hindi, Hmong, Japanese, Korean, and Ilocano. A commenter specifically requested a translation to translation to Haitian Creole and another commenter requested that we ensure that the translated versions of the surveys are fully valid and reliable for all targeted languages.

Response: We thank the commenters for their recommendations regarding future translations of HCAHPS and further validation of existing translated versions and we will take these recommendations into consideration for future program years.

Comment: A commenter recommended that patients should be given the option of Spanish and English versions so that the patient can select

[607] Beckett MK, Elliott MN, Gaillot S, Haas A, Dembosky JW, Giordano LA, Brown J. (2016) ''Establishing limits for supplemental items on a standardized national survey.'' *Public Opinion Quarterly* 80(4): 964–976 DOI: *https://doi.org/10.1093/poq/nfw028.*

[608] HCAHPS Quality Assurance Guidelines V18.0. *https://www.hcahpsonline.org/en/quality-assurance/.*

the version best aligning with their language preferences or those of their proxy.

Response: We refer readers to the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27114) where we proposed that hospitals be required to collect information about patient language preferences. This additional requirement will help to ensure that patients receive the version that best aligns with their language preferences.

Comment: A commenter requested clarification on whether the requirement for hospitals to collect information about the language spoken by patients during their hospital also applies to separate certified Electronic Health Record technology (CEHRT) requirements, and recommended CMS consider this extension.

Response: We wish to clarify that this proposal applied only to the HCAHPS Survey, however, we thank the commenter for their recommendation and will consider this in future program years.

Comment: A commenter recommended the survey administration process be updated to allow for both preferred reading languages and preferred speaking languages as these may differ for some patients.

Response: We thank the commenter for their suggestion and will take this into consideration for future program years. If a hospital collects detailed information about the language a patient prefers to read versus a language a patient prefers to speak, there is nothing in the HCAHPS protocols that would prevent the hospital from sharing this information with their survey vendor.

Comment: A commenter requested clarification on whether HCAHPS survey translations would be available in all survey modes.

Response: We thank the commenter for their concern and wish to clarify that language translations are available in additional modes for some but not all official HCAHPS translations. In the Web-Mail mode, the web survey will be available in all of the languages in which the Mail survey is available. In the Web-Phone mode, the web survey will be available in all of the languages in which the Phone survey is available. We would refer readers to the HCAHPS Quality Assurance Guidelines for further information on which HCAHPS translations are offered for additional survey modes.

After consideration of the public comments we received, we are finalizing this policy as proposed.

(g) Removal of Two Administration Methods

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27114), we proposed to remove two currently available options for administration of the HCAHPS Survey that are not used by participating hospitals. The Active Interactive Voice Response (IVR) survey mode, also known as touch-tone IVR, has not been employed by any hospital since 2016 and has never been widely used for the HCAHPS Survey. To streamline HCAHPS oversight and training, we proposed to discontinue IVR as an approved mode of survey administration beginning in January 2025. With the proposed addition of three new web-based modes in January 2025, hospitals will have the option to choose among six modes of survey administration: Mail Only, Phone Only, Mixed Mode (mail followed by phone), Web-Mail mode, Web-Phone mode, and Web-Mail-Phone mode (web followed by mail, followed by phone).

To streamline HCAHPS oversight and training, we also proposed to discontinue ''Hospitals Administering HCAHPS for Multiple Sites'' as an option for HCAHPS Survey administration beginning in January 2025. The option for a hospital to administer the HCAHPS Survey for other hospitals, known as ''Hospitals Administering HCAHPS for Multiple Sites'', has not been utilized by any hospitals since 2019 and has never been widely used. Hospitals will continue to have two options for HCAHPS Survey administration: either contracting with an approved HCAHPS survey vendor, currently utilized by about 3,112 hospitals (99 percent of IPPS hospitals); or self-administration of the HCAHPS Survey, currently utilized by fewer than 20 IPPS hospitals (less than one percent of IPPS hospitals).

In addition to the previous proposals, we encourage participating hospitals to carefully consider the impact of mode of survey administration on response rates and the representativeness of survey respondents. High response rates for all patient groups promote our health equity goals. Our research on the HCAHPS Survey indicates that there are pronounced differences in response rates by mode of survey administration for some patient characteristics. In particular, Black, Hispanic, Spanish language-preferring, younger, and maternity patients are more likely to respond to a telephone survey, while older patients are more likely to respond to a mail survey. Choosing a mode that is easily accessible to the diversity of a hospital's patient population provides a more complete representation of patients' care experiences. For more information, we refer hospitals to the podcast ''Improving Representativeness of the HCAHPS Survey'' on the HCAHPS website: *https://hcahpsonline.org/en/podcasts/#ImprovingRepresentativeness*.

We invited public comment on the proposed removal of two HCAHPS administration methods.

Comment: Many commenters expressed support for the removal of two HCAHPS administration methods.

Response: We thank the commenters for their support.

Comment: A few commenters recommended that CMS temporarily suspend the Active Interactive Voice Response (IVR) survey mode and conduct further research as to why this mode is not widely utilized rather than permanently remove this mode from HCAHPS.

Response: We thank the commenters for their recommendations. As noted in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27114), the touch-tone IVR survey mode has not been employed by any hospital since 2016. Given the addition of three new survey modes, further assessment of the touch-tone IVR survey mode would not represent a responsible use of resources. Furthermore, the removal of this underutilized survey mode is necessary to streamline HCAHPS oversight and training, and to reduce HCAHPS administration burden.

After consideration of the public comments we received, we are finalizing this policy as proposed.

(h) Data Collection

The HCAHPS Survey will be administered and data collected in exactly the same manner as the current HCAHPS Survey, except for the proposed changes described in this section of this final rule. There will be no changes to HCAHPS patient eligibility or exclusion criteria (we note that the immediately following section includes a request for information regarding patient eligibility). Detailed information on HCAHPS data collection protocols can be found in the current HCAHPS Quality Assurance Guidelines, located at: *https://www.hcahpsonline.org/en/quality-assurance/*.

We invited public comments on these proposals.

Comment: Many commenters expressed their support these proposed changes.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing this policy as proposed.

i. Request for Information on Potential Addition of Patients With a Primary Psychiatric Diagnosis to the HCAHPS Survey Measure

We solicited comments about the inclusion of patients with a primary psychiatric diagnosis in the HCAHPS Survey. The HCAHPS Survey was designed, tested, and validated for patients in the medical, surgical, and maternity service lines of short-term, acute care hospitals. Patients with a primary psychiatric diagnosis are currently not eligible for this survey; patients with a secondary psychiatric diagnosis are currently eligible for the HCAHPS Survey.

We sought public input on the potential inclusion of patients with a primary psychiatric diagnosis who are admitted to short-term, acute care hospitals for the HCAHPS Survey. Specifically, we requested public comment on whether all patients in the psychiatric service line (that is, MS–DRG codes of 876, 880–887, 894–897) or particular sub-groups thereof should be included in the HCAHPS Survey; whether the current content of the HCAHPS Survey is appropriate for these patients; and whether the current HCAHPS Survey measure implementation procedures might face legal barriers or pose legal risks when applied to patients with primary psychiatric diagnoses. The HCAHPS Survey measure instrument can be found at *https://hcahpsonline.org/en/survey-instruments/*. HCAHPS Survey measure implementation procedures can be found in the HCAHPS Quality Assurance Guidelines, V18.0 at *https://hcahpsonline.org/en/quality-assurance/*.

We invited public comments on these topics.

Comment: We received many comments in support of the potential inclusion of patients with a primary psychiatric diagnosis in the HCAHPS Survey. Many of these commenters recommended that we conduct further testing within this population and engage hospitals and other interested parties in technical expert panels before proposing to include this group in the HCAHPS Survey population. Several commenters also recommended that we capture responses from patients with a primary psychiatric diagnosis who receive care in the Emergency Department. A commenter recommended adjusting the minimal sample size to ensure the psychiatric patient population is adequately represented in reporting.

Other commenters did not support the potential inclusion of patients with a primary psychiatric diagnosis in the HCAHPS Survey. Several of these commenters instead recommended that we conduct a separate survey for patients with a primary psychiatric diagnosis that could be used across all care settings. A few commenters highlighted concerns about the ability to reach patients with a primary psychiatric diagnosis for follow-up surveys given higher rates of housing insecurity within this patient population. A few commenters recommended survey administration at discharge for this patient population.

Response: We thank the commenters for their valuable input. We will consider their feedback if we make proposals on this subject in the future.

Comment: A commenter recommended using a separate patient experience survey that addresses psychiatric care rather than the traditional HCAHPS survey.

Response: We also wish to note that currently, the HCAHPS Survey excludes discharged patients with a primary diagnosis code related to psychiatric care (discharged patients who have a secondary diagnosis code related to psychiatric care are included). During the development of the HCAHPS Survey in the early 2000s, the exclusion of discharged patients with a primary diagnosis code related to psychiatric care occurred due to concerns about the sensitivity and privacy of such information and the possible risk of harm to the patient if the primary diagnosis was disclosed during survey administration. Because patients who receive psychiatric inpatient care were excluded from development of the survey, HCAHPS may not fully address aspects of their experiences that are associated with quality care.

The Agency for Healthcare Research and Quality (AHRQ) has funded a patient experience of care survey development project that is exploring issues regarding inpatient care and patients with a primary psychiatric diagnosis. They are exploring issues around patient privacy issues, safety, and differences in state requirements, as well as the relevance of HCAHPS survey items and potential additional items for this population. The research team is following a standardized and rigorous development and testing process, including conducting Technical Expert Panels (TEPs) with relevant stakeholders and field testing. CMS plans to monitor this work closely and use information gleaned from this work to determine the best way to add patients with a primary psychiatric diagnosis to CMS's efforts to evaluate the patient experience of care in the inpatient acute care setting.

j. Data Submission and Reporting Requirements for Structural Measures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51643 and 51644) and the FY 2013 IPPS/LTCH PPS final rule (77 FR 53538 and 53539) for details on the data submission requirements for structural measures. Hospitals are required to submit information for structural measures once annually using a CMS-approved web-based data collection tool available within the HQR System. The data submission period for structural measures begins in April and has the same submission deadline as the fourth calendar quarter chart-abstracted measure deadline. For example, for the FY 2025 payment determination, hospitals will be required to submit the required information between April 1, 2024, and May 15, 2024, with respect to the measure reporting period of January 1, 2023, through December 31, 2023.

We did not propose any changes to these policies in the proposed rule.

k. Data Submission and Reporting Requirements for CDC NHSN Measures

For details on the data submission and reporting requirements for measures reported via the CDC's National Healthcare Safety Network (NHSN), we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51629 through 51633; 51644 and 51645), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50821 and 50822), and the FY 2015 IPPS/LTCH PPS final rule (79 FR 50259 through 50262). The data submission deadlines are posted on the QualityNet website at: *https://qualitynet.cms.gov* (or other successor CMS designated websites).

We did not propose any changes to these policies in the proposed rule.

l. Data Submission and Reporting Requirements for Patient-Reported Outcome-Based Performance Measures (PRO–PMs)

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49246 through 49257), we finalized the adoption of the hospital-level THA/TKA PRO–PM into the Hospital IQR Program measure set. In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49305), we further finalized the reporting and submission requirements for PRO–PM measures as a new type of measure to the Hospital IQR Program (87 FR 49305 through 49308).

We did not propose any changes to these policies in the proposed rule.

11. Validation of Hospital IQR Program Data

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27115 through 27116), we proposed to update our targeting criteria for validation of hospitals granted an extraordinary circumstances exception (ECE). Specifically, we proposed to modify the validation targeting criteria to include any hospital with a two-tailed confidence interval that is less than 75 percent and which submitted less than four quarters of data due to receiving an ECE for one or more quarters, beginning with the FY 2027 payment determination.

a. Background

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53539 through 53553), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50822 through 50835), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50262 through 50273), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49710 through 49712), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57173 through 57181), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38398 through 38403), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41607 and 41608), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42509), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58942 through 58953), the FY 2022 IPPS/LTCH PPS final rule (86 FR 45423 through 45426), and the FY 2023 IPPS/LTCH PPS final rule (87 FR 49308 through 49310) for detailed information on and previous changes to chart-abstracted and eCQM data validation requirements for the Hospital IQR Program.

In the FY 2021 IPPS/LTCH PPS final rule, we combined the validation processes for eCQMs and chart-abstracted measures. In that rule, we adopted a policy to remove the separate process for eCQM validation, beginning with the validation affecting the FY 2024 payment determination (for validation commencing in CY 2022 using data from the CY 2021 reporting period) (85 FR 58942 through 58953). Beginning with validation affecting the FY 2024 payment determination and subsequent years, we finalized a policy to incorporate eCQMs into the existing validation process for chart-abstracted measures such that there will be one pool of hospitals selected through random selection and one pool of hospitals selected using targeting criteria, for both chart-abstracted measures and eCQMs (85 FR 58942 through 58953). Under the aligned validation process, a single hospital could be selected for validation of both eCQMs and chart-abstracted measures and is expected to submit data for both chart-abstracted measures and eCQMs (85 FR 58942 through 58953). We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57179 and 57180) for details on the Hospital IQR Program data submission requirements for chart-abstracted measures.

We select a random sample of up to 200 hospitals for validation purposes, and select up to 200 additional hospitals for validation purposes based on the following targeting criteria:

- Any hospital with abnormal or conflicting data patterns. One example of an abnormal data pattern would be if a hospital has extremely high or extremely low values for a particular measure. As described in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53552), we define an extremely high or low value as one that falls more than three standard deviations from the mean which is consistent with the Hospital Outpatient Quality Reporting (OQR) Program (76 FR 74485). An example of a conflicting data pattern would be if two records were identified for the same patient episode of care but the data elements were mismatched for primary diagnosis. Primary diagnosis is just one of many fields that should remain constant across measure sets for an episode of care. Other examples of fields that should remain constant across measure sets are patient age and sex. Any hospital not included in the base validation annual sample and with statistically significantly more abnormal or conflicting data patterns per record than would be expected based on chance alone ($p < .05$), would be included in the population of hospitals targeted in the supplemental sample.
- Any hospital with rapidly changing data patterns. For this targeting criterion, we define a rapidly changing data pattern as a hospital which improves its quality for one or more measure sets by more than two standard deviations from one year to the next and has a statistically significant difference in improvement (one-tailed $p < .05$) (77 FR 53553).
- Any hospital that submits data to NHSN after the Hospital IQR Program data submission deadline has passed.
- Any hospital that joined the Hospital IQR Program within the previous three years, and which has not been previously validated.
- Any hospital that has not been randomly selected for validation in any of the previous three years.
- Any hospital that passed validation in the previous year, but had a two-tailed confidence interval that included 75 percent.
- Any hospital which failed to report to NHSN at least half of actual HAI events detected as determined during the previous year's validation effort.

b. Addition of Targeting Criterion for Validation

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27115 through 27116), beginning with validations of CY 2024 reporting period data for the FY 2027 payment determination, we proposed to add a new criterion to the six established targeting criteria used to select up to 200 additional hospitals for validation. We proposed that a hospital with less than four quarters of data subject to validation due to receiving an ECE for one or more quarters and with a two-tailed confidence interval that is less than 75 percent would be targeted for validation in the subsequent validation year. These hospitals would not fail the validation-related requirements for the Annual Payment Update (APU) determination for the payment year for which an ECE provides hospitals with an exception from data reporting or validation requirements. These hospitals could be selected for validation in the following year. We proposed this additional criterion because such a hospital would have less than four quarters of data available for validation and its validation results could be considered inconclusive for a payment determination. Hospitals that meet this criterion will be required to submit medical records to the CDAC contractor within 30 days of the date identified on the written request as finalized in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57179 and 57180).

It is important to clarify that, consistent with our previously finalized policy, a hospital is subject to both payment reduction and targeting for validation in the subsequent year if it either: (a) has less than four quarters of data, but does not have an ECE for one

more or more quarters and does not meet the 75 percent threshold; or (b) has four quarters of data subject to validation and does not meet the 75 percent threshold (77 FR 53539 through 53553).

Specifically, we proposed to add the following criterion for targeting up to 200 additional hospitals for validation:

- Any hospital with a two-tailed confidence interval that is less than 75 percent, and that had less than four quarters of data due to receiving an ECE for one or more quarters.

Our proposal was intended to allow us to appropriately address instances in which hospitals that submit fewer than four quarters of data due to receiving an ECE for one or more quarters might face payment reduction under the current validation policies. This proposal was also to align targeting criteria across the Hospital IQR and Hospital OQR Programs. In the CY 2023 OPPS/ASC final rule, we finalized the addition of this criterion to the Hospital OQR Program's targeting criteria for validation selection beginning with validations affecting the CY 2023 reporting period/CY 2025 payment determination (87 FR 72115 and 72116).

We invited public comment on our proposal.

Comment: A few commenters supported the proposed update to the targeting criterion.

Response: We thank commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal as proposed.

12. Data Accuracy and Completeness Acknowledgement (DACA) Requirements

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554) for previously adopted details on DACA requirements.

We did not propose any changes to this policy in the proposed rule.

13. Public Display Requirements

Section 1886(b)(3)(B)(viii)(VII) of the Act requires the Secretary to report quality measures of process, structure, outcome, patients' perspectives on care, efficiency, and costs of care that relate to services furnished in inpatient settings in hospitals on the internet website of CMS. Section 1886(b)(3)(B)(viii)(VII) of the Act also requires that the Secretary establish procedures for making information regarding measures available to the public after ensuring that a hospital has the opportunity to review its data before they are made public. Our current policy is to report data from the Hospital IQR Program as soon as it is feasible on CMS websites such as the Compare tool hosted by HHS, currently available at: *https://www.medicare.gov/care-compare*, or its successor website, after a 30-day preview period (78 FR 50776 through 50778). We refer readers to the FY 2008 IPPS/LTCH PPS final rule (72 FR 47364), the FY 2011 IPPS/LTCH PPS final rule (75 FR 50230), the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650), the FY 2013 IPPS/LTCH PPS final rule (77 FR 53554), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49712 and 49713), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57181), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38403 through 38409), the FY 2019 IPPS/LTCH PPS final rule (83 FR 41538 and 41539), the FY 2020 IPPS/LTCH PPS final rule (84 FR 42509), the FY 2021 IPPS/LTCH PPS final rule (85 FR 58953), the FY 2022 IPPS/LTCH PPS final rule (86 FR 45426), and the FY 2023 IPPS/LTCH PPS final rule (87 FR 49310) for details on public display requirements.

We did not propose any changes to these policies in the proposed rule.

a. Public Reporting of eCQM Data

We refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58953 through 58959) where we finalized public reporting requirements of eCQM data reported by hospitals for the CY 2021 reporting period/FY 2023 payment determination and for subsequent years.

In the FY 2023 IPPS/LTCH PPS final rule, we finalized policies that further incrementally increases eCQM data that is publicly reported from four to six eCQMs for the CY 2024 reporting period/FY 2026 payment determination and subsequent years (87 FR 49298 through 49302). We refer readers to section IX.C.10.e. of the proposed rule (88 FR 27110 through 27112) for a discussion of our previously finalized eCQM reporting and submission policies.

We did not propose any changes to these policies in the proposed rule.

b. Overall Hospital Star Ratings

In the CY 2021 OPPS/ASC final rule with comment period and interim final rule with comment period (85 FR 86193 through 86236), we finalized a methodology to calculate the Overall Hospital Quality Star Rating (Overall Star Ratings). The Overall Star Ratings utilizes data collected on hospital inpatient and outpatient measures that are publicly reported on a CMS website, including data from the Hospital IQR Program. We refer readers to section XVI. of the CY 2021 OPPS/ASC final rule with comment period for details (85 FR 86193 through 86236).

We did not propose any changes to these policies in the proposed rule.

14. Reconsideration and Appeal Procedures

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51650 and 51651), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836), and 42 CFR 412.140(e) for details on reconsideration and appeal procedures for the FY 2017 payment determination and subsequent years.

We did not propose any changes to these policies in the proposed rule.

15. Hospital IQR Program Extraordinary Circumstances Exceptions (ECE) Policy

We refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51651 and 51652), the FY 2014 IPPS/LTCH PPS final rule (78 FR 50836 and 50837), the FY 2015 IPPS/LTCH PPS final rule (79 FR 50277), the FY 2016 IPPS/LTCH PPS final rule (80 FR 49713), the FY 2017 IPPS/LTCH PPS final rule (81 FR 57181 and 57182), the FY 2018 IPPS/LTCH PPS final rule (82 FR 38409 through 38411), and 42 CFR 412.140(c)(2) for details on the current Hospital IQR Program ECE policy. We also refer readers to the QualityNet website at: *https://qualitynet.cms.gov* for our current requirements for submission of a request for an exception.

We did not propose any changes to these policies in the proposed rule.

D. Updates to the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

1. Background

The PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program is authorized by section 1866(k) of the Act and applies to hospitals described in section 1886(d)(1)(B)(v) (referred to as ''PPS-Exempt Cancer Hospitals'' or ''PCHs''). For additional background information, including previously finalized measures and other policies for the PCHQR Program, we refer readers to the following final rules:

- The FY 2013 IPPS/LTCH PPS final rule (77 FR 53555 through 53567);
- The FY 2014 IPPS/LTCH PPS final rule (78 FR 50837 through 50853);
- The FY 2015 IPPS/LTCH PPS final rule (79 FR 50277 through 50286);
- The FY 2016 IPPS/LTCH PPS final rule (80 FR 49713 through 49723);
- The FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57193);
- The FY 2018 IPPS/LTCH PPS final rule (82 FR 38411 through 38425);

- The FY 2019 IPPS/LTCH PPS final rule (83 FR 41609 through 41624);
- The CY 2019 OPPS/ASC final rule with comment period (83 FR 59149 through 59154);
- The FY 2020 IPPS/LTCH PPS final rule (84 FR 42509 through 42524);
- The FY 2021 IPPS/LTCH PPS final rule (85 FR 58959 through 58966);
- The FY 2022 IPPS/LTCH PPS final rule (86 FR 45426 through 45437); and
- The FY 2023 IPPS/LTCH PPS final rule (87 FR 49311 through 49314).

We also refer readers to 42 CFR 412.23(f) and 412.24 for the PCHQR Program regulations.

2. Measure Retention and Removal Factors for the PCHQR Program

For a detailed discussion regarding our retention and removal factors, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57182 through 57183), where we adopted policies for measure retention and removal, the FY 2019 IPPS/LTCH PPS final rule (83 FR 41609 through 41611), where we updated our measure removal factors, and the FY 2023 IPPS/LTCH PPS final rule (87 FR 49311), where we updated our measure removal policy. We did not propose any changes to our measure removal or retention policies.

We proposed to adopt four new measures for the PCHQR Program: (i) three health equity-focused measures: the Facility Commitment to Health Equity measure, the Screening for Social Drivers of Health measure, and the Screen Positive Rate for Social Drivers of Health measure; and (ii) a patient preference-focused measure, the Documentation of Goals of Care Discussions Among Cancer Patients measure (88 FR 27117 through 27121, 27122 through 27128, 27128 through 27130). We also referred readers to the proposed modifications of the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure in the PCHQR, Hospital Inpatient Quality Reporting, and Long-Term Care Hospital Quality Reporting Programs and refer readers to section IX.B. of this final rule.

3. Adoption of the Facility Commitment to Health Equity Measure Beginning With the FY 2026 Program Year

a. Background

Significant and persistent disparities in healthcare outcomes exist in the U.S. For example, belonging to a racial or ethnic minority group, being a member of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community, being a member of a religious minority, living in a rural area, being a person with a disability or disabilities, or being near or below the poverty level, is often associated with worse health outcomes.[609] [610] [611] [612] [613] [614] [615] [616] [617] [618] Numerous studies have shown that among Medicare beneficiaries, individuals who are racial and ethnic minorities often receive lower quality hospital care, report lower experiences of care, and experience more frequent hospital readmissions and procedural complications.[619] [620] [621] [622] [623] [624] Readmission rates in the Hospital Readmissions Reduction Program have shown to be higher among Black and Hispanic Medicare beneficiaries with common conditions, including congestive heart failure and acute myocardial infarction.[625] [626] [627] [628] [629] Data indicate that, even after accounting for factors such as socioeconomic conditions, members of racial and ethnic minority groups reported experiencing lower quality healthcare.[630] Evidence of differences in quality of care received by people from racial and ethnic minority groups show worse health outcomes, including a higher incidence of diabetes complications such as retinopathy.[631] Additionally, inequities in the drivers of health affecting these groups, such as

[609] Joynt KE, Orav E, Jha AK. (2011). Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. *JAMA,* 305(7), 675–681. Available at: doi:10.1001/jama.2011.123.

[610] Lindenauer PK, Lagu T, Rothberg MB, et al. (2013). Income Inequality and thirty-Day Outcomes After Acute Myocardial Infarction, Heart Failure, and Pneumonia: Retrospective Cohort Study. *BMJ,* 346. Available at: *https://doi.org/10.1136/bmj.f521.*

[611] Trivedi AN, Nsa W, Hausmann LRM, et al. (2014). Quality and Equity of Care in U.S. Hospitals. *N Engl J Med,* 371(24), 2298–2308. Available at: doi: 10.1056/NEJMsa1405003.

[612] Polyakova, M, Udalova V, Kocks, G, Genadek K, Finlay K, Finkelstein AN. (2021). Racial Disparities In Excess All-Cause Mortality During The Early COVID–19 Pandemic Varied Substantially Across States. *Health Affairs,* 40(2), 307–316. Available at: *https://doi.org/10.1377/hlthaff.2020.02142.*

[613] Rural Health Research Gateway. (2018). Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. Available at: *https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf.*

[614] HHS Office of Minority Health. (2020). Progress Report to Congress, 2020 Update on the Action Plan to Reduce Racial and Ethnic Health Disparities. Department of Health and Human Services. Available at: *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf.*

[615] Heslin KC, Hall JE. (2021). Sexual Orientation Disparities in Risk Factors for Adverse COVID–19-Related Outcomes, by Race/Ethnicity—Behavioral Risk Factor Surveillance System, United States, 2017–2019. MMWR Morb Mortal Wkly Rep, 70(5), 149. doi: 10.15585/mmwr.mm7005a1.

[616] Poteat TC, Reisner SL, Miller M, Wirtz AL. (2020). COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. medRxiv. doi: 10.1101/2020.07.21.20159327.

[617] Vu M, Azmat A, Radejko T, Padela AI. (2016). Predictors of Delayed Healthcare Seeking Among American Muslim Women. *Journal of Women's Health,* 25(6), 586–593. doi: 10.1089/jwh.2015.5517.

[618] Nadimpalli SB, Cleland CM, Hutchinson MK, Islam N, Barnes LL, Van Devanter N. (2016). The Association Between Discrimination and the Health of Sikh Asian Indians. *Health Psychology,* 35(4), 351–355. *https://doi.org/10.1037/hea0000268.*

[619] CMS Office of Minority Health. (2020). Racial, Ethnic, and Gender Disparities in Healthcare in Medicare Advantage. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/files/document/2020-national-level-results-race-ethnicity-and-gender-pdf.pdf.*

[620] CMS Office of Minority Health. (Updated August 2018). Guide to Reducing Disparities in Readmissions. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[621] Singh JA, Lu X, Rosenthal GE, Ibrahim S, Cram P. (2014). Racial Disparities in Knee and Hip Total Joint Arthroplasty: An 18-year analysis of national Medicare data. Ann Rheum Dis., 73(12), 2107–15. Available at: doi:10.1136/annrheumdis-2013–203494.

[622] Rivera-Hernandez M, Rahman M, Mor V, Trivedi AN. (2019). Racial Disparities in Readmission Rates among Patients Discharged to Skilled Nursing Facilities. J Am Geriatr Soc., 67(8), 1672–1679. Available at: *https://doi.org/10.1111/jgs.15960.*

[623] Joynt KE, Orav E, Jha AK. (2011). Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA, 305(7), 675–681. Available at: doi:10.1001/jama.2011.123.

[624] Tsai TC, Orav EJ, Joynt KE. (2014). Disparities in Surgical 30-day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. Ann Surg., 259(6), 1086–1090. Available at: doi: 10.1097/SLA.0000000000000326.

[625] Rodriguez F, Joynt KE, Lopez L, Saldana F, Jha AK. (2011). Readmission Rates for Hispanic Medicare Beneficiaries with Heart Failure and Acute Myocardial Infarction. Am Heart J., 162(2), 254–261 e253. Available at: *https://doi.org/10.1016/j.ahj.2011.05.009.*

[626] Centers for Medicare & Medicaid Services. (2014) Medicare Hospital Quality Chartbook: Performance Report on Outcome Measures. Available at: *https://www.hhs.gov/guidance/document/medicare-hospital-quality-chartbook-performance-report-outcome-measures.*

[627] CMS Office of Minority Health. (Updated August 2018) Guide to Reducing Disparities in Readmissions. Baltimore, MD: Centers for Medicare & Medicaid Services. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/OMH_Readmissions_Guide.pdf.*

[628] Prieto-Centurion V, Gussin HA, Rolle AJ, Krishnan JA. (2013). Chronic Obstructive Pulmonary Disease Readmissions at Minority Serving Institutions. Ann Am Thorac Soc., 10(6), 680–684. Available at: *https://doi.org/10.1513/AnnalsATS.201307-223OT.*

[629] Joynt KE, Orav E, Jha AK. (2011). Thirty-Day Readmission Rates for Medicare Beneficiaries by Race and Site of Care. JAMA, 305(7), 675–681. Available at: doi:10.1001/jama.2011.123.

[630] Nelson AR. (2003). Unequal Treatment: Report of the Institute of Medicine on Racial and Ethnic Disparities in Healthcare. The Annals of thoracic surgery, 76(4), S1377–S1381. doi: 10.1016/s0003–4975(03)01205–0.

[631] Peek, ME, Odoms-Young, A, Quinn, MT, Gorawara-Bhat, R, Wilson, SC, & Chin, MH. (2010). Race and Shared Decision-Making: Perspectives of African-Americans with diabetes. Social Science & Medicine, 71(1), 1–9. Available at: doi:10.1016/j.socscimed.2010.03.014.

poverty and healthcare access, are interrelated and influence a wide range of health and quality-of-life outcomes and risks.[632]

In the FY 2022 IPPS/LTCH PPS proposed rule (86 FR 25601), the PCHQR Program requested information on our Equity Plan for Improving Quality in Medicare, which outlines our commitment to improved data collection to better measure and analyze disparities across programs and policies in order to close equity gaps. The request for information asked for public comment regarding the potential stratification of quality measure results by race and ethnicity and the potential creation of a hospital equity score in CMS quality reporting and value-based purchasing programs, including the PCHQR Program.

Additionally, we note that the Agency for Healthcare Research and Quality (AHRQ) and The Joint Commission identified that hospital leadership plays an important role in promoting a culture of quality and safety.[633] [634] [635] AHRQ research shows that hospital boards can influence quality and safety in a variety of ways; not only through strategic initiatives, but also through more direct interactions with frontline workers.[636] Because we are working toward the goal of all patients receiving high-quality healthcare, regardless of individual characteristics, we are committed to supporting healthcare organizations in building a culture of safety *and* equity that focuses on educating and empowering their workforce to recognize and eliminate health disparities. This includes patients receiving the right care, at the right time, in the right setting for their condition(s), regardless of those characteristics.

In alignment with the same measures adopted for the Hospital IQR Program, we believe that strong and committed leadership from PCH executives and board members is essential and can play a role in shifting organizational culture and advancing equity goals for PCHs. Studies demonstrate that hospital leadership can positively influence culture for better quality, patient outcomes, and experience of care.[637] [638] [639] A systematic review of 122 published studies showed that strong leadership that prioritized safety, quality, and the setting of clear guidance with measurable goals for improvement resulted in a high-performing hospital with better patient outcomes.[640] We believe leadership commitment to health equity will have a parallel effect in contributing to a reduction in health disparities.

The Institute for Healthcare Improvement's (IHI's) research of 23 health systems throughout the U.S. and Canada also shows that health equity must be a priority championed by leadership teams to improve both patient access to needed healthcare services and outcomes among populations that have been disadvantaged by the healthcare system.[641] This IHI study specifically identified concrete actions to make advancing health equity a core strategy, including establishing this goal as a leader-driven priority alongside organizational development structures and processes.[642] Based upon these findings, we believe that PCH leadership can be instrumental in setting specific, measurable, attainable, realistic, and time-based (SMART) goals to assess progress towards achieving equity goals and ensuring high-quality care is accessible to all. Therefore, we proposed to adopt an attestation-based structural measure, Facility Commitment to Health Equity, beginning with the FY 2026 program.

The first pillar of our strategic priorities[643] reflects our deep commitment to improvements in health equity by addressing the health disparities that underly our health system. In line with this strategic pillar, we developed this structural measure to assess facility commitment to health equity across five domains (see Table IX.D–01) using a suite of organizational competencies aimed at achieving health equity for racial and ethnic minority groups, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. We believe these elements are actionable focus areas and assessment of PCH leadership commitment to them is foundational.

We also believe this measure will incentivize PCHs to collect and utilize data to identify critical equity gaps, implement plans to address said gaps, and ensure that resources are dedicated toward addressing health equity initiatives. While many factors contribute to achieving health equity, we believe this measure is an important step toward assessing PCH leadership commitment, and a fundamental step toward closing the gap in equitable care for all populations. We note that this measure is not intended to encourage PCHs to act on any one data element or domain, but instead encourages PCHs to analyze their own findings to understand if there are any demographic factors (for example, race, national origin, primary language, and ethnicity), as well as social determinant of health information (for example, housing status and food security) associated with underlying inequities; and, in turn, develop solutions to deliver more equitable care. Thus, the measure aims to support PCHs in leveraging available data, pursuing focused quality improvement activities, and promoting efficient and effective use of resources.

The five questions of the structural measure are adapted from the CMS Office of Minority Health's Building an

[632] Department of Health and Human Services. (2021) Healthy People 2020: Disparities. Available at: *www.healthypeople.gov/2020/about/foundation-health-measures/Disparities*.

[633] Agency for Healthcare Research and Quality. Leadership Role in Improving Patient Safety. Patient Safety Primer, September 2019. Available at: *https://psnet.ahrq.gov/primer/leadership-role-improving-safety*.

[634] Joint Commission on Accreditation of Healthcare Organizations, USA. The essential role of leadership in developing a safety culture. Sentinel Event Alert. 2017 (Revised June 2021). Available at: *https://www.jointcommission.org/-/media/tjc/documents/resources/patient-safety-topics/sentinel-event/sea-57-safety-culture-and-leadership-final2.pdf*.

[635] See information on launch of new ''Health Care Equity Certification'' in July 2023 from Joint Commission on Accreditation of Healthcare Organizations, USA, available at: *https://www.jointcommission.org/our-priorities/health-care-equity/health-care-equity-prepublication/*.

[636] Agency for Healthcare Research and Quality. Leadership Role in Improving Patient Safety. Patient Safety Primer, September 2019: Available at: *https://psnet.ahrq.gov/primer/leadership-role-improving-safety*.

[637] Bradley EH, Brewster AL, McNatt Z, et al. (2018) How Guiding Coalitions Promote Positive Culture Change in Hospitals: A Longitudinal Mixed Methods Interventional Study. BMJ Qual Saf., 27(3), 218–225. doi:10.1136/bmjqs-2017–006574.

[638] Smith SA, Yount N, Sorra J. (2017). Exploring Relationships Between Hospital Patient Safety Culture and Consumer Reports Safety Scores. BMC Health Services Research, 17(1), 143. doi:10.1186/s12913–017–2078–6.

[639] Keroack MA, Youngberg BJ, Cerese JL, Krsek C, Prellwitz LW, Trevelyan EW. (2007). Organizational Factors Associated with High Performance in Quality and Safety in Academic Medical Centers. Acad Med., 82(12), 1178–86. doi: 10.1097/ACM.0b013e318159e1ff.

[640] Millar R, Mannion R, Freeman T, et al. (2013). Hospital Board Oversight of Quality and Patient Safety: A Narrative Review and Synthesis of Recent Empirical Research. The Milbank quarterly, 91(4), 738–70. doi:10.1111/1468–0009.12032.

[641] Mate KS and Wyatt R. (2017). Health Equity Must Be a Strategic Priority. NEJM Catalyst. Available at: *https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0556*.

[642] Mate KS and Wyatt R. (2017). Health Equity Must Be a Strategic Priority. NEJM Catalyst. Available at: *https://catalyst.nejm.org/doi/full/10.1056/CAT.17.0556*.

[643] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Centers for Medicare & Medicaid. Available at: *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms*. Also see *https://www.cms.gov/cms-strategic-plan*.

Organizational Response to Health Disparities framework, which focuses on data collection, data analysis, culture of equity, and quality improvement.[644] The measure aligns with the measure previously adopted in the Hospital IQR Program, and we refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49191 through 49201). This measure also aligns with our efforts under the Meaningful Measures Framework, which identifies high-priority areas for quality measurement and improvement to assess core issues most critical to high-quality healthcare and improving patient outcomes.[645] In 2021, we launched Meaningful Measures 2.0 to promote innovation and modernization of all aspects of quality, and to address a wide variety of settings, stakeholders, and measure requirements.[646] We are addressing healthcare priorities and gaps with Meaningful Measures 2.0 by leveraging quality measures to promote equity and close gaps in care. The Facility Commitment to Health Equity measure supports these efforts and is aligned with the Meaningful Measures Area of ''Equity of Care'' and the Meaningful Measures 2.0 goal to ''Leverage Quality Measures to Promote Equity and Close Gaps in Care.'' This measure also supports the Meaningful Measures 2.0 objective to ''Commit to a patient-centered approach in quality measure and value-based incentives programs to ensure that quality and safety measures address healthcare equity.''

[644] Centers for Medicare & Medicaid Services. (2021) Building an Organizational Response to Health Disparities [Fact Sheet]. U.S. Department of Health and Human Services. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Health-Disparities-Guide.pdf.*

[645] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.*

[646] Centers for Medicare & Medicaid Services. (2021) Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization.*

b. Overview of Measure

The Facility Commitment to Health Equity measure assesses PCH commitment to health equity using a suite of equity-focused organizational competencies aimed at achieving health equity for populations that have been disadvantaged, marginalized, and underserved by the healthcare system. As previously noted, this includes, but is not limited to racial and ethnic minority groups, people with disabilities, members of the LGBTQ+ community, individuals with limited English proficiency, rural populations, religious minorities, and people facing socioeconomic challenges. Table IX.D.–01 includes the five attestation domains and the elements within each of those domains to which a PCH will affirmatively attest for the PCH to receive credit for that domain.

TABLE IX.D.-01: THE FACILITY COMMITMENT TO HEALTH EQUITY MEASURE'S FIVE ATTESTATIONS*

Attestation	Elements: Select all that apply (Note: Affirmative attestation of all elements within a domain would be required for the facility to receive a point for the domain in the numerator)
Domain 1: Equity is a Strategic Priority	
Facility commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority. Please attest that your hospital has a strategic plan for advancing health equity** and that it includes all the following elements.	(A) Our facility strategic plan identifies priority populations who currently experience health disparities. (B) Our facility strategic plan identifies health equity** goals and discrete action steps to achieving these goals. (C) Our facility strategic plan outlines specific resources which have been dedicated to achieving our equity goals. (D) Our facility strategic plan describes our approach for engaging key stakeholders, such as community-based organizations.
Domain 2: Data Collection	
Collecting valid and reliable demographic and social determinant of health data on patients served in a facility is an important step in identifying and eliminating health disparities. Please attest that your hospital engages in the following activities.	(A) Our facility collects demographic information, *** such as self-reported race, national origin, primary language, and ethnicity data) and/or social determinant of health information on the majority of our patients. (B) Our facility has training for staff in culturally sensitive collection of demographic and/or social determinant of health information. (C) Our facility inputs demographic and/or social determinant of health information collected from patients into structured, interoperable data elements using certified EHR technology.
Domain 3: Data Analysis	
Effective data analysis can provide insights into which factors contribute to health disparities and how to respond. Please attest that your facility engages in the following activities.	(A) Our facility stratifies key performance indicators by demographic and/or social determinants of health variables to identify equity gaps and includes this information on hospital performance dashboards.
Domain 4: Quality Improvement	
Health disparities are evidence that high-quality care has not been delivered equitably to all patients. **** Engagement in quality improvement activities can improve quality of care for all patients.	(A) Our facility participates in local, regional, or national quality improvement activities focused on reducing health disparities.
Domain 5: Leadership Engagement	
Leaders and staff can improve their capacity to address disparities by demonstrating routine and thorough attention to equity and setting an organizational culture of equity. Please attest that your facility engages in the following activities.	(A) Our facility senior leadership, including chief executives and the entire facility board of trustees, annually reviews our strategic plan for achieving health equity. (B) Our facility senior leadership, including chief executives and the entire facility board of trustees, annually reviews key performance indicators stratified by demographic and/or social factors.

* We have clarified the language in the table to refer to "facility" or "facilities" instead of "hospital" or "hospitals" to align with the measure language from the 2022 Measures Under Consideration (MUC) List.
**After publication of the 2022 MUC List, we clarified the language in Domain 1 to refer to "health equity" instead of "healthcare equity.
***After publication of the 2022 MUC List, we clarified the language in Domain 2 to refer to example demographic information.
**** After publication of the 2022 MUC List, we clarified the language in Domain 4: "Health disparities are evidence that high quality care has not been delivered *equitably* to all patients."

c. Measure Calculation

The Facility Commitment to Health Equity measure consists of five attestation-based questions, each representing a separate domain of commitment. Some of the domains have multiple elements to which a PCH will be required to attest. For a PCH to affirmatively attest ''yes'' to a domain, and receive credit for that domain, the PCH will evaluate and determine whether it engages in each of the sub-elements that comprise the domain. PCHs will only receive a point for each domain if they attest ''yes'' to all related sub-elements. There is no ''partial credit'' for sub-elements. Each of the domains will be represented in the denominator as a point, for a total of 5 points (one per domain).

For example, for Domain 1 (''Facility commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority''), a PCH will evaluate and determine whether its strategic plan meets each of the elements described in (A) through (D) (see Table IX.D.-01). If the PCH's plan meets all four of these elements, the PCH will affirmatively attest to Domain 1 and receive one (1) point for that attestation. A PCH will not be able to receive partial credit for a domain. In other words, if a PCH's strategic plan meets elements (A) and (B) but not (C) and (D), the PCH will not be able to affirmatively attest to Domain 1 and will not receive a point for that attestation.

The numerator will capture the total number of domain attestations to which the PCH is able to affirm. For example, a PCH that affirmatively attests each element of the 5 domains will receive the maximum 5 points.

Specifications for the measure are available on the CMS Measure Inventory page with the file name ''Facility Commitment to Health Equity Measure Specifications'' at: *https://cmit.cms.gov/cmit/#/*.

d. Data Submission and Reporting

In the proposed rule, we proposed to require PCHs to submit information for the Facility Commitment to Health Equity measure once on an annual basis using a CMS-approved web-based data collection tool available within the Hospital Quality Reporting (HQR) System beginning with the FY 2026 program year. PCHs will follow the submission and reporting requirements for web-based measures for the PCHQR Program posted on the QualityNet website.

e. Review by the Measure Applications Partnership

The Facility Commitment to Health Equity measure was included for consideration in the PCHQR Program on the publicly available ''List of Measures Under Consideration for December 1, 2022'' (MUC List), a list of measures under consideration for use in various Medicare quality programs.[647] The CBE-convened Measure Applications Partnership (MAP)[648] Health Equity Advisory Group reviewed the MUC List and the Facility Commitment to Health Equity measure (MUC2022–027) in detail on December 6–7, 2022.[649] The Health Equity Advisory Group expressed concern that this is more of a ''checklist'' measure that may not directly address health inequities at a systemic level, but the advisory group generally agreed that a structural measure such as this one represents progress toward improving equitable care.[650] In addition, on December 8–9, 2022, the MAP Rural Health Advisory Group reviewed the 2022 MUC List, and the MAP Hospital Workgroup reviewed the 2022 MUC List on December 13–14, 2022.[651] The MAP recognized that reducing health care disparities would represent a substantial benefit to overall quality of care, but expressed reservations about the measure's link to clinical outcomes; the MAP Workgroup members voted to conditionally support the measure for rulemaking pending: (1) endorsement by a consensus-based entity (CBE); (2) committing to look at outcomes in the future; (3) providing more clarity on the measure and supplementing interpretations with results; and (4) verifying attestation provided by the accountable entities.[652] Thereafter, the MAP Coordinating Committee deliberated on January 24–25, 2023, and ultimately voted to conditionally support the Facility Commitment to Health Equity measure for rulemaking with the same conditions.[653]

We believe this measure establishes an important foundation to prioritize the achievement of health equity among PCHs. Our approach to developing equity-focused measures has been incremental to date, but we see inclusion of such measures in the PCHQR Program as informing efforts to advance and achieve health equity among PCHs by allowing for the recognition and tracking of disparities for the population served by PCHs. We additionally believe this measure to be a building block that lays the groundwork for a future meaningful suite of measures that could assess PCH progress in providing high-quality healthcare for all patients, regardless of social risk factors or demographic characteristics.

[647] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[648] Interested parties convened by the consensus-based entity will provide input and recommendations on the Measures Under Consideration (MUC) list as part of the pre-rulemaking process required by section 1890A of the Act. We refer readers to *https://p4qm.org/PRMR-MSR* for more information.

[649] Interested parties convened by the consensus-based entity will provide input and recommendations on the Measures Under Consideration (MUC) list as part of the pre-rulemaking process required by section 1890A of the SSA. We refer readers to *https://p4qm.org/PRMR-MSR* for more information.

[650] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[651] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[652] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[653] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

f. Consensus-Based Entity Endorsement

We have not submitted this measure for consensus-based entity (CBE) [654] endorsement at this time. Although section 1866(k)(3)(A) of the Act generally requires that measures specified by the Secretary for use in the PCHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, section 1866(k)(3)(B) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and, therefore, we believe the exception in section 1866(k)(3)(B) of the Act applies.

g. Public Display

In the proposed rule, we proposed to publicly display the PCH-specific results for the Facility Commitment to Health Equity measure and refer readers to Table IX.D.-04 in the preamble of this final rule for the public display requirements.

We invited public comment on this proposal.

Comment: Many commenters expressed support for the measure believing it promotes health equity. A commenter expressed support for the measure because the measure includes several important domains of health equity, including inclusion in strategic plans, assessment of a commitment to data collection and reporting, and stratification of that data that will show whether there is improvement over time. Another commenter expressed its belief that the measure can incentivize hospitals to collect and use data to identify and address quality gaps. Another commenter expressed support for the measure believing it assesses important aspects of a hospital's commitment to health equity including an organizational commitment to reducing health disparities, collecting demographic data, and training staff on best practices for data collection. Another commenter expressed its support for the measure believing it supports efforts to identify and track institutional biases in the reimbursement structure and healthcare system.

Response: We thank commenters for their support of our proposal to adopt the Facility Commitment to Health Equity measure. We agree that the measure assesses important aspects of a PCH's commitment to health equity and will incentivize the collection and use of data by PCHs to address health equity to identify and address quality gaps and deliver equitable culturally competent care to all patients.

Comment: A few commenters expressed support for the measure with some concerns including that the measure should be monitored for unintended consequences and updating, that the data lack reliability or validity testing in the PCH setting, and that the measure may require data from outside of the hospital-setting. Another commenter recommended analyzing lessons learned from the Hospital IQR Program to inform implementation strategy.

Response: We appreciate the commenters support and recommendations. We also understand commenters' concerns regarding the accuracy of provider self-reported data; however, while we do not have a specific means to validate PCHs' attestation to this measure, we do require all PCHs participating in the PCHQR Program to complete the Data Accuracy and Completeness Acknowledgement (DACA) each year which requires attestation that the quality measure results and any and all data including numerator and denominator data provided are accurate and complete. For more information on the PCHQR Program's DACA requirements, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53563). We also acknowledge commenters' desire to be able to learn from the experiences of PCH reporting of this measure over time. We note that the Hospital IQR Program adopted the Facility Commitment to Health Equity measure last year and that hospitals participating in the Hospital IQR Program will have already reported data on this measure before the reporting of the Facility Commitment to Health Equity Measure for the PCHQR Program begins, so we believe PCHs will have the opportunity to learn from the experiences of hospitals when hospital data is publicly reported in addition to monitoring the experience of PCHs when data reporting is required.

Comment: A commenter expressed its belief that the data should be standardized and validated and collected in a way that minimizes burden. A commenter expressed concern that the measure may add burden without demonstrable benefits because it only requires attestation.

Response: We recognize the commenter's concerns about burden of participating in the PCHQR Program and have aligned PCHQR Program measures with the Hospital IQR Program as appropriate, including the reporting of the Facility Commitment to Health Equity measure. We also believe the benefits of encouraging PCH commitment to health equity outweighs the burden of attestation under this measure.

Comment: A commenter recommended the measure be submitted for CBE review and endorsement.

Response: While we recognize the value of measures undergoing CBE endorsement review, measures of health equity are a priority for CMS, and we believe it is important to implement this measure as soon as possible. We note that under section 1886(s)(4)(D)(ii) of the Act the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and therefore, we believe the exception in section 1886(s)(4)(D)(ii) of the Act applies. We believe the Facility Commitment to Health Equity measure is sufficiently accurate and reliable without CBE endorsement, noting its adoption in the Hospital IQR Program, and that this measure establishes an important foundation to prioritize the achievement of health equity among PCHs.

Comment: A commenter expressed support and requested more data on how high- and low-quality care facilities will be differentiated and used for quality improvement versus penalties.

[654] In previous years, we referred to the consensus-based entity by corporate name. We have updated this language to refer to the consensus-based entity more generally.

Response: We believe strong and committed leadership from PCH executives and board members is essential and can play a role in advancing equity goals for PCHs. The measure is intended to provide information to PCHs on the level of unmet need among their patients and potentially in the community and not for comparison between PCHs. We believe this measure is an important step toward assessing PCH leadership commitment and a fundamental step toward closing the gap in equitable care for all populations. The PCHQR Program does not include a financial incentive or penalty for PCHs, and we encourage providers to analyze their own data to understand the many factors, including race, ethnicity, and various drivers of health, such as housing stability and food security, to deliver more equitable care and, in turn, improve patient outcomes.

Comment: A commenter recommended CMS revisit the measure as more sophisticated measures are developed and assess outcomes. Another commenter recommended CMS consider measuring other concepts such as accessibility and appropriateness of services, forming the right community partnerships, and improving patient experiences by reducing discrimination and implicit bias.

Response: We appreciate the commenter's recommendations and believe this measure to be a building block that lays the groundwork for a more comprehensive suite of measures that could assess progress in providing high-quality healthcare for all patients regardless of social risk factors or demographic characteristics. A more comprehensive suite of measures could potentially include health equity related outcome measures.

Comment: A commenter recommended that CMS delay public reporting until the data's accuracy are verified. Another commenter recommended making reporting voluntary and not subject to public display for the first year of the measure in the program.

Response: We believe that adopting the Facility Commitment to Health Equity measure beginning with the FY 2026 program year and displaying the data publicly beginning July 2026 or as soon as feasible thereafter would allow PCHs the opportunity to review the accuracy of their data prior to public display and refer readers to Table IX.D.–04 for our finalized public display requirements.

Comment: A commenter did not support the measure believing it is built on the false premise not supported by evidence that medical institutions are mired by bigotry, racism, and discrimination. The commenter expressed its belief that disparate health outcomes should not be assumed to be a direct result of quality of care provided by a hospital. The commenter also expressed concerns that the proposal would force cancer hospitals to make a commitment to health equity beginning in FY 2026 with an adjustment to the funding formula.

Response: We believe this measure is an important foundational measure for improving health equity among those that have been disadvantaged or underserved by the healthcare system, and there is substantial research showing differences in care and experiences among these populations and refer readers to the literature discussed in this section. We encourage providers to analyze their own data to understand the many factors, including race, ethnicity, and various drivers of health, such as housing stability and food security, to deliver more equitable care and in turn improve patient outcomes for all patients. We also believe the public display of data provides the opportunity for CMS, patients, and other stakeholders to recognize PCHs that provide equitable health care and refer readers to Table IX.D.–04 for our finalized public display requirements.

After consideration of the public comments we received, we are finalizing this measure.

4. Adoption of the Screening for Social Drivers of Health Measure Beginning With Voluntary Reporting for the FY 2026 Program Year and Mandatory Reporting Beginning With the FY 2027 Program Year

Health-related social needs (HRSNs), which we define as individual-level, adverse social conditions that negatively impact a person's health or healthcare, are significant risk factors associated with worse health outcomes as well as increased healthcare utilization.[655] We believe that consistently pursuing identification of HRSNs will have two significant benefits. First, these social risk factors disproportionately impact populations that have historically been underserved by the healthcare system and screening helps identify individuals who may have HRSNs.[656] Second, screening for social risk factors could support ongoing PCH quality improvement initiatives by providing data with which to stratify patient risk and organizational performance. Further, we believe collecting patient-level HRSN data through screening is essential for the long-term in encouraging meaningful collaboration between healthcare providers and community-based organizations, and in implementing and evaluating related innovations in health and social care delivery.

As a first step towards leveraging the opportunity to close equity gaps by identifying patients' HRSNs, we finalized the adoption of two evidence-based measures in the Hospital IQR Program, the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49201 through 49220). These two social drivers of health measures support identification of specific risk factors for inadequate healthcare access and adverse health outcomes among patients. These measures also enable systematic collection of HRSN data. This activity aligns with our other efforts beyond the acute care setting, including the CY 2023 Medicare Advantage and Part D final rule in which we finalized the policy requiring that all Special Needs Plans (SNPs) include one or more questions on housing stability, food security, and access to transportation in their Health Risk Assessment (HRA) using questions from a list of screening instruments specified in sub-regulatory guidance (87 FR 27726 through 27740), as well as the CY 2023 PFS final rule in which we adopted the Screening for Social Drivers of Health measure in the Merit-based Incentive Payment System (87 FR 70054 through 70055).

These measures will allow PCHs to identify patients with HRSNs, who are known to experience the greatest risk of poor health outcomes, thereby improving the accuracy of high-risk prediction calculations. Improvement in risk prediction has the potential to reduce healthcare access barriers, address the disproportionate expenditures attributed to populations with greatest risk, and improve the

[655] Centers for Medicare & Medicaid Services. (2021) A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Available at: *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion.* Accessed: November 23, 2021.

[656] American Hospital Association. (2020) Health Equity, Diversity & Inclusion Measures for Hospitals and Health System Dashboards. December 2020. Accessed: January 18, 2022. Available at: *https://ifdhe.aha.org/system/files/media/file/2020/12/ifdhe_inclusion_dashboard.pdf.*

PCH's quality of care.[657] [658] [659] [660] Further, these data could guide future public and private resource allocation to promote focused collaboration between PCHs, health systems, community-based organizations, and others in support of improving patient outcomes.

We provide further details on each measure in the subsequent discussion and section IX.D.5. of the preamble of this final rule.

a. Background

Health disparities manifest primarily as worse health outcomes in population groups where access to care is inequitable.[661] [662] [663] [664] [665] Such differences persist across geography and healthcare settings irrespective of improvements in quality of care over time.[666] [667] [668] Assessment of HRSNs is an essential mechanism for capturing the interaction between social, community, and environmental factors associated with health status and health outcomes.[669] [670] [671] Growing evidence demonstrates that specific social risk factors are directly associated with patient health outcomes as well as healthcare utilization, costs, and performance in quality reporting and payment programs.[672] [673] While widespread interest in addressing HRSNs exists, action is inconsistent, with 92 percent of hospitals screening for one or more of the five HRSNs—food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety—specified in the Screening for Social Drivers of Health and the Screen Positive for Social Drivers of Health measures, but only 24 percent of hospitals screening for all five HRSNs.[674]

In 2017, CMS's Center for Medicare and Medicaid Innovation launched the Accountable Health Communities (AHC) Model to test the impact of systematically identifying and addressing the HRSNs of community-dwelling Medicare and Medicaid beneficiaries (through screening, referral, and community navigation on their health outcomes and related healthcare utilization and costs).[675] [676] [677] [678] The AHC Model is one of the first Federal pilots to systematically test whether identifying and addressing core HRSNs improves healthcare costs, utilization, and outcomes with 29 participating bridge organizations.[679] [680] The AHC Model had a 5-year period of performance that began in May 2017 and ended in April 2022, with beneficiary screening beginning in the summer of 2018.[681] [682] Evaluation of the AHC Model data is still underway.

While social risk factors account for 50 to 70 percent of health outcomes, the mechanisms by which this connection emerges are complex and multifaceted.[683] [684] [685] [686] The persistent

[657] Baker, M.C., Alberti, P.M., Tsao, T.Y., Fluegge, K., Howland, R.E., & Haberman, M. (2021). Social Determinants Matter for Hospital Readmission Policy: Insights From New York City. Health Affairs, 40(4), 645–654. Available at: *https://doi.org/10.1377/hlthaff.2020.01742*.

[658] Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. Circulation: Cardiovascular Quality and Outcomes, 13 (6) 290–299. Available at: *https://doi.org/10.1161/CIRCOUTCOMES.120.006752*.

[659] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://pubmed.ncbi.nlm.nih.gov/33139407/*.

[660] Jaffrey, J.B., Safran, G.B., Addressing Social Risk Factors in Value-Based Payment: Adjusting Payment Not Performance to Optimize Outcomes and Fairness. Health Affairs Blog, April 19, 2021. Available at: *https://www.healthaffairs.org/do/10.1377/forefront.20210414.379479/full/*.

[661] Seligman, H.K., & Berkowitz, S.A. (2019). Aligning Programs and Policies to Support Food Security and Public Health Goals in the United States. Annual Review of Public Health, 40(1), 319–337. Available at: *https://pubmed.ncbi.nlm.nih.gov/30444684/*.

[662] The Physicians Foundation. (2020) Survey of America's Patients, Part Three. Available at: *https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf*.

[663] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress*.

[664] Trivedi AN, Nsa W, Hausmann LRM, et al. Quality and Equity of Care in U.S. Hospitals. New England Journal of Medicine. 2014; 371(24):2298–2308.

[665] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b*.

[666] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress*.

[667] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://pubmed.ncbi.nlm.nih.gov/33139407/*.

[668] Khullar, D., MD. (2020, September 8). Association Between Patient Social Risk and Physician Performance American academy of Family Physicians. Addressing Social Determinants of Health in Primary Care team-based approach for advancing health equity. Available at: *https://www.aafp.org/dam/AAFP/documents/patient lowbar;care/everyonelowbar;project/team-based-approach.pdf*.

[669] Institute of Medicine (2014). Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/18951*.

[670] Alley, D.E., C.N. Asomugha, P.H. Conway, and D.M. Sanghavi. (2016). Accountable Health Communities–Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8–11. Available at: *https://doi.org/10.1056/NEJMp1512532*.

[671] Centers for Disease Control and Prevention. CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. July 2020. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html*. Accessed November 17, 2021.

[672] Zhang Y, Li J, Yu J, Braun RT, Casalino LP. (2021). Social Determinants of Health and Geographic Variation in Medicare per Beneficiary Spending. *JAMA Network Open*. 2021;4(6):e2113212.doi:10.1001/jamanetworkopen.2021.13212.

[673] Khullar, D., Schpero, W.L., Bond, A.M., Qian, Y., & Casalino, L.P. (2020). Association Between Patient Social Risk and Physician Performance Scores in the First Year of the Merit-based Incentive Payment System. JAMA, 324(10), 975–983. *https://doi.org/10.1001/jama.2020.13129*.

[674] TK Fraze, AL Brewster, VA Lewis, LB Beidler, GF Murray, CH Colla. Prevalence of screening for food insecurity, housing instability, utility needs, transportation needs, and interpersonal violence by US physician practices and hospitals. JAMA Network Open 2019; 2:e1911514.10.1001/jamanetworkopen.2019.11514.31532515.

[675] Centers for Medicare & Medicaid Services. (2021) A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Accessed: November 23, 2021. Available at: *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion*.

[676] Alley, D.E., C.N. Asomugha, P.H. Conway, and D.M. Sanghavi. 2016. Accountable Health Communities–Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8–11. Available at: *https://doi.org/10.1056/NEJMp1512532*.

[677] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b*.

[678] Centers for Medicare & Medicaid Services. (2021) Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Accessed November 23, 2021. Available at: *https://innovation.cms.gov/innovation-models/ahcm*.

[679] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*.

[680] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*.

[681] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*.

[682] We note that the model officially concluded in April 2022 but many awardees are continuing with no-cost extensions to continue utilizing unspent cooperative agreement funding and all awardees will conclude by April 2023.

[683] Kaiser Family Foundation. (2021) Racial and Ethnic Health Inequities and Medicare. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/*. Accessed November 23, 2021.

[684] Khullar, D., MD. (2020, September 8). Association Between Patient Social Risk and

Continued

interactions between individuals' HRSNs, medical providers' practices/behaviors, and community resources significantly impact healthcare access, quality, and ultimately costs, as described in the CMS Equity Plan for Improving Quality in Medicare.[687] [688] In their 2018 survey of 8,500 physicians, the Physicians Foundation found almost 90 percent of physician respondents reported their patients had a serious health problem linked to poverty or other social conditions.[689] Additionally, associations between disproportionate health risk, hospitalization, and adverse health outcomes have been highlighted and magnified by the COVID–19 pandemic.[690] [691]

The following five core domains were selected to screen for HRSNs among Medicare and Medicaid beneficiaries under the AHC Model: (1) food insecurity; (2) housing instability; (3) transportation needs; (4) utility difficulties; and (5) interpersonal safety. These domains were chosen based upon literature review and expert consensus utilizing the following criteria: (1) availability of high-quality scientific evidence linking a given HRSN to adverse health outcomes and increased healthcare utilization, including hospitalizations and associated costs; (2) ability for a given HRSN to be screened and identified in the inpatient setting prior to hospital discharge, addressed by community-based services, and potentially improve health care outcomes, including reduced hospital re-admissions; and (3) evidence that a given HRSN is not systematically addressed by healthcare providers.[692] In addition to established evidence of their association with health status, risk, and outcomes, these five domains were also selected because they can be assessed across the broadest spectrum of individuals in a variety of settings.[693] [694] [695]

These five evidence-based HRSN domains, which informed development of the two social drivers of health measures, are described in Table IX.D.–02.

Physician Performance American academy of Family Physicians. (2020). Addressing Social Determinants of Health in Primary Care team-based approach for advancing health equity.

[685] Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. Circulation: Cardiovascular Quality and Outcomes, 13 (6) 290–299. Available at: *https://doi.org/10.1161/CIRCOUTCOMES.120.006752*.

[686] The Physicians Foundation. (2021) Viewpoints: Social Determinants of Health. Available at: *https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf*. Accessed December 8, 2021.

[687] Centers for Medicare & Medicaid Services. (2021) Paving the Way to Equity: A Progress Report. Accessed January 18, 2022. Available at: *https://www.cms.gov/files/document/paving-way-equity-cms-omh-progress-report.pdf*.

[688] Centers for Medicare & Medicaid Services Office of Minority Health. (2021) The CMS Equity Plan for Improving Quality in Medicare. 2015–2021. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/OMH_Dwnld-CMS_EquityPlanforMedicare_090615.pdf*.

[689] The Physicians Foundation. (2019) Viewpoints: Social Determinants of Health. Available at: *https://physiciansfoundation.org/wp-content/uploads/2019/08/The-Physicians-Foundation-SDOH-Viewpoints.pdf*.

Accessed December 8, 2021.

[690] Centers for Disease Control and Prevention. (2020) CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. July 2020. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html*. Accessed November 17, 2021.

[691] Kaiser Family Foundation. (2021) Racial and Ethnic Health Inequities and Medicare. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/*. Accessed November 23, 2021.

[692] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b*.

[693] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017) Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b*.

[694] Centers for Medicare & Medicaid Services. (2021. Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Accessed November 23, 2021. Available at: *https://innovation.cms.gov/innovation-models/ahcm*.

[695] Kamyck, D., Senior Director of Marketing. (2019. CMS releases standardized screening tool for health-related social needs. Activate Care. Available at: *https://blog.activatecare.com/standardized-screening-for-health-related-social-needs-in-clinical-settings-the-accountable-health-communities-screening-tool/*.

TABLE IX.D.-02: THE FIVE CORE HRSN DOMAINS TO SCREEN FOR SOCIAL DRIVERS OF HEALTH

Domain	Description
Food Insecurity	Food insecurity is defined as limited or uncertain access to adequate quality and quantity of food at the household level. It is associated with diminished mental and physical health and increased risk for chronic conditions.[696,697] Individuals experiencing food insecurity often have inadequate access to healthier food options which can impede self-management of chronic diseases like diabetes and heart disease, and require individuals to make personal trade-offs between food purchases and medical needs, including prescription medication refills and preventive health

Domain	Description
	services.[698,699] Food insecurity is associated with high-cost healthcare utilization including emergency department (ED) visits and hospitalizations.[700,701,702]
Housing Instability	Housing instability encompasses multiple conditions ranging from inability to pay rent or mortgage, frequent changes in residence including temporary stays with friends and relatives, living in crowded conditions, and actual lack of sheltered housing in which an individual does not have a personal residence.[703,704] Population surveys consistently show that people from some racial and ethnic minority groups constitute the largest proportion of the U.S. population experiencing unstable housing.[705] Housing instability is associated with higher rates of chronic illnesses, injuries, and complications and more frequent utilization of high-cost healthcare services.[706,707]
Transportation Needs	Unmet transportation needs include limitations that impede transportation to destinations required for all aspects of daily living.[708] Groups disproportionately affected include older adults (aged >65 years), people with lower incomes, people with impaired mobility, residents of rural areas, and people from some racial and ethnic minority groups. Transportation needs contribute to postponement of routine medical care and preventive services which ultimately lead to chronic illness exacerbation and

Domain	Description
	more frequent utilization of high-cost healthcare services including emergency medical services, Eds, and hospitalizations.[709,710,711,712]
Utility Difficulties	Inconsistent availability of electricity, water, oil, and gas services is directly associated with housing instability and food insecurity.[713] Specifically, interventions that increase or maintain access to such services have been associated with individual and population-level health improvements.[714]
Interpersonal Safety	Interpersonal safety affects individuals across the lifespan, from birth to old age, and is directly linked to mental and physical health. Assessment for this domain includes screening for exposure to intimate partner violence, child abuse, and elder abuse.[715] Exposure to violence and social isolation are reflective of individual-level social relations and living conditions that are directly associated with injury, psychological distress, and death in all age groups.[716,717]

Utilization of screening tools to identify the burden of unmet HRSNs can be a helpful first step for PCHs identifying necessary community partners and connecting individuals to resources in their communities. We believe collecting data on the same five HRSN domains under the PCHQR Program that were screened under the AHC Model will illuminate their impact on health outcomes, their contribution to related disparities, and the associated care-cost burden for PCHs, particularly for PCHs that serve patients experiencing disproportionately high levels of social risk. In addition, data collection in this care setting could inform more meaningful and sustainable solutions for provider-types participating in other quality reporting programs to close equity gaps among the communities they serve.[718] [719] [720] [721] [722]

For data collection of this measure, PCHs can use a self-selected screening tool and collect these data in multiple ways, which can vary to accommodate the population they serve and their individual needs.[723] [724] For example, the AHC Model employed a 10-item AHC Health-Related Social Needs Screening Tool to enable providers to identify HRSNs in the five core domains (described in Table IX.D.–02) among community-dwelling Medicare, Medicaid, and dually eligible beneficiaries.[725] The AHC Model was tested across varied care-delivery sites in diverse geographic locations across the U.S.[726] We reviewed literature that shows that the Tool was evaluated psychometrically and demonstrated evidence of both reliability and validity, including inter-rater reliability and concurrent and predictive validity.[727] Moreover, the screening instrument can be implemented in a variety of places where patients seek healthcare, including cancer hospitals.[728]

[696] Berkowitz SA, Seligman HK, Meigs JB, Basu S. Food insecurity, healthcare utilization, and high cost: a longitudinal cohort study. Am J Managed Care. 2018 Sep;24(9):399–404. PMID: 30222918; PMCID: PMC6426124.

[697] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://pubmed.ncbi.nlm.nih.gov/33139407/*.

[698] Seligman, H.K., & Berkowitz, S.A. (2019). Aligning Programs and Policies to Support Food Security and Public Health Goals in the United States. Annual Review of Public Health, 40(1), 319–337. Available at: *https://pubmed.ncbi.nlm.nih.gov/30444684/*.

[699] National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/23285*.

[700] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://pubmed.ncbi.nlm.nih.gov/33139407/*.

[701] Berkowitz SA, Seligman HK, Meigs JB, Basu S. Food insecurity, healthcare utilization, and high cost: a longitudinal cohort study. Am J Managed Care. 2018 Sep;24(9):399–404. PMID: 30222918; PMCID: PMC6426124.

[702] Dean, E.B., French, M.T., & Mortensen, K. (2020a). Food insecurity, health care utilization, and health care expenditures. Health Services Research, 55(S2), 883–893. Available at: *https://doi.org/10.1111/1475-6773.13283*.

[703] Larimer, M.E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. JAMA, 301(13), 1349. Available at: *https://doi.org/10.1001/jama.2009.414*.

[704] Hill-Briggs, F. (2021). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://pubmed.ncbi.nlm.nih.gov/33139407/*.

[705] Henry M., de Sousa, T., Roddey, C., Gayen, S., Bednar, T.; Abt Associates. The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness, January 2021. U.S. Department of Housing and Urban Development. Accessed November 24, 2021. Available at: *https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf*.

[706] Larimer, M.E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. JAMA, 301(13), 1349. Available at: *https://doi.org/10.1001/jama.2009.414*.

[707] Baxter, A., Tweed, E., Katikireddi, S., Thomson, H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness: systematic review and meta-analysis of randomized controlled trials. Journal of Epidemiology and Community Health, 73; 379–387. Available at: *https://jech.bmj.com/content/jech/73/5/379.full.pdf*.

[708] National Academies of Sciences, Engineering, and Medicine (2006). Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/23285*.

[709] National Academies of Sciences, Engineering, and Medicine 2006. Executive Summary: Cost-Benefit Analysis of Providing Non-Emergency Medical Transportation. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/23285*.

[710] Hill-Briggs, F. (2021, January 1). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: *https://pubmed.ncbi.nlm.nih.gov/33139407/*.

[711] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b*.

[712] Shier, G., Ginsburg, M., Howell, J., Volland, P., & Golden, R. (2013). Strong Social Support Services, Such as Transportation And Help For Caregivers, Can Lead To Lower Health Care Use And Costs. Health Affairs, 32(3), 544–551. Available at: *https://doi.org/10.1377/hlthaff.2012.0170*.

[713] Baxter, A., Tweed, E., Katikireddi, S., Thomson, H. (2019). Effects of Housing First approaches on health and well-being of adults who are homeless or at risk of homelessness: systematic review and meta-analysis of randomized controlled trials. Journal of Epidemiology and Community Health, 73; 379–387. Available at: *https://jech.bmj.com/content/jech/73/5/379.full.pdf*.

[714] Wright, B.J., Vartanian, K.B., Li, H.F., Royal, N., & Matson, J.K. (2016). Formerly Homeless People Had Lower Overall Health Care Expenditures After Moving into Supportive Housing. Health Affairs, 35(1), 20–27. Available at: *https://doi.org/10.1377/hlthaff.2015.0393*.

[715] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b*.

[716] Henry M., de Sousa, T., Roddey, C., Gayen, S., Bednar, T.; Abt Associates. The 2020 Annual Homeless Assessment Report (AHAR) to Congress; Part 1: Point-in-Time Estimates of Homelessness, January 2021. U.S. Department of Housing and Urban Development. Accessed November 24, 2021. Available at: *https://www.huduser.gov/portal/sites/default/files/pdf/2020-AHAR-Part-1.pdf*.

[717] Larimer, M.E. (2009). Health Care and Public Service Use and Costs Before and After Provision of Housing for Chronically Homeless Persons with Severe Alcohol Problems. JAMA, 301(13), 1349. Available at: *https://doi.org/10.1001/jama.2009.414*.

[718] The Physicians Foundation: 2020 Survey of America's Patients, Part Three. Available at: *https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf*.

[719] Office of the Assistant Secretary for Planning and Evaluation (ASPE) (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress*.

[720] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b*.

[721] Baker, M.C., Alberti, P.M., Tsao, T.Y., Fluegge, K., Howland, R.E., & Haberman, M. (2021). Social Determinants Matter for Hospital Readmission Policy: Insights From New York City. Health Affairs, 40(4), 645–654. Available at: *https://doi.org/10.1377/hlthaff.2020.01742*.

[722] De Marchis, E., Knox, M., Hessler, D., Willard-Grace, R., Oliyawola, JN, et al. (2019). Physician Burnout and Higher Clinic Capacity to Address Patients' Social Needs. The Journal of the American Board of Family Medicine, 32 (1), 69–78.

[723] Social Interventions Research & Evaluation Network. (2019) Social Needs Screening Tool Comparison Table. Available at: *https://sirenetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison*. Accessed January 18, 2021.

[724] Centers for Medicare & Medicaid Services. (2021) A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights (June 2021). Available at: *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion*. Accessed January 18, 2021.

[725] More information on the HRSN Screening Tool is available at: *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf*.

[726] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*.

[727] Lewis C., Wellman R., Jones S., Walsh-Bailey C., Thompson E., Derus A., Paolino A., Steiner J., De Marchis E., Gottlieb L., and Sharp A. (2020). Comparing the Performance of Two Social Risk Screening Tools in a Vulnerable Subpopulation. J Family Med Prim Care. 2020 Sep; 9(9): 5026–5034. Available at: *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7652127/*.

[728] CMS. A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights. June 2021. Accessed: November 23, 2021.

The intent of this measure is to promote adoption of HRSN screening by PCHs. We encourage PCHs to use the screening as a basis for developing their own individual action plans (which could include navigation services and subsequent referral), as well as an opportunity to initiate and/or improve partnerships with community-based service providers. This effort will yield actionable information to close equity gaps by encouraging PCHs to identify HRSNs; with a reciprocal goal of strengthening linkages between PCHs and community-based partners so as to promptly connect patients and families to the support they need.

Under our Meaningful Measures Framework,[729] the Screening for Social Drivers of Health measure, in addition to the Screen Positive Rate for Social Drivers of Health measure discussed in section IX.D.5. of the preamble of this final rule, address the quality priority of ''Work with Communities to Promote Best Practices of Healthy Living'' through the Meaningful Measures Area of ''Equity of Care.'' Additionally, pursuant to Meaningful Measures 2.0, this measure addresses the ''healthcare equity'' priority area and aligns with our commitment to introduce plans to close health equity gaps and promote equity through quality measures, including to ''develop and implement measures that reflect social and economic determinants.'' [730] Development and proposal of this measure also align with our strategic pillar to advance health equity by addressing the health disparities that underlie our health system.[731]

In alignment with the measure's adoption in the Hospital IQR Program in the FY 2023 IPPS/LTCH final rule (87 FR 49202 through 49215), the Screening for Social Drivers of Health measure (alongside the Screen Positive Rate for Social Drivers of Health measure described in section IX.D.5. of the preamble of this final rule) is the first patient-level measurement of social drivers of health in the PCHQR Program. We believe this measure is appropriate for the measurement of the quality of care furnished by PCHs. Screening will allow healthcare providers to identify and potentially help address HRSNs as part of discharge planning and contribute to long-term improvements in patient outcomes. This will have a direct and positive impact on cancer hospital quality performance. Moreover, collecting baseline data via this measure is crucial in informing design of future measures that can enable us to set appropriate performance targets for PCHs.

b. Overview of Measure

The Screening for Social Drivers of Health measure will assess whether a PCH implements screening for all patients who are 18 years or older at time of admission for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. To report on this measure, PCHs will provide: (1) The number of patients admitted to the PCH who are 18 years or older at time of admission and who are screened for all of the five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety; and (2) the total number of patients who are admitted to the PCH who are 18 years or older on the date they are admitted.

Measure specifications for this measure are currently available at: *https://cmit.cms.gov/cmit/#/*.

(g) Cohort

The Screening for Social Drivers of Health measure will assess the total number of patients, aged 18 years and older, screened for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

(2) Numerator

The numerator consists of the number of patients who are 18 years or older on the date of their PCH admission and are screened for all of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety.

(3) Denominator

The denominator consists of the number of patients who are admitted to a PCH and who are 18 years or older on the date of admission. The following patients will be excluded from the denominator: (1) Patients who opt-out of screening; and (2) patients who are themselves unable to complete the screening during their PCH stay and have no legal guardian or caregiver able to do so on the patient's behalf during their PCH stay.

c. Measure Calculation

The Screening for Social Drivers of Health measure will be calculated as the number of patients admitted to a PCH stay who are 18 years or older on the date of admission screened for all five HRSNs (food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety) divided by the total number of patients 18 years or older on the date of admission admitted to the PCH.

D. Data Submission and Reporting

In the proposed rule, we proposed to require PCHs to report this measure on an annual basis beginning with voluntary reporting in the FY 2026 program year and mandatory reporting in the FY 2027 program year. In alignment with the Hospital IQR Program, we will allow PCHs flexibility to select a tool or tools to screen patients for food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. Potential sources of these data for incorporation in a tool could include, for example, administrative claims data, electronic clinical data, standardized patient assessments, or patient-reported data and surveys. Additionally, multiple screening tools exist and are publicly available. PCHs could refer to evidence-based resources like the Social Interventions Research and Evaluation Network (SIREN) website, for example, for comprehensive information about the most widely used HRSN screening tools.[732] [733] SIREN contains descriptions of the content and characteristics of various tools, including information about intended populations, completion time, and number of questions. We encourage PCHs to implement digital standardized screening tools and refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49207) where we noted that use of certified health IT can support capture and exchange of HRSN information in an interoperable fashion so that these data can be shared across

Available at: *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion*.

[729] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy*.

[730] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization*. We note that Meaningful Measures 2.0 is still under development.

[731] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Available at: *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms*.

[732] Social Interventions Research & Evaluation Network. (2019) Social Needs Screening Tool Comparison Table. Available at: *https://sirenetwork.ucsf.edu/tools-resources/resources/screening-tools-comparison*. Accessed January 18, 2021.

[733] The Social Interventions Research and Evaluation Network (SIREN) at University of California San Francisco was launched in the spring of 2016 to synthesize, disseminate, and catalyze research on the social determinants of health and healthcare delivery.

the care continuum to support coordinated care.

PCHs will be required to submit information for the Screening for Social Drivers of Health measure once annually using a CMS-approved web-based data collection tool available within the Hospital Quality Reporting (HQR) System. PCHs will follow the established submission and reporting requirements for web-based measures for the PCHQR Program posted on the QualityNet website.

e. Review by the Measure Applications Partnership

The Screening for Social Drivers of Health measure was included for consideration in the PCHQR Program on the publicly available MUC List, a list of measures under consideration for use in various Medicare programs.[734] The CBE-convened MAP Health Equity Advisory Group reviewed the MUC List and the Screening for Social Drivers of Health measure (MUC 2022–053) in detail and at the same time as the Screening Positive Rate for Social Drivers of Health measure on December 6–7, 2022.[735] The Health Equity Advisory Group expressed support for the data collection related to social drivers of health, but raised concerns about public reporting of the data and redundancy in asking for the same information of patients. In addition, on December 8–9, 2022, the MAP Rural Health Advisory Group reviewed the 2022 MUC List and the MAP Hospital Workgroup did so on December 13–14, 2022.[736] The Rural Health Advisory Group noted some potential reporting challenges including the potential masking of health disparities that are underrepresented in some areas and that sample size and populations served may be an issue, but expressed that the measure serves as a starting point to determine where screening is occurring. The MAP Hospital Workgroup expressed strong support for the measure but noted that interoperability will be important and cautioned about survey fatigue. The MAP Hospital Workgroup members conditionally supported the measure pending: (1) testing of the measure's reliability and validity; (2) endorsement by a consensus-based entity (CBE); (3) additional details on how potential tools map to the individual drivers, as well as best practices; (4) what resources may be available to assist patients; and (5) alignment with data standards, particularly the GRAVITY project.[737] Thereafter, the MAP Coordinating Committee deliberated on January 24–25, 2023, and ultimately voted to conditionally support the Screening for Social Drivers of Health measure for rulemaking with the same conditions.[738]

We believe this measure establishes an important foundation to prioritizing the achievement of health equity among PCHs. Our approach to developing health equity-focused measures is incremental, and we believe that health care equity outcomes in the PCHQR Program will inform future efforts to advance and achieve health care equity by PCHs. We additionally believe this measure to be a building block that lays the groundwork for a future meaningful suite of measures that could assess PCH progress in providing high-quality healthcare for all patients, regardless of social risk factors or demographic characteristics.

f. CBE Endorsement

We have not submitted this measure for CBE endorsement at this time. Although section 1866(k)(3)(A) of the Act generally requires that measures specified by the Secretary for use in the PCHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, section 1866(k)(3)(B) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and, therefore, we believe the exception in section 1866(k)(3)(B) of the Act applies.

g. Public Display

In the proposed rule, we proposed to publicly display the PCH-specific results for the Social Drivers of Health measure and refer readers to Table IX.D.–04 in the preamble of this final rule for the public display requirements.

We invited public comment on this proposal.

Comment: Many commenters expressed support believing the measure improves health equity. A few commenters expressed support for the measure for encouraging attention and resources for social needs. A commenter expressed support for the measure believing it addresses structural inequities faced in rural and underserved communities. Another commenter expressed support for screening believing it is an opportunity to build trust between patients and providers. Another commenter expressed support for public reporting of facility specific results. Another commenter expressed support for the measure noting that the delayed date for mandatory reporting may assist with concerns about creating additional burden capturing the required data elements.

Response: We thank the commenters for their support.

Comment: A few commenters expressed support for the measure, but with recommendations including that data may be more appropriately reported at the system or regional level, economic insecurity should be added as a social risk factor for screening, and occupational therapists should be included in the list of professionals who gather data for this measure.

Response: We appreciate the commenters' support and recommendations. We note that this measure is considered a building block and lays the groundwork for future measures that could consider additional factors such as economic insecurity. We note that the Screening for Social Drivers of Health measure requires data collection at the PCH level rather than the system or regional level that allows PCHs to identify patients with HRSNs who are known to experience the greatest risk of poor health outcomes thereby improving the accuracy of high-risk prediction outcomes. We will work with PCHs to monitor the data reported and for feedback on opportunities to improve the quality of the data or data collection and reporting processes.

Comment: A few commenters recommended minimizing burden including standardizing data collection and validation, revising the measure to not burden patients with repeated requests for information within a single hospital stay, and allowing for use of prior screening information to satisfy the measure.

Response: We recognize the concerns about burden of participating in the

[734] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[735] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[736] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[737] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[738] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

PCHQR Program and have aligned PCHQR Program measures with the Hospital IQR Program as appropriate. While we understand implementation of HRSN screening processes and reporting of the Social Drivers of Health measures is associated with some burden, as discussed in sections VI.B. and VII.A of this final rule, we believe the benefits outweigh the burden as screening for and identifying patients' HRSNs is a critical step towards treating the whole patient, improving clinical outcomes, and eliminating health disparities. We also note that hospitals participating in the Hospital IQR Program will have already reported data on this measure before the reporting of the Screening for Social Drivers of Health measure for the PCHQR Program begins, so we believe PCHs will have the opportunity to learn from the experiences of hospitals including processes for data collection.

Comment: A commenter recommended that CMS provide hospitals with additional flexibility to incorporate the patient screening for health-related social needs at the most appropriate care location, whether in inpatient hospital, outpatient, or physician office locations. Another commenter recommended technical assistance and funding pathways to support connecting patients to services. Another commenter recommended CMS provide financial support for connecting with community resources.

Response: While PCHs must meet the reporting requirements of the Screening for Social Drivers of Health measure for purposes of the PCHQR Program, we encourage PCHs to use the screening as a basis for developing their own individual action plans that could include additional settings other than the inpatient setting. For additional information on how to apply and report these screenings, we refer readers to the Hospital IQR Program's Frequently Asked Questions document regarding this measure in the Hospital IQR Program, available at: *https://www.qualityreportingcenter.com/globalassets/2023/04/iqr/sdoh-measure--faqs_vfinal_04012023508.pdf*. We will develop a similar Frequently Asked Questions document for PCHs as part of providing educational and training materials; this document will be conveyed through routine communication channels to hospitals, vendors, and QIOs, including, but not limited to, issuing memos, emails, and notices on the QualityNet website. Regarding the comment about financial support, it is not available through the PCHQR Program. However, the intent of the two Social Drivers of Health measures is to promote adoption of screening patients for HRSNs by healthcare providers as well as taking action to connect patients who identify one or more HRSNs with available resources. Evaluation of the AHC Model concluded that universal screening may identify needs that would otherwise remain undetected.[739] While broad availability of community-based resources that address patients' health-related social needs would be ideal, we believe that one of the benefits of collecting data from screening for HRSNs will be identification of opportunities to enable meaningful action, including prioritizing and investing in such resources. Beginning to collect the data on patients' HRSNs remains imperative and a crucial step in developing resources for advancing health equity. Such data collection has already allowed some entities to reallocate resources to address particular HRSNs that disproportionately affect a given patient population or geographic region, as noted in the FY 2023 IPPS/LTCH PPS final rule, in which the Hospital IQR Program adopted these measures (87 FR 49213).

Comment: A commenter recommended analyzing lessons learned from the Hospital IQR Program to inform best practices and to identify pitfalls for the implementation of health equity measures.

Response: We appreciate the recommendation and note that hospitals participating in the Hospital IQR Program will have already reported data on this measure before the reporting of the Screening for Social Drivers of Health measure for the PCHQR Program begins allowing PCHs the opportunity to learn from the experiences of hospitals when hospital data are publicly reported.

Comment: A commenter recommended CMS revisit the topic as more sophisticated measures are developed to assess action by providers to address identified social needs.

Response: We believe this measure to be a building block that lays the groundwork for a more comprehensive suite of measures that could assess progress in providing high-quality healthcare for all patients regardless of social risk factors or demographic characteristics. This more comprehensive suite of measures could eventually include health equity related outcome measures.

Comment: A commenter supported the inclusion of this measure if sufficient time is allowed before implementation to develop the supporting infrastructure to train staff, develop documentation, and refine reporting.

Response: Given the urgency of achieving health equity, we believe it is important to implement this measure as soon as possible while balancing PCHs' need for sufficient time to implement screening and data collection processes if not already implemented, which is why we proposed to adopt the measure beginning with voluntary reporting in the FY 2026 program year and mandatory reporting beginning with the FY 2027 program year.

Comment: A commenter expressed several concerns with the lack of alignment with other similar measures such as NCQA's Social Need Screening and Intervention measure proposed for adoption in HEDIS and the Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health measures under review for the Medicaid Core Set workgroup's annual review believing the misalignment will cause confusion and waste resources. This commenter recommended that the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure align with the Gravity Project's standards to lessen burden on patients and reduce missing data, and because the standards use interoperable data and are risk adjusted. This commenter also recommended CMS leverage interoperability requirements and other ways to connect with a person's record from their primary care provider to retrieve information. This commenter recommended CMS work with Core Quality Measures Collaborative (CQMC) and NCQA to harmonize the specifications of these measures through a multistakeholder process, such as the CBE endorsement process.

Response: The current Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health measures mirror the core domains of NCQA by including food insecurity, housing insecurity, and transportation insecurity. We commend additional stakeholder efforts currently underway to expand capabilities to capture drivers of health data elements using health IT standards, including the Gravity Project, a public-private collaborative focused on standard development for the collection, use, and exchange of data to address social determinants of health, referenced by a commenter. We have prioritized the five HRSN domains in the Screening for Social Drivers of Health measure based on existing evidence from the AHC

[739] RTI International. (2020) Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*.

Model including recommendations from a Technical Expert Panel that informed the initial selection. We note that the five domains covered by the Screening for Social Drivers of Health measure are included within the ''social risk domains'' of the Gravity Project. We also note ongoing reevaluation efforts that aim to improve the Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health measures through the development of the Addressing Social Needs (ASN) electronic clinical quality measure (eCQM). We support harmonization of social risk factor data for interoperable electronic health information exchange and encourage use of tools that can enable interoperable exchange of this data. In addition, adoption of the Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health measures for the PCHQR Program aligns with other quality reporting and value-based purchasing programs; specifically, the Hospital IQR Program and the Merit-based Incentive Payment System (87 FR 70055) as well as the same measure proposals for the Inpatient Psychiatric Facility Quality Reporting Program in the FY 2024 IPF PPS proposed rule (88 FR 21280) and the End-Stage Renal Disease (ESRD) Quality Incentive Program in the CY 2024 ESRD PPS proposed rule (88 FR 42515). We appreciate commenter concern about the potential for misalignment with NCQA's Social Need Screening and Intervention measure proposed for adoption in HEDIS and for Social Drivers of Health measures that could be included in the Medicaid Core Set; however, we wish to reiterate that our approach to developing health equity measures is incremental and will evolve over time to capture health equity outcomes in the PCHQR Program and we will continue to look for ways to minimize provider reporting burden. While we recognize the value of measures undergoing CBE endorsement review, given the urgency of achieving health equity, we believe it is important to implement this measure in the PCH setting as soon as possible.

Comment: A commenter recommended implementation of health equity measures over a longer period of time to ensure resources support patient outcomes and do not erode consumer trust.

Response: We believe that adopting the Screening for Social Drivers of Health measure beginning with voluntary reporting for the FY 2026 program year and mandatory reporting beginning with the FY 2027 program year will allow PCHs to have the time needed to prepare to collect these data if not already doing so and to identify community partners for connecting individuals to resources in their communities. However, we will continue to monitor implementation and consider feedback.

Comment: A commenter recommended the Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health measures be implemented consistently and allow fair comparisons across providers and regions citing concerns with resource differences between hospitals and the potential for inaccurate or biased results for indicators that may have small denominators.

Response: The Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health measures support the identification of specific risk factors for inadequate healthcare access and adverse health outcomes among patients. The Screening for Social Drivers of Health measure supports data collection for PCHs to inform more meaningful and sustainable solutions for closing equity gaps among the communities they serve. The Screen Positive Rate for Social Drivers of Health measure is intended to provide information to PCHs on the level of unmet need among their patients and potentially in the community while providing an opportunity to compare PCHs and to promote higher levels of screening. We believe public reporting of healthcare quality data promotes transparency in the delivery of care by increasing the involvement of leadership in healthcare quality improvement, creating a sense of accountability, helping to focus organizational priorities, and providing a means of delivering important healthcare information to consumers and patient advocates. To support patient and patient understanding and to minimize confusion, we intend to conduct outreach and education with providers and patients to share information about the two Social Drivers of Health measures in conjunction with public reporting.

Comment: A commenter recommended CMS ensure social needs screenings are done in a respectful and person-centered way that build trust consumers on why hospitals are collecting these data, how it will be used, how it will not be used, and how it will be protected.

Response: We agree with the commenter that it is important for the screening for HRSNs to be accomplished in a way that is respectful, person-centered, and engenders trust. We recommend that PCHs evaluate the requirements for administration (such as whether the screening instrument can be administered by peer support specialists) as part of their instrument selection process. We note that the AHC instrument described in this section of the preamble of the final rule allows administration by clinicians and staff[740] and would allow administration by peer support specialists. We note that the data produced by these screenings are considered protected health information and are therefore covered by the HIPAA Privacy Rule. Therefore, PCHs are responsible for adopting reasonable safeguards to ensure that these data are not disclosed. We defer to PCHs to make the appropriate disclosures to their patients regarding how the collected data are used as well as ensuring that the patient and their caregiver(s) are informed of their option to opt-out of screening.

Comment: A commenter recommended that CMS address the technical challenges of this measure including working with ONC to standardize documentation across EHRs and add the capability to screen for social needs and document the results to the ONC Health IT Certification Program.

Response: We recognize that there are multiple sources for HRSN data that could be incorporated into a tool, such as administrative claims data, electronic clinical data, standardized patient assessments, patient-reported data and surveys, and multiple publicly available screening tools. We also recognize that this could present some technical challenges for PCHs. We encourage PCHs to implement digital standardized screening tools which conform to health IT vocabulary standards that enable interoperability of this data across systems. We note that the use of certified health IT can support the capture and exchange of HRSN information in an interoperable fashion so that these data can be shared across the care continuum to support coordinated care, for instance, through use of standards for SDOH Assessment data identified as part of the United States Core Data for Interoperability.[741]

Comment: A commenter expressed its belief that the measure is vague and recommended it be submitted for review and endorsement by a CBE to ensure feasibility and scientific acceptability.

Response: The two Social Drivers of Health measures are derived from

[740] *https://nam.edu/standardized-screening-for-health-related-social-needs-in-clinical-settings-the-accountable-health-communities-screening-tool/.*

[741] *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

existing evidence from both the AHC Model [742] and emerging evidence of correlations between the designated drivers of health and higher healthcare utilization of emergency departments and hospitals, worse health outcomes and/or drivers of health for which interventions have shown marked improvements in health outcomes and health care utilization. We disagree with the characterization of the measure as vague and refer to the measure specifications available at: *https://cmit.cms.gov/cmit/#/*. While we recognize the value of measures undergoing CBE endorsement review, given the urgency of achieving health equity, we believe it is important to implement this measure as soon as possible while balancing PCHs' need for sufficient time to implement screening and data collection processes if not already implemented, which is why we proposed to adopt the measure beginning with voluntary reporting in the FY 2026 program year and mandatory reporting beginning with the FY 2027 program year. We note that under section 1886(s)(4)(D)(ii) of the Act the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and therefore, we believe the exception in section 1886(s)(4)(D)(ii) of the Act applies.

Comment: A commenter recommended that the initiation of public display be contingent upon verification of accuracy of data reported.

Response: We believe that adopting the Screening for Social Drivers of Health measure beginning with voluntary reporting for the FY 2026 program year and mandatory reporting beginning with the FY 2027 program year and displaying the data publicly beginning July 2027 or as soon as feasible thereafter would allow PCHs the opportunity to review the accuracy of their data prior to public display.

After consideration of the public comments we received, we are finalizing this measure.

[742] RTI International. (2020) Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt.*

5. Adoption of the Screen Positive Rate for Social Drivers of Health Beginning With Voluntary Reporting for the FY 2026 Program Year and Mandatory Reporting Beginning With the FY 2027 Program Year

a. Background

The impact of social risk factors on health outcomes has been well-established in the literature.[743] [744] [745] [746] [747] The Physicians Foundation reported that 73 percent of the physician respondents to their annual survey agreed that social risk factors such as housing instability and food insecurity would drive health services demand in 2021.[748] Recognizing the need for a more comprehensive approach to closing equity gaps, we have prioritized quality measures that identify drivers of health among patients served in various care settings and, in turn, support providers in addressing the impact of these drivers on disparities in patient outcomes, healthcare utilization, and costs.[749] [750] [751] Specifically, in the inpatient setting, we aim to encourage systematic identification of patients' HRSNs as part of discharge planning, with the intention of promoting linkages with relevant community-based services that address those needs and support sustainable improvements in health outcomes following discharge from the PCH.

While the Screening for Social Drivers of Health measure (discussed previously in section IX.D.4. of the preamble of this final rule) enables identification of individuals with HRSNs, the Screen Positive Rate for Social Drivers of Health measure would allow providers to capture the magnitude of these needs and even estimate the impact of individual-level HRSNs on healthcare utilization when evaluating quality of care.[752] [753] [754] The Screen Positive Rate for Social Drivers of Health measure will require the reporting of the resulting screen positive rates for each domain. Reporting the screen positive rate for social drivers of health for each domain could inform actionable planning by PCHs towards closing equity gaps unique to the populations they serve and enable the development of individual patient action plans (including navigation and referral).

The Screen Positive Rate for Social Drivers of Health measure will assess the percent of patients admitted to the PCH who are 18 years or older at time of admission who were screened for HRSN and who screen positive for one or more of the core HRSNs, including food insecurity, housing instability, transportation needs, utility difficulties, or interpersonal safety (reported as five separate rates).[755] We refer readers to

[743] Institute of Medicine (2014). Capturing Social and Behavioral Domains and Measures in Electronic Health Records: Phase 2. Washington, DC: The National Academies Press. Available at: *https://doi.org/10.17226/18951*.

[744] Centers for Medicare & Medicaid Services. (2021) Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: *https://innovation.cms.gov/innovation-models/ahcm*. Accessed November 23, 2021.

[745] Kaiser Family Foundation. (2021) Racial and Ethnic Health Inequities and Medicare. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/*. Accessed November 23, 2021.

[746] Milkie Vu et al. Predictors of Delayed Healthcare Seeking Among American Muslim Women, Journal of Women's Health 26(6) (2016) at 58; Nadimpalli SB, Cleland CM, Hutchinson MK, Islam N, Barnes LL, Van Devanter N. (2016) The Association between Discrimination and the Health of Sikh Asian Indians. Health Psychology, 35(4), 351–355. *https://doi.org/10.1037/hea0000268*.

[747] Office of the Assistant Secretary for Planning and Evaluation (ASPE). (2020). Report to Congress: Social Risk Factors and Performance Under Medicare's Value-Based Purchasing Program (Second of Two Reports). Available at: *https://aspe.hhs.gov/pdf-report/second-impact-report-to-congress*.

[748] The Physicians Foundation. (2020) 2020 Survey of America's Patients, Part Three. Available at: *https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf*.

[749] Alley, D.E., C.N. Asomugha, P.H. Conway, and D.M. Sanghavi. 2016. Accountable Health Communities–Addressing Social Needs through Medicare and Medicaid. The New England Journal of Medicine 374(1):8–11. Available at: *https://doi.org/10.1056/NEJMp1512532*.

[750] Centers for Medicare & Medicaid Services. (2021). Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: *https://innovation.cms.gov/innovation-models/ahcm*. Accessed November 23, 2021.

[751] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool. NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b*.

[752] Baker, M.C., Alberti, P.M., Tsao, T.Y., Fluegge, K., Howland, R.E., & Haberman, M. (2021). Social Determinants Matter for Hospital Readmission Policy: Insights From New York City. Health Affairs, 40(4), 645–654. Available at: *https://doi.org/10.1377/hlthaff.2020.01742*.

[753] CMS. Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: *https://innovation.cms.gov/innovation-models/ahcm*. Accessed November 23, 2021.

[754] Hammond, G., Johnston, K., Huang, K., Joynt Maddox, K. (2020). Social Determinants of Health Improve Predictive Accuracy of Clinical Risk Models for Cardiovascular Hospitalization, Annual Cost, and Death. Circulation: Cardiovascular Quality and Outcomes, 13 (6) 290–299. Available at: *https://doi.org/10.1161/CIRCOUTCOMES.120.006752*.

[755] Billioux, A., Verlander, K., Anthony, S., & Alley, D. (2017). Standardized Screening for Health-Related Social Needs in Clinical Settings: The Accountable Health Communities Screening Tool.

Continued

the discussion of the identification process resulting in the selection of these five domains in section IX.D.4. of the preamble of this final rule.

The COVID–19 pandemic underscored the overwhelming impact that these five core domains have on disparities, health risk, healthcare access, and health outcomes, including premature mortality.[756] [757] Adoption of the Screen Positive Rate for Social Drivers of Health measure seeks to encourage PCHs to track the prevalence of specific HRSNs among patients over time and use the data to stratify risk as part of quality improvement efforts. This measure may also prove useful to patients by providing data transparency and signifying PCHs' familiarity, expertise, and commitment regarding these issues. For example, evaluation of AHC Model participation demonstrated positive feedback and enhanced trust among patients.[758] This measure also has the potential to reduce healthcare provider burden and burnout by both acknowledging patients' non-clinical needs that nevertheless greatly contribute to adverse clinical outcomes and linking providers with community-based organizations to enhance patient-centered treatment and discharge planning.[759] [760] [761] Finally, we believe this measure has the potential to facilitate data-informed collaboration with community-based services and focused community investments, including the development of pathways and infrastructure to more seamlessly connect patients to local community resources.

Ultimately, we are focused on supporting effective and sustainable collaboration between healthcare delivery and community-based providers to meet the unmet needs of people they serve. Reporting data from both the Screening for Social Drivers of Health and Screen Positive Rate for Social Drivers of Health measures would enable both identification and quantification of HRSNs among communities served by PCHs. These measures harmonize, as it is important to know both if screening occurred and the results from the screening to develop sustainable solutions. As with the theory of change for the AHC Model, we also expect resultant clinical-community collaborations, and an associated increase in system capacity and community investments, to yield a net reduction in costly healthcare utilization by promoting more appropriate healthcare service consumption.[762]

Pursuant to the Meaningful Measures 2.0 Framework and in alignment with the measures previously adopted for hospitals participating in the Hospital IQR Program, this measure will address the ''healthcare equity'' priority area and align with our commitment to introduce plans to close health equity gaps and promote equity through quality measures, including to ''develop and implement measures that reflect social and economic determinants.'' [763] Under CMS' Meaningful Measures Framework, the Screen Positive Rate for Social Drivers of Health measure will address the quality priority of ''Work with Communities to Promote Best Practices of Healthy Living'' through the Meaningful Measures Area of ''Equity of Care.'' [764] Development of this measure also aligns with our strategic pillar to advance health equity by addressing the health disparities that underlie our health system.[765]

b. Overview of Measure

The Screen Positive Rate for Social Drivers of Health measure is intended to enhance standardized data collection that can identify people who are at higher risk for poor health outcomes related to HRSNs who could benefit from connection via the PCH to targeted community-based services.[766] The measure will identify the proportion of patients who screened positive for one or more of the following five HRSNs on the date of admission to the PCH: Food insecurity, housing instability, transportation needs, utility difficulties, and interpersonal safety. PCHs will report this measure as five separate rates. We note that this measure is intended to provide information to PCHs on the level of unmet social needs among patients served, and not for comparison between PCHs.

Measure specifications for this measure are currently available at: *https://cmit.cms.gov/cmit/#/*.

(1) Cohort

The Screen Positive Rate for Social Drivers of Health is a process measure that provides information on the percent of patients, 18 years or older on the date of admission for a PCH stay, who were screened for an HRSN, during their inpatient stay and who screened positive for one or more of the following five HRSNs: Food insecurity, housing instability, transportation needs, utility difficulties, or interpersonal safety.

(2) Numerator

The numerator consists of the number of patients admitted for an PCH stay who are 18 years or older on the date of admission, who were screened for an HRSN, and who screen positive for having a need in one or more of the following five HRSNs (calculated separately): food insecurity, housing instability, transportation needs, utility difficulties or interpersonal safety.

(3) Denominator

The denominator consists of the number of patients admitted for a PCH stay who are 18 years or older on the date of admission and are screened for an HRSN (food insecurity, housing instability, transportation needs, utility difficulties and interpersonal safety) during their PCH stay. The following patients will be excluded from the

NAM Perspectives, 7(5). Available at: *https://doi.org/10.31478/201705b*.

[756] Kaiser Family Foundation. (2021) Racial and Ethnic Health Inequities and Medicare. Available at: *https://www.kff.org/medicare/report/racial-and-ethnic-health-inequities-and-medicare/*. Accessed November 23, 2021.

[757] Centers for Disease Control and Prevention. (2019) CDC COVID–19 Response Health Equity Strategy: Accelerating Progress Towards Reducing COVID–19 Disparities and Achieving Health Equity. July 2020. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/community/health-equity/cdc-strategy.html*. Accessed November 17, 2021.

[758] RTI International. (2020) Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*.

[759] The Physicians Foundation. (2020) Survey of America's Patients, Part Three. Available at: *https://physiciansfoundation.org/wp-content/uploads/2020/10/2020-Physicians-Foundation-Survey-Part3.pdf*.

[760] De Marchis, E., Knox, M., Hessler, D., Willard-Grace, R., Oliyawola, JN, et al. (2019). Physician Burnout and Higher Clinic Capacity to Address Patients' Social Needs. The Journal of the American Board of Family Medicine, 32 (1), 69–78.

[761] Kung, A., Cheung, T., Knox, M., Willard-Grace, R., Halpern, J., et.al, (2019). Capacity to Address Social Needs Affect Primary Care Clinician Burnout. Annals of Family Medicine. 17 (6), 487–494. Available at: *https://doi.org/10.1370/afm.2470*.

[762] Centers for Medicare & Medicaid Services. (2021) Accountable Health Communities Model. Accountable Health Communities Model | CMS Innovation Center. Available at: *https://innovation.cms.gov/innovation-models/ahcm*. Accessed November 23, 2021.

[763] Centers for Medicare & Medicaid Services. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. Available at: *https://www.cms.gov/meaningful-measures-20-moving-measure-reduction-modernization*.

[764] Centers for Medicare & Medicaid Services. (2021) CMS Measures Management System Blueprint (Blueprint v 17.0). Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/MMS-Blueprint*.

[765] Brooks-LaSure, C. (2021). My First 100 Days and Where We Go From Here: A Strategic Vision for CMS. Available at: *https://www.cms.gov/blog/my-first-100-days-and-where-we-go-here-strategic-vision-cms*.

[766] Centers for Medicare & Medicaid Services. (2021) A Guide to Using the Accountable Health Communities Health-Related Social Needs Screening Tool: Promising Practices and Key Insights (June 2021). Available at: *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion*. Accessed November 23, 2021.

denominator: (1) Patients who opt-out of screening; and (2) patients who are themselves unable to complete the screening during their inpatient stay and have no caregiver able to do so on the patient's behalf during their inpatient stay.

c. Measure Calculation

The result of this measure will be calculated as five separate rates. Each rate is derived from the number of patients admitted for a PCH stay and who are 18 years or older on the date of admission, screened for an HRSN, and who screen positive for each of the five HRSNs—food insecurity, housing instability, transportation needs, utility difficulties, or interpersonal safety—divided by the number of patients 18 years or older on the date of admission screened for each of the five HRSNs.

d. Data Collection, Submission and Reporting

In the proposed rule, we proposed to require PCHs to submit information for this measure once annually using a CMS-approved web-based data collection tool available within the Hospital Quality Reporting (HQR) System beginning with voluntary reporting for the FY 2026 program year and mandatory reporting beginning with the FY 2027 program year. PCHs will follow the established submission and reporting requirements for web-based measures for the PCHQR Program posted on the QualityNet website.

e. Review by the Measure Applications Partnership

The Screen Positive Rate for Social Drivers of Health measure was included for consideration in the PCHQR Program on the publicly available MUC List, a list of measures under consideration for use in various Medicare programs.[767] The CBE-convened MAP Health Equity Advisory Group reviewed the MUC List and the Screen Positive Rate for Social Drivers of Health measure (MUC 2022–050) in detail and at the same time as the Screening for Social Drivers of Health measure on December 6–7, 2022.[768] The Health Equity Advisory Group expressed support for the collection of data related to social health drivers, but raised concerns regarding public reporting and the repetition of asking patients the same questions. In addition, on December 8–9, 2022, the MAP Rural Health Advisory Group reviewed the 2022 MUC List and was also reviewed by the MAP Hospital Workgroup on December 13–14, 2022.[769] The Rural Health Advisory Group noted potential reporting challenges including the potential masking of health disparities that are underrepresented in some areas and that sample size and populations served may be an issue, but also expressed support that the measure seeks to advance the drivers of health and serves as a starting point to determine where screening is occurring. The MAP Hospital Workgroup recommended conditional support for the measure for rulemaking pending endorsement by a CBE to address reliability and validity concerns, attentiveness to how results are shared and contextualized for public reporting, and encouragement for CMS to examine any differences in reported rates by reporting process (to assess whether they are the same or different across PCHs).[770] Thereafter, the MAP Coordinating Committee deliberated on January 24–25, 2023, and ultimately voted to conditionally support the Screen Positive Rate for Social Drivers of Health measure for rulemaking with the same conditions.[771]

We agree with the MAP Coordinating Committee's support for the Screen Positive Rate for Social Drivers of Health measure. We believe this measure establishes an important foundation to prioritizing the achievement of health equity among providers participating in a comprehensive quality reporting program. Our approach to developing health equity-focused measures is incremental, and we believe that health care equity outcomes in the PCHQR Program will inform future efforts to advance and achieve health care equity by PCHs. We additionally believe this measure to be a building block that lays the groundwork for a future meaningful suite of measures that could assess PCH progress in providing high-quality healthcare for all patients, regardless of social risk factors or demographic characteristics.

f. CBE Endorsement

We have not submitted this measure for CBE endorsement at this time. Although section 1866(k)(3)(A) of the Act generally requires that measures specified by the Secretary for use in the PCHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, section 1866(k)(3)(B) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and, therefore, we believe the exception in section 1866(k)(3)(B) of the Act applies.

g. Public Display

In the proposed rule, we proposed to publicly display the PCH-specific results for the Screen Positive Rate for Social Drivers of Health measure and refer readers to Table IX.D.–04 in the preamble of this final rule for the public display requirements.

We invited public comment on this proposal.

We note that we have addressed comments that broadly referred to both the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure in the previous section IX.D.4. of this final rule.

Comment: Many commenters expressed support for the measure to advance health equity. A few commenters expressed support for the measure as an important step in addressing equity through quality measurement. A commenter expressed support for the measure believing it will focus attention and resources on patient needs, address a measurement gap in CMS quality programs for hospitals, and help inform more comprehensive care and discharge planning. A commenter expressed support for the measure believing it is a positive first step toward considering and tracking SDOH.

Response: We thank the commenters for their support.

Comment: A few commenters expressed concern with how the results of the Screen Positive Rate for Social Drivers of Health measure would be communicated and displayed believing the results could be misunderstood by consumers.

Response: We appreciate the commenters' concerns. As we discussed previously, the measure provides a means of delivering important

[767] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[768] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[769] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[770] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[771] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

healthcare information to consumers and patient advocates on the level of unmet need among PCH patients and potentially in the community, and not for comparison between PCHs. We believe public reporting of healthcare quality data promotes transparency in the delivery of care by increasing the involvement of leadership in healthcare quality improvement, creating a sense of accountability, helping to focus organizational priorities, and providing a means of delivering important healthcare information to consumers and patient advocates. We intend to conduct outreach and education with providers and patients to share information about the two Social Drivers of Health measures in conjunction with public reporting.

After consideration of the public comments we received, we are finalizing this measure.

6. Adoption of the Documentation of Goals of Care Discussions Among Cancer Patients Measure Beginning With the FY 2026 Program Year

a. Background

Goals of care discussions are intended to inform future treatment decisions that account for and are responsive to the interests expressed by patients with advanced cancer and can also impact referrals to palliative care and end-of-life treatments. Goal of care discussions are discussions between the patient and the oncology team and the primary oncologist is responsible for ensuring documentation of these discussions.

While 99 percent of clinicians believe that serious illness conversations are important, only 29 percent of clinicians report having received serious illness communication training.[772] One study found that Americans report having a serious illness conversation with their clinician only 11 percent of the time.[773] In the 2017 publication *Patient-Clinician Communication: American Society of Clinical Oncology Consensus Guideline,* the American Society of Clinical Oncology (ASCO) recommended clinician training in communication skills and discussion of goals of care and prognosis, treatment selection, end-of-life care, and facilitating family involvement in care.[774]

We believe the lack of these conversations creates a gap in the care delivered when the oncology team, including the oncologist, does not know their patients' goals of care. While 92 percent of Americans say that they would be comfortable having these discussions with their clinicians, among seriously ill patients who prefer comfort care, only 41 percent report care consistent with their wishes.[775] Care inconsistent with preferences is associated with a lower quality of care and higher medical costs.[776]

Guidelines suggest that goal of care discussions should be conducted early for patients with metastatic cancer who have a life expectancy of less than one year.[777] However, most oncology settings do not adequately support documentation that is most relevant to goals of cancer care. In 2020, the Alliance of Dedicated Cancer Centers (ADCC) initiated the Improving Goal Concordant Care (IGCC) to address system gaps and to establish new expectations for when and how goals-of-care conversations occur. The initiative places responsibility on the primary oncology team with the oncologist responsible for ensuring documentation of these discussions, for timely initiation and ongoing conversations regarding goals of care with their patients and recommends a structured goals-of-care documentation in electronic health records, including a minimum set of structured fields and functionality to promote access and retrieval across providers and settings.

Goals of care documentation should be discrete and structured whenever possible to both ease entry and to facilitate retrieval. We note that the oncology team, including the oncologist, is responsible for the goals of care discussion and the oncologist is responsible for ensuring documentation of these discussions. The ADCC made the following structure and functionality recommendations:[778]

- Minimizing documentation burden is critical to support clinician workflow and promote efficiencies.
- Core documentation should be in a 'single source of truth' in one location in the EHR, reflecting conversations across time, settings, and providers.
- Designated, authorized members of the care team (which might include advanced practice providers, oncology nurses and social workers, as designated by the center) should be able to document appropriate fields related to goals of care communications.

We believe documentation of goals in structured fields prompts meaningful patient-centered discussions, enhances care quality and efficiency, promotes accessibility, and supports concordant care.

b. Overview of Measure

This measure assesses goals of care discussion documentation among patients with cancer who die while receiving care at the reporting PCH. On an annual basis, PCHs will report the percent of cancer patients who died during the reporting period and had patients' goals of care documented prior to death, beginning with the FY 2026 program year.

The Documentation of Goals of Care Discussions Among Cancer Patients measure is a process measure which focuses on the essential process of documenting goals of care conversations in the EHR by assessing the presence of this documentation in the medical record. The intent of this measure is for PCHs to track and improve this documentation to ensure that that such conversations have taken place, have been properly documented in a manner that is retrievable by all members of the PCH healthcare team, and to facilitate the delivery of care that aligns with patients' and families' values and unique priorities.

This measure requires the use of both hospital administrative data (non-claims) for clinical information and discrete documentation in the EHR documenting the goals of care discussion. Measure specifications can be found here: *https://cmit.cms.gov/cmit/#/.*

(1) Measure Population

The population is the number of patients who died in the measurement period, including patients participating in clinical trials, as long as these

[772] Fulmer T, Escobedo M, Berman A, Koren MJ, Hernández S, Hult A. Physicians' Views on Advance Care Planning and End-of-Life Conversations. *Journal of the American Geriatrics Society.* 208;66(6):1201–1205.

[773] Hamel, Liz, et al. *Views and Experiences with End-of-Life Medical Care in the U.S.* 2017.

[774] Gilligan T, Coyle N, Frankel RM, et al. Patient-Clinician Communication: American Society of Clinical Oncology Consensus Guideline. *Journal of Clinical Oncology,* 2017; *35*(31), 3618–3632. *https://doi.org/10.1200/JCO.2017.75.2311.*

[775] Teno JM, Fisher ES, Hamel MB, Coppola K, Dawson NV. Medical Care Inconsistent with Patients' Treatment Goals: Association with 1-Year Medicare Resources Use and Survival. *Journal of the American Geriatrics Society. 2002;50(3):496–500.*

[776] Khandelwal N, Curtis JR, Freedman VA, et al. How Often is End-of-Life Care in the United States Inconsistent with Patients' Goals of Care? *Journal of Palliative Medicine.* 2017;20(12): 1400–1404.

[777] American Society of Clinical Oncology Quality Oncology Practice Initiative: Quality Clinical Data Registry Measures. 2014. *https://www.instituteforquality.org/quality-oncology-practice-initiative-qopi*; see also, Berger MJ, Ettinger DS, Aston J, et al.: NCCN guidelines insights: Antiemesis, version 2.2017. J Natl Compr Canc Netw 15:883–893, 2017.

[778] Alliance of Dedicated Cancer Centers. Improving Goal Concordant Care Initiative Implementation Planning Guide. September 2020.

patients meet the criteria for the measure's population. This population is defined using PCH administrative data (non-claims) and discrete documentation in the electronic health record as follows:

- Patients who died at the PCH in the measurement period; and
- Who had a diagnosis of cancer; and
- Who had a least two eligible contacts at the PCH within the six months prior to their date of death. Eligible contacts are inpatient admissions and hematology or oncology ambulatory visits at the reporting hospital.

(2) Denominator

The denominator is the number of patients meeting the criteria for inclusion in the measure's population in the reporting period.

(3) Numerator

The numerator is the number of patients who were included in the denominator for whom a Goals of Care conversation was documented in a structured field in the medical record. The measure will require any documentation in one or more patient goals fields. To meet the requirements for inclusion in the numerator, the documentation in the EHR will be required to include either of the following:

- Any documentation in one or more patient goals fields in the electronic medical record, or
- Documentation that the patient opted not to have a goals of care discussion. Documentation may originate from any visit type or provider as permitted by the PCH. Any member of the PCH health care team could perform such documentation for purposes of the measure, but we strongly encourage a patient's oncologist to ensure appropriate discussions of goals of care occur and to oversee the documentation of the goals of care discussion.

c. Calculation of Performance Score

Performance is reported as a proportion (percentage) determined by calculating [(Numerator ÷ Denominator)] × 100. A higher score is better.

d. Data Submission and Reporting

In the proposed rule, we proposed to require PCHs to submit information for this measure once annually using a CMS-approved web-based data collection tool available within the Hospital Quality Reporting (HQR) System (previously referred to as the QualityNet Secure Portal) beginning with the FY 2026 program year. PCHs will follow the submission and reporting requirements for web-based measures for the PCHQR Program posted on the QualityNet website.

e. Review by the Measure Applications Partnership

The Documentation of Goals of Care Discussions Among Cancer Patients measure was included in the publicly available MUC List, a list of measures under consideration for use in various Medicare quality programs.[779] The CBE-convened MAP reviewed the MUC List and the Documentation of Goals of Care Discussions Among Cancer Patients measure (MUC 2022–120) in detail on December 6–7, 2022.[780] In addition, on December 8–9, 2022, the MAP Rural Health Advisory Group reviewed the 2022 MUC List and the MAP Hospital Workgroup reviewed the measure on December 13–14, 2022. The Rural Health Advisory Group expressed strong support for the measure. The MAP Hospital Workgroup recommended conditional support for rulemaking pending testing indicating the measure is reliable and valid, and endorsement by a consensus-based entity (CBE).[781] Thereafter, the MAP Coordinating Committee deliberated on January 24–25, 2023, and ultimately voted to conditionally support the Documentation of Goals of Care Discussions Among Cancer Patients measure for rulemaking with the same conditions.[782]

We agree with the MAP that measuring documentation of goals of care discussions is an important step toward achieving the outcome of goal-concordant care and that documentation of goals in structured fields prompts discussions, enhances their quality and efficiency, and promotes accessibility. We also believe goals of care discussions with patients are associated with better patient and family outcomes.

f. CBE Endorsement

The measure has not been submitted by its steward, ADCC, for CBE endorsement at this time. Although section 1866(k)(3)(A) of the Act generally requires that measures specified by the Secretary for use in the PCHQR Program be endorsed by the entity with a contract under section 1890(a) of the Act, section 1866(k)(3)(B) of the Act states that in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a) of the Act, the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. We reviewed CBE-endorsed measures and were unable to identify any other CBE-endorsed measures on this topic, and, therefore, we believe the exception in section 1866(k)(3)(B) of the Act applies.

g. Public Display

In the proposed rule, we proposed to publicly display the PCH-specific results for the Documentation of Goals of Care Discussion Among Cancer Patients measure and refer readers to Table IX.D.–04 in the preamble of this final rule for the public display requirements.

We invited public comment on this proposal.

Comment: Several commenters expressed support for the Documentation of Goals of Care Discussions Among Cancer Patients measure. A commenter believed the measure is an initial step toward person-centered cancer care. Another commenter supported the measure because it supports delivering concordant care to cancer patients, particularly for coordination with primary care settings in rural communities. A few commenters expressed support for future public display.

Response: We appreciate commenters' support for the Documentation of Goals of Care Discussions Among Cancer Patients measure. We agree that this measure is an important step in alignment with our commitment to person centered care. We also agree that public display is an important part of quality improvement in cancer care.

Comment: A few commenters recommended CMS consider replacing the measure with a process or outcomes measure at a future point. A commenter recommended that occupational therapists should be added to the list of professionals who gather measure data citing their expertise gathering patient information and guiding patients through care planning. Another commenter recommended the measure should not include advance care

[779] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[780] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[781] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[782] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

planning because it has not yet proven to have significant impact on end-of-life care.

Response: We thank the commenters for their recommendations. We will consider the potential role for occupational therapists in future rulemaking. We note the commenter's concern about including advance care planning in the Documentation of Goals of Care Discussions Among Cancer Patients measure and will continue to work with PCHs for opportunities to improve the quality of data in the PCHQR Program.

Comment: Another commenter recommended delaying public reporting at least one year to allow verification of data accuracy.

Response: We appreciate the commenter's recommendation; however, we believe that adopting the Documentation of Goals of Care Discussions Among Cancer Patients measure beginning with the FY 2026 program year and publicly displaying PCH-specific results in July 2026 or as soon as feasible thereafter would provide the time needed for PCHs to review data for accuracy. We refer readers to Table IX.D.–04 for previously finalized and newly finalized public display requirements.

After consideration of the public comments we received, we are finalizing this measure.

7. Summary of Previously Adopted and New PCHQR Program Measures for the FY 2026 Program Year and Subsequent Years

For ease of reference, Table IX.D.–03 summarizes the previously adopted and the newly finalized measures for the PCHQR Program measures for the FY 2026 program year and subsequent years.

TABLE IX.D.-03: PREVIOUSLY ADOPTED MEASURES AND NEW MEASURES FOR THE PCHQR PROGRAM MEASURE SET FOR FY 2026 PROGRAM YEAR AND SUBSEQUENT YEARS

Short Name	CBE Number	Measure Name
Safety and Healthcare-Associated Infection (HAI) Measures		
CAUTI	0138	National Healthcare Safety Network (NHSN) Catheter-associated Urinary Tract Infection (CAUTI) Outcome Measure
CLABSI	0139	NHSN Central line-associated Bloodstream Infection (CLABSI) Outcome Measure
Flu HCP Vaccination	0431	Influenza Vaccination Coverage Among Healthcare Personnel (HCP)
COVID-19 HCP Vaccination	N/A	COVID-19 Vaccination Coverage Among HCP *
Colon and Abdominal Hysterectomy SSI	0753	American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure (currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery)
MRSA	1716	NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure
CDI	1717	NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure
Clinical Process/Oncology Care Measures		
EOL-Chemo	0210	Proportion of Patients Who Died from Cancer - Receiving Chemotherapy in the Last 14 Days of Life
EOL-Hospice	0215	Proportion of Patients Who Died from Cancer - Not Admitted to Hospice
Intermediate Clinical Outcome Measures		
EOL-ICU	0213	Proportion of Patients Who Died from Cancer - Admitted to the ICU in the Last 30 Days of Life
EOL-3DH	0216	Proportion of Patients Who Died from Cancer - Admitted to Hospice for Less Than Three Days
Patient Engagement/Experience of Care Measure		
HCAHPS	0166	Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey
N/A	N/A	Documentation of Goals of Care Discussions Among

Short Name	CBE Number	Measure Name
		Cancer Patients**
Claims Based Outcome Measures		
N/A	N/A	Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy
N/A	3188	30-Day Unplanned Readmissions for Cancer Patients
N/A	N/A	Surgical Treatment Complications for Localized Prostate Cancer
Health Equity Measures		
N/A	N/A	Facility Commitment to Health Equity**
N/A	N/A	Screening for Social Drivers of Health***
N/A	N/A	Screen Positive Rate for Social Drivers of Health***

* We are modifying the COVID-19 Vaccination Coverage Among HCP measure in section IX.B. of this final rule beginning with the Quarter 3 2023 reporting period for the FY 2025 program year.
**Indicates new measures finalized in this final rule.
*** Indicates new measures finalized in this final rule beginning with voluntary reporting for the FY 2026 program year and mandatory reporting beginning with the FY 2027 program year.

8. Maintenance of Technical Specifications for Quality Measures

We maintain and periodically update technical specifications for the PCHQR Program measures. The specifications may be found on the QualityNet website at *https://qualitynet.cms.gov/pch*. We also refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50281), where we adopted a policy to use a subregulatory process to make nonsubstantive updates to measures used for the PCHQR Program. We did not propose any changes to our processes for maintaining technical specifications for PCHQR Program measures.

9. Public Display Requirements

a. Background

Section 1866(k)(4) of the Act requires us to establish procedures for making the data submitted under the PCHQR Program available to the public. We refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57191 through 57192) for a detailed discussion of our public display procedures. We did not propose any changes to our previously finalized public display requirements.

b. Public Display of the Surgical Treatment Complications for Localized Prostate Cancer Measure Beginning With the FY 2025 Program Year

In the FY 2020 IPPS/LTCH PPS final rule, we adopted the Surgical Treatment Complications for Localized Prostate Cancer Measure (PCH–37) for the PCHQR measure set beginning with the FY 2022 program year (84 FR 42514 through 42517). We also finalized that we would confidentially report PCH performance on this measure to individual PCHs and that we would propose to publicly display PCH performance on this measure in the future (84 FR 42517).

Under our current policy, the PCH–37 measure is calculated on an annual basis using a one-year reporting period that is based on data collected from July 1 of the year that is three years prior to the program year to June 30 of the year that is two years prior to the program year (84 FR 42515). For the FY 2023 program year data, we confidentially reported to PCHs their data and measure calculations on the PCH–37 measure in July of 2022 reflecting the July 1, 2019 to June 30, 2020 reporting period. Additionally, we will confidentially report this measure for the FY 2024 program year data in the summer of 2023, reflecting the July 1, 2020 to June 30, 2021 reporting period.

We believe that providing PCHs confidential facility specific reports for 2 years will allow us to assess and confirm the feasibility of PCHs providing statistically robust, reliable, and valid measure results for the PCH–37 measure. Therefore, we proposed to publicly display the PCH-specific results for the PCH–37 measure beginning with the FY 2025 program year data in the summer of 2024, which would reflect PCH performance for the July 1, 2021 through June 30, 2022 reporting period. We will make these data publicly available following a 30-day period in which PCHs would have an opportunity to review the data. We will announce the exact timeframe on a CMS website and our applicable listservs.

We invited public comment on the proposal.

Comment: Many commenters expressed support for the public reporting of the Surgical Treatment Complications for Localized Prostate Cancer measure. A commenter expressed support believing the two years of confidential data reporting prior to public display ensures data accuracy. Another commenter believed it is an important factor for patient choice of providers.

Response: We thank the commenters for their support. We agree that two years of confidential data reporting prior to public reporting gives sufficient time ensure data accuracy. We also agree that publicly reporting this data will provide beneficiaries with important information when considering choice of providers.

Comment: Another commenter expressed its belief that information gathered from the PCH–37 measure should be made available to the public; however, the commenter also expressed concerns with how the data for the PCHQR Program are displayed to patients believing it is difficult to find data that would help a patient identify a provider or facility that would meet their specific needs. This commenter recommended that the data should be made easier to find, understandable by patients at all levels of health literacy, and include a variety of elements related to patient care such as proximity to home, cultural competency of the

healthcare facility, quality of services, and communication protocols.

Response: We strive to ensure all publicly reported data are reported both accurately and in a way that can be accessed by all our beneficiaries. We thank the commenter for the suggestion and intend to review for opportunities to increase useability of the data.

After consideration of the public comments we received, we are finalizing this policy.

c. Summary of Previously Finalized and Newly Finalized Public Display Requirements for the PCHQR Program

Our previously finalized and newly finalized public display requirements for the PCHQR Program measures are shown in the following Table IX.D.–04:

TABLE IX.D.-04: PREVIOUSLY FINALIZED AND NEWLY FINALIZED PUBLIC DISPLAY REQUIREMENTS FOR THE PCHQR PROGRAM

Summary of Previously Finalized and Newly Finalized Public Display Requirements	
Measures	**Public Reporting**
• HCAHPS (CBE #0166)	2016 and subsequent years
• American College of Surgeons – Centers for Disease Control and Prevention (ACS-CDC) Harmonized Procedure Specific Surgical Site Infection (SSI) Outcome Measure [currently includes SSIs following Colon Surgery and Abdominal Hysterectomy Surgery] (CBE #0753) • NHSN Facility-wide Inpatient Hospital-onset Methicillin-resistant *Staphylococcus aureus* Bacteremia Outcome Measure (CBE #1716) • NHSN Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure (CBE #1717) • NHSN Influenza Vaccination Coverage Among Healthcare Personnel (CBE #0431)	2019 and subsequent years
• COVID-19 Vaccination Coverage Among Healthcare Personnel	October 2022 and subsequent years
• Admissions and Emergency Department (ED) Visits for Patients Receiving Outpatient Chemotherapy	April 2020 and subsequent years
• CAUTI (CBE #0138) • CLABSI (CBE #0139)	October 2022 and subsequent years
• Proportion of Patients Who Died from Cancer Receiving Chemotherapy in the Last 14 Days of Life (CBE #0210) • Proportion of Patients Who Died from Cancer Not Admitted to Hospice (CBE #0215) • Proportion of Patients Who Died from Cancer Admitted to the ICU in the Last 30 Days of Life (CBE #0213) • Proportion of Patients Who Died from Cancer Admitted to Hospice for Less Than Three Days (CBE #0216)	July 2024 or as soon as feasible thereafter
• 30-day Unplanned Readmissions for Cancer Patients (CBE #3188)	October 2023 or as soon as feasible thereafter
• Surgical Treatment Complications for Localized Prostate Cancer Measure (PCH-37)*	July 2024 or as soon as feasible thereafter
• Facility Commitment to Health Equity*	July 2026 or as soon as feasible thereafter
• Screening for Social Drivers of Health*	July 2027 or as soon as feasible thereafter
• Screen Positive Rate for Social Drivers of Health*	July 2027 or as soon as feasible thereafter
• Documentation of Goals of Care Discussions Among Cancer Patients*	July 2026 or as soon as feasible thereafter

*Indicates policies finalized in this final rule.

10. Form, Manner, and Timing of Data Submissions

a. Background

We refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53563 through 53567); the FY 2014 IPPS/LTCH PPS final rule (78 FR 50848 through 50853); the FY 2015 IPPS/LTCH PPS final rule (79 FR 50282 through 50286); the FY 2016 IPPS/LTCH PPS final rule (80 FR 49722 through 49723); the FY 2017 IPPS/LTCH PPS final rule (FR); FY 2018 IPPS/LTCH PPS final rule (82 FR 38424); the FY 2019 IPPS/LTCH PPS final rule (83 FR 41623); FY 2020 IPPS/LTCH PPS final rule (84 FR 42523 through 42524); and the FY 2022 IPPS/LTCH PPS final rule (86 FR 45436) for our previously finalized procedural requirements for the PCHQR Program. Data submission requirements and deadlines for the PCHQR Program are posted on the QualityNet website.

b. Updates to the Data Submission and Reporting Requirements for the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey Measure (CBE #0166) Beginning with the FY 2027 Program Year

(1) Background

We partnered with the Agency for Healthcare Research and Quality (AHRQ) to develop the HCAHPS patient experience of care survey (CBE #0166) (hereinafter referred to as the HCAHPS Survey). We adopted the HCAHPS Survey in the PCHQR Program in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50852 through 50853) and refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49720 through 49722) and the FY 2020 IPPS/LTCH PPS final rule (84 FR 42510 through 42512) for details on previously adopted HCAHPS Survey measure submission and reporting requirements. We also refer PCHs and HCAHPS Survey vendors to the official HCAHPS website at *https://www.hcahpsonline.org* for new information and program updates regarding the HCAHPS Survey, its administration, oversight, and data adjustments.

The HCAHPS Survey (OMB control number 0938–0981) is the first national, standardized, publicly reported survey of patients' experience of hospital care and asks discharged patients 29 questions about their recent hospital stay. The HCAHPS Survey is administered to a random sample of adult patients who receive medical, surgical, or maternity care between 48 hours and six weeks (42 calendar days) after discharge and is not restricted to Medicare beneficiaries.[783] Hospitals must survey patients throughout each month of the year.[784] The HCAHPS Survey is available in official English, Spanish, Chinese, Russian, Vietnamese, Portuguese, German, Tagalog, and Arabic versions.

The HCAHPS Survey and its protocols for sampling, data collection and coding, and file submission can be found in the current HCAHPS Quality Assurance Guidelines, which is available on the official HCAHPS website at: *https://www.hcahpsonline.org/en/quality-assurance/*. AHRQ carried out a rigorous scientific process to develop and test the HCAHPS Survey instrument. This process entailed multiple steps, including: a public call for measures; literature reviews; cognitive interviews; consumer focus groups; multiple opportunities for additional stakeholder input; a three-State pilot test; small-scale field tests; and notice-and-comment rulemaking. A CBE first endorsed the HCAHPS Survey in 2005,[785] and re-endorsed the measure in 2010, 2015, and 2019.[786]

In 2021, we conducted a large-scale mode experiment to test adding the web mode and other updates to the form, manner, and timing of HCAHPS Survey data collection and reporting. The 2021 mode experiment employed a nationwide random sample of short-term acute care hospitals that participate in the HCAHPS Survey, including those from each of CMS's 10 geographic regions. Participating hospitals contributed patients discharged from April through September 2021. Within each hospital, the patients were randomly assigned to each mode of survey administration. In total, we received responses to a revised version of the HCAHPS Survey from 36,001 patients in 46 hospitals.

The design of the experiment was of sufficient scale to test survey items on new topics, revisions to existing survey items, and new and revised composite measures. It also enabled precise estimation of mode adjustments for current and new HCAHPS items for three currently approved HCAHPS Survey mode protocols and an additional three web-based protocols. This mode experiment was designed to have the power and precision of adjustment estimates comparable to those that are used and have proven necessary for adjustment of previous HCAHPS data.

The 2021 HCAHPS mode experiment had four main goals: (1) test the large-scale feasibility of web-first sequential multimode survey administrations in an inpatient setting; (2) investigate whether mode effects significantly differ between individuals with email addresses available to the data collection vendor compared to individuals without email addresses available to the vendor; (3) develop mode adjustments to be used in future national implementation; and, (4) test potential new survey items. This experiment included three currently approved mode protocols most commonly used by hospitals participating in HCAHPS: Mail Only, Phone Only, and Mail-Phone (mail with phone follow-up of non-responders). In this experiment, three additional mode protocols that added an initial Web phase to these current modes were considered: Web-Mail, Web-Phone, and Web-Mail-Phone. In addition, the mode experiment employed a 49-day data collection period for all six modes, which extended the standard HCAHPS data collection period by seven days. Doing so preserved the survey response period of the current survey while adding time for the Web phase. Unlike the current HCAHPS Survey, proxy respondents were not prohibited from completing the survey.

Another goal of the 2021 HCAHPS mode experiment was to test new survey content related to care coordination, discharge experience, communication with patient families, emotional support, sleep, and summoning help. We are using the mode experiment results to inform decisions about potential changes to administration protocols and survey content. Potential measure changes will be submitted to the MUC List in 2023 and may be proposed in future rulemaking. We did not propose changes to the HCAHPS Survey's content.

(2) Addition of Three New Modes of Survey Implementation

We proposed to add three new modes of survey administration (Web-Mail mode, Web-Phone mode, and Web-Mail-Phone mode) in addition to the current Mail Only, Phone Only and Mail-Phone modes, beginning with January 2025 discharges. We noted that the 2021 HCAHPS mode experiment added an initial web component to three current HCAHPS modes of survey

[783] HHS: HCAHPS: Patients' Perspectives of Care Survey, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalHCAHPS*.

[784] *Ibid.*

[785] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalHCAHPS*.

[786] HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) Survey. Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=91&sectionNumber=1*.

administration resulting in increased response rates. Overall, 9,642 patients completed a survey, resulting in a 28 percent response rate. The response rate for Mail Only mode was 22 percent, compared to 29 percent for Web-Mail mode. The response rate for Phone Only mode was 23 percent compared to 30 percent through Web-Phone mode. The response rate for Mail-Phone was 31 percent compared to 36 percent for Web-Mail-Phone mode.

Analysis of 2021 mode experiment data also revealed that patients who supplied an email address had a statistically significant higher response rate (31 percent) than patients without an email address (22 percent). The percentage of sampled patients with an email address varied by hospital, ranging from 11 percent to 94 percent. Overall, 63 percent of patients supplied an email address. Evidence from this and previous HCAHPS mode experiments indicate that sequential mixed modes of survey administration (for example, web followed by mail, or phone, or both) result in overall higher response rates and better representation of younger, Spanish language-preferring, racial and ethnic minority, and maternity care patients.

We invited public comment on this proposed update.

Comment: A commenter expressed support for proposed changes to the administration of HCAHPS.

Response: We thank the commenter for their support.

Comment: Several commenters supported the additional survey administration modes believing the changes reflect current communication preferences, will increase response rates, and increase patient satisfaction with the survey. A commenter expressed its belief that the expanded internet methods would increase the response rates overall and among younger, Spanish-language preferring, racial and ethnic minority, and maternity care patients. Another commenter believed the addition of the new modes would meaningfully aid in streamlining the data procurement and analysis process, substantially reduce data entry errors, enhance data security, and be cost effective.

Response: We thank the commenters for their support and agree that the addition of these three new modes of survey implementation will likely increase response rates for all patient populations. We also agree that these new modes of survey implementation have the potential to reduce the data collection and management burden while reducing survey administration costs in the long run. We will send a second and third email invitation in the Web-Mail and Web-Phone modes, and a second email invitation in the Web-Mail-Phone mode, to patients who did not respond to earlier email invitations. We note that procedures for survey administration will be clearly defined in the HCAHPS Quality Assurance Guidelines for all survey administration modes.

After consideration of the public comments we received, we are finalizing this policy.

(3) Removal of Prohibition of Proxy Respondents to the HCAHPS Survey

In response to stakeholder feedback, and evidence that proxy response does occur in mail administration despite the current protocol that asks that only the patient complete the survey, the mode experiment assessed the impact of not excluding proxy respondents. We found that not excluding proxies did not impact HCAHPS measure scores and, as such, it is not necessary to control for completion of the survey by a proxy in patient-mix adjustment. Consequently, we proposed to remove the requirement that only the patient may respond to the survey and allow a patient's proxy to respond to the survey, beginning with January 2025 discharges. We will, however, still encourage patients to respond to the survey rather than proxies.

We invited public comment on this proposed update.

Comment: Several commenters expressed support for the allowance of proxies believing it will increase response rates among certain hard to reach groups, provide valuable insight into care improvement, and that the risk of a proxy's response not being reflective of a patient's experience is outweighed by the need to attempt to capture the experiences of vulnerable patient populations. A commenter expressed support believing that proxy completion is critical to older patients with serious illness.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing this policy.

(4) Extension of the Data Collection Period

The 2021 mode experiment showed that extending the data collection period from 42 to 49 days allows time for respondents in the web-first modes to respond by email before contacting non-responders with the secondary mode of administration while also preserving adequate time for the secondary mode (either mail, phone, or mail followed by phone). Nearly 13 percent of respondents in the mode experiment completed the survey between days 43 and 49. Compared to the first 42 days, during days 43 to 49 there was a statistically significant increase in responses from patients typically under-represented in HCAHPS, including patients who speak Spanish at home, are Black, ages 25 to 34 years old, and with an 8th grade education or less. We therefore proposed to extend the data collection period for the HCAHPS Survey from 42 to 49 days, beginning with January 2025 discharge.

We invited public comment on the proposed change in the length of the data collection period.

Comment: A few commenters expressed support for the extension of the data collection period believing it will improve accessibility; increase engagement with disadvantaged groups and patients, including individuals recovering from an injury or illness; and allow for a more robust data set.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing this policy.

(5) Limit on the Number of Supplemental HCAHPS Survey Items

Currently, we do not place a limit on the number of supplemental items that may be added to the HCAHPS survey for quality improvement purposes. We are concerned that this policy has contributed to decline in the survey's response rate. Other CMS CAHPS surveys limit the number of supplemental items that may be added to prevent the survey from becoming so long that the response rate is negatively impacted. For example, the Medicare Advantage and Prescription Drug Plan (MA & PDP) CAHPS survey limits the number of supplemental items to a maximum of 12. Evidence from the 2016 HCAHPS mode experiment, as well as from the MA & PDP CAHPS Survey, strongly indicates that survey response rates decrease as the number of supplemental items increases. Analysis of the 2016 HCAHPS mode experiment data revealed that in the Mixed Mode (mail survey with phone follow-up of non-responders) 12 supplemental items would be expected to reduce HCAHPS response rates by 2.7 percentage points. An analysis of data from the MA & PDP CAHPS project found a 2.5 percentage point reduction in response rate associated with 12 supplemental items in Mixed Mode.[787] This is particularly

[787] Beckett MK, Elliott MN, Gaillot S, Haas A, Dembosky JW, Giordano LA, Brown J. (2016)

relevant because it includes both mail and phone, the two most commonly used survey modes for HCAHPS. Declines of this magnitude represent a substantial loss in response rate. The proposed limit of 12 supplemental items aligns with other CMS CAHPS surveys.

We invited public comment on our proposal to limit the number of supplemental items. We also welcomed suggestions for alternative limits below 12 supplemental items.

Comment: A few commenters expressed support for the proposed limit on the number of supplemental HCAHPS Survey items preferring shorter surveys.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing this policy.

(6) Requirement to Use Official Spanish Translation for Spanish Language-Preferring Patients

We have created official translations of the HCAHPS Survey in eight languages in addition to English to accommodate patient populations.[788] PCHs' use of these translations, however, is voluntary. To ensure that all Spanish language-preferring patients, who constitute about four percent of HCAHPS respondents, have the opportunity to receive the Spanish translation of the HCAHPS Survey, we proposed that PCHs be required to collect information about the language that the patient speaks while in the PCH (whether English, Spanish, or another language), and that the official CMS Spanish translation of the HCAHPS Survey be administered to all patients who prefer Spanish, beginning with January 2025 discharges.

We invited public comment on the proposed requirement to administer the survey in Spanish. We also welcomed suggestions for additional translations beyond the existing translations in Spanish, Chinese, Russian, Vietnamese, Portuguese, German, Tagalog, and Arabic.

Comment: A few commenters expressed support believing the requirement will improve accessibility and engagement with patients and lead to better collection of preferred language at admission.

Response: We thank the commenters for their support.

Comment: A few commenters made recommendations including that CMS expand the list of approved languages to include Haitian Creole and that CMS use the data from hospitals tracking languages spoken to make additional official translations available or mandated.

Response: We thank the commenters for their recommendations regarding future translations of HCAHPS and further validation of existing translated versions and we will take these recommendations into consideration for future program years.

Comment: A commenter expressed support for the proposal, but also expressed its belief that the proposal would require a patient that is a Spanish speaker to be provided the official CMS Spanish translation of the HCAHPS Survey and recommended the patient should be given the option of both versions.

Response: We appreciate the commenter's support. We would also clarify that the proposal would not require that a Spanish speaker be provided the Spanish language version of the HCAHPS survey, but instead that the Spanish language version would be offered to patients who identify as Spanish-preferred, not all Spanish-speaking patients.

After consideration of the public comments we received, we are finalizing this policy.

(7) Removal of an Administration Method

We proposed to remove one of the currently available options for administration of the HCAHPS Survey that are not used by participating PCHs. The Active Interactive Voice Response (IVR) survey mode, also known as touch-tone IVR, has not been employed by any hospital since 2016 and has never been widely used for the HCAHPS Survey. To streamline HCAHPS oversight and training, we proposed to discontinue IVR as an approved mode of survey administration beginning in January 2025. With the addition of three new web-based modes in January 2025, PCHs will have the option to choose among six modes of survey administration: Mail Only, Phone Only, Mixed Mode (mail followed by phone), Web-Mail mode, Web-Phone mode, and Web-Mail-Phone mode (web followed by mail, followed by Phone).

In addition, we encouraged participating PCHs to carefully consider the impact of mode of survey administration on response rates and the representativeness of survey respondents. High response rates for all patient groups promote our health equity goals. Our research on the HCAHPS Survey indicates that there are pronounced differences in response rates by mode of survey administration for some patient characteristics. In particular, Black, Hispanic, Spanish language-preferring, younger, and maternity patients are more likely to respond to a phone survey, while older patients are more likely to respond to a mail survey. Choosing a mode that is easily accessible to the diversity of a PCH's patient population provides a more complete representation of patients' care experiences. For more information, we refer PCHs to the podcast, ''Improving Representativeness of the HCAHPS Survey'' on the HCAHPS website: *https://hcahpsonline.org/en/podcasts/#ImprovingRepresentativeness*.

Comment: Several commenters expressed support for the removal of an administration method that has not been used by hospitals.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing this policy.

(8) Data Collection

The HCAHPS Survey will be administered and data collected in exactly the same manner as the current HCAHPS Survey, except for the changes described in this section of the preamble of this final rule. There will be no changes to HCAHPS patient eligibility or exclusion criteria. Detailed information on HCAHPS data collection protocols can be found in the current HCAHPS Quality Assurance Guidelines, located at: *https://www.hcahpsonline.org/en/quality-assurance/*.

We invited public comments on these proposals.

Comment: A commenter expressed support for the update to data collection.

Response: We thank the commenter for their support.

After consideration of the public comments we received, we are finalizing this policy.

(9) Public Reporting

The scoring of the updated HCAHPS Survey will be the same as the current HCAHPS Survey. Detailed information on how the measure will be scored for purposes of public reporting can be found on the HCAHPS website at: *https://hcahpsonline.org/en/hcahps-star-ratings/*.

We invited public comments on these proposals.

''Establishing limits for supplemental items on a standardized national survey.'' *Public Opinion Quarterly* 80(4): 964–976 DOI: *https://doi.org/10.1093/poq/nfw028*.

[788] HCAHPS Quality Assurance Guidelines V18.0. *https://www.hcahpsonline.org/en/quality-assurance/*.

We did not receive any public comments on this topic; therefore, we are finalizing this policy.

11. Extraordinary Circumstances Exceptions (ECE) Policy Under the PCHQR Program

We refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41623 through 41624), for a discussion of the Extraordinary Circumstances Exceptions (ECE) policy under the PCHQR Program. We did not propose any changes to this policy.

E. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

1. Background and Statutory Authority

The Long-Term Care Hospital Quality Reporting Program (LTCH QRP) is authorized by section 1886(m)(5) of the Act, and it applies to all hospitals certified by Medicare as Long-Term Care Hospitals (LTCHs). Section 1886(m)(5)(C) of the Act requires LTCHs to submit to the Secretary quality measure data specified under section 1886(m)(5)(D) in a form and manner, and at a time, specified by the Secretary. In addition, section 1886(m)(5)(F) of the Act requires LTCHs to submit data on quality measures under section 1899B(c)(1) of the Act, resource use or other measures under section 1899B(d)(1) of the Act, and standardized patient assessment data required under section 1899B(b)(1) of the Act. LTCHs must submit the data required under section 1886(m)(5)(F) of the Act in the form and manner, and at the time, specified by the Secretary. Under the LTCH QRP, the Secretary must reduce by 2 percentage points the annual update to the LTCH PPS standard Federal rate for discharges for an LTCH during a fiscal year (FY) if the LTCH has not complied with the LTCH QRP requirements specified for that FY. Section 1890A of the Act requires that the Secretary establish and follow a pre-rulemaking process, in coordination with the consensus-based entity (CBE) with a contract under section 1890(a) of the Act, to solicit input from certain groups regarding the selection of quality and efficiency measures for the LTCH QRP. We have codified our program requirements in our regulations at 42 CFR 412.560.

In the proposed rule, we proposed to modify one measure in the LTCH QRP as described in section IX.E. of the preamble of this final rule. Second, we proposed to adopt two new measures, and remove two existing measures. Third, we sought information on principles CMS could use to select and prioritize LTCH QRP quality measures in future years. Fourth, we provided an update on our efforts to close the health equity gap. Fifth, we proposed to change the LTCH QRP data completion thresholds. Finally, we proposed to begin public reporting of four measures.

2. General Considerations Used for the Selection of Quality Measures for the LTCH QRP

For a detailed discussion of the considerations we historically use for the selection of LTCH QRP quality, resource use, and other measures, we refer readers to the FY 2016 Inpatient Prospective Payment System (IPPS)/LTCH PPS final rule (80 FR 49728).

3. Quality Measures Currently Adopted for the FY 2024 LTCH QRP

The LTCH QRP currently has 18 measures for the FY 2024 LTCH QRP, which are set out in Table IX.E.–01. For a discussion of the factors used to evaluate whether a measure should be removed from the LTCH QRP, we refer readers to the FY 2019 IPPS/LTCH PPS final rule (83 FR 41624 through 41634) and to the regulations at 42 CFR 412.560(b)(3).

Table IX.E.-01. Quality Measures Currently Adopted for the FY 2024 LTCH QRP

Short Name	Measure Name & Data Source
LTCH CARE Data Set	
Pressure Ulcer/Injury	Changes in Skin Integrity Post-Acute Care: Pressure Ulcer/Injury
Application of Falls	Application of Percent of Residents Experiencing One or More Falls with Major Injury (Long Stay)
Functional Assessment	Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function
Application of Functional Assessment/Care Plan	Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function
Change in Mobility	Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital (LTCH) Patients Requiring Ventilator Support
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)
Compliance with SBT	Compliance with Spontaneous Breathing Trial (SBT) by Day 2 of the LTCH Stay
Ventilator Liberation	Ventilator Liberation Rate
TOH–Provider	Transfer of Health Information to the Provider Post-Acute Care (PAC)
TOH–Patient	Transfer of Health Information to the Patient Post-Acute Care (PAC)
NHSN	
CAUTI	National Healthcare Safety Network (NHSN) Catheter-Associated Urinary Tract Infection (CAUTI) Outcome Measure
CLABSI	National Healthcare Safety Network (NHSN) Central Line-associated Bloodstream Infection (CLABSI) Outcome Measure
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset *Clostridium difficile* Infection (CDI) Outcome Measure
HCP Influenza Vaccine	Influenza Vaccination Coverage among Healthcare Personnel
HCP COVID-19 Vaccine	COVID-19 Vaccination Coverage among Healthcare Personnel (HCP)
Claims-Based	
MSPB LTCH	Medicare Spending Per Beneficiary (MSPB)–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)
DTC	Discharge to Community (DTC)–Post Acute Care (PAC) Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)
PPR	Potentially Preventable 30-Day Post-Discharge Readmission Measure for Long-Term Care Hospital (LTCH) Quality Reporting Program (QRP)

4. Overview of LTCH QRP Quality Measures

In the proposed rule, we included LTCH QRP proposals for FY 2025 and FY 2026 LTCH QRP. Beginning with the FY 2025 LTCH QRP, we proposed to (1) modify the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure; (2) adopt the Discharge Function Score,[789] which we are specifying under section 1886(m)(5)(F)(i) of the Act; and (3) remove two current measures: (i) the Application of Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function measure and (ii) the Percent of LTCH Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function measure.

Beginning with the FY 2026 LTCH QRP, we proposed to adopt the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure, which we are specifying under section 1899B(d)(1) of the Act.

a. Modification of the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning With the FY 2025 LTCH QRP

As we stated in the FY 2022 LTCH PPS final rule (86 FR 45375) and in the Guidance for Staff Vaccination Requirements,[790] vaccination is a critical part of the Nation's strategy to effectively counter the spread of COVID–19. While the PHE status ended on May 11, 2023,[791] HHS has stated that the public health response to COVID–19 remains a public health priority with a whole of government approach to combatting the virus, including through vaccination efforts.[792] We continue to

[789] This measure was submitted to the Measures Under Consideration (MUC) List as the Cross-Setting Discharge Function Score. Subsequent to the MAP Workgroup meetings, the measure developer modified the name. Discharge Function Score for Long-Term Care Hospitals (LTCHs) Technical Report. *https://www.cms.gov/files/document/ltch-discharge-function-score-technical-report-february-2023.pdf.*

[790] Centers for Medicare & Medicaid Services. Revised Guidance for Staff Vaccination Requirements QSO–23–02–ALL. October 26, 2022. *https://www.cms.gov/files/document/qs0-23-02-all.pdf.*

[791] *https://www.whitehouse.gov/wp-content/uploads/2023/01/SAP-H.R.-382-H.J.-Res.-7.pdf.*

[792] U.S. Dept. of Health and Human Services. Fact Sheet: COVID–19 Public Health Emergency Transition Roadmap. February 9, 2023. Available at: *https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html.*

believe it is important to incentivize and track HCP vaccination in LTCHs through quality measurement in order to protect healthcare workers, patients, and caregivers, and to help sustain the ability of LTCHs to continue serving their communities throughout the public health emergency (PHE) and beyond. We proposed to modify the COVID–19 Vaccination Coverage among HCP (HCP COVID–19 Vaccine) measure to utilize the term ''up to date'' in the HCP vaccination definition and update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID–19 vaccines, including booster doses, beginning with the FY 2025 LTCH QRP.

The full proposal can be found in section IX.B. of this final rule. We invited public comment on our proposal to modify the HCP COVID–19 Vaccine measure, beginning with the FY 2025 LTCH QRP. A summary of the comments we received on our proposal to modify the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the FY 2025 LTCH QRP and our responses can be found in section IX.B. of this final rule.

b. Discharge Function Score Measure Beginning With the FY 2025 LTCH QRP

(1) Background

LTCHs provide medical care for clinically complex patients with multiple acute or chronic conditions, including patients requiring mechanical ventilation, and who require care for a relatively extended period of time. Many LTCH patients are at a high risk for profound debilitation due to functional limitations arising from their highly complex conditions and treatment requirements.[793] Patients frequently have respiratory conditions, including pulmonary edema and respiratory failure and respiratory system diagnoses with ventilator support, septicemia, renal failure, heart failure, skin ulcers, infectious and parasitic disease, or diabetes.[794] As a result of the COVID–19 PHE, post-COVID patients who required or still require ventilator support are often treated at LTCHs. For these patients, research has shown that addressing their functional deficits can improve patients' mobility, their capabilities in daily life activities, and their participation in society, all of which can lead to an improved quality of life.[795] [796]

Section 1886(m)(5)(F)(i) of the Act, cross-referencing subsections (b), (c), and (d) of section 1899B of the Act, requires CMS to develop and implement standardized quality measures from five quality measure domains, including the domain of functional status, cognitive function, and changes in function and cognitive function, across the post-acute care (PAC) settings, including LTCHs. To satisfy this requirement, CMS adopted the Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (Application of Functional Assessment/Care Plan) measure, for the LTCH QRP in the FY 2015 IPPS/LTCH PPS final rule (80 FR 49739 through 49747). While that process measure allowed for the standardization of functional assessments across assessment instruments and facilitated cross-setting data collection, quality measurement, and interoperable data exchange, we believe it is now topped out and proposed to remove it in section IX.E.4.c of the proposed rule. While there is an additional outcome measure addressing functional status [797] that can reliably distinguish performance among providers in the LTCH QRP, that outcome measure only captures patients requiring ventilator support at admission. In contrast, a cross-setting functional outcome measure would include the LTCH population regardless of ventilation status. Moreover, the proposed measure specifications would be aligned across settings, including the use of a common set of standardized functional assessment data elements.

(a) Measure Importance

Maintenance or improvement of physical function among older adults is increasingly an important focus of health care. Adults age 65 years and older constitute the most rapidly growing population in the United States, and functional capacity in physical (non-psychological) domains has been shown to decline with age.[798] Moreover, impaired functional capacity is associated with poorer quality of life and an increased risk of all-cause mortality, postoperative complications, and cognitive impairment, the latter of which can complicate the return of a patient to the community from post-acute care.[799] [800] [801] Nonetheless, evidence suggests that physical functional abilities, including mobility and self-care, are modifiable predictors of patient outcomes across PAC settings, including functional recovery or decline after post-acute care,[802] [803] [804] [805] rehospitalization rates,[806] [807] [808]

[793] Medicare Payment Advisory Commission. Report to the Congress: Medicare Payment Policy. March 2021. *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf.*

[794] Medicare Payment Advisory Commission. Report to the Congress: Medicare and the Health Care Delivery System. June 2021. *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/jun21_medpac_report_to_congress_sec.pdf.*

[795] Matsushima S, Kasahara Y, Aikawa S, Fuzimura T, Yokoyama H, Katata H. Impairment in Physical Function and Mental Status in a Survivor of Severe COVID–19 at Discharge from an Acute Care a Hospital: A Case Report. Phys Ther Res. 2021 Jun 11;24(3):285–290. doi: 10.1298/ptr.E10083. PMID: 35036264; PMCID: PMC8752843.

[796] Khan F, Amatya B. Medical Rehabilitation in Pandemics: Towards a New Perspective. J Rehabil Med. 2020 Apr 14;52(4):jrm00043. doi: 10.2340/16501977–2676. PMID: 32271393.

[797] The measure is Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support.

[798] High KP, Zieman S, Gurwitz J, Hill C, Lai J, Robinson T, Schonberg M, Whitson H. Use of Functional Assessment to Define Therapeutic Goals and Treatment. J Am Geriatr Soc. 2019 Sep;67(9):1782–1790. doi: 10.1111/jgs.15975. Epub 2019 May 13. PMID: 31081938; PMCID: PMC6955596.

[799] Clouston SA, Brewster P, Kuh D, Richards M, Cooper R, Hardy R, Rubin MS, Hofer SM. The dynamic relationship between physical function and cognition in longitudinal aging cohorts. Epidemiol Rev. 2013;35(1):33–50. doi: 10.1093/epirev/mxs004. Epub 2013 Jan 24. PMID: 23349427; PMCID: PMC3578448.

[800] Michael YL, Colditz GA, Coakley E, Kawachi I. Health Behaviors, Social Networks, and Healthy Aging: Cross-Sectional Evidence from the Nurses' Health Study. Qual Life Res. 1999 Dec;8(8):711–22. doi: 10.1023/a:1008949428041. PMID: 10855345.

[801] High KP, Zieman S, Gurwitz J, Hill C, Lai J, Robinson T, Schonberg M, Whitson H. Use of Functional Assessment to Define Therapeutic Goals and Treatment. J Am Geriatr Soc. 2019 Sep;67(9):1782–1790. doi: 10.1111/jgs.15975. Epub 2019 May 13. PMID: 31081938; PMCID: PMC6955596.

[802] Deutsch A, Palmer L, Vaughan M, Schwartz C, McMullen T. Inpatient Rehabilitation Facility Patients' Functional Abilities and Validity Evaluation of the Standardized Self-Care and Mobility Data Elements. Arch Phys Med Rehabil. 2022 Feb 11:S0003–9993(22)00205–2. doi: 10.1016/j.apmr.2022.01.147. Epub ahead of print. PMID: 35157893.

[803] Hong I, Goodwin JS, Reistetter TA, Kuo YF, Mallinson T, Karmarkar A, Lin YL, Ottenbacher KJ. Comparison of Functional Status Improvements Among Patients With Stroke Receiving Postacute Care in Inpatient Rehabilitation vs Skilled Nursing Facilities. JAMA Netw Open. 2019 Dec 2;2(12):e1916646. doi: 10.1001/jamanetworkopen.2019.16646. PMID: 31800069; PMCID: PMC6902754.

[804] Alcusky M, Ulbricht CM, Lapane KL. Postacute Care Setting, Facility Characteristics, and Poststroke Outcomes: A Systematic Review. Arch Phys Med Rehabil. 2018;99(6):1124–1140.e9. doi: 10.1016/j.apmr.2017.09.005. PMID: 28965738; PMCID: PMC5874162.

[805] Chu CH, Quan AML, McGilton KS. Depression and Functional Mobility Decline in Long Term Care Home Residents with Dementia: a Prospective Cohort Study. Can Geriatr J. 2021;24(4):325–331. doi:10.5770/cgj.24.511. PMID: 34912487; PMCID: PMC8629506.

[806] Li CY, Haas A, Pritchard KT, Karmarkar A, Kuo YF, Hreha K, Ottenbacher KJ. Functional Status Across Post-Acute Settings is Associated With 30-Day and 90-Day Hospital Readmissions. J Am Med Dir Assoc. 2021 Dec;22(12):2447–2453.e5. doi: 10.1016/j.jamda.2021.07.039. Epub 2021 Aug 30. PMID: 34473961; PMCID: PMC8627458.

discharge to community,[809] [810] and falls.[811]

The implementation of interventions that improve patients' functional outcomes and reduce the risks of associated undesirable outcomes as a part of a patient-centered care plan is essential to maximizing functional improvement. For many people, the overall goals of LTCH care may include optimizing functional improvement, returning to a previous level of independence, maintaining functional abilities, or avoiding institutionalization. Studies have suggested that rehabilitation services provided in LTCHs can improve patients' motor function at discharge for geriatric patients and patients with various diagnoses, including dementia.[812] [813] [814] [815] [816] Moreover, assessing functional status as a health outcome in LTCHs may provide valuable information in determining treatment decisions throughout the care continuum, such as the need for rehabilitation service and discharge planning,[817] [818] [819] as well as provide information to consumers about the effectiveness of skilled nursing services and rehabilitation services delivered. Because evidence shows that older adults experience aging heterogeneously and require individualized and comprehensive health care, functional status can serve as a vital component in informing the provision of health care and thus indicate an LTCH's quality of care.[820] [821]

We proposed to adopt the Discharge Function Score (DC Function) measure [822] in the LTCH QRP beginning with the FY 2025 LTCH QRP. This assessment-based outcome measure evaluates functional status by calculating the percentage of LTCH patients who meet or exceed an expected discharge function score. If finalized, this measure would replace the topped-out Application of Functional Assessment/Care Plan process measure. Like the cross-setting process measure we proposed to remove in section IX.E.4.c. of the preamble of the proposed rule the proposed measure would be calculated using standardized patient assessment data from the current LTCH assessment tool, the Long-Term Care Hospital (LTCH) Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS).

The proposed DC Function measure supports current CMS priorities. Specifically, the measure aligns with the Streamline Quality Measurement domain in CMS's Meaningful Measures 2.0 framework in two ways.[823] First, the proposed outcome measure could further CMS's objective to prioritize outcome measures by replacing the current cross-setting process measure (see section IX.E.4.c. of the preamble of the proposed rule). Unlike the existing functional outcomes measures, the proposed DC Function measure uses a set of cross-setting assessment items which would facilitate data collection, quality measurement, outcome comparison, and interoperable data exchange among PAC settings. Second, this measure adds no additional provider burden since it would be calculated using data from the LCDS that are already reported to the Medicare program for payment and quality reporting purposes.

The proposed DC Function measure would also follow a calculation approach similar to the existing functional outcome measures, which are CBE endorsed, with some modifications.[824] Specifically, the measure (1) considers two dimensions of function [825] (self-care and mobility activities) and (2) accounts for missing data by using statistical imputation to improve the validity of measure performance. The statistical imputation

[807] Middleton A, Graham JE, Lin YL, Goodwin JS, Bettger JP, Deutsch A, Ottenbacher KJ. Motor and Cognitive Functional Status Are Associated with 30-day Unplanned Rehospitalization Following Post-Acute Care in Medicare Fee-for-Service Beneficiaries. J Gen Intern Med. 2016 Dec;31(12):1427–1434. doi: 10.1007/s11606–016–3704–4. Epub 2016 Jul 20. PMID: 27439979; PMCID: PMC5130938.

[808] Gustavson AM, Malone DJ, Boxer RS, Forster JE, Stevens-Lapsley JE. Application of High-Intensity Functional Resistance Training in a Skilled Nursing Facility: An Implementation Study. Phys Ther. 2020;100(10):1746–1758. doi: 10.1093/ptj/pzaa126. PMID: 32750132; PMCID: PMC7530575.

[809] Minor M, Jaywant A, Toglia J, Campo M, O'Dell MW. Discharge Rehabilitation Measures Predict Activity Limitations in Patients with Stroke Six Months after Inpatient Rehabilitation. Am J Phys Med Rehabil. 2021 Oct 20. doi: 10.1097/PHM.0000000000001908. Epub ahead of print. PMID: 34686630.

[810] Dubin R, Veith JM, Grippi MA, McPeake J, Harhay MO, Mikkelsen ME. Functional Outcomes, Goals, and Goal Attainment among Chronically Critically Ill Long-Term Acute Care Hospital Patients. Ann Am Thorac Soc. 2021;18(12):2041–2048. doi: 10.1513/AnnalsATS.202011–1412OC. PMID: 33984248; PMCID: PMC8641806.

[811] Hoffman GJ, Liu H, Alexander NB, Tinetti M, Braun TM, Min LC. Posthospital Fall Injuries and 30-Day Readmissions in Adults 65 Years and Older. JAMA Netw Open. 2019 May 3;2(5):e194276. doi: 10.1001/jamanetworkopen.2019.4276. PMID: 31125100; PMCID: PMC6632136.

[812] Dubin R, Veith JM, Grippi MA, McPeake J, Harhay MO, Mikkelsen ME. Functional Outcomes, Goals, and Goal Attainment among Chronically Critically Ill Long-Term Acute Care Hospital Patients. Ann Am Thorac Soc. 2021;18(12):2041–2048. doi:10.1513/AnnalsATS.202011–1412OC. PMID: 33984248; PMCID: PMC8641806.

[813] Lane NE, Stukel TA, Boyd CM, Wodchis WP. Long-Term Care Residents' Geriatric Syndromes at Admission and Disablement Over Time: An Observational Cohort Study. J Gerontol A Biol Sci Med Sci. 2019;74(6):917–923. doi: 10.1093/gerona/gly151. PMID: 29955879; PMCID: PMC6521919.

[814] Kowalski RG, Hammond FM, Weintraub AH, Nakase-Richardson R, Zafonte RD, Whyte J, Giacino JT. Recovery of Consciousness and Functional Outcome in Moderate and Severe Traumatic Brain Injury. JAMA Neurol. 2021;78(5):548–557. doi: 10.1001/jamaneurol.2021.0084. PMID: 33646273; PMCID: PMC7922241.

[815] Chu CH, Quan AML, McGilton KS. Depression and Functional Mobility Decline in Long Term Care Home Residents with Dementia: a Prospective Cohort Study. Can Geriatr J. 2021;24(4):325–331. doi:10.5770/cgj.24.511. PMID: 34912487; PMCID: PMC8629506.

[816] Khan F, Amatya B. Medical Rehabilitation in Pandemics: Towards a New Perspective. J Rehabil Med. 2020 April 14;52(4):jrm00043. doi: 10.2340/16501977–2676. PMID: 32271393.

[817] Dubin R, Veith JM, Grippi MA, McPeake J, Harhay MO, Mikkelsen ME. Functional Outcomes, Goals, and Goal Attainment among Chronically Critically Ill Long-Term Acute Care Hospital Patients. Ann Am Thorac Soc. 2021;18(12):2041–2048. doi:10.1513/AnnalsATS.202011–1412OC. PMID: 33984248; PMCID: PMC8641806.

[818] Warren M, Knecht J, Verheijde J, Tompkins J. Association of AM–PAC ''6-Clicks'' Basic Mobility and Daily Activity Scores With Discharge Destination. Phys Ther. 2021 Apr 4;101(4):pzab043. doi: 10.1093/ptj/pzab043. PMID: 33517463.

[819] Cogan AM, Weaver JA, McHarg M, Leland NE, Davidson L, Mallinson T. Association of Length of Stay, Recovery Rate, and Therapy Time per Day With Functional Outcomes After Hip Fracture Surgery. JAMA Netw Open. 2020 Jan 3;3(1):e1919672. doi: 10.1001/jamanetworkopen.2019.19672. PMID: 31977059; PMCID: PMC6991278.

[820] Criss MG, Wingood M, Staples WH, Southard V, Miller KL, Norris TL, Avers D, Ciolek CH, Lewis CB, Strunk ER. APTA Geriatrics' Guiding Principles for Best Practices in Geriatric Physical Therapy: An Executive Summary. J Geriatr Phys Ther. 2022 Apr–June;45(2):70–75. doi: 10.1519/JPT.0000000000000342. PMID: 35384940.

[821] Cogan AM, Weaver JA, McHarg M, Leland NE, Davidson L, Mallinson T. Association of Length of Stay, Recovery Rate, and Therapy Time per Day With Functional Outcomes After Hip Fracture Surgery. JAMA Netw Open. 2020 Jan 3;3(1):e1919672. doi: 10.1001/jamanetworkopen.2019.19672. PMID: 31977059; PMCID: PMC6991278.

[822] This measure was submitted to the Measures Under Consideration (MUC) List as the Cross-Setting Discharge Function Score. Subsequent to the MAP workgroup meetings, CMS modified the name. For more information, refer to the Discharge Function Score for Long Term Care Hospital (LTCHs) Technical Report, which is available on the LTCH Quality Reporting Program Measures and Technical Information web page at *https://www.cms.gov/files/document/ltch-discharge-function-score-technical-report-february-2023.pdf.*

[823] Meaningful Measures 2.0 can be found at *https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization.*

[824] The existing measures are the IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients measure (Discharge Self-Care Score) and the IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients measure (Discharge Mobility Score).

[825] RTI International. Post-Acute Care Payment Reform Demonstration Report to Congress Supplement—Interim Report. May 2011. *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Reports/Downloads/GAGE_PACPRD_RTC_Supp_Materials_May_2011.pdf.*

approach recodes missing functional status data to *the most likely value* had the status been assessed, whereas the current imputation approach implemented in existing functional outcome measures recodes missing data to the *lowest* functional status. A benefit of statistical imputation is that it uses patient characteristics to produce an unbiased estimate of the score on each item with a missing value. In contrast, the current approach treats patients with missing values and patients who were coded to the lowest functional status similarly, despite evidence suggesting varying measure performance between the two groups, which can to lead less accurate measure performances.

(b) Measure Testing

Measure testing using FY 2019 data was conducted on the DC Function measure to assess validity, reliability, and reportability, all of which informed interested parties' feedback and Technical Expert Panel (TEP) input (see section IX.E.4.b.3. of the preamble of the proposed rule). Validity was assessed for the measure performance, the risk adjustment model, face validity, and statistical imputation models. Validity testing of measure performance entailed determining Spearman's rank correlations between the proposed measure's performance for providers with 20 or more stays and the performance of other publicly reported LTCH quality measures. Results indicated that the measure captures the intended outcome based on the directionalities and strengths of correlation coefficients and are further detailed in Table IX.E.–02.

TABLE IX.E.-02. SPEARMAN'S RANK CORRELATION RESULTS OF DC FUNCTION MEASURE WITH PUBLICLY REPORTED LTCH QUALITY MEASURES

Measure – Long Name	Measure – Short Name	ρ
Discharge to Community – PAC LTCH QRP	Discharge to Community	0.40
Potentially Preventable 30-Days Post-Discharge Readmission Measure for LTCH QRP	Potentially Preventable Readmissions within 30 Days Post-Discharge	-0.19
Medicare Spending Per Beneficiary – PAC LTCH QRP	Medicare Spending Per Beneficiary	-0.13
Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support	Change in Mobility	0.76

Validity testing of the risk adjustment model showed good model discrimination as the measure model has the predictive ability to distinguish patients with low expected functional capabilities from those with high expected functional capabilities.[826] The ratios of observed-to-predicted discharge function score across eligible stays, by deciles of expected functional capabilities, ranged from 0.96 to 1.06. Both the Cross-Setting Discharge Function TEPs and patient-family feedback showed strong support for the face validity and importance of the proposed measure as an indicator of quality of care (see section IX.G.4.b.3 of the proposed rule). Lastly, validity testing of the measure's statistical imputation models indicated that the models demonstrate good discrimination and produce more precise and accurate estimates of function scores for items with missing scores when compared to the current imputation approach implemented in the LTCH QRP functional outcome measure, Change in Mobility Among LTCH Patients Requiring Ventilator Support.

Reliability and reportability testing also yielded results that support the measure's scientific acceptability. Split-half testing revealed the proposed measure's excellent reliability, indicated by an intraclass correlation coefficient value of 0.94. Reportability testing indicated high reportability (97 percent) of providers meeting the public reporting threshold of 20 eligible stays. For additional measure testing details, we refer readers to the document titled *Discharge Function Score for Long-Term Care Hospital (LTCHs) Technical Report.*[827]

(2) Competing and Related Measures

Section 1899B(e)(2)(A) of the Act requires that, absent an exception under section 1899B(e)(2)(B) of the Act, measures specified under section 1899B of the Act be endorsed by the consensus-based entity (CBE) with a contract under section 1890(a). In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed, section 1899B(e)(2)(B) permits the Secretary to specify a measure that is not so endorsed, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

The proposed DC Function measure is not CBE endorsed, so we considered whether there are other available measures that (1) assess both functional domains of self-care and mobility in LTCHs and (2) satisfy the requirement of the Act to specify standardized quality measures with respect to functional status, cognitive function, and changes in function and cognitive function. While the Application of Functional Assessment/Care Plan measure assesses both functional domains and satisfies the Act's requirement, this cross-setting process measure is not CBE endorsed and the performance on this measure among LTCHs is so high and unvarying across most LTCHs that the measure does not offer meaningful distinctions in performance. Additionally, after review of CBE-endorsed measures, we were unable to identify any CBE-endorsed measures for LTCHs that meet the aforementioned requirements. While the LTCH QRP includes a CBE endorsed outcome measure addressing functional status, the Change in Mobility measure, this measure assesses a single domain of function and captures only a subset of the assessed LTCH population.

[826] ''Expected functional capabilities'' is defined as the predicted discharge function score.

[827] Discharge Function Score for Long-Term Care Hospital (LTCHs) Technical Report. *https://www.cms.gov/files/document/ltch-discharge-function-score-technical-report-february-2023.pdf.*

Therefore, after consideration of other available measures, we found that the exception under section 1899B(e)(2)(B) of the Act applies and proposed to adopt the DC Function measure beginning with the FY 2025 LTCH QRP. We intend to submit the proposed measure to the CBE for consideration of endorsement when feasible.

(3) Interested Parties and Technical Expert Panel (TEP) Input

In our development and specification of this measure, we employed a transparent process in which we sought input from interested parties and national experts and engaged in a process that allowed for pre-rulemaking input, in accordance with section 1890A of the Act. To meet this requirement, we provided the following opportunities for interested parties' input: a Patient and Family Engagement Listening Session, two TEPs, and public comments through a request for information (RFI).

First, the measure development contractor convened a Patient and Family Engagement Listening Session, during which patients and caregivers provided support for the proposed measure concept. Participants emphasized the importance of measuring functional outcomes and found self-care and mobility to be critical aspects of care. Additionally, they expressed a strong interest in metrics assessing the number of patients discharged from particular facilities with improvements in self-care and mobility, and their views of self-care and mobility aligned with the functional domains captured by the proposed measure. All feedback was used to inform measure development efforts.

The measure development contractor subsequently convened TEPs on July 14–15, 2021, and January 26–27, 2022, to obtain expert input on the development of a cross-setting function measure for use in the LTCH QRP. The TEPs consisted of interested parties with a diverse range of expertise, including LTCH and PAC subject matter knowledge, clinical expertise, patient and family perspectives, and measure development experience. The TEPs supported the proposed measure concept and provided the following substantive feedback regarding the measure's specifications and measure testing data.

First, the TEP was asked whether they prefer a cross-setting measure that is modeled after measures currently adopted in the Inpatient Rehabilitation Facility (IRF) QRP and the Skilled Nursing Facility (SNF) QRP, the IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (Discharge Mobility Score) and IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (Discharge Self-Care Score) measures, or one that is modeled after the currently adopted IRF Functional Outcome Measure: Change in Mobility for Medical Rehabilitation Patients (Change in Mobility Score) and IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (Change in Self-Care Score). With the Discharge Mobility Score and Change in Mobility Score measures and the Discharge Self-Care Score and Change in Self-Care Score measures being both highly correlated and not appearing to measure unique concepts, the TEP favored the Discharge Mobility Score and Discharge Self-Care Score measures over the Change in Mobility Score and Change in Self-Care Score measures and recommended moving forward with utilizing the Discharge Mobility Score and Discharge Self-Care Score measures for the development of a cross-setting measure.

Second, in deciding the standardized functional assessment data elements to include in the cross-setting measure, the TEP recommended removing redundant data elements. Strong correlations between scores of functional items within the same functional domain suggested that certain items may be redundant in eliciting information about patient function and inclusion of these items could lead to overrepresentation of a particular functional area. Subsequently, our measure development contractor focused on the Discharge Mobility Score measure as a starting point for cross-setting development due to the greater number of cross-setting standardized functional assessment data elements for mobility while also identifying redundant functional items that could be removed from a cross-setting functional measure.

Third, the TEP supported including the cross-setting self-care items such that the cross-setting function measure would capture both self-care and mobility. Panelists agreed that self-care items added value to the measure and are clinically important to function. The TEP provided refinements to imputation strategies to more accurately represent function performance across all PAC settings, including the support of using statistical imputation over the current imputation approach implemented in existing functional outcome measures in the PAC QRPs. We considered all the TEP's recommendations for developing a cross-setting function measure, and applied those recommendations where technically feasible and appropriate. Summaries of the TEP proceedings titled *Technical Expert Panel (TEP) for the Refinement of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) Function Measures Summary Report* (July 2021 TEP) [828] and *Technical Expert Panel (TEP) for Cross-Setting Function Measure Development Summary Report* (January 2022 TEP) [829] are available on the CMS Measures Management System (MMS) Hub.

Finally, we solicited feedback from interested parties on the importance, relevance, and applicability of a cross-setting functional outcome measure for LTCHs through an RFI in the FY 2023 LTCH PPS proposed rule (87 FR 28568). Commenters were supportive of a cross-setting functional outcome measure that is inclusive of both self-care and mobility items, but also provided information related to potential risk adjustment methodologies as well as other measures that could be used to capture functional outcomes across PAC settings (87 FR 49316).

(4) Measure Application Partnership (MAP) Review

In accordance with section 1890A of the Act, our pre-rulemaking process includes making publicly available a list of quality and efficiency measures, called the Measures Under Consideration (MUC) List, that the Secretary is considering adopting for use in Medicare programs. This allows interested parties to provide recommendations to the Secretary on the measures included on the MUC list.

We included the DC Function measure under the LTCH QRP on the publicly available MUC List for December 1, 2022.[830] After the MUC List was published, the CBE convened Measure Applications Partnership (MAP) received one comment supporting the DC Function measure for rulemaking. Shortly after, several CBE

[828] Technical Expert Panel (TEP) for the Refinement of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) Function Measures Summary Report (July 2021 TEP). *https://mmshub.cms.gov/sites/default/files/TEP-Summary-Report-PAC-Function.pdf.*

[829] Technical Expert Panel (TEP) for Cross-Setting Function Measure Development Summary Report (January 2022 TEP). *https://mmshub.cms.gov/sites/default/files/PAC-Function-TEP-Summary-Report-Jan2022-508.pdf.*

[830] Centers for Medicare & Medicaid Services. Overview of the List of Measures Under Consideration for December 1, 2022. *https://mmshub.cms.gov/sites/default/files/2022-MUC-List-Overview.pdf.*

convened MAP workgroups met virtually to provide input on the measure. First, the MAP Health Equity Advisory Group convened on December 6–7, 2022. The Health Equity Advisory Group did not share any health equity concerns related to the implementation of the measure, and only asked for clarification regarding measure specifications from measure developers. The MAP Rural Health Advisory Group met on December 8–9, 2022, during which two members provided support for the DC Function measure and other Rural Health Advisory Group members did not express rural health concerns regarding the measure.

The MAP Post-Acute Care/Long-Term Care (PAC/LTC) workgroup met on December 12, 2022 and provided input on the DC Function measure. During this meeting, we were able to address several concerns raised by interested parties after the publication of the MUC List. Specifically, we clarified that the expected discharge scores are not calculated using self-reported functional goals, and are simply calculated by risk-adjusting the observed discharge scores (see section IV.E.4.b.5. of the preamble of the proposed rule). Therefore, we believe that these scores cannot be ''gamed'' by reporting less-ambitious functional goals. We also pointed out that the measure is highly usable as it is similar in design and complexity to existing function measures and that the data elements used in this measure are already in use. Lastly, we clarified that the DC Function measure is intended to supplement, rather than replace the existing LTCH QRP measure for mobility, and implements improvements on the existing Application of Functional Assessment/Care Plan and Functional Assessment/Care Plan measures that make the measure more valid and harder to game.

The MAP PAC/LTC workgroup went on to discuss several concerns with the measure, including (1) whether the measure is truly cross-setting due to varying denominator populations across settings, (2) whether the measure would adequately represent the full picture of function, especially for patients who may have a limited potential for functional gain, and (3) that the range of expected scores was too large to offer a valid facility-level score. We clarified that the denominator population in each measure setting represents the assessed population within the setting and that the measure satisfies the requirement at section 1886(m)(5) of the Act for a cross-setting measure in the functional status domain specified under section 1899B(c)(1) of the Act. Additionally, we noted that the TEP had reviewed the item set and determined that all the self-care and mobility items were suitable for all settings. Further, we clarified that, because the DC Function measure would assess whether a patient met *or* exceeded their expected discharge score, it accounts for patients who are not expected to improve. Lastly, we noted that the DC Function measure has a high degree of correlation with the existing function measures and that the range of expected scores is consistent with the range of observed scores. The PAC/LTC workgroup voted to support the staff recommendation of conditional support for rulemaking, with the condition that we seek CBE endorsement.

In response to the PAC/LTC workgroup's preliminary recommendation, the CBE received two additional comments from interested parties supporting the PAC–LTC workgroup's preliminary recommendation of conditional support for rulemaking. A commenter recommended the DC Function measure under the condition that it be reviewed and refined such that implementation would support patient autonomy and result in care that aligns with patients' personal functional goals. The second commenter provided support for the measure under the condition that it produces statistically meaningful information that can inform improvements in care processes, while also expressing concern that the measure is not truly cross-setting because it utilizes different patient populations and risk-adjustment models with setting-specific covariates across settings. Additionally, this commenter noted that using a single set of cross-setting section GG items is not appropriate since the items may not be relevant across varying patient populations.

Finally, the MAP Coordinating Committee convened on January 24–25, 2023. CMS noted again that the TEP had reviewed the item set and determined that all the self-care and mobility items were suitable for all settings. Coordinating Committee members expressed support for reviewing existing measures for removal as well as support for the DC Function measure, favoring the implementation of a single, standardized function measure across PAC settings. The Coordinating Committee unanimously upheld the PAC/LTC workgroup recommendation of conditional support for rulemaking. We refer readers to the final MAP recommendations, titled *2022–2023 MAP Final Recommendations,*[831] for more information.

(5) Quality Measure Calculation

The proposed outcome measure estimates the percentage of LTCH patients who meet or exceed an expected discharge score during the reporting period. The proposed measure's numerator is the number of LTCH stays with an observed discharge function score that is equal to or greater than the calculated expected discharge function score. The observed discharge function score is the sum of individual function item values at discharge. The expected discharge function score is computed by risk-adjusting the observed discharge function score for each LTCH stay. Risk adjustment controls for patient characteristics such as admission function score, age, and clinical conditions. The denominator is the total number of LTCH stays with an LCDS record in the measure target period (four rolling quarters) that do not meet the measure exclusion criteria. For additional details regarding the numerator, denominator, risk adjustment, and exclusion criteria, refer to the *Discharge Function Score for Long Term Care Hospitals (LTCHs) Technical Report.*[832]

The proposed measure implements a statistical imputation approach for handling ''missing'' standardized functional assessment data elements. The coding guidance for standardized functional assessment data elements allows for using ''Activity Not Attempted'' (ANA) codes, resulting in ''missing'' information about a patient's functional ability on at least some items, at admission and/or discharge, for a substantive portion of LTCH patients. Currently, the functional outcome measures in the LTCH QRP use a simple imputation method whereby all ANA codes or otherwise missing scores, on both admission and discharge records, are recoded to ''1'' or ''most dependent.'' Statistical imputation, on the other hand, replaces these missing values with a variable based on the values of other, non-missing variables in the assessment and on the values of other assessments which are otherwise similar to the assessment with a missing value. Specifically, in the proposed DC Function measure's statistical imputation allows missing values (for example, the ANA codes) to be replaced

[831] 2022–2023 MAP Final Recommendations. *https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx.*

[832] Discharge Function Score for Long Term Care Hospitals (LTCHs) Technical Report. *https://www.cms.gov/files/document/ltch-discharge-function-score-technical-report-february-2023.pdf.*

with any value from 1 to 6, based on a patient's clinical characteristics and codes assigned on other standardized functional assessment data elements. The measure implements separate imputation models for each standardized functional assessment data element used in construction of the admission score and the discharge score. Relative to the current simple imputation method, this statistical imputation approach increases precision and accuracy and reduces the bias in estimates of missing item scores. We refer readers to the *Discharge Function Score for Long Term Care Hospitals (LTCHs) Technical Report* [833] for measure specifications and additional details.

We invited public comment on our proposal to adopt the DC Function measure beginning with the FY 2025 LTCH QRP. The following is a summary of the comments we received on our proposal to adopt the DC Function measure, beginning with the FY 2025 LTCH QRP, and our responses.

Comment: Several commenters provided support for the DC Function measure. A commenter supported the proposed adoption of the DC Function measure, noting its importance as a patient-centered measure; however, this commenter strongly encouraged CMS to submit the measure for CBE endorsement.

Response: We thank the commenters for their support of the proposed measure. We intend to submit the proposed measure to the CBE for consideration of endorsement when feasible.

Comment: A commenter preferred separate quality measures for self-care and mobility to ensure each setting is able to capture the items most relevant to its patient population needs and goals and use the measures to determine meaningful quality improvement activities. However, this commenter stated that if CMS uses one measure, then they would support the proposed measure since it does capture both self-care and mobility items, but encouraged the review and refinement of the measure as needed.

Response: We thank the commenter for their support and agree with the importance of capturing both self-care and mobility items in the proposed measure as well as capturing each dimension of function in separate measures, one of which is reflected in the Change in Mobility Score for Ventilator Patients measure in the LTCH QRP. As with all other measures, we will routinely monitor this measure to ensure the measure maintains strong scientific acceptability and utility to ensure it captures the relevant patient population needs and goals.

Comment: Several commenters opposed the proposed DC Function measure stating LTCH patients' capabilities and goals differ from other post-acute care settings, making this measure inappropriate for LTCHs. Two of these commenters explained that improved function upon discharge is not the primary goal of critically ill LTCH patients. One of these two commenters expanded that the functional improvements LTCH patients likely experience would not be visible in the DC Function measure, and they are concerned with using the DC Function measure to assess quality or using it in public reporting since measure scores between LTCHs and other PAC settings may be inappropriately compared. Finally, another commenter believed that to see LTCH patients' progression reflected in the proposed measure, LTCHs would be required to keep patients longer, causing financial burden for potential unpaid days.

Response: We acknowledge that different patient populations are served across the PAC settings, including LTCHs, and the capabilities and goals of these populations differ. However, measuring function is important in all PAC settings and is appropriate for LTCHs. The PFAs we engaged in the development of the DC Function measure supported this measure's concept. We also understand that for many people, the overall goals of LTCH care may include maintaining functional abilities and avoiding institutionalization in addition to optimizing functional improvement and returning to a previous level of independence. We acknowledge that significant improvement may not be attainable in very low or high acuity patients. Because we recognized these cases, the proposed measure assesses whether a patient met or exceeded their expected discharge score and thus accounts for patients who are not expected to improve during their LTCH stay. For each stay included in the measure calculations, the observed function score is compared to the expected discharge score, which is adjusted to account for clinical characteristics, admission functional status, and demographic characteristics of the patient. Risk adjustment creates an individualized expectation for discharge function score for each stay that controls for these factors and ensures that each stay is measured against an expectation that is calibrated to the patient's individual circumstances when determining the numerator for each discharge function score.

Because LTCHs determine when a patient is ready for discharge, keeping in mind the patient's health and safety, and are responsible to have an effective discharge planning process that is consistent with the patient's goals for care [834] they coordinate the appropriate transition plan. Also, to clarify that cross-setting measures do not necessarily suggest that facilities can and should be compared across settings. Instead, these measures are intended to compare providers within a specific setting while standardizing measure specifications across settings. The proposed measure does just this, by aligning measure specifications across settings and using a common set of standardized functional assessment data elements.

Comment: A commenter believed the Discharge to Community measure captures LTCH patient outcomes better than the DC Function measure.

Response: This commenter did not elaborate on why they believe the Discharge to Community (DTC) measure captures patient outcomes better, so we cannot address their point. However, we agree the DTC measure is an important measure for capturing LTCH patient outcomes. The DTC and DC Function measures have a correlation of 0.45, demonstrating that the proposed measure and the DTC measure each capture different aspects of care, with the proposed measure capturing functional status at discharge and the DTC measure capturing the successful discharge to the community after an LTCH stay. As such, each measure provides different insight into the quality of patient care and therefore, adds a different value to the LTCH QRP measure set.

Comment: Three commenters opposed the proposed DC Function measure because they believe the measure is not cross-setting. Two of these commenters stated that the measure is only ''cross-setting'' in name and that while the measure attempts to take into account the ''myriad of differences'' in the patient populations across settings, the DC Function measure is nevertheless four different measures across settings because the differences in patient populations alter

[833] Discharge Function Score for Long Term Care Hospitals (LTCHs) Technical Report. *https://www.cms.gov/files/document/ltch-discharge-function-score-technical-report-february-2023.pdf.*

[834] Section 482.43, Condition of participation: Discharge planning.

the underlying calculation of the cross-setting measure.

Response: We acknowledge that different patient populations are served across the post-acute care settings and the capabilities and goals of these populations differ. However, we would like to clarify that cross-setting measures do not necessarily suggest that facilities can and should be compared across settings. Instead, these measures are intended to compare providers within a specific setting while standardizing measure specifications across settings. The proposed measure does just this by aligning measure specifications across settings and using a common set of standardized functional assessment data elements. This alignment satisfies the requirement of section 1886(m)(5) of the Act for a cross-setting measure in the functional status domain specified under section 1899B(c)(1) of the Act.

Comment: A commenter requested a rationale as to why confidence intervals were not calculated and reported for the expected function scores and utilized in determining meaningful differences between the observed and expected function score. This commenter also stated that the minimum clinical difference in discharge function scores that indicates a change is meaningful to patient progress has not been identified.

Response: The proposed DC function measure uses the same approach in determining whether an observed discharge score is different than its associated, expected discharge score as the currently adopted function measures that are CBE endorsed. Specifically, the DC Function measure reports the proportion of a given provider's stays where observed discharge function matches or exceeds expected discharge function. The measure score is a continuous variable with values between 0 and 100, allowing for intuitive interpretation and comparisons. Our TEP supported that patients and families are more likely to understand a measure that expresses functional outcome as a simple proportion of patients who meet expectation for their discharge functional status, rather than units of change in a scoring system that is unfamiliar to most Care Compare website users (the primary audience for this measure). Measure scores based on statistical significance of differences between observed and expected values (based on confidence intervals) place providers in broad categories, such as ''No different than national average,'' which do not allow more granular provider comparisons for the public reviewing the measure's data on Care Compare. Given the excellent reliability of the DC Function measure, reporting provider scores as broad categories is not warranted.

Comment: A commenter noted the variability in median scores and believed this range suggests the measure may not be valid, and that the variability may be problematic when making comparisons among providers.

Response: We would like to clarify that median scores are not used in the calculation of this measure. While we would require additional information regarding the median scores referenced in this comment to provide a more complete response, we acknowledge that the measure has a large range of average expected discharge scores, as calculated for each provider. This range is consistent with the range of observed discharge scores, indicating that the measure is capturing the range of patient's functional abilities, and thus, in fact, supports the validity of the measure.

Comment: A commenter noted that intrinsic to the discharge scores are the associated admission scores, and suggested an analysis of this measure to assess the variability in initial admission function scores between hospitals for similar types of patients as differences may account for the gaps in the observed discharge function scores.

Response: We acknowledge that the observed gap in discharge function scores may be due to variability in the initial admission function scores. The admission function scores are included as covariates in the risk adjustment model and thus are accounted for in the calculations of the expected discharge function scores.

Comment: A commenter questioned CMS' characterization of the adjusted R-squared value of 0.65 for the proposed DC Function measure's risk adjustment model. This commenter believed a 0.65 suggested moderate, rather than ''good'' model discrimination. This commenter suggested CMS should address the ability of the risk adjustment model to make predictions by comparing R-squared values of the ''training'' and ''validation'' sets and reporting ''predicted R-squared'' values.

Response: We want to clarify that the adjusted R-squared for the DC Function measure, as reported in the *Discharge Function Score for Long-Term Care Hospitals (LTCHs) Technical Report,*[835] was 0.65. This value indicates ''good'' model discrimination and it is comparable to or greater than those of existing LTCH QRP measures, such as the Medicare Spending Per Beneficiary (0.45) and Change in Mobility for Ventilator Patients (0.16) measures. Additionally, because the measure model uses all available data, the concepts of 'training' and 'validation' sets (and any related 'predicted R-squared') are not applicable. Rather, adjusted R-squared values capture model fit for the risk-adjustment model.

Comment: Several commenters did not support the adoption of this proposed measure because it lacks CBE endorsement or has not undergone the CBE endorsement process. Three of these commenters noted that the CBE endorsement process provides information on whether or not the measure provides valuable information that can be used to inform improvements in care.

Response: We direct readers to section IX.E.4.b.1. of this final rule, where we discuss this topic in detail. Measures adopted in the LTCH QRP are not required to be CBE endorsed. Section 1899B(e)(2)(B) of the Act permits the Secretary to specify a measure that is not CBE endorses, as long as due consideration is given to the measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Despite the current absence of CBE endorsement for this measure, it is important to adopt the DC Function measure into the LTCH QRP because the DC Function measure relies on functional status data elements collected in all PAC settings. The measure also satisfies the requirement for a cross-setting quality measure as set forth in sections 1886(m)(5) and 1899B(c)(1)(A) of the Act, and assesses both domains of self-care and mobility. We also direct readers to section IX.E.4.b.2. of this final rule, where we discuss measurement gaps that the DC function measure fulfills in relation to competing and related measures. We also acknowledge the importance of the CBE endorsement process and plan to submit the proposed measure for CBE endorsement when feasible. We direct readers to section IX.E.4.b.1.b. of this final rule, and the technical report for detailed measures testing results demonstrating that the measure provides meaningful information which can be used to improve quality of care, and to the TEP report summaries[836] [837]

[835] *Discharge Function Score for Long-Term Care Hospitals (LTCHs) Technical Report. https://www.cms.gov/files/document/ltch-discharge-function-score-technical-report-february-2023.pdf.*

[836] Technical Expert Panel (TEP) for the Refinement of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) Function Measures Summary Report (July 2021 TEP) is available at *https://mms-*

which detail TEP support for the proposed measure concept.

Comment: Two commenters opposed the adoption of the DC Function measure because they do not believe it is appropriate or accurate for CMS to override the clinical judgement of the clinicians who are treating the patient by using statistical imputation to impute a value to a data element when an ANA (Activity Not Attempted) code is used. These commenters noted that the ''Activity Not Attempted'' codes allow clinicians to use their professional judgement when certain activities should not or could not be safely attempted by the patient, which may be due to medical reasons.

Response: We acknowledge that the ''Activity Not Attempted'' (ANA) codes allow clinicians to use their professional judgement when certain activities should not or could not be attempted safely by the patient and that there may be medical reasons that a patient cannot safely attempt a task. We note that we did not propose any changes to the coding guidance for using ANA codes, and we would not expect LTCH coding practices to change. However, we want to clarify that utilizing statistical imputation to calculate a quality measure does not override the clinical judgement of clinicians who are expected to continue determining whether certain activities can be safely attempted by patients at the time of admission and discharge, and utilize that information to determine appropriate goals and treatment interventions for their LTCH patients. Rather, statistical imputation is a component in measure calculation of reported data and improves upon the current imputation approach in the currently adopted Change in Mobility Score for Ventilator Patients measure. In this currently adopted measure, ANA codes are always imputed to 1 (dependent) when calculating the measure scores, regardless of a patient's own clinical and functional information. However, the imputation approach implemented in the proposed DC Function measure uses each patient's available functional and clinical information to estimate each ANA value had the item been completed. Testing demonstrates that, relative to the current simple imputation method, the statistical imputation approach used in this DC Function measure increases precision and accuracy and reduces bias in estimates of ANA values.

Comment: Three commenters expressed concern about the calculation of expected scores. Two of these commenters believed that the proposed measure numerator is not wholly attributed to facility's quality of care and that the calculation of the ''expected'' discharge score is opaque, resulting in difficulty for providers to determine the score that they're striving for. These commenters further noted that functional goals are not based on statistical regression and are identified via individual-specific goals related to function, independence, and overall health. One of these commenters requested clarification about whether the expected scores are calculated by using patient admission goals or risk adjustment.

Response: We agree with the commenter that functional goals are identified for each patent as a result of an individual assessment and clinical decisions, rather than statistics. We want to remind commenters that the DC Function measure is not calculated using the goals identified in clinical process. The ''expected'' discharge score is calculated by risk-adjusting the observed discharge score (that is, the sum of individual function item values at discharge) for admission functional status, age, and clinical characteristics using an ordinary least squares linear regression model. To clarify, the model intercept and risk adjustor coefficients are determined by running the risk adjustment model on all eligible LTCH stays. For more detailed measure specifications, we direct readers to the document titled *Discharge Function Score for Long-Term Care Hospitals (LTCHs) Technical Report.*[838] The risk-adjustment model for this measure controls for clinical, demographic, and function characteristics to ensure that the score fully reflects a facility's quality of care.

Comment: A commenter suggested for CMS to be more involved with clinicians in discussions surrounding the assessment and coding of patients rather than using an imputation approach if there is concern that ANA codes are not truly reflective of patients' function abilities.

Response: We have engaged with post-acute care providers on several occasions. As described in Section IX.E.4.b.3. of this final rule, our measure development contractor convened two TEPs to obtain expert clinician input on the development of the measure. The TEPs consisted of interested parties with a diverse range of expertise, including LTCH and other PAC subject matter expertise, clinical knowledge, and measure development experience. As described in the PAC QRP Functions TEP Summary Report—March 2022,[839] panelists agreed that the recode approach used in the already adopted functional outcome measures could be improved upon and reiterated that not all ANAs reflect dependence on a function activity. Based on the extensive testing results presented to the TEP, a majority of panelists favored the statistical imputation over alternative methodologies and an imputation method that is more accurate over one that is simpler.

Comment: A commenter expressed concern with the proposed statistical imputation approach utilized in the DC Function measure, and suggested it might lead to this measure score varying significantly from the existing function outcome measure.

Response: It is important to capture both self-care and mobility items in the proposed measure as well as capturing each dimension of function in separate measures, which is reflected in the Change in Mobility Score for Ventilator Patients measure in the LTCH QRP. The DC Function measure captures information that is distinct from the Change in Mobility Score for Ventilator Patients measure. Specifically, the DC Function measure considers both dimensions of function (utilizing a subset of self-care and mobility GG items on the LCDS), controls for admission function levels, and applies to a much larger set of LTCH patients, while the Change in Mobility Score for Ventilator Patients measure considers one dimension of function (utilizing only mobility GG items), does not control for mobility at admission, and is only applied to a subset of patients (those requiring ventilator support). For these same reasons, we expect to see differences in outcome percentages among these two measures for reasons unrelated to the imputation approach used.

Comment: A commenter expressed that the adoption of the proposed measure would result in additional provider burden. This commenter explained that the measure would increase costs and administrative

test.battelle.org/sites/default/files/TEP-Summary-Report-PAC-Function.pdf.

[837] Technical Expert Panel (TEP) for Cross-Setting Function Measure Development Summary Report (January 2022 TEP) is available at *https://mmshub.cms.gov/sites/default/files/PAC-Function-TEP-Summary-Report-Jan2022508.pdf.*

[838] *Discharge Function Score for Long-Term Care Hospitals (LTCHs) Technical Report. https://www.cms.gov/files/document/ltch-discharge-function-score-technical-report-february-2023.pdf.*

[839] Technical Expert Panel (TEP) for Cross-Setting Function Measure Development Summary Report (January 2022 TEP) is available at *https://mmshub.cms.gov/sites/default/files/PAC-Function-TEP-Summary-Report-Jan2022-508.pdf.*

burden due to the measure's complexity.

Response: The adoption of the proposed measure would not result in additional burden because we are not proposing changes to the number of items required or the reporting frequency of the items reported. In fact, this measure requires the same set of data elements that are currently reported. Additionally, CMS calculates this measure for LTCHs, and provides LTCHs with various resources to review and monitor their own performance on this measure.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the DC Function measure as an assessment-based outcome measure beginning with the FY 2025 LTCH QRP as proposed.

c. Removal of the Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function Measure Beginning With the FY 2025 LTCH QRP

We proposed to remove the process measure, Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (Application of Functional Assessment/Care Plan), from the LTCH QRP beginning with the FY 2025 LTCH QRP. Section 412.560 of our regulations describes eight factors we consider for measure removal from the LTCH QRP. We believe this measure should be removed because it satisfies two of these factors. First, the Application of Functional Assessment/Care Plan measure meets the conditions for measure removal factor one: measure performance among LTCHs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.[840] Second, this measure meets the conditions for measure removal factor six: there is an available measure that is more strongly associated with desired patient functional outcomes. We believe the proposed DC Function measure discussed in section IX.E.4.b. of the preamble of this final rule better measures functional outcomes than the current Application of Functional Assessment/Care Plan measure. We discuss each of these reasons in more detail in this section of this rule.

In regard to removal factor one, the Application of Functional Assessment/Care Plan measure has become topped out,[841] with average performance rates reaching nearly 100 percent over the past three years (ranging from 99.4 percent to 99.6 percent during calendar years [CYs] 2019–2021).[842] [843] [844] For the 12-month period of Q3 2020 through Q2 2021 (7/1/2020 through 6/30/2021), LTCHs had an average score for this measure of 99.4 percent, with nearly 70 percent of LTCHs scoring 100 percent,[845] and for CY 2021, LTCHs had an average score of 99.4 percent, with nearly 63 percent of LTCHs scoring 100 percent.[846] The proximity of these mean rates to the maximum score of 100 percent suggests a ceiling effect and a lack of variation that restricts distinction between facilities.

In regard to measure removal factor six, the proposed DC Function measure is more strongly associated with desired patient functional outcomes than the current Application of Functional Assessment/Care Plan measure. As described in section IX.E.4.b.(1).(b). of the preamble of this final rule, the proposed DC Function measure has the predictive ability to distinguish patients with low expected functional capabilities from those with high expected functional capabilities.[847] CMS has been collecting standardized functional assessment elements across PAC settings since 2016, which has allowed for the development of the proposed DC Function measure and meets the requirements of the IMPACT Act to submit standardized patient assessment data and other necessary data with respect to the domain of functional status, cognitive function, and changes in function and cognitive function. In light of this development, the process measure Application of Functional Assessment/Care Plan, which measures only whether a functional assessment is completed and a functional goal is included in the care plan, is no longer necessary, and can be replaced with a measure that evaluates the LTCH's outcome of care on a patient's function.

Because the Application of Functional Assessment/Care Plan measure meets measure removal factors one and six under § 412.560(b)(3), we proposed to remove it from the LTCH QRP beginning with the FY 2025 LTCH QRP. We also proposed that public reporting of the Application of Functional Assessment/Care Plan measure would end by the September 2024 Care Compare refresh or as soon as technically feasible when public reporting of the DC Function measure is proposed to begin (see section IX.E.9.b. of the preamble of this final rule).

Under our proposal, LTCHs would no longer be required to report a Self-Care Discharge Goal (that is, GG0130, Column 2) or a Mobility Discharge Goal (that is, GG0170, Column 2) for the purposes of the Application of Functional Assessment/Care Plan measure beginning with patients admitted on October 1, 2023. We would remove the items for Self-Care Discharge Goal (that is, GG0130, Column 2) and Mobility Discharge Goal (that is, GG0170, Column 2) with the next release of the LCDS.

We invited public comment on our proposal to remove the Application of Functional Assessment/Care Plan measure from the LTCH QRP beginning with the FY 2025 LTCH QRP. The following is a summary of the comments we received on our proposal to remove the Application of Functional Assessment/Care Plan measure from the LTCH QRP beginning with the FY 2025 LTCH QRP and our responses.

Comment: Several commenters expressed support for the removal of the Application of Functional Assessment/Care Plan measure. A commenter noted their support in conjunction with the adoption of the DC Function measure. Meanwhile, another commenter, supported the removal given that the value of the measure has remained consistent over the last few years. The commenter indicated that the potential for improvement is very limited and therefore, the measure represents little to no value to the LTCH QRP. Additionally, the commenter recommends the immediate removal of

[840] For more information on the factors CMS uses to base decisions for measure removal, we refer readers to the Code of Federal Regulations, § 412.560(b)(3). *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-412/subpart-O/section-412.560.*

[841] Centers for Medicare & Medicaid Services. 2023 Annual Call for Quality Measures Fact Sheet, p. 10 *https://www.cms.gov/files/document/mips-call-quality-measures-overview-fact-sheet-2022.pdf.*

[842] Centers for Medicare & Medicaid Services. Long-term Care Hospitals Data Archive, 2020, Annual File National Data 12–2020. PDC, *https://data.cms.gov/provider-data/archived-data/long-term-care-hospitals.*

[843] Centers for Medicare & Medicaid Services. Long-Term Care Hospitals Data Archive, 2022, Annual Files National Data 04–22. PDC, *https://data.cms.gov/provider-data/archived-data/long-term-care-hospitals.*

[844] Centers for Medicare & Medicaid Services. Long-Term Care Hospitals Data Archive, 2022, Annual Files National Data 09–22. PDC, *https://data.cms.gov/provider-data/archived-data/long-term-care-hospitals.*

[845] Centers for Medicare & Medicaid Services. Long-Term Care Hospitals Data Archive, 2022, Annual Files Provider Data 04–22.'' PDC, *https://data.cms.gov/provider-data/archived-data/long-term-care-hospitals.*

[846] Centers for Medicare & Medicaid Services. Long-Term Care Hospitals Data Archive, 2022, Annual Files Provider Data 09–22. PDC, *https://data.cms.gov/provider-data/archived-data/long-term-care-hospitals.*

[847] ''Expected functional capabilities'' is defined as the predicted discharge function score.

the Application of Functional Assessment/Care Plan measure from the LTCH QRP rather than waiting until FY 2025.

Response: We thank the commenters for their support and agree that the Application of Functional Assessment/Care Plan measure should be removed due to topped-out performance. With respect to the commenter's request that the Application of Functional Assessment/Care Plan measure be removed immediately, we refer the commenter to section IX.E.4.c of this final rule where we proposed LTCHs would no longer be required to report a Self-Care Discharge Goal (that is, GG0130, Column 2) or a Mobility Discharge Goal (that is, GG0170, Column 2) for the purposes of the Application of Functional Assessment/Care Plan measure beginning with patients admitted on October 1, 2023. Data reported in quarter four of 2023 counts toward the FY 2025 QRP.

After consideration of the public comments we received, we are finalizing our proposal to remove the Application of Functional Assessment/Care Plan measure from the LTCH QRP beginning with the FY 2025 LTCH QRP as proposed.

d. Removal of the Percent of LTCH Patients With an Admission and Discharge Functional Assessment and a Care Plan Measure Beginning With the FY 2025 LTCH QRP

We proposed to remove the process measure, Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function (Functional Assessment/Care Plan) measure from the LTCH QRP beginning with the FY 2025 LTCH QRP. We proposed this measure's removal because the Functional Assessment/Care Plan measure satisfies factor one of our measure removal factors, as described at 42 CFR 412.530(b)(3)(i), measure performance among LTCHs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50291 through 50298), we adopted the Functional Assessment/Care Plan measure. This quality measure reports the percent of LTCH patients with both an admission and a discharge functional assessment and a care plan that addresses function. This process measure requires the collection of admission and discharge functional status data which assess specific functional activities such as self-care and mobility. The treatment goal provides documentation that a care plan with a goal has been established for the patient.

Since its adoption into the LTCH QRP, the Functional Assessment/Care Plan measure has become topped out,[848] with average performance rates reaching nearly 100 percent over the past three years (ranging from 99.3 percent to 99.5 percent during CYs 2019–2021).[849] [850] [851] The proximity of these mean rates to the maximum score of 100 percent suggests a ceiling effect and a lack of variation that restricts distinction between facilities. Additionally, for the 12-month period of Q3 2020 through Q2 2021 (7/1/2020 through 6/30/2021), 67 percent of LTCHs scored 100 percent,[852] and for CY 2021, 61 percent of LTCHs scored 100 percent.[853]

Our proposal to remove this measure does not mean that CMS no longer considers functional assessment and functional outcomes in LTCH settings important. The functional status and outcomes of LTCH patients are represented in the LTCH QRP through the Functional Outcome Measure: Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support. In addition, the proposed DC Function measure would assess whether the LTCH has achieved expected discharge scores for all patients admitted to an LTCH. Therefore, we proposed to remove the Functional Assessment/Care Plan measure from the LTCH QRP beginning with the FY 2025 LTCH. If finalized as proposed, public reporting of the Functional Assessment/Care Plan measure would end by September 2024 or as soon as technically feasible.

If finalized as proposed, LTCHs would no longer be required to submit Admission Performance for Wash Upper Body, a Self-Care Discharge Goal, and a Mobility Discharge Goal for purposes of the Functional Assessment/Care Plan measure beginning with patients admitted on or after October 1, 2023. We would remove the items for Wash Upper Body, the Self-Care Discharge Goals, and the Mobility Discharge Goals with the next release of the LCDS.

We invited public comment on our proposal to remove the Functional Assessment/Care Plan That Addresses Function measure from the LTCH QRP beginning with the FY 2025 LTCH QRP. The following is a summary of the comments we received on our proposal to remove the Functional Assessment/Care Plan measure from the LTCH QRP beginning with the FY 2025 LTCH QRP and our responses.

Comment: Several commenters expressed support for the removal of the Functional Assessment/Care Plan Measure. A commenter noted their support in conjunction with the adoption of the DC Function measure.

Response: We thank the commenters for their support of the removal of this measure in conjunction with the adoption of the DC Function score measure. We agree the Functional Assessment/Care Plan measure should be removed due to topped-out performance.

After consideration of the public comments we received, we are finalizing our proposal to remove the Functional Assessment/Care Plan measure from the LTCH QRP beginning with the FY 2025 LTCH QRP as proposed.

e. COVID–19 Vaccine: Percent of Patients/Residents Who Are Up To Date Beginning With the FY 2026 LTCH QRP

(1) Background

COVID–19 has been and continues to be a major challenge for PAC facilities, including LTCHs. The Secretary first declared COVID–19 a PHE on January 31, 2020. As of June 19, 2023, the U.S. has reported 103.9 million cumulative cases of COVID–19, and 1.13 million deaths due to COVID–19 in the United States.[854] Although all age groups are at risk of contracting COVID–19, older persons are at a significantly higher risk of mortality and severe disease following infection, with those over age 80 dying at five times the average

[848] Centers for Medicare & Medicaid Services. 2023 Annual Call for Quality Measures Fact Sheet, p. 10. *https://www.cms.gov/files/document/mips-call-quality-measures-overview-fact-sheet-2022.pdf.*

[849] Centers for Medicare & Medicaid Services. Long-Term Care Hospitals Data Archive. 2021, Annual Files National Data 09–21. PDC, *https://data.cms.gov/provider-data/archived-data/long-term-care-hospitals.*

[850] Centers for Medicare & Medicaid Services. Long-Term Care Hospitals Data Archive. 2022, Annual Files National Data 04–22. PDC, *https://data.cms.gov/provider-data/archived-data/long-term-care-hospitals.*

[851] Centers for Medicare & Medicaid Services. Long-Term Care Hospitals Data Archive. 2022, Annual Files National Data 10–22. PDC, *https://data.cms.gov/provider-data/archived-data/long-term-care-hospitals.*

[852] Centers for Medicare & Medicaid Services. Long-Term Care Hospitals Data Archive. 2022, Annual Files Provider Data 07–22. PDC, *https://data.cms.gov/provider-data/archived-data/long-term-care-hospitals*; Long-Term Care Hospitals Data Archive. 2022, Annual Files 09–22. PDC, *https://data.cms.gov/provider-data/archived-data/long-term-care-hospitals.*

[853] Centers for Medicare & Medicaid Services. Long-Term Care Hospitals Data Archive. 2022, Annual Files Provider Data 09–22. PDC, *https://data.cms.gov/provider-data/archived-data/long-term-care-hospitals.*

[854] Centers for Disease Control and Prevention. COVID Data Tracker. 2023. *https://covid.cdc.gov/covid-data-tracker.*

rate.[855] Older adults, in general, are prone to both acute and chronic infections owing to reduced immunity, and are a high-risk population.[856] Adults age 65 and older comprise over 75 percent of total COVID–19 deaths despite representing 13.2 percent of reported cases.[857] COVID–19 has impacted older adults' access to care, leading to poorer clinical outcomes, as well as taking a serious toll on their mental health and well-being due to social distancing.[858]

Since the development of the vaccines to combat COVID–19, studies have shown they continue to provide strong protection against severe disease, hospitalization, and death in adults, including during the predominance of Omicron BA.4 and BA.5 variants.[859] Initial studies showed the efficacy of FDA-approved or authorized COVID–19 vaccines preventing COVID–19. Prior to the emergence of the Delta variant of the virus, vaccine effectiveness against COVID–19-associated hospitalization among adults age 65 and older was 91 percent for those who were fully vaccinated with a mRNA vaccine [860] (Pfizer-BioNTech or Moderna), and 84 percent for those receiving a viral vector vaccine [861] (Janssen). Adults age 65 and older who were fully vaccinated with an mRNA COVID–19 vaccine had a 94 percent reduction in risk of COVID–19 hospitalization; those who were partially vaccinated had a 64 percent reduction in risk.[862] Further, after the emergence of the Delta variant, vaccine effectiveness against COVID–19-associated hospitalization for adults who were fully vaccinated was 76 percent among adults age 75 and older.[863]

More recently, since the emergence of the Omicron variant and availability of booster doses, multiple studies have shown that while vaccine effectiveness has waned, protection is higher among those receiving booster doses than among those only receiving the primary series.[864] [865] [866] Centers for Disease Control and Prevention (CDC) data show that, among people age 50 and older, those who have received both a primary vaccination series and booster dose have a lower risk of hospitalization and dying from COVID–19 than their non-vaccinated counterparts.[867] Additionally, a second vaccine booster dose has been shown to reduce risk of severe outcomes related to COVID–19, such as hospitalization or death.[868] Early evidence also demonstrates that the bivalent boosters, specifically aimed to provide better protection against disease caused by the prevalent BA.4/BA.5 Omicron subvariants, have been quite effective, and underscores the role of up-to-date vaccination protocols in effectively countering the spread of COVID–19.[869] [870]

(a) Measure Importance

Despite the availability and demonstrated effectiveness of COVID–19 vaccinations, significant gaps continue to exist in vaccination rates.[871] As of March 15, 2023, vaccination rates among people age 65 and older are generally high for the primary vaccination series (94.3 percent) but lower for the first booster (73.6 percent among those who received a primary series) and even lower for the second booster (59.9 percent among those who received a first booster).[872] Additionally, though the uptake in boosters among people age 65 and older has been much higher than among people of other ages, booster uptake still remains relatively low compared to primary vaccination among older adults.[873] Variations are also present when examining vaccination rates by race, gender, and geographic location.[874] For example, 66.2 percent of the Asian, non-Hispanic population have completed the primary series and 21.2 percent have received a bivalent booster dose, whereas 44.9 percent of the Black, non-Hispanic population have completed the primary series and only 8.9 percent have received a bivalent booster dose. Among Hispanic populations, 57.1 percent of the population have completed the primary

[855] United Nations. Policy Brief: The Impact of COVID–19 on Older Persons. May 2020. *https://unsdg.un.org/sites/default/files/2020-05/Policy-Brief-The-Impact-of-COVID-19-on-Older-Persons.pdf.*

[856] Lekamwasam R, Lekamwasam S. Effects of COVID–19 Pandemic on Health and Wellbeing of Older People: a Comprehensive Review. Ann Geriatr Med Res. 2020;24(3):166–172. doi: 10.4235/agmr.20.0027. PMID: 32752587; PMCID: PMC7533189.

[857] Centers for Disease Control and Prevention. Demographic Trends of COVID–19 Cases and Deaths in the US Reported to CDC. COVID Data Tracker. 2023. *https://covid.cdc.gov/covid-data-tracker/#demographics.*

[858] United Nations. Policy Brief: The Impact of COVID–19 on Older Persons. May 2020. *https://unsdg.un.org/sites/default/files/2020-05/Policy-Brief-The-Impact-of-COVID-19-on-Older-Persons.pdf.*

[859] Chalkias S, Harper C, Vrbicky K, et al. A Bivalent Omicron-Containing Booster Vaccine Against COVID–19. N Engl J Med. 2022;387(14):1279–1291. doi: 10.0156/NEJMoa2208343. PMID: 36112399; PMCID: PMC9511634.

[860] A person is fully vaccinated with an mRNA vaccine when they receive two doses of a primary series.

[861] A person is fully vaccinated with a viral vector vaccine after receiving one dose of a primary series.

[862] Centers for Disease Control and Prevention. Fully Vaccinated Adults 65 and Older Are 94% Less Likely to Be Hospitalized with COVID–19. April 28, 2021. *https://www.cdc.gov/media/releases/2021/p0428-vaccinated-adults-less-hospitalized.html.*

[863] Interim Estimates of COVID–19 Vaccine Effectiveness Against COVID–19—Associated Emergency Department or Urgent Care Clinic Encounters and Hospitalizations Among Adults During SARS–CoV–2 B.1.617.2 (Delta) Variant Predominance—Nine States, June–August 2021 (Grannis SJ, et al. *MMWR Morb Mortal Wkly Rep.* 2021;70(37):1291–1293. doi: 10.15585/mmwr.mm7037e2).

[864] Surie D, Bonnell L, Adams K, et al. Effectiveness of Monovalent mRNA Vaccines Against COVID–19—Associated Hospitalization Among Immunocompetent Adults During BA.1/BA.2 and BA.4/BA.5 Predominant Periods of SARS–CoV–2 Omicron Variant in the United States—IVY Network, 18 States, December 26, 2021–August 31, 2022. MMWR Morb Mortal Wkly Rep. 2022;71(42):1327–1334. doi: 10.15585/mmwr.mm7142a3.

[865] Andrews N, Stowe J, Kirsebom F, et al. Covid–19 Vaccine Effectiveness Against the Omicron (B.1.1.529) Variant. N Engl J Med. 2022;386(16):1532–1546. doi: 10.1056/NEJMoa2119451. PMID: 35249272; PMCID: PMC8908811.

[866] Buchan SA, Chung H, Brown KA, et al. Estimated Effectiveness of COVID–19 Vaccines Against Omicron or Delta Symptomatic Infection and Severe Outcomes. JAMA Netw Open. 2022;5(9):e2232760. doi: 10.1001/jamanetworkopen.2022.32760. PMID: 36136332; PMCID: PMC9500552.

[867] Centers for Disease Control and Prevention. Rates of laboratory-confirmed COVID–19 hospitalizations by vaccination status. COVID Data Tracker. 2023, February 9. Last accessed March 22, 2023. *https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination.*

[868] Centers for Disease Control and Prevention. COVID–19 Vaccine Effectiveness Monthly Update. COVID Data Tracker. November 10, 2022. *https://covid.cdc.gov/covid-data-tracker/#vaccine-effectiveness.*

[869] Chalkias S, Harper C, Vrbicky K, et al. A Bivalent Omicron-Containing Booster Vaccine Against COVID–19. N Engl J Med. 2022;387(14):1279–1291. doi: 10.0156/NEJMoa2208343. PMID: 36112399; PMCID: PMC9511634.

[870] Tan ST, Kwan AT, Rodriguez-Barraquer I, et al. Infectiousness of SARS–CoV–2 Breakthrough Infections and Reinfections During the Omicron Wave. Nat Med 29, 358–365 (2023). Preprint at medRxiv: doi: 10.1101/2022.08.08.22278547.

[871] Centers for Disease Control and Prevention. COVID–19 Vaccinations in the United States. COVID Data Tracker. January 5, 2023. *https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-booster-percent-pop5.*

[872] Centers for Disease Control and Prevention. COVID–19 Vaccination Age and sex Trends in the United States, National and Jurisdictional. *https://data.cdc.gov/Vaccinations/COVID-19-Vaccination-Age-and-Sex-Trends-in-the-Uni/5i5k-6cmh.*

[873] Freed M, Neuman T, Kates J, Cubanski J. Deaths Among Older Adults Due to COVID–19 Jumped During the Summer of 2022 Before Falling Somewhat in September. Kaiser Family Foundation. October 6, 2022. *https://www.kff.org/coronavirus-covid-19/issue-brief/deaths-among-older-adults-due-to-covid-19-jumped-during-the-summer-of-2022-before-falling-somewhat-in-september/.*

[874] Saelee R, Zell E, Murthy BP, et al. Disparities in COVID–19 Vaccination Coverage Between Urban and Rural Counties—United States, December 14, 2020–January 31, 2022. MMWR Morb Mortal Wkly Rep. 2022;71:335–340. doi: 10.15585/mmwr.mm7109a2. PMID: 35239636; PMCID: PMC8893338.

series and 8.5 percent have received a bivalent booster dose, while in White, non-Hispanic populations, 51.9 percent have completed the primary series and 16.2 percent have received a bivalent booster dose.[875] Disparities have been found in vaccination rates between rural and urban areas, with lower vaccination rates found in rural areas.[876] [877] Data show that 55.2 percent of the eligible population in rural areas have completed the primary vaccination series, as compared to 66.5 percent of the eligible population in urban areas.[878] Receipt of bivalent booster doses among those eligible has been lower, with 18 percent of urban population having received a booster dose, and 11.5 percent of the rural population having received the booster dose.[879]

We proposed to adopt the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID–19 Vaccine) measure for the LTCH QRP beginning with the FY 2026 LTCH QRP. The proposed measure has the potential to increase COVID–19 vaccination coverage of patients in LTCHs, as well as prevent the spread of COVID–19 within the LTCH patient population. This measure would also support the goal of the CMS Meaningful Measure Initiative 2.0 to ''Empower consumers to make good health care choices through patient-directed quality measures and public transparency objectives.'' The proposed Patient/Resident COVID–19 Vaccine measure would be reported on Care Compare and would provide patients and caregivers, including those who are at high risk for developing serious complications from COVID–19, with valuable information they can consider when choosing an LTCH. The proposed Patient/Resident COVID–19 Vaccine measure would facilitate patient care and care coordination during the hospital discharge planning process. Because this measure would be reported on Care Compare, a discharging acute care hospital, in collaboration with the patient and family, could use the information on Care Compare, to coordinate care and ensure patient preferences are considered in the discharge plan. Additionally, the measure would be an indirect measure of provider action. Since the patient's vaccination status would be reported at discharge from the LTCH, if a patient is not up to date with their vaccine at the time of LTCH admission, the LTCH has the opportunity to educate the patient and provide information on why that patient should become up to date. LTCHs may also choose to administer the vaccine to the patient prior to discharge from the LTCH or coordinate a follow-up visit for the patient to obtain the vaccine at a physician's office or local pharmacy.

(b) Item Testing

The measure development contractor conducted testing with LTCHs on the proposed standardized patient/resident COVID–19 vaccination coverage assessment item using patient scenarios and cognitive interviews to assess their comprehension of the item and the associated guidance. A team of clinical experts, assembled by CMS's measure development contractor, developed patient scenarios to represent the most common scenarios LTCH providers would encounter. The results of the item testing demonstrated that LTCHs that used the guidance had a high percentage of accurate responses, supporting its reliability. The testing also provided information to improve the item itself, as well as the accompanying guidance.

(2) Competing and Related Measures

Section 1899B(e)(2)(A) of the Act requires that, absent an exception under section 1899B(e)(2)(B) of the Act, each measure specified under section 1899B of the Act be endorsed by a CBE with a contract under section 1890(a) of the Act. In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed, section 1899B(e)(2)(B) of the Act permits the Secretary to specify a measure that is not so endorsed, as long as due consideration is given to the measures that have been endorsed or adopted by a consensus organization identified by the Secretary. The proposed Patient/Resident COVID–19 Vaccine measure is not CBE endorsed, and after review of other CBE-endorsed measures, we were unable to identify any CBE-endorsed measures for LTCHs focused on capturing COVID–19 vaccination coverage of LTCH patients. We found only one related measure addressing COVID–19 vaccination, the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure, adopted for the FY 2023 LTCH QRP (87 FR 45438 through 45446), which captures the percentage of HCPs who receive a complete COVID–19 vaccination course.

Therefore, after consideration of other available measures that assess COVID–19 vaccination rates, we believe the exception under section 1899B(e)(2)(B) of the Act applies. We intend to submit the proposed measure to the CBE for consideration of endorsement when feasible.

(3) Interested Parties and Technical Expert Panel (TEP) Input

First, the measure development contactor convened a focus group of patient and family/caregiver advocates (PFAs) to solicit input. The PFAs felt a measure capturing raw vaccination rate, irrespective of provider action, would be most helpful in decision making. Next, a TEP was held on November 19, 2021 and December 15, 2021 to solicit feedback on the development of patient/resident COVID–19 vaccination measures and assessment items for the PAC settings. The TEP panelists voiced their support for PAC patient/resident COVID–19 vaccination measures and agreed that developing a measure to report the rate of vaccination in an LTCH setting without denominator exclusions was an important goal. We considered all the TEP's recommendations for developing vaccination-related measures, and applied those recommendations where technically feasible and appropriate. A summary of the TEP proceedings titled *Technical Expert Panel (TEP) for the Development of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) COVID–19 Vaccination-Related Items and Measures Summary Report* is available on the CMS Measures Management System (MMS) web page.[880]

[875] Centers for Disease Control and Prevention. Trends in Demographic Characteristics of People Receiving COVID–19 Vaccinations in the United States. COVID Data Tracker. 2023. *https://covid.cdc.gov/covid-data-tracker/#vaccination-demographics-trends.*

[876] Saelee R, Zell E, Murthy BP, et al. Disparities in COVID–19 Vaccination Coverage Between Urban and Rural Counties—United States, December 14, 2020–January 31, 2022. MMWR Morb Mortal Wkly Rep. 2022;71:335–340. doi: 10.15585/mmwr.mm7109a2. PMID: 35239636; PMCID: PMC8893338.

[877] Sun Y, Monnat SM. Rural-Urban and Within-Rural Differences in COVID–19 Vaccination Rates. J Rural Health. 2022;38(4):916–922. doi: 10.1111/jrh.12625. PMID: 34555222; PMCID: PMC8661570.

[878] Centers for Disease Control and Prevention. Vaccination Equity. COVID Data Tracker; 2023. *https://covid.cdc.gov/covid-data-tracker/#vaccination-equity.*

[879] Centers for Disease Control and Prevention. Vaccination Equity. COVID Data Tracker; 2023. *https://covid.cdc.gov/covid-data-tracker/#vaccination-equity.*

[880] *Technical Expert Panel (TEP) for the Development of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) COVID–19 Vaccination-Related Items and Measures Summary Report* is available at *https://mmshub.cms.gov/sites/default/files/COVID19-Patient-Level-Vaccination-TEP-Summary-Report-NovDec2021.pdf.*

To seek input on the importance, relevance, and applicability of a patient/resident COVID–19 vaccination coverage measure, we solicited public comments in an RFI for publication in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 47553).[881] Commenters stated they understood why CMS was considering a measure addressing COVID–19 vaccination coverage among patients, but noted CMS should postpone considering this measure since the definition of ''fully vaccinated'' is evolving.

(4) Measure Applications Partnership (MAP) Review

We included the Patient/Resident COVID–19 Vaccine measure under the LTCH QRP on the publicly available ''List of Measures Under Consideration for December 1, 2022'' (MUC List),[882] a list of quality and efficiency measures the Secretary is considering adopting for use in Medicare programs. The MUC List allows interested parties to provide recommendations to the Secretary on measures included on the MUC List.

After the MUC List was published, the MAP received three comments from interested parties on the Patient/Resident COVID–19 Vaccine measure. Commenters were mostly supportive of the measure and recognized the importance of patient COVID–19 vaccination, and that measurement and reporting is one important method to help healthcare organizations assess their performance in achieving high rates of up-to-date vaccination. A commenter noted the benefit of less-specific criteria for inclusion in the numerator and denominator, which would provide flexibility for the measure to remain relevant to current circumstances, while others raised concerns over measure specifications, including using the concept of ''up to date'' given the evolving definition of the term, the fact that patient refusals are not excluded, and the frequency of data submission. Two interested parties noted there could be unintended consequences to patient access if the measure was adopted.

Subsequently, several MAP workgroups met to provide input on the measure. First, the MAP Health Equity Advisory Group convened on December 6, 2022. One MAP member noted that the percentage of true contraindications for the COVID–19 vaccine is low, and the lack of exclusions on the measure makes sense to avoid varying interpretations of valid contraindications.[883] Similarly, the MAP Rural Health Advisory Group met on December 8, 2022 and expressed that the measure is important for rural communities.[884]

Next, the MAP Post-Acute Care/Long-Term Care (PAC/LTC) workgroup met on December 12, 2022, where the PAC/LTC workgroup members discussed their concerns about: (1) the evolving vaccine recommendations, (2) the lack of denominator exclusions, and (3) the reporting frequency for this measure. CMS noted that the Patient/Resident COVID–19 Vaccine measure does not have exclusions for patient refusals because the measure was intended to report raw rates of vaccination. CMS explained that raw rates of vaccination collected by the Patient/Resident COVID–19 vaccine measure are important for consumer choice and PAC providers, including LTCHs, are in a unique position to leverage their care processes to increase vaccination coverage in their settings to protect patients and prevent negative outcomes. CMS also clarified that the measure defines ''up to date'' in a manner that provides flexibility to reflect future changes in CDC guidance. Finally, CMS clarified that, like the existing COVID–19 HCP Vaccine measure, this measure would continue to be reported quarterly because the CDC has not yet determined that COVID–19 is seasonal. Ultimately, the PAC/LTC workgroup reached consensus on the vote, ''Do not support for rulemaking,'' for the Patient/Resident COVID–19 Vaccine measure.[885]

The MAP received four comments by industry commenters in response to the PAC/LTC workgroup recommendations. The commenters generally understood the importance of COVID–19 vaccinations' role in preventing the spread of COVID–19; however, most commenters did not recommend the inclusion of this measure for the LTCH QRP. Specifically, commenters were concerned about providers' inability to influence results based on factors outside of their control, including COVID–19 vaccine hesitancy. Commenters also noted that the measure has not been fully tested and questioned whether the measure would produce meaningful results. Commenters also encouraged CMS to monitor the measure for unintended consequences. Another commenter supported the measure and recommended that CMS consider an exclusion for medical contraindications, and also seek CBE endorsement.

Finally, the MAP Coordinating Committee convened on January 24, 2023, and noted concerns previously discussed in the PAC/LTC workgroup, such as the lack of exclusions for medical contraindications and potential for patient selection bias based on patients' vaccination status. CMS was able to clarify that this measure does not have exclusions for patient refusals since this is a process measure intended to report raw rates of vaccination, and is not intended to be a measure of LTCHs' actions. CMS acknowledged that a measure accounting for variables, such as LTCHs' actions to vaccinate patients, could be important, but CMS is focused on a measure which would provide and publicly report vaccination rates for consumers given the importance of this information to patients and their caregivers.

The MAP Coordinating Committee recommended three mitigation strategies for the Patient/Resident COVID–19 Vaccine measure: (1) reconsider exclusions for medical contraindications; (2) complete reliability and validity measure testing; and (3) seek CBE endorsement. The Coordinating Committee ultimately reached 90 percent consensus on the vote of ''Do not support with potential for mitigation.'' [886] Despite the MAP Coordinating Committee's vote, we believed it was still important to propose the Patient/Resident COVID–19 Vaccine measure for the LTCH QRP. As we stated in the FY 2024 PPS proposed rule (88 FR 27148), we did not include exclusions for medical contraindications because the PFAs we met with told us that a measure capturing raw vaccination rate, irrespective of any medical contraindications, would be most helpful in patient and family/caregiver decision-making. We do plan to conduct reliability and validity measure testing

[881] 87 FR 25070.

[882] Centers for Medicare & Medicaid Services. Overview of the List of Measures Under Consideration for December 1, 2022. *https://mmshub.cms.gov/sites/default/files/2022-MUC-List-Overview.pdf.*

[883] CMS Measures Management System (MMS). Measure Implementation: Pre-rulemaking MUC Lists and MAP reports. Last accessed March 22, 2023. *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[884] CMS Measures Management System (MMS). Measure Implementation: Pre-rulemaking MUC Lists and MAP reports. Last accessed March 22, 2023. *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[885] CMS Measures Management System (MMS). Measure Implementation: Pre-rulemaking MUC Lists and MAP reports. Last accessed March 22, 2023. *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[886] National Quality Forum Measure Applications Partnership. 2022–2023 MAP Final Recommendations. *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=98102.*

once we have collected enough data, and we intend to submit the proposed measure to the CBE for consideration of endorsement when feasible. We refer readers to the final MAP recommendations, titled *2022–2023 MAP Final Recommendations.*[887]

(5) Quality Measure Calculation

The proposed Patient/Resident COVID–19 Vaccine measure is a process measure that reports the percent of stays in which patients in an LTCH are up to date on their COVID–19 vaccinations per CDC's latest guidance.[888] This measure has no exclusions and is not risk adjusted.

The numerator for the measure would be the total number of LTCH stays in the denominator in which patients are up to date with the COVID–19 vaccine during the reporting period. The denominator for the measure would be the total number of LTCH stays discharged during the reporting period.

The data source for the proposed quality measure is the LCDS assessment instrument. For more information about the proposed data submission requirements, we refer readers to section VI.8.d. of the preamble of this final rule. For additional technical information about this final measure, we refer readers to the draft measure specifications document titled *Patient-Resident-COVID-Vaccine-Draft-Specs.pdf*[889] on the LTCH QRP Measures Information web page.

We invited public comments on the proposal to adopt the Patient/Resident COVID–19 Vaccine measure beginning with the FY 2026 LTCH QRP. The following is a summary of the comments we received on our proposal to adopt the Patient/Resident COVID–19 Vaccine measure beginning with the FY 2026 LTCH QRP and our responses.

Comment: Four commenters supported the adoption of this measure into the LTCH QRP beginning FY2026. A commenter noted that COVID–19 pandemic has had a disproportionate and devastating impact on older adults, particularly those residing in long-term care and congregate care settings.

Response: We thank the commenters for their support.

A number of commenters did not support the proposal to adopt the Patient/Resident COVID–19 Vaccine measure to the IRF QRP for various reasons. The following is a summary of these public comments received on our proposal and our responses.

Comment: Several commenters did not support the proposal due to the measure not being fully tested for reliability and validity, and questioned whether it was feasible for LTCHs to collect the information and whether the measure would produce statistically meaningful information. Two of these commenters noted that CMS should validate the data collection tool used in the measure prior to adopting the measure. These commenters also suggested CMS ''rushed through'' the validation process to add the measure to the LTCH QRP as soon as possible, pointing to the fact that CMS did not provide support showing the measure is practical or feasible.

Response: We acknowledge the concerns raised by the commenters related to the measure testing. However, we have tested the item proposed for the LCDS to capture data for this measure and its feasibility and appropriateness. Since a COVID–19 vaccination item does not exist within the LCDS, we developed clinical vignettes to test item-level reliability of a draft Patient/Resident COVID–19 vaccination. The clinical vignettes were a proxy for patient records with the most common and challenging cases providers would encounter, similar to the approach that CMS uses to train providers on all new assessment items, and the results demonstrated strong agreement (that is, 80 percent).

Validity testing has not been completed yet, since a COVID–19 vaccination item does not currently exist on the LCDS. However, the Patient/Resident COVID–19 Vaccine measure was constructed based on prior use of similar items, such as the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) for the IRF QRP and LTCH QRP. We have used these types of patient vaccination assessment items in the calculation of vaccination quality measures in our PAC QRPs and intend to conduct reliability and validity testing for this specific Patient/Resident COVID–19 Vaccine measure once a COVID–19 vaccination item has been added to the LCDS and we have collected sufficient data.

Additionally, we solicited feedback from our Technical Expert Panel (TEP) on the proposed assessment item and its feasibility. No concerns were raised by the TEP regarding obtaining information required to complete the new COVID–19 vaccination item.[890]

Comment: A few commenters did not support the measure due to lack of support from the MAP and urged CMS to delay adoption of the measure until concerns raised by the MAP Coordinating Committee have been addressed. Specifically, they noted that the MAP is a multi-stakeholder panel of experts representing providers, patients and payers and they encouraged CMS to address the MAP's recommendations for adding exclusions to the measure, conducting measure testing and submitting the measure for CBE endorsement. Several of these commenters specifically requested that exclusions for medical contraindications, religious beliefs, cultural norms, and patient refusals be added to the measure specifications, noting that without them the vaccination rates could be misleading.

Response: As part of the pre-rulemaking process, HHS takes into consideration the recommendations of the MAP in selecting candidate quality and efficiency measures. HHS selects candidate measures and publishes proposed rules in the **Federal Register**, which allows for public comment and further consideration before a final rule is issued. If the CMS CBE has not endorsed a candidate measure, then HHS must publish a rationale for the use of the measure described in section 1890(b)(7)(B) of the Act in the notice. We would like to reiterate that this measure is intended to promote transparency of raw data regarding COVID–19 vaccination rates for patients/caregivers to make informed decisions for selecting facilities, providing potential patients with an important piece of information regarding vaccination rates as part of their process of identifying providers they would want to seek care from. As we stated in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27148), we did not include exclusions for medical contraindications, religious beliefs, cultural norms, and patient refusals because the PFAs we met with told us that a measure capturing raw vaccination rate, irrespective of any medical contraindications, would be most helpful in patient and family/

[887] 2022–2023 MAP Final Recommendations. *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[888] The definition of ''up to date'' may change based on CDC's latest guidelines and can be found on the CDC web page, ''Stay Up to Date with COVID–19 Vaccines Including Boosters,'' at *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html* (updated January 9, 2023).

[889] Patient-Resident-COVID-Vaccine-Draft-Specs.pdf. *https://www.cms.gov/files/document/patient-resident-covid-vaccine-draft-specs.pdf.*

[890] Technical Expert Panel (TEP) for the Development of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) COVID–19 Vaccination-Related Items and Measures Summary Report. *https://mmshub.cms.gov/sites/default/files/COVID19-Patient-Level-Vaccination-TEP-Summary-Report-NovDec2021.pdf.*

caregiver decision-making. Our TEP also agreed that developing a measure to report the rate of vaccination without denominator exclusions was an important goal.[891] Based on this feedback, excluding patients/residents with contraindications from the measure would distort the intent of the measure of providing raw COVID–19 patient vaccination rates, while making the information more difficult for patients/caregivers to interpret, and therefore we did not include any exclusions. We also stated in the FY 2024 IPPS/LTCH proposed rule (88 FR 27149) that we intend to conduct measure testing once sufficient data on the COVID–19 vaccination item is collected through the LCDS and plan to submit the measure for CBE endorsement when it is technically feasible to do so.

Comment: A commenter noted that vaccination administration rates can ebb and flow significantly based on factors outside the control of LTCHs, including holidays, weather, vaccine/pharmaceutical supply chain management, staff availability and more. As a result, they do not believe the rates will accurately depict the vaccination rate of an LTCH's patients.

Response: LTCHs will be able to administer the COVID–19 vaccine if a patient consents. This measure does not require LTCHs to administer the vaccine themselves. They could arrange for the patient to obtain the vaccine outside of their facility, or work with community pharmacies to obtain vaccines.

Comment: A few commenters opposed the measure because they believe vaccine uptake is subject to patient-level factors outside the control of the LTCH, including a patient's transparency regarding their vaccination status, and therefore the Patient/Resident COVID–19 Vaccine measure would not be a reflection of the actions or efforts taken by an LTCH to improve patient care. Three of these commenters referenced the MAP's Health Equity Advisory Group who ''expressed concerns about vaccine hesitancy due to cultural norms,'' and they want to honor the choice of their patients once they have been offered clinical advice. Two of these commenters noted that disparities in vaccine uptake exist among racial and geographic categories because of differences deeply rooted in culture, religion, ethnicity, socioeconomic status, and are not related to the local LTCH's efforts to vaccine their patients. A commenter noted that requiring vaccination data to be reported will not sway those individuals who are reluctant to continue receiving vaccines, while two other commenters noted that it is possible for an LTCH to encourage vaccination among their patients and still have a relatively low rate of vaccination.

Response: We appreciate providers' commitment to ensuring that patients are educated and encouraged to receive vaccinations, and we acknowledge that individuals have a choice about whether to receive a COVID–19 vaccine or booster, despite an LTCH's best efforts. However, it is also true that patients and family/caregivers have choices about selecting and LTCH, and it is our intention to empower them with the information they need to make an informed decision by publicly reporting the data we receive from LTCHs on this measure. We understand that there may be instances where a patient chooses not to be vaccinated, and we want to remind LTCHs that this measure does not mandate patients be up to date with their COVID–19 vaccination, only that the LTCH report on patients' vaccination status. LTCHs are able to successfully report the measure, and comply with the LTCH QRP requirements, irrespective of the number of patients who have been vaccinated.

Comment: Two commenters believe it is often infeasible or inappropriate to offer vaccination for patients due to length of stay, ability to manage side effects and medical contraindications, or other logistical challenges to gathering information from a patient who may have received care from multiple proximal providers. Another commenter noted that patients admitted to an LTCH almost exclusively come from a general acute care hospital following a complex course of illness or a traumatic event, and it is not unusual for such complex and compromised patients to be inappropriate to receive immunizations. Two commenters raised concerns that CMS had not addressed how LTCHs should report vaccination data for patients that are on mechanical ventilators.

Response: We understand concerns about post-acute care length of stay, acuity of patient health, or effect of the vaccine on patient care. LTCHs should continue to use clinical judgement to determine if a patient is eligible to receive the vaccination, as well as when it is appropriate for a patient to receive vaccination, keeping in mind patient's health and safety. Regarding the commenters' concerns about reporting data for patients on mechanical ventilators, providers will be able to use multiple sources of information available to obtain the vaccination data, such as patient interviews, medical records, proxy response, and vaccination cards provided by the patient/caregivers.[892] Therefore, coding of this item in the LCDS would not be limited by a patient's ability to respond.

Comment: A commenter noted that sometimes patients may not have the opportunity to 'shop' for an LTCH outside of their region simply based on the COVID–19 vaccinations rates. They noted that insurance and proximity to loved ones are often the drivers for selecting an LTCH.

Response: We acknowledge that sometimes patients may not have access to as many LTCH choices as others. However, the information provided by this measure will still be valuable to potential LTCH patients and their caregivers who may have geographic limitations.

Comment: Several commenters opposed the Patient/Resident COVID–19 Vaccine measure because they believe it will have minimal impact on patient health while increasing administrative burden on LTCHs, including burden associated with data collection, education, and updates to IT systems. Two of these commenters noted that collecting this information would be especially burdensome in cases where patients are unable or unwilling to provide the necessary information. Another commenter suggested that with extreme staffing shortages, the resources to spend additional time gathering COVID–19 vaccine data, administering the vaccine, or doing extensive education on vaccination are limited. A commenter was concerned that this would increase the burden associated with managing and updating IT system changes and re-training staff in data collection.

Response: We think the measure could have an impact on patient health. This measure will provide potential patients with an important piece of information regarding vaccination rates as part of their process of identifying providers they would want to seek care from, empowering them to make informed decisions about their health care. Additionally, as noted in the

[891] Technical Expert Panel (TEP) for the Development of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) COVID–19 Vaccination-Related Items and Measures Summary Report. *https://mmshub.cms.gov/sites/default/files/COVID19-Patient-Level-Vaccination-TEP-Summary-Report-NovDec2021.pdf.*

[892] COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Draft Measure Specifications. *https://www.cms.gov/files/document/patient-resident-covid-vaccine-draft-specs.pdf.*

COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Draft Measure Specifications,[893] providers will be able to use all sources of information available to obtain the vaccination data, such as patient interviews, medical records, proxy response, and vaccination cards provided by the patient/caregivers. Therefore, coding would not be limited to a patient response. Regarding the comment about the additional time LTCHs would have to spend gathering COVID–19 vaccine data, LTCHs should be assessing whether patients are up to date with COVID–19 vaccination as a part of their routine care and infection control processes. During our item testing, we heard from LTCHs that they are already routinely inquiring about COVID–19 vaccination status when admitting patients. Additionally, this measure does not require LTCHs to administer the vaccine themselves. They could arrange for the patient to obtain the vaccine outside of their facility, or work with community pharmacies to obtain vaccines. In response to the comment on the burden associated with managing and updating IT systems, we will be posting the Final Measure Specifications and Draft Data Submission Specifications for the Patient/Resident COVID–19 Vaccine measure in the Fall of 2023, and believe IT vendors will have enough time to update their software prior to October 1, 2024. The item and response options are not complex, and the item is only required at discharge. The time, form, and manner in which the LCDS will be submitted is not changing; rather, it is the addition of one item to be collected at one time point. Therefore, the implementation of this proposal should not require health IT vendors to completely rewrite their software. Finally, as with any new assessment item, we will provide free training and education to LTCHs as well as publish coding guidance and instructions for LTCHs to be prepared for data collection.

Comment: A commenter requested that CMS consider utilizing the short-stay hospital questionnaire on this metric as its base and not require the LTCH to also collect this information. They noted that if a patient comes to an LTCH without having a predecessor short-stay hospital stay, only then an LTCH should be required to submit that data.

Response: We are unable to determine what short-stay hospital questionnaire the commenter is referring to, and therefore are unable to respond.

Comment: Two commenters believed the adoption of a patient-level measure of COVID–19 vaccination status would face similar challenges to the Percent of Residents of Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (CBE #0680) that was retired in the FY 2019 IRF PPS final rule (83 FR 38514). They also stated that LTCH performance on this proposed measure will fail to show meaningful distinctions in improvements since 94.3 percent of the United States population at least 65 years of age had completed their primary series as of May 2023.

Response: We interpret the commenter to be referring to the Percent of Residents of Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (CBE #0680) that was removed from the LTCH QRP measure set in the FY 2018 LTCH PPS final rule (82 FR 38433 through 38439). However, we do not believe this measure is at risk of being retired early. The proposed Patient/Resident COVID–19 Vaccine measure reports the percentage of patients in an LTCH who are up to date on their COVID–19 vaccinations per the CDC's latest guidance, rather than capturing the rates of primary vaccination series only. Because the measure reflects an ''up to date'' status, it minimizes the potential for topping out. We believe that continued monitoring of up to date vaccination will remain an important tool to minimize severe illness, hospitalization, and death in post-acute care facilities. Additionally, we find there is substantial room for improvement in measure performance. As of May 2023, while the vaccination rates among people 65 and older were high for the primary vaccination series (94.3 percent), the vaccination rates are lower for the first booster (73.9 percent among those who received a primary series) and even lower for the second booster dose (60.4 percent among those who received a first booster).[894] However, we routinely monitor measures to determine if they meet any of the measure removal factors, set forth in § 412.560(b)(3), and if identified, we may remove the measure through the rulemaking process.

Comment: A commenter noted that CMS should not adopt this proposed measure due to the end of the PHE, and that CMS should eliminate any tracking of vaccines with the end of Federal vaccination mandates. Two commenters noted that adding a new quality measure to the LTCH QRP now for reporting patient COVID–19 vaccination status is inconsistent with the agency's decision to remove the vaccination requirements for health care personnel from the hospital conditions of participation. These commenters said they found it confusing that CMS has proposed this new measure because it contradicts CMS's statement to treat COVID–19 like other infectious diseases going forward, specifically influenza, and they point out that there is no existing measure in the LTCH QRP addressing patient influenza vaccination status.

Response: Despite the announcement of the end of the COVID–19 PHE, many people continue to be affected by COVID–19, particularly seniors, people who are immunocompromised, and people with disabilities. As mentioned in the End of COVID–9 Public Health Emergency Fact Sheet,[895] our response to the spread of SARS-CoV–2, the virus that causes COVID–19, remains a public health priority. Even with the end of the COVID–19 PHE, we continue to work to protect Americans from the virus and its worst impacts by supporting access to COVID–19 vaccines, treatments, and tests, including for people without health insurance. Given the continued impacts of COVID–19, it is important to promote patient vaccination and education, which this measure aims to achieve. As mentioned previously, continued monitoring of up to date COVID–19 vaccination will remain an important tool to minimize severe illness, hospitalization, and death in LTCHs because, as stated earlier, there is substantial room for improvement in measure performance. As of May 2023, while the vaccination rates among people 65 and older were high for the primary vaccination series (94.3 percent), the vaccination rates are lower for the first booster (73.9 percent among those who received a primary series) and even lower for the second booster dose (60.4 percent among those who received a first booster).[896]

[893] COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Draft Measure Specifications. *https://www.cms.gov/files/document/patient-resident-covid-vaccine-draft-specs.pdf.*

[894] Centers for Disease Control and Prevention. COVID–19 vaccination age and sex trends in the United States, national and jurisdictional. Last updated May 11, 2023. *https://data.cdc.gov/Vaccinations/COVID-19-Vaccination-Age-and-Sex-Trends-in-the-Uni/5i5k-6cmh.*

[895] Fact Sheet: End of the COVID–19 Public Health Emergency. U.S. Department of Health and Human Services. May 9, 2023. *https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html.*

[896] Centers for Disease Control and Prevention. COVID–19 vaccination age and sex trends in the United States, national and jurisdictional. Last

Continued

We also want to note that the proposed Patient/Resident COVID–19 Vaccine measure is not associated with the Conditions of Participation. This measure is being proposed for the LTCH QRP to support the goal of the CMS Meaningful Measure Initiative 2.0 to ''Empower consumers to make good health care choices through patient-directed quality measures and public transparency objectives,'' which is consistent with previous vaccination measures.

Comment: A commenter noted that the NHSN measure reflecting all patients provides a better picture of each facility. Two commenters suggested that having a single yes or no item on the LCDS without any requirements for documentation or validation of vaccination status would amount to a mere checkmark in a box with no evidence that it leads to improved quality of care.

Response: Although some LTCHs may voluntarily submit patient-level COVID–19 vaccine data to the NHSN, we do not collect patient-level COVID vaccination data as part of the LTCH QRP. Therefore, adding an LCDS item for the purposes of collecting patient-level COVID vaccination data would be appropriate for data collection, similar to other assessment-based measures. As stated earlier in this section, assessment-based measures have several benefits, including patient-level data and a variety of reports LTCHs can use to assess performance, inform patient engagement and refine infection control processes. Additionally, this data will allow for granular analyses of vaccinations, including identification of potential disparities within the LTCH QRP.

Comment: A commenter noted that the CDC maintains different definitions of ''up to date'' and ''fully vaccinated.'' This commenter believed that the public has a limited appreciation for the differences in these definitions and could easily misreport their vaccination status to facility staff when asked, giving the public a misleading picture of the vaccination levels of a LTCH's patient population.

Response: Gathering information about patient vaccination status gives LTCHs the opportunity to educate patients about what it means to be up to date per CDC guidelines, so that the item can be completed accurately. The CDC has also published FAQs that clearly state the difference in the terms 'fully vaccinated' and 'up to date.' When completing the item, LTCHs can access the CDC website at *https://www.cdc.gov/coronavirus/2019-ncov/vaccines/stay-up-to-date.html* to find the definition of up to date, in addition to using the LCDS Guidance Manual. Our item testing demonstrated strong agreement with the correct responses when facilities used the available guidance, and rates of correct responses increased when LTCHs accessed the CDC website.

Comment: A few commenters provided alternate measure recommendations, such as the number of times during a stay the LTCH offered education, support and information concerning the vaccine to the patient and/or family, actions providers take in encouraging vaccination, or data reporting about patient respiratory illness.

Response: We appreciate the input from the commenters. However, these alternate recommendations do not meet the intent of the measure, which is a raw rate of patient vaccinations, irrespective of LTCH actions. We will use this input to inform our future measure development efforts.

After consideration of the public comments we received, we are finalizing our proposal to adopt the Patient/Resident COVID–19 Vaccine measure as an assessment-based measure beginning with the FY 2026 LTCH QRP as proposed.

5. Principles for Selecting and Prioritizing LTCH QRP Quality Measures and Concepts Under Consideration for Future Years: Request for Information (RFI)

a. Solicitation of Comments

We solicited general comments on the principles for identifying LTCH QRP measures, as well as additional comments about measurement gaps, and suitable measures for filling these gaps. Specifically, we solicited comment on the following questions:

- Principles for Selecting and Prioritizing LTCH QRP Measures

++ To what extent do you agree with the principles for selecting and prioritizing measures?

++ Are there principles that you believe CMS should eliminate from the measure selection criteria?

++ Are there principles that you believe CMS should add to the measure selection criteria?

- LTCH QRP Measurement Gaps

++ CMS requests input on the identified measurement gaps, including in the areas of cognitive function, behavioral and mental health, patient experience and patient satisfaction, and chronic conditions and pain management.

++ Are there gaps in the LTCH QRP measures that have not been identified in this RFI?

- Measures and Measure Concepts Recommended for Use in the LTCH QRP

++ Are there measures that you believe are either currently available for use, or that could be adapted or developed for use in the LTCH QRP program to assess performance in the areas of: (1) cognitive functioning; (2) behavioral and mental health; (3) patient experience and patient satisfaction; (4) chronic conditions; (5) pain management; or (6) other areas not mentioned in this RFI?

CMS also sought input on data available to develop measures, approaches for data collection, perceived challenges or barriers, and approaches for addressing challenges.

We received several comments in response to this RFI in the proposed rule, which are summarized later in this section.

Comments: A commenter indicated that the principles for measure selection and prioritization identified by CMS in the RFI in the proposed rule are consistent with the principles inherent in the CMS Measure Management System (MMS), and recommended that MMS measure development principles be integrated into the LTCH QRP principles. The same commenter suggested that clearly delineated processes are required in order to guide the application of these principles. Two commenters expressed concern about the addition of measures to the QRP given the administrative burden associated with measure reporting. These commenters suggested that CMS' guiding principles consider whether a measure is important, well-defined, has scientific merit, is feasible and useable, and does not duplicate existing measures. A commenter recommended that CMS support testing through the CBE.

Although several commenters agreed with CMS on the presence of measurement gaps in the LTCH QRP, not all commenters thought that measures should be added to the LTCH QRP. A commenter recommended that CMS continually evaluate whether measures are necessary, and remove measures that are deemed unnecessary. Another commenter, who agreed with CMS on the need to fill measurement gaps in the areas identified in the RFI, encouraged CMS to utilize measures and/or assessment data already available (for example, claims data, LCDS, and NHSN) in order to reduce LTCH burden. This commenter further

updated May 11, 2023. *https://data.cdc.gov/Vaccinations/COVID-19-Vaccination-Age-and-Sex-Trends-in-the-Uni/5i5k-6cmh.*

suggested that CMS reduce administrative burden by streamlining LTCH data collection (for example, incorporating additional skip logic to bypass questions that are not relevant to an LTCH).

Three commenters recommended that CMS prioritize operational improvements to the LTCH QRP rather than the addition of new measures. Operational issues identified by the commenters included the lack of training on new instruments, time necessary to conduct patient assessments, and the need to remove ''low-value'' measures when new measures are added to the QRP. Another commenter urged CMS to ensure that reported measures account for LTCHs high-acuity patient population, and focus on topics that LTCHs are able to directly impact.

A couple of commenters agreed that the area of cognitive function was an important LTCH QRP measurement gap that needs to be filled. A commenter encouraged CMS to select measures of cognitive functioning that are reliable, feasible, valid, and that are, or could be, endorsed by a CBE. The other commenter expressed concern about the inability of cognitive function tools to identify mild and moderate cognitive impairment. A commenter acknowledged the prevalence of behavioral and mental health issues in the U.S. adult population and recommended that, given occupational therapists' role in addressing behavioral and mental health issues, they be included in quality measures.

A commenter agreed that the area of chronic condition and pain management is an important LTCH QRP measurement gap that needed to be filled. The commenter encouraged CMS to select measures that are reliable, feasible, valid, and that are, or could be, endorsed by a CBE. Another commenter expressed support for assessments of pain and its effect on sleep, participation in therapy, and ability to perform activities of daily living.

A few commenters indicated that measurement gaps exist in areas not identified in the RFI. A commenter recommended that measures focusing on care rendered to patients with chronic kidney disease (CKD) be included as part of the LTCH QRP measure set. The commenter urged CMS to consider a suite of measures that addressed kidney care. Among the recommended measures, the commenter identified the Kidney Health Evaluation for Patients with Diabetes (KED) in order to promote screening and monitoring of kidney health; patient reported outcome measures that address care planning and shared-decision making; measures of CKD patients that are on a cardio-renal protective agent; and post-discharge measures of care coordination and medication management.

Some commenters recommended that CMS incorporate measures of health equity in the LTCH QRP. Measures recommended for consideration included the Screening and Referral to Services for Social Needs, and the Screening for Social Drivers of Health. Two commenters further recommended that CMS report quality measures using stratification, such as race, socioeconomic status, dual eligibility status, disability status, sexual orientation and gender identity, to identify disparities in health outcomes. A commenter urged CMS to adopt measures of malnutrition in order to address health equity.

Other measures and measurement concepts suggested by commenters included a measure of patients that are pharmacologically restrained during an acute inpatient stay, and that are subsequently discharged to an LTCH to be titrated off their medications; measures associated with issues related to vents, wounds, nutrition, and dialysis; and an updated version of the NHSN healthcare associated clostridioides difficile infection outcome measure derived from EHR data and microbiologic evidence.

Response: We appreciate the input provided by commenters. While we will not be responding to specific comments submitted in response to this RFI in this final rule, we intend to use this input to inform our future measure development efforts.

6. Health Equity Update

a. Background

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28570 through 28576), we included an RFI entitled ''Overarching Principles for Measuring Equity and Healthcare Quality Disparities Across CMS Quality Programs.'' We define health equity as ''the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.'' [897] We are working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs and models, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our enrollees need to thrive. Our goals outlined in the *CMS Framework for Health Equity 2022–2023* [898] are in line with Executive Order 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.'' [899] The goals included in the CMS Framework for Health Equity serve to further advance health equity, expand coverage, and improve health outcomes for the more than 170 million individuals supported by our programs, and set a foundation and priorities for our work, including: strengthening our infrastructure for assessment, creating synergies across the health care system to drive structural change, and identifying and working to eliminate barriers to CMS-supported benefits, services, and coverage. The CMS Framework for Health Equity outlines the approach CMS will use to promote health equity for enrollees, mitigate health disparities, and prioritize CMS's commitment to expanding the collection, reporting, and analysis of standardized data.[900]

In addition to the CMS Framework for Health Equity, we seek to advance health equity and whole-person care as one of eight goals comprising the CMS National Quality Strategy (NQS).[901] The NQS identifies a wide range of potential quality levers that can support our advancement of equity, including: (1) establishing a standardized approach for patient-reported data and stratification; (2) employing quality and value-based programs to address closing equity gaps; and (3) developing equity-focused data collections, analysis, regulations,

[897] Centers for Medicare and Medicaid Services. Health Equity. *https://www.cms.gov/pillar/health-equity*. October 3, 2022.

[898] Centers for Medicare & Medicaid Services. CMS Framework for Health Equity 2022–2032. *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf*.

[899] The White House. Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. Executive Order 13985, January 20, 2021. *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government*.

[900] Centers for Medicare and Medicaid Services. The Path Forward: Improving Data to Advance Health Equity Solutions. *https://www.cms.gov/files/document/path-forwardhe-data-paper.pdf*. July 11, 2023.

[901] Centers for Medicare & Medicaid Services. What Is the CMS Quality Strategy? *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*.

oversight strategies, and quality improvement initiatives.

A goal of this NQS is to address persistent disparities that underlie our healthcare system. Racial disparities in health, in particular, are estimated to cost the U.S. $93 billion in excess medical costs and $42 billion in lost productivity per year, in addition to economic losses due to premature deaths.[902] At the same time, racial and ethnic diversity has increased in recent years with an increase in the percentage of people who identify as two or more races accounting for most of the change, rising from 2.9 percent to 10.2 percent between 2010 and 2020.[903] Therefore, we need to consider ways to reduce disparities, achieve equity, and support our diverse beneficiary population through the way we measure quality and display the data.

We solicited public comments via the aforementioned RFI on changes that we should consider in order to advance health equity. We refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49317 through 49319) for a summary of the public comments and suggestions we received in response to the health equity RFI. We will take these comments into account as we continue to work to develop policies, quality measures, and measurement strategies on this important topic.

b. Anticipated Future State

We are committed to developing approaches to meaningfully incorporate the advancement of health equity into the LTCH QRP. One option we are considering is including social determinants of health (SDOH) as part of new quality measures.

Social determinants of health are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks. They may have a stronger influence on the population's health and well-being than services delivered by practitioners and healthcare delivery organizations.[904] Measure stratification by CMS is important for better understanding differences in health outcomes from across different patient population groups according to specific demographic and SDOH variables. For example, when ''pediatric measures over the past two decades are stratified by race, ethnicity, and income, they show that outcomes for children in the lowest income households and for Black and Hispanic children have improved faster than outcomes for children in the highest income households or for White children, thus narrowing an important health disparity.'' [905] This analysis and comparison of the SDOH items in the assessment instruments support our desire to understand the benefits of measure stratification. Hospital providers receive such information in their confidential feedback reports (CFRs) and we think this learning opportunity would benefit post-acute care providers. The goals of the CFR are to provide LTCHs with their results so they can compare certain quality measures stratified by dual eligible status and race and ethnicity. The process is meant to increase provider's awareness of their data. We will solicit feedback from LTCHs for future enhancements to the CFRs.

In the proposed rule, we said that we are considering whether health equity measures we have adopted for other settings, such as hospitals, could be adopted in post-acute care settings. We are exploring ways to incorporate SDOH elements into the measure specifications. For example, we could consider a future health equity measure like screening for social needs and interventions using our current SDOH data items of preferred language, interpreter services, health literacy, transportation, and social isolation. With 30 percent to 55 percent of health outcomes attributed to SDOH,[906] a measure capturing and addressing SDOH could encourage LTCHs to identify patients' specific needs and connect them with the community resources necessary to overcome social barriers to their wellness. We could specify a health equity measure using the same SDOH data items that we currently collect as standardized patient assessment data elements under the LTCH. These SDOH data items assess health literacy, social isolation, transportation problems, and preferred language (including need or want of an interpreter). We also see value in aligning SDOH data items according to existing health information technology (IT) vocabulary and codes sets where applicable and appropriate such as those included in the Office of the National Coordinator for Health Information (ONC) United States Core Data for Interoperability (USCDI) [907] across all care settings as we develop future health equity quality measures under our LTCH QRP statutory authority. This would further the NQS to align quality measures across our programs as part of the Universal Foundation.[908]

Although we did not directly solicit feedback to our update, we did receive some public comments, which we summarize later in this section.

Comment: Commenters were overwhelmingly supportive of CMS' efforts to develop ways to measure and mitigate health inequities. Four commenters applauded CMS' continuing efforts to advance health equity and encouraged CMS to continue to develop and adopt measures of social determinants of health (SDOH) into the LTCH QRP. One of these commenters suggested that CMS should ensure any quality measure is feasible and would have an intended impact within the LTCH.

A commenter encouraged stratified reporting of all LTCH QRP quality measures by race, dual eligibility status, disability status, sexual orientation and gender identity, and socioeconomic status to provide visibility to clinicians and LTCHs as to where disparities exist within each measure. Another commenter believed collecting race and ethnicity information and other SDOH would provide LTCHs an opportunity to stratify their own data for patient populations to better plan for needed services; identify members of a target population to whom elements of an intervention would apply; understand potential patterns in access and outcomes for different segments of the patient population; and increase patient and provider understanding.

We also received two comments supporting the adoption of screening or structural measures in the LTCH QRP. Both of these commenters supported the Screening and Referral to Services for Social Needs measure and the Screening for Social Drivers of Health measure,

[902] Turner A. The Business Case for Racial Equity: A Strategy for Growth. April 24, 2018. W.K. Kellogg Foundation and Altaru. *https://altarum.org/RacialEquity2018.*

[903] Agency for Healthcare Research and Quality. 2022 National Healthcare Quality and Disparities Report. Content last reviewed November 2022. *https://www.ahrq.gov/research/findings/nhqrdr/nhqdr22/index.html.*

[904] Agency for Healthcare Research and Quality. 2022 National Healthcare Quality and Disparities Report. November 2022. *https://www.ahrq.gov/research/findings/nhqrdr/nhqdr22/index.html.*

[905] Agency for Healthcare Research and Quality. 2022 National Healthcare Quality and Disparities Report. Content last reviewed November 2022. *https://www.ahrq.gov/research/findings/nhqrdr/nhqdr22/index.html.*

[906] World Health Organization. Social Determinants of Health. *https://www.who.int/westernpacific/healthtopics/social-determinants-of-health.*

[907] United States Core Data for Interoperability (USCDI), *https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi.*

[908] Jacobs DB, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher LA. Aligning Quality Measures across CMS—The Universal Foundation. N Engl J Med. 2023 Mar 2;338:776–779. doi: 10.1056/NEJMp2215539. PMID: 36724323.

noting that both of these align with the CMS Universal Foundation Set for adults. One of these commenters also supported CMS' structural measures. This commenter acknowledged that structural measures are not a complete solution, but believe they play an important role in achieving patient safety and health equity goals, and when combined with public reporting has the potential to focus the commitment of leaders and impact organizational cultures in LTCHs to address existing problems with both explicit and implicit bias.

We also received feedback on other ways to incorporate health equity into the LTCH QRP. A commenter pointed out that nutritional status, and by consequence malnutrition, is often influenced by a variety of SDOH domains and could result in certain populations, such as the elderly, disabled, and the poorest segments of society, having a higher degree of malnutrition. This commenter recommended CMS adopt a diagnosis of malnutrition as a measure to address health equity to ensure appropriate identification and nutritional management of malnourished patients. Another commenter strongly urged CMS to adopt IT standards and consistent guidance across programs for the collection of structured data that addresses the capture, use, and exchange of relevant health data. This commenter noted that SDOH is a data class in USCDI, and referenced the work of the Gravity Project on health equity, SDOH, and other health-related social needs (HRSN) data.[909] Finally, A commenter who noted that the ability to collect and analyze data is crucial to advance health equity also cautioned that there may be significant operational challenges for entities either not using electronic health records or not using them with standardized data entry.

Response: We thank all the commenters for responding to our update on this important CMS priority. We will continue to prioritize our efforts to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all people served by our program.

7. Form, Manner, and Timing of Data Submission Under the LTCH QRP

a. Background

We refer readers to the regulatory text at 42 CFR 412.560(b) for information regarding the current policies for reporting LTCH QRP data.

b. Reporting Schedule for the LCDS Assessment Data for the Discharge Function Score Measure Beginning With the FY 2025 LTCH QRP

As discussed in section IX.E.4.b. of the preamble of this final rule, we proposed to adopt the DC Function measure beginning with the FY 2025 LTCH QRP. We proposed that LTCHs would be required to report these LCDS assessment data beginning with patients admitted or discharged on October 1, 2023 for purposes of the FY 2025 LTCH QRP. Starting in CY 2024, LTCHs would be required to submit data for the entire calendar year beginning with the FY 2026 LTCH QRP. Because the DC Function quality measure is calculated based on data that are currently submitted to the Medicare program, there would be no new burden associated with data collection for this measure.

We invited public comments on this proposal. We did not receive public comments on this proposed provision, and therefore, we are finalizing as proposed.

c. Reporting Schedule for the LCDS Assessment Data for the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure Beginning With the FY 2026 LTCH QRP

As discussed in section IX.E.4.e. of this final rule, we proposed to adopt the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date quality measure beginning with the FY 2026 LTCH QRP. We proposed that LTCHs would be required to report these LCDS assessment data beginning with patients discharged on October 1, 2024 for purposes of the FY 2026 LTCH QRP. Starting in CY 2025, LTCHs would be required to submit data for the entire calendar year beginning with the FY 2027 LTCH QRP.

We also proposed to add a new item to the LCDS in order for LTCHs to report the proposed measure. A new item would be added to the discharge item sets to collect information on whether a patient is up to date with their COVID–19 vaccine at the time of discharge. A draft of the new item is available in the *COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date* Draft Measure Specifications.[910]

We invited public comments on this proposal. The following is a summary of the comments we received on our proposal to require LTCHS to report a new LCDS assessment data item for the Patient/Resident COVID–19 Vaccine measure beginning with patients discharged on October 1, 2024 and our responses.

Comment: Two commenters provided an alternate recommendation, encouraging CMS to explore other methods of collecting patient COVID–19 vaccine data rather than imposing new reporting requirements on providers. They cited a Washington Post article that found that only around 20 percent of healthcare facilities are ''equipped to report disease cases electronically to state health departments.'' [911] These commenters stated CMS should therefore continue to explore improvements in gathering data through the states rather than imposing these burdensome reporting requirements on providers.

Response: We do not find this article to be applicable to the LTCH QRP, nor do we think this article is relevant to the proposed measure since the proposed Patient/Resident COVID–19 Vaccine measure reports vaccination status, and not a disease case. LTCHs have been successfully reporting disease cases to the NHSN since 2013 and currently report Catheter-Associated Urinary Tract Infection (CAUTI), Central Line-Associated Bloodstream Infection (CLABSI) and Clostridium difficile Infection (CDI) information to NHSN as part of the LTCH QRP. We find assessment-based measures like the Patient/Resident COVID–19 Vaccine measure have several benefits that are not provided by state reported data, such as patient-level data, a variety of reports LTCHs can use to assess performance, as well as public reporting of the data. This measure will be included in LTCH Review and Correct reports as well as QM patient and facility level confidential feedback reports. Additionally, this data will allow for granular analyses of vaccinations, including identification of potential disparities within the LTCH QRP.

After consideration of the public comments we received, we are finalizing our proposal to require LTCHs to report the new LCDS assessment data item for the Patient/Resident COVID–19 Vaccine measure beginning with patients discharged on October 1, 2024 for the FY 2026 LTCH QRP.

[909] The Gravity Project, *https://thegravityproject.net.*

[910] *COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date* Draft Measure Specifications is available at *https://www.cms.gov/files/document/patient-resident-covid-vaccine-draft-specs.pdf.*

[911] End of covid emergency highlights U.S. weakness in tracking outbreaks. The Washington Post. May 9, 2023. *https://www.washingtonpost.com/health/2023/05/09/covid-data-public-health-emergency-ends/.*

d. LTCH QRP Data Completion Thresholds for LCDS Data Items Beginning With the FY 2026 Payment Determination

In the FY 2015 IPPS/LTCH PPS final rule (79 FR 50312 through 50315), we finalized that LTCHs would need to complete 100 percent of the data collected using the LCDS on at least 80 percent of the LCDS assessments they submit through the CMS-designated submission system in order to be considered in compliance with the LTCH QRP reporting requirements for the applicable program year. We established this data completion threshold in order to give LTCHs time to become familiar with quality reporting, and that their experience and understanding with respect to reporting quality data using a standardized data collection instrument, and thus their compliance, would increase over time. We also noted at that time our intent to raise the proposed 80 percent threshold in subsequent program years.[912]

We proposed that, beginning with the FY 2026 LTCH QRP, LTCHs would be required to report 100 percent of the required quality measures data and standardized patient assessment data collected using the LCDS on at least 90 percent of the assessments they submit through the CMS-designated submission system.

Complete data are needed to help ensure the validity and reliability of quality data items, including risk-adjustment models. The proposed threshold of 90 percent is based on the need for substantially complete records, which allows appropriate analysis of quality measure data for the purposes of updating quality measure specifications as they undergo yearly and triennial measure maintenance reviews with the CBE. CMS wants to ensure complete quality data from LTCHs, which will ultimately be reported to the public, allowing our beneficiaries to gain a more complete understanding of LTCH performance related to these quality metrics, and helping them to make informed healthcare choices. Finally, the proposal would contribute to further alignment of data completion thresholds across the PAC settings.

We believe LTCHs should be able to meet the proposed requirement for the LTCH QRP because our data shows that LTCHs are already in compliance with, or exceeding, the proposed threshold. The complete list of items required under the LTCH QRP is updated annually and posted on the LTCH QRP Measures Information page.[913]

We proposed that LTCHs would be required to comply with the proposed new completion threshold beginning with the FY 2026 LTCH QRP LTCH QRP. Starting in CY 2024, LTCHs would be required to report 100 percent of the required quality measures data and standardized patient assessment data collected using the LCDS on at least 90 percent of all assessments submitted January 1 through December 31 for that calendar year's payment determination. We also proposed to update § 412.560(f)(1) of our regulations to reflect this new policy (see the regulation text in this final rule).

We invited public comment on the proposed schedule for the increase of LTCH QRP data completion thresholds for the LCDS Data Items beginning with the FY 2026 LTCH QRP. The following is a summary of the comments we received and our responses.

Comment: A commenter supported our proposal to increase the data compliance threshold for LCDS data items for the LTCH QRP.

Response: We thank the commenter for their support.

Comment: A number of commenters opposed the proposal to increase the data compliance threshold for LCDS data items and referenced CMS' statement in the proposed rule (88 FR 27154) that our data shows LTCHs are already in compliance with, or exceeding, the proposed threshold. They stated the existing 80 percent data completion threshold is a sufficient incentive for ensuring that CMS obtains the quality data it needs and the proposed higher threshold is unlikely to significantly increase the rate of complete LCDS assessments submitted by LTCHs, since many are already satisfying the 90 percent compliance threshold.

Three of these commenters suggested that the increased threshold would put unnecessary pressure on those who were achieving the minimum 80 percent threshold and potentially negatively affect the accuracy of the data. These commenters stated that increasing the data completion threshold from 80 percent to 90 percent would disadvantage LTCHs that care for the most vulnerable, highly complex patients while not providing any additional incentive for others to report better data.

Response: We acknowledge the commenters concerns but we still think increasing the threshold will result in a greater number of complete LCDS assessments submitted by LTCHs. While we acknowledge that patients in LTCHs can be complex and acutely ill, it is for those reasons that collection of more complete data is important. The LCDS is composed of data items designed to inform quality measure calculations, including risk-adjustment calculations. Increasing the data completion threshold will further inform our quality work at CMS, allowing for the continued improvement in quality of care. Additionally, having more complete information will ensure we recognize the acuity and complexity of these patients for LTCH measures' risk adjustment, while also allowing our beneficiaries to gain a more complete understanding of LTCH performance related to LTCH QRP measures, and helping them to make informed healthcare choices.

Comment: Several commenters opposed the increase in data completion threshold stating that the buffer is necessary in order to accommodate those instances in which it is not possible to complete the assessment for clinical reasons, such as when patients are discharged or transferred to an acute care hospital under emergency circumstances. They believe that in these cases, it would be inappropriate to stop the emergency discharge or transfer process to undertake, for example, a skin assessment of the patient. They believe that for facilities who serve larger proportions of complex and/or acutely ill patients, these cases are more frequent and increasing the threshold to 90 percent would put these facilities that have otherwise been in compliance with the reporting requirements at a serious disadvantage. A commenter noted that they are concerned CMS will use the higher compliance threshold to impose the 2 percent LTCH QRP payment penalty on more LTCH providers for unplanned discharges. They referenced the LCDS Manual V5.0 that states CMS is are ''aware that there are certain circumstances in which LTCHs may not be able to complete every item on the LCDS assessment.''

Two of these commenters suggested that CMS should not adopt the 90 percent data completion threshold until they also adopted an exclusion for unplanned discharges and hospital readmissions within 30 days of admission from the LTCH QRP data compliance calculation. They believe this exclusion is necessary because there are a significant number of unplanned or emergent discharges

[912] 79 FR 50312 through 50313.

[913] The LTCH QRP Measures Information page is available at *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/ltch-quality-reporting/ltch-quality-reporting-measures-information.*

where it is impossible to fully complete all LCDS data items. Another commenter suggested removing the skin assessment from the unplanned discharge LCDS item set.

Response: We believe LTCHs consider patient care of paramount importance and should use clinical judgement when patients are discharged or transferred to an acute care hospital under emergency circumstances. The LCDS Manual V5.0 provides guidance on how to code LCDS items on discharge, and we encourage LTCHs to use the guidance as well as submit comments to the LTCH QRP Help Desk as needed. We also acknowledge the statement the commenters reference in the LCDS Manual V5.0 Chapter 2, and note that section of the manual goes on to say that we expect dash use to be a rare occurrence.[914]

We have considered emergent discharges as one reason that LTCHs may not meet data completion thresholds approaching 90 percent, but believe that LTCHs should be able to meet the proposed threshold of 90 percent and can confirm that the majority of LTCHs are meeting this threshold presently. Additionally, there is an LCDS item set specifically for unplanned discharges that contains a reduced set of data elements. The LCDS Version 5.0, Unplanned Discharge item set is 33 percent shorter than the LCDS Version 5.0, Planned Discharge item set, and has approximately 33 percent fewer items to complete. For each of the items on the Unplanned Discharge item set, the LCDS guidance manual provides instructions for how to code the items if the item does not apply to the patient or the patient is unable to respond. Selecting these responses when applicable counts toward the data completion threshold. Additionally, the assessments of the special services, treatments, and interventions with multiple responses are formatted as a ''check all that apply'' format. Therefore, when treatments do not apply, the assessor need only check one row for ''None of the Above,'' and the data completion requirement is met.

Regarding the commenters' suggestion that we exclude unplanned discharges or discharges from the LTCH within 30 days of admission from the calculation of an LTCH's data completion, we believe collecting quality data using the LCDS on these patients is just as important as data we collect on patients who have a planned discharge.

[914] CMS LCDS Manual Version 5.0—Effective October 1, 2022. Chapter 2, Page 2–2. *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/ltch-quality-reporting/ltch-care-data-set-and-ltch-qrp-manual.*

Comment: Several commenters expressed concern that if CMS were to raise the data completion threshold, it would be used to impose the 2 percent payment penalty on more LTCH providers for technical issues or system problems that LTCHs frequently experience with CDC's National Healthcare Safety Network (NHSN) and CMS's internet Quality Improvement and Evaluation System (iQIES) data submission systems. They believe that until CMS adopts safeguards against these technical non-compliance and system errors, it should not increase the LCDS data completion threshold because it would punish more providers that make unintentional technical errors, experience challenges outside of their control, or are attempting to report data timely in good faith.

Three of these commenters also request that CMS reconsider its position that only categorically and absolutely perfect quality data reporting is sufficient, without any leeway to correct clerical or administrative errors, or any grace period for inadvertently omitted data. They request CMS adopt a short grace period after each reporting deadline to allow LTCHs to confer with CMS, NHSN and iQIES staff to determine the specific data that was not properly submitted or received by CMS, and resolve the issue in a productive and collaborative way before the LTCH is penalized. Such a grace period would achieve the agency's goal of increased compliance and data completion, and reduce unnecessary payment penalties on well-intentioned providers. They also noted concerns with NHSN data submission.

Response: Regarding the commenters' concerns about the CDC's NHSN, our proposal was specific to the data completion threshold for assessment-based data and therefore, we will not be responding to the comments about the NHSN.

We acknowledge that there are occasional technical issues with the iQIES data submission system. However, in CY 2022, all of the known issues posted on the iQIES website [915] were corrected with ample time remaining in the data submission window for LTCHs to submit data. In the FY 2016 IPPS/LTCH final rule (80 FR 49751), we finalized data submission and correction timelines for LTCH QRP data. LTCHs have 4.5 months (approximately 135 days) from the end of a calendar year quarter to submit, review, and correct their quality data for that CY quarter. This timeline aligns with other quality reporting programs' data submission and correction deadlines and meets the goal of providing a 'grace period' where LTCHs and CMS can resolve any issues.

We also want to remind providers that there are several reports available to providers to monitor their compliance with the QRP reporting requirements during the year. These reports are available within iQIES to providers, including the LTCH Final Validation Report (FVR) and the Provider Threshold Report (PTR). The LTCH FVR is automatically generated in iQIES within 24 hours of the submission of a file and placed in the provider's My Reports folder. The FVR provides detailed information about the status of submission files, including warnings and fatal errors encountered. The PTR allows providers to monitor their compliance status regarding the required data submission for the LTCH QRP measures for the current Annual Payment Update (APU). It is a user requested and on-demand report, meaning that it can be pulled anytime by the LTCH. LTCHs can sign up to receive informational messages if you are not meeting the APU threshold. These are sent out on a quarterly basis ahead of each submission deadline.[916] The iQIES Help Desk is also available to answer any questions related to data submission.[917]

Finally, if LTCHs believe they have received the QRP penalty unfairly, they can choose to use the LTCH QRP Reconsideration and Exception and Extension process. LTCHs may file for reconsideration if they believe the finding of non-compliance is an error, or they have evidence of the impact of extraordinary circumstances that prevented timely submission of data. LTCHs dissatisfied with the reconsideration ruling may file a claim under 42 CFR part 405, subpart R (a Provider Reimbursement Review Board [PRRB] appeal).[918] Details are available on the PRRB Review Instructions web page. Alternatively, LTCHs can request an exception or extension from the program's reporting requirements in the event they were unable to submit quality data due to extraordinary circumstances beyond their control, as

[915] Internet Quality Improvement and Evaluation System, iQIES Known Issues. *https://iqies.cms.gov/known-issues.*

[916] If you need to add or change the email addresses to which these messages are sent, please email *QRPHelp@swingtech.com* and be sure to include your facility name and CCN along with any requested email updated.

[917] iQIES Help Desk at *iqies@cms.hhs.gov.*

[918] PRRB Instructions. Available at: *https://www.cms.gov/Regulations-and-Guidance/Review-Boards/PRRBReview/PRRB-Instructions.*

long as they submit the request within 90 days of the event.

Comment: Two commenters believed that the statutory language Congress passed as part of the Patient Protection and Affordable Care Act (ACA) gives CMS the discretion to take a more flexible approach to the administration of the LTCH QRP. They point to paragraph (5) of the LTCH PPS statute at 42 U.S.C. 1395ww(m) that directs CMS to apply a 2 percent payment penalty when the LTCH does not submit data on quality measures in the form and manner required by CMS. However, they suggested that CMS' interpretation of the statute is too strict since an LTCH must have essentially perfect compliance with the form, manner, and timing of its LTCH QRP data submissions to avoid the 2 percent payment penalty, and they believe there is no basis for this strict application.

Response: We strive to have a program that enables the submission of complete measure data which informs not only the provider but the public on the care received during an LTCH stay. The goal is always to have 100 percent of the quality data submission, rather than an expectation that LTCHs will meet the minimum threshold of the compliance required. However, we understand that at times data cannot be gathered or entered perfectly. We have accounted for this in a variety of ways through outreach, reports, our exception and extension process, as well as the ability to use the 'dash' within the assessment itself. We see this increase in the compliance threshold as moving the goal post to incentivize higher quality of care, rather than a punitive action. Currently, the threshold is set at 80 percent, and we proposed a 90 percent data submission threshold, which still allows a 10 percent buffer for LCDS assessments that fail to report 100 percent of the data required.

We do not have the same interpretation of the statute. Our interpretation is based on the Affordable Care Act enacted by the 111th Congress, which stipulated that the Secretary of HHS set forth administration requirements for LTCH QRP. Specifically, section 1886(m)(5)(C) of the Act requires that, for the FY 2014 payment determination and subsequent years, each LTCH submit data on quality measures specified by the Secretary in a form and manner, and at a time, specified by the Secretary. In the FY 2015 IPPS/LTCH PPS final rule (79 FR 28273 through 28275), we adopted specific LTCH QRP thresholds for completeness of LTCH quality data beginning with data affecting the FY 2016 payment determination and subsequent years, and these are codified at § 412.560(f). We want to reiterate that CMS does not use the data completion thresholds as a punitive tool but rather a way to benchmark the quality of care using quality measures. We must adhere to the standards previously enacted through notice and comment rulemaking, and currently the standard is that LTCH's must achieve at least 80 percent for completion of measures data and standardized patient assessment data collected using the LCDS submitted through the CMS designated data submission system.

Comment: Several commenters opposed the proposal to increase the LTCH data completion thresholds for LCDS data items due to the burden associated with the increased number of items on the LCDS V5.0. Two of these commenters also related the burden to the ongoing workforce challenges, while two others related it to the complexity of their patients or the number of unplanned discharges they experience, both of which they stated are out of their control. Four of these commenters stated that before implementing any changes, CMS should do four things: (1) assess the actual burden of completing the LCDS; (2) gain an understanding of the data elements and factors driving below 90 percent response rates (for example, unplanned discharge assessments); (3) assess the quality of the information it has already collected; and (4) document how existing information is being used to improve patient outcomes.

Response: We have strived to balance the scope and level of detail of the data elements against the potential burden placed on LTCHs. We have provided multiple training resources and opportunities for LTCHs to take advantage of in order to become more familiar and proficient with completing the LCDS. These continue to be available to LTCHs on the LTCH QRP Training web page so LTCHs can use them with new staff.[919] While we acknowledge the impacts of the ongoing workforce challenges, these challenges also make it especially important now to monitor quality of care.[920] We must maintain commitment to the quality of care for all patients, and we continue to believe that the collection of the standardized patient assessment data elements and other data elements on the LCDS will contribute to this effort. That includes staying committed to achieving health equity by improving data collection to better measure and analyze disparities across programs and policies[921] and improving the quality of care in LTCHs through a reduction in preventable adverse events, such as emergent and unplanned discharges.

In response to the commenters' four recommendations CMS should undertake before raising the threshold, we address each of those next. First, we do assess the burden of completing the LCDS. Prior to adding any new data element to the LCDS, we evaluate the need for the information collection and its usefulness to the LTCH QRP, as well as the quality, utility, and clarity of the information to be collected. We employ a transparent process to seek input from interested parties and national experts and engage in a process that allows for pre-rulemaking input on proposed data elements and consider all recommendations to minimize the information collection burden on LTCHs. The data elements are proposed in formal notice and comment rulemaking, so there is transparency for LTCHs in evaluating the proposal and the estimate of burden that accompanies it. Each time CMS has proposed adding a new item or items, we have followed this process.[922]

In response to the commenters' recommendation that CMS gain an understanding of the specific data elements and factors that contribute to LTCHs failing to achieve the data completion threshold, we do routinely monitor the LTCH data to identify performance gaps and trends. At the end of each reporting period, CMS reviews the data submitted by LTCHs to understand which item(s) may have contributed to a provider(s) lower compliance threshold. We use this information to build our education and

[919] *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/ltch-quality-reporting/ltch-quality-reporting-training.*

[920] *https://psnet.ahrq.gov/primer/nursing-and-patient-safety.*

[921] Centers for Medicare & Medicaid Services. CMS Quality Strategy. 2016. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/CMS-Quality-Strategy.pdf.* Report to Congress: Improving Medicare Post-Acute Care Transformation (IMPACT) Act of 2014 Strategic Plan for Accessing Race and Ethnicity Data. January 5, 2017. Available at: *https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/Research-Reports-2017-Report-to-Congress-IMPACT-ACT-of-2014.pdf.* Rural Health Research Gateway. Rural Communities: Age, Income, and Health Status. Rural Health Research Recap. November 2018. *https://www.minorityhealth.hhs.gov/assets/PDF/Update_HHS_Disparities_Dept-FY2020.pdf. www.cdc.gov/mmwr/volumes/70/wr/mm7005a1.htm.* Poteat TC, Reisner SL, Miller M, Wirtz AL. COVID–19 Vulnerability of Transgender Women With and Without HIV Infection in the Eastern and Southern U.S. Preprint. *medRxiv.* 2020;2020.07.21.20159327. Published 2020 Jul 24. doi:10.1101/2020.07.21.20159327.

[922] FY 2013, FY 2014, FY 2015, FY 2016, FY 2017, FY 2018, FY 2020.

outreach programs. In response to the recommendations that we assess the quality of the information we have collected and document how existing information is being used to improve patient outcomes, we already undertake these activities. For example, we assess the quality of the information we collect each quarter before we publicly report the data on Care Compare. We have an obligation to beneficiaries to ensure complete and accurate LTCH QRP measure data, which allows our beneficiaries to gain a more complete understanding of LTCH performance, helping them to make informed healthcare choices. We also routinely monitor the individual data elements and the quality measures they contribute to, in order to ensure they produce statistically meaningful information that can inform improvements in care processes.

In response to comments received, while still maintaining our goal of moving towards more complete data, we note that as part of this final rule, we are updating the proposed compliance threshold of 90 percent to 85 percent. This iterative approach will incentivize LTCHs to strive for more complete data submission at the same time they meet the compliance threshold of 85 percent. Consequently, LTCHs will be required to collect and report LCDS assessment data on at least 85 percent of assessments beginning with FY 2026. CMS will closely monitor LTCH's performance at this threshold. As we stated in previous rules [923] it was always our intent to raise the 80 percent threshold, and it is still our intent to raise this threshold in order to further align data completion thresholds across the PAC settings. Such revisions would be proposed through the notice and comment rulemaking process.

Comment: Three commenters suggested that if CMS finalizes the proposed increase to the LCDS data completion threshold it will not improve the data available to CMS, but it would lead to more LTCHs receiving the 2 percent payment penalty even when reporting data timely in good faith. However, they request that if CMS does increase the LCDS data completion threshold to 90 percent, CMS should also set a uniform 90 percent threshold for the LTCH QRP by decreasing the NHSN compliance threshold from 100 percent to 90 percent. They believe the current 100 percent threshold for NHSN quality measures has a clear history of being used in a punitive way that frequently results in consequences for LTCHs that they believe are impacted by NHSN system issues or minor clerical errors LTCHs make.

Response: Increasing the LCDS data completion threshold will improve the data available to CMS and help ensure the validity and reliability of quality data items, including risk-adjustment models. As we stated in the FY 2024 IPPS/LTCH proposed rule (88 FR 27154), the increase in threshold percent is based on the need for substantially complete records and would contribute to further alignment of the data completion thresholds across the PAC settings. Regarding the commenters' suggestion that CMS should lower the NHSN compliance threshold from 100 percent to 90 percent, we did not propose to modify the NSHN threshold and therefore we will not be responding to the comment.

Comment: Two commenters believe it is imperative that CMS address the calculation method of the LCDS data completion percentage. They do not believe CMS should treat a patient assessment with a single item omitted the same way a patient assessment missing 95 percent of the items is treated. As a result, they disagree that the proposed increase in the threshold from 80 percent to 90 percent ensures a significant increase in the patient assessment data CMS receives, but instead would result in 2 percent payment penalties to well-intentioned LTCHs that submit nearly flawless patient assessment.

Response: The LCDS data completion threshold was adopted in the FY 2015 IPPS/LTCH final rule (79 FR 50312–50313), and was based on the need for ''complete'' quality data, and therefore partial data submission cannot be considered to meet the quality standards. An LCDS is ''complete'' when the required data elements have actual patient data reported, as opposed to a non-informative response, such as a dash (-), that indicates the LTCH was unable to provide patient data. ''Complete'' LCDS data is needed to create complete records, which allows for appropriate analysis of quality measure data for the purposes of updating quality measure specifications as they undergo yearly and triennial measure maintenance reviews with the CBE. In addition, complete data is needed to understand the validity and reliability of quality data items, including risk-adjustment models. Finally, we want to ensure complete quality data from LTCHs, which will ultimately be reported to the public.

Comment: A commenter is especially concerned with the proposed increase in the data completion threshold because of the required Standardized Patient Assessment Data Elements (SPADEs) that they believe are neither used for quality reporting purposes nor proposed for use in any quality measure for the LTCH QRP. They state that CMS has not provided any additional information related to the intended use of many of the data elements other than the intent to levy payment penalties should the information not be collected. In addition, limited testing was conducted on the feasibility of collecting the new SPADEs and consideration was not given to whether these new data elements would differentiate patient characteristics or provider performance.

Response: The standardized patient assessment data elements adopted for the LTCH QRP underwent extensive testing over several years. The Improving Medicare Post-Acute Care Transformation Act of 2014 (the IMPACT Act) required the reporting of standardized patient assessment data with regard to quality measures and standardized patient assessment data elements. Development of the candidate standardized patient assessment data items began in 2015 and there were multiple opportunities for input and comment by interested parties through technical expert panels, listening sessions, townhalls, and requests for information in formal notice and comment rulemaking. We encourage the commenter to go to the IMPACT Act web page where these materials are available for review.[924]

Comment: A commenter shared feedback on LCDS Version 5.0 (effective October 1, 2022) and the challenges that were created with the most recent data collection and submission requirements.

Response: Because we consider these public comments to be outside the scope of the proposed rule, we are not addressing them in this final rule.

After consideration of the public comments we received, we are finalizing our proposal with modification to require LTCHs to report 100 percent of the required quality measures data and standardized patient assessment data collected using the LCDS on at least 85 percent of all assessments submitted beginning with the FY 2026 payment determination and subsequent years.

[923] 79 FR 50312 through 50313.

[924] IMPACT Act of 2014 Data Standardization & Cross Setting Measures. *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/post-acute-care-quality-initiatives/impact-act-of-2014/impact-act-of-2014-data-standardization-and-cross-setting-measures.*

9. Policies Regarding Public Display of Measure Data for the LTCH QRP

a. Background

Section 1886(m)(5)(E) of the Act requires the Secretary to establish procedures for making the LTCH QRP data available to the public after ensuring that LTCHs have the opportunity to review their data prior to public display.

b. Public Reporting of the Transfer of Health Information to the Patient Post-Acute Care and Transfer of Health Information to the Provider Post-Acute Care Measures Beginning with the FY 2025 LTCH QRP

We proposed to begin publicly displaying data for the measures: (1) Transfer of Health (TOH) Information to the Provider—Post-Acute Care (PAC) Measure (TOH-Provider) and (2) TOH Information to the Patient—PAC Measure (TOH-Patient) beginning with the September 2024 Care Compare refresh or as soon as technically feasible. We adopted these measures in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42525 through 42535). In response to the COVID–19 PHE, we released an interim final rule (85 FR 27595 through 27597) which delayed the compliance date for the collection and reporting of the TOH-Provider and TOH-Patient measures to October 1 of the year that is at least one full FY after the end of the COVID–19 PHE. Subsequently, in the CY 2022 Home Health PPS Rate Update final rule (86 FR 62386 through 62390), the compliance date for the collection and reporting of the TOH-Provider and TOH-Patient measures was revised to October 1, 2022. Data collection for these two assessment-based measures began with patients admitted and discharged on or after October 1, 2022.

We proposed to publicly display data for these two assessment-based measures based on four rolling quarters, initially using discharges from January 1, 2023 through December 31, 2023 (Quarter 1 2023 through Quarter 4 2023), and to begin publicly reporting these measures with the September 2024 refresh of Care Compare, or as soon as technically feasible. To ensure the statistical reliability of the data, we proposed that we would not publicly report an LTCH's performance on a measure if the LTCH had fewer than 20 eligible cases in any four consecutive rolling quarters for that measure. LTCHs that have fewer than 20 eligible cases would be distinguished with a footnote that states: ''The number of cases/patient stays is too small to publicly report.''

We invited public comment on our proposal for the public display of the (1) Transfer of Health (TOH) Information to the Provider—Post-Acute Care (PAC) Measure (TOH-Provider) and (2) Transfer of Health (TOH) Information to the Patient—Post-Acute Care (PAC) Measure (TOH-Patient) assessment-based measures. The following is a summary of the comments we received and our responses.

Comment: We received overwhelming support for the proposal to publicly report the Transfer of Health Information to the Provider-PAC Measure and the Transfer of Health Information to the Patient-PAC Measure beginning with the September 2024 Care Compare refresh or as soon as possible.

Response: We appreciate these commenters' support for the proposed public reporting of these measures.

After consideration of the public comments we received, we are finalizing our proposal to begin publicly displaying data for the measures: (1) Transfer of Health (TOH) Information to the Provider—Post-Acute Care (PAC) Measure (TOH-Provider); and (2) TOH Information to the Patient—PAC Measure (TOH-Patient) beginning with the September 2024 Care Compare refresh or as soon as technically feasible.

c. Public Reporting of the Discharge Function Score Measure Beginning With the FY 2025 LTCH QRP

We proposed to begin publicly displaying data for the DC Function measure beginning with the September 2024 refresh of Care Compare, or as soon as technically feasible, using data collected from January 1, 2023, through December 31, 2023 (Quarter 1 2023 through Quarter 4 2023). We proposed that an LTCH's DC Function score would be displayed based on four quarters of data. Provider preview reports would be distributed in June 2024, or as soon as technically feasible. Thereafter, an LTCH's DC Function score would be publicly displayed based on four quarters of data and updated quarterly. To ensure the statistical reliability of the data, we proposed that we would not publicly report an LTCH's performance on the measure if the LTCH had fewer than 20 eligible cases in any quarter. LTCHs that have fewer than 20 eligible cases would be distinguished with a footnote that states: ''The number of cases/patient stays is too small to publicly report.''

We invited public comment on the proposal for the public display of the Discharge Function Score measure beginning with the September 2024 refresh of Care Compare, or as soon as technically feasible. The following is a summary of the comments we received and our responses.

Comment: A commenter provided support to publicly report the DC Function measure.

Response: We thank the commenter for their support to publicly report the DC Function measure.

After consideration of the public comments we received, we are finalizing our proposal to begin publicly displaying data for the DC Function measure beginning with the September 2024 Care Compare refresh or as soon as technically feasible.

d. Public Reporting of the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure Beginning With the FY 2026 LTCH QRP

We proposed to begin publicly displaying data for the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure beginning with the September 2025 refresh of Care Compare or as soon as technically feasible using data collected for Q4 2024 (October 1, 2024, through December 31, 2024). We proposed that an LTCH's Patient/Resident level COVID–19 Vaccine percent of patients who are up to date would be displayed based on one quarter of data. Provider preview reports would be distributed in June 2025 for data collected in Q4 2024, or as soon as technically feasible. Thereafter, the percent of LTCH patients who are up to date with their COVID–19 vaccinations would be publicly displayed based on one quarter of data and updated quarterly. To ensure the statistical reliability of the data, we proposed that we would not publicly report an LTCH's performance on the measure if the LTCH had fewer than 20 eligible cases in any quarter. LTCHs that have fewer than 20 eligible cases would be distinguished with a footnote that states: ''The number of cases/patient stays is too small to publicly report.''

We invited public comment on the proposal for the public display of the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure beginning with the September 2025 refresh of Care Compare, or as soon as technically feasible. The following is a summary of the comments we received and our responses.

Comment: Three commenters supported public reporting of this measure. One of the commenters noted their support stating this would help patients, caregivers and loved ones make informed decisions about LTCH choices that might best suit their individual health care needs, especially

if they are greater risk of serious complications from COVID–19.

Response: We thank the commenters for their support and agree this measure will provide potential patients with important information regarding COVID–19 vaccination rates as part of their process of identifying providers they would want to seek care from, in addition to other measures available on Care Compare.

After consideration of the public comments we received, we are finalizing our proposal to begin publicly displaying data for the Patient/Resident COVID–19 measure beginning with the September 2025 Care Compare refresh or as soon as technically feasible.

F. Changes to the Medicare Promoting Interoperability Program

1. Statutory Authority for the Medicare Promoting Interoperability Program for Eligible Hospitals and Critical Access Hospitals (CAHs)

The Health Information Technology for Economic and Clinical Health Act (HITECH Act) (Title IV of Division B of the American Recovery and Reinvestment Act of 2009 (ARRA), together with Title XIII of Division A of the ARRA) authorized incentive payments under Medicare and Medicaid, as well as downward payment adjustments under Medicare, for the adoption and meaningful use of certified electronic health record technology (CEHRT). Incentive payments under Medicare were available to eligible hospitals and critical access hospitals (CAHs) for certain payment years (as authorized under sections 1886(n) and 1814(l)(3) of the Act, respectively) if they successfully demonstrated the meaningful use of CEHRT for an electronic health record (EHR) reporting period. In accordance with the timeframe set forth in the statute, these incentive payments under Medicare are no longer available. Sections 1886(b)(3)(B)(ix) and 1814(l)(4) of the Act authorize downward payment adjustments under Medicare, beginning with FY 2015 (and beginning with FY 2022 for subsection (d) Puerto Rico hospitals), for eligible hospitals and CAHs that do not successfully demonstrate meaningful use of CEHRT for an EHR reporting period for a payment adjustment year. For more information, we refer readers to the regulations at 42 CFR 412.64(d)(3) and (4) and 413.70(a)(5) and (6) and part 495.

2. EHR Reporting Periods

a. EHR Reporting Period in CY 2025 for Eligible Hospitals and CAHs

Under the definition of EHR reporting period for a payment adjustment year at 42 CFR 495.4, for eligible hospitals and CAHs that are new or returning participants in the Medicare Promoting Interoperability Program, the EHR reporting period in calendar year (CY) 2024 is a minimum of any continuous 180-day period within CY 2024, as finalized in the FY 2022 Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System (IPPS/LTCH PPS) final rule (86 FR 45460 through 45462). We believe that maintaining a 180-day EHR reporting period for an additional year will provide consistency with the prior years' EHR reporting period and afford eligible hospitals and CAHs the flexibility they may need to work with their chosen vendors on continuing to develop and update their CEHRT, as required. For eligible hospitals and CAHs that are new or returning participants in the Medicare Promoting Interoperability Program, we proposed in the FY 2024 IPPS/LTCH PPS proposed rule that the EHR reporting period in CY 2025 would continue to be a minimum of any continuous 180-day period within CY 2025 (88 FR 27155 through 27156). We described in the proposed rule that a 180-day EHR reporting period would be the minimum length, and eligible hospitals and CAHs would be encouraged to use longer periods, up to and including the full CY 2025. We proposed corresponding revisions to the definition of EHR reporting period for a payment adjustment year at § 495.4 (88 FR 27155 through 27156).

We invited public comment on this proposal.

Comment: Many commenters supported our proposal to maintain a 180-day EHR reporting period in CY 2025 for eligible hospitals and CAHs. One commenter specifically supported the proposal because they believed that vendors have consistently proven they are able to release software updates that can accommodate this length of a reporting period. Another commenter supported the proposal, while recommending CMS provide flexibility for hospitals that may switch EHRs within an EHR reporting period, and those that have an EHR vendor acquired or divested. A few commenters supported the proposal because they believed that it would maintain stability, flexibility, and consistency. One such commenter believed that program consistency has led to nearly universal EHR adoption among non-Federal acute care hospitals and use by most office-based physicians. Another such commenter believed that the 180-day EHR reporting period would allow hospitals to adequately account for system upgrades and other pertinent changes to their EHR technology, ensuring accurate and comprehensive reporting.

Response: We thank the commenters for their support. We agree that maintaining a minimum 180-day EHR reporting period for an additional year will provide consistency with the prior years' EHR reporting period and afford eligible hospitals and CAHs the flexibility they may need to work with their chosen vendors on continuing to develop and update their CEHRT, as required. For commenters asking for additional flexibility to account for a change in EHR vendor, we do not specify which 180-days must be chosen, only that the chosen 180-days are continuous. We recommend eligible hospitals and CAHs work with their chosen vendor on the timing of their system updates in advance.

Comment: Many commenters did not support our proposal to maintain a 180-day EHR reporting period in CY 2025 for eligible hospitals and CAHs. A few commenters believed that 180-days of continued reporting would be difficult to achieve and would place more burden on providers. One such commenter expressed that annual releases for the Medicare Promoting Interoperability Program measure specifications are usually made available during the second quarter of the calendar year from EHR developers. This commenter believed that the program measures require significant time and resources to configure, validate, optimize, and implement in the EHR. This commenter further believed that a period of one year or less when a new measure is released to mandatory reporting would not be adequate for the necessary preparations to report in a 180-day reporting period. Several commenters wished to maintain a 90-day EHR reporting period for CY 2024 onwards. One of these commenters believed that a 90-day EHR reporting period would give providers flexibility to develop their reporting infrastructure and make necessary updates to their EHR systems to comply with the Merit-based Incentive Payment System (MIPS) Promoting Interoperability performance category requirements. This commenter also believed that a shorter reporting period would give hospitals time to adjust to these changes and make system changes necessitated by revised

measures or vendor changes and upgrades. A few commenters expressed a preference for a 90-day reporting period because they believed that EHRs are continually undergoing software upgrades, system downtime, expansions to other sites within a system, and a variety of other improvement and maintenance activities. A commenter believed that changing the reporting period to a continuous 180-day EHR reporting period would not produce a more comprehensive score card of reliable data.

Response: We thank the commenters for their feedback. We would like to remind commenters that under the definition of EHR reporting period for a payment adjustment year at § 495.4, for eligible hospitals and CAHs that are new or returning participants in the Medicare Promoting Interoperability Program, the EHR reporting period in calendar year (CY) 2024 is already a minimum of any continuous 180-day period within CY 2024, as previously finalized in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45460 through 45462). The proposal in the FY 2024 IPPS/LTCH PPS proposed rule was for a continuation of our existing 180-day EHR reporting period established for CY 2025. We disagree with commenters who believe that 180-days of continued reporting would be difficult to achieve and would place additional burden on health care providers. We believe that after finalizing the 180-day EHR reporting period for CY 2024 in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45460 through 45462), and proposing to continue with the 180-day EHR reporting period in CY 2025 (88 FR 27155 through 27156), eligible hospitals and CAHs will have had more than three years of advance planning with their vendors to build upon and utilize investments already made within their infrastructure to meet site-specific needs for implementation. We also note that the EHR reporting period has remained at 90-days since its adoption in 2011, where at that time, we indicated that we would continue to increase the number of days in an EHR reporting period (75 FR 44320). We believe that maintaining an EHR reporting period of 180 days for CY 2025 will not impact eligible hospitals' and CAHs' efforts to update, implement, and test the EHR systems to maintain effective use of CEHRT in furtherance of meaningful use. Reporting on additional data will provide eligible hospitals and CAHs the opportunity to continuously monitor their performance and identify areas that may require investigation and corrective action. Maintaining the 180-day EHR reporting period in CY 2025 is important for the continued improvement of interoperability and health information exchange by producing more comprehensive and reliable data for patients and providers, which are key goals of the Medicare Promoting Interoperability Program. In response to commenters requesting that the Medicare Promoting Interoperability Program maintain alignment with the MIPS Promoting Interoperability performance category, we refer readers to the CY 2024 PFS proposed rule (FR Doc. 2023–14624, publishing in the **Federal Register** on August 7, 2023; available at *https://www.federalregister.gov/public-inspection/2023-14624/medicare-and-medicaid-programs-cy-2024-payment-policies-under-the-physician-fee-schedule-and-other*), where we have proposed a minimum of a continuous 180-day performance period for MIPS eligible clinicians in CY 2024, in order to maintain alignment with the Medicare Promoting Interoperability Program's 180-day EHR reporting period.

Comment: Several commenters did not support our proposal to maintain a 180-day EHR reporting period in CY 2025 for eligible hospitals and CAHs because they believed that vendors and providers need more time and additional resources. Several commenters believed that vendors need additional time to develop and deploy technology, understand CEHRT requirements, capabilities, and functionalities. Further, other commenters believed that eligible hospitals and CAHs need additional time to budget for the adoption and implementation of this requirement, and time to identify and resolve software issues. A few commenters believed that eligible hospitals, CAHs, and other health care organizations needed more time to recover from the financial, workforce, and operational challenges the COVID–19 pandemic placed on them, such as provider burnout, staffing shortages, and other burdens and disruptions. A commenter believed that eligible hospitals and CAHs need more time to return to the traditional reporting and regulatory landscape as they adjust clinical and administrative processes until all PHE flexibilities expire.

Response: We thank commenters for sharing their concerns. We believe that continuing the 180-day EHR reporting period in CY 2025 will not impact eligible hospitals' and CAHs' efforts to update, implement, and test their EHR systems to maintain effective use of CEHRT in furtherance of meaningful use. For commenters concerned with limited flexibility in choosing a 180-day EHR reporting period when considering general updates to health IT systems or transitions between health IT systems, we suggest early planning with vendors on the timing of routine system updates and downtimes to allow for maximum flexibility in choosing their 180-day EHR reporting period. Additionally, we would like to remind commenters that the Medicare Promoting Interoperability Program allows hardship exception applications for extreme and uncontrollable circumstances, including certain vendor issues, as permitted by section 1886(b)(3)(B)(ix)(II) of the Act. Additional information on this process is available at: *https://www.cms.gov/files/document/medicare-pi-program-hardship-exception-fact-sheet-2023-04-06.pdf*. Moreover, we understand there are residual impacts of the COVID–19 public health emergency (PHE) on eligible hospitals and CAHs. We believe that the COVID–19 PHE highlighted areas where we can focus our efforts, to include allowing eligible hospitals and CAHs the opportunity to monitor their performance over a longer EHR reporting period, and to identify areas that may require investigation and corrective action. This is important for the continued improvement of interoperability and health information exchange, which are key goals of the Medicare Promoting Interoperability Program. For additional information on our proposal to increase the EHR reporting period from 90-days to 180-days in CY 2024, we refer readers to the discussion in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45461).

After consideration of the public comments we received, we are finalizing that the EHR reporting period in CY 2025 will be a minimum of any continuous 180-day period within CY 2025. We are also finalizing our proposal to revise the definition of EHR reporting period for a payment adjustment year at § 495.4.

b. Changes to the EHR Reporting Period for a Payment Adjustment Year for Eligible Hospitals

In the definition of EHR reporting period for a payment adjustment year, under paragraphs (2)(vii) and (viii) of § 495.4, we specify that the EHR reporting periods in CYs 2023 and 2024 that apply for purposes of determining whether an eligible hospital may be subject to a downward payment adjustment in a later year, read as follows:

For CY 2023: (A) If an eligible hospital has not successfully demonstrated it is a meaningful EHR

user in a prior year, the EHR reporting period is any continuous 90-day period within CY 2023 and applies for the FY 2024 and 2025 payment adjustment years. For the FY 2024 payment adjustment year, the EHR reporting period must end before, and the eligible hospital must successfully register for and attest to meaningful use no later than October 1, 2023. (B) If in a prior year an eligible hospital has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 90-day period within CY 2023 and applies for the FY 2025 payment adjustment year.

For CY 2024: (A) If an eligible hospital has not successfully demonstrated it is a meaningful EHR user in a prior year, the EHR reporting period is any continuous 180-day period within CY 2024 and applies for the FY 2025 and 2026 payment adjustment years. For the FY 2025 payment adjustment year, the EHR reporting period must end before and the eligible hospital must successfully register for and attest to meaningful use no later than October 1, 2024. (B) If in a prior year an eligible hospital has successfully demonstrated it is a meaningful EHR user, the EHR reporting period is any continuous 180-day period within CY 2024 and applies for the FY 2026 payment adjustment year.

Stated generally, the EHR reporting period occurs 2 years before the payment adjustment year, unless an eligible hospital is demonstrating meaningful use for the first time, in which case the EHR reporting period occurs one year before the payment adjustment year, subject to an October 1 deadline for registration and attestation. Beginning with the EHR reporting period in CY 2025, we proposed to change the rule for eligible hospitals that have not successfully demonstrated they are a meaningful EHR user in a prior year (88 FR 27156 through 27157). We have made technological modifications to the data submission process for the Medicare Promoting Interoperability Program, including the registration and attestation processes. As a result of these modifications, an October 1 deadline is no longer feasible, as the submission period is only open during the 2 months following the close of the CY in which the EHR reporting period occurs (or a later date specified by CMS), annually. Eligible hospitals that have not successfully demonstrated meaningful use in a prior year and seek to attest by October 1 of CY 2023 or CY 2024 should contact the CCSQ help desk for assistance at *QnetSupport@cms.hhs.gov* or 1–866–288–8912 for instructions.

According to the ONC ''National Trends in Hospital and Physician Adoption of Electronic Health Records,'' Health IT Quickstat #61, a majority (96%) of non-Federal acute care hospitals, most of which are eligible hospitals or CAHs, but which include pediatric and specialty cancer hospitals, have adopted CEHRT.[925] We believe that few eligible hospitals or CAHs will be new participants in the Medicare Promoting Interoperability Program, and therefore, few eligible hospitals or CAHs are likely to be affected by this change. In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42591), we removed the October 1, 2019 deadline for eligible hospitals for the FY 2020 payment adjustment year. This policy was finalized in response to public comments that supported CMS eliminating the October 1, 2019 deadline for eligible hospitals that had not successfully demonstrated meaningful EHR use in a prior year. When we removed the October 1 deadline for the FY 2020 payment adjustment year, we did so with public support, and did not experience operational concerns related to its removal, so we believed that this proposal was feasible. Therefore, beginning with the EHR reporting period in CY 2025, we proposed in the FY 2024 IPPS/LTCH PPS proposed rule to no longer differentiate between those eligible hospitals that have successfully demonstrated they are meaningful EHR users in a prior year and those that have not, with regard to the EHR reporting period that applies for purposes of a payment adjustment year (88 FR 27156 through 27157).

We also proposed that for all eligible hospitals (new and returning participants), the EHR reporting period in CY 2025 will apply for purposes of the FY 2027 payment adjustment year (88 FR 27156 through 27157). Eligible hospitals and CAHs will submit data during the 2 months following the close of the CY in which the EHR reporting period occurs, or by a later date specified by CMS. This will mean that for eligible hospitals that have not successfully demonstrated they are meaningful EHR users in a prior year, there will be a 2-year period between the EHR reporting period in CY 2025 and the FY 2027 payment adjustment year, which is the same submission timeframe that eligible hospitals that have previously demonstrated they are meaningful EHR users are currently required to meet. Therefore, beginning with the EHR reporting period in CY 2025, eligible hospitals that have not demonstrated they are meaningful EHR users in a prior year will not have to attest to meaningful use by October 1, 2025. Instead, similar to eligible hospitals that have demonstrated meaningful use, these eligible hospitals would attest during the same submission period that occurs during the 2 months following the close of the CY in which the EHR reporting period occurs, or by a later date specified by CMS, and, if applicable, a payment adjustment will be applied for the FY 2027 payment adjustment year. We proposed corresponding revisions to the definition of EHR reporting period for a payment adjustment year at § 495.4 (88 FR 27156 through 27157).

We invited comment on this proposal.

Comment: A few commenters supported our proposal to eliminate the requirement for eligible hospitals to attest to meaningful use by October 1 of the year prior to the payment adjustment year if they have not successfully demonstrated meaningful use in a prior year. A commenter believed that it will reduce confusion and level the playing field, as longer EHR reporting periods are now required. Another commenter appreciated our proposal to simplify the regulatory language at § 495.4. Another commenter believed that requiring first time attesters to attest prior to October 1 of the reporting year is unworkable with the 180-day reporting period, and that allowing first time attesters the ability to attest during the two months following the end of the reporting year is appropriate.

Response: We thank commenters for their support. We agree that eliminating the requirement for eligible hospitals to attest to meaningful use by October 1 (or by a later date specified by CMS) of the year prior to the payment adjustment year, and to allow first time attesters to attest during the two months following the end of the reporting year will level the playing field for new and returning eligible hospitals. We thank commenters for also supporting our proposal to make corresponding changes to the regulatory text.

After consideration of the public comments we received, we are finalizing our proposal that beginning with the EHR reporting period in CY 2025 for all eligible hospitals (new and returning participants), the EHR reporting period in CY 2025 will apply for purposes of the FY 2027 payment adjustment year, and we are finalizing

[925] Office of the National Coordinator for Health Information Technology. (2023). National Trends in Hospital and Physician Adoption of Electronic Health Records. Available at: *https://www.healthit.gov/data/quickstats/national-trends-hospital-and-physician-adoption-electronic-health-records.*

our proposed changes to § 495.4, which reflect this proposal.

3. Safety Assurance Factors for EHR Resilience Guides (SAFER Guides)

a. Background

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45479 through 45481), we adopted the SAFER Guides measure under the Protect Patient Health Information Objective beginning with the EHR reporting period in CY 2022. Eligible hospitals and CAHs are required to attest to whether they have conducted an annual self-assessment using all nine SAFER Guides (*https://www.healthit.gov/topic/safety/safer-guides*), at any point during the calendar year in which the EHR reporting period occurs, with one ''yes/no'' attestation statement. Beginning in CY 2022, the attestation of this measure was required, but eligible hospitals and CAHs were not scored, and an attestation of ''yes'' or ''no'' were both acceptable answers without penalty. For additional information, please refer to the discussion of the SAFER Guides measure in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45479 through 45481).

b. Change to the SAFER Guides Measure

The SAFER Guides measure is intended to incentivize eligible hospitals and CAHs to use all nine SAFER Guides to: annually assess EHR implementation, safety and effectiveness; identify vulnerabilities; and develop a ''culture of safety'' within their organization. By implementing the SAFER Guides' recommended practices, eligible hospitals and CAHs may be better positioned to operate CEHRT responsibly in care delivery, and able to make improvements to the safety and safe use of EHRs as necessary over time. The intent of the measure is for eligible hospitals and CAHs to regularly assess their progress and status on important facets of patient safety. Given our interest in more strongly promoting safety and the safe use of EHRs, we proposed to require eligible hospitals and CAHs to conduct the annual SAFER Guides self-assessments and attest a ''yes'' response accounting for a completion of the self-assessment for all nine guides. We stated that we believe this is feasible for eligible hospitals and CAHs, as they have had time to grow familiar with the use of the SAFER Guides by attesting either ''yes'' or ''no'' to conducting the self-assessment. We also noted the availability of resources to assist eligible hospitals and CAHs with completing the self-assessment as required by the SAFER Guides measure. One example of such resources is the SAFER Guides authors' paper titled ''Guidelines for US Hospitals and Clinicians on Assessment of Electronic Health Record Safety Using SAFER Guides,'' available to download or use at *https://jamanetwork.com/journals/jama/fullarticle/2788984*.

In the FY 2024 IPPS/LTCH PPS proposed rule, we proposed to modify our requirements for the SAFER Guides measure beginning with the EHR reporting period in CY 2024 and continuing in subsequent years, to require eligible hospitals and CAHs to attest ''yes'' to having conducted an annual self-assessment using all nine SAFER Guides (available at *https://www.healthit.gov/topic/safety/safer-guides*), at any point during the calendar year in which the EHR reporting period occurs (88 FR 27157). Under this proposal, an attestation of ''no'' would result in the eligible hospital or CAH not meeting the measure requirements, and not satisfying the definition of a meaningful EHR user under § 495.4, which would subject the eligible hospital or CAH to a downward payment adjustment. We refer readers to Table IX.F.–03. in this final rule for a description of the measure.

We invited public comment on this proposal.

Comment: Many commenters expressed support for the proposal to require eligible hospitals and CAHs to attest ''yes'' to having conducted an annual self-assessment of all nine SAFER Guides. Several commenters expressed support because they believe that the self-assessment promotes patient safety and EHR system security and reliability.

Response: We appreciate the commenters' support to require an annual self-assessment with all nine SAFER Guides. We agree that yearly self-assessments of all nine SAFER Guides supports EHR-related patient safety and security practices.

Comment: A commenter expressed support for the proposal to require an annual self-assessment with the SAFER Guides, but requested a delay of at least one additional year to ensure hospitals have had sufficient time for full adoption of the SAFER Guides' recommended practices.

Response: We thank the commenter for their support and suggestion. We remind readers that the SAFER Guides measure only requires that eligible hospitals and CAHs attest ''yes'' to having conducted an annual self-assessment using all nine SAFER Guides at any point during the calendar year in which the EHR reporting period occurs. There is no requirement to implement any of the best practices identified while performing the self-assessment, and we defer to eligible hospitals and CAHs to identify an appropriate timeline and utility of adopting specific best practices contained within the SAFER Guides. We disagree that a delay in requiring an annual self-assessment would be helpful to prepare hospitals for full adoption, because implementation of SAFER Guides recommended practices is not required as part of the attestation.

Comment: A commenter supported the proposal but requested that CMS include detailed instructions for completing the self-assessment after the first year.

Response: We thank the commenter for their support and request for detailed instructions. As with other Medicare Promoting Interoperability Program measures, CMS will provide resources such as specification sheets, fact sheets, webinars, and public announcements to communicate details about the SAFER Guides measure requirements and how to fulfill them. CMS and ONC will continue to provide supporting material as necessary for the completion of the SAFER Guides self-assessment, and we will continue to obtain publicly available materials for participants. We remind readers to visit the CMS resource library website at *https://www.cms.gov/regulations-guidance/promoting-interoperability/resource-library* and the ONC website at *https://www.healthit.gov/topic/safety/safer-guides* for resources on the content and appropriate use of the SAFER Guides.

We expect that after the first year of conducting the initial SAFER Guides self-assessment, the answers to the assessment questions may not change significantly unless an eligible hospital or CAHs has made significant system upgrades or transitions between systems or vendors. If there have been no significant intervening changes to a participant's EHR system, vendor, or its relevant policies and procedures, then the participant's responses can be held to remain valid and repeated after confirmation of that fact while completing their annual self-assessments. Our larger focus is for eligible hospitals and CAHs to regularly assess their progress and status on important facets of patient safety.

Comment: Many commenters did not support this proposal and expressed concerns regarding the perceived burden of requiring a ''yes'' attestation to having conducted an annual self-assessment using all nine SAFER Guides. While commenters acknowledged the importance of implementing safety practices for

planned or unplanned EHR downtime, many believed that that requiring an annual assessment of all nine guides would place significant burden on acute care hospitals and CAHs, particularly small, rural hospitals with limited resources. A few commenters stated that it would be challenging for both smaller hospitals and large organizations to gather the required documentation from various staff, partner organizations, and other vendors. A commenter cautioned CMS against inadvertently passing the burden down through implementation requirements. Another commenter believed that the annual cost was drastically different from the entirety of the proposed changes to the Hospital IQR Program. Another commenter recommended performing a one-time self-assessment instead of annual self-assessments.

Response: We thank commenters for sharing their feedback and concerns. We would like to clarify and emphasize that this proposal does not require eligible hospitals and CAHs to confirm that they have implemented any of the SAFER Guides practices. We are requiring eligible hospitals and CAHs to affirmatively attest that they have completed the self-assessment using each of the nine SAFER Guides. We believe that this requirement will incentivize hospitals and CAHs to conduct the annual self-assessment and assist them in actively understanding and addressing potential safety vulnerabilities routinely, which may significantly impact their organization's safety posture in a timelier manner. With regard to the estimated annual costs associated with the proposal, in section I.O. of appendix A we acknowledge that while an upfront investment of resources and staff time may be needed to conduct a SAFER Guides self-assessment, we believe the cost is outweighed by the potential for improved healthcare outcomes, increased efficiency, reduced risk of data breaches and ransomware attacks, and decreased malpractice premiums.

Comment: A few commenters did not support this proposal because they believe that the SAFER Guides self-assessment is redundant with other efforts. A few commenters believed that this proposal was redundant to the required annual Security Risk Assessment and other policies and procedures that hospitals already enforce. Another commenter believed that this proposal overlaps with the CEHRT review requirements. A few commenters believed that some of the ''Recommended Practices'' and ''Recommended Risk Assessments'' within the SAFER Guides were related to the hospitals' EHR vendor, and that hospitals were relying on the EHR developers and vendors to make an accurate, thorough self-assessment. Therefore, these commenters were concerned that this proposal, if finalized, would impose unfair penalties on some healthcare providers.

Response: We thank these commenters for sharing their feedback and concerns. The SAFER Guides were intended to be utilized by EHR users, developers, patient safety organizations, and those who are concerned with optimizing the safety and safe use of health IT. Therefore, eligible hospitals and CAHs may need to work together with their EHR vendors on implementation of EHR safety practices. Regarding other program requirements, while the SAFER Guides provide overall guidelines and practical recommendations to ensure users are advancing EHR safety, the Security Risk Analysis (*https://www.cms.gov/files/document/security-risk-analysis-fact-sheet.pdf*) is specifically focused on identifying and analyzing security risks related to protecting health information, and health IT certification criteria related to security concentrate on the security aspects of EHR technology and compliance with health IT standards. We believe these different requirements complement rather than duplicate each other.

Comment: A few commenters did not support this proposal because of their concerns about the time necessary to meet the requirement of this proposal. One vendor stated that they would not have time to provide any development or other software support to their clients given the current list of health IT requirements to meet in CY 2023. Another commenter stated that their organization does not have sufficient time by CY 2024 to operationalize these requirements. A few commenters recommended that CMS continue the existing requirement and delay implementation of a required ''yes'' attestation to a later year.

Response: We appreciate the commenters sharing their concerns. We recognize that conducting the SAFER Guides self-assessments may entail a time commitment for some eligible hospitals and CAHs. However, the benefits of ensuring EHR safety far outweigh the necessary investment of time. In addition, we would like to emphasize again that the measure only requires self-assessment using the SAFER Guides and does not require implementation of the practices described in the Guides. Furthermore, we expect that after the first year of conducting the initial SAFER Guides self-assessment, the answers to the assessment questions may not change significantly unless an eligible hospital or CAH has made significant system upgrades or transitions between systems or vendors. If there have been no significant intervening changes to a participant's EHR system, vendor, or its relevant policies and procedures, then the participant's responses can be held to remain valid and repeated after confirmation of that fact while completing their annual self-assessments. Eligible hospitals and CAHs may need to work together with health IT developers and other vendors to perform these self-assessments; however, the self-assessment requirement does not require any immediate updates or upgrades of their EHR systems. We believe that in conducting an annual self-assessment with the SAFER Guides promotes EHR-related safety practices, therefore we disagree with the recommendation to delay its requirement.

Comment: One commenter believed that the acceptance of a ''no'' attestation in prior years did not entirely incentivize hospitals to adopt such a time-consuming process for all nine SAFER Guides.

Response: We thank the commenter for their feedback. We understand that the initial self-assessment is the most time-consuming, and self-assessments may be less burdensome in subsequent years. We offered eligible hospitals and CAHs a two year period to begin the process, without penalty for not being able to complete the self-assessments. Additionally, this two year period without penalty offered eligible hospitals and CAHs time to review available resources, work with staff and vendors on establishing an annual review process, where they would not be penalized for not having completed the self-assessments.

Comment: A few commenters did not support this proposal and stated that requiring the SAFER Guides self-assessment is an inappropriate use of the Medicare Promoting Interoperability Program. A commenter believed that requiring an annual self-assessment of the SAFER Guides was to create an across-the-board requirement for all participants in the program as they believed that the Medicare Promoting Interoperability Program was supposed to provide differential rewards based on how hospitals perform in order to incentivize the adoption of a particular practice through adopting performance-based scoring. Another commenter believed that this proposal would impose a potential downward payment adjustment and penalty instead of an

incentive, and believed that it was counterintuitive to CMS' stated intention for the SAFER Guides measure.

Response: We thank the commenters for sharing their concerns. The Medicare Promoting Interoperability Program uses both performance-based and attestation measures to assess the performance of eligible hospitals and CAHs, and potentially applies downward payment adjustments based on their performance scores and the results of their attestation measures as the financial consequence of not meeting the definition of a meaningful EHR user under § 495.4. As we discussed in the Stage 2 final rule when we adopted the Protect Patient Health Information objective (77 FR 54002 through 54003), it is essential to all aspects of meaningful use to ensure that patient health information is protected and secure. Under the Protect Patient Health Information objective, the SAFER Guides measure is one way that we encourage eligible hospitals and CAHs, and their vendors, to proactively assess their readiness for EHR safety. Therefore, we respectfully disagree with the commenters' perspective.

Comment: A commenter did not support this proposal and expressed concerns that there are no scholarly articles, journals, or systematic research citing or indicating the guides can offer any of the ''potential'' CMS claims. Another commenter believed that ONC intended to use the SAFER Guides for informational purposes instead of legal compliance purposes. Another commenter believed that the SAFER Guides was a framework from a specific vendor instead of providing general standards.

Response: We thank the commenters for expressing their concerns. We note that the SAFER Guides are based on extensive research and input from various stakeholders in the healthcare industry, have been widely adopted in the industry, and are not specific to any one vendor. The SAFER Guides provide general guidance and best practices for enhancing the safety and resilience of an organization's EHR system. Readers can visit the CMS resource library website at *https://www.cms.gov/regulations-guidance/promoting-interoperability/resource-library* and the ONC website at *https://www.healthit.gov/topic/safety/safer-guides* for resources on the content and appropriate use of the SAFER Guides. By providing practical guidance on enhancing security and resilience of EHR systems, the SAFER Guides meet the goal of the Medicare Promoting Interoperability Program to improve the safety, quality, and equity of healthcare systems.

The proposal to update the SAFER Guides measure in the Medicare Promoting Interoperability Program was developed in consultation with ONC. The SAFER Guides themselves are not intended to be used for legal compliance purposes, and implementation of a recommended practice does not guarantee compliance with HIPAA, the HIPAA Security Rule, Medicare or Medicaid Conditions of Participation, or any other laws or regulations. The SAFER Guides are for informational purposes only and are not intended to be an exhaustive or definitive source, nor do they constitute legal advice. Users of the SAFER Guides are encouraged to consult with their own legal counsel regarding compliance with Medicare or Medicaid program requirements, HIPAA, and any other laws. However, attesting ''yes'' to the SAFER Guides measure each year would be a requirement for an eligible hospital or CAH to avoid a downward payment adjustment in the Medicare Promoting Interoperability Program.

Comment: A commenter did not support this proposal and believed that the SAFER Guides were not applicable to every organization, which could cause extreme financial and workforce burden.

Response: We thank the commenters for expressing their concerns, and we will take them under consideration. We acknowledge that every organization faces unique circumstances and will implement a particular safety practice differently. As a result, some of the specific examples in the SAFER Guides for recommended practices may not be applicable to every organization. However, conducting the self-assessments using the nine SAFER Guides can be valuable for any organization that utilizes EHR systems. In addition, it is important for eligible hospitals and CAHs to perform the annual self-assessment required by the SAFER Guides measure to address vulnerabilities early on.

Comment: A few commenters requested clarification on what level of action is required to attest ''yes'' to having conducted the self-assessment with the SAFER Guides. Specifically, commenters wanted to know if implementation of recommended practices is a necessary requirement for a ''yes'' attestation.

Response: Only a review and annual self-assessment of each of the nine SAFER Guides is required for eligible hospitals and CAHs to attest ''yes'' to the SAFER Guides measure. Implementation of any of the recommended practices is not required as part of our proposal. We recognize that participants will have unique circumstances, priorities, and constraints that inform their decision-making regarding when and how to undertake EHR safety improvements that may be identified through the assessment process. The requirement for the measure is thus only that eligible hospitals and CAHs affirmatively attest to having conducted a review of their own EHR safety practices using all nine SAFER Guides, and we defer to eligible hospitals and CAHs to determine what improvements, if any, are needed in their EHR safety practices.

Comment: One commenter recommended that if CMS were to finalize the proposal, it should do so in a way where eligible hospitals and CAHs are able to complete self-assessments with minimal vendor support.

Response: We thank the commenter for their suggestion. We believe that although many SAFER Guides self-assessment questions can be addressed by a hospital's clinical, administrative, and information technology staff, the SAFER Guides were intended to be best utilized by EHR users in collaboration with developers, and others who are concerned with optimizing the safe use of health IT. The appropriate configuration and maintenance of EHRs impacts patient safety and necessarily involves EHR vendors. Although eligible hospitals and CAHs have primary responsibility for performing the SAFER Guides self-assessment under this measure, participants may need to solicit information from their EHR vendors to understand how EHR vendor installation or configuration decisions impact patient safety.

Comment: A few commenters recommended that CMS and ONC update the SAFER Guides, citing that the SAFER Guides were last updated in 2016. These commenters questioned the relevancy of the SAFER Guides to patient safety in hospitals due to the rapid advancement of health IT. Two commenters suggested changing the guides to remove what they believe is redundant material between the nine guides, and a commenter suggested a more focused approach to address gap areas in EHR safety. Another commenter recommended convening technical experts to inform best practices in making updates to the SAFER Guides. Another commenter supported the proposal but encouraged CMS to work with ONC to update the SAFER Guides prior to requiring eligible hospitals and CAHs to report on all nine SAFER Guides, because they believed that ONC

and CMS should use current evidence and recommendations to update the guides and ensure that healthcare organizations have access to reliable and timely resources.

Response: We thank the commenters for their suggestions, and for expressing their concerns. The SAFER Guides have been widely used in the healthcare industry to enhance the safety and resilience of EHR systems. CMS will continue to work with ONC to consider whether updates to the Guides are needed, for instance, to reflect new research available. We will also work to ensure the relevance of the SAFER Guides' content for eligible hospitals and CAHs specifically. However, we believe that the current SAFER Guides reflect relevant and valuable guidelines for safe practices with respect to current EHR systems. We do not believe that there is a safety benefit in delaying the requirement to conduct the self-assessment until after any future updates are made to the SAFER Guides, because the self-assessments themselves remain up to date and valuable as a means to promote EHR safety. In cases where a participant believes that a SAFER Guide question is redundant with one contained in another Guide, we expect that the additional burden of self-assessment would therefore be minimal, since the participant would have already answered it; however, we will continue to explore opportunities with ONC to identify these issues as part of future updates. We appreciate additional suggestions from commenters for consideration in any future updates to the Guides.

Comment: A few commenters recommended that, rather than requiring self-assessment with all nine SAFER Guides, CMS should require self-assessment using fewer guides, citing the belief that this would increase flexibility by invoking less burden while still promoting high-priority practices.

Response: Because each SAFER Guide addresses a different component of EHR safety, and each SAFER Guide contains recommended practices not addressed in other guides, we believe that the safety benefit of conducting a self-assessment using all nine Guides is a better approach to promoting EHR safety than requiring only a subset of SAFER Guides for review. We therefore believe that the safety benefit of self-assessment with all nine SAFER Guides outweighs its burden.

Comment: A few commenters requested additional educational resources to assist eligible hospitals and CAHs in completing all nine SAFER Guides. A commenter noted that a supporting resource (''Guidelines for US Hospitals and Clinicians on Assessment of Electronic Health Record Safety Using SAFER Guides,'' accessible at *https://jamanetwork.com/journals/jama/article-abstract/2788984*) cited in the proposed rule is not freely available. Another commenter made a specific request for resources tailored to small and medium-sized health care organizations.

Response: We agree that eligible hospitals and CAHs should have the necessary resources available to successfully complete a self-assessment and attest ''yes'' to the SAFER Guides measure. As with other Medicare Promoting Interoperability Program measures, CMS will provide resources such as specification sheets, fact sheets, webinars, and events to communicate details about the SAFER Guides measure and its appropriate fulfillment. CMS and ONC will continue to provide supporting material as necessary for the completion of the SAFER Guides self-assessment, and we will work to obtain free access to available materials for participants.

Comment: Two commenters requested clarification on how eligible hospitals and CAHs will be alerted when there are any updates to the SAFER Guides.

Response: As with other Medicare Promoting Interoperability Program measures, we will provide resources such as specification sheets, fact sheets, webinars, and events to communicate details about the SAFER Guides measure. Updates to the SAFER Guides would be provided with accompanying educational and promotional materials to notify participants, in collaboration with ONC.

Comment: A commenter requested that CMS include detailed instructions for completing the self-assessment in subsequent years after having completed a first self-assessment.

Response: We expect that eligible hospitals and CAHs completing the SAFER Guides self-assessment will have a lower burden of completion after their first year conducting the self-assessment. For a given SAFER Guide Recommended Practice, within a given self-assessment, if there have been no significant intervening changes to a participant's EHR system, vendor, or its relevant policies and procedures, then the participant's responses can be held to remain valid and repeated on a subsequent self-assessment after confirmation of that fact. As with other Medicare Promoting Interoperability Program measures, we will provide resources such as specification sheets, fact sheets, webinars, and events to communicate details about the SAFER Guides measure.

Comment: A commenter recommended that CMS promote EHR safety in other ways such as promoting certain approaches or guidelines rather than using a measure in the Medicare Promoting Interoperability Program.

Response: We thank the commenter for their suggestion. Although CMS has other means available to disseminate best practices in EHR safety, we believe that the Medicare Promoting Interoperability Program is a very valuable means to promote the regular review of EHR-related safety practices by eligible hospitals and CAHs and using standard review criteria. Whereas the publication of guidelines alone is useful for proactive eligible hospitals and CAHs, the use of Medicare Promoting Interoperability Program measures incentivizes every eligible hospital and CAH to undertake a self-assessment of their EHR safety practices. As such, we believe that the Medicare Promoting Interoperability Program is the appropriate program to ensure broad attention to EHR safety in acute care hospitals.

After consideration of the public comments we received, we are finalizing our proposal to modify our requirement for the SAFER Guides measure beginning with the EHR reporting period in CY 2024 and continuing in subsequent years, to require eligible hospitals and CAHs to attest ''yes'' to having conducted an annual self-assessment using all nine SAFER Guides, at any point during the calendar year in which the EHR reporting period occurs.

4. Scoring Methodology for the EHR Reporting Period in CY 2024

In the FY 2019 IPPS/LTCH PPS final rule (83 FR 41636 through 41645), we adopted a new performance-based scoring methodology for eligible hospitals and CAHs attesting under the Medicare Promoting Interoperability Program beginning with the EHR reporting period in CY 2019, which included a minimum scoring threshold of a total score of 50 points or more, which eligible hospitals and CAHs must meet to satisfy the requirement to report on the objectives and measures of meaningful use under § 495.24. In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45491 through 45492), we increased the minimum scoring threshold from 50 to 60 points beginning with the EHR reporting period in CY 2022. As shown in Table IX.F.–01., the points associated with the required measures sum to 100 points, and the optional measures may add additional bonus points. The scores for each of the measures are added together to calculate a total score of up

to 100 possible points for each eligible hospital or CAH (83 FR 41636 through 41645).

We did not propose any changes to the scoring methodology for the EHR reporting period in CY 2024. We refer readers to Table IX.F.–01. in this final rule, which reflects the objectives, measures, maximum points available, and whether a measure is required or optional for the EHR reporting period in CY 2024 based on our previously adopted policies.

TABLE IX.F.-01.: PERFORMANCE-BASED SCORING METHODOLOGY FOR EHR REPORTING PERIODS IN CY 2024

Objective	Measure	Maximum Points	Required/Optional
Electronic Prescribing	e-Prescribing	10 points	Required
	Query of Prescription Drug Monitoring Program (PDMP)	10 points	Required
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	15 points	Required (eligible hospitals and CAHs must choose one of the three reporting options)
	-AND-		
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	15 points	
	-OR-		
	Health Information Exchange Bi-Directional Exchange	30 points	
	-OR-		
	Enabling Exchange under the Trusted Exchange Framework and Common Agreement (TEFCA)	30 points	
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	25 points	Required
Public Health and Clinical Data Exchange	Report the following five measures: • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Electronic Reportable Laboratory Result Reporting • Antimicrobial Use and Resistance (AUR) Surveillance	25 points	Required
	Report one of the following measures: • Public Health Registry Reporting • Clinical Data Registry Reporting	5 points (*bonus*)	Optional

Notes: The Security Risk Analysis measure, SAFER Guides measure, and attestations required by section 106(b)(2)(B) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) are required but will not be scored. eCQM measures are required but will not be scored. Eligible hospitals and CAHs must also submit their level of active engagement for measures under the Public Health and Clinical Data Exchange objective. Participants may spend only one EHR reporting period at the Option 1: Pre-production and Validation level per measure and must progress to Option 2: Validated Data Production level for the next EHR reporting period. See FY 2023 IPPS/LTCH PPS final rule (87 FR 49337) for more details about active engagement.

The maximum points available in Table IX.F.–01. in this final rule do not include the points that would be redistributed in the event an exclusion is claimed for a given measure. We did not propose any changes to our policy

for point redistribution in the event an exclusion is claimed for the EHR reporting period in CY 2024. We refer readers to Table IX.F.–02. in this final rule, which shows how points would be redistributed among the objectives and measures for the EHR reporting period in CY 2024, in the event an eligible hospital or CAH claims an exclusion.

TABLE IX.F.-02.: EXCLUSION REDISTRIBUTION FOR EHR REPORTING PERIOD IN CY 2024

Objective	Measure	Redistribution if Exclusion is Claimed
Electronic Prescribing	e-Prescribing	10 points to Health Information Exchange (HIE) Objective
	Query of PDMP	10 points to e-Prescribing measure
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information	No exclusion
	-AND-	
	Support Electronic Referral Loops by Receiving and Reconciling Health Information	No exclusion
	-OR-	
	Health Information Exchange Bi-Directional Exchange	No exclusion
	-OR-	
	Enabling Exchange under the Trusted Exchange Framework and Common Agreement (TEFCA)	No exclusion
Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information	No exclusion
Public Health and Clinical Data Exchange	Report the following five measures: • Syndromic Surveillance Reporting • Immunization Registry Reporting • Electronic Case Reporting • Electronic Reportable Laboratory Result Reporting • Antimicrobial Use and Resistance (AUR) Surveillance	If an exclusion is claimed for each of the five measures, 25 points are redistributed to the Provide Patients Electronic Access to their Health Information measure

5. Changes to Calculation Considerations Related To Counting Unique Patients or Actions

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49349 through 49357), we included Table IX.H.–07. for ease of reference, which lists the objectives and measures for the EHR reporting period in CY 2023 as revised to reflect the final policies established in that final rule. Table IX.H.–07. includes a column titled Calculation Considerations Related to Counting Unique Patients or Actions (referred to as ''calculation considerations''), and the information in that column was previously codified at § 495.24(e)(3). For more information regarding the previous codification of the objectives, measures, and other policies under § 495.24(e), we refer readers to the discussion in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49347 through 49350). The calculation considerations column of Table IX.H.–07. indicates whether the measures that count unique patients or actions may be calculated by reviewing only the actions for patients whose records are maintained using CEHRT or must be calculated by reviewing all patient records.

As we stated in the CY 2024 IPPS/LTCH PPS proposed rule (88 FR 27159 through 27160), we have reviewed the descriptions of the calculation considerations in Table IX.H.–07. and believe that some are not applicable to certain measures. We believe that the term ''calculation considerations'' is not applicable to all measures, as there are measures that require a ''Yes/No'' response instead of requiring numerators and denominators. We believe that the inclusion of the calculation considerations for these measures has the potential to cause confusion for eligible hospitals and CAHs attempting to report on the measures for the Medicare Promoting Interoperability Program.

Therefore, beginning with the EHR reporting period in CY 2024, we proposed to modify the way we refer to calculation considerations related to

unique patients or actions for measures for which there is no numerator and denominator, and for which unique patients or actions are not counted, to read ''N/A (measure is Yes/No)'' (88 FR 27159 through 27160). The following measures will be affected by this proposal because they do not have a numerator and denominator and they require a ''Yes/No'' response: Query of PDMP measure; HIE Bi-Directional Exchange measure; Enabling Exchange under TEFCA measure; Immunization Registry Reporting measure; Syndromic Surveillance Reporting measure; Electronic Case Reporting measure; Electronic Reportable Laboratory (ELR) Result Reporting measure; Public Health Registry Reporting measure; Clinical Data Registry Reporting measure; Antimicrobial Use and Resistance (AUR) Surveillance measure; Security Risk Analysis measure; and the SAFER Guides measure. We stated that we believe this policy will reduce potential confusion regarding which measures require calculations related to unique patients or actions. We have included the changes in Table IX.F.–03.

We invited public comment on this proposal.

Comment: A few commenters supported our proposal to modify the calculation considerations related to unique patients or actions for measures which have no numerator or denominator, and for which unique patients or actions are not counted.

Response: We thank the commenters for their support. We believe that this update will reduce potential confusion regarding which measures require calculations related to unique patients or actions.

After consideration of the public comments we received, we are finalizing our proposal that beginning with the EHR reporting period in CY 2024, we will refer to calculation considerations related to unique patients or actions for measures for which there is no numerator and denominator, and for which unique patients or actions are not counted, to read ''N/A (measure is Yes/No)''.

6. Overview of Objectives and Measures for the Medicare Promoting Interoperability Program for the EHR Reporting Period in CY 2024

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49347 through 49349), we added a new paragraph (f) at § 495.24, regarding the Stage 3 objectives and measures for eligible hospitals and CAHs attesting to CMS in CY 2023 and subsequent years, which did not include the objectives and measures text for the Medicare Promoting Interoperability Program, such as that text found at § 495.24(e). We inadvertently neglected to make the associated changes to the demonstration of meaningful use criteria requirements at § 495.40(b)(2)(i), stating that for CY 2024 and subsequent years, an eligible hospital or CAH attesting to CMS would satisfy the required objectives and associated measures for meaningful use as defined by CMS. We proposed to update the regulatory text at § 495.40 to make it consistent with § 495.24(f) (88 FR 27160).

We invited public comment on this proposal.

Comment: A few commenters expressed support for our proposal to update the objectives and measures regulatory text at § 495.40 for consistency with § 495.24(f) for CY 2024 and subsequent years.

Response: We thank the commenters for their support.

After consideration of the public comments we received, we are finalizing our proposal to update the regulatory text at § 495.40 to make it consistent with § 495.24(f).

For ease of reference, Table IX.F.–03. lists the objectives and measures for the Medicare Promoting Interoperability Program for the EHR reporting period in CY 2024 as revised to reflect the changes adopted in this final rule. Table IX.F.–04. lists the 2015 Edition certification criteria required to meet the objectives and measures.

BILLING CODE 4201–01–P

TABLE IX.F.-03.: SUMMARY OF OBJECTIVES AND MEASURES FOR THE MEDICARE PROMOTING INTEROPERABILITY PROGRAM FOR THE EHR REPORTING PERIOD IN CY 2024

Objective	Measure	Numerator	Denominator	Exclusion	Calculation Considerations Related to Counting Unique Patients or Actions for CY 2024 and Subsequent Years*
Electronic Prescribing	e-Prescribing: For at least one hospital discharge medication order for permissible prescriptions (for new and changed prescriptions) are transmitted electronically using CEHRT.	The number of prescriptions in the denominator generated and transmitted electronically.	The number of new or changed prescriptions written for drugs requiring a prescription in order to be dispensed, other than controlled substances for patients discharged during the EHR reporting period.	Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions, and there are no pharmacies that accept electronic prescriptions within 10 miles at the start of their EHR reporting period.	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.
Electronic Prescribing	Query of PDMP: For at least one Schedule II opioid or Schedule III or IV drug electronically prescribed using CEHRT during the EHR reporting period, the eligible hospital or CAH uses data from CEHRT to conduct a query of a PDMP for prescription drug history.	N/A (measure is Y/N)	N/A (measure is Y/N)	(1) Any eligible hospital or CAH that does not have an internal pharmacy that can accept electronic prescriptions for controlled substances that include Schedule II, III and IV drugs and is not located within 10 miles of any pharmacy that accepts electronic prescriptions for controlled substances at the start of their EHR reporting period. (2) Any eligible hospital or CAH that could not report on this measure in accordance with applicable law.	N/A (measure is Y/N)*
Health Information Exchange	Support Electronic Referral Loops by Sending Health Information: For at least one transition of care or referral, the eligible hospital or CAH that transitions or refers its patient to another setting of care or provider of care: (1) Creates a summary of care record using CEHRT; and (2) Electronically exchanges the summary of care record.	Number of transitions of care and referrals in the denominator where a summary of care record was created using CEHRT and exchanged electronically.	Number of transitions of care and referrals during the EHR reporting period for which the eligible hospital or CAH inpatient or emergency department (Place of Service [POS] 21 or 23) was the transitioning or referring provider.	None	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.

Health Information Exchange	Support Electronic Referral Loops by Receiving and Reconciling Health Information: For at least one electronic summary of care record received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the receiving party of a transition of care or referral, or for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient, the eligible hospital or CAH conducts clinical information reconciliation for medication, medication allergy, and current problem list using CEHRT.	Number of electronic summary of care records in the denominator for which clinical information reconciliation is completed using CEHRT for the following three clinical information sets: (1) Medication – Review of the patient's medication, including the name, dosage, frequency, and route of each medication; (2) Medication Allergy – Review of the patient's known medication allergies; and (3) Current Problem List – Review of the patient's current and active diagnoses.	Number of electronic summary of care records received using CEHRT for patient encounters during the EHR reporting period for which an eligible hospital or CAH was the reconciling party of a transition of care or referral, and for patient encounters during the EHR reporting period in which the eligible hospital or CAH has never before encountered the patient.	None	Measure may be calculated by reviewing only actions for patients whose records are maintained using CEHRT for which sufficient data were entered in the CEHRT to allow the record to be saved and not rejected due to incomplete data.

Health Information Exchange	HIE Bi-Directional Exchange The eligible hospital or CAH must attest to the following: (*1*) Participating in an HIE in order to enable secure, bi-directional exchange of information to occur for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy. (*2*) Participating in an HIE that is capable of exchanging information across a broad network of unaffiliated exchange partners including those using disparate EHRs, and not engaging in exclusionary behavior when determining exchange partners. (*3*) Using the functions of CEHRT to support bi-directional exchange with an HIE.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N)*

Health Information Exchange	Enabling Exchange under TEFCA The eligible hospital or CAH must attest to the following: (1) Participating as a signatory to a Framework Agreement (as that term is defined by the Common Agreement for Nationwide Health Information Interoperability as published in the **Federal Register** and on ONC's website) in good standing (that is, not suspended) and enabling secure, bi-directional exchange of information to occur, in production, for all unique patients discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23), and all unique patient records stored or maintained in the EHR for these departments, during the EHR reporting period in accordance with applicable law and policy. (2) Using the functions of CEHRT to support bi-directional exchange of patient information, in production, under this Framework Agreement.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N)*

Provider to Patient Exchange	Provide Patients Electronic Access to Their Health Information: For at least one unique patient discharged from the eligible hospital or CAH inpatient or emergency department (POS 21 or 23): (1) the patient (or patient-authorized representative) is provided timely access to view online, download, and transmit their health information; and (2) the eligible hospital or CAH ensures the patient's health information is available for the patient (or patient-authorized representative) to access using any application of their choice that is configured to meet the technical specifications of the application programming interface (API) in the eligible hospital's or CAH's CEHRT.	The number of patients in the denominator (or patient authorized representatives) who are provided timely access to health information to view online, download and transmit to a third party and to access using an application of their choice that is configured to meet the technical specifications of the API in the eligible hospital's or CAH's CEHRT.	The number of unique patients discharged from an eligible hospital or CAH inpatient or emergency department (POS 21 or 23) during the EHR reporting period.	None	Measure must be calculated by reviewing all patient records, not just those maintained using CEHRT.

Public Health and Clinical Data Exchange	Immunization Registry Reporting: The eligible hospital or CAH is in active engagement with a public health agency (PHA) to submit immunization data and receive immunization forecasts and histories from the public health immunization registry or immunization information system (IIS).	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the immunization registry reporting measure if the eligible hospital or CAH: (1) Does not administer any immunizations to any of the populations for which data is collected by its jurisdiction's immunization registry or IIS during the EHR reporting period; (2) Operates in a jurisdiction for which no immunization registry or IIS is capable of accepting the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no immunization registry or IIS has declared readiness to receive immunization data as of 6 months prior to the start of the EHR reporting period.	N/A (measure is Y/N)*
Public Health and Clinical Data Exchange	Syndromic Surveillance Reporting: The eligible hospital or CAH is in active engagement with a PHA to submit syndromic surveillance data from an emergency department (POS 23).	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the syndromic surveillance reporting measure if the eligible hospital or CAH: (1) Does not have an emergency department; (2) Operates in a jurisdiction for which no PHA is capable of receiving electronic syndromic surveillance data from eligible hospitals or CAHs in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive syndromic surveillance data from eligible hospitals or CAHs as of 6 months prior to the start of the EHR reporting period.	N/A (measure is Y/N)*

Public Health and Clinical Data Exchange	Electronic Case Reporting: The eligible hospital or CAH is in active engagement with a PHA to submit case reporting of reportable conditions.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure if the eligible hospital or CAH: (1) Does not treat or diagnose any reportable diseases for which data is collected by its jurisdiction's reportable disease system during the EHR reporting period; (2) Operates in a jurisdiction for which no PHA is capable of receiving electronic case reporting data in the specific standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive electronic case reporting data as of 6 months prior to the start of the EHR reporting period.	N/A (measure is Y/N)*
Public Health and Clinical Data Exchange	Electronic Reportable Laboratory (ELR) Result Reporting: The eligible hospital or CAH is in active engagement with a PHA to submit ELR results.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the ELR result measure if the eligible hospital or CAH: (1) Does not perform or order laboratory tests that are reportable in its jurisdiction during the EHR reporting period; (2) Operates in a jurisdiction for which no PHA is capable of accepting the specific ELR standards required to meet the CEHRT definition at the start of the EHR reporting period; or (3) Operates in a jurisdiction where no PHA has declared readiness to receive ELR results from an eligible hospital or CAH as of 6 months prior to the start of the EHR reporting period.	N/A (measure is Y/N)*

Public Health and Clinical Data Exchange	AUR Surveillance: The eligible hospital or CAH is in active engagement with CDC's National Healthcare Safety Network (NHSN) to submit antimicrobial use and resistance (AUR) data for the EHR reporting period and receives a report from NHSN indicating their successful submission of AUR data for the EHR reporting period.	N/A (measure is Y/N)	N/A (measure is Y/N)	Any eligible hospital or CAH meeting one or more of the following criteria may be excluded from the case reporting measure if the eligible hospital or CAH: (1) Does not have any patients in any patient care location for which data are collected by the NHSN during the EHR reporting period; (2) Does not have electronic medication administration records (eMAR)/barcoded medication administration (BCMA) records or electronic admission discharge transfer (ADT) system during the EHR reporting period; (3) Does not have an electronic laboratory information system or ADT system during the EHR reporting period.	N/A (measure is Y/N)*
Public Health and Clinical Data Exchange	Public Health Registry Reporting: The eligible hospital or CAH is in active engagement with a PHA to submit data to public health registries.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N)*
Public Health and Clinical Data Exchange	Clinical Data Registry Reporting: The eligible hospital or CAH is in active engagement to submit data to a clinical data registry.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N)*

Protect Patient Health Information	Security Risk Analysis Conduct or review a security risk analysis in accordance with the requirements under 45 CFR 164.308(a)(1), including addressing the security (including encryption) of data created or maintained by CEHRT in accordance with requirements under 45 CFR 164.312(a)(2)(iv) and 164.306(d)(3), implement security updates as necessary, and correct identified security deficiencies as part of the provider's risk management process. Actions included in the security risk analysis measure may occur any time during the calendar year in which the EHR reporting period occurs.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N)*
Protect Patient Health Information	SAFER Guides* Conduct an annual self-assessment using all nine SAFER Guides at any point during the calendar year in which the EHR reporting period occurs.	N/A (measure is Y/N)	N/A (measure is Y/N)	None	N/A (measure is Y/N)*

* Signifies a finalized proposal made in this FY 2024 IPPS/LTCH PPS final rule.

TABLE IX.F.-04.: MEDICARE PROMOTING INTEROPERABILITY PROGRAM OBJECTIVES AND MEASURES AND 2015 EDITION CERTIFICATION CRITERIA

Objective	Measure	2015 Edition (EHR Reporting Period in CY 2024)*/**
Electronic Prescribing	e-Prescribing	§ 170.315(b)(3) Electronic prescribing
	Query of PDMP	§ 170.315(b)(3) Electronic prescribing
Health Information Exchange	Support electronic referral loops by sending health information	§ 170.315(b)(1) Transitions of care
	Support electronic referral loops by receiving and reconciling health information	§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
Health Information Exchange (alternative)	Health Information Exchange (HIE) Bi-Directional Exchange	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Health Information Exchange (alternative)	Participation in TEFCA	Examples of certified health IT capabilities to support the actions of this measure may include but are not limited to technology certified to the following criteria:
		§ 170.315(b)(1) Transitions of care
		§ 170.315(b)(2) Clinical information reconciliation and incorporation
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Provider to Patient Exchange	Provide patients electronic access to their health information	§ 170.315(e)(1) View, download, and transmit to 3rd party
		§ 170.315(g)(7) Application access — patient selection
		§ 170.315(g)(9) Application access — all data request
		§ 170.315(g)(10) Application access — standardized API for patient and population services
Public Health and Clinical Data Exchange	Immunization registry reporting	§ 170.315(f)(1) Transmission to immunization registries
	Syndromic surveillance reporting	§ 170.315(f)(2) Transmission to public health agencies — syndromic surveillance
	Electronic case reporting	§ 170.315(f)(5) Transmission to public health agencies — electronic case reporting
	Public health registry reporting	§ 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting
		§ 170.315(f)(7) Transmission to public health agencies — health care surveys
	Clinical data registry reporting	No 2015 health IT certification criteria at this time.
	Electronic reportable laboratory result reporting	§ 170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results
	AUR Surveillance Reporting	§ 170.315(f)(6) Transmission to public health agencies — antimicrobial use and resistance reporting
Electronic Clinical Quality Measures (eCQMs)	eCQMs for eligible hospitals and CAHs	§ 170.315(c)(1)
		§ 170.315(c)(2)
		§ 170.315(c)(3)(i) and (ii)
Protect Patient Health Information	Security Risk Assessment	No 2015 health IT certification criteria at this time.
	Safety Assurance Factors for EHR Resilience Guides (SAFER Guides)	No 2015 health IT certification criteria at this time.

*The ONC 21st Century Cures Act final rule made updates to the 2015 Edition Health IT Certification Criteria by introducing new criteria and revising and removing existing criteria (85 FR 25667 through 25668). These changes are required for the EHR reporting period in CY 2023, and subsequent years.

** The CY 2024 PFS proposed rule (FR Doc. 2023-14624, pubslihing in the **Federal Register** on August 7, 2023; available at https://www.federalregister.gov/public-inspection/2023-14624/medicare-and-medicaid-programs-cy-2024-payment-policies-under-the-physician-fee-schedule-and-other) includes a proposal to revise the definitions of CEHRT in 42 CFR 495.4 and 414.1305 for the Medicare Promoting Interoperability Program and for the Quality Payment Program so these definitions would be consistent with the "edition-less" approach to health IT certification as proposed in the ONC HT-1 proposed rule (88 FR 23746 through 23917), should the ONC proposal be finalized.

BILLING CODE 4120–01–C

7. Clinical Quality Measurement for Eligible Hospitals and CAHs Participating in the Medicare Promoting Interoperability Program

a. Changes to Clinical Quality Measures in Alignment With the Hospital IQR Program

(1) Background

Under sections 1814(l)(3)(A) and 1886(n)(3)(A)(iii) of the Act, and the definition of ''meaningful EHR user'' under § 495.4, eligible hospitals and CAHs must report on clinical quality measures selected by CMS using CEHRT (also referred to as electronic clinical quality measures, or eCQMs), as part of being a meaningful EHR user under the Medicare Promoting Interoperability Program.

Tables IX.F.–05. and IX.F.–06. in this final rule summarize the previously finalized eCQMs available for eligible hospitals and CAHs to report under the Medicare Promoting Interoperability Program for the CY 2023 reporting period and the CY 2024 reporting period and subsequent years (87 FR 45360).

TABLE IX.F.-05.: PREVIOUSLY FINALIZED ECQMS FOR ELIGIBLE HOSPITALS AND CAHS FOR THE CY 2023 REPORTING PERIOD

Short Name	Measure Name	CBE^ No.
Safe Use of Opioids*	Safe Use of Opioids – Concurrent Prescribing	3316e
ED-2 **	Admit Decision Time to ED Departure Time for Admitted Patients	0497
HH-01	Hospital Harm – Severe Hypoglycemia	3503e
HH-02	Hospital Harm – Severe Hyperglycemia	3533e
PC-05 **	Exclusive Breast Milk Feeding	0480
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by End of Hospital Day Two	0438
STK-06 **	Discharged on Statin Medication	0439
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
ePC-07/SMM	Severe Obstetric Complications	N/A
ePC-02	Cesarean Birth	N/A

^ In previous years, we referred to the consensus-based entity by corporate name. We have updated this language to refer to the consensus-based entity more generally.

*Reporting the Safe Use of Opioids-Concurrent Prescribing eCQM is mandatory beginning with the CY 2022 reporting period.

**CY 2023 is the last year to report on Admit Decision Time to ED Departure Time for Admitted Patients, Exclusive Breast Milk Feeding, and Discharged on Statin Medication eCQMs as one of the self-selected eCQMs.

TABLE IX.F.-06.: PREVIOUSLY FINALIZED ECQMS FOR ELIGIBLE HOSPITALS AND CAHS FOR THE CY 2024 REPORTING PERIOD AND SUBSEQUENT YEARS

Short Name	Measure Name	CBE No.
Safe Use of Opioids*	Safe Use of Opioids – Concurrent Prescribing	3316e
ePC-07/SMM**	Severe Obstetric Complications	N/A
ePC-02**	Cesarean Birth	N/A
HH-01	Hospital Harm – Severe Hypoglycemia	3503e
HH-02	Hospital Harm – Severe Hyperglycemia	3533e
HH-03	Hospital Harm – Opioid-Related Adverse Events	3501e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by End of Hospital Day Two	0438
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
GMCS	Global Malnutrition Composite Score	3592e

*Reporting the Safe Use of Opioids-Concurrent Prescribing eCQM is mandatory beginning with the CY 2022 reporting period.

**Reporting the Severe Obstetric Complications eCQM and Cesarean Birth eCQM are mandatory beginning with CY 2024 reporting period.

(2) eCQM Adoptions

As we stated in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38479), we intend to continue to align the eCQM reporting requirements for the Medicare Promoting Interoperability Program with similar requirements under the Hospital IQR Program to the extent feasible. Section 1886(n)(3)(B)(i)(I) of the Act provides, in part, that in selecting clinical quality measures for the Medicare Promoting Interoperability Program, the Secretary shall provide preference to such measures that have been selected for purposes of the Hospital IQR Program (section 1886(b)(3)(B)(viii) of the Act). In addition, section 1886(n)(3)(B)(iii) of the Act provides that in selecting clinical quality measures for the Medicare Promoting Interoperability Program, and in establishing the form and manner for reporting, the Secretary shall seek to avoid redundant or duplicative reporting with reporting otherwise required, including reporting under the Hospital IQR Program. To minimize redundant or duplicative reporting, while maintaining a set of meaningful clinical quality measures that continue to incentivize improvement in the quality of care provided to patients, and in alignment with proposals for the Hospital IQR Program eCQM measure set as discussed in section IX.C. of this final rule, we proposed to adopt three new eCQMs for the Medicare Promoting Interoperability Program, beginning with the CY 2025 reporting period (88 FR 27171 through 27173). Specifically, we proposed to add the following two eCQMs that address factors contributing to hospital harm to the Medicare Promoting Interoperability Program eCQM measure set on which hospitals can self-select to report, beginning with the CY 2025 reporting period: (1) the Hospital Harm—Pressure Injury eCQM (CBE #3498e); and (2) the Hospital Harm—Acute Kidney Injury eCQM (CBE #3713e). In addition, we proposed to add the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Inpatient) eCQM (CBE #3663e) to the Medicare Promoting Interoperability Program eCQM measure set on which hospitals can self-select to report, beginning with CY 2025 reporting period. We refer readers to the discussion of the proposals for the Hospital IQR Program in sections IX.C.5.a, IX.C.5.b., and IX.C.5.c. of the preamble of this final rule for more information about these three measures and our policy reasons for finalizing them. Table IX.F.–07. in this final rule summarizes previously finalized, and newly proposed, eCQMs in the Medicare Promoting Interoperability Program for the CY 2025 reporting period and subsequent years.

TABLE IX.F.-07.: ECQMS FOR ELIGIBLE HOSPITALS AND CAHS FOR THE CY 2025 REPORTING PERIOD AND SUBSEQUENT YEARS

Short Name	Measure Name	CBE No.
Safe Use of Opioids*	Safe Use of Opioids – Concurrent Prescribing	3316e
ePC-07/SMM**	Severe Obstetric Complications	N/A
ePC-02**	Cesarean Birth	N/A
HH-01	Hospital Harm – Severe Hypoglycemia	3503e
HH-02	Hospital Harm – Severe Hyperglycemia	3533e
HH-03	Hospital Harm – Opioid-Related Adverse Events	3501e
STK-02	Discharged on Antithrombotic Therapy	0435
STK-03	Anticoagulation Therapy for Atrial Fibrillation/Flutter	0436
STK-05	Antithrombotic Therapy by End of Hospital Day Two	0438
VTE-1	Venous Thromboembolism Prophylaxis	0371
VTE-2	Intensive Care Unit Venous Thromboembolism Prophylaxis	0372
GMCS	Global Malnutrition Composite Score	3592e
HH-PI ***	Hospital Harm – Pressure Injury	3498e
HH-AKI ***	Hospital Harm – Acute Kidney Injury	3713e
Excessive Radiation ***	Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level – Inpatient)	3663e

*Reporting the Safe Use of Opioids-Concurrent Prescribing eCQM is mandatory beginning with the CY 2022 reporting period.

**Reporting the Severe Obstetric Complications eCQM and Cesarean Birth eCQM are mandatory beginning with CY 2024 reporting period.

***Newly adopted in this final rule to add to the eCQM measure set, beginning with the CY 2025 reporting period.

We invited public comment on these proposals.

Comment and Response: We received many comments about the Hospital Harm—Pressure Injury eCQM (CBE #3498e). To continue alignment of eCQM policies across the Medicare Promoting Interoperability Program and the Hospital IQR Program, we refer readers to section IX.C.5.a. of this final rule for a detailed summary of the comments received and our responses thereto.

Comment and Response: We received many comments about the Hospital Harm—Acute Kidney Injury eCQM (CBE #3713e). To continue alignment of eCQM policies across the Medicare Promoting Interoperability Program and the Hospital IQR Program, we refer readers to section IX.C.5.b. of this final rule for a detailed summary of the comments received and our responses thereto.

Comment and Response: We received many comments about the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Inpatient) eCQM (CBE #3663e). To continue alignment of eCQM policies across the Medicare Promoting Interoperability Program and the Hospital IQR Program, we refer readers to section IX.C.5.c. of this final rule for a detailed summary of the comments received and our responses thereto.

Comment: A commenter commended CMS's continued effort to align quality measures across its public reporting programs.

Response: We thank the commenter for their support.

After consideration of the public comments we received, we are finalizing these policies as proposed for both the Medicare Promoting Interoperability Program and the Hospital IQR Program. We refer readers to the discussion of these same measures for the Hospital IQR Program in sections IX.C.5.a, IX.C.5.b, and IX.C.5.c. of the preamble of this final rule for more information about these finalized policies.

b. eCQM Reporting and Submission Requirements for the CY 2025 Reporting Period and Subsequent Years

Consistent with our goal to align the eCQM reporting periods and criteria in the Medicare Promoting Interoperability Program with the Hospital IQR Program, in the FY 2023 IPPS/LTCH PPS final rule, we finalized our policy to modify the eCQM reporting and submission requirements under the Medicare Promoting Interoperability Program for eligible hospitals and CAHs beginning with the CY 2024 reporting period (87 FR 49365 through 49367). Specifically, eligible hospitals and CAHs will be required to report four calendar quarters of data for each required eCQM: (1) Three self-selected eCQMs; (2) the Safe Use of Opioids—Concurrent Prescribing eCQM; (3) the Severe Obstetric Complications eCQM; and (4) the Cesarean Birth eCQM, for a total of six eCQMs, beginning with the CY 2024 reporting period and for subsequent years (87 FR 49365). Additionally, as finalized in the FY 2023 IPPS/LTCH PPS final rule, the Severe Obstetric Complications eCQM and the Cesarean Birth eCQM are available for eligible hospitals and CAHs to select as one of their three self-selected eCQMs for the CY 2023 reporting period, and then beginning with the CY 2024 reporting period and for subsequent years, all eligible hospitals and CAHs are required to report these two eCQMs.

We previously finalized our policy to eliminate attestation as a method for reporting CQMs for the Medicare Promoting Interoperability Program, and instead require all eligible hospitals and CAHS to submit their CQM data electronically through the reporting methods available for the Hospital IQR Program beginning with the reporting period in CY 2023. We did not propose any changes to the policy for CY 2024. For more information, we refer readers to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42601 through 42602).

After consideration of the public comments we received, we are finalizing our proposal to adopt the Hospital Harm—Pressure Injury eCQM, the Hospital Harm—Acute Kidney Injury eCQM, and the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Inpatient) eCQM, as measures

available for self-selection, in alignment with the Hospital IQR Program.

X. Other Provisions Included in This Final Rule

A. Medicare Program—Special Requirements for Rural Emergency Hospitals (REHs)

1. Background

This final rule would codify requirements for additional information that an eligible facility would be required to submit when applying for enrollment as a Rural Emergency Hospital (REH), as specified in the Consolidated Appropriations Act (CAA), 2021. Section 125 of Division CC of the CAA was signed into law on December 27, 2020 and establishes REHs as a new Medicare provider that will receive Medicare payment for services furnished on or after January 1, 2023. Section 125 of the CAA added section 1861(kkk) to the Act, which sets forth the requirements for REHs. The establishment of REHs as a Medicare provider is intended to promote equity in health care for those living in rural communities by facilitating access to needed services, such as emergency, urgent, and observation care services, as well as other additional outpatient medical and health services that an REH might elect to provide.

In the November 23, 2022 **Federal Register** (87 FR 71748), we published a final rule with comment period titled ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID–19'' (*https://www.federalregister.gov/d/2022-23918*). Included as part of this rule were the provider enrollment procedures for REHs, including that REHs: (1) must comply with all applicable provider enrollment provisions in 42 CFR part 424, subpart P, in order to enroll in Medicare; and (2) must submit a Form CMS–855A change of information application (rather than an initial enrollment application) to convert to an REH. These enrollment requirements became effective on January 1, 2023.

On January 26, 2023, CMS released QSO–23–07–REH (*https://www.cms.gov/files/document/qso-23-07-reh.pdf*), which provided the additional information requirements specified by section 1861(kkk)(4)(A)(i)-(iv) of the Act as well as guidance regarding the process by which eligible facilities must submit the additional information detailed here. We proposed to codify these additional information requirements in this rule, and we have included a proposed Information Collection Requirement (ICR) in section B.10. of this rule for solicitation of public comments and for OMB approval of this ICR. We note that the processing of the REH enrollment applications (as those requirements were finalized in the November 23, 2022, rule) is not dependent on the finalization of the provisions of this final rule.

We also proposed to update certain definitions in the survey and certification regulations to address REHs. Specifically, we proposed the definition of a ''Provider of services or provider'' at 42 CFR 488.1 to include REHs as well as add REHs to the other applicable provisions contained in 42 CFR parts 488 and 489: §§ 488.2, ''Statutory basis''; 488.18, ''Documentation of findings''; and 489.102, ''Requirements for providers.''

2. Proposed Revision to the Definition of ''Provider of Services or Provider'' (§ 488.1)

We proposed to revise the definition of ''Provider of services or provider'' at § 488.1. The proposed new definition of ''provider of services or provider'' would state that it refers to a hospital, critical access hospital, rural emergency hospital, skilled nursing facility, nursing facility, home health agency, hospice, comprehensive outpatient rehabilitation facility, or a clinic, rehabilitation agency or public health agency that furnishes outpatient physical therapy or speech pathology services.

3. Proposed Addition to the Statutory Basis for Part 488 (§ 488.2)

We proposed to add the statutory basis for REHs to the Statutory Basis section of part 488 at § 488.2. The proposed revision would add section 1861(kkk) of the Act, which sets forth the statutory basis for REHs.

4. Proposed Addition to the Section ''Documentation of Findings'' (§ 488.18(d))

We proposed to add REHs to the provider-types subject to the requirement at § 488.18(d). The proposed revision at § 488.18(d) would specify that if the State agency receives information to the effect that a hospital, critical access hospital (as defined in section 1861(mm)(1) of the Act) or a rural emergency hospital (as defined in section 1861(kkk)(2) of the Act) has violated § 489.24 (regarding compliance with EMTALA provisions), the State agency must report the information to CMS promptly.

We also announce in this final rule that OMB approved information collection requirements in § 488.18(d) that were published at 59 FR 32120, June 22, 1994, on January 30, 1995.

5. Proposed Special Requirements for REHs (§ 488.70)

We proposed to add new regulation text at § 488.70, so that an eligible facility that submits an application for enrollment as an REH under section 1866(j) of the Act must also submit additional information as specified in this final rule. In accordance with section 1861(kkk)(4)(A)(i) through (iv) of the Act, we specifically propose to add § 488.70(a) through (d), so that the provider must include an action plan containing: (1) A plan for initiating REH services (as those services are defined in 42 CFR 485.502, including mandatory provision of emergency department services and observation care); (2) a detailed transition plan that lists the specific services that the provider will retain, modify, add, and discontinue as an REH; (3) a detailed description of other outpatient medical and health services that it intends to furnish on an outpatient basis as an REH; and (4) information regarding how the provider intends to use the additional facility payment provided under section 1834(x)(2) of the Act, including a description of the services that the additional facility payment would be supporting, such as the operation and maintenance of the facility and the furnishing of covered services (for example, telehealth services and ambulance services). Although section 1861(kkk)(4)(A)(iv) of the Act gives us the authority to require such additional information as the Secretary may deem necessary, we did not propose any additional information submissions at this time.

6. Proposed Requirements for Providers (§ 489.102) (Advance Directives)

We proposed to add REHs to the applicable provisions at § 489.102(a) and add a new § 489.102(b)(5) to also include a provision for REHs.

Comment: We received comments on the proposed Special Requirements for Rural Emergency Hospitals at § 488.70 that expressed appreciation to CMS for providing additional clarity in the proposed rule on how hospitals might become REHs. However, one commenter was concerned that these additional regulations could create barriers and burdens on rural hospitals seeking to

become REHs. The commenter recognized the value of having a detailed action plan, but noted that additional or burdensome paperwork could impact a rural hospital's ability to transition to an REH. The commenter requested that CMS implement the final regulation with an understanding of the challenges rural hospitals and communities face while maintaining standards for safety and high-quality care. The commenter stated that CMS must balance the need for oversight while minimizing the administrative burden for rural hospitals with limited capacities.

Response: We appreciate the comments received on these requirements and recognize the need to minimize the burden of unnecessary paperwork requirements for rural hospitals and CAHs applying to become REHs. However, the proposed requirements at § 488.70 contain only those provisions that are required by statute. Our guidance for the requirements at § 488.70 (QSO–23–07–REH, issued January 26, 2023) provides details for rural hospitals and CAHs considering conversion to an REH and also provides flexibility in the process by allowing applicants to use either the model template attached to our memo or the facility's own letterhead with a description of the action plan and additional information as required by the statute at section 1861(kkk) of the Act (*https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/policy-and-memos-states/guidance-rural-emergency-hospital-provisions-conversion-process-and-conditions-participation*).

Comment: A commenter thanked CMS for implementing Congressional intent in creating these hospitals and noted that they serve an important role in our health care system. The commenter also agreed with CMS' proposed change to the definition of ''provider of services'' at § 488.1 to now include REHs. The commenter also requested that CMS ensure that the submission of the action plan and additional information require adequate nurse staffing at REHs. Specifically, the commenter asked for CMS to ensure that appropriate nurse staffing is included in sections regarding transition plans for services maintained, added, or removed during the transition to an REH and that nursing is included in a detailed description of services that the REH intends to furnish.

Response: We appreciate the commenter's support of the proposed changes and thank them for their recommendations regarding nurse staffing for REHs. Our guidance (QSO–23–07–REH) for these requirements specifically state that the action plan should include details regarding staffing provisions and the number and type of qualified staff for the provision of REH services. We expect that these staffing details would include the REH's plans for nursing staffing as well as those for other qualified staff providing services to patients of the REH.

Comment: We received comments which expressed support for the special requirements for REHs and thanked CMS for codifying guidance on documentation for hospitals' REH applications and enrollment procedures. One commenter also encouraged CMS to incentivize maternity care in REHs to expand access to care for this critical service and improve maternal health outcomes.

Response: We appreciate the commenter's expressed concern regarding access to maternal health services in rural communities and the improvement of maternal health outcomes. Section 1861(kkk)(1)(A)(ii) of the Act allows REHs to provide additional outpatient medical and health services which may include maternal health services that are aligned with the health needs of the community served by the REH as required by § 485.524(a). This aligns with a priority of the Biden-Harris Administration to improve access to maternal health care services. Therefore, we expect that REHs will provide various outpatient services including, but not limited to services such as, low-risk labor and delivery supported by any emergency surgical procedures necessary if identified by a health needs assessment of their community and in accordance with the CoPs for additional outpatient medical and health services.

Comment: One commenter requests CMS clarification that a hospital may qualify for Rural Emergency Hospital status if the number of actual beds in use on December 27, 2020, was 50 beds or less as many hospitals report beds based on the licensed number of beds.

Response: We thank the commenter for expressing the need for clarification as it relates to the methodology used to determine if a rural hospital with not more than 50 beds meets the bed count requirement to seek REH designation. The final rule titled ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID–19'' (*https://www.federalregister.gov/documents/2022/11/23/2022-23918/medicare-program-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center-pay*) finalized the methodology used to determine if a rural hospital with not more than 50 beds meets the bed count requirement to seek REH designation. Based on the methodology finalized, this will be determined by calculating the number of available bed days during the most recent cost reporting period divided by the number of days in the most recent cost reporting period. We use this methodology to determine if Medicare-dependent small rural hospitals meet the required bed count for that program. We believe this is an appropriate methodology for determining if a rural hospital meets the bed count requirement to seek REH designation, as this is a known and existing methodology for small rural hospitals seeking to determine bed count for eligibility in Medicare programs.

After consideration of the public comments we received, we are finalizing the requirements as proposed.

B. Physician Self-Referral Law: Physician-Owned Hospitals

1. Background

a. Statutory and Regulatory History: General

Section 1877 of the Act, also known as the physician self-referral law: (1) prohibits a physician from making referrals for certain designated health services payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless the requirements of an applicable exception are satisfied; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third-party payor) for any improperly referred designated health services. A financial relationship may be an ownership or investment interest in the entity or a compensation arrangement with the entity. The statute establishes a number of specific exceptions and grants the Secretary of the Department of Health and Human Services (the Secretary) the authority to create regulatory exceptions for financial relationships that do not pose a risk of program or patient abuse. Section 1903(s) of the Act extends aspects of the physician self-referral law's prohibitions to Medicaid. (For additional information about section 1903(s) of the Act, see 66 FR 857 through 858.)

The following discussion provides a chronology of our more significant and comprehensive rulemakings; it is not an exhaustive list of all rulemakings related to the physician self-referral law. After the passage of section 1877 of the Act, we proposed rulemakings in 1992 (related only to referrals for clinical laboratory services) (57 FR 8588) (the 1992 proposed rule) and 1998 (addressing referrals for all designated health services) (63 FR 1659) (the 1998 proposed rule). We finalized the proposals from the 1992 proposed rule in 1995 (60 FR 41914) (the 1995 final rule) and issued final rules following the 1998 proposed rule in three stages. The first final rulemaking (Phase I) was a final rule with comment period that appeared in the January 4, 2001 **Federal Register** (66 FR 856). The second final rulemaking (Phase II) was an interim final rule with comment period that appeared in the March 26, 2004 **Federal Register** (69 FR 16054). Due to a printing error, a portion of the Phase II preamble was omitted from the March 26, 2004 **Federal Register** publication. That portion of the preamble, which addressed reporting requirements and sanctions, appeared in the April 6, 2004 **Federal Register** (69 FR 17933). The third final rulemaking (Phase III) was a final rule that appeared in the September 5, 2007 **Federal Register** (72 FR 51012).

After passage of the Patient Protection and Affordable Care Act of 2010 (Pub. L. 111–148) (the Affordable Care Act), we issued final regulations in the CY 2011 PFS final rule with comment period that codified a disclosure requirement established by the Affordable Care Act for the in-office ancillary services exception (75 FR 73443). In the CY 2016 PFS final rule, we issued regulations to reduce burden and facilitate compliance (80 FR 71300 through 71341). In that rulemaking, we established two new exceptions to the physician self-referral law, clarified certain provisions of the physician self-referral regulations, updated regulations to reflect changes in terminology, and revised definitions related to hospitals with physician ownership or investment. A final rule entitled ''Modernizing and Clarifying the Physician Self-Referral Regulations'' (the MCR final rule) appeared in the December 2, 2020 **Federal Register** (85 FR 77492) and established three new exceptions to the physician self-referral law applicable to compensation arrangements that qualify as ''value-based arrangements,'' established exceptions for limited remuneration to a physician and the donation of cybersecurity technology and services, and revised or clarified several existing exceptions. The MCR final rule also provided guidance and updated or established regulations related to the fundamental terminology used in many provisions of the physician self-referral law. Most notably, we defined the term ''commercially reasonable'' in regulation, established an objective test for evaluating whether compensation is considered to take into account the volume or value of referrals or other business generated between the parties, and revised the definitions of ''fair market value'' and ''general market value.'' The MCR final rule also revised the definition of ''indirect compensation arrangement,'' which was further revised in the CY 2022 PFS final rule (86 FR 65343).

b. Statutory and Regulatory Background: Physician-Owned Hospitals

(1) Exceptions to the Physician Self-Referral Law for Ownership or Investment in a Hospital

Section 1877(d) of the Act sets forth exceptions related to ownership or investment interests held by a physician (or an immediate family member of a physician) in an entity that furnishes designated health services. Section 1877(d)(2) of the Act provides an exception for ownership or investment interests in rural providers (the ''rural provider exception''). To use the rural provider exception, an entity must furnish substantially all of the designated health services that it furnishes to residents of a rural area (as defined in section 1886(d)(2) of the Act). To satisfy the requirements of the rural provider exception, the designated health services must be furnished in a rural area and, in the case where the entity is a hospital, the hospital must meet the requirements of section 1877(i)(1) of the Act no later than September 23, 2011. Section 1877(d)(3) of the Act provides an exception for ownership or investment interests in a hospital located outside of Puerto Rico (the ''whole hospital exception''). To satisfy the requirements of the whole hospital exception, the referring physician must be authorized to perform services at the hospital, the ownership or investment interest must be in the hospital itself (and not merely in a subdivision of the hospital), and the hospital must meet the requirements of section 1877(i)(1) of the Act no later than September 23, 2011. These exceptions are codified in our regulations at § 411.356(c)(1) and (3), respectively.

In a series of reports reviewing the growth in specialty hospitals that are largely for-profit and owned, in part, by physicians, the United States Government Accountability Office (GAO) (formerly known as the United States General Accounting Office) found that these hospitals were much less likely to have emergency departments, treat smaller percentages of Medicaid patients, and derive a smaller share of their revenues from inpatient services.[926] Following the issuance of these reports, the Congress held hearings and began to consider policies to limit the growth of these facilities.[927] Section 6001(a) of the Affordable Care Act effectively eliminated the exceptions for physician ownership or investment in hospitals, although hospitals with physician ownership or investment and a Medicare provider agreement on December 31, 2010, are ''grandfathered'' to continue using the rural provider exception, if applicable, and the whole hospital exception.

(2) Prohibition on Facility Expansion

Section 6001(a)(3) of the Affordable Care Act amended the rural provider exception and the whole hospital exception to provide that a hospital with physician ownership or investment may not increase the number of operating rooms, procedure rooms, and beds beyond that for which the hospital was licensed on March 23, 2010 (or, in the case of a hospital that did not have a Medicare provider agreement in effect as of this date, but did have a provider agreement in effect on December 31, 2010, the effective date of such provider agreement). However, the Secretary may grant an exception from the prohibition on facility expansion.

Section 6001(a)(3) of the Affordable Care Act added new section 1877(i)(3)(A)(i) of the Act, which required the Secretary to establish and implement a process under which a hospital that is an ''applicable hospital'' may apply for an exception from the prohibition on expansion of facility capacity. Section 1106 of the Health Care and Education Reconciliation Act

[926] For example, GAO, Geographic Location, Services Provided, and Financial Performance, *https://www.gao.gov/assets/gao-04-167-highlights.pdf*, and GAO Operational and Clinical Changes Largely Unaffected by Presence of Competing Specialty Hospitals, *https://www.gao.gov/assets/gao-06-520-highlights.pdf*.

[927] For example, Grassley, Baucus Introduce Bill to Rein In Physician-owned Specialty Hospitals (*https://www.finance.senate.gov/release/grassley-baucus-introduce-bill-to-rein-in-physician-owned-specialty-hospitals*) and Bristol N. US Congress scrutinises hospitals owned by doctors after patient's death. BMJ. 2006 Feb 25;332(7539):442. doi: 10.1136/bmj.332.7539.442-c. PMID: 16497744; PMCID: PMC1382571.

of 2010 (Pub. L. 111–152) (HCERA) amended section 1877(i)(3)(A)(i) of the Act to require the Secretary to establish and implement such a process for hospitals that meet the criteria for an applicable hospital or a ''high Medicaid facility.'' (We refer herein to the Affordable Care Act and HCERA together as the Affordable Care Act.) These terms are defined at sections 1877(i)(3)(E) and (F) of the Act, respectively. The requirements for an applicable hospital are set forth at existing § 411.362(c)(2) and the requirements for a high Medicaid facility are set forth at existing § 411.362(c)(3). In the CY 2012 OPPS/ASC final rule, we issued regulations setting forth the process for a hospital to request an exception from the prohibition on facility expansion (the expansion exception process) and related definitions at existing § 411.362(c) and (a), respectively (76 FR 74517 through 74527). We revised these regulations in the CY 2015 OPPS/ASC final rule to permit a requesting hospital to use additional data sources to show that it meets the criteria for an applicable hospital or high Medicaid facility and to clarify certain aspects of the expansion exception process (79 FR 66987 through 66997).

Section 1877(i)(3)(B) of the Act provides that the expansion exception process shall permit an applicable hospital to apply for an exception from the prohibition on expansion of facility capacity up to once every 2 years. In the CY 2012 OPPS/ASC final rule, we extended this provision to high Medicaid facilities using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(1) of the Act (76 FR 74525). We stated that, although the statute provides that an applicable hospital may request an exception up to once every 2 years, we believe that providing a high Medicaid facility the opportunity to request an exception once every 2 years (while also limiting its total growth) balances the Congress' intent to prohibit expansion of physician-owned hospitals with the purpose of the expansion exception process (76 FR 74524). Citing alignment with the Patients over Paperwork initiative—a former initiative launched by CMS in 2017 to evaluate and streamline regulations with a goal to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience—in the CY 2021 OPPS/ASC final rule, we reversed this temporal program integrity requirement for high Medicaid facilities, noting that the plain language of the statute does not impose the same limitations on the expansion of high Medicaid facilities as it does on the expansion of applicable hospitals (85 FR 86257).

Section 1877(i)(3)(C)(ii) of the Act provides that the Secretary shall not permit an increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed to the extent such increase would result in the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed exceeding 200 percent of the baseline number of operating rooms, procedure rooms, and beds of the applicable hospital. In the CY 2012 OPPS/ASC final rule, using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we adopted a parallel limit in the increase in the number of operating rooms, procedure rooms, and beds for which a high Medicaid facility may request an exception from the prohibition on expansion of facility capacity (76 FR 74524). Citing alignment with the Patients over Paperwork initiative, in the CY 2021 OPPS/ASC final rule, we reversed this program integrity requirement for high Medicaid facilities, noting that the plain language of the statute does not impose the same limitations on the expansion of high Medicaid facilities as it does on the expansion of applicable hospitals (85 FR 86257).

Section 1877(i)(3)(D) of the Act provides that any increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed may occur only in facilities on the main campus of the applicable hospital. In the CY 2012 OPPS/ASC final rule, using our rulemaking authority under sections 1871 and 1877(i)(3)(A)(i) of the Act, we extended this limitation on the location of expansion facility capacity to high Medicaid facilities, explaining that we believe that applying the same limitation to applicable hospitals and high Medicaid facilities will result in an efficient and consistent process (76 FR 74524). Citing alignment with the Patients over Paperwork initiative, in the CY 2021 OPPS/ASC final rule, we reversed this program integrity requirement for high Medicaid facilities, noting that the plain language of the statute does not impose the same limitations on the expansion of high Medicaid facilities as it does on the expansion of applicable hospitals (85 FR 86257).

2. Proposals

a. Process for Requesting an Exception From the Prohibition on Expansion of Facility Capacity

To satisfy the requirements of the rural provider exception or the whole hospital exception, a hospital must comply with the requirements of section 1877(i) of the Act and existing § 411.362 of our regulations no later than September 23, 2011. Thus, the physician self-referral law prohibits a referral made on or after September 23, 2011, by a physician who has (or whose immediate family member has) an ownership or investment interest in the hospital if the number of operating rooms, procedure rooms, and beds for which the hospital is licensed (referred to in this final rule as ''facility capacity'') at the time of the referral is greater than its baseline number of operating rooms, procedure rooms, and beds (as defined at existing § 411.362(a) and referred to in this final rule as ''baseline facility capacity''), unless the hospital has been granted an exception from the prohibition on expansion of facility capacity (referred to in this final rule as an ''expansion exception''). The regulations at existing § 411.362(c) set forth the current expansion exception process.

As stated in the proposed rule, we recently reviewed the expansion exception process, including a fresh examination of the statutory language and certain legislative history of the Affordable Care Act. Section 1877(i)(3)(A)(i) of the Act requires the establishment of a process under which an applicable hospital or high Medicaid facility may *apply* for an exception from the prohibition on expansion of facility capacity, and section 1877(i)(3)(C)(i) of the Act imposes certain program integrity restrictions on a hospital *granted* an exception under the process (emphasis added). The Secretary's authority to grant an expansion exception is limited by section 1877(i)(3)(C)(ii) of the Act, which states that the Secretary shall not *permit* an increase in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed that results in a hospital's facility capacity exceeding 200 percent of its baseline facility capacity (emphasis added). In addition, section 1877(i)(3)(H) of the Act requires the Secretary to publish in the **Federal Register** the final *decision* with respect to a hospital's *application* (emphasis added). We interpret this statutory language to mean that, to request an expansion exception with respect to which CMS may issue a decision, a hospital must first establish

that it meets the criteria for an applicable hospital or a high Medicaid facility. We further interpret this statutory language to mean that CMS has discretion to approve or deny a request for an expansion exception even if the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility. Put another way, it is our position that, under section 1877(i)(3)(A)(i) of the Act, meeting the criteria for an applicable hospital or a high Medicaid facility merely makes a hospital eligible to request an expansion exception, but it does not guarantee approval of such a request. We note that, for purposes of interpreting the statutory provisions, codification in our regulations, and discussion in our rulemakings, we use the term ''request'' in the same way as ''apply'' and ''application,'' and use the term ''approve'' in the same way as ''grant.'' (See 76 FR 74517 (when the statute refers to an ''application,'' we use the term ''request'') and 79 FR 64801 and 64802 (''II. Exception Approval Process'' and ''decision to approve'' a request, respectively).)

Section 1877(i)(3)(A)(ii) of the Act requires that the expansion exception process shall provide for community input with respect to an expansion exception request. We have always interpreted the requirement to provide for community input ''with respect to [an] application'' to require CMS to permit *any* input with respect to the expansion exception request—not just input related to whether the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility. In the CY 2012 OPPS/ASC proposed and final rules, we noted examples of community input, such as documentation demonstrating that the requesting hospital does not satisfy one or more of the data criteria or that the requesting hospital discriminates against beneficiaries of Federal health programs; however, we stated that these are examples only and that we do not restrict the type of community input that may be submitted (76 FR 42352 and 74522). We believe that, if the Congress did not intend for the Secretary to have discretion to approve or deny an expansion exception request from a hospital that meets the criteria for an applicable hospital or a high Medicaid facility, the statutorily required community input would be limited to whether the hospital met such criteria. The plain language of the statute is not so limited.

To clarify our interpretation of the Secretary's authority, ensure that approval of a request to expand a hospital's facility capacity occurs only in appropriate circumstances, and facilitate compliance with the process for requesting an expansion exception, we proposed to modify and clarify our regulations at existing § 411.362(c). Specifically, we proposed to revise the regulations that set forth the expansion exception process and separate them from the requirements that a hospital must satisfy under the rural provider exception and the whole hospital exception. We proposed to renumber existing § 411.362(c), as well as certain related definitions in existing § 411.362(a), at new § 411.363, noting that having a separate regulation dedicated to the expansion exception process could provide greater transparency and facilitate compliance with the expansion exception process. To provide clarity and transparency for hospitals that wish to request an expansion exception and other interested parties, we proposed to revise our regulations to clarify that CMS will only consider expansion exception requests from eligible hospitals, clarify the data and information that must be included in an expansion exception request, identify factors that CMS will consider when making a decision on an expansion exception request, and revise certain aspects of the process for requesting an expansion exception.

(1) Relevant Definitions

We proposed to include at new § 411.363(a) definitions for the terms ''baseline number of operating rooms, procedure rooms, and beds,'' ''external data source,'' ''main campus of the hospital,'' and ''procedure room'' for purposes of the expansion exception process set forth in proposed § 411.363. These definitions are currently included in existing § 411.362(a). Because the terms ''baseline number of operating rooms, procedure rooms, and beds,'' ''external data source,'' and ''main campus of the hospital'' are not used in § 411.362 as it would be revised, we proposed to remove their definitions from § 411.362(a). Because the term ''procedure room'' is used in both existing § 411.362 and proposed § 411.363, we proposed to define the term ''procedure room,'' for purposes of new § 411.363(a) to have the meaning set forth at existing § 411.362(a).

(2) CMS Consideration of an Expansion Exception Request and Publication in the **Federal Register**

We proposed to revise § 411.362(c)(1) and renumber it at § 411.363(b) to clarify that CMS will not consider an expansion exception request from a hospital that is not eligible to request an expansion exception. To be eligible to request an expansion exception, a hospital must first meet the criteria as an applicable hospital or a high Medicaid facility, which we proposed to renumber at § 411.363(c) and (d), respectively. We proposed certain clarifying and other revisions to these regulations, which are discussed in sections X.B.2.a.(4). and (6). of the preamble in this final rule.

To facilitate the proposed reinstatement of the program integrity restriction regarding the maximum aggregate expansion of a hospital, we proposed at § 411.363(b)(2)(i) that CMS would not consider an expansion exception request from a hospital for which CMS had previously approved an expansion exception that would allow the hospital's facility capacity to reach 200 percent of its baseline facility capacity if the full expansion is utilized, even if the hospital met the criteria for an applicable hospital or a high Medicaid facility. We also proposed to apply this eligibility restriction to any hospital requesting an expansion exception. We illustrated this proposal with the following example. A hospital with a baseline facility capacity of 100 that was granted an expansion exception for 100 additional operating rooms, procedure rooms, and beds would have a potential facility capacity of 200, or 200 percent of its baseline number of operating rooms, procedure rooms, and beds. Consequently, the hospital would not be eligible to request another expansion exception. A hospital with a baseline facility capacity of 100 that was granted an expansion exception for 75 additional operating rooms, procedure rooms, and beds could request to further expand its facility capacity by no more than an additional 25 operating rooms, procedure rooms, and beds, because CMS would be prohibited under section 1877(i)(3)(C)(ii) of the Act from approving the subsequent expansion exception request if it would allow the hospital's aggregate facility capacity to exceed 200 percent of its baseline facility capacity.

We proposed to implement section 1877(i)(3)(B) of the Act at proposed § 411.363(b)(2)(ii), which permits an applicable hospital to request an expansion exception up to once every 2 years, and apply the limitation to *any* hospital requesting an expansion exception. In the proposed rule we noted that, after receiving no comments on our proposals in the CY 2012 OPPS/ASC final rule to allow an applicable hospital *or high Medicaid facility* to request an expansion exception up to once every 2 years from the date of a CMS decision on the hospital's most

recent request, using our authority in sections 1871 and 1877 of the Act, we implemented section 1877(i)(3)(B) of the Act at existing § 411.362(c)(1) (76 FR 74525). (In that final rule, we stated that we would consider the date of a CMS decision to be the date of the decision letter sent to the requesting party (76 FR 74525).) However, as we noted in the proposed rule, in the CY 2021 OPPS/ASC final rule, we reversed the regulatory extension of statutory program integrity restrictions—including the restriction on frequency of expansion exception requests—for hospitals that meet the criteria for a high Medicaid facility (85 FR 86256). Therefore, since January 1, 2021, a high Medicaid facility has been permitted to request an expansion exception at any time, provided that it has not submitted another request for an expansion exception for which CMS has not issued a decision. In the proposed rule, we also noted that, even though we reversed the regulatory extension of the restriction on the frequency of expansion exception requests for hospitals that meet the criteria for a high Medicaid facility, in the CY 2021 OPPS/ASC final rule, we nonetheless limited a high Medicaid facility to applying for an expansion exception only when it does not have another expansion exception request pending with CMS. We reiterated that we did so to preserve CMS resources and continue to maintain an orderly and efficient expansion exception process (85 FR 86256), noting that, historically, CMS has worked with requesting hospitals for several weeks or months following the initial submission to complete the request so that CMS can publish notice of the request in the **Federal Register**. Depending on the amount of time from submission to publication of the notice of the request in the **Federal Register**, and given the timeframes under the expansion exception process for deeming a request complete, reviewing the request, and publishing CMS's decision regarding a request, it could take well over a year to receive a CMS decision on an expansion exception request. We emphasized that we continue to believe that permitting a hospital to submit a subsequent request before CMS has made a decision on an earlier request would be an improper use of agency resources, could result in confusion to interested parties that wish to provide community input, and would unnecessarily complicate the expansion exception process. Therefore, we proposed at § 411.363(b)(2)(ii) that CMS would not consider an expansion exception request from a hospital—even if it meets the criteria for an applicable hospital or a high Medicaid facility—if it has been less than 2 years from the date of the most recent decision by CMS approving or denying the hospital's most recent (prior) request for an expansion exception.

Under the proposed regulations, CMS would consider an expansion exception request submitted by a hospital that meets the criteria for an applicable hospital or a high Medicaid facility and is otherwise eligible to request the expansion exception, provided that the request includes all information required under proposed § 411.363(e). In the proposed rule we stated that, in processing an expansion exception request, we would first determine whether the requesting hospital is eligible to request the expansion exception (that is, whether the hospital meets the criteria for an applicable hospital or a high Medicaid facility). This would include providing an opportunity for community input regarding whether the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility (depending on the specific request). If the hospital meets the criteria for an applicable hospital or a high Medicaid facility, and is not otherwise precluded from making an expansion exception request under proposed § 411.363(b)(2), we would then decide whether to approve or deny the request. This would include providing an opportunity for community input regarding, among other things, the factors that CMS will consider in deciding whether to approve or deny the hospital's expansion exception request. Because community input would be relevant to both the determination that a requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility and our decision whether to approve or deny the expansion exception request, we stated that we anticipate publication in the **Federal Register** of any expansion exception request that a requesting hospital has not elected to withdraw following its initial submission, provided that the hospital is otherwise eligible to request an expansion exception. We noted that, in the **Federal Register** notice, we would seek community input on both whether the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility (depending on the specific request) and whether CMS should approve or deny the request. We believe this approach would be the most efficient use of CMS and governmental resources, as well as eliminate the duplication of efforts by individuals and entities in the community that wish to provide input on a hospital's expansion exception request.

In the proposed rule, we stated that, following publication of the notice of the expansion exception request in the **Federal Register**, receipt of community input, if any, and receipt of the requesting hospital's rebuttal notice, if any, CMS would first determine whether the hospital meets the criteria for an applicable hospital or a high Medicaid facility (depending on the specific request). We proposed to codify this part of the process at § 411.363(h). If CMS determines that the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility, CMS would then decide whether to approve or deny the expansion exception request. As previously explained, it is our position that the authority granted to the Secretary in section 1877(i) of the Act provides CMS discretion to approve or deny an expansion exception request. In making its decision whether to approve or deny an expansion exception request, CMS would consider data and information provided by the hospital in its request, included in the community input, if any, and provided by the hospital in its rebuttal statement, if any. CMS may also consider any other data and information relevant to its decision. We proposed to codify this part of the process at § 411.363(i)(1). Other data and information relevant to CMS' decision may include, but is not limited to, data and information that is publicly available, provided to CMS by the requesting hospital or interested parties in other contexts, or provided by CMS' law enforcement partners and other government agencies (whether publicly available or not). For example, CMS may use the internet or other sources to perform an environmental scan of the geographic area of the country in which the requesting hospital is located, identify trends, recent events, or planned events (such as expected population growth or new employers entering the local market), or review information related to the quality of care at the requesting hospital and other hospitals in its community.

We also proposed a nonsubstantive revision to the introductory language at existing § 411.362(c)(2) and (3). The existing regulations state the criteria that an applicable hospital or a high Medicaid facility, respectively, must satisfy. To conform to our regulations in 42 CFR part 411, subpart J more closely, we proposed to use the word ''meets'' in place of ''satisfies'' in the introductory language of these regulations, which we

proposed would be renumbered at § 411.363(c) and (d).

(3) CMS Decision To Approve or Deny an Expansion Exception Request

In proposed § 411.363(i)(2), we identified factors that CMS would always consider when deciding whether to approve or deny an expansion exception request. As proposed, these factors include: (1) the specialty (for example, maternity, psychiatric, or substance use disorder care) of the hospital or the services furnished by or to be furnished by the hospital if CMS approves the request; (2) program integrity or quality of care concerns related to the hospital; (3) whether the hospital has a need for additional operating rooms, procedure rooms, or beds; and (4) whether there is a need for additional operating rooms, procedure rooms, or beds in the county in which the main campus of the hospital is located, in any county in which the hospital provides inpatient or outpatient hospital services as of the date the hospital submits the expansion exception request, or in any county in which the hospital plans to provide inpatient or outpatient hospital services if CMS approves the request. We stated that we believe these factors are especially relevant to CMS' decision whether to approve or deny an expansion exception request; however, proposed § 411.363(i)(2) did not limit CMS to the enumerated factors in making its decision. By way of example, we stated that CMS may also consider any other factors it deems relevant to its decision to approve or deny an expansion exception request, such as program integrity or quality concerns related to other hospitals in the requesting hospital's community or their ability to serve a growing patient population in the community. As explained in section X.B.2.A.(8). of this final rule, we are not finalizing our proposal to require information regarding how or where a requesting hospital would use approved expansion facility capacity if its request is approved. Therefore, we are not finalizing our proposal to include as a factor for our consideration of an expansion exception request whether there is a need for additional operating rooms, procedure rooms, or beds in any county in which the hospital plans to provide inpatient or outpatient hospital services if CMS approves the request. In the proposed rule, we noted that expansion exception requests are now and would continue to be assessed on a case-by-case basis, and CMS would base its decision to approve or deny an expansion exception request on the totality of the information available to the agency. Thus, decisions to approve or deny requests from hospitals that appear similar with respect to overall capacity to serve Medicaid and other underserved populations could differ based on factors such as planned expansion of needed psychiatric services instead of general acute care services or whether the requesting hospital seeks an expansion exception to replace operating rooms, procedure rooms, or beds that it has relocated (or intends to relocate) from its main campus to other areas in need of services.

As required in section 1877(i)(3)(H) of the Act, no later than 60 days after receiving a complete request, CMS will publish in the **Federal Register** its final decision with respect to a hospital's expansion exception request. This requirement is codified in our regulations at existing § 411.362(c)(7), which we proposed to revise for clarity and renumber at § 411.363(k). In the proposed rule, we noted that, if CMS determines that the requesting hospital does not meet the criteria for an applicable hospital or a high Medicaid facility (depending on the specific request), under proposed § 411.363(b)(1), the hospital would not be eligible to request the expansion exception and CMS would not further consider the request. In that case, the required **Federal Register** notice would address only the determination that the requesting hospital does not meet the criteria for an applicable hospital or a high Medicaid facility. We noted further that, if CMS determines that the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility, as required by statute, CMS must decide whether to approve or deny the expansion exception request and publish its decision in the **Federal Register**. In that case, the required **Federal Register** notice would address both CMS' determination that the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility (depending on the specific request) and its decision to approve or deny the request.

Section 1877(i)(3)(I) of the Act and our regulation at existing § 411.362(c)(8) state that there shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the expansion exception process (including the establishment of such process). We stated that we interpret the statute to mean that neither the process itself nor CMS' decision whether to approve or deny an expansion exception request are subject to administrative or judicial review. Therefore, we proposed to revise the regulation to expressly state that the limitation on review of the expansion exception process under § 411.363 includes any CMS determination or decision under the process, noting that this would include determinations regarding whether a hospital meets the criteria for an applicable hospital or a high Medicaid facility and decisions regarding whether to approve or deny a hospital's request. We also proposed to renumber the regulation at § 411.363(l).

(4) Required Information From a Requesting Hospital

Existing § 411.362(c)(4)(ii) sets forth information that must be included in an expansion exception request for CMS to consider the request. We proposed to revise the introductory language of this regulation and renumber it at § 411.363(e)(2) to clarify that inclusion of the required information is a prerequisite to consideration of the request by CMS. We did not propose any revisions to existing § 411.362(c)(4)(ii)(A), which requires that an expansion exception request must include the name, address, National Provider Identification number(s) (NPI), Tax Identification Number(s) (TIN), and CMS Certification Number(s) (CCN) of the hospital requesting the expansion exception; however, we proposed to renumber this regulation at § 411.363(e)(2)(i). We proposed to revise existing § 411.362(c)(4)(ii)(C), which requires that an expansion exception request must include the name, title, address, and daytime telephone number of a contact person who will be available to discuss the request with CMS on behalf of the requesting hospital, to clarify that the request must include an address for receipt of hard copy mail by the contact person. We also proposed to require an electronic mail address for correspondence with the contact person. Finally, we proposed to renumber this regulation at § 411.363(e)(2)(iii).

We proposed to revise existing § 411.362(c)(4)(ii)(B) and renumber this regulation at § 411.363(e)(2)(ii). As proposed, an expansion exception request must include the name of the county in which the main campus of the requesting hospital is located and the names of any counties in which the hospital provides inpatient or outpatient hospital services or plans to provide inpatient or outpatient hospital services if CMS approves the request. We stated that it is important to our ability to thoroughly consider an expansion exception request to understand where the expansion facility capacity would be

located. As explained in section X.B.2.a.(8). of this final rule, we are not finalizing our proposal to require a hospital to include in its expansion exception request the names of any counties in which the hospital plans to provide inpatient or outpatient hospital services if CMS approves the request.

Under existing § 411.362(c)(4)(ii)(D), an expansion exception request must include a statement identifying the hospital as an applicable hospital or a high Medicaid facility and a detailed explanation with supporting documentation regarding whether and how the hospital satisfies each of the criteria for an applicable hospital or a high Medicaid facility. In addition, the request must state that the requesting hospital does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries. We proposed to bifurcate this regulation such that the first element of existing § 411.362(c)(4)(ii)(D) (identification as an applicable hospital or a high Medicaid facility and supporting document regarding satisfaction of the criteria for such) would be separate from the requirement for information regarding nondiscrimination against beneficiaries of Federal health care programs. We also proposed to renumber this regulation at § 411.363(e)(2)(iv) and replace the word ''satisfies'' with the word ''meets'' to conform to the conventions in our regulations. We proposed to move the requirement regarding nondiscrimination to a separate regulation at proposed § 411.363(e)(2)(v) and revise this requirement to state that the expansion exception request must include a statement and, if available, supporting documentation regarding the hospital's compliance with the requirement that it does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries. The existing regulation requires only that the expansion exception request must ''state'' that the hospital does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries. In the proposed rule, we stated that, although we believe that most parties would understand that we require the requesting hospital to show that it meets this criterion for applicable hospitals (proposed § 411.363(c)(3)) and high Medicaid facilities (proposed § 411.363(d)(3)), for clarity, we proposed to revise the regulation to expressly require a statement that explains *how* the hospital meets the criterion (as opposed to merely stating that it meets the criterion).

In the proposed rule, we observed that the needs of all patients, but especially Medicaid beneficiaries and other underinsured or underserved populations, for specialty care—such as maternity, psychiatric, and substance use disorder care—often go unaddressed. Both the Department and CMS have prioritized improving access to maternal health services, psychiatric care, and substance use disorder treatment. (See, for example, the White House Blueprint for Addressing the Maternal Health Crisis, *https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf*, and CMS Behavioral Health Strategy, *https://www.cms.gov/cms-behavioral-health-strategy*.) We explained that, in light of this, it is important to understand whether and how a hospital requesting an expansion exception could improve access for underserved populations to these critically necessary services for underserved populations if the request is approved. Therefore, we proposed to require that, in addition to the documentation supporting the hospital's calculations of its baseline facility capacity, the hospital's current facility capacity, and the number of operating rooms, procedure rooms, and beds by which the hospital is requesting to expand that is currently required at existing § 411.362(c)(4)(ii)(E), the expansion exception request must include information regarding whether and how the hospital has used any expansion facility capacity previously approved by CMS and whether it plans to use expansion facility capacity to provide specialty services if the request is approved. We proposed to include this revised requirement at § 411.363(e)(2)(vi) (renumbered from existing § 411.362(c)(4)(ii)(E)). After consideration of the comments and as described in section X.B.2.a.(8). of this final rule, we are not mandating the inclusion of documentation supporting whether the requesting hospital plans to use expansion facility capacity to provide specialty care services if the request is approved.

We also proposed to require at new § 411.363(e)(2)(vii) that an expansion exception request must include information regarding the requesting hospital's need for additional operating rooms, procedure rooms, or beds to serve Medicaid, uninsured, and underserved populations. Under proposed § 411.363(e)(2)(vii), the request must also include information regarding the need (generally) for additional operating rooms, procedure rooms, or beds in the county in which the main campus of the hospital is located, any county in which the hospital provides inpatient or outpatient hospital services as of the date the hospital submits the request, and any county in which the hospital plans to provide inpatient or outpatient hospital services if CMS approves the request. We stated that we are not prescribing the data points or other criteria the requesting hospital should or may use to support its assertion of need for expansion facility capacity. We emphasized that we believe that an important purpose of authorizing the Secretary to approve expansion of a hospital's facility capacity is to allow limited growth of grandfathered hospitals in circumstances of clear community need. (See, for example, Conference Committee report, H. Rept. No. 443, 111th Cong., 2nd Sess. 357 (2010) and 76 FR 42353 and 74524.) And, because the criteria to qualify to request an expansion exception (that is, to meet the criteria for an applicable hospital or a high Medicaid facility) focus on inpatient admissions under Medicaid, we believe that approved expansion facility capacity should be used, at least in part, to address the need for services to Medicaid and other underserved populations in the community where the hospital's main campus is located. After consideration of the comments and as described in section X.B.2.a.(8). of this final rule, we are not mandating the inclusion of this information in an expansion exception request.

Finally, we proposed to revise existing § 411.362(c)(4)(i) and renumber it at § 411.363(e)(1) to eliminate the requirement that an original and one copy of a written expansion exception request must be mailed to CMS. Instead, all expansion exception requests would be submitted electronically to CMS according to the instructions specified on the CMS website. This is consistent with current agency practice with respect to other submissions, such as advisory opinion requests and submissions under the CMS Voluntary Self-Referral Disclosure Protocol (SRDP). Similarly, we proposed at § 411.363(e)(1) to require that the signed certification required under existing § 411.362(c)(4)(iii) and proposed § 411.363(e)(3) must be submitted only in electronic form and according to the instructions specified on the CMS website. For consistency with the SRDP,

which also requires specific certifications related to submissions to CMS, we proposed to revise the definition of ''authorized representative'' at proposed § 411.363(e)(3) to mean the chief executive officer, chief financial officer, or other individual who is authorized by the hospital to make the request.

(5) Community Input

Existing § 411.362(c)(5) implements the mandate at section 1877(i)(3)(A)(ii) of the Act that the expansion exception process provides individuals and entities in the community in which the requesting hospital is located with the opportunity to provide input with respect to the request. As we stated in the proposed rule, we believe that the Congress intended for hospitals, patients, and others that are most likely to be affected by the expansion of the requesting hospital to have input in CMS' decision whether to approve or deny the request, as well as to provide information that may confirm or refute the requesting hospital's claim that it meets the criteria for an applicable hospital or a high Medicaid facility. We noted that our current regulations do not define the ''community'' in which the requesting hospital is located. To eliminate uncertainty, we proposed to define the requesting hospital's ''community'' at proposed § 411.363(f)(3)(ii) to include the geographic area served by the hospital, as defined at § 411.357(e)(2) of our regulations, and the counties in which the requesting hospital's main campus is located, the requesting hospital provides inpatient or outpatient hospital services as of the date the hospital submits the expansion exception request, and the requesting hospital plans to provide inpatient or outpatient hospital services if CMS approves the request. We highlighted that certain exceptions to the physician self-referral law's prohibitions identify the geographic area served by a hospital to define the location where specified activity may occur (for example, the location of a recruited physician's medical practice) and stated that we believe that it is desirable to employ a consistent approach to identifying a hospital's service area for purposes of our exceptions and identifying which individuals and entities are eligible to provide input related to an expansion exception request. As explained in section X.B.2.a.(8). of this final rule, we are not finalizing our proposal to include in the definition of ''community'' the counties in which the requesting hospital plans to provide inpatient or outpatient hospital services if CMS approves the request.

We also proposed at § 411.363(f)(2) that the requesting hospital must provide actual notification that it is requesting an expansion exception directly to hospitals whose data are part of the comparisons required to determine whether the hospital meets the criteria for an applicable hospital or a high Medicaid facility and to hospitals located in the requesting hospital's community. Thus, hospitals in the requesting hospital's community that wish to provide input related to the expansion exception request would be aware of the request. As explained in in section X.B.2.a.(8). of this final rule, we are not finalizing our proposal to require actual notification directly to any hospital whose data are not part of the comparisons required to determine whether the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility (depending on the specific request). In the proposed rule, we recognized that, by defining the requesting hospital's ''community,'' input from individuals and entities that are not located in the defined areas could be excluded from consideration by CMS when reviewing a hospital's expansion exception request. We stated that, if this proposal was finalized, we would encourage parties that wish to have their input considered to address how they are part of the requesting hospital's community in their submissions.

In the proposed rule, we noted our existing policy that the type of community input that we will accept is not restricted in any way (76 FR 74522). To support the two-step process for first determining whether a requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility and, if so, deciding whether to approve or deny the request, we proposed to revise existing § 411.362(c)(5) and renumber it at § 411.363(f)(3) to expressly state that individuals and entities in the requesting hospital's community may provide input regarding, but not limited to: (i) whether the hospital is eligible to request the expansion exception; and (ii) the factors that CMS will consider in deciding whether to approve or deny an expansion exception request. We stated that we believe that this regulatory language would encourage individuals and entities submitting input with respect to an expansion exception request to provide data and information that confirms or refutes the requesting hospital's eligibility to request an expansion exception (that is, whether the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility), as well as information pertinent to CMS' decision whether to approve or deny the request.

It is our experience that the volume of community input with respect to an expansion exception request can vary greatly. We have not received any community input on some requests and have received hundreds of pages of community input on others. In the proposed rule, we stated that we believe that the revised expansion process would result in more robust community input than what interested parties have historically submitted because language in prior approval notices may have implied that we would not consider input unrelated to whether a requesting hospital met the criteria for an applicable hospital or a high Medicaid facility (80 FR 55852). Therefore, to provide adequate time for interested parties to develop and submit community input, we proposed to revise existing § 411.362(c)(5) and renumber it at § 411.363(f)(3)(iii) to provide a 60-day period following the publication of the notice of the expansion exception request in the **Federal Register** for the submission of community input. We stated that we did not believe that an extension of the 30-day period for the requesting hospital to submit a rebuttal statement was necessary but sought comment regarding whether we should extend this timeframe to 60 days to provide the requesting hospital additional time to review and respond to any community input.

(6) Permissible Data Sources

When we first established the expansion exception process, we required the use of data from the Healthcare Cost Report Information System (HCRIS) to perform the calculations necessary to show that a hospital meets the criteria for an applicable hospital or a high Medicaid facility (76 FR 74518 through 74521). Following the implementation of the expansion exception process in 2012, hospitals and their representatives informed us of certain limitations regarding the required use of HCRIS data, and our own review confirmed that HCRIS was not sufficiently complete for all hospitals that wished to request an expansion exception to have access to the process because, at that time, HCRIS did not capture Medicaid managed care admissions or discharge data. We also recognized that, if all hospitals in the county in which the requesting hospital is located did not have Medicare provider agreements during each of the years for which comparisons are required, the

requesting hospital would be unable to show that it met the statutory and regulatory criteria as an applicable hospital or a high Medicaid facility because HCRIS contains only the data of hospitals that participate in Medicare (79 FR 66988). To address the limitations regarding the required use of HCRIS data, in the CY 2015 OPPS/ASC final rule, we modified the expansion exception process to permit the use of external data sources for the calculations necessary to estimate inpatient Medicaid admissions (79 FR 66988 through 66993). Around the same time, CMS revised the hospital cost report to require reporting of Medicaid managed care discharges in addition to Medicaid fee-for-service discharges (79 FR 66990). In the CY 2015 OPPS/ASC final rule, we stated that, as a result of this revision, a correctly completed hospital cost report will include Medicaid managed care discharges; at some point in the future, HCRIS should be sufficiently complete to estimate the percentages of Medicaid inpatient admissions required under the statute and our regulations; and the limitations that led to permitting the use of external data sources will be resolved (*Id.*). Therefore, we modified our regulations at existing § 411.362(c)(2)(ii) and (c)(3)(ii) to permit the use of external data sources only until such time that the Secretary determines that HCRIS contains sufficiently complete inpatient Medicaid discharge data.

In the proposed rule, we announced that HCRIS now contains sufficiently complete inpatient Medicaid discharge data to complete the calculations to estimate Medicaid inpatient admissions, both as currently required and as would be required if we finalized our proposals to revise the expansion exception process. Although the regulations at existing § 411.362(c)(2)(ii) and (c)(3)(ii) do not require the Secretary to announce his determination that HCRIS contains sufficiently complete inpatient Medicaid discharge data through notice-and-comment rulemaking, we proposed at § 411.363(c)(2) and (d)(2) to eliminate the use of external data sources for purposes of the expansion exception process with respect to requests submitted on or after the effective date of the revised regulations if our proposals were finalized. As we stated in the CY 2012 OPPS/ASC final rule, we believe that requiring the use of filed Medicare hospital cost report data from HCRIS for all expansion exception requests will result in the use of uniform and consistent data, which will minimize inconsistent application of the criteria for applicable hospitals and high Medicaid facilities (76 FR 74518).

We recognize that requiring the use of filed Medicare hospital cost report data from HCRIS for all expansion exception requests will not resolve every issue identified in the CY 2015 OPPS/ASC proposed and final rules (79 FR 66988). For example, all the hospitals to which the requesting hospital must compare itself (the comparison hospitals) may not have participated in Medicare in all years for which comparisons are required. As explained in the proposed rule (88 FR 27181 through 27182) and in this section X.2.B.a.(6)., if Medicaid inpatient admissions data is not available for every hospital in a county for a particular comparison year, it would be impossible for any hospital in that county to meet the criteria for an applicable hospital or a high Medicaid facility under section 1877(i)(3)(E) or (F) of the Act, respectively, during the period when the use of data from that comparison year is required under the statute and our regulations. We do not believe that the Congress intended that a hospital that meets the criteria for an applicable hospital or a high Medicaid facility and is willing to expand in a community where there is a clear need for additional facility capacity would be foreclosed from doing so because one or more of the other hospitals in its community did not participate in Medicare (or if Medicaid inpatient admissions data was otherwise unavailable for all hospitals in the county in which the requesting hospital is located). Therefore, even though sections 1877(i)(3)(E)(ii) and (F)(ii) of the Act necessitate the use of data regarding Medicaid inpatient admissions for *each* hospital in the county in which the requesting hospital is located, using our authority at sections 1871 and 1877 of the Act, we proposed that the comparisons required to show that a hospital meets the Medicaid inpatient admissions criteria for an applicable hospital at proposed § 411.363(c)(2) or a high Medicaid facility at proposed § 411.363(d)(2) must be made using only data from those hospitals that have a Medicare participation agreement with CMS. In the proposed rule, we stated that we consider our proposal to align with the intent of the Congress in establishing the criteria for applicable hospitals and high Medicaid facilities and are confident that it would provide a robust comparison that allows CMS to be sure the requesting hospital has a history of and commitment to serving Medicaid beneficiaries, uninsured patients, and other underserved populations. We further stated that we believe that our proposal to permit only the use of filed Medicare hospital cost report data from HCRIS for purposes of the calculations required at proposed § 411.363(c)(2) and (d)(2) while requiring comparisons only to hospitals that have a Medicare provider agreement with CMS strikes the appropriate balance between effectuating the intent of the statute and requiring strict compliance with the exact standards set forth in sections 1877(i)(3)(E)(ii) and (F)(ii) of the Act. As we stated in the proposed rule, we anticipate that requiring the use of filed Medicare hospital cost report data from HCRIS for all comparison calculations will have little practical impact on whether a requesting hospital meets the criteria for an applicable hospital or high Medicaid facility and that we do not believe that a requesting hospital would be prejudiced by this requirement.

We also proposed to revise the terminology used in our regulations to describe the comparisons that a hospital requesting an expansion exception must make to show that it is an applicable hospital or a high Medicaid facility. We did so solely for consistency in the terminology; we do not view this as a change to our interpretation of the statutory requirements for the comparisons. Section 1877(i)(3)(E) of the Act defines the term ''applicable hospital'' and section 1877(i)(3)(F) of the Act defines the term ''high Medicaid facility.'' With respect to Medicaid inpatient admissions, an applicable hospital is a hospital whose annual percent of Medicaid inpatient admissions is equal to or greater than the average percent with respect to such admissions for ''all'' hospitals located in the county where the hospital is located, and a high Medicaid facility is a hospital that, with respect to each of the 3 most recent years for which data are available, has an annual percent of Medicaid inpatient admissions that is greater than the percent of such admissions for ''any other'' hospital in the county. Our existing regulations use the terms ''all'' hospitals (with respect to applicable hospitals) and ''every'' hospital (with respect to high Medicaid facilities). In setting forth the permissible data sources to be used for making the required comparisons, our existing regulations use the term ''all'' hospitals (with respect to applicable hospitals) and ''every other'' hospital (with respect to high Medicaid facilities). We interpret the statute to mean that a hospital requesting an expansion exception as an applicable hospital must use data for itself and

each of the other hospitals in the county in which it is located to determine the county average for Medicaid inpatient admissions, and a hospital requesting an expansion exception as a high Medicaid facility must compare itself to each of the other hospitals in the county in which it is located. We do not view the term ''any other''—as used in section 1877(i)(3)(F) of the Act—and the terms ''each,'' ''every,'' and ''every other''—as used in our existing regulations—to have disparate meanings or refer to different subsets of comparison hospitals. However, for consistency and to eliminate any misinterpretation of the comparison requirements, we proposed to revise the references in our regulations to refer to ''each'' or ''each other'' hospital (where appropriate). We did not propose to revise the reference in existing § 411.362(c)(2)(ii) (with respect to applicable hospitals) to the average percent of Medicaid inpatient admissions for ''all'' hospitals located in the county where the requesting hospital is located, as the existing language is consistent with the required comparison. However, for clarity, we proposed at renumbered § 411.363(c)(2) to expressly state that the requesting hospital's percent of Medicaid inpatient admissions must be included with the percent of Medicaid inpatient admissions for each of the other hospitals in the county when determining the average percent of Medicaid inpatient admissions for ''all'' hospitals in the county in which the requesting hospital is located.

Under proposed § 411.363(c)(2), to meet the Medicaid inpatient admissions criterion for an applicable hospital, the requesting hospital must have an annual percent of total inpatient admissions under Medicaid that is equal to or greater than the average percent with respect to such admissions for all hospitals (including the requesting hospital) that have Medicare participation agreements with CMS and are located in the county in which the requesting hospital is located during the most recent 12-month period for which data are available as of the date that the hospital submits its request. The proposed regulation provided that the most recent 12-month period for which data are available means the most recent 12-month period for which the data source used contains all data from the requesting hospital and each other hospital that has a Medicare participation agreement with CMS and is located in the county in which the requesting hospital is located. In the proposed rule, we also explained that, with respect to requests submitted on or after the effective date of the revised regulations if our proposals were finalized, a hospital may use only filed Medicare hospital cost report data from HCRIS to estimate its annual percent of total inpatient admissions under Medicaid and the average percent with respect to such admissions for all hospitals (including the requesting hospital) in the county in which the hospital is located. Under proposed § 411.363(d)(2), to meet the Medicaid inpatient admissions criterion for a high Medicaid facility, with respect to each of the three most recent 12-month periods for which data are available as of the date the hospital submits its request, the requesting hospital must have an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for each other hospital that has a Medicare participation agreement with CMS and is located in the county in which the requesting hospital is located. The proposed regulation provided that the most recent 12-month period for which data are available means the most recent 12-month period for which the data source used contains all data from the requesting hospital and each other hospital that has a Medicare participation agreement with CMS and is located in the county in which the requesting hospital is located. We noted that, with respect to requests submitted on or after the effective date of the revised regulations if our proposals were finalized, a hospital may use only filed Medicare hospital cost report data from HCRIS to estimate its annual percent of total inpatient admissions under Medicaid and the average percent with respect to such admissions for each other hospital that has a Medicare participation agreement with CMS and is located in the county in which the hospital is located.

In the proposed rule, we recognized that it is possible that a facility that is provider-based to a hospital is located in a county other than the county in which the main campus of the hospital is located. To provide clarity for purposes of completing the necessary calculations to demonstrate that a hospital meets the criteria for an applicable hospital or a high Medicaid facility, we proposed at § 411.363(c)(6) (for an applicable hospital) to consider the location of a hospital to be the county and State in which the main campus of the hospital is located and at and § 411.363(d)(4) (for a high Medicaid facility) to consider the location of a hospital to be the county in which the main campus of the hospital is located. This would apply to the requesting hospital and any hospital to which the requesting hospital must compare itself for purposes of the calculations related to percentage increase in population, Medicaid inpatient admissions, average bed capacity, and average bed occupancy rate.

(7) Timing of a Complete Request

In the CY 2015 OPPS/ASC final rule, in addition to expanding the permissible data sources a hospital may use to show that it meets the criteria for an applicable hospital or a high Medicaid facility, we also amended the expansion exception process to increase the period of time after which an expansion exception request will be deemed complete when an external data source is used by a requesting hospital or in the community input to determine whether a hospital meets the criteria for an applicable hospital or a high Medicaid facility, reasoning that it is possible (if not likely) that, when reviewing an expansion exception request, CMS would need to verify the data (and other information, if any) provided by the requesting hospital and any commenters, as well as consider the data in light of the information otherwise available to CMS (79 FR 66995). Because we proposed at § 411.363(c)(2) and (d)(2) that only filed Medicare hospital cost report data from HCRIS may be used to show that the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility, in the proposed rule, we stated that we did not believe that we would continue to need the full 180 days currently provided for at existing § 411.362(c)(5)(ii) to deem an expansion exception request complete. Therefore, we proposed to revise and renumber this regulation to deem an expansion exception request complete no later than 90 days after the end of the 60-day comment period if CMS does not receive written comments from the community, or no later than 90 days after the end of the rebuttal period, regardless of whether the requesting hospital submits a rebuttal statement, if CMS receives written comments from the community. We proposed that the regulation would be renumbered at § 411.363(g), which would also include other existing regulations related to the timing of a complete expansion exception request, amended to recognize the proposed increase to a 60-day period for community input. Because the data used for the Medicaid inpatient admissions comparisons, as well as the data for the other calculations required under the expansion exception process, would be

maintained by CMS, we stated that we believed that 90 days would be sufficient to review the data and information in the expansion exception request, community input (if any), and rebuttal statement (if any) regarding whether the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility and whether CMS should approve or deny the request. We also stated that our proposals would not affect expansion exception requests submitted before the effective date of the revised regulations if our proposals were finalized.

(8) Provisions of the Final Rule: Expansion Exception Process

We received comments both in support of and opposition to our proposals to modify and clarify the process for requesting an exception from the prohibition on facility expansion. Many of the assertions and suggestions made by commenters were founded on the commenter's view of whether section 1877(i) of the Act authorizes the Secretary to deny an expansion exception request from a hospital that meets the criteria for an applicable hospital or a high Medicaid facility. Some commenters agreed with CMS that the statute confers discretion for CMS to deny a request for an expansion exception even if the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility. These commenters viewed our proposals to identify the information required from a requesting hospital and the factors that CMS will consider in deciding whether to approve or deny an expansion exception request as bringing transparency to the expansion exception process to ensure that all parties are treated comparably in the process. Other commenters interpreted the statute to mean that CMS may not prohibit a hospital from expanding if the hospital meets the statutory criteria for an applicable hospital or a high Medicaid facility and completes any procedural requirements established by CMS under section 1877(i)(3)(A) of the Act. Because of this foundational view, these commenters viewed our proposals as adding criteria to the definitions of ''applicable hospital'' and ''high Medicaid facility.''

We are finalizing our proposals with modifications. Under the final rule, we are establishing a new § 411.363 that will include the expansion exception process and, therefore, removing existing § 411.362(c) from our regulations. At § 411.363(a), we are including definitions for purposes of the expansion exception process. At § 411.363(b), we are finalizing our proposal to expressly state that CMS will not consider an expansion exception request from a hospital that is not eligible to request the exception. Under the final regulation, a hospital that meets the criteria for an applicable hospital or a high Medicaid facility is eligible to request an expansion exception, provided that: (i) the hospital has not already been approved by CMS for an expansion exception that would allow the hospital to reach 200 percent of its baseline facility capacity; and (ii) it has been at least 2 calendar years from the date of the most recent decision by CMS approving or denying the hospital's most recent expansion exception. We note that, because section 1877(i)(3)(C)(ii) of the Act prohibits CMS from approving an increase in a hospital's facility capacity to the extent such increase would result in the hospital's facility capacity exceeding 200 percent of its baseline facility capacity, CMS could not approve further expansion of a hospital that CMS has already approved to expand to 200 percent of its baseline facility capacity. Therefore, under the final regulation at § 411.363(b)(2)(i), such a hospital would be ineligible to request an additional expansion exception. To consider an expansion exception request that CMS is prohibited to approve would not be an appropriate use of agency and other Federal resources.

Final § 411.363(c) states the criteria that a hospital must meet to be an applicable hospital. In addition to incorporating the existing criteria for an applicable hospital, the final regulation provides that, for purposes of the statutorily required comparisons with respect to Medicaid inpatient admissions, the hospital need only compare itself to other hospitals that have a Medicare participation agreement with CMS and are located in the county in which the hospital is located. The final regulation also clarifies that a hospital is located in the county and State in which the main campus of the hospital is located. In addition, beginning with expansion exception requests submitted on or after October 1, 2023, the requesting hospital may use only filed Medicare cost report data from HCRIS to perform the required calculations. Final § 411.363(d) states the criteria that a hospital must meet to be a high Medicaid facility. In addition to incorporating the existing criteria for high Medicaid facilities, the final regulation provides that, for purposes of the statutorily required comparisons with respect to Medicaid inpatient admissions, the hospital need only compare itself to other hospitals that have a Medicare participation agreement with CMS and are located in the county in which the hospital is located. The final regulation clarifies that a hospital is located in the county in which the main campus of the hospital is located. In addition, beginning with expansion exception requests submitted on or after October 1, 2023, the requesting hospital may use only filed Medicare cost report data from HCRIS to perform the required calculations.

We are finalizing our proposals (with modification) to revise the procedure a hospital must follow in submitting an expansion exception request and the information that it must provide to CMS. Under final § 411.363(e)(1), a hospital must submit its expansion exception request and the required signed certification electronically to CMS according to the instructions specified on the CMS website. We are making a slight technical modification to § 411.363(e)(2)(i) to state that, among the other required demographic information for a hospital, the hospital must include its tax identification number and CMS certification number. The regulation at existing § 411.362(c)(4)(ii)(A) requires that the hospital must include tax identification number(s) and CMS certification number(s). However, because an ''entity'' (for purposes of the physician self-referral law) that furnishes designated health services would have only a single tax identification number and single CMS certification number (if it has a Medicare participation agreement with CMS), we are revising the regulation to eliminate potential confusion regarding the need to submit more than one tax identification number or CMS certification number. Also, with respect to the documentation that must be included in an expansion exception request, under the final regulations, certain information will be mandatory and other information may be submitted at the election of the requesting hospital but is not required to ensure that CMS will consider the expansion exception request. In addition to the information currently required to support that the hospital meets the criteria for an applicable hospital or a high Medicaid facility, we are requiring the hospital to submit documentation supporting whether and how it has used any expansion facility capacity approved in a prior request. However, other information may be submitted at the election of the requesting hospital. For example, a hospital may, but is not required to, submit information regarding whether it plans to use

expansion facility capacity to provide specialty services if the request is approved. Likewise, a hospital may, but is not required to, submit information regarding the current or future need for additional operating rooms, procedure rooms, or beds for itself, in the county where its main campus is located, or in any county where it provides inpatient or outpatient hospital services (that is, in any county in which one or more of its hospital-based facilities, if any, is located). We believe that the final regulations reduce the burden on a hospital that seeks approval for an expansion of its facility capacity while providing an opportunity to submit additional information that it wishes CMS to consider. We emphasize that the fact that a hospital elects not to provide information beyond what is required under § 411.363(e)(2) will not factor into CMS' decision to approve or deny the request.

We are also finalizing our proposals regarding the community input that may be provided with respect to an expansion exception request. First, we are finalizing the definition of ''community'' at § 411.363(f)(3)(ii) to mean all of the following: the geographic area served by the hospital (as defined at § 411.357(e)(2) of our regulations); the county in which the requesting hospital's main campus is located; and the counties in which the requesting hospital provides inpatient or outpatient hospital services as of the date that it submits its request. Final § 411.363(f)(1) replicates our existing process by requiring that, upon submitting a request for an expansion exception and until the hospital receives a CMS decision on the request, the hospital must disclose on any public website for the hospital that it is requesting the expansion exception. However, we are making one notable modification in the final regulations. At § 411.363(f)(2), we are requiring the hospital requesting the expansion exception to provide actual notification of its request only to hospitals whose data are part of the comparisons required to show that it meets the criteria for an applicable hospital or a high Medicaid facility. The notice must be provided directly to these hospitals. We are not finalizing our proposal to require that the requesting hospital also provide actual notice directly to hospitals that are located in the remainder of the requesting hospital's community (as defined at § 411.363(f)(3)(ii)). Lastly, we are finalizing our proposal to extend the period for community input from the current 30 days to 60 days. Based on the comments received on this proposal, at § 411.363(f)(3)(iv), we are also extending the period for the requesting hospital to submit a rebuttal statement from the current 30 days to 60 days.

We are finalizing our proposal that, no later than 60 days after an expansion exception request is deemed complete, CMS will publish its determination whether the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility and, if so, its decision whether to approve or deny the request. In keeping with final § 411.363(c)(2)(ii) and (d)(2)(ii), which require the use of CMS-provided Medicare filed Medicare hospital cost report data from HCRIS for all expansion exception requests submitted on or after October 1, 2023, we are finalizing our proposal to deem a request complete no later than 90 days after the end of the comment period if we do not receive community input or, if we do receive community input, 90 days after the end of the rebuttal period, regardless of whether the requesting hospital submits a rebuttal statement. For expansion exception requests that are submitted prior to October 1, 2023, and include data from an external data source in the expansion exception request, community input, or the hospital's rebuttal statement, the request will continue to be deemed complete no later than 180 days after the end of the comment period if we do not receive community input or, if we do receive community input, 180 days after the end of the rebuttal period, regardless of whether the requesting hospital submits a rebuttal statement.

We are also finalizing the regulations at § 411.363(h) and (i) to clarify that CMS will take a two-step approach to considering expansion exception requests. First, CMS will determine whether the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility using the information provided by the hospital in its expansion exception request and rebuttal statement, if any, and the community input, if any. Second, using data and information provided from these sources, as well as data and information that is otherwise available to CMS and relevant to its decision, CMS will decide whether to approve or deny the expansion exception request. Final § 411.363(i)(2) identifies the factors that CMS will consider in deciding whether to approve or deny a hospital's request for an expansion exception. These factors include: (i) the specialty of the requesting hospital or the services furnished by (or to be furnished by) the hospital if CMS approves the expansion exception request; (ii) program integrity or quality of care concerns related to the hospital; (iii) whether the hospital has a need for additional operating rooms, procedure rooms, or beds; and (iv) whether there is a need for additional operating rooms, procedure rooms, or beds in the county in which the main campus of the hospital is located or in any county in which the hospital provides inpatient or outpatient hospital services as of the date the hospital submits the request. As § 411.363(i)(2) expressly states, CMS is not limited to consideration of these factors in deciding whether to approve or deny a hospital's expansion exception request.

At § 411.363(k), we are finalizing our proposal regarding the information that will be published in the **Federal Register** following CMS' consideration of an expansion exception request. Specifically, if CMS determines that the hospital does not meet the criteria for an applicable hospital or a high Medicaid facility, CMS will publish in the **Federal Register** notice of such determination. If CMS determines that the hospital meets the criteria for an applicable hospital or a high Medicaid facility, CMS will publish in the **Federal Register** notice of such determination and its decision regarding the hospital's request for an expansion exception. At § 411.363(l), we are finalizing our proposal to codify that, under section 1877(i)(3)(I) of the Act, there is no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the process under this section (including the establishment of such process and any CMS determination or decision under such process).

To facilitate readers' understanding of our final policies, we provide here a high-level summary of the expansion exception process as finalized. Under the regulations finalized in this final rule, a hospital may submit its expansion exception request to CMS. CMS will confirm that the request includes all required information and that CMS is not precluded from considering the expansion exception request under final § 411.363(b)(2)(i) or (ii). CMS will also confirm the accuracy of the required calculations (as we do under the existing process). If the requesting hospital has performed the required calculations incorrectly, CMS will continue its current practice and inform the hospital of the error(s) and work with the hospital to ensure the required calculations are performed correctly. After these steps are completed, if the hospital does not withdraw the expansion exception request, CMS will publish notice of the

expansion exception request in the **Federal Register**. Community input may be submitted during the 60-day comment period as set forth at final § 411.363(f). If CMS receives community input on the expansion exception request, it will be provided to the requesting hospital. Under final § 411.363(f)(3)(iv), the hospital will have 60 days to submit a rebuttal statement if it chooses to do so. Following the receipt of community input (if any) and the hospital's rebuttal statement (if any), CMS will determine whether the hospital meets the criteria for an applicable hospital or a high Medicaid facility. If the hospital meets the criteria for an applicable hospital or a high Medicaid facility, CMS will then consider the factors identified at § 411.363(i)(2) and decide whether to approve or deny the expansion exception request. CMS will publish notice of its determination whether the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility in the **Federal Register**. If CMS determines that the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility, CMS will also publish notice of its decision to approve or deny the expansion exception request in the same **Federal Register** notice.

We received the following comments on our proposals to revise and clarify the expansion exception process. Our responses follow.

Comment: We received comments regarding our interpretation of section 1877(i)(3) of the Act as affording the Secretary the discretion to approve or deny a hospital's request for an expansion exception. Many commenters endorsed our interpretation of the statute, concurring that the language of section 1877(i)(3) of the Act provides CMS with discretion to consider and ultimately approve or deny requests for expansion exceptions, even if the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility. One of these commenters stressed that CMS' interpretation of its authority is consistent with the statutory requirement for the Secretary to implement a process under which an applicable hospital or high Medicaid facility may ''apply'' for an exception from the prohibition on facility expansion and the statutory language referencing the ''grant'' of exceptions. Other commenters disagreed with our interpretation of the authority granted to the Secretary in section 1877(i)(3) of the Act. These commenters interpreted the statute as prohibiting the Secretary from denying a request for an expansion exception from a hospital that meets the criteria for an applicable hospital or a high Medicaid facility. One of these commenters described CMS' assessment that the words ''apply,'' ''granted,'' ''permit,'' and ''decision'' support a statutory grant of authority to approve or deny an application (that is, request) for an expansion exception as a contrived contortion of the English language, and further described our interpretation of CMS's authority as overriding an unambiguous statutory scheme in order to supersede it with the preferred policy of certain trade associations and competitors of physician-owned hospitals. This commenter interpreted the language of sections 1877(i)(3)(E) and (F) of the Act, which set forth the definitions of an ''applicable hospital'' and a ''high Medicaid facility,'' respectively, as establishing two expansion exceptions, which are automatically granted to any applicable hospital or high Medicaid facility that completes the procedural steps established by the Secretary under section 1877(i)(3)(A) of the Act. Another commenter asserted that nothing about establishing a process to grant expansion exceptions connotes discretion to approve or deny them. Both of these commenters asserted that, because section 1877(i)(3)(A)(i) of the Act directs the Secretary to establish and implement a process under which a hospital that meets the criteria for an applicable hospital or a high Medicaid facility ''may'' apply for an exception from the prohibition on facility expansion, the statute affords discretion to the requesting hospital (that is, discretion to apply or not to apply for an expansion exception) but not to the Secretary.

Response: We are not persuaded by the arguments of the commenters that disagree with our interpretation of the authority granted to the Secretary in section 1877(i)(3) of the Act or that our reading of the statute's use of the terms ''apply,'' ''granted,'' ''permit,'' and ''decision'' is a contrived contortion of the English language. As we stated in the proposed rule, section 1877(i)(3)(A)(i) of the Act directs CMS to establish a process under which an applicable hospital or a high Medicaid facility may *apply* for an exception from the prohibition on facility expansion, and section 1877(i)(3)(C)(i) of the Act imposes certain program integrity restrictions on a hospital *granted* an exception under the process (emphasis added). The Secretary's authority to grant an expansion exception is limited by section 1877(i)(3)(C)(ii) of the Act, which states that the Secretary shall not *permit* an increase in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed that results in a hospital's facility capacity exceeding 200 percent of its baseline facility capacity. In addition, section 1877(i)(3)(H) of the Act requires the Secretary to publish in the **Federal Register** the final *decision* with respect to a hospital's application.

The dictionary definition of the term ''apply'' in this context is ''to make an appeal or request, especially in the form of a written application.'' [928] Further, *Black's Law Dictionary* (2nd ed. 1910) defines the term ''apply'' to mean ''to make a formal request or petition, usually in writing, to a court, officer, board, or company, for the granting of some favor, or of some rule or order, which is within his or their power or discretion.'' [929] (As we noted in the proposed rule, we use the term ''apply'' in the same way as the term ''request'' (88 FR 27177), which is supported in these definitions.) It follows that, in the case of a submitted application, a decision to approve or deny the application would be expected from the party that holds the discretion to grant the requested action. The dictionary definition of the term ''grant'' in this context is ''to agree to give somebody what they ask for, especially formal or legal permission to do something'' or ''to permit as a right, privilege, or favor.'' [930] In addition, the dictionary definition of ''permit'' in this context is ''to consent to, expressly or formally.'' [931] Essentially, the terms ''grant'' and ''permit'' are synonymous,[932] and both require the action or decision of the party to whom the application or request is made. The dictionary definition of ''decision'' in this context is ''a determination arrived at after consideration.'' [933] Even though the terms ''approve'' and ''deny'' do not appear in the text of section 1877(i)(3) of the Act, the plain meanings of the terms that are used in section 1877(i)(3) of the Act are reasonably interpreted to confer discretion to approve or deny an expansion exception request made to CMS. We believe that this is the best interpretation of the statute. Accordingly, we also disagree with the

[928] *https://www.merriam-webster.com/dictionary/apply.*

[929] *https://thelawdictionary.org/apply/.*

[930] *https://www.oxfordlearnersdictionaries.com/us/definition/english/grant_1;* and *https://www.merriam-webster.com/dictionary/grant.*

[931] *https://www.merriam-webster.com/dictionary/permit.*

[932] *https://www.merriam-webster.com/thesaurus/permit.*

[933] *https://www.merriam-webster.com/dictionary/decision.*

commenters that the definitions of the terms ''applicable hospital'' and ''high Medicaid facility'' in sections 1877(i)(3)(E) and (F) of the Act merely establish an automatic authorization to expand facility capacity for any hospital that meets the criteria of one of these sections, rendering the Secretary powerless to deny an expansion exception request from a hospital that completes any procedural steps set forth in our regulations.

We agree with the commenters that section 1877(i)(3)(A)(i) of the Act affords certain discretion to the requesting hospital (that is, discretion to apply or not to apply for an expansion exception). This provision clearly does not mandate that a hospital request an expansion exception at any given time or ever. However, we disagree that this is the only discretion that the statute affords. For the reasons discussed in this final rule, we interpret section 1877(i)(3) of the Act to also afford the Secretary discretion to approve or deny an expansion exception request made to CMS.

Comment: One commenter asserted that CMS had previously made clear that CMS may not consider criteria not in the statute when reviewing an expansion exception request and, therefore, may not finalize its proposals based on the interpretation of the Secretary's statutory authority set forth in the proposed rule. The commenter cited a CMS 2015 statement that it cannot consider any concerns raised in the community input that are unrelated to the statutory and regulatory eligibility criteria when determining whether to grant an exception to a requesting hospital (80 FR 55852). The commenter also cited CMS' statement that, if a hospital qualifies as an applicable hospital or a high Medicaid facility, CMS does not have the discretion to grant less than the requested increase in facility capacity (*Id.*).

Response: The specific language cited by the commenter appeared in a decision notice published in the **Federal Register** announcing CMS' approval of an expansion exception request. We understand the commenter to suggest that CMS is permanently bound by the statement in the 2015 notice. We disagree. An essential function of the agency is to implement the statute as enacted by the Congress. Assessing and, as necessary, reassessing the statutory authority granted to the Secretary is a critical step in implementing any statutory provision. As we stated in the proposed rule, we recently reviewed the expansion exception process, including a fresh examination of the statutory language and certain legislative history of the Affordable Care Act. The policies announced in this final rule supersede any prior statements regarding CMS' authority to approve or deny an expansion exception request. For all expansion exception requests submitted on or after October 1, 2023, receiving approval for an exception from the prohibition on expansion of facility capacity at section 1877(i)(B) of the Act is a two-step process. Meeting the criteria for an applicable hospital or a high Medicaid facility is the first step and makes a hospital eligible to request an expansion exception, subject to the limitations of final § 411.363(b)(2). The second step for approval of an expansion exception request requires a decision by CMS after consideration of the data and information provided by the hospital in its request and rebuttal statement (if any), the community input (if any), and data and information otherwise available to CMS and relevant to its decision.

Comment: We received two comments asserting that the statutory criteria that a hospital must meet to be an applicable hospital or a high Medicaid facility are the same and *only* criteria that must be met for a hospital to be granted an expansion exception. One of these commenters further asserted that CMS previously acknowledged that it did not have authority to create additional criteria for classification as an applicable hospital or high Medicaid facility.

Response: We disagree with the commenters that a hospital is entitled to an expansion exception merely because it meets the definition of an ''applicable hospital'' or a ''high Medicaid facility.'' The plain language of section 1877(i)(3)(A) of the Act anticipates that an applicable hospital or a high Medicaid facility must apply for an expansion exception. It is our position that, when a hospital applies for an expansion exception request, it is making a request to CMS to grant permission for the hospital to expand its facility capacity without violating the prohibition set forth in section 1877(i)(1)(B) of the Act. We have considered the assertions of the commenters but are not persuaded to adopt their view that the use of the word ''apply'' in the statute is akin to exercising a right to an expansion exception for a hospital that meets the definition of an ''applicable hospital'' or a ''high Medicaid facility.''

As we explained in the proposed rule and in section X.B.2.a. of this final rule, we interpret section 1877(i)(3) of the Act to mean that a hospital must first establish that it meets the criteria for an applicable hospital or a high Medicaid facility and, if it does, it may request—but is not guaranteed—an exception from the prohibition on facility expansion. With respect to the comment regarding authority to create additional criteria for classification as an applicable hospital or a high Medicaid facility, we agree that sections 1877(i)(3)(E) and (F) of the Act, which define the terms ''applicable hospital'' and ''high Medicaid facility,'' respectively, do not authorize CMS to establish additional criteria in regulation that a hospital must meet to be an applicable hospital or a high Medicaid facility. We did not propose to do so (88 FR 27178 through 27179), nor are we finalizing regulations that establish criteria beyond the statutory criteria for applicable hospitals and high Medicaid facilities. Rather, our proposals and final policies establish the sources of information and factors that CMS will consider when deciding whether to approve or deny an expansion exception request.

Comment: We received little comment on our proposal to permit only the use of filed Medicare hospital cost report data from HCRIS to show that a hospital meets the criteria for an applicable hospital or a high Medicaid facility, although one commenter expressed support for the proposal as it would standardize data sources for all interested parties.

Response: In accordance with existing § 411.362(c)(2)(ii) and (c)(3)(ii), we announced in the proposed rule the Secretary's determination that HCRIS now contains sufficiently complete inpatient Medicaid discharge data to perform the calculations to estimate Medicaid inpatient admissions as required under both our existing expansion exception process and under this final rule (88 FR 27182). For the reasons explained in the CY 2012 OPPS/ASC final rule—namely, that requiring the use of filed Medicare hospital cost report data from HCRIS for all expansion exceptions requests will result in the use of uniform and consistent data, which will minimize inconsistent application of the criteria for applicable hospitals and high Medicaid facilities—we are finalizing our proposal to require the use of filed Medicare hospital cost report data from HCRIS in all expansion exception requests submitted on or after October 1, 2023.

Comment: We received comments generally in support of our proposed clarification of and revisions to the expansion exception process, as well as comments either opposed to any changes to the regulations that set forth the expansion exception process or the

statutory prohibition on the expansion of facility capacity in general. The commenters in support of the clarification and revisions cited benefits such as transparency, clarity, and uniform application of the process and CMS' decision making if we finalize our proposals. The commenters opposed to the proposals asserted that they represent an unfair departure from CMS' previously neutral stance in the friction between hospitals that have physician ownership and those that do not, and emphasized that hospitals with physician ownership or investment provide high-quality care, have high patient satisfaction ratings, and promote competition among health care providers. These commenters also suggested that the proposals, if finalized, would create barriers to access to care and lengthen the process for an applicable hospital or a high Medicaid facility to expand its facility capacity.

Response: The prohibition on the expansion of a hospital's facility capacity in the rural provider exception and the whole hospital exception is statutory and may not be rescinded through regulation. The prohibition applies equally to any hospital seeking to use the rural provider exception or the whole hospital exception, regardless of whether the hospital provides high quality care, has high patient satisfaction scores, or promotes competition among health care providers. We are aware of the studies highlighted by commenters both in support of and opposition to our proposals. The policies that we are finalizing in this rulemaking do not represent an assessment of the quality or cost of care provided by any hospital, whether invested in by physicians or not, or the impact of any hospital on its local community or economy. We are not taking sides in what the commenter referred to as the friction between hospitals that have physician ownership and those that do not. CMS is statutorily obligated to establish a process for requesting an expansion exception, and we believe that providing transparency is essential to its implementation. Further, we are not persuaded (and the commenter provided no support for its suggestion) that ensuring transparency by refining the process for making, considering, and deciding an expansion exception request would harm access to care for Medicare or Medicaid beneficiaries, uninsured patients, or other underserved populations. Finally, because we are limiting the data that may be used in an expansion exception request submitted on or after October 1, 2023, to filed Medicare hospital cost report data from HCRIS, which CMS makes readily available on its website, we believe that the final regulations that update the expansion exception process may shorten the period from receipt of an expansion exception request until the issuance of CMS' decision on the request.

Comment: Two commenters objected to the proposed requirement that a requesting hospital must identify where and how it plans to provide inpatient or outpatient hospital services if CMS approves its expansion exception request. One of the commenters noted that a hospital may not know at the time of its request what its future expansion plans may entail.

Response: As explained in section X.B.2.b. of this final rule, we are finalizing our proposal to reinstate the program integrity restriction regarding the location of permitted expansion facility capacity. Consequently, all approved expansion facility capacity under an expansion exception request that is submitted on or after October 1, 2023, will be restricted to the main campus of the requesting hospital. Thus, it is unnecessary to request information regarding the location of any planned CMS-approved expansion of operating rooms, procedure rooms, or beds. To address the commenters' concerns regarding the potential that a hospital may not know how it will use expansion facility capacity if CMS approves its expansion exception request, we are removing from the list of required information at § 411.363(e)(2)(vi) information regarding whether the hospital plans to use expansion facility capacity to provide specialty services if the request is approved. Instead, under final § 411.363(e)(3), a hospital may—but is not required to—provide this information in its expansion exception request. Also, we are not requiring information regarding the hospital's need for additional facility capacity to serve Medicaid, uninsured, and underserved populations, or the need for additional operating rooms, procedure rooms, and beds in the county in which the main campus of the hospital is located or any county in which the hospital provides inpatient or outpatient hospital services as of the date the hospital submits its expansion exception request. Like information regarding the hospital's planned use of any approved expansion facility capacity, this information is optional and may be submitted at the requesting hospital's election.

Even though we are not finalizing our proposal to require information from a requesting hospital regarding its plans for any potential approved expansion facility capacity or the need for such expansion facility capacity, we remind readers that, as we stated in the proposed rule and prior rules, we believe that an important purpose of authorizing the Secretary to approve expansion of a hospital's facility capacity is to allow limited growth of grandfathered hospitals in cases of clear community need (88 FR 27180 and 76 FR 74524). And, because the statutory criteria for an applicable hospital and a high Medicaid facility focus on Medicaid inpatient admissions, we believe that approved expansion facility capacity should be used, at least in part, to address the need for services to Medicaid and other underserved populations in the hospital's community (88 FR 27180). It remains relevant to our decision with respect to an expansion exception request to ascertain whether the approval of the request could improve access to specialty services for populations whose need for such services often goes unaddressed. To the extent a requesting hospital has information regarding the need for additional facility capacity or is aware of its future plans for any approved expansion facility capacity, we welcome such information, but we emphasize that the fact that a hospital elects not to provide information beyond what is required under § 411.363(e)(2) will *not* factor into CMS' decision to approve or deny the request.

Comment: We received several comments from parties that viewed proposed § 411.363(e)(2)(vi) and (vii), which (as proposed) set forth the information required to be included in an expansion exception request, and proposed § 411.363(i)(2), which sets forth factors that CMS would consider in deciding whether to approve or deny a hospital's request for an expansion exception, as resembling, if not establishing, a Federal certificate of need (CON) program. In other words, the commenters viewed the proposed information requirements and factors as minimum thresholds that a requesting hospital must meet to prove that it deserves approval of its expansion exception request. Many of these commenters described CON programs as anti-competitive, time-consuming, and ineffective. One of these commenters questioned why CMS would require a Federal CON in instances where a hospital has been approved for expansion through a state CON process, while another expressed concern that the proposed factors could result in fewer approvals of expansion exception

requests and diminished competition among hospitals.

Response: CMS is obligated to follow the statutory provisions of section 1877(i)(3) of the Act. The regulations finalized in this rulemaking are intended to support the purpose of the expansion exception process, which, as we stated in the proposed rule and the CY 2012 OPPS/ASC final rule, is to provide the opportunity to expand in areas where a sufficient need for access is demonstrated (88 FR 27184 and 76 FR 74524). The proposed regulations were not designed to make it harder for a hospital to obtain approval of an expansion exception request. To be clear, the proposed regulations were not intended to establish an actual or *de facto* Federal CON program or to establish minimum thresholds that must be met or maximum thresholds that may not be exceeded by a hospital to establish a showing of need for additional facility capacity. As the other commenters correctly assessed, the required information and enumerated factors were (and, as finalized, are) intended to aid a requesting hospital and interested parties in providing useful information that could assist CMS in deciding whether to approve or deny an expansion exception request.

We emphasize that the final regulations do not establish an actual or *de facto* Federal CON program or establish minimum thresholds that must be met or maximum thresholds that may not be exceeded by a hospital to establish a showing of need for additional facility capacity. We encourage hospitals to include in their expansion exception requests information (beyond the data showing that they meet the criteria for an applicable hospital or a high Medicaid facility) to support that there is a need for additional operating rooms, procedure rooms, and beds for the hospital to serve Medicaid, uninsured, and underserved populations, or generally in the county in which the main campus of the hospital is located or any other county in which the hospital provides inpatient or outpatient hospital services as of the date it submits its expansion exception request. A hospital requesting an expansion exception may include any information it considers relevant or useful to support its request, and is not limited to specific data points, such as bed occupancy levels or expected population growth, to support that there is a need for additional facility capacity. We also remind parties that the statutory prohibition on expansion of facility capacity limits only the expansion of the hospital's aggregate number of operating rooms, procedure rooms, and beds.

Comment: Some commenters viewed our proposals to identify the information required from a requesting hospital and the factors that CMS will consider in deciding whether to approve or deny an expansion exception request as a tool to facilitate the provision of useful information from the requesting hospital and in the community input with respect to an expansion exception request. These commenters expressed appreciation for the transparency and specificity of the information and factors that CMS will consider in deciding whether to approve or deny an expansion exception request. Other commenters asserted that CMS' consideration of anything other than whether the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility is inappropriate, if not impermissible. Some of these commenters specifically objected to proposed § 411.363(i)(1), which describes the sources of the data and information that CMS will consider in reviewing an expansion exception request, and includes data and information provided by the hospital in its request, included in the community input (if any), and provided by the hospital in its rebuttal statement (if any), and makes clear that CMS may also consider any other data and information relevant to its decision. One of these commenters expressed concern that CMS' ability to consider data and information not provided by the requesting hospital or in the community input could result in arbitrary decisions whether to approve or deny expansion exception requests.

Response: As a preliminary matter, we note that the comments addressing our proposals to require particular information in an expansion exception request and to identify the factors that CMS will consider in deciding whether to approve or deny a hospital's request were generally derivative of the commenter's view of CMS' statutory authority to deny an expansion exception request from a hospital that meets the criteria for an applicable hospital or a high Medicaid facility. That is, commenters that interpreted section 1877(i)(3) of the Act to authorize the Secretary to decide whether or not to grant an exception from the prohibition on expansion of facility capacity at section 1877(i)(1)(B) of the Act viewed our proposals as modifications and clarifications of the expansion exception process. Commenters that interpreted the statute as prohibiting the Secretary from denying a request for an expansion exception from a hospital that meets the criteria for an applicable hospital or a high Medicaid facility viewed our proposals as unauthorized additional criteria to qualify as an applicable hospital or a high Medicaid facility and secure a hospital's guaranteed right to expand.

We are pleased that some commenters recognized our intention to bring transparency and uniformity to the expansion exception process. We agree that communicating the factors that CMS will consider in deciding whether to approve or deny a hospital's expansion exception request should assist hospitals and interested in parties with the preparation and submission of expansion exception requests and community input. We do not agree that the expansion exception process, as finalized, will result in inconsistent outcomes or arbitrary decisions to approve or deny expansion exception requests. Rather, we anticipate that, because expansion exception requests submitted on or after October 1, 2023, should include similar information (or categories of information) linked to the factors enumerated in § 411.363(i)(2), the final regulations identifying the information that is pertinent to our consideration of an expansion exception request will facilitate the uniform consideration of expansion exception requests.

We reiterate that receiving approval for an expansion exception is a two-step process. Meeting the criteria for an applicable hospital or a high Medicaid facility is the first step and makes a hospital eligible to request an expansion exception, subject to the limitations of § 411.363(b)(2). The second step for approval of an expansion exception requires a decision by CMS after consideration of the data and information provided by the hospital in its request and rebuttal statement (if any), the community input (if any), and data and information otherwise available to CMS and relevant to its decision. As we stated in the proposed rule, each expansion exception request will be assessed on a case-by-case basis, and we will consider the totality of the information available to CMS in deciding whether to approve or deny an expansion exception request (88 FR 27179). For each expansion exception request, CMS will consider the factors set forth in final § 411.363(i)(2), as well as any other information provided by the requesting hospital or in the community input. No single factor, data point, or other piece of information is dispositive to a decision. Of course, a lack of information regarding a particular factor or factors could impact

CMS' decision with respect to an expansion exception request. We disagree that this will result in arbitrary decisions with respect to expansion exception requests. As required in section 1877(i)(3)(H) of the Act, CMS will publish a notice of each decision to approve or deny an expansion exception request in the **Federal Register**, and we will explain in detail the rationale for the approval or denial of the request in that notice.

Under the final regulations, the information that must be included in a request is identical to that required under the historical expansion exception process, with two exceptions. First, we are requiring at § 411.363(e)(2)(iii) that the hospital provide an address where hard copy mail may be sent to the contact person identified as available to discuss the request with CMS on behalf of the hospital. Second, final § 411.363(e)(2)(vi) requires the requesting hospital to submit documentation supporting whether and how the hospital has used any expansion facility capacity approved in a prior request because this information is relevant to our decision to approve or deny an expansion exception request. Knowing whether the hospital has unused, previously approved expansion facility capacity (or has the ability to return to its baseline facility capacity if it has reduced its aggregate number of operating rooms, procedure rooms, and beds below the baseline prior to the date it submits its expansion exception request) will help us assess whether the hospital has a current or future need for additional facility capacity to serve Medicaid, uninsured, and underserved populations, as well as whether there is such a need in the counties where the hospital's main campus and hospital-based facilities, if any, are located. It is important to require this information, especially because we are not requiring the requesting hospital to provide information about the need for additional operating rooms, procedure rooms, and beds for the hospital or in the counties in which it operates.

Final § 411.363(i)(2) sets forth the factors that CMS will consider in its decision with respect to an expansion exception request. These are: the specialty (for example, maternity, psychiatric, or substance use disorder care) of the hospital or the services furnished by or to be furnished by the hospital if CMS approves the request; program integrity or quality of care concerns related to the requesting hospital; whether the requesting hospital has a need for additional facility capacity; and whether there is a need for additional operating rooms, procedure rooms, or beds in counties where the hospital's main campus and hospital-based facilities, if any, are located as of the date the hospital submits the request. Final § 411.363(i)(2) also makes clear that CMS will consider factors other than those expressly stated in the regulation; for example, depending on the facts and circumstances of the particular expansion exception request, CMS may consider program integrity or quality concerns related to other hospitals in the requesting hospital's community or their ability to serve a growing patient population in the community (88 FR 27179).

Final § 411.363(i)(2)(i) includes the specialty (for example, maternity, psychiatric, or substance abuse disorder care) of the requesting hospital or the services furnished by or to be furnished by the hospital if CMS approves the request as a factor for CMS' consideration. As we stated in the proposed rule, we believe it is important to understand whether and how a hospital requesting an expansion exception could improve access to specialty care, such as maternity, psychiatric, and substance use disorder care, the need for which often goes unaddressed, especially for Medicaid beneficiaries and other underinsured or underserved populations (88 FR 27180). Although we understand that a hospital may not know at the time of its request what its future expansion plans may entail, it is still pertinent to our decision to approve or deny an expansion exception request, indeed to our faithful implementation of the statutorily required expansion exception process, to understand how approved expansion facility capacity could address the need for specialty services for Medicaid and other underserved populations in the hospital's community (see 88 FR 27180).

Final § 411.363(i)(2)(ii) includes program integrity or quality of care concerns related to the requesting hospital as a factor for CMS' consideration. Because the underlying purpose of the physician self-referral law is to protect against the abuse of the Medicare program and its beneficiaries, program integrity concerns or quality of care concerns related to the requesting hospital or, for that matter, any hospital in the counties where the hospital's main campus and hospital-based facilities (if any) are located would be relevant to CMS' decision whether to approve or deny an expansion exception request. The nature and extent of the program integrity or quality of care concerns, as well as whether they relate to the requesting hospital or another hospital in its community, are most pertinent to our consideration of this factor.

Final § 411.363(i)(2)(iii) and (iv) list factors that relate to a community's general need for additional operating rooms, procedure rooms, and beds as factors for CMS' consideration. We are not prescribing the data points or other criteria that the requesting hospital or community input may use to support an assertion of the need for (or lack of need for) expansion facility capacity. Data and information that could relate to a hospital's or community's need for additional operating rooms, procedure rooms, and beds could include a number and variety of things, such as impediments to accessing timely care (for example, long wait times to schedule elective surgery), the closure of a hospital outside the community that could lead to increased utilization of the hospital and other services in the community, or information regarding population increase, bed occupancy, and bed capacity in the community, even with respect to expansion exception requests from high Medicaid facilities (which need not meet specific criteria related to these data points to qualify as a high Medicaid facility under section 1877(i)(3)(F) of the Act). We do not believe that a need for additional operating rooms, procedure rooms, and beds in a community is shown simply because the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility. For example, two of the criteria for an applicable hospital are that the hospital has an average bed occupancy rate that is higher than the average bed occupancy rate in the State in which it is located and that the State must have an average bed capacity that is less than the national bed capacity during the relevant time period. We do not see a clear or obvious indication of community need, for example, where a hospital that has a bed occupancy rate of only 60 percent is located in a State that has a bed occupancy rate of 59 percent or where a hospital is located in a State that has an average hospital bed capacity of 125 compared to the national average bed capacity of 126, both of which would meet the statutory criteria.

We have not assigned a weight to any of these factors or to any particular data point that may be provided to support the assertions of a hospital or in the community input regarding one or more of the factors. We acknowledge the unique characteristics and needs of each community to which an expansion exception request may relate. Because the CMS decision to approve or deny an

expansion exception request will be made on a case-by-case basis, the significance of each factor (and any other information that CMS may consider when making its decision) will vary among requests. However, all expansion exception requests will be treated the same in that all factors will be considered. As we noted in the proposed rule, decisions to approve or deny requests from hospitals that appear similar could differ because of factors such as planned expansion of needed psychiatric (or other specialty) services instead of general acute care services or whether the requesting hospital seeks an expansion exception to replace facility capacity on its main campus that it has relocated or intends to relocate to other areas in need of services (88 FR 27179). Other examples of information that could impact CMS' decision include but are not limited to: an expected increase in the number of Medicaid beneficiaries or uninsured patients in the community; an expected change in the population (or portion of the population) in the community; program integrity, quality of care, or patient safety concerns with providers or suppliers of services in the community; and development or planned development of additional operating rooms, procedure rooms, or beds in the community. CMS will consider any data and information provided by the requesting hospital or in the community input related to impediments to accessing timely care. In all instances where CMS has determined that the requesting hospital has met the criteria for an applicable hospital or a high Medicaid facility, CMS will provide a detailed explanation of its decision and the rationale for approving or denying the hospital's request in the **Federal Register** notice announcing the decision.

Comment: One commenter objected to our proposal to require a hospital requesting an expansion exception request to provide actual notice of its request directly to hospitals whose data are part of the comparisons required to show that the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility and/or to hospitals located in the requesting hospital's community, citing burden and asserting that the actual notice is unnecessary because the requesting hospital must disclose on any public website for the hospital that it is requesting an expansion exception. Other commenters urged CMS to expand the definition of ''community'' to allow widespread public comment from any interested parties.

Response: Under our existing regulation at § 411.362(c)(5), a hospital requesting an expansion exception currently must provide actual notice of its request directly to hospitals whose data are part of the comparisons required to show that the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility. As we explained in the CY 2015 OPPS/ASC proposed rule, the purpose of this requirement is to ensure that that comparison hospitals are aware of the opportunity to provide input. (At that time, we had not defined in regulation the requesting hospital's ''community'' for purposes of the statutory requirement that individuals and entities in the requesting hospital's community must have an opportunity to provide input with respect to the expansion exception request.) We are retaining this requirement at § 411.363(f)(2).

As discussed in section X.B.2.a.(8). of this final rule, we are finalizing regulations at § 411.363(e)(2)(vi) and (vii) and (i)(2) that set forth the information required to be included in an expansion exception request, information that may be included in an expansion exception request at the requesting hospital's election, and factors that CMS will consider in deciding whether to approve or deny a hospital's request for an expansion exception, respectively. Although we believe that hospitals located in the geographic area served by the requesting hospital (as defined at existing § 411.357(e)(2)) or in the counties in which the requesting hospital provides inpatient or outpatient hospital services as of the date it submits its expansion exception request would likely have information relevant and useful to CMS' decision to approve or deny a request, we are not finalizing our proposal to require actual notification of an expansion exception request to these hospitals. We do not believe that the incremental burden of providing actual notice to such hospitals, if any, outweighs the benefit of having the most comprehensive body of information for use in deciding whether to approve or deny a hospital's expansion exception request. However, we recognize that multiple configurations of the geographic area served by a requesting hospital could exist at any single point in time, and the regulation as proposed does not provide sufficient clarity and direction to requesting hospitals regarding which hospitals (other than the comparison hospitals) must receive actual notification of the expansion exception request. Therefore, we are not finalizing the proposed regulation at § 411.363(f)(2) which would have required actual notification by a hospital that it is requesting an exception, in either electronic or hard copy form, directly to hospitals located in the requesting hospital's community (other than the comparison hospitals, which must receive actual notification). We are finalizing the regulation at § 411.363(f)(1), which replicates our current requirement for disclosure on any public website for the hospital that it is requesting an exception from the prohibition on facility expansion.

We decline to expand the definition of ''community'' as suggested by the last commenter. Section 1877(i)(3)(A)(ii) of the Act identifies the individuals and entities entitled to an opportunity to provide input with respect to an expansion exception request as those that are located in the community in which the requesting hospital is located. We interpret this statutory provision as establishing a geographic nexus between the individual or entity providing the input and the hospital requesting the expansion exception. We are confident that our definition of ''community'' for purposes of final § 411.363 will allow for robust input on an expansion exception request while ensuring this important nexus. As we did in the proposed rule (88 FR 27181), we encourage parties that wish to have their input considered to address how they are part of the requesting hospital's community in their submissions.

Comment: Recognizing that our existing regulations permitting community input with respect to all expansion exception requests were established through notice-and-comment rulemaking, one commenter nonetheless requested that we not permit community input with respect to an expansion exception request made by a high Medicaid facility because the statute does not expressly require community input with respect to such hospitals. Other commenters suggested that we limit community input to whether the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility. One commenter objected to our proposal to establish a 60-day timeframe for the submission of community input. This commenter suggested that, if we extend the period for community input, we should also extend the period for the requesting hospital's rebuttal statement from the current 30 days to 60 days. In contrast, some commenters highlighted our longstanding policy that community input is not confined to the narrow question of whether the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility and supported our position that

the Congress intended for hospitals, patients, and others that are most likely to be affected by the expansion of the requesting hospital to have input in CMS' decision whether to approve or deny the request. One commenter asserted that broad community input on expansion exception requests will better enable CMS to provide case-by-case evaluation of requests and ensure that they are only approved where the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility and the totality of the information supports the appropriateness of the expansion.

Response: We decline to adopt the first commenter's suggestion. We agree with the commenters on the proposed rule, as well as commenters on the CY 2021 OPPS/ASC proposed rule, some of which supported proposals to eliminate the program integrity restrictions on high Medicaid facilities, that community input is a valuable part of the expansion exception process and that it was the Congress' intent to include it (85 FR 86258). We also decline to limit community input to whether the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility. The plain language of section 1877(i)(3)(A)(ii) of the Act requires that the expansion exception process provide for community input ''with respect to the application'' (that is, the expansion exception request). It is our position that, by not limiting community input to whether the requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility, the Congress intended for CMS to obtain and consider community input on the entire application (or request) for an expansion exception. Moreover, our longstanding policy, established through notice-and-comment rulemaking, is not to restrict the types of community input that may be submitted (76 FR 74522 through 74523). Finally, the final regulations should bring clarity regarding the factors that CMS will consider in deciding whether to approve or deny an expansion exception request and will likely result in the submission of more varied information than we have historically received from both requesting hospitals and parties that submit community input on their expansion exception requests. Therefore, we believe that extending the period for both community input and the requesting hospital's rebuttal statement, if any, to 60 days is appropriate.

b. Program Integrity Restrictions on Approved Facility Expansion

As discussed in sections X.B.1.b. of this final rule, in the CY 2012 OPPS/ASC final rule, we issued regulations setting forth the expansion exception process at existing § 411.362(c) and related definitions at § 411.362(a) (76 FR 74122). Using our rulemaking authority in sections 1871 and 1877(i)(3) of the Act, we extended to high Medicaid facilities certain statutory program integrity restrictions related to the expansion of a hospital with physician ownership or investment and the process for requesting an exception from the prohibition on expansion of facility capacity that applied expressly by statute to applicable hospitals. In the CY 2021 OPPS/ASC final rule, we removed the regulatory program integrity restrictions on high Medicaid facilities. There, we stated that we continue to believe that our then-current regulations, for which the Secretary appropriately used his authority and which treat high Medicaid facilities the same as applicable hospitals, are consistent with the Congress' intent to prohibit expansion of physician-owned hospitals generally (85 FR 86256). Nevertheless, because the statute does not expressly apply to high Medicaid facilities the program integrity restrictions related to the frequency of permitted requests for exceptions to the prohibition on expansion of facility capacity, the total amount of permitted expansion of facility capacity, or the location of permitted expansion facility capacity, citing the former Patients over Paperwork initiative, we removed these restrictions from our regulations as they applied to high Medicaid facilities (*Id.*).

We remain steadfast in our belief that the Secretary appropriately used his authority in the CY 2012 OPPS/ASC final rule in establishing an expansion exception process that treated high Medicaid facilities the same as applicable hospitals, and that such treatment is consistent with the Congress' intent to generally prohibit expansion of hospitals with physician ownership or investment. As noted, the removal of the program integrity restrictions as they apply to high Medicaid facilities was not the result of a determination that they were unnecessary. Rather, the purpose of the regulatory change was to streamline regulations to eliminate potential burden under the former Patients over Paperwork initiative.

(1) Proposals

As we explained in the proposed rule, we recently reviewed the CY 2021 OPPS/ASC regulatory revisions, including the comments on our proposals in that rulemaking, and considered whether those revisions currently pose a risk of the types of program or patient abuse that the physician self-referral law is intended to thwart. Commenters opposed to our proposal in the CY 2021 OPPS/ASC proposed rule to remove the program integrity restrictions on high Medicaid facilities highlighted their concern that a hospital that meets the criteria for a high Medicaid facility could expand into markets without large Medicaid patient populations, creating additional campuses far away from the patients the expansion is intended to serve. In addition, commenters asserted that hospitals with physician ownership or investment present a risk of program or patient abuse through cherry-picking patients, avoiding Medicaid and uninsured patients, and treating fewer medically complex patients, and that unrestricted expansion of such hospitals could exacerbate the risk (85 FR 86256 through 86257). We also reviewed community input related generally to the expansion of hospitals with physician ownership or investment that we received in conjunction with an expansion exception request submitted after the effective date of the CY 2021 OPPS/ASC final rule. One of the comments included in the community input asserted that the removal of the program integrity restrictions on high Medicaid facilities posed grave risk to the stability and integrity of patient care, and another asserted that removal of the restrictions contravenes and undermines the Congress' intent to strictly limit expansion of hospitals with physician ownership or investment.

We stated in the proposed rule that our position, following this recent review, is that not applying the program integrity restrictions regarding the frequency of expansion exception requests, maximum aggregate expansion of a hospital, and location of expansion facility capacity to high Medicaid facilities poses a significant risk of program or patient abuse. We noted that, although we are cognizant that the plain language of section 1877(i) of the Act does not expressly apply these program integrity restrictions to high Medicaid facilities in the same way that they pertain to applicable hospitals, we must balance the risk to patients and the Medicare program against any burden that the program integrity restrictions may impose on high Medicaid facilities. It is our position that protecting the Medicare program and its beneficiaries,

as well as Medicaid beneficiaries, uninsured patients, and other underserved populations, from harms such as overutilization, patient steering, cherry-picking, and lemon-dropping outweighs any perceived burden on high Medicaid facilities. In addition, as we stated in the proposed rule, we believe that treating all hospitals the same under the expansion exception process by applying the program integrity restrictions to both applicable hospitals and high Medicaid facilities will promote consistency among decisions to approve or deny expansion exception requests. For these reasons, we proposed to reinstate the program integrity restrictions regarding the frequency of expansion exception requests, maximum aggregate expansion of a hospital, and location of expansion facility capacity as they apply to high Medicaid facilities.

We proposed to revise existing § 411.362(c)(6) to reinstate, with respect to high Medicaid facilities, the program integrity restrictions on the maximum aggregate expansion of a hospital and location of expansion facility capacity. We also proposed to renumber this regulation at § 411.363(j). We noted that these program integrity restrictions would not apply to an increase in facility capacity approved by CMS with respect to an expansion exception request submitted by a high Medicaid facility between January 1, 2021, and the day before the effective date of the revised regulations if our proposals were finalized. We did not propose any change to program integrity restrictions affecting applicable hospitals, which have been subject to the same limitations on maximum aggregate expansion of facility capacity and location of expansion facility capacity under our regulations since January 1, 2012. In addition to the regulation at proposed § 411.363(j), the restriction on the maximum aggregate expansion of a hospital is also implemented at proposed § 411.363(b)(2)(i), which provides that CMS will not consider a request from a hospital if CMS has previously approved a request from the hospital that would allow the hospital's facility capacity to reach 200 percent of its baseline facility capacity if the full expansion is utilized. We note that all but two of the expansion exception requests approved to date have permitted an increase in facility capacity that, if fully utilized, would allow the requesting hospital to reach 200 percent of its baseline number of operating rooms, procedure rooms, and beds. (See *https://www.cms.gov/medicare/fraud-and-abuse/physicianselfreferral/physician_owned_hospitals*.) Therefore, CMS would not consider a future expansion exception request from those hospitals on or after October 1, 2023. The two hospitals that were approved for expansion facility capacity less than their baseline number of operating rooms, procedure rooms, and beds would not be precluded from submitting a future expansion exception request if they are eligible to request another expansion exception request at § 411.363(b) at the time of the request.

The program integrity restriction on the location of expansion facility capacity proposed at § 411.363(j) requires that any approved expansion occur only on the main campus of the hospital. We noted in the proposed rule, however, that nothing in our existing physician self-referral regulations affects a hospital's ability to relocate some or all of the ''original'' operating rooms, procedure rooms, or beds that are part of its baseline facility capacity. On April 18, 2019, we published on the CMS website a FAQ regarding this issue (*https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/FAQs-Physician-Self-Referral-Law.pdf*). The FAQ states:

Question: Where the Secretary has granted a physician-owned hospital (''POH'') an exception to the prohibition on facility expansion under section 1877(i) of the Social Security Act (the ''Act'') and 42 CFR 411.362(c), does the physician self-referral law prohibit the POH from relocating operating rooms, procedure rooms, or beds that were licensed on March 23, 2010, from its main campus to a remote location of the POH before implementing the approved facility expansion on the POH's main campus?

Answer: The physician self-referral law does not prohibit the relocation of operating rooms, procedure rooms, or beds that were licensed on March 23, 2010,[934] from a POH's main campus to a remote location. However, because the regulation at 42 CFR 411.362(c)(6) provides that any increase in the number of operating rooms, procedure rooms, or beds permitted by the Secretary through an exception may occur only in facilities on the POH's main campus, any operating rooms, procedure rooms, or beds added as a result of the Secretary's approval can be located only on the main campus of the POH and may not subsequently be relocated from the main campus. We note that all hospitals must comply with applicable Federal and state laws and regulations regarding, among other things, the licensure, location, construction, and use of operating rooms, procedure rooms, and beds. These laws and regulations may impose additional requirements or limitations on a POH that wishes to relocate operating rooms, procedure rooms, or beds from its main campus.

In the proposed rule, we noted that our policy has not changed since the publication of the FAQ, and this continues to be the case. We reiterate that the physician self-referral law does not prohibit the relocation of ''original'' operating rooms, procedure rooms, or beds from a hospital's main campus to a remote location, but note that a hospital that wishes to expand its service area by locating operating rooms, procedure rooms, or beds in a location beyond its main campus must comply with other Medicare, Federal, and State laws and regulations related to such expansion, which may require that actions occur in a particular sequential order. We also caution that, to avoid the physician self-referral law's referral and billing prohibitions under the rural provider exception or the whole hospital exception, an ownership or investment interest must satisfy the requirements of the applicable exception at the time of the physician's referral, and the hospital must meet the requirements of section 1877(i) of the Act and § 411.362 no later than September 23, 2011. Section 1877(i)(1)(A) of the Act and § 411.362(b)(1) require that *the* hospital had physician ownership or investment on December 31, 2010, and a provider agreement under section 1866 of the Act on that date. Put another way, for a hospital to bill Medicare (or another individual, entity, or third-party payor) for a designated health service furnished as a result of a physician owner's referral following the relocation of ''original'' operating rooms, procedure rooms, or beds to a location other than the main campus of a hospital, the hospital (including all of its provider-based locations) must remain the *same hospital* that had both physician ownership or investment and a Medicare provider agreement on December 31, 2010. (See 87 FR 44798 for a complete discussion of this requirement.) Parties may request an advisory opinion from CMS regarding whether a hospital is (or would be) ''the *same* hospital'' following the relocation of ''original'' operating rooms, procedure rooms, or beds to a location

[934] In the case of a POH that did not have a provider agreement in effect as of March 23, 2010, but had a provider agreement in effect on December 31, 2010, the response provided in this FAQ would apply to beds, procedure rooms and operating rooms that were licensed on the effective date of such agreement.

other than the main campus of a hospital.

Finally, to ensure consistency in the application of the expansion exception process, as well as preserve CMS resources and maintain an orderly and efficient expansion exception process, we also proposed, with respect to high Medicaid facilities, to reinstate the program integrity restriction on the frequency of expansion exception requests at proposed § 411.363(b)(2)(ii). Specifically, we proposed that a hospital may not request an expansion exception unless it has been at least 2 calendar years from the date of the most recent decision by CMS approving or denying the hospital's most recent request for an exception from the prohibition on facility expansion. As we noted in the proposed rule, applicable hospitals have been subject to this limitation under our regulations since the effective date of our CY 2012 OPPS/ASC final rule. We did not propose any substantive change to the application of the limitation on applicable hospitals. However, we proposed to slightly revise the language of existing § 411.362(c)(1) and renumber it at § 411.363(b)(2)(ii).

(2) Provisions of the Final Rule: Program Integrity Restrictions

We are finalizing our proposals to reinstate the limitations on high Medicaid facilities with respect to the maximum aggregate expansion of a hospital and location of expansion facility capacity. Specifically, final § 411.363(j) provides that an increase in facility capacity approved by CMS may not result in the hospital's aggregate facility capacity exceeding 200 percent of its baseline facility capacity and that the expansion facility capacity may occur only in facilities on the hospital's main campus. With respect to applicable hospitals, these program integrity restrictions apply to all increases in facility capacity approved by CMS. With respect to high Medicaid facilities, these program integrity restrictions do not apply to an increase in facility capacity approved by CMS with respect to an expansion exception request submitted between January 1, 2021, and September 30, 2023. As discussed in section X.B.2.a.(8). of this final rule, under final § 411.363(b)(2)(ii), a hospital may submit an expansion exception request, provided that it has been at least 2 calendar years from the date of the most recent decision by CMS approving or denying the hospital's most recent expansion exception request.

We received the following comments on our proposals to reinstate certain program integrity restrictions on high Medicaid facilities and our responses follow.

Comment: We received comments in support of our proposals to reinstate, with respect to high Medicaid facilities, the program integrity restrictions on the maximum aggregate expansion of a hospital and the location of expansion facility capacity, as well as the limitation on the frequency of expansion exception requests. We also received comments that objected to these proposals. Commenters in support of finalizing the proposals identified benefits such as uniform application of the expansion exception process to both applicable hospitals and high Medicaid facilities and the appropriate use of agency resources. Importantly, these commenters asserted that finalizing these policies is necessary to protect the Medicare program and patients from abuses resulting when medical decision making is affected by a physician's financial self-interest, such as an ownership or investment interest in a hospital to which the physician refers Medicare and other patients for designated health services. These commenters also asserted that preventing such abuses outweighs any perceived burden on high Medicaid facilities. One commenter expressed concern that it has seen and would continue to see expansion exception requests from hospitals seeking to bring physician ownership to entirely new markets previously barred by section 1877(i)(1)(B) of the Act and CMS regulations. Other commenters in support of our proposals stated that the application of the program integrity restrictions to all hospitals requesting an expansion exception will encourage a wider breadth of access and choice among Medicare beneficiaries. In contrast, commenters opposed to the application of program integrity restrictions to high Medicaid facilities variously asserted that, recognizing the need to increase access to health care for Medicaid beneficiaries, the Congress intentionally did not apply the program integrity restrictions to high Medicaid facilities and that the application of such restrictions would create barriers to care and exacerbate poor health outcomes for patients with lower incomes and socioeconomic disadvantages because high Medicaid facilities serve many patients in such categories. One of these commenters suggested that CMS should not impose these program restrictions on high Medicaid facilities in the absence of a showing of cherry-picking, lemon-dropping, and the other harms of self-referral. Another of these commenters maintained that, because there have been a limited number of expansion exception requests to date, there is no need for consistency in the treatment of applicable hospitals and high Medicaid facilities.

Response: As we stated in the proposed rule, we recently undertook a fresh review of the CY 2021 OPPS/ASC regulatory revisions, including the comments on our proposals in that rulemaking, and considered whether those revisions currently pose a risk of the types of program or patient abuse that the physician self-referral law is intended to thwart. We also reviewed community input related generally to the expansion of hospitals with physician ownership or investment (not specifically related to an individual hospital that requested an expansion exception) that we received in conjunction with an expansion exception request submitted after the effective date of the CY 2021 OPPS/ASC final rule (88 FR 27185). Based on that review and the comments that we received on the FY 2024 IPPS proposed rule, we share many of the concerns expressed by commenters that support the application of the program integrity restrictions on all hospitals seeking an exception from the prohibition on expansion of facility capacity at section 1877(i)(1)(B) of the Act. As we have stated in previous rulemakings, we are concerned that, when physicians have a financial incentive to refer a patient to a particular entity, that incentive can affect utilization, patient choice, and competition. Physicians can overutilize by ordering items and services for patients that, absent a profit motive, they would not have ordered. A patient's choice is diminished when physicians steer patients to less convenient, lower quality, or more expensive providers of health care just because the physicians are sharing profits with, or receiving remuneration from, the providers. And lastly, where referrals are controlled by those sharing profits or receiving remuneration, the medical marketplace suffers if new competitors cannot win business with superior quality, service, or price (80 FR 41926 and 81 FR 80533).

Section 1877 of the Act was enacted to combat the potential that financial self-interest would affect a physician's medical decision making and ensure that patients have options for quality care. The law's prohibitions were intended to prevent a patient from being referred for services that are not needed or steered to certain health care providers because the patient's physician may improve their financial standing through those referrals. These

prohibitions also aim to prevent the steering of ''desirable'' Medicare beneficiaries (that is, those who may have few complicating or other medical conditions or are economically advantaged) to entities from which the referring physician may benefit financially. Importantly, they protect the Medicare program from increased costs from physician referrals that are influenced by financial self-interest. (See, for example, 85 FR 77493.) At their core, our regulations, including those that govern the process for requesting an exception from the prohibition on expansion of facility capacity, share a common purpose with the statutory prohibitions. Their primary objective is to protect against program or patient abuse, which may occur for any of the reasons noted. To protect the Medicare program and its beneficiaries, as well as Medicaid beneficiaries, uninsured patients, and other underserved populations from potential harms such as (but not limited to) overutilization, patient steering, cherry-picking, and lemon-dropping, we are finalizing our proposals to reinstate program integrity restrictions on high Medicaid facilities. Under final § 411.363(j) and (b)(2)(ii), with respect to expansion exception requests submitted on or after October 1, 2023, a high Medicaid facility may not expand beyond 200 percent of its baseline facility capacity, must locate all approved expansion facility capacity on its main campus, and may request an expansion exception no earlier than 2 calendar years from the date of the most recent decision by CMS approving or denying the hospital's most recent expansion exception request.

As we stated in the proposed rule, we believe that not applying the program integrity restrictions regarding the frequency of expansion exception requests, maximum aggregate expansion of a hospital, and location of expansion facility capacity to high Medicaid facilities poses a significant risk of program or patient abuse (88 FR 27185). Although we are cognizant that section 1877(i)(3) of the Act does not expressly apply these restrictions to high Medicaid facilities in the same way that they are applied to applicable hospitals, unlike the commenters opposed to our proposals, we see nothing in the plain language of the statute to indicate that this was intentional or that the Congress did not apply the restrictions to high Medicaid facilities because, as one commenter contended, it recognized the need to increase access to health care for Medicaid beneficiaries and the expansion of such hospitals would increase this access. In fact, the statutory criteria defining an applicable hospital and the statutory criteria defining a high Medicaid facility both include the hospital's Medicaid inpatient admissions as a criterion, indicating that any hospital that may request an expansion exception must show that it provides a certain level of access to health care for Medicaid beneficiaries relative to the other hospitals in the county in which it is located. Moreover, we are not persuaded that reinstating the program integrity restrictions on high Medicaid facilities would result in barriers to care for Medicaid, uninsured, or other underserved populations. We acknowledge that some high Medicaid facilities may serve a large number of Medicaid beneficiaries, but it is not true that—by definition—every high Medicaid facility serves a large (or even significant) number of Medicaid beneficiaries. Determining whether a hospital meets the criteria for a high Medicaid facility requires a relativity assessment. A hospital that meets the criteria for a high Medicaid facility need only have a higher annual percent of total inpatient admissions under Medicaid than each other hospital in the county that participates in the Medicare program for the relevant time period. For example, a hospital may have only 3 percent of its inpatient admissions under Medicaid and still be a high Medicaid facility if the each of the other Medicare-participating hospitals in the county have less than 3 percent of their inpatient admissions under Medicaid.

As we stated in the proposed rule, we must balance the risk to patients and the Medicare program against any burden that the program integrity restrictions may impose on high Medicaid facilities (88 FR 27185). It remains our position that protecting the Medicare program and its beneficiaries, as well as Medicaid beneficiaries, uninsured patients, and other underserved populations, from potential harms such as overutilization, patient steering, cherry-picking, and lemon-dropping outweighs any perceived burden on high Medicaid facilities. With respect to the commenter that suggested that CMS should not impose these program restrictions on high Medicaid facilities in the absence of a showing of cherry-picking, lemon-dropping, and the other harms of self-referral, we note that we have addressed similar comments in prior rulemakings. In the CY 2017 PFS final rule, we stated that an agency's reasoned assessment of the potential for abuse inherent in a particular business arrangement justifies the issuance of a prophylactic rule and cited longstanding judicial holdings in support of our position (81 FR 80532). Our position has not changed.

Like the commenters that highlighted the benefits of uniform treatment of all hospitals requesting an expansion exception, we believe that treating all hospitals the same under the expansion exception process by applying the program integrity restrictions to both applicable hospitals and high Medicaid facilities will promote consistency among decisions to approve or deny expansion exception requests. Moreover, as these commenters asserted, doing so would be an appropriate use of (and may conserve) agency resources. As we stated in previous rulemaking—and commenters agreed—uniform treatment of all hospitals seeking an expansion exception balances the general ban on new or expanded hospitals with physician ownership or investment with the policy that allows limited growth of certain hospitals (76 FR 74523 through 74524.) Finally, we are unclear regarding the basis of the last commenter's assertion that, because there have been a limited number of expansion exception requests to date, there is no need for consistency in the treatment of applicable hospitals and high Medicaid facilities. As such, we are unable to respond to this comment.

Comment: Highlighting CMS' statement in the proposed rule that the program integrity restrictions on high Medicaid facilities, if finalized, would apply prospectively only (88 FR 27185), one commenter agreed that they should not be applied to expansion exceptions already approved by CMS.

Response: Final § 411.363(j), which implements the program integrity restrictions on the maximum aggregate expansion of a hospital and location of expansion facility capacity, does not apply to an increase in facility capacity approved by CMS with respect to an expansion exception request submitted by a high Medicaid facility between January 1, 2021, and September 30, 2023. The final regulation at § 411.363(j)(2) expressly states this limitation. Final § 411.363(b)(2), which implements the restriction on requesting an expansion exception more frequently than once every 2 calendar years, applies to all hospitals seeking an expansion exception request on or after the effective date of this final rule.

c. Technical and Grammatical Revisions

We proposed certain technical and grammatical revisions to our regulations setting forth the expansion exception process. First, we proposed to revise the reference at § 411.362(b)(2) to the

expansion exception process by substituting ''§ 411.363'' (the proposed location of the regulations setting forth the expansion exception process) for the current reference to ''paragraph (c) of this section.'' In addition, to conform the terminology regarding ''approval'' of a request to that used throughout our proposals, we also proposed to substitute the word ''approved'' for the reference to ''granted'' at § 411.362(b)(2). We proposed to use the same phrasing of ''exception from the prohibition on facility expansion'' wherever that language appears in the regulations. We proposed to use defined acronyms, such as HCRIS, where those terms appear following the initial designation of the acronym. In addition, we proposed to clarify that the references to section 1869 and 1878 in existing § 411.362(c)(8) (renumbered to at § 411.363(l) under this final rule) are references to the Social Security Act. For consistency with our regulations in this subpart J, we proposed to revise the term ''Web site'' to ''website'' wherever the term appears in existing § 411.362. We also proposed to change numbers to words and vice versa where those conventions are correct in the Code of Federal Regulations. Finally, we proposed minor changes to correct grammatically the wording of certain regulations. For example, we proposed to restate the regulation at existing § 411.362(c)(2)(iii) and renumber it at § 411.363(c)(3) to read ''*The hospital* does not discriminate against beneficiaries of Federal health programs and does not permit physicians practicing at the hospital to discriminate against beneficiaries.'' Currently, the regulation does not include the words ''The hospital.'' We received no comments on our proposed technical and grammatical revisions to the regulations and are finalizing these proposals without modification.

C. Technical Corrections to 42 CFR 411.353 and 411.357

On November 16, 2020, the Department issued a final rule titled ''Regulatory Clean-up Initiative'' (85 FR 72899) that contained multiple technical corrections to various regulations. Among the changes finalized in that rule was an amendment to 42 CFR 411.353(d) to reflect an updated cross-reference to the definition of ''timely basis'' at 42 CFR 1003.110 (previously § 1003.101), as updated by 81 FR 88334 on December 7, 2016. However, in our December 2, 2020 (85 FR 77492) final rule entitled ''Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations'' (hereinafter referred to as the ''MCR final rule''), we inadvertently reverted to the prior regulatory text. There were also additional typographical errors in the text of 42 CFR 411.357(s) introduced in the MCR final rule. We proposed to correct these technical errors. Specifically, in § 411.353(d) we proposed to amend paragraph (d) by removing the parenthetical phrase ''§ 1003.101 of this title.'' and adding in its place ''§ 1003.110 of this title.'' We also proposed to amend § 411.357 as follows:

- In paragraph (s)(3) by removing the parenthetical phrase ''governing body;'' and adding in its place ''governing body; and''.
- In paragraph (s)(4) by removing the parenthetical phrase ''financial need; and'' and adding in its place ''financial need.''.

We received no comments on these proposals and are therefore finalizing them as proposed.

D. Safety Net Hospitals—Request for Information

1. Background

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27187 through 27190), consistent with President Biden's Executive Order 13985 on ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' [935] and Executive Order 14091 on ''Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' [936] CMS has made advancing health equity the first pillar in its Strategic Plan. We define health equity as the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, and other factors that affect access to care and health outcomes. CMS is working to advance health equity by designing, implementing, and operationalizing policies and programs that support health for all the people served by our programs, eliminating avoidable differences in health outcomes experienced by people who are disadvantaged or underserved, and providing the care and support that our beneficiaries need to thrive.[937]

Among the goals of CMS's health equity pillar is to evaluate policies to determine how CMS can support safety-net providers, partner with providers in underserved communities, and ensure care is accessible to those who need it.[938] In the FY 2024 IPPS/LTCH PPS proposed rule, we noted that, although various approaches exist to identifying ''safety-net providers,'' this term is commonly used to refer to health care providers that furnish a substantial share of services to uninsured and low-income patients.[939] As such, safety-net providers, including acute care hospitals, play a crucial role in the advancement of health equity by making essential services available to the uninsured, underinsured, and other populations that face barriers to accessing health care, including people from racial and ethnic minority groups, the LGBTQ+ community, rural communities, and members of other historically disadvantaged groups. Whether located in urban centers or geographically isolated rural areas, safety-net hospitals are often the sole providers in their communities of specialized services such as burn and trauma units, neonatal care and inpatient psychiatric facilities.[940] They also frequently partner with local health departments and other institutions to sponsor programs that address homelessness, food insecurity and other social determinants of health, and offer culturally and linguistically appropriate care to their patients. During the COVID–19 pandemic, safety-net hospitals provided emergency care to many of the country's most at-risk patients and leveraged their position as trusted providers to drive vaccine uptake in their communities.[941]

In the proposed rule, we also noted that, because they serve many low-income and uninsured patients, safety-net hospitals may experience greater financial challenges compared to other hospitals. Among the factors that negatively impact safety-net hospital finances, MedPAC pointed specifically to the greater share of patients insured by public programs, which it stated typically pay lower rates for the same

[935] *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[936] 88 FR 10825 (February 22, 2023) (*https://www.federalregister.gov/documents/2023/02/22/2023-03779/further-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal*).

[937] *https://www.cms.gov/sites/default/files/2022-04/Health%20Equity%20Pillar%20Fact%20Sheet_1.pdf.*

[938] *https://www.cms.gov/sites/default/files/2022-04/Health%20Equity%20Pillar%20Fact%20Sheet_1.pdf.*

[939] *https://www.ncbi.nlm.nih.gov/books/NBK224519/.*

[940] *https://www.ncbi.nlm.nih.gov/books/NBK224521/.*

[941] *https://www.nejm.org/doi/full/10.1056/NEJMp2114010.*

services than commercial payers; the increased costs associated with treating low-income patients, whose conditions may be complicated by social determinants of health, such as homelessness and food insecurity; and the provision of higher levels of uncompensated care.[942] Moreover, the financial pressures on many safety-net hospitals have been further exacerbated by the impacts of the COVID–19 pandemic.[943] In response to the challenges posed by COVID–19, HHS had authorized several targeted distributions from the Provider Relief Fund to safety-net hospitals and other hospitals that serve vulnerable populations.[944]

In its June 2022 Report to Congress, MedPAC expressed concern over the financial position of safety-net hospitals.[945] The Commission noted that the limited resources of many safety-net hospitals may make it difficult for them to compete with other hospitals for labor and technology, and observed that ''[t]his disadvantage, in turn, could lead to difficulty maintaining quality of care and even to hospital closure.'' [946] During the earlier phases of the COVID–19 pandemic, for example, studies showed higher rates of mortality among patients who received treatment at certain safety-net hospitals, with researchers citing understaffing and lack of access to advanced therapies as some of the factors that may have contributed to negative health outcomes.[947] Other research shows that the closure of a safety-net hospital can have ripple effects within the community, making it more difficult for disadvantaged patients to access care and shifting uncompensated care costs onto neighboring facilities.[948] [949]

As explained in the FY 2024 IPPS/LTCH PPS proposed rule, two of the ways the Medicare statute currently recognizes the additional costs of safety-net hospitals are through disproportionate share hospital (DSH) payments and uncompensated care payments. In its June 2022 Report, however, MedPAC raised concerns about whether these payments appropriately target safety-net hospitals.[950] The Medicare statute also includes special payment provisions for other hospitals in underserved communities, including sole community hospitals, which are the sole source of care in their areas, as well as Critical Access Hospitals and Rural Emergency Hospitals.

In the proposed rule, we stated that given the critical importance of safety-net hospitals to the communities they serve, it is important to be able to identify these hospitals for policy purposes. We next discussed two potential approaches, as outlined in the following sections: the Safety-Net Index (SNI), which MedPAC has developed as a measure of the degree to which a hospital functions as a safety-net hospital, and area-level indices, which are intended to capture local socioeconomic factors correlated with medical disparities and underservice.

2. Methodological Considerations When Identifying Safety Net Hospitals Using the SNI

As explained in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27188), the SNI developed by MedPAC is calculated as the sum of—(1) the share of the hospital's Medicare volume associated with low-income beneficiaries; (2) the share of its revenue spent on uncompensated care; and (3) an indicator of how dependent the hospital is on Medicare.

a. Medicare Low-Income Subsidy (LIS) Enrollment Ratio

For the share of the hospital's Medicare volume associated with low-income beneficiaries, MedPAC's definition of low-income beneficiaries includes all those who are dually eligible for full or partial Medicaid benefits, and those who do not qualify for Medicaid benefits in their states but who receive the Part D low-income subsidy (LIS) because they have limited assets and an income below 150 percent of the Federal poverty level. Collectively, MedPAC refers to this population as ''LIS beneficiaries'' because those who receive full or partial Medicaid benefits are automatically eligible to receive the LIS. MedPAC states that its intent in defining low-income beneficiaries in this manner is to reduce the effect of variation in states' Medicaid policies on the share of beneficiaries whom MedPAC considers low-income, but to allow for appropriate variation across states based on the share of beneficiaries who are at or near the Federal poverty level.

In the FY 2024 IPPS/LTCH PPS proposed rule, we explained that to calculate the LIS ratio for a hospital for a fiscal year, we could use the number of inpatient discharges of Medicare beneficiaries who are also LIS beneficiaries during the month of discharge, divided by the total number of inpatient discharges of Medicare beneficiaries. In a similar manner to how we currently use the most recent fiscal year MedPAR claims for ratesetting purposes,[951] we could use the most recent MedPAR claims for the discharge information needed to calculate the LIS ratio. We could merge onto this MedPAR data the LIS beneficiary information needed to calculate the LIS ratio.

b. Uncompensated Care Costs to Total Operating Revenue Ratio

In the FY 2024 IPPS/LTCH PPS proposed rule, we stated that, for the share of a hospital's revenue spent on uncompensated care, we could use the ratio of uncompensated care costs to total operating hospital revenue from the most recent available audited cost report data.[952] Specifically, the ratio could be calculated as Worksheet S–10 column 1, line 30 (Total cost of uncompensated care) divided by Worksheet G–3 column 1, line 3 (Net patient revenues) using these existing lines from the most recent available audited cost report data.

c. Medicare Share of Total Inpatient Days

For the indicator of how dependent a hospital is on Medicare, MedPAC's recommendation is to use one-half of the Medicare share of total inpatient days.

In the FY 2024 IPPS/LTCH PPS proposed rule, we stated that, in calculating the Medicare share of total

[942] *https://www.medpac.gov/wp-content/uploads/2022/06/Jun22_MedPAC_Report_to_Congress_v2_SEC.pdf.*

[943] *https://www.nejm.org/doi/full/10.1056/NEJMp2114010.*

[944] *https://www.hrsa.gov/provider-relief/payments-and-data/targeted-distribution.*

[945] The June 2022 Report sets forth a conceptual framework for identifying safety-net hospitals and a rationale for better-targeted Medicare funding for such hospitals through a new Medicare Safety-Net Index (MSNI), as discussed in more detail later in this request for information. In its March 2023 Report to Congress, MedPAC discusses its recommendation to Congress to redistribute disproportionate share hospital and uncompensated care payments through the MSNI: *https://www.medpac.gov/wp-content/uploads/2023/03/Mar23_MedPAC_Report_To_Congress_SEC.pdf.*

[946] *https://www.medpac.gov/wp-content/uploads/2022/06/Jun22_MedPAC_Report_to_Congress_v2_SEC.pdf.*

[947] *https://www.nytimes.com/2020/07/01/nyregion/Coronavirus-hospitals.html*; *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2768602.*

[948] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3272769/.*

[949] *https://www.healthaffairs.org/do/10.1377/forefront.20180503.138516/full/.*

[950] *https://www.medpac.gov/wp-content/uploads/2022/06/Jun22_MedPAC_Report_to_Congress_v2_SEC.pdf.*

[951] The most recent fiscal year MedPAR data lag two years behind the rulemaking year (for example, FY 2022 MedPAR data are available for this FY 2024 final rule).

[952] The most recent available cost report data for this purpose generally lags four years behind the rulemaking year (for example, FY 2020 cost report data were available for the FY 2024 proposed rule).

inpatient days for a hospital, the most recent available audited cost report data could be used. The numerator could be calculated from existing lines on the cost report as follows: the sum of Worksheet S–3 Part I, column 6, line 2 (MA days and days for individuals enrolled in Medicare cost plans); Worksheet S–3 Part I, column 6, line 14 (Medicare adult and pediatric hospital days excluding SNF and NF swing-bed, observation bed, and hospice days); Worksheet S–3 Part I, column 6, line 32 (total Medicare labor and delivery days); and subtracting Worksheet S–3 Part I, column 6, line 5 (total Medicare adult and pediatric SNF swing bed days) and Worksheet S–3 Part I, column 6, line 6 (total Medicare adult and pediatric NF swing bed days).

The denominator could be calculated from existing lines on the cost report as follows: the sum of Worksheet S–3 Part I, column 8, line 14 (total all patients' adult and pediatric hospital days excluding SNF and NF swing-bed, observation bed, and hospice days); Worksheet S–3 Part I, column 8, line 30 (total all patients' employee discount days); Worksheet S–3 Part I, column 8, line 32 (total all patients' labor room days); and subtracting Worksheet S–3 Part I, column 8, line 5 (total swing-bed SNF patient days) and Worksheet S–3 Part I, column 8, line 6 (total swing-bed NF patient days).

In the proposed rule, we also noted that, when calculating the SNI, the following circumstances may be encountered: new hospitals (for example, hospitals that begin participation in the Medicare program after the available audited cost report data), hospital mergers, hospitals with multiple cost reports and/or cost reporting periods that are shorter or longer than 365 days, cost reporting periods that span fiscal years, and potentially aberrant data. We solicited comments on how MedPAC's SNI calculation should address these circumstances and whether the approaches used in the uncompensated care payment methodology might be appropriate. We discussed in section IV.E.3. of the preamble to the proposed rule how these circumstances are addressed in the uncompensated care payment methodology.

For MedPAC's SNI calculation, we also solicited comments on whether a multi-year approach using the three most recently available years of data may be appropriate to increase the stability of the index, similar to the approach used in the uncompensated care payment methodology.

3. An Alternative Approach to Identifying Safety Net Hospitals—Area-level Indices

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27188 through 27189), an alternative to using an SNI approach could be to identify safety-net hospitals using area-level indices. This approach could potentially better target policies to address the social determinants of health as well as address the lack of community resources that may increase risk of poor health outcomes and risk of disease in the population. We noted that the Office of the Assistant Secretary for Planning and Evaluation (ASPE) had recently commissioned three environmental scans of: (1) area-level indices of social risk; (2) measures used in government programs that target areas, providers, or populations with social risk; and (3) existing payment models that incorporate measures of social risk. ASPE suggested that an area-level index could be used to prioritize communities for funding and other assistance to improve social determinants of health (SDOH)—such as affordable housing, availability of food stores, and transportation infrastructure. Although ASPE concluded that none of the existing area-level indices are ideal, they concluded that the area deprivation index (ADI) or the Social Deprivation Index (SDI) were the best available choices when selecting an index for addressing health related social needs or social determinants of health.[953]

The ADI was developed by researchers at the National Institutes of Health with the goal of quantifying and comparing social disadvantage across geographic neighborhoods. It is a composite measure derived through a combination of 17 input variables from census data. The ADI measure is intended to capture local socioeconomic factors correlated with medical disparities and underservice. Several peer reviewed research studies demonstrate that neighborhood-level factors for those residing in disadvantaged neighborhoods also have a relationship to worse health outcomes for these residents. Living in an area with an ADI score of 85 or above, a validated measure of neighborhood disadvantage, is shown to be a predictor of 30-day readmission rates, lower rates of cancer survival, poor end-of-life care for patients with heart failure, and longer lengths of stay and fewer home discharges post-knee surgery even after accounting for individual social and economic risk factors.[954] [955] [956] [957] [958] Many rural areas also have relatively high levels of neighborhood disadvantage and high ADI levels.

In the FY 2024 IPPS/LTCH PPS proposed rule, we noted that Medicare already uses ADI to assess underserved beneficiary populations in the Shared Savings Program. In the CY 2023 PFS final rule, CMS adopted a policy to provide eligible Accountable Care Organizations (ACOs) with an option to receive advanced investment payments (87 FR 69778). Advance investment payments are intended to encourage low-revenue ACOs that are inexperienced with risk to participate in the Shared Savings Program and to provide additional resources to such ACOs to support care improvement for underserved beneficiaries (87 FR 69845 through 69849).[959]

Medicare uses ADI to calculate the amount of advance investment payments it will make on a quarterly basis to an ACO. There are two types of advance investment payments: a one-time payment of $250,000 and quarterly payments. When calculating the quarterly payments, CMS first determines the ACO's assigned

[953] Report: ''Landscape of Area-Level Deprivation Measures and Other Approaches to Account for Social Risk and Social Determinants of Health in Health Care Payments.'' Accessed at *https://aspe.hhs.gov/reports/area-level-measures-account-sdoh* on September 27, 2022.

[954] Kind AJ, et al., ''Neighborhood socioeconomic disadvantage and 30-day rehospitalization: a retrospective cohort study.'' *Annals of Internal Medicine*. No. 161(11), pp 765–74, doi: 10.7326/M13–2946 (December 2, 2014), available at *https://www.acpjournals.org/doi/epdf/10.7326/M13-2946*.

[955] Jencks SF, et al., ''Safety-Net Hospitals, Neighborhood Disadvantage, and Readmissions Under Maryland's All-Payer Program.'' *Annals of Internal Medicine*. No. 171, pp 91–98, doi:10.7326/M16–2671 (July 16, 2019), available at *https://www.acpjournals.org/doi/epdf/10.7326/M16-2671*.

[956] Cheng E, et al., ''Neighborhood and Individual Socioeconomic Disadvantage and Survival Among Patients With Nonmetastatic Common Cancers.'' *JAMA Network Open Oncology*. No. 4(12), pp 1–17, doi: 10.1001/jamanetworkopen.2021.39593 (December 17, 2021), available at *https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2787244*.

[957] Hutchinson RN, et al., ''Rural disparities in end-of-life care for patients with heart failure: Are they due to geography or socioeconomic disparity?'' *The Journal of Rural Health*. No. 38, pp 457–463, doi: 10.1111/jrh.12597 (2022), available at *https://onlinelibrary.wiley.com/doi/epdf/10.1111/jrh.12597*.

[958] Khlopas A, et al., ''Neighborhood Socioeconomic Disadvantages Associated With Prolonged Lengths of Stay, Nonhome Discharges, and 90-Day Readmissions After Total Knee Arthroplasty.'' *The Journal of Arthroplasty*. No. 37(6), pp S37–S43, doi: 10.1016/j.arth.2022.01.032 (June 2022), available at *https://www.sciencedirect.com/science/article/pii/S0883540322000493*.

[959] Under 42 CFR 425.630(g)(1), CMS will recoup advance investment payments made to an ACO from any shared savings the ACO earns until CMS has recouped in full the amount of advance investment payments made to the ACO.

beneficiary population. CMS then assigns each beneficiary a risk factors-based score as follows: (A) the risk factors-based score will be set to 100 if the beneficiary is enrolled in the Medicare Part D LIS or is dually eligible for Medicare and Medicaid; (B) the risk factors-based score will be set to the ADI national percentile rank matched to the beneficiary's mailing address if the beneficiary is not enrolled in the LIS or is not dually eligible for Medicare and Medicaid and sufficient data is available to match the beneficiary to an ADI national percentile rank; and (C) the risk factors-based score will be set to 50 if the beneficiary is not enrolled in the LIS or is not dually eligible for Medicare and Medicaid and sufficient data is not available to match the beneficiary to an ADI national percentile rank.

The risk-factors based scores assigned to the beneficiaries assigned to the ACO form the basis for determining the quarterly advanced investment payment to the ACO. For additional detail, please see the quarterly payment amount calculation methodology at 42 CFR 425.630(f)(2).

4. Request for Information

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27189 through 27190), we stated that we were interested in public feedback on the challenges faced by safety-net hospitals, and potential approaches to help safety-net hospitals meet those challenges. We welcomed all feedback on this issue and asked the following questions to help facilitate that feedback.

- How should safety-net hospitals be identified or defined?
- What factors should not be considered when identifying or defining a safety-net hospital and why?
- What are the different types of safety-net hospitals?
- What are the main challenges facing safety-net hospitals?
- What are particular challenges facing rural safety-net hospitals?
- What new approaches or modifications to existing approaches should be implemented or considered to address these challenges, either for safety-net hospitals in general, or for specific types of safety-net hospitals, including rural safety-net hospitals?
- How helpful is it to have multiple types or definitions of safety-net hospitals that may be used for different purposes or to help address specific challenges?
- For Medicare purposes, would these new or modified approaches require new statutory authority, or could they be accomplished using existing statutory authority? If there is existing statutory authority, we requested that commenters identify the existing statutory authority.
- Are there specific payment approaches either as previously described or otherwise to consider for rural safety-net hospitals, including acute care hospitals and CAHs, to address challenges?
- For any new or modified approaches, how can specific hospitals be identified as safety-net hospitals, or a type of safety-net hospital, using existing data sources? Are there new data sources that should be developed to better identify these hospitals?
- Is MedPAC's SNI an appropriate basis for identifying safety-net hospitals for Medicare purposes?

++ How might it be improved?

++ Should there be a threshold for identifying safety net hospitals using the SNI?

- Should an area-level index, such as the ADI, be part of an appropriate basis for identifying safety-net hospitals?

++ Would it be appropriate to adapt the risk-factors based scores used in the Shared Savings Program to the identification of safety-net hospitals?

++ How might it be adapted?

- Are there social determinants data collected by hospitals that could be used to inform an approach to identify safety net hospitals? Are there HHS or CMS policies that could support that data collection?
- What challenges do safety-net hospitals face around investments in information technology infrastructure?

++ What are ways that HHS policy could advance more robust investments in infrastructure for safety net hospitals?

++ How could any potential payment adjustments be determined?

- Should safety-net hospitals' reporting burden and compensation be different than other hospitals? If so, how?
- What are the patient demographics at safety-net hospitals? What challenges do patients of safety net hospitals face before and after receiving care at the hospital?
- Given Administration efforts to reduce the patient burden of medical debt, are there ways to develop payment approaches for safety net hospitals that would also support hospital patients that need financial assistance?

We greatly appreciate the many thoughtful and wide-ranging comments we received in response to this RFI, including comments from organizations representing safety-net hospitals, State hospital associations, industry trade groups, health systems, and other interested parties. Our public collaboration on these issues has been and will continue to be critical in achieving our mutual goal of helping safety-net hospitals meet the unique challenges they face. We are expeditiously conducting an in-depth review of the comments we received, and this will help to inform and guide our future rulemaking and other actions in this area.

E. Disclosures of Ownership and Additional Disclosable Parties Information for Skilled Nursing Facilities and Nursing Facilities—Applicability to Other Providers and Suppliers

In the February 15, 2023 **Federal Register** (88 FR 9820), we published a proposed rule titled ''Disclosures of Ownership and Additional Disclosable Parties Information for Skilled Nursing Facilities and Nursing Facilities'' (hereinafter occasionally referred to as the first disclosures proposed rule). This proposed rule would implement portions of section 6101 of the Affordable Care Act, which require the disclosure of certain ownership, managerial, and other information regarding Medicare skilled nursing facilities (SNFs) and Medicaid nursing facilities. It also proposed definitions of the terms ''private equity company'' (PEC) and ''real estate investment trust'' (REIT) (88 FR 9829). Specifically, a private equity company would be defined in 42 CFR 424.502 as a publicly-traded or non-publicly traded company that collects capital investments from individuals or entities (that is, investors) and purchases an ownership share of a provider (for example, SNF, home health agency, etc.). A REIT would be defined in the same regulation as a publicly-traded or non-publicly traded company that owns part or all of the buildings or real estate in or on which the provider operates. The purpose of these definitions was to assist SNFs that complete the Form CMS–855A enrollment application (Medicare Enrollment Application—Institutional Providers; OMB Control No. 0938–0685) in determining whether an owning or managing entity reported in Section 5 of the application must be identified therein as a PEC and REIT.

We outlined in the first disclosures proposed rule our concerns about the quality of care furnished by PEC-owned and REIT-owned SNFs and the consequent need for transparency regarding such owners (88 FR 9822 and 9823). Yet these concerns about PEC and REIT ownership are not limited to SNFs but extend to other provider and supplier types. Given the linkage discussed in the first disclosures proposed rule between PEC and REIT

ownership and a decline in nursing home quality, we believed it was critical for us to collect this information from all providers and suppliers that complete the Form CMS–855A. Doing so would enable us to: (1) determine whether a similar connection exists with respect to non-SNF providers and suppliers; and (2) help us take measures to improve beneficiary quality of care to the extent such connections exist. Indeed, it was with this in mind that we proposed on December 15, 2022, to revise the Form CMS–855A application in a Paperwork Reduction Act submission (87 FR 76626) to require all owning and managing entities listed on any provider's or supplier's Form CMS–855A submission to disclose whether they are a PEC or a REIT.[960]

For the foregoing reasons and to assist these entities in completing the Form CMS–855A, we proposed in the May 1, 2023 IPPS/LTCH PPS proposed rule that the aforementioned definitions of PEC and REIT would apply to all providers and suppliers completing the Form CMS–855A enrollment application. The definitions would not be limited to SNFs. We solicited comment on the propriety of the PEC and REIT definitions first proposed in the February 15, 2023 proposed rule and welcomed suggested revisions. We also sought comment and feedback on whether: (1) our proposed PEC definition should include publicly-traded PECs; and (2) CMS should consider collecting information on other types of private ownership besides PECs and REITs.

We received approximately 10 sets of comments on our proposed application of the PEC and REIT definitions to all providers and suppliers that complete the Form CMS–855A application. As many of these comments closely aligned with those we received on the first disclosure proposed rule's PEC and REIT provisions, we believe that addressing all of them at one time would facilitate consistency, clarity, and a more streamlined approach. Accordingly, we are not finalizing in this rule the PEC and REIT proposals (including the associated information collection estimates) we made in the May 1, 2023 proposed rule. They will instead be addressed as part of a final rule that we will publish at a later date that will also address the February 15, 2023 disclosures proposed rule.

[960] *https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-855a.*

XI. MedPAC Recommendations and Publicly Available Files

A. MedPAC Recommendations

Under section 1886(e)(4)(B) of the Act, the Secretary must consider MedPAC's recommendations regarding hospital inpatient payments. Under section 1886(e)(5) of the Act, the Secretary must publish in the annual proposed and final IPPS rules the Secretary's recommendations regarding MedPAC's recommendations. We have reviewed MedPAC's March 2023 ''Report to the Congress: Medicare Payment Policy'' and have given the recommendations in the report consideration in conjunction with the policies set forth in this final rule. MedPAC recommendations for the IPPS for FY 2024 are addressed in appendix B to this final rule.

For further information relating specifically to the MedPAC reports or to obtain a copy of the reports, contact MedPAC at (202) 653–7226, or visit MedPAC's website at *https://www.medpac.gov*.

B. Publicly Available Files

IPPS-related data are available on the internet for public use. The data can be found on the CMS website at *https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/AcuteInpatientPPS/index*. We listed the data files available in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27190 through 27192).

Commenters interested in discussing any data files used in construction of this final rule should contact Michael Treitel at (410) 786–4552.

XII. Collection of Information Requirements

A. Statutory Requirement for Solicitation of Comments

Under the Paperwork Reduction Act (PRA) of 1995, 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. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 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.

In the FY 2024 IPPS/LTCH PPS proposed rule, we solicited public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs) except for the ICRs related to our proposal on counting certain days associated with section 1115 demonstrations in the Medicaid fraction, for which we solicited public comment in a proposed rule published in the **Federal Register** on February 28, 2023 (CMS–1788–P (88 FR 12623)). The following ICRs are listed in the order of appearance within the preamble (see sections II. through X. of the preamble of this final rule).

B. Collection of Information Requirements

1. ICRs for the Hospital Wage Index for Acute Care Hospitals

Section III.I.2.a. of the preamble of this final rule, FY 2023 Reclassification Application Requirements and Approvals, references the information collection request 0938–0573 which expired on January 31, 2021. A reinstatement of the information collection request (ICR) is currently being developed. The public will have an opportunity to review and submit comments regarding the reinstatement of this ICR through a public notice and comment period separate from this rulemaking.

2. ICR Relating to Counting Certain Days Associated With Section 1115 Demonstrations in the Medicaid Fraction

In February 2023, we issued a proposed rule (88 FR 12623) to revise our regulations on the counting of days associated with individuals eligible for certain benefits provided by section 1115 demonstrations in the Medicaid fraction of a hospital's disproportionate patient percentage. In section IV.F. of the preamble of this final rule, we are revising the criteria for a hospital to count days associated with individuals eligible for certain benefits provided by section 1115 demonstrations in the Medicaid fraction of a hospital's disproportionate patient percentage (DPP): for the patient days of individuals to be included in the DPP Medicaid fraction numerator (if they are not also entitled to Medicare Part A), the demonstration must provide those patients with insurance that includes coverage of inpatient hospital services, or the insurance the patient purchased

with premium assistance provided by the demonstration must include coverage of inpatient hospital service; and that for days of patients who have bought health insurance that provides inpatient hospital benefits using premium assistance obtained through a section 1115 demonstration, that assistance must be equal to 100 percent of the premium cost to the patient.

In section IV.F. of the preamble of this final rule, we summarized and responded to a comment that Connecticut recently received approval for a premium assistance program under section 1115 that pays through the health insurance exchange 100 percent of the premium costs to cover low-income individuals ineligible for Medicaid under the State plan. For this final rule, we are including Connecticut in the list of states that have section 1115 demonstrations with premium assistance programs.

Overall, we estimate 340 hospitals will be affected by the requirement under our premium assistance policy, which is the total number of Medicare certified subsection (d) hospitals in the eight States (Arkansas, Connecticut, Massachusetts, Oklahoma, Rhode Island, Tennessee, Utah, and Vermont) that currently operate approved section 1115 demonstrations with premium assistance programs. This estimated total burden is $20,899,060 a year (1,978,141 inquiries a year × 0.25 hours per inquiry × (wages of $21.13/hour × 2 (fringe benefits)) = $20,899,060/year).

The number of inquiries is calculated by subtracting the total CY 2019 Medicare discharges from total CY 2019 discharges for all payers for all subsection (d) hospitals in each State with a currently approved premium assistance section 1115 demonstration. We used annualized discharges for both Medicare and all payer discharge figures rather than actual discharges, as some hospitals' cost reports do not provide data for an entire calendar year. To determine whether a patient's premiums for inpatient hospital services insurance are paid for by subsidies provided by a section 1115 demonstration, we believe hospitals would need to conduct inquiries for all patients with non-Medicare insurance for purposes of reporting on the Medicare cost report.[961] The estimated difference between all payer annualized discharges and annualized Medicare discharges was 1,978,141 in CY 2019.

We estimate that hospitals will use their existing communication methods that are in place to verify insurance information when collecting the information under this ICR. We estimate that verifying whether a patient receives 100 percent of the cost of their premium as premium assistance authorized by a section 1115 demonstration will take 15 minutes per individual. We believe that information clerks will be making these inquiries. Based on the Bureau of Labor Statistics Occupational Employment Statistics data (May 2021) for Category 43–4199,[962] Information and Record Clerks, All Other, the mean hourly wage for an Information and Record Clerk is $21.13. We have added 100 percent for fringe and other indirect costs benefits which calculates to $42.26 per hour. We estimate this total annual cost is $20,899,060 (1,978,141 inquiries × 0.25 hours per inquiry × $42.26 per hour).

In addition, in section IV.F. of the preamble of this final rule, we summarized and responded to comments regarding Massachusetts' premium assistance program authorized under section 1115. The commentator asserted that the Massachusetts 1115 demonstration provides premium assistance to Medicaid enrollees and other non-Medicaid-eligible residents who purchase health insurance in the state's health insurance exchange that supports low-income individuals enrolled in the Massachusetts Medicaid program who have access to employer-sponsored health insurance, and that this may cause an increased burden on Massachusetts and the providers in that state to determine which patients receive 100 percent premium assistance. In addition, the Massachusetts demonstration provides premium assistance to some non-Medicaid-eligible individuals at levels less than 100 percent of the individual's premium cost.

In response to this comment, we stated that while it may be that the premium assistance policy proposed will lead to an increased burden on Massachusetts and providers in that state to identify which non-Medicaid-eligible patients have received premium assistance that covers 100 percent of their costs for that patient day to be included in the DPP Medicaid fraction numerator, we do not believe that the burden involved is unreasonable. The commenters did not provide any information in support of their allegation as to the extent of the burden and why they believe it would be unreasonable.

We are providing an estimate of the increase in burden with regard to Massachusetts to identify whether any non-Medicaid-eligible patients have received premium assistance that covers less than 100 percent of their costs for their patient day to be included in the DPP Medicaid fraction numerator. We estimate 56 hospitals will be affected by this requirement, which is the total number of Medicare certified subsection (d) hospitals in Massachusetts. This estimated total burden is $479,322 a year (453,689 inquiries × 0.025 hours per × $42.26 per hour).

To determine whether any non-Medicaid-eligible patients have received premium assistance that covers less than 100 percent of their premium costs, we estimate that hospitals will use their existing communication methods. As discussed previously, we estimated that verifying whether a patient receives 100 percent of the cost of their premium as premium assistance authorized by a section 1115 demonstration will take 15 minutes per individual. We believe in many cases verifying whether a patient receives premium assistance under the demonstration that provides less than 100 percent of the individual's premium cost can occur during that same 15 minutes. However, to account for circumstances where additional time may be needed, we estimated this additional verification will take 1.5 minutes (or 10 percent more time in addition to the time we have estimated it will take to determine whether any non-Medicaid-eligible patients have received premium assistance that covers 100 percent of their premium costs). Overall, we estimate the difference between all payer annualized discharges and annualized Medicare discharges for the 56 Massachusetts hospitals was 453,689 in CY 2019. Similar to the previous discussion, we believe that information clerks will be making these inquiries, and we have used the Bureau of Labor Statistics Occupational Employment Statistics data (May 2021) for Category 43–4199,[963] Information and Record Clerks, All Other, with the mean hourly wage for an Information and Record Clerk of $21.13. We have added 100 percent for fringe and other indirect costs benefits, which calculates to $42.26 per hour. We estimate the total annual cost is $479,322 for this additional verification (453,689 inquiries × 0.025 hours per inquiry × $42.26 per hour).

In summary, we estimate that the total annual burden for Medicare certified subsection (d) hospitals in the eight states with currently approved premium assistance demonstrations to determine whether any non-Medicaid-eligible patients have received premium

[961] CMS–Form–2552–10 OMB No. 0938–0050.

[962] *https://www.bls.gov/oes/2021/may/oes_nat.htm.*

[963] *https://www.bls.gov/oes/2021/may/oes_nat.htm.*

assistance from a section 1115 demonstration that covers 100 percent of their premium costs under this requirement is $21,386,382 ($20,899,060 + $479,322).

3. ICRs for Payments for Low-Volume Hospitals

As discussed in section V.E. of the preamble of this final rule, under section 1886(d)(12) of the Act, as amended, the low-volume hospital definition and payment adjustment methodology in effect for FYs 2019 through 2022 under section 50204 of the Bipartisan Budget Act of 2018 are extended through FY 2024. Therefore, for FYs 2019 through 2024, in order to qualify as a low-volume hospital, a subsection (d) hospital must be more than 15 road miles from another subsection (d) hospital and have less than 3,800 total discharges during the fiscal year. In section V.E. of the preamble of this final rule, we also discuss the process for requesting and obtaining the low-volume hospital payment adjustment under § 412.101. Under this previously established process, a hospital makes a written request to its MAC. This request must contain sufficient documentation to establish that the hospital meets the applicable mileage and discharge criteria. The MAC will determine if the hospital qualifies as a low-volume hospital by reviewing the data the hospital submits with its request for low-volume hospital status in addition to other available data. The MAC and CMS may review available data such as the number of discharges, in addition to the data the hospital submits with its request for low-volume hospital status, to determine whether or not the hospital meets the qualifying criteria. (For qualifying hospitals, MACs determine the applicable low-volume hospital payment amount, and no additional action is needed by the hospital.) The burden associated with this requirement is estimated to be 1 hour per hospital. The burden associated with these requests is the time and effort for the hospital to provide the MAC with evidence that it meets the specified mileage and discharge requirements. The burden associated with this requirement is estimated to be 1 hour per hospital. An accountant and auditor would perform this at the wage rate of $40.37. The wage would be doubled to include overhead. We estimate it would take 650 annual hours (1 hour × 650 hospitals seeking the low-volume payment adjustment). Therefore, the cost is $52,481 (650 hours × $80.74). The information collection request under OMB control number 0938–NEW will be submitted to OMB for approval.

We did not receive comments regarding the ICRs for payments for low-volume hospitals.

4. ICRs Relating to the Hospital Readmissions Reduction Program

In section V.J. of the preamble of this final rule, we discuss requirements for the Hospital Readmissions Reduction Program. In the FY 2024 IPPS/LTCH PPS proposed rule, we did not propose any changes to the Hospital Readmissions Reduction Program for FY 2024 (88 FR 27024). All six of the current Hospital Readmissions Reduction Program's measures are claims-based measures. We believe that continuing to use these claims-based measures will not create or reduce any information collection burden for hospitals because they will continue to be collected using Medicare FFS claims that hospitals are already submitting to the Medicare program for payment purposes.

5. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section V.K. of the preamble of this final rule, we discuss updates to the Hospital VBP Program. Specifically, in the FY 2024 IPPS/LTCH PPS proposed rule, we proposed to adopt substantial measure updates to the MSPB Hospital measure beginning with the FY 2028 program year and to the Hospital-Level Risk-Standardized Complication Rate (RSCR) Following Elective Primary Total Hip Arthroplasty (THA) and/or Total Knee Arthroplasty (TKA) measure beginning with the FY 2030 program year (88 FR 27025 through 27026). We also proposed to adopt the Severe Sepsis and Septic Shock: Management Bundle measure beginning with the FY 2026 program year (88 FR 27027 through 27029). Additionally, we proposed to adopt technical changes to the form and manner of the administration of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey measure (88 FR 27031 through 27032). We also proposed a scoring methodology change that adjusts for treating a high proportion of underserved patients, defined by dual eligibility, that rewards hospitals for providing excellent care to this population beginning with the FY 2026 program year (88 FR 27039 through 27049). We also requested feedback on potential additional changes to the Hospital VBP Program that would address health equity (88 FR 27049 through 27050). Lastly, we proposed to modify the Total Performance Score (TPS) maximum to be 110, resulting in numeric score range of 0 to 110 (88 FR 27049). In the FY 2024 IPPS/LTCH PPS proposed rule, we discussed collection of information burden for these proposals (88 FR 27193). In this final rule, we are finalizing all of the Hospital VBP's Program's proposals, as proposed.

Data collections for the Hospital VBP Program are associated with the Hospital Inpatient Quality Reporting (IQR) Program under OMB control number 0938–1022, the National Healthcare Safety Network under OMB control number 0920–0666, and the HCAHPS survey under OMB control number 0938–0981. The Hospital VBP Program will use data that are also used to calculate quality measures in other programs and Medicare FFS claims data that hospitals are already submitting to CMS for payment purposes, so therefore the program does not estimate any change in burden associated with these finalized measures. There is also no change in burden due to the finalized scoring methodology change because the policy does not require hospitals to submit any additional information but instead changes how hospitals are scored based on the information already being submitted.

6. ICRs Relating to the Hospital-Acquired Condition (HAC) Reduction Program

OMB has currently approved 28,800 hours of burden and approximately $1.2 million under OMB control number 0938–1352 (expiration date November 30, 2025), accounting for information collection burden experienced by 400 subsection (d) hospitals selected for validation each year in the HAC Reduction Program. In the FY 2024 IPPS/LTCH PPS proposed rule, we did not propose to add or remove any measures from the HAC Reduction Program.

In the FY 2024 IPPS/LTCH PPS proposed rule, we proposed to provide hospitals the opportunity to request reconsideration of their final validation score prior to HAC Reduction Program scoring beginning with the FY 2025 program year and future years (88 FR 27054 through 27055). In section V.L. of the preamble of this final rule, we are finalizing this process. This reconsideration process will be conducted once per program fiscal year after validation of HAIs for all four quarters of the given fiscal year's data period and after the confidence interval has been calculated. A hospital requesting HAC Reduction Program reconsideration must submit a reconsideration request form. As we previously finalized for purposes of the

Hospital IQR Program, information collection requirements imposed subsequent to an administrative action are not subject to the PRA under 5 CFR 1320.4(a)(2) (75 FR 50411). Therefore, there is no change in burden associated with this process.

In the FY 2024 IPPS/LTCH PPS proposed rule, we proposed to modify the validation targeting criteria to include any hospital with a ERUB of the two-tailed confidence interval that is less than 75 percent and received an extraordinary circumstances exception (ECE) for one or more quarters beginning with the FY 2027 program year (88 FR 27055). In section V.L. of the preamble of this final rule, we are finalizing this modification. Because we are neither modifying the number of hospitals that will be selected for validation nor the number of records each selected hospital is required to submit, we do not estimate any changes to our currently approved burden estimates as a result of this policy.

7. ICRs for the Hospital Inpatient Quality Reporting (IQR) Program

a. Background

Data collections for the Hospital IQR Program are associated with OMB control number 0938–1022. OMB has currently approved 1,772,318 hours of burden and approximately $72 million under OMB control number 0938–1022 (expiration date January 31, 2026), accounting for information collection burden experienced by approximately 3,150 IPPS hospitals and 1,350 non-IPPS hospitals for the FY 2025 payment determination. In the FY 2024 IPPS/LTCH PPS proposed rule, we described the burden changes regarding collection of information under OMB control number 0938–1022, for IPPS hospitals (88 FR 27194 through 27196).

For more detailed information on our finalized policies for the Hospital IQR Program, we refer readers to section IX.C. of the preamble of this final rule. In the FY 2024 IPPS/LTCH PPS proposed rule, we proposed to adopt three electronic clinical quality measures (eCQMs) beginning with the CY 2025 reporting period/FY 2027 payment determination: (1) Hospital Harm–Pressure Injury eCQM, (2) Hospital Harm–Acute Kidney Injury eCQM, and (3) Excessive Radiation eCQM (88 FR 27079 through 27084). We proposed to modify two measures within the Hospital IQR Program measure set beginning with the performance data from July 1, 2024 through June 30, 2025, impacting the FY 2027 payment determination: the (1) Hybrid Hospital-Wide All-Cause Risk Standardized Mortality measure and (2) the Hybrid Hospital-Wide All-Cause Risk Standardized Readmission measure (88 FR 27085 through 27088). We proposed to modify the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the Q4 2023 reporting period/FY 2025 payment determination (88 FR 27074 through 27078). We proposed to remove the Elective Delivery measure beginning with the CY 2024 reporting period/FY 2026 payment determination (88 FR 27091 through 27093). We proposed to remove two Medicare FFS claims-based measures: the Hospital-Level RSCR Following Elective Primary THA and/or TKA measure beginning with the April 1, 2025 through March 31, 2028 reporting period impacting the FY 2030 payment determination, and the MSPB Hospital measure beginning with the CY 2026 reporting period/FY 2028 payment determination (88 FR 27089 through 27091). We proposed to modify the validation targeting criteria to include any hospital with a two-tailed confidence interval that is less than 75 percent and which submitted less than four quarters of data due to receiving an extraordinary circumstances exception (ECE) for one or more quarters beginning with the FY 2027 payment determination (88 FR 27116). Lastly, we proposed to modify data collection and reporting requirements for the HCAHPS survey measure beginning with the FY 2027 payment determination (88 FR 27112 through 27114). In this final rule, we are finalizing all of the Hospital IQR Program's proposals, as proposed.

Our finalized policies to remove the Elective Delivery measure beginning with the CY 2024 reporting period/FY 2026 payment determination and to modify data collection and reporting requirements for the HCAHPS survey measure beginning with the FY 2027 payment determination result in changes of collection of information burden as detailed in this section. The remaining policies being finalized will not affect the information collection burden associated with the Hospital IQR Program.

The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $22.43 per hour for medical records specialists.[964] We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate ($22.43 × 2 = $44.86) to estimate total cost is a reasonably accurate estimation method. Accordingly, unless otherwise specified, we will calculate cost burden to hospitals using a wage plus benefits estimate of $44.86 per hour throughout the discussion in this section of this rule for the Hospital IQR Program.

In the FY 2023 IPPS/LTCH PPS final rule (86 FR 45507), our burden estimates were based on an assumption of approximately 3,150 IPPS hospitals. For this final rule, based on data from the FY 2023 Hospital IQR Program payment determination, which supports this assumption, we will continue to estimate that 3,150 IPPS hospitals will report data to the Hospital IQR Program.

b. Information Collection Burden Estimate for the Finalized Removal of the Elective Delivery Measure Beginning With the CY 2024 Reporting Period/FY 2026 Payment Determination

In section IX.C.7.c. of this final rule, we discuss the removal of the Elective Delivery measure beginning with the CY 2024 reporting period/FY 2026 payment determination. In the FY 2013 IPPS/LTCH PPS final rule, we finalized a burden of 10 minutes, or 0.167 hours, per record to report this measure (77 FR 53666). The currently approved burden estimate for this measure assumes each IPPS hospital will report 76 records quarterly for this measure. We estimate a total reduction in burden of 51 hours (0.167 hours/record × 76 records × 4 quarters) at a cost of $2,288 (51 hours × $44.86) per IPPS hospital associated with the removal of this measure. For the CY 2024 reporting period and subsequent years, we estimate a total burden decrease of 159,600 hours (51 hours × 3,150 hospitals) at a cost of $7,159,656 (159,600 hours × $44.86) related to this policy.

c. Information Collection Burden Estimate for the Finalized Adoption of Three eCQMs Beginning With the CY 2025 Reporting Period/FY 2027 Payment Determination: (1) Hospital Harm—Pressure Injury eCQM; (2) Hospital Harm—Acute Kidney Injury eCQM; and (3) Excessive Radiation eCQM

In sections IX.C.5.a., b., and c. of the preamble of this final rule, we are adopting three new eCQMs: (1) Hospital Harm—Pressure Injury eCQM; (2) Hospital Harm—Acute Kidney Injury eCQM; and (3) Excessive Radiation

[964] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records Specialists. Accessed on January 13, 2023. Available at: *https://www.bls.gov/oes/current/oes292072.htm.*

eCQM—beginning with the CY 2025 reporting period/FY 2027 payment determination. Under OMB control number 0938–1022 (expiration date January 31, 2026) and as finalized in the FY 2023 IPPS/LTCH PPS final rule, the currently approved burden estimate for reporting and submission of eCQM measures is one hour per IPPS hospital for all six required eCQM measures (87 FR 49387). The addition of these three eCQMs does not affect the information collection burden associated with submitting eCQM measure data under the Hospital IQR Program. As finalized in the FY 2023 IPPS/LTCH PPS final rule, current Hospital IQR Program policy requires hospitals to select six eCQMs from the eCQM measure set on which to report (87 FR 49299 through 49302). In other words, although these new eCQMs are being added to the eCQM measure set, hospitals are not required to report more than a total of six eCQMs.

For the Excessive Radiation eCQM, hospitals will also be required to log in through the measure developer's secure portal and run the Alara Imaging Software for CMS Measure Compliance inside the firewall. The software runs automatically to create the three intermediate data elements needed for the measure. Once the software finishes creating these intermediate variables, hospitals can either: (1) send the data to a hospital's EHR for reporting; (2) send the data to another vendor for reporting; or (3) have the measure developer submit the data on behalf of and at the behest of hospitals to CMS. No manual data entry is required. We estimate that each hospital will spend approximately 15 minutes (0.25 hours) annually to conduct these activities prior to data submission and therefore estimate a total annual burden of 788 hours (0.25 hours × 3,150 hospitals) at a cost of $35,327 (788 hours × $44.86/hour).

With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.L. of appendix A of this final rule).

d. Information Collection Burden Estimate for the Two Hybrid Measure Refinements

In sections IX.C.6.a. and b. of this final rule, we are modifying the: (1) Hybrid Hospital-Wide All-Cause Risk Standardized Mortality measure; and (2) Hybrid Hospital-Wide All-Cause Risk Standardized Readmission measure beginning with the performance data from July 1, 2024 through June 30, 2025, impacting the FY 2027 payment determination.

Although the finalized modifications of both measures will expand the measure cohort to include MA patients, the burden associated with submission of claims data continues to be accounted for under OMB control number 0938–1197 (expiration date October 31, 2023) and the burden associated with submission of eCQM data under OMB control number 0938–1022 (expiration date March 31, 2026) remains unchanged as hospitals will not be required to submit any additional data. Therefore, we are not finalizing any changes in burden associated with the finalized modifications of these measures.

e. Information Collection Burden for the Refinement of the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning With the Quarter 4 CY 2023 Reporting Period/FY 2025 Payment Determination

In the FY 2022 IPPS/LTCH PPS final rule, we finalized adoption of the COVID–19 Vaccination Coverage among HCP measure for the Hospital IQR Program (86 FR 45374 through 45382). In section IX.B. of this final rule, we are replacing the term ''complete vaccination course'' with the term ''up to date'' in the HCP vaccination definition and update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID–19 vaccines, including booster doses, beginning with the Quarter 4 CY 2023 reporting period/FY 2025 payment determination. We previously discussed information collection burden associated with this measure in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45509).

We do not believe that the use of the term ''up to date'' or the update to the numerator will impact information collection or reporting burden because the modification changes neither the amount of data being submitted nor the frequency of data submission. Additionally, because we are not finalizing any updates to the form, manner, and timing of data submission for this measure, there will be no increase in burden associated with the proposal. Furthermore, the modified COVID–19 Vaccination Coverage among HCP measure will continue to be calculated using data submitted to the CDC under a separate OMB control number (0920–1317; expiration date March 31, 2026). However, the CDC currently has a PRA waiver for the collection and reporting of vaccination data under section 321 of the National Childhood Vaccine Injury Act of 1986 (Pub. L. 99–660, enacted on November 14, 1986).

f. Information Collection Burden for the Finalized Removal of Two Claims-Based Measures

In sections IX.C.7.a. and b. of the preamble of this final rule, we are removing two claims-based measures: the Hospital-Level RSCR Following Elective Primary THA/TKA and the MSPB Hospital measures. Because these measures are calculated using Medicare FFS claims that are already reported to the Medicare program for payment purposes, removing these measures will not result in a change to the burden estimates provided in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49384 through 49392).

g. Information Collection Burden for the Finalized Modification of Validation Targeting Criteria Beginning With the FY 2027 Payment Determination

In section IX.C.11.b. of the preamble of this final rule, we are modifying the validation targeting criteria to include any hospital with a two-tailed confidence interval that is less than 75 percent and which submitted less than four quarters of data due to receiving an ECE for one or more quarters beginning with the FY 2027 payment determination.

Because we are neither modifying the number of IPPS hospitals that will be selected for validation nor the number of records each selected IPPS hospital will be required to submit, we are not finalizing any changes to our currently approved burden estimates as a result of this proposal.

h. Information Collection Burden for the Finalized Modification of Data Collection and Reporting Requirements for the HCAHPS Survey Beginning With the CY 2025 Reporting Period/FY 2027 Payment Determination

In section IX.C.10.h. of the preamble of this final rule, we are finalizing updates to the data collection and reporting for the HCAHPS survey measure beginning with the CY 2025 reporting period/FY 2027 program year. Specifically, we are finalizing to: (1) add three new modes of survey administration (Web-Mail mode, Web-Phone mode, and Web-Mail-Phone mode) in addition to the current Mail Only, Telephone Only and Mail-Phone modes; (2) remove the rule that only the patient may respond to the survey and allow a patient's proxy to respond to the survey; (3) extend the data collection period for the HCAHPS Survey from 42 to 49 days; (4) limit the number of supplemental items that may be added

to the HCAHPS survey for quality improvement purposes to 12 items; (5) require hospitals to collect information about the language that the patient speaks while in the hospital (whether English, Spanish, or another language), and that the official Spanish translation of the HCAHPS Survey be administered to all patients who prefer Spanish; and (6) remove two currently available options for administration of the HCAHPS survey that are not used by participating hospitals (Active Interactive Voice Response and Hospitals Administering HCAHPS for Multiple Sites).

With the exception of the removal of two currently available options for administering the survey that are not in use, which CMS estimates to have no effect on the information collections, the remaining policies are estimated to result in a five percent increase from the 2,313,192 respondents who completed and submitted the HCAHPS survey as part of the Hospital IQR Program, which equates to 115,660 additional respondents (2,313,192 × .05). We do not believe any of these proposals will affect the time required to complete the survey, which is estimated to be 7.25 minutes (0.120833 hours) per respondent, as currently approved under OMB control number 0938–0981 (expiration date September 30, 2024).

We believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $20.71/hr. The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices identifies the approach for valuing time when individuals undertake activities on their own time.[965] To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of $998, divided by 40 hours to calculate an hourly pre-tax wage rate of $24.95/hr. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent, resulting in the post-tax hourly wage rate of $20.71/hr. Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment. We therefore estimate a burden increase of 13,976 hours (115,660 respondents × 0.120833 hours) at a cost of $289,443 (13,976 hours × $20.71).

We are not making any revisions to the information collection at this time; however, we will submit a revised information collection request to OMB for approval under OMB control number 0938–0981 as part of the FY 2025 IPPS/LTCH PPS rulemaking cycle.

[965] *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

i. Summary of Information Collection Burden Estimates for the Hospital IQR Program

In summary, under OMB control number 0938–1022 (expiration date January 31, 2026), we estimate that the policies promulgated in this final rule will result in a total decrease of 158,812 hours at a savings of $7,124,329 annually for 3,150 IPPS hospitals from the CY 2024 reporting period/FY 2026 payment determination through the CY 2028 reporting period/FY 2030 payment determination. Under OMB control number 0938–0981 (expiration date September 30, 2024), we estimate that the policies promulgated in this final rule will result in a total increase of 13,976 hours at a cost of $289,443 annually for 3,150 hospitals beginning with the CY 2025 reporting period/FY 2027 payment determination. We will submit the revised information collection estimates to OMB for approval under OMB control numbers 0938–1022. The information collection request approved under OMB control number 0938–0981 will be revised and submitted as part of the FY 2025 rulemaking cycle.

TABLE XII.B-01: SUMMARY OF HOSPITAL IQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2024 REPORTING PERIOD/FY 2026 PAYMENT DETERMINATION

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1022 for the CY 2024 Reporting Period / FY 2026 Payment Determinations								
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of respondents reporting**	**Average number records per respondent per quarter**	**Annual burden (hours) per respondent**	**Finalized Annual burden (hours) across hospitals**	**Previously finalized annual burden (hours) across hospitals**	**Net difference in annual burden hours**
Removal of Elective Delivery (PC-01) measure	10	4	3,150	76	51	159,600	N/A	-159,600
	Total Change in Information Collection Burden Hours: -159,600							
	Total Cost Estimate: Updated Hourly Wage ($44.86) x Change in Burden Hours (-159,600) = **-$7,159,656**							

TABLE XII.B-02: SUMMARY OF HOSPITAL IQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE CY 2025 REPORTING PERIOD/FY 2027 PAYMENT DETERMINATION

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-0981 for the FY 2027 Payment Determination								
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of respondents reporting**	**Average number records per respondent per quarter**	**Annual burden (hours) per respondent**	**Finalized Annual burden (hours) across hospitals**	**Previously finalized annual burden (hours) across hospitals**	**Net difference in annual burden hours**
Adopt Excessive Radiation eCQM	15	1	3,150	1	0.25	788	0	+788
Adopt Updates to the Data Collection and Reporting of HCAHPS	7.25	1	2,428,852	1	0.120833	293,486	279,510	+13,976
	Total Change in Information Collection Burden Hours: +14,764							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+14,764) = **$324,770**							

8. ICRs for PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

OMB has currently approved 0 hours of burden under OMB control number 0938–1175 (expiration date January 31, 2025), accounting for the annual information collection requirements for 11 PCHs for the PCHQR Program for measures finalized through the CY 2023 IPPS/LTCH PPS final rule. The PCHQR program also includes measures that are calculated using data submitted via the National Healthcare Safety Network (NHSN) under OMB control number 0920–0666, claims data that is already reported to the Medicare program for payment purposes, and survey-based measures that are calculated using data collected via the HCAHPS survey under OMB control number 0938–0981. In this final rule, we describe the collection of information impact under the same OMB control number for PPS-exempt cancer hospitals (PCHs).

In the FY 2024 IPPS/LTCH PPS proposed rule, we proposed to adopt four new measures that we expect to affect our collection of information burden estimates: (1) the Documentation of Goals of Care Discussions Among Cancer Patients measure beginning with the FY 2026 program year; (2) the Facility Commitment to Health Equity measure beginning with the FY 2026 program year; (3) the Screening for Social Drivers of Health measure with voluntary reporting for the FY 2026 program year and mandatory reporting beginning with the FY 2027 program year; and (4) the Screen Positive Rate for Social Drivers of Health measure with voluntary reporting for the FY 2026 program year and mandatory reporting beginning with the FY 2027 program year (88 FR 27117 through 27132). We also proposed updates to the data collection and reporting for the HCAHPS survey measure (NQF #0166) beginning with the FY 2027 program year (88 FR 27135 through 27138). In the FY 2024 IPPS/LTCH PPS proposed rule, we discussed our proposed burden estimates associated with these proposed policies (88 FR 27197 through 27202).

We also proposed policies which will not affect the information collection burden associated with the PCHQR Program. As discussed in the FY 2024 IPPS/LTCH PPS proposed rule, we proposed to modify the COVID–19 Vaccination Coverage among HCP measure beginning with the FY 2025 program year (88 FR 27074 through 27078). In addition, we proposed to begin public reporting of the Surgical Treatment Complications for Localized Prostate Cancer (PCH–37) measure with the FY 2025 Program Year (88 FR 27134). In this final rule, we are finalizing all of the PCHQR Program's proposals as proposed.

The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $22.43 per hour for a medical records specialist.[966] We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in publicly available literature. Nonetheless, we believe that doubling the hourly wage rate ($22.43 × 2 = $44.86) to estimate total cost is a reasonably accurate estimation method and is consistent with OMB guidance. Accordingly, we will calculate cost burden to PCHs using a wage plus benefits estimate of $44.86 per hour throughout the discussion in this section of this final rule for the PCHQR Program.

a. Information Collection Burden Estimate for the Documentation of Goals of Care Discussions Among Cancer Patients Measure Beginning With the FY 2026 Program Year

In section IX.D.6. of the preamble of this final rule, we are adopting the Documentation of Goals of Care Discussions Among Cancer Patients measure beginning with the FY 2026 program year. PCHs will report data through the Hospital Quality Reporting (HQR) System on annual basis during the submission period.

Similar to other measures reported via the HQR System for the PCHQR program, we estimate a burden of no more than 10 minutes per hospital per year, as each hospital will only be required to report one aggregate numerator and denominator for all patients. Using the estimate of 10 minutes (or 0.167 hours) per PCH per year, and the updated wage estimate as described previously, we estimate that this policy will result in a total annual burden of approximately 2 hours across all PCHs (0.167 hours × 11 PCHs) at a cost of $90 (2 hours × $44.86). With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.M. of appendix A of this final rule).

[966] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records Specialists. Accessed on January 13, 2023. Available at: *https://www.bls.gov/oes/current/oes292072.htm.*

b. Information Collection Burden Estimate for the Facility Commitment to Health Equity Structural Measure Beginning With the FY 2026 Program Year

In section IX.D.3. of the preamble of this final rule, we are adopting the Facility Commitment to Health Equity Structural Measure beginning with the FY 2026 program year. This measure was previously adopted for the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule with an estimated burden of no more than 10 minutes per hospital per year, as it involves attesting to as many as five questions one time per year for a given reporting period (87 FR 49385). We believe the estimated burden will be the same for PCHs.

PCHs will report data through the HQR System on an annual basis during the submission period. Using the estimate of 10 minutes (or 0.167 hours) per PCH per year, and the updated wage estimate as described previously, we estimate that this policy will result in a total annual burden of approximately 2 hours across all PCHs (0.167 hours × 11 PCHs) at a cost of $90 (2 hours × $44.86). With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.M. of appendix A of this final rule).

c. Information Collection Burden for the Screening for Social Drivers of Health Measure Beginning With the FY 2026 Program Year

In section IX.D.4. of the preamble of this final rule, we are adopting the Screening for Social Drivers of Health measure beginning with voluntary reporting for the FY 2026 program year followed by mandatory reporting on an annual basis beginning with the FY 2027 program year. This measure was previously adopted for the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule with an estimated burden of 2 minutes (0.033 hours) per patient to conduct this screening and 10 minutes (0.167 hours) per hospital response to transmit the measure data (87 FR 49385 through 49386). We believe the estimated burden for both patient screening and data submission will be the same for PCHs. As discussed in the preamble of this final rule, PCHs will be able to collect data and report the measure via multiple methods. We believe that most PCHs will likely collect data through a screening tool incorporated into their electronic health record (EHR) or other patient intake process. For data submission, PCHs will report measure data through the HQR System annually.

We believe that the cost for beneficiaries undertaking administrative and other tasks on their own time is a post-tax wage of $20.71/hr. The Valuing Time in U.S. Department of Health and Human Services Regulatory Impact Analyses: Conceptual Framework and Best Practices identifies the approach for valuing time when individuals undertake activities on their own time. To derive the costs for beneficiaries, a measurement of the usual weekly earnings of wage and salary workers of $998, divided by 40 hours to calculate an hourly pre-tax wage rate of $24.95/hr. This rate is adjusted downwards by an estimate of the effective tax rate for median income households of about 17 percent, resulting in the post-tax hourly wage rate of $20.71/hr. Unlike our State and private sector wage adjustments, we are not adjusting beneficiary wages for fringe benefits and other indirect costs since the individuals' activities, if any, would occur outside the scope of their employment. Based on the most recent patient data from PCHs, approximately 275 patients will be screened annually in each PCH, for a total of 3,025 patients across all 11 PCHs. Similar to our assumptions for the Hospital IQR Program, for the purposes of calculating burden for voluntary reporting in the FY 2026 program year, we assume 50 percent of PCHs will screen 50 percent of patients. For the FY 2027 program year, we assume 100 percent of PCHs will screen 100 percent of patients. For the FY 2026 program year, we estimate that 828 total patients will be screened (6 PCHs × 138 patients) for a total annual burden for patient screening of 28 hours (828 respondents × 0.033 hours) at a cost of $580 (28 hours × $20.71). For data submission for the FY 2026 program year, we estimate a burden of 1 hour (0.167 hours × 6 PCHs) at a cost of $45 (1 hour × $44.86). For the FY 2027 program year, we estimate a total annual burden for patient screening of 101 hours (3,025 respondents × 0.033 hours) at a cost of $2,092 (101 hours × $20.71) across all PCHs. For data submission for the FY 2027 program year, we estimate a total annual burden of approximately 2 hours across all PCHs (0.167 hours × 11 PCHs) at a cost of $90 (2 hours × $44.86/hour).

With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.M. of appendix A of this final rule).

d. Information Collection Burden for the Screen Positive Rate for Social Drivers of Health Measure Beginning With the FY 2026 Program Year

In section IX.D.5. of the preamble of this final rule, we are adopting the Screen Positive Rate for Social Drivers of Health measure with voluntary reporting for the FY 2026 program year followed by mandatory reporting on an annual basis beginning with the FY 2027 program year. This measure was previously adopted for the Hospital IQR Program in the FY 2023 IPPS/LTCH PPS final rule with an estimated burden of 10 minutes (0.167 hours) per hospital response to transmit the measure data as we estimate only the additional burden for a hospital reporting via the HQR System since patients will not need to provide any additional information for this measure (87 FR 49386). We believe the estimated burden will be the same for PCHs. Similar to our assumptions for the Hospital IQR Program, for the purposes of calculating burden for voluntary reporting in the FY 2026 program year, we assume 50 percent of PCHs would transmit measure data. For the FY 2027 program year, we assume 100 percent of PCHs would transmit measure data.

We estimate a total burden in the FY 2026 program year of 1 hour (0.167 hours × 6 PCHs) at a cost of $45 (1 hour × $44.86/hour). We estimate a total annual burden beginning with the FY 2027 program year of 2 hours across all PCHs (0.167 hours × 11 PCHs) at a cost of $90 (2 hours × $44.86).

e. Information Collection Burden Estimate for the Updates to the Data Collection and Reporting for the HCAHPS Survey Measure (NQF #0166) Beginning With the FY 2027 Program Year

In section IX.D.10. of the preamble of this final rule, we are finalizing updates to the data collection and reporting for the HCAHPS survey measure beginning with the FY 2027 program year. Specifically, we are finalizing the following: (1) add three new modes of survey administration (Web-Mail mode, Web-Phone mode, and Web-Mail-Phone mode) in addition to the current Mail Only, Telephone Only and Mail-Phone modes; (2) remove the rule that only the patient may respond to the survey and allow a patient's proxy to respond to the survey; (3) extend the data collection period for the HCAHPS Survey from 42 to 49 days; (4) limit the number of supplemental items that may be added to the HCAHPS survey for quality improvement purposes to 12 items; (5) require hospitals to collect information about the language that the patient speaks while in the hospital (whether English, Spanish, or another language), and that the official Spanish translation of the HCAHPS Survey be administered to all patients who prefer Spanish; and (6) remove two currently available options for administration of the HCAHPS Survey that are not used by participating hospitals (Active Interactive Voice Response and Hospitals Administering HCAHPS for Multiple Sites).

With the exception of the removal of two currently available options for administering the survey that are not in use, the remaining proposals are estimated to result in a 5 percent increase from the 13,064 respondents who completed and submitted the HCAHPS survey as part of the PCHQR program, which equates to 653 additional respondents (13,064 × 5 percent). We do not believe any of these proposals will affect the time required to complete the survey, which is estimated to be 7.25 minutes (0.120833 hours) per respondent, as currently approved under OMB control number 0938–0981 (expiration date September 30, 2024). We therefore estimate a burden increase of 79 hours (653 respondents × 0.120833 hours/respondent) at a cost of $1,636 (79 hours × $20.71).

We are not making revisions to the information collection at this time; however, we will submit a revised information collection request to OMB for approval under OMB control number 0938–0981 as part of the FY 2025 IPPS rulemaking cycle.

f. Information Collection Burden Estimate for the Refinement of the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning With the FY 2025 Program Year

In the FY 2022 IPPS/LTCH PPS final rule, we adopted the COVID–19 Vaccination Coverage among HCP Measure for the PCHQR Program (86 FR 45428 through 45434). In section IX.B. of the preamble of this final rule, we are modifying the COVID–19 Vaccination Coverage among HCP Measure to replace the term ''complete vaccination course'' with the term ''up to date'' in the HCP vaccination definition and update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID–19 vaccines, including booster doses, beginning with the FY 2025 program year. We previously discussed information collection burden associated with this

measure in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45513).

We do not believe that the change in terminology to refer to ''up to date'' instead of ''complete vaccination course'' will impact information collection or reporting burden because the modification changes neither the amount of data being submitted nor the frequency of data submission. Furthermore, the COVID–19 Vaccination Coverage among HCP measure will be calculated using data submitted to the CDC under a separate OMB control number (0920–1317; expiration date January 31, 2024).

g. Information Collection Burden Estimate for the Policy to Begin Public Reporting of the Surgical Treatment Complications for Localized Prostate Cancer (PCH–37) Measure Beginning With the FY 2025 Program Year Data

In section IX.D.9.b. of the preamble of this final rule, we are finalizing that we will begin public reporting of the Surgical Treatment Complications for Localized Prostate Cancer (PCH–37) measure beginning with the FY 2025 program year data. Because this measure was previously finalized for inclusion in the PCHQR Program and we are not requiring PCHs to collect or submit any additional data, we do not estimate any change in information collection burden associated with this final rule.

h. Summary of Information Collection Burden Estimates for the PCHQR Program

In summary, under OMB control number 0938–1175 (expiration date January 31, 2025), we estimate that the policies promulgated in this final rule will result in a total increase of 109 hours at a cost of $2,452 annually for 11 PCHs from the FY 2026 program year through the FY 2027 program year. The subsequent tables summarize the total burden changes for each respective FY program year compared to our currently approved information collection burden estimates (the table for the FY 2027 program year reflects the total burden change associated with these policies). Under OMB control number 0938–0981 (expiration date September 30, 2024), we estimate that the policies promulgated in this final rule will result in a total increase of 79 hours at a cost of $1,636 annually for 11 PCHs beginning with the FY 2027 program year. The total increase in burden associated with this information collection is approximately 188 hours at a cost of $4,088. We will submit the revised information collection estimates to OMB for approval under OMB control number 0938–1175. The information collection request approved under OMB control number 0938–0981 will be revised and submitted to OMB as part of the FY 2025 IPPS rulemaking cycle.

TABLE XII.B-03. SUMMARY OF PCHQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE FY 2026 PROGRAM YEAR

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1175 for the FY 2026 Program Year								
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of respondents reporting**	**Average number records per respondent per quarter**	**Annual burden (hours) per respondent**	**Finalized Annual burden (hours) across PCHs**	**Previously finalized annual burden (hours) across PCHs**	**Net difference in annual burden hours**
Adopt Proposed Documentation of Goals of Care Discussions Among Cancer Patients Measure	10	1	11	1	.167	2	N/A	+2
Adopt Proposed Facility Commitment to Health Equity Measure	10	1	11	1	.167	2	N/A	+2
Adopt Proposed Screening for Social Drivers of Health Measure (Survey)	2	N/A	828	N/A	4.6	28	N/A	+28
Adopt Proposed Screening for Social Drivers of Health Measure (Reporting)	10	1	6	1	0.167	1	N/A	+1
Adopt Proposed Screen Positive Rate for Social Drivers of Health	10	1	11	1	0.167	2	N/A	+2
	Total Change in Information Collection Burden Hours: 35							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+35) = **$895**							

TABLE XII.B-04--SUMMARY OF PCHQR PROGRAM ESTIMATED INFORMATION COLLECTION BURDEN CHANGE FOR THE FY 2027 PROGRAM YEAR

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-1175 for the FY 2027 Program Year								
Activity	**Estimated time per record (minutes)**	**Number reporting quarters per year**	**Number of respondents reporting**	**Average number records per respondent per quarter**	**Annual burden (hours) per respondent**	**Finalized Annual burden (hours) across PCHs**	**Previously finalized annual burden (hours) across PCHs**	**Net difference in annual burden hours**
Adopt Proposed Documentation of Goals of Care Discussions Among Cancer Patients Measure	10	1	11	1	.167	2	N/A	+2
Adopt Proposed Facility Commitment to Health Equity Measure	10	1	11	1	.167	2	N/A	+2
Adopt Proposed Screening for Social Drivers of Health Measure (Survey)	2	N/A	3,025	N/A	9.167	101	N/A	+101
Adopt Proposed Screening for Social Drivers of Health Measure (Reporting)	10	1	11	1	0.167	2	N/A	+2
Adopt Proposed Screen Positive Rate for Social Drivers of Health	10	1	11	1	0.167	2	N/A	+2
	Total Change in Information Collection Burden Hours: 109							
	Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+109) = **$2,452**							

Annual Recordkeeping and Reporting Requirements Under OMB Control Number 0938-0981 for the FY 2027 Program Year								
Activity	Estimated time per record (minutes)	Number reporting quarters per year	Number of respondents reporting	Average number records per respondent per quarter	Annual burden (hours) per respondent	Finalized Annual burden (hours) across PCHs	Previously finalized annual burden (hours) across across PCHs	Net difference in annual burden hours
Adopt Proposed Updates to the Data Collection and Reporting of HCAHPS	7.25	1	13,717	1	0.120833	1,657.5	1,578.6	+79
Total Change in Information Collection Burden Hours: 79								
Total Cost Estimate: Updated Hourly Wage (Varies) x Change in Burden Hours (+79) = **$1,636**								

9. ICRs for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

An LTCH that does not meet the requirements of the LTCH QRP for a fiscal year will receive a 2-percentage point reduction to its otherwise applicable annual update for that fiscal year.

The burden associated with the LTCH QRP is the time and effort associated with complying with the requirements of the LTCH QRP. In sections IX.C. and IX.E. of the preamble of this final rule, we proposed to modify one measure, adopt two measures and remove two measures from the LTCH QRP, and increase the LTCH QRP data completion thresholds for the LCDS items. The following is a discussion of these information collections, some of which have already received OMB approval.

As stated in section IX.E. of the preamble of this final rule, we proposed that LTCHs submit data on one modified quality measure, the HCP COVID–19 Vaccine measure beginning with the FY 2025 LTCH QRP. LTCHs will be required to report the modified measure data to the CDC's NHSN. The burden associated with the HCP COVID–19 Vaccine measure is accounted for under the CDC PRA package currently approved under OMB control number 0920–1317 (expiration 1/31/2024). Because we did not propose any updates to the form, manner, and timing of data submission for this measure, there would be no increase in burden associated with this final rule. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45448 through 45449) for these policies.

In section IX.E.4.a. of the preamble of the proposed rule, we proposed the DC Function measure beginning with the FY 2025 LTCH QRP. This assessment-based quality measure will be calculated using data from the LCDS that are already reported to the Medicare program for payment and other quality reporting purposes. There will be no additional burden for LTCHs because the measure will not require LTCHs to report new data elements.

In section IX.E.4.b and IX.E.4.c. of the preamble of the proposed rule, we proposed to remove the Application of Functional Assessment/Care Plan and Functional Assessment/Care Plan measures beginning with the FY 2025 LTCH QRP. We estimated that the removal of these two measures will result in a decrease of 0.01 hour [967] (0.6 minutes/60 minutes) minutes of clinical staff time at admission and a decrease of 0.005 hour (0.3 minutes/60 minutes) of clinical staff time at the time of planned discharge beginning with the FY 2025 LTCH QRP. We believe the LCDS items affected by the proposed removal of these two measures are completed by Registered Nurses (RN), Licensed Practical and Licensed Vocational Nurses (LVN), Speech-Language Pathologists (SLP), Occupational Therapists (OT), and/or Physical Therapists (PT) depending on the item. We identified the staff type per item based on past LTCH burden calculations. Our assumptions for staff type were based on the categories generally necessary to perform an assessment. Individual providers determine the staffing resources necessary; therefore, we averaged the national average for these labor types and established a composite cost estimate. This composite estimate was calculated by weighting each salary based on the following breakdown regarding provider types most likely to collect this data: OT 50 percent; PT 40 percent; RN 5 percent; LVN 2.5 percent; SLP 2.5 percent. For the purposes of calculating the costs associated with the collection of information requirements, we obtained mean hourly wages for these staff from the U.S. Bureau of Labor Statistics' May 2021 National Occupational Employment and Wage Estimates.[968] To account for overhead and fringe benefits, we have doubled the hourly wage. These amounts are detailed in Table XII.B.–05.

TABLE XII.B-05: U.S. BUREAU OF LABOR AND STATISTICS' MAY 2021 NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Overhead and Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Registered Nurse (RN)	29-1141	$39.78	$39.78	$79.56
Licensed Vocational Nurse (LVN)	29-2061	$24.93	$24.93	$49.86
Speech Language Pathologist (SLP)	29-1127	$41.26	$41.26	$82.52
Physical Therapist (PT)	29-1123	$44.67	$44.67	$89.34
Occupational Therapist (OT)	29-1122	$43.02	$43.02	$86.04

As a result of these two measure removal proposals, the estimated burden and cost for LTCHs for complying with requirements of the FY 2025 LTCH QRP will decrease. The removal of the measure will result in a decrease of 18 seconds (0.3 min or 0.005 hr) of clinical staff time at admission beginning with the FY 2025 LTCH QRP. The LCDS item affected by the proposed removal of the Application of Functional Assessment/Care Plan measure is completed by Occupational Therapists (OT), Physical Therapists (PT), Registered Nurses (RN), Licensed Practical and Licensed Vocational Nurses (LVN), and/or Speech-Language Pathologists (SLP) depending on the functional goal selected. We identified the staff type per LCDS item based on past LCDS burden calculations. Our assumptions for staff type were based on the categories generally necessary to perform an assessment, however, individual LTCHs determine the staffing resources necessary. Therefore, we averaged BLS' National Occupational Employment and Wage Estimates (see Table XII.B–05) for these labor types and established a composite cost estimate using our adjusted wage estimates. The composite estimate of $86.2085/hr was calculated by weighting each hourly wage based on the following breakdown regarding provider types most likely to collect this data: OT 45 percent at $86.04/hr; PT 45 percent at $89.34/hr; RN 5 percent at

[967] A correction to the FY 2024 IPPS/LTCH proposed rule is made. The proposed rule inadvertently referenced a decrease of 0.1 hour.

[968] *https://www.bls.gov/oes/current/oes_nat.htm.*

$79.56/hr; LVN 2.5 percent at $49.86/hr; and SLP 2.5 percent at $82.52/hr.

Specifically, there will be a 0.01 hour decrease in clinical staff time to report data for each LCDS completed at admission and a 0.005 hour decrease in clinical staff time to report data for each LCDS completed for planned discharges. Using data collected for CY 2021, we estimated 148,088 admissions and 111,251 planned discharges from 330 LTCHs annually. This equates to a decrease of 1,480.88 hours in burden at admission for all LTCHs (0.01 hour × 148,088 admissions), and a decrease of 556.255 hours in burden for planned discharges for all LTCHs (0.005 hour × 111,251 planned discharges).

Given 0.3 minutes of occupational therapist time at $86.04 per hour, 0.24 minutes of physical therapist time at $89.34 per hour, 0.03 minutes registered nurse time at $79.56 per hour, 0.015 minutes of licensed vocational nurse time at $49.86 per hour, and 0.015 minutes of speech language pathologist time at $82.52 per hour to complete an average of 449 LCDS admission assessments and 337 LCDS planned discharge assessments per provider per year, we estimated the total cost will be decreased by $175,610 for all LTCHs annually (1,481 hours at admission + 556 hours at discharge = 2,037 total hours; 2,037 hours × $86.21 composite wage = $175,618.35) or $532.18 per LTCH annually ($175,618.35/330 LTCHs).

In section IX.E.8.a. of the preamble of the proposed rule, we proposed that beginning with the FY 2026 payment determination, LTCHs must report 100 percent of the required quality measures data and standardized patient assessment data collected using the LCDS on at least 90 percent of the assessments they submit through the CMS designated submission system. After consideration of the public comments we received, we are modifying our proposal and finalizing that LTCHs are required to report 100 percent of the required quality measures data and standardized patient assessment data collected using the LCDS on at least 85 percent of all assessments submitted beginning with the FY 2026 payment determination and subsequent years. Because LTCHs have been required to submit LCDS assessments in this manner since October 1, 2012, there will be no increase in burden to LTCH providers associated with this final rule.

In section IX.E.4.d. of the preamble of the proposed rule, we proposed to adopt the Patient/Resident COVID–19 Vaccine measure beginning with the FY 2026 LTCH QRP. The proposed measure will be collected using the LCDS. The LCDS V5.0 has been approved under OMB control number 0938–1163 (expiration date: 08/31/2025). One data element will be added to the LCDS in order to allow for collection of this measure and will result in an increase of 0.005 hours (0.3 minutes/60) of clinical staff time at discharge. Using data collected for CY 2021, we estimated a 148,965 total discharges (that is planned, unplanned, and expired) from 330 LTCHs annually. This equates to an increase of 744.825 hours for all LTCHs (148,965 × 0.005 hrs) and 2.26 hours per LTCH.

The additional COVID–19 vaccine data element will be completed equally by RNs and LVNs. Individual LTCHs determine the staffing resources necessary. We averaged BLS' National Occupational Employment and Wage Estimates (see Table XII.B–05) for these labor types and established a composite cost estimate using our adjusted wage estimates. The composite estimate of $64.71/hr was calculated by weighting each hourly wage equally ([(148,965 assessments × 0.50 = 372.42 hours) × $79.56/hr] + [(148,965 assessments*0.50 = 372.42 hours) × $49.86/hr] = $48,199); ($48,199/744.825 total hours). We estimated the total cost will be increased by $146.05 per LTCH annually, or $48,197.63 for all LTCHs annually.

As described in following table, under OMB control number 0938–1163, we estimate that the policies finalized in this final rule for the LTCH QRP will result in an overall decrease of 1,292.31 hours annually for 330 LTCHs. The total cost decrease related to this information collection is approximately $127,420.728. The decrease in burden will be accounted for in a revised information collection request under OMB control number (0938–1163).

Proposal	Per LTCH		All LTCHs	
	Change in Annual Burden Hours	Change in Annual Cost ($)	Change in Annual Burden Hours	Change in Annual Cost ($)
Change in Burden associated with proposed removal the Functional Assessment and Application of Functional Assessment/Care Plan measures beginning with the FY 2025 LTCH QRP	(6.17)	(532.1768)	(2,037.135)	(175,618.353)
Change in Burden associated with proposed Patient/Resident COVID-19 vaccine beginning with the FY 2026 LTCH QRP	2.26	146.0534	744.825	48,197.625
Total Change in burden for the LTCH QRP associated with the proposed rule	(3.91)	(386.1234)	(1,292.31)	(127,420.728)

We invited public comments on the proposed information collection requirements.

The following is a summary of the public comment received on the proposed revisions and our responses:

Comment: A commenter suggested that CMS' burden estimates underestimated the burden on providers to complete the assessments, including the time it takes to conduct an interview, obtain a patient response, and change workflows to accomplish the collection. They also point to the burden of training and educating personnel, the burden on informatics to update paper-based facility forms and EMR builds increase the cost significantly. This commenter stated that it currently takes its members a minimum of 30 minutes to complete each LCDS V5.0 on admission and on discharge. However, they report that other members have estimated that it takes between 100 and 110 minutes to complete a full patient assessment, which is nearly three times more than the time CMS has estimated it takes to complete an assessment. This commenter also believes the data may be duplicative of other data captured in the medical chart, as well as being rarely relevant for ongoing training needs and facility-wide improvement efforts, and therefore takes time away from actual patient care without contributing to improved quality. Finally, this commenter also referenced a 2018 report by the General Accounting Office that found calculation errors and inconsistencies across documentation that led to underestimates of time cost.

Response: We appreciate the time and effort LTCHs invest in completing the LCDS. The LCDS is an evaluation and assessment tool and the data collected is *directly* relevant to patient care, such as hearing, speech, vision, cognition, mood, function, bladder and bowel function, pain, swallowing, nutrition, skin integrity, high-risk medications,

special treatments and procedures, and ventilator status. Each of these data elements contributes to the development of a patient-centered plan of care. We also would like to point out that LTCHs have been collecting the data elements in the LCDS V5.0 since October 1, 2022, and our proposal to increase the data completion threshold does not increase the number of items an LTCH must collect at admission or discharge.

As the commenter pointed out in their example, the patient must be assessed and information gathered. After the patient assessment is completed, the LCDS is coded with the information and submitted to iQIES, and we want to remind LTCHs, that it is these steps (after the patient assessment) that the estimated burden and cost captures. The burden estimated is based on past LTCH burden calculations and represents the time it takes to encode the LCDS. Our assumptions for staff type were based on the categories generally necessary to perform an assessment, and subsequently encode it, which is consistent with past collection of information estimates. While we acknowledge that some LTCHs may train and utilize other personnel, our estimates are based on the categories of personnel necessary to complete the LCDS.

We continually look for opportunities to minimize burden associated with collection of the LCDS for information users through strategies that simplify collection and submission requirements. At the time we adopt new items, we ensure that all instructions and notices are written in plain language and provide step-by-step examples for completing the LCDS. We provide a dedicated help desk to support users and respond to questions about the data collection. Additionally, a dedicated LTCH QRP web page houses multiple modes of tools, such as instructional videos, case studies, user manuals, and frequently asked questions which support understanding of the items collected on the LCDS generally, and these can be used by current and assist new users of the LCDS. We utilize a listserv to facilitate outreach to users, such as communicating timely and important new material(s), and we continue to use those outreach resources when providing training and information. We create data collection specifications for LTCH electronic health record (EHR) software with 'skip' patterns associated with the items used for LTCH QRP compliance to ensure the LCDS is limited to the minimum data required to meet quality reporting requirements. These specifications are available free of charge to all LTCHs and their technology partners. Further, these minimum requirements are standardized for all users of the LCDS assessment forms. Finally, we provide LTCHs with various resources to review and monitor their own performance on APU, and provide a free internet-based system through which users can access on-demand reports for feedback on the collection of the LCDS associated with their facility.

10. ICRs for the Medicare Promoting Interoperability Program

a. Historical Background

In section IX.F. of the preamble of this final rule, we discuss requirements for the Medicare Promoting Interoperability Program. OMB has currently approved 29,588 hours of burden and approximately $1.3 million under OMB control number 0938–1278 (expiration date August 31, 2025), accounting for information collection burden experienced by approximately 3,150 eligible hospitals and 1,350 CAHs for the EHR reporting period in CY 2023. In the FY 2024 IPPS/LTCH PPS proposed rule, we described the burden changes regarding collection of information under OMB control number 0938–1278 for eligible hospitals and CAHs (88 FR 27204 through 27205). The collection of information burden analysis in this final rule focuses on all eligible hospitals and CAHs that could participate in the Medicare Promoting Interoperability Program and attest to the objectives and measures, and report eCQMs, under the Medicare Promoting Interoperability Program for the EHR reporting periods in CY 2024 and CY 2025.

For more detailed information on our finalized policies for the Medicare Promoting Interoperability Program, we refer readers to section IX.F. of the preamble of this final rule. In the FY 2024 IPPS/LTCH PPS proposed rule, we proposed several policies that will not affect the information collection burden associated with the Medicare Promoting Interoperability Program. We proposed to adopt three electronic clinical quality measures (eCQMs) beginning with the CY 2025 reporting period: (1) Hospital Harm—Pressure Injury eCQM, (2) Hospital Harm—Acute Kidney Injury eCQM, and (3) Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Inpatient) eCQM (88 FR 27172 through 27173). We also proposed to modify the SAFER Guides measure to require eligible hospitals and CAHs to submit a ''yes'' attestation to fulfill the measure beginning with the EHR reporting period in CY 2024 (88 FR 27157). Lastly, we proposed to establish an EHR reporting period of a minimum of any continuous 180-day period in CY 2025 (88 FR 27155 through 27156). In this final rule, we are finalizing all of these policies as proposed.

The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $22.43 per hour for a medical records specialist.[969] We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in publicly available literature. Nonetheless, we believe that doubling the hourly wage rate ($22.43 × 2 = $44.86) to estimate total cost is a reasonably accurate estimation method and is consistent with OMB guidance. Accordingly, we will calculate cost burden to hospitals using a wage plus benefits estimate of $44.86 per hour throughout the discussion in this section of this rule for the Medicare Promoting Interoperability Program.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49392), our burden estimates were based on an assumption of 4,500 eligible hospitals and CAHs. For this final rule, based on data from the EHR reporting period in CY 2021, we continue to estimate 3,150 eligible hospitals and 1,350 CAHs will report data to the Medicare Promoting Interoperability Program, for a total number of 4,500 respondents.

b. Information Collection Burden Estimate for the Finalized Adoption of Three eCQMs Beginning With the CY 2025 Reporting Period: (1) Hospital Harm—Pressure Injury eCQM, (2) Hospital Harm—Acute Kidney Injury eCQM, and (3) Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Inpatient) eCQM

In sections IX.F.7.a.(2). of the preamble of this final rule, we are adopting three new eCQMs beginning with the CY 2025 reporting period: (1) Hospital Harm—Pressure Injury eCQM, (2) Hospital Harm—Acute Kidney Injury eCQM, and (3) Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT)

[969] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records Specialists. Accessed on January 13, 2023. Available at: *https://www.bls.gov/oes/current/oes292072.htm.*

in Adults (Hospital Level—Inpatient) eCQM.

The addition of these three eCQMs does not affect the information collection burden of submitting eCQMs under the Medicare Promoting Interoperability Program. Current policy requires eligible hospitals and CAHs to select three eCQMs from the eCQM measure set on which to report in addition to reporting three mandatory eCQMs for a total of six eCQMs (87 FR 49365 through 49367). In other words, although these new eCQMs are being added to the eCQM measure set, eligible hospitals and CAHs are not required to report more than a total of six eCQMs. The burden associated with the reporting of eCQM measures for 3,150 eligible hospitals and 1,350 CAHs as part of the Hospital Inpatient Quality Reporting program is included under OMB control number 0938–1022 (CAHs are referred to as non-IPPS hospitals under OMB 0938–1022).

With respect to any costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.O of appendix A of this final rule).

c. Information Collection Burden Estimate for the Finalized Modification to the SAFER Guides Measure

In section IX.F.3. of the preamble of this final rule, we are modifying the SAFER Guides measure to require eligible hospitals and CAHs to submit a ''yes'' attestation to fulfill the measure beginning with the EHR reporting period in CY 2024. In the FY 2022 IPPS/LTCH PPS final rule, we adopted the SAFER Guides measure and required eligible hospitals and CAHs to attest ''yes'' or ''no'' as to whether they completed an annual self-assessment on each of the nine SAFER Guides at any point during the calendar year in which their EHR reporting period occurs (86 FR 45479 through 45481).

Because we are not modifying the information that eligible hospitals and CAHs will be required to submit but are instead requiring an attestation of ''yes,'' we are not finalizing any changes to our currently approved burden estimates as a result of this policy.

With respect to additional costs/burdens unrelated to data submission, we refer readers to the Regulatory Impact Analysis (section I.O. of appendix A of this final rule).

d. Information Collection Burden for the Establishment of an EHR Reporting Period of a Minimum of Any Continuous 180-Day Period in CY 2025

In section IX.F.2.a. of the preamble of this final rule, we are establishing an EHR reporting period of a minimum of any continuous 180-day period in CY 2025. Because we are not modifying the type or amount of data each eligible hospital and CAH will be required to submit, we are not finalizing any changes to our currently approved burden estimates as a result of this policy.

e. Summary of Estimates Used To Calculate the Collection of Information Burden

In summary, under OMB control number 0938–1278 (expiration date August 31, 2025), we estimate that the policies in this final rule will not result in a change in burden. We continue to estimate an annual burden of 6.6 hours per eligible.

11. ICRs Regarding Special Requirements for Rural Emergency Hospitals (REHs) (§ 488.70)

The special requirements for REHs require an eligible facility (a CAH or a small rural hospital with not more than 50 beds) to submit additional information that must include an action plan containing four specific elements when the facility submits an application for enrollment as an REH. The estimated burden related to this regulation is discussed in this section.

a. Sources of Data Used in Estimates of Burden Hours and Cost Estimates

For the estimated costs contained in this analysis, we used data from the U.S. Bureau of Labor Statistics (BLS) to determine the mean hourly wage for the positions used in this analysis.[970] For the total hourly cost, we doubled the mean hourly wage for a 100 percent increase to cover overhead and fringe benefits, according to standard HHS estimating procedures. If the total cost after doubling resulted in 0.50 or more, the cost was rounded up to the next dollar. If it was 0.49 or below, the total cost was rounded down to the next dollar. The total costs used in this analysis are indicated in Table 1.

b. Burden Associated With Submission of Additional Information on the Action and Transition Plans for Enrollment as an REH

An eligible facility that submits an application for enrollment as an REH under section 1866(j) of the Act must also submit additional information as specified in this final rule. In accordance with section 1861(kkk)(4)(A)(i) through (iv) of the Act, we specifically require an eligible facility to submit additional information that must include an action plan containing: (1) a plan for initiating REH services (as those services are defined in 42 CFR 485.502, and which must include the provision of emergency department services and observation care); (2) a detailed transition plan that lists the specific services that the provider will retain, modify, add, and discontinue as an REH; (3) a detailed description of other outpatient medical and health services that it intends to furnish on an outpatient basis as an REH; and (4) information regarding how the provider intends to use the additional facility payment provided under section 1834(x)(2) of the Act, including a description of the services that the additional facility payment would be supporting, such as the operation and maintenance of the facility and the furnishing of covered services (for example, telehealth services and ambulance services).

We estimate that approximately 68 eligible facilities (that is, CAHs and small rural hospitals with not more than 50 beds) would elect to convert to REHs. This is the same estimate used in the final rule titled ''Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID–19,'' which was published in the November 23, 2022 **Federal Register** (87 FR 71748).[971]

We estimate that it would take each CAH or small rural hospital 4 hours to prepare this action plan containing the four required elements specified previously. We further estimate that the annual time burden across all 68 facilities would be 272 hours (4 hours × 68 facilities).

We believe that the person at the facility who would perform this task would be the hospital administrator or CEO. This person would fall under the U.S. Bureau of Labor Statistics job category of Medical and Health Services Manager. According the U.S. Bureau of Labor Statistics, the mean hourly wage for a Medical and Health Services Manager is $57.61 [972] This wage,

[970] BLS. *May 2020 National Occupational Employment and Wage Estimates United States.* United States Department of Labor. Accessed at *https://www.bls.gov/oes/current/naics4_551100.htm* (accessed on February 08, 2023).

[971] *https://www.federalregister.gov/d/2022-23918/p-4515.*

[972] *https://www.bls.gov/oes/current/oes119111.htm.*

adjusted for the employer's fringe benefits and overhead would be $115.

We estimate that the cost burden to each facility for preparing the action plan containing the four required elements would be $460 (4 hours × $115). We further estimate that the cost burden across all CAHs and small rural hospitals converting to REHs would be $31,280 (272 hours × $115 per hour).

It is important to note that this is a one-time burden to the facility. After this task has been completed, this burden will be non-recurring. The information collection request under the OMB control number 0938–NEW will be sent to OMB for approval.

12. ICRs for Physician-Owned Hospitals

In section X.B. of the preamble of this final rule, we discuss our changes pertaining to the process for hospitals with physician ownership or investment that request an exception from the prohibition against facility expansion and program integrity restrictions on approved facility expansion.

Specifically, we are making certain technical and clarifying changes to the information that must be submitted for an expansion exception request. These changes include: (1) providing an email address as well as a hard copy mailing address for the contact person for the hospital; (2) providing the names of any counties in which the hospital provides inpatient or outpatient hospital services, in addition to the name of the county in which the main campus of the requesting hospital is located; (3) providing a statement and, if available, supporting documentation regarding the hospital's compliance with the requirement that it does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries (as opposed to merely stating that it complies with this criterion); and (4) providing information regarding whether and how the hospital has used any expansion facility capacity approved in a prior request. The final rule also identifies additional information that a requesting hospital may submit in support of its request for an exception from the prohibition on facility expansion, including, but not limited to, whether it plans to use expansion facility capacity to provide specialty services if the request is approved and information about the current or future need for additional operating rooms, procedure rooms, or beds to serve Medicaid, uninsured, and underserved populations in the county where its main campus is located or in any county where it provides inpatient or outpatient hospital services. In addition, we are requiring electronic submission of requests following instructions posted on the CMS website and eliminating both the option to mail hard copy requests and the requirement to mail an original hard copy of the signed certification statement to CMS. We are also eliminating the use of external data sources for determining whether a hospital meets the criteria for an applicable hospital or a high Medicaid facility. Finally, we are reinstating, with respect to high Medicaid facilities, the program integrity restrictions on the frequency of expansion exception requests at final § 411.363(b)(2)(ii), which provides that CMS will not consider an expansion exception request unless the date of submission is at least 2 calendar years from the date of the most recent decision by CMS approving or denying the hospital's most recent request for an exception from the prohibition on facility expansion.

As we stated in the proposed rule, we do not believe any of these revisions, as finalized, will result in any changes in burden under the PRA. The changes to the information required to be submitted under this final rule are primarily technical or clarifying in nature, and we do not anticipate that they will meaningfully affect the time needed to prepare and submit a request. In addition, we do not anticipate that the changes will affect the annual number of respondents. We did not propose any changes to the definitions of an applicable hospital or a high Medicaid facility, and we anticipate that requiring the use of HCRIS data for all comparison calculations will have little practical impact on whether a requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility. Also, although our regulations have permitted high Medicaid facilities to potentially request an exception to the prohibition on expansion of facility capacity more frequently than once every 2 years since January 1, 2021, no high Medicaid facility has made a request more frequently than every 2 years.

While information collection would normally be subject to the PRA, we continue to believe in this instance it is exempt. The universe of potential respondents is extremely small and represents a tiny fraction of the hospital industry. The expansion exception process is available only to ''grandfathered'' hospitals with physician ownership and a Medicare provider agreement on December 31, 2010 that also meet the criteria for an applicable hospital or a high Medicaid facility. As stated in the CY 2021 OPPS/ASC final rule (85 FR 86255), an applicable hospital means a hospital: (1) that is located in a county in which the percentage increase in the population during the most recent 5-year period (as of the date that the hospital submits its request for an exception to the prohibition on expansion of facility capacity) is at least 150 percent of the percentage increase in the population growth of the State in which the hospital is located during that period, as estimated by the Bureau of the Census; (2) whose annual percent of total inpatient admissions under Medicaid is equal to or greater than the average percent with respect to such admissions for all hospitals in the county in which the hospital is located during the most recent 12-month period for which data are available (as of the date that the hospital submits its request for an exception to the prohibition on expansion of facility capacity); (3) that does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries; (4) that is located in a state in which the average bed capacity in the state is less than the national average bed capacity; and (5) that has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located. In the same final rule we stated that a high Medicaid facility means a hospital that: (1) is not the sole hospital in a county; (2) with respect to each of the three most recent 12-month periods for which data are available, has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for any other hospital located in the county in which the hospital is located; and (3) does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries. These criteria greatly limit the universe of potential respondents. For example, hospitals that provide only specialized services often do not have the same or a higher percentage of Medicaid inpatient admissions as general acute care hospitals in the counties in which they are located and, thus, could not meet the threshold criteria to use the expansion exception process. The number of potential respondents is further reduced to include only those hospitals with the desire and resources to expand their facility capacity, and then limited to

those that can meet applicable state or local requirements for expansion (such as certificate of need). Given all of these factors, we continue to estimate that we would receive one expansion exception request per year. This estimate is consistent with our experience with the expansion exception process to date. Since January 1, 2012 (the effective date of the regulations setting forth the expansion exception process), on average, we have received approximately one expansion exception request per year. Therefore, in accordance with the implementing regulations of the PRA at 5 CFR 1320.3(c)(4), we believe that the information collection is exempt as it affects less than 10 entities in a 12-month period. Although we believe the information collection is exempt, we note that we estimate that it takes approximately 6 hours and 45 minutes to prepare an expansion exception request and that a request is prepared by a lawyer. To estimate the cost to prepare an expansion exception request, we use a 2021 wage rate of $71.17 for lawyers from the Bureau of Labor Statistics,[973] and we double that wage to account for overhead and benefits. The total estimated annual cost is $960.79.

Comment: A commenter asserted that the solicitation of community input on expansion exception requests is subject to the PRA. The commenter stated that CMS did not propose an information collection process for the solicitation of community input, provide a burden estimate, or request public comment on the proposed collection of information associated with the solicitation of community input. The commenter further asserted that CMS did not request approval from OMB.

Response: We disagree that the solicitation of community input is subject to the PRA. For purposes of the PRA, ''information'' is defined at 5 CFR 1320.3(h); facts or opinions submitted in response to general solicitations of comments in the **Federal Register** or other publications do not constitute ''information'' subject to the requirements of the PRA. Further, as noted earlier in this section, we addressed the information collection requirements for our proposals in the proposed rule. The proposed rule, including the determination that the process for requesting an expansion exception is exempt from the PRA, was reviewed by OMB.

[973] U.S. Department of Labor, Bureau of Labor Statistics, May 2021 National Occupational Employment and Wage Estimates United States, *https://www.bls.gov/oes/current/oes_nat.htm.*

Chiquita Brooks-LaSure, Administrator of the Center for Medicare & Medicaid Services, approved this document on July 24, 2023.

List of Subjects

42 CFR Part 411

Diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 412

Administrative practice and procedure, Health facilities, Medicare, Puerto Rico, Reporting and recordkeeping requirements.

42 CFR Part 419

Hospitals, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Health facilities, Health maintenance organizations (HMO), Health professions, Health records, Medicaid, Medicare, Penalties, Privacy, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 1. The authority citation for part 411 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn.

§ 411.353 [Amended]

■ 2. Section 411.353 is amended in paragraph (d) by removing the text ''§ 1003.101 of this title'' and adding in its place ''§ 1003.110 of this title''.

§ 411.357 [Amended]

■ 3. Section 411.357 is amended by—
■ a. In paragraph (s)(3), adding the word ''and'' at the end of the paragraph; and
■ b. In paragraph (s)(4), removing ''; and'' and adding in its place a period.

§ 411.362 [Amended]

■ 4. Section 411.362 is amended by—
■ a. In paragraph (a), removing the definitions of ''Baseline number of operating rooms, procedure rooms, and beds,'' ''External data source,'' and ''Main campus of the hospital'';
■ b. In paragraph (b)(2), removing the phrase ''is granted pursuant to paragraph (c) of this section'' and adding in its place the phrase ''is approved under § 411.363''; and
■ c. Removing paragraph (c).

■ 5. Section 411.363 is added to read as follows:

§ 411.363 Process for requesting an exception from the prohibition on facility expansion.

(a) *Definitions.* For purposes of this section—

Baseline number of operating rooms, procedure rooms, and beds means the number of operating rooms, procedure rooms, and beds for which the applicable hospital or high Medicaid facility is licensed as of March 23, 2010 (or, in the case of a hospital that did not have a provider agreement in effect as of March 23, 2010, but does have a provider agreement in effect on December 31, 2010, the date of effect of such agreement). For purposes of determining the number of beds in a hospital's baseline number of operating rooms, procedure rooms, and beds, a bed is included if the bed is considered licensed for purposes of State licensure, regardless of the specific number of beds identified on the physical license issued to the hospital by the State.

External data source means a data source that—

(i) Is generated, maintained, or under the control of a State Medicaid agency;

(ii) Is reliable and transparent;

(iii) Maintains data that, for purposes of the process described in this section, are readily available and accessible to the requesting hospital, comparison hospitals, and CMS; and

(iv) Maintains or generates data that, for purposes of the process described in this section, are accurate, complete, and objectively verifiable.

Main campus of the hospital means ''campus'' as defined at § 413.65(a)(2) of this chapter.

Procedure room has the meaning set forth at § 411.362(a).

(b) *CMS consideration of requests for an exception from the prohibition on facility expansion.* (1) CMS will not consider a request for an exception from the prohibition on facility expansion from a hospital that is not eligible to request the exception.

(2) A hospital that meets the criteria for an applicable hospital or a high Medicaid facility is eligible to request an exception from the prohibition on

facility expansion for consideration by CMS, provided that—

(i) CMS has not previously approved a request for an exception from the prohibition on facility expansion that would allow the hospital's number of operating rooms, procedure rooms, and beds for which the hospital is licensed to reach 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds if the full expansion is utilized; and

(ii) It has been at least 2 calendar years from the date of the most recent decision by CMS approving or denying the hospital's most recent request for an exception from the prohibition on facility expansion.

(c) *Criteria for an applicable hospital.* An applicable hospital is a hospital that meets the following criteria:

(1) *Population increase.* The hospital is located in a county that has a percentage increase in population that is at least 150 percent of the percentage increase in population of the State in which the hospital is located during the most recent 5-year period for which data are available as of the date that the hospital submits its request. To calculate State and county population growth, a hospital must use Bureau of the Census estimates.

(2) *Medicaid inpatient admissions.* The hospital has an annual percent of total inpatient admissions under Medicaid that is equal to or greater than the average percent with respect to such admissions for all hospitals (including the requesting hospital) that have Medicare participation agreements with CMS and are located in the county in which the hospital is located during the most recent 12-month period for which data are available as of the date that the hospital submits its request. For purposes of this paragraph (c)(2), the most recent 12-month period for which data are available means the most recent 12-month period for which the data source used contains all data from the requesting hospital and each other hospital that has a Medicare participation agreement with CMS and is located in the county in which the requesting hospital is located.

(i) With respect to requests submitted before October 1, 2023, a hospital may use filed Medicare hospital cost report data from the Healthcare Cost Report Information System (HCRIS) or data from an external data source (as defined in paragraph (a) of this section) to estimate its annual percent of total inpatient admissions under Medicaid and the average percent with respect to such admissions for all hospitals (including the requesting hospital) that have Medicare participation agreements with CMS and are located in the county in which the hospital is located.

(ii) With respect to requests submitted on or after October 1, 2023, a hospital may use only filed Medicare hospital cost report data from HCRIS to estimate its annual percent of total inpatient admissions under Medicaid and the average percent with respect to such admissions for all hospitals (including the requesting hospital) that have Medicare participation agreements with CMS and are located in the county in which the hospital is located.

(3) *Nondiscrimination.* The hospital does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(4) *Average bed capacity.* The hospital is located in a State in which the average bed capacity in the State is less than the national average bed capacity during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number of hospitals to determine a State's average bed capacity and the national average bed capacity.

(i) CMS will provide on its website State average bed capacities and the national average bed capacity.

(ii) For purposes of this paragraph (c)(4), *sufficient number* means the number of hospitals, as determined by CMS that would ensure that the determination under this paragraph (c)(4) would not materially change after additional hospital data are reported.

(5) *Average bed occupancy.* The hospital has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number of hospitals to determine the requesting hospital's average bed occupancy rate and the relevant State's average bed occupancy rate.

(i) A hospital must use filed hospital cost report data from HCRIS to determine its average bed occupancy rate.

(ii) CMS will provide on its website State average bed occupancy rates. For purposes of this paragraph (c)(5), *sufficient number* means the number of hospitals, as determined by CMS that would ensure that the determination under this paragraph (c)(5) would not materially change after additional hospital data are reported.

(6) *Hospital location.* For purposes of this paragraph (c), a hospital is located in the county and State in which the main campus of the hospital is located.

(d) *Criteria for a high Medicaid facility.* A high Medicaid facility is a hospital that meets all of the following criteria:

(1) *Sole hospital.* The hospital is not the sole hospital in the county in which the hospital is located.

(2) *Medicaid inpatient admissions.* With respect to each of the three most recent 12-month periods for which data are available as of the date the hospital submits its request, the hospital has an annual percent of total inpatient admissions under Medicaid that is estimated to be greater than such percent with respect to such admissions for each other hospital that has a Medicare participation agreement with CMS and is located in the county in which the hospital is located. For purposes of this paragraph (d)(2), the most recent 12-month period for which data are available means the most recent 12-month period for which the data source used contains all data from the requesting hospital and each other hospital that has a Medicare participation agreement with CMS and is located in the county in which the requesting hospital is located.

(i) With respect to requests submitted before October 1, 2023, a hospital may use filed Medicare hospital cost report data from HCRIS or data from an external data source (as defined in paragraph (a) of this section) to estimate its annual percentage of total inpatient admissions under Medicaid and the annual percentages of total inpatient admissions under Medicaid for each other hospital that has a Medicare participation agreement with CMS and is located in the county in which the hospital is located.

(ii) With respect to requests submitted on or after October 1, 2023, a hospital may use only filed Medicare hospital cost report data from HCRIS to estimate its annual percentage of total inpatient admissions under Medicaid and the annual percentages of total inpatient admissions under Medicaid for each other hospital that has a Medicare participation agreement with CMS and is located in the county in which the hospital is located.

(3) *Nondiscrimination.* The hospital does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(4) *Hospital location.* For purposes of this paragraph (d), a hospital is located in the county in which the main campus of the hospital is located.

(e) *Procedure for submitting a request for an exception from the prohibition on facility expansion.* (1) A hospital must submit the request for an exception from the prohibition on facility expansion and the signed certification set forth in paragraph (e)(3) of this section electronically to CMS according to the instructions specified on the CMS website.

(2) For a hospital's request for an exception from the prohibition on facility expansion to be considered by CMS, the request must include all of the following information:

(i) The name, address, national provider identification number(s) (NPI), tax identification number (TIN), and CMS certification number (CCN) for the hospital.

(ii)(A) The name of the county in which the main campus is located; and

(B) The names of any counties in which the hospital provides inpatient or outpatient hospital services.

(iii) The name, title, daytime telephone number, electronic mail address, and hard copy mail address for the contact person who will be available to discuss the request with CMS on behalf of the hospital.

(iv)(A) A statement identifying the hospital as an applicable hospital or high Medicaid facility; and

(B) A detailed explanation with supporting documentation regarding whether and how the hospital meets each of the criteria for an applicable hospital or high Medicaid facility.

(v) A statement and supporting documentation, if available, explaining how the hospital satisfies the criterion in paragraph (c)(3) or (d)(3) of this section that it does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries.

(vi) Documentation supporting—

(A) The hospital's calculations of its baseline number of operating rooms, procedure rooms, and beds;

(B) The number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of the date that the hospital submits a request for an exception;

(C) Whether and how the hospital has used any expansion facility capacity approved in a prior request; and

(D) The additional number of operating rooms, procedure rooms, and beds by which the hospital requests to expand.

(3) A hospital may submit other information with respect to the request, including but not limited to information regarding—

(i) Whether the hospital plans to use expansion facility capacity to provide specialty services (for example, maternity, psychiatric services, or substance use disorder care) if the request is approved; and

(ii) The current or future need, if any, for additional operating rooms, procedure rooms, and beds—

(A) For the hospital to serve Medicaid, uninsured, and underserved populations;

(B) In the county in which the main campus of the hospital is located; and

(C) In any county in which the hospital provides inpatient or outpatient hospital services as of the date the hospital submits the request.

(4) A request for an exception from the prohibition on facility expansion must include the following certification signed by an authorized representative of the hospital: ''With knowledge of the penalties for false statements provided by 18 U.S.C. 1001, I certify that all of the information provided in the request and all of the documentation provided with the request is true and correct to the best of my knowledge and belief.'' An authorized representative is the chief executive officer, chief financial officer, or other individual who is authorized by the hospital to make the request.

(f) *Community input.* (1) Upon submitting a request for an exception from the prohibition on facility expansion and until the hospital receives a CMS decision on the request, the hospital must disclose on any public website for the hospital that it is requesting an exception from the prohibition on facility expansion.

(2) A hospital submitting a request for an exception from the prohibition on facility expansion must provide actual notification that it is requesting an exception, in either electronic or hard copy form, directly to hospitals whose data are part of the comparisons in paragraphs (c)(2) and (d)(2) of this section.

(3)(i) Individuals and entities in the hospital's community may provide input with respect to the hospital's request for an exception from the prohibition on facility expansion, including, but not limited to, input regarding whether the hospital meets the criteria for an applicable hospital or a high Medicaid facility and the factors listed in paragraph (i)(2) of this section that CMS will consider in deciding whether to approve or deny a hospital's request.

(ii) The hospital's community includes the geographic area served by the hospital (as defined at § 411.357(e)(2)) and all of the following:

(A) The county in which the hospital's main campus is located.

(B) The counties in which the hospital provides inpatient or outpatient hospital services as of the date the hospital submits the request.

(iii) Community input must be—

(A) In the form of written comments;

(B) Submitted according to the instructions in the **Federal Register** notice of the hospital's request; and

(C) Received no later than 60 days after CMS publishes notice of the hospital's request in the **Federal Register**.

(iv) If CMS receives written comments from the community, the hospital has 60 days after CMS notifies the hospital of the written comments to submit a rebuttal statement.

(g) *Timing of complete request.* (1) If only filed Medicare hospital cost report data from HCRIS are used in the hospital's request for an exception from the prohibition on facility expansion, the written comments, and the hospital's rebuttal statement, a request will be deemed complete no later than 90 days after the end of—

(i) The 60-day comment period if CMS does not receive written comments from the community.

(ii) The 60-day rebuttal period, regardless of whether the hospital submits a rebuttal statement, if CMS receives written comments from the community.

(2) If data from an external data source are used in the hospital's request for an exception from the prohibition on facility expansion, the written comments, or the hospital's rebuttal statement, a request will be deemed complete no later than 180 days after the end of—

(i) The 60-day comment period if CMS does not receive written comments from the community.

(ii) The 60-day rebuttal period, regardless of whether the hospital submits a rebuttal statement, if CMS receives written comments from the community.

(h) *Determination that the hospital is an applicable hospital or a high Medicaid facility.* Based on the information described in paragraph (e) of this section and the community input described in paragraph (f) of this section, if any, CMS will first determine whether the hospital meets the criteria for an applicable hospital or a high Medicaid facility.

(i) *CMS decision to approve or deny a request for an exception from the prohibition on facility expansion*—(1) *Data and information for consideration by CMS.* In reviewing a request for an

exception from the prohibition on facility expansion, CMS—

(i) Will consider data and information provided by the hospital in its request, included in the community input, if any, and provided by the hospital in its rebuttal statement, if any; and

(ii) May also consider any other data and information relevant to its decision.

(2) *Factors considered by CMS.* Factors that CMS will consider in deciding whether to approve or deny a hospital's request for an exception from the prohibition on facility expansion include but are not limited to the following:

(i) The specialty (for example, maternity, psychiatric, or substance use disorder care) of the hospital or the services furnished by or to be furnished by the hospital if CMS approves the request.

(ii) Program integrity or quality of care concerns related to the hospital.

(iii) Whether the hospital has a need for additional operating rooms, procedure rooms, or beds.

(iv) Whether there is a need for additional operating rooms, procedure rooms, or beds in the county in which the main campus of the hospital is located or in any county in which the hospital provides inpatient or outpatient hospital services as of the date the hospital submits the request.

(j) *Permitted increase in facility capacity.* (1) Except as provided in paragraph (j)(2) of this section, a permitted increase under this section—

(i) May not result in the number of operating rooms, procedure rooms, and beds for which the hospital is licensed exceeding 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds; and

(ii) May occur only in facilities on the hospital's main campus.

(2) The limitations of paragraph (j)(1) of this section do not apply to an increase in facility capacity approved by CMS with respect to a request for an exception from the prohibition on facility expansion submitted by a high Medicaid facility between January 1, 2021, and September 30, 2023.

(k) *Publication of final determination and decision.* Not later than 60 days after receiving a complete request—

(1) If CMS determines that the hospital does not meet the criteria for an applicable hospital or a high Medicaid facility, CMS will publish in the **Federal Register** notice of such determination; or

(2) If CMS determines that the hospital meets the criteria for an applicable hospital or a high Medicaid facility, CMS will publish in the **Federal Register** notice of such determination and its decision regarding the hospital's request for an exception from the prohibition on facility expansion.

(l) *Limitation on review.* There shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the process under this section (including the establishment of such process and any CMS determination or decision under such process).

PART 412—PROSPECTIVE PAYMENT SYSTEMS FOR INPATIENT HOSPITAL SERVICES

■ 6. The authority citation for part 412 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 7. Section 412.87 is amended by—

■ a. Redesignating paragraph (e) as paragraph (f);

■ b. Adding a new paragraph (e);

■ c. In newly redesignated paragraph (f)(2)—

■ i. Removing the reference ''paragraph (e)(3)'' and adding in its place the reference ''paragraph (f)(3)''; and

■ ii. Removing the phrase ''authorization by July 1 prior'' and adding in its place the phrase ''authorization by May 1 prior''; and

■ d. In newly redesignated paragraph (f)(3), removing the phrase ''by the July 1 deadline specified in paragraph (e)(2) of this section may be conditionally approved for the new technology add-on payment for a particular fiscal year'' and adding in its place the phrase ''by July 1 prior to the particular fiscal year for which the applicant applied for new technology add-on payments may be conditionally approved for the new technology add-on payment for that fiscal year''.

The addition reads as follows:

§ 412.87 Additional payment for new medical services and technologies: General provisions.

* * * * *

(e) *FDA status requirement.* CMS only considers, for add-on payments for a particular fiscal year, an application for which one of the following conditions are met at the time of new technology add-on payment application submission:

(1) The new medical service or technology is FDA market authorized for the indication that is the subject of the new technology add-on payment application.

(2) The new medical service or technology is the subject of a complete and active FDA marketing authorization request and documentation of FDA acceptance or filing of the request is provided to CMS.

* * * * *

§ 412.90 [Amended]

■ 8. Section 412.90 is amended in paragraph (j) by removing the date ''October 1, 2022'' and adding in its place the date ''October 1, 2024''.

■ 9. Section 412.92 is amended by–

■ a. In paragraph (b)(1)(v), removing the term ''forward'' and adding the term ''forwards'' in its place;

■ b. In paragraph (b)(2)(i), removing the second reference to ''paragraph (b)(2)(v) of this section'' and adding in its place the reference ''paragraphs (b)(2)(v) and (vi) of this section'';

■ c. Revising paragraphs (b)(2)(ii)(C) and (b)(2)(iv); and

■ d. Adding paragraph (b)(2)(vi).

The revisions and addition read as follows:

§ 412.92 Special treatment: Sole community hospitals.

* * * * *

(b) * * *

(2) * * *

(ii) * * *

(C) If the hospital's application for sole community hospital status was received on or after October 1, 2018, the effective date is as provided in paragraph (b)(2)(i) of this section.

* * * * *

(iv) For applications received on or before September 30, 2018, a hospital classified as a sole community hospital receives a payment adjustment, as described in paragraph (d) of this section, effective with discharges occurring on or after 30 days after the date of CMS' approval of the classification. For applications received on or after October 1, 2018, a hospital classified as a sole community hospital receives a payment adjustment, as described in paragraph (d) of this section, effective with discharges occurring on or after the effective date as provided in paragraph (b)(2)(i) of this section.

* * * * *

(vi) For applications received on or after October 1, 2023, where eligibility for sole community hospital classification is dependent on the hospital's merger with another hospital, sole community hospital status is effective as of the effective date of the approved merger if, and only if, the date that the Medicare administrative contractor (MAC) receives the complete application is within 90 days of CMS' written notification to the hospital of the approval of the merger.

* * * * *

§ 412.101 [Amended]

■ 10. Section 412.101 is amended by—
■ a. In paragraph (b)(2)(i), removing the phrase ''FY 2010 and FY 2023 and subsequent'' and adding in its place the phrase ''FY 2010 and FY 2025 and subsequent'';
■ b. In paragraph (b)(2)(iii), removing the phrase ''For FY 2019 through FY 2022'' and adding in its place the phrase ''For FY 2019 through FY 2024'';
■ c. In paragraph (c)(1), removing the phrase ''FY 2010 and FY 2023 and subsequent'' and adding in its place the phrase ''FY 2010 and FY 2025 and subsequent''; and
■ d. In paragraph (c)(3) introductory text, removing the phrase ''For FY 2019 through FY 2022'' and adding in its place the phrase ''For FY 2019 through FY 2024''.

■ 11. Section 412.103 is amended by–
■ a. In paragraph (d)(1), removing the reference ''paragraph (d)(2) of this section'' and adding in its place the reference ''paragraphs (d)(2) and (3) of this section''; and
■ b. Adding paragraph (d)(3).

The addition reads as follows:

§ 412.103 Special treatment: Hospitals located in urban areas and that apply for reclassification as rural.

* * * * *

(d) * * *

(3) CMS will consider a hospital that satisfies the criteria set forth in paragraph (a)(3) of this section and which qualifies for sole community hospital status in accordance with the requirements of § 412.92(b)(2)(vi) as being located in the rural area of the State in which the hospital is located as of the effective date set forth in § 412.92(b)(2)(vi).

* * * * *

■ 12. Section 412.106 is amended by—
■ a. Revising paragraphs (b)(4) introductory text and (b)(4)(i) and (ii);
■ b. Redesignating paragraphs (b)(4)(iii) and (iv) as paragraphs (b)(4)(iv) and (v), respectively; and
■ c. Adding a new paragraph (b)(4)(iii).

The revisions and addition read as follows:

§ 412.106 Special treatment: Hospitals that serve a disproportionate share of low-income patients.

* * * * *

(b) * * *

(4) *Second computation.* The fiscal intermediary determines, for the same cost reporting period used for the first computation, the number of the hospital's patient days of service for patients who were not entitled to Medicare Part A, and who were either eligible for Medicaid on such days as described in paragraph (b)(4)(i) of this section or who were regarded as eligible for Medicaid on such days and the Secretary has determined to include those days in this computation as described in paragraph (b)(4)(ii)(A) or (B) of this section. The fiscal intermediary then divides that number by the total number of patient days in the same period. For purposes of this second computation, the following requirements apply:

(i) For purposes of this computation, a patient is eligible for Medicaid on a given day if the patient is eligible on that day for inpatient hospital services under a State Medicaid plan approved under title XIX of the Act, regardless of whether particular items or services were covered or paid for on that day under the State plan.

(ii) For purposes of this computation, a patient is regarded as eligible for Medicaid on a given day if the patient receives health insurance authorized by a demonstration approved by the Secretary under section 1115(a)(2) of the Act for that day, where the cost of such health insurance may be counted as expenditures under section 1903 of the Act, or the patient has health insurance for that day purchased using premium assistance received through a demonstration approved by the Secretary under section 1115(a)(2) of the Act, where the cost of the premium assistance may be counted as expenditures under section 1903 of the Act, and in either case regardless of whether particular items or services were covered or paid for on that day by the health insurance. Of these patients regarded as eligible for Medicaid on a given day, only the days of patients meeting the following criteria on that day may be counted in this second computation:

(A) Patients who are provided by a demonstration authorized under section 1115(a)(2) of the Act health insurance that covers inpatient hospital services; or

(B) Patients who purchase health insurance that covers inpatient hospital services using premium assistance provided by a demonstration authorized under section 1115(a)(2) of the Act and the premium assistance accounts for 100 percent of the premium cost to the patient.

(iii) Patients whose health care costs, including inpatient hospital services costs, for a given day are claimed for payment by a provider from an uncompensated, undercompensated, or other type of funding pool authorized under section 1115(a) of the Act to fund providers' uncompensated care costs are not regarded as eligible for Medicaid for purposes of paragraph (b)(4)(ii) of this section on that day and the days of such patients may not be included in this second computation.

* * * * *

§ 412.108 [Amended]

■ 13. Section 412.108 is amended by—
■ a. In paragraph (a)(1) introductory text, removing the date ''October 1, 2022'' and adding in its place the date ''October 1, 2024''; and
■ b. In paragraph (c)(2)(iii) introductory text, removing the date ''October 1, 2022'' and adding in its place the date ''October 1, 2024''.

■ 14. Section 412.140 is amended by adding paragraph (g) to read as follows:

§ 412.140 Participation, data submission, and validation requirements under the Hospital Inpatient Quality Reporting (IQR) Program.

* * * * *

(g) *Retention and removal of quality measures under the Hospital IQR Program*—(1) *General rule for the retention of quality measures.* Quality measures adopted for the Hospital IQR Program measure set for a previous payment determination year are retained for use in subsequent payment determination years, except when they are removed, suspended, or replaced as set forth in paragraphs (g)(2) and (3) of this section.

(2) *Immediate measure removal.* For cases in which CMS believes that the continued use of a measure raises specific patient safety concerns, CMS will immediately remove a quality measure from the Hospital IQR Program and will promptly notify hospitals and the public of the removal of the measure and the reasons for its removal through the Hospital IQR Program ListServ and the QualityNet website, as applicable.

(3) *Measure removal, suspension, or replacement through the rulemaking process.* Unless a measure raises specific safety concerns as set forth in paragraph (g)(2) of this section, CMS will use the regular rulemaking process to remove, suspend, or replace quality measures in the Hospital IQR Program to allow for public comment.

(i) *Factors for consideration of removal of quality measures.* CMS will weigh whether to remove a measure based on the following factors:

(A) *Factor 1.* Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measure).

(B) *Factor 2.* A measure does not align with current clinical guidelines or practice.

(C) *Factor 3.* The availability of a more broadly applicable measure (across settings or populations), or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.

(D) *Factor 4.* Performance or improvement on a measure does not result in better patient outcomes.

(E) *Factor 5.* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.

(F) *Factor 6.* Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

(G) *Factor 7.* It is not feasible to implement the measure specifications.

(H) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Criteria to determine topped-out measures.* For the purposes of the Hospital IQR Program, a measure is considered to be topped-out under paragraph (g)(3)(i)(A) of this section when it meets both of the following criteria:

(A) Statistically indistinguishable performance at the 75th and 90th percentiles (defined as when the difference between the 75th and 90th percentiles for a hospital's measure is within 2 times the standard error of the full data set).

(B) A truncated coefficient of variation less than or equal to 0.10.

(iii) *Application of measure removal factors.* The benefits of removing a measure from the Hospital IQR Program will be assessed on a case-by-case basis.

■ 15. Section 412.160 is amended by—

■ a. Adding the definitions of ''Health equity adjustment bonus points'' and ''Measure performance scaler'' in alphabetical order;

■ b. Revising the definition of ''Total Performance Score''; and

■ c. Adding the definition of ''Underserved multiplier'' and ''Underserved population'' in alphabetical order.

The additions and revision read as follows:

§ 412.160 Definitions for the Hospital Value-Based Purchasing (VBP) Program.

* * * * *

Health equity adjustment bonus points means the points that a hospital can earn for a fiscal year based on its performance and proportion of inpatient stays for patients with dual eligibility status.

* * * * *

Measure performance scaler means the sum of the points awarded to a hospital for each domain for the fiscal year based on the hospital's performance on the measures in those domains.

* * * * *

Total Performance Score means the numeric score awarded to each hospital based on its performance under the Hospital VBP Program with respect to a fiscal year.

Underserved multiplier means the mathematical result of applying a logistic function to the number of hospital inpatient stays for patients in the underserved population out of the hospital's total Medicare inpatient population during the calendar year that is 2 years prior to the applicable fiscal year.

Underserved population, as used in this section, means hospital inpatients who are Medicare beneficiaries and also dually eligible for full Medicaid benefits during the month of discharge or, if a patient died during that month, during the previous month.

* * * * *

■ 16. Section 412.162 is amended by revising paragraph (b)(3) to read as follows:

§ 412.162 Process for reducing the base operating DRG payment amount and applying the value-based incentive payment amount adjustment under the Hospital Value-Based Purchasing (VBP) Program.

* * * * *

(b) * * *

(3) *Calculation of the value-based incentive payment percentage.* The value-based incentive payment percentage is calculated as the product of all of the following:

(i) The applicable percent as defined in § 412.160.

(ii)(A) For fiscal years before FY 2026, the hospital's Total Performance Score divided by 100; or

(B) Beginning with FY 2026, the hospital's Total Performance Score divided by 110; and

(iii) The linear exchange function slope.

* * * * *

■ 17. Section 412.164 is amended by—

■ a. In paragraph (b), removing the phrase ''. for at least'' and adding in its place the phrase '', for at least''; and

■ b. Adding paragraph (c).

The addition reads to read as follows:

§ 412.164 Measure selection under the Hospital Value-Based Purchasing (VBP) Program.

* * * * *

(c)(1) *Updating of measure specifications.* CMS uses rulemaking to make substantive updates to the specifications of measures used in the Hospital VBP Program. CMS announces technical measure specification updates through the QualityNet website (*https://qualitynet.cms.gov*) and listserv announcements.

(2) *Measure retention.* All measures selected under paragraph (a) of this section remain in the measure set unless CMS, through rulemaking, removes or replaces them.

(3) *Measure removal factors*—(i) *General rule.* CMS may remove or replace a measure based on one of the following factors:

(A) *Factor 1.* Measure performance among hospitals is so high and unvarying that meaningful distinctions and improvements in performance can no longer be made (''topped out'' measures), defined as: statistically indistinguishable performance at the 75th and 90th percentiles; and truncated coefficient of variation ≤0.10.

(B) *Factor 2.* A measure does not align with current clinical guidelines or practice.

(C) *Factor 3.* The availability of a more broadly applicable measure (across settings or populations) or the availability of a measure that is more proximal in time to desired patient outcomes for the particular topic.

(D) *Factor 4.* Performance or improvement on a measure does not result in better patient outcomes.

(E) *Factor 5.* The availability of a measure that is more strongly associated with desired patient outcomes for the particular topic.

(F) *Factor 6.* Collection or public reporting of a measure leads to negative unintended consequences other than patient harm.

(G) *Factor 7.* It is not feasible to implement the measure specifications.

(H) *Factor 8.* The costs associated with a measure outweigh the benefit of its continued use in the program.

(ii) *Application of measure removal factors.* CMS assesses the benefits of removing a measure from the Hospital VBP Program on a case-by-case basis.

(iii) *Patient safety exception.* Upon a determination by CMS that the continued requirement for hospitals to submit data on a measure raises specific patient safety concerns, CMS may elect to immediately remove the measure from the Hospital VBP measure set. CMS will, upon removal of the measure—

(A) Provide notice to hospitals and the public at the time CMS removes the measure, along with a statement of the specific patient safety concerns that would be raised if hospitals continued to submit data on the measure; and

(B) Provide notice of the removal in the **Federal Register**.

■ 18. Section 412.165 is amended by—

■ a. In paragraph (a)(1), adding a sentence at the end of the paragraph followed by a table;
■ b. Redesignating paragraph (b)(5) as paragraph (b)(6);
■ c. Adding a new paragraph (b)(5); and
■ d. Revising newly redesignated paragraph (b)(6).

The additions and revision read as follows:

§ 412.165 Performance scoring under the Hospital Value-Based Purchasing (VBP) Program.

(a) * * *

(1) * * * The applicable minimum number of cases are set forth as follows:

TABLE 1 TO PARAGRAPH (a)(1)—MINIMUM CASE NUMBER REQUIREMENTS FOR HOSPITAL VBP PROGRAM

Measure short name	Minimum number of cases
Person and Community Engagement Domain	
HCAHPS	Hospitals must report a minimum number of 100 completed Hospital Consumer Assessment of Healthcare providers and Systems (HCAHPS) surveys.
Clinical Outcomes Domain	
MORT–30–AMI	Hospitals must report a minimum number of 25 cases.
MORT–30–HF	Hospitals must report a minimum number of 25 cases.
MORT–30–PN (updated cohort)	Hospitals must report a minimum number of 25 cases.
MORT–30–COPD	Hospitals must report a minimum number of 25 cases.
MORT–30–CABG	Hospitals must report a minimum number of 25 cases.
COMP–HIP–KNEE	Hospitals must report a minimum number of 25 cases.
Safety Domain	
CAUTI	Hospitals have a minimum of 1.000 predicted infections as calculated by the Centers for Disease Control and Prevention (CDC).
CLABSI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
Colon and Abdominal Hysterectomy SSI.	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
MRSA Bacteremia	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
CDI	Hospitals have a minimum of 1.000 predicted infections as calculated by the CDC.
SEP–1	Hospitals must report a minimum number of 25 cases.
Efficiency and Cost Reduction Domain	
MSPB	Hospitals must report a minimum number of 25 cases.

* * * * *

(b) * * *

(5) Beginning with FY 2026, CMS will calculate the number of health equity adjustment bonus points the hospital has earned for the fiscal year as follows:

(i) Calculating the measure performance scaler for each domain in which the hospital reported the minimum number of cases by—

(A) Awarding 4 points where the hospital's performance on the domain for the fiscal year meets or exceeds the top third of performance of all hospitals on the domain for the same fiscal year;

(B) Awarding 2 points where the hospital's performance on the domain for the fiscal year meets or exceeds the middle third of performance, but is less than the top third of performance, of all hospitals on the domain for the same fiscal year;

(C) Awarding 0 points where the hospital's performance on the domain is less than the middle third of performance of all hospitals on the domain for the fiscal year; and

(D) Summing the points awarded under paragraph (b)(5)(i) of this section to calculate the measure performance scaler for the hospital.

(ii) Calculating the underserved multiplier for the hospital.

(iii) Multiplying the measure performance scaler calculated under paragraph (b)(5)(i) of this section by the underserved multiplier and, if the resulting product is greater than 10, capping that product at 10.

(6) The hospital's Total Performance Score for the fiscal year is as follows:

(i) For fiscal years before FY 2026, the sum of the weighted domain scores up to a maximum score of 100.

(ii) Beginning with FY 2026, the sum of the weighted domain scores and the health equity adjustment bonus points up to a maximum score of 110.

§ 412.320 [Amended]

■ 19. Section 412.320 is amended in paragraph (a)(1)(iii) by adding the phrase ''and before October 1, 2023,'' after ''October 1, 2006,''.

■ 20. Section 412.560 is amended by revising paragraph (f)(1) to read as follows:

§ 412.560 Requirements under the Long-Term Care Hospital Quality Reporting Program (LTCH QRP).

* * * * *

(f) * * *

(1) Long-term care hospitals must meet or exceed the following data completeness thresholds with respect to a fiscal year:

(i)(A) The threshold set at 100 percent completion of measures data and standardized patient assessment data collected using the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS) on at least 80 percent of the assessments LTCHs submit through the CMS designated data submission system for the FY 2014 through the FY 2025 LTCH QRP.

(B) The threshold set at 100 percent completion of measures data and standardized patient assessment data collected using the LCDS on at least 85 percent of the assessments LTCHs submit through the CMS designated data submission system beginning with the FY 2026 LTCH QRP.

(ii) The threshold set at 100 percent for measures data collected and submitted using the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) for

FY 2014 and all subsequent payment updates.

* * * * *

PART 419—PROSECTIVE PAYMENT SYSTEMS FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES

■ 21. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 22. Section 419.92 is amended by adding paragraph (d) to read as follows:

§ 419.92 Payment to rural emergency hospitals.

* * * * *

(d) *REH payment for the costs of graduate medical education.* (1) For portions of cost reporting periods beginning on or after October 1, 2023, an REH that incurs costs of training full-time equivalent (FTE) residents that rotate to the REH may receive direct graduate medical education payments for those costs.

(2) Payment is equal to the Medicare reasonable costs that the REH incurs to train the FTE residents that rotate to the REH, as determined in accordance with section 1861(v)(1)(A) of the Act and the applicable principles of cost reimbursement in part 413 of this chapter, except that the following payment principles are excluded:

(i) Lesser of cost or charges.

(ii) Ceilings on hospital operating costs.

(3) An REH that does not incur costs of training FTE residents that rotate to the REH is considered a nonprovider setting for purposes of graduate medical education payments, consistent with §§ 412.105(f)(1)(ii)(E) and 413.78(g) of this chapter.

(4) Direct graduate medical education payments to REHs made under this section are made from the Federal Hospital Insurance Trust Fund.

PART 488—SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

■ 23. The authority citation for part 488 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 488.1 [Amended]

■ 24. Section 488.1 is amended in the definition of ''Provider of services or provider'' by adding the phrase ''rural emergency hospital,'' after ''critical access hospital,''.

■ 25. Section 488.2 is revised to read as follows:

§ 488.2 Statutory basis.

This part is based on the indicated provisions of the following sections of the Act:

TABLE 1 TO § 488.2

Section	Subject
1128	Exclusion of entities from participation in Medicare.
1128A	Civil money penalties.
1138(b)	Requirements for organ procurement organizations and organ procurement agencies.
1814	Conditions for, and limitations on, payment for Part A services.
1819	Requirements for skilled nursing facilities (SNFs).
1820	Requirements for critical access hospitals (CAHs).
1822	Hospice Program survey and enforcement procedures.
1832(a)(2)(C)	Requirements for Organizations that provide outpatient physical therapy and speech language pathology services.
1832(a)(2)(F)	Requirements for ambulatory surgical centers (ASCs).
1832(a)(2)(J)	Requirements for partial hospitalization services provided by community mental health centers (CMHCs).
1861(e)	Requirements for hospitals.
1861(f)	Requirements for psychiatric hospitals.
1861(m)	Requirements for Home Health Services.
1861(o)	Requirements for Home Health Agencies.
1861(p)(4)	Requirements for rehabilitation agencies.
1861(z)	Institutional planning standards that hospitals and SNFs must meet.
1861(aa)	Requirements for rural health clinics (RHCs) and federally qualified health centers (FQHCs).
1861(cc)(2)	Requirements for comprehensive outpatient rehabilitation facilities (CORFs).
1861(dd)	Requirements for hospices.
1861(ee)	Discharge planning guidelines for hospitals.
1861(ff)(3)(A)	Requirements for CMHCs.
1861(ss)(2)	Accreditation of religious nonmedical health care institutions.
1861(kkk)	Requirements for rural emergency hospitals (REHs).
1863	Consultation with state agencies, accrediting bodies, and other organizations to develop conditions of participation, conditions for coverage, conditions for certification, and requirements for providers or suppliers.
1864	Use of State survey agencies.
1865	Effect of accreditation.
1875(b)	Requirements for performance review of CMS-approved accreditation programs.
1880	Requirements for hospitals and SNFs of the Indian Health Service.
1881	Requirements for end stage renal disease (ESRD) facilities.
1883	Requirements for hospitals that furnish extended care services.
1891	Conditions of participation for home health agencies; home health quality.
1902	Requirements for participation in the Medicaid program.
1913	Medicaid requirements for hospitals that provide nursing facility (NF) care.
1919	Medicaid requirements for NFs.

§ 488.18 [Amended]

■ 26. Section 488.18 is amended in paragraph (d) by adding the phrase ''or a rural emergency hospital (as defined in section 1861(kkk)(2) of the Act)'' after the parenthetical phrase ''(as defined in section 1861(mm)(1) of the Act)''.

■ 27. Section 488.70 is added to read as follows:

§ 488.70 Special requirements for rural emergency hospitals (REHs).

An eligible facility submitting an application for enrollment under section 1866(j) of the Act to become a rural emergency hospital (REH) (as defined in § 485.502 of this chapter) must also submit an action plan containing the following additional information:

(a) *Plan for provision of services.* The provider must submit an action plan for initiating rural emergency hospital (REH) services (as defined in § 485.502 of this chapter, and which must include the provision of emergency department services and observation care).

(b) *Transition plan.* The provider must submit a detailed transition plan that lists the specific services that the provider will retain, modify, add, and discontinue as an REH.

(c) *Other outpatient medical and health services.* The provider must submit a detailed description of the other medical and health services that it intends to furnish on an outpatient basis as an REH.

(d) *Use of additional facility payment.* The provider must submit information regarding how the provider intends to use the additional facility payment provided in accordance with section 1834(x)(2) of the Act, including a description of the services that the additional facility payment would be supporting, such as the operation and maintenance of the facility and the furnishing of covered services (for example, telehealth services, and ambulance services).

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 28. The authority citation for part 489 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i–3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh.

■ 29. Section 489.102 is amended by—
■ a. In paragraph (a) introductory text, adding the phrase ''rural emergency hospitals,'' after ''critical access hospitals,''; and
■ b. Adding paragraph (b)(5).

The addition reads as follows:

§ 489.102 Requirements for providers.

* * * * *

(b) * * *

(5) In the case of a rural emergency hospital, at the time of the individual's registration as a patient.

* * * * *

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 30. The authority citation for part 495 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 31. Section 495.4 is amended in the definition of ''EHR reporting period for a payment adjustment year'' by adding paragraphs (2)(ix) and (3)(ix) to read as follows:

§ 495.4 Definitions.

* * * * *

EHR reporting period for a payment adjustment year. * * *

(2) * * *

(ix) For an eligible hospital in CY 2025, the EHR reporting period is any continuous 180-day period within CY 2025 and applies for the FY 2027 payment adjustment year.

(3) * * *

(ix) For a CAH in CY 2025, the EHR reporting period is any continuous 180-day period within CY 2025 and applies for the FY 2025 payment adjustment year.

* * * * *

■ 32. Section 495.40 is amended by—
■ a. Redesignating paragraphs (b)(2)(i)(H) through (J) as paragraphs (b)(2)(i)(I) through (K); and
■ b. Adding a new paragraph (b)(2)(i)(H).

The addition reads as follows:

§ 495.40 Demonstration of meaningful use criteria.

* * * * *

(b) * * *

(2) * * *

(i) * * *

(H) For CY 2024 and subsequent years, for an eligible hospital or CAH attesting to CMS, satisfied the required objectives and associated measures for meaningful use as defined by CMS.

* * * * *

Dated: July 26, 2023.

Xavier Becerra,

Secretary, Department of Health and Human Services.

Note: The following addendum and appendices will not appear in the Code of Federal Regulations.

Addendum—Schedule of Standardized Amounts, Update Factors, Rate-of-Increase Percentages Effective With Cost Reporting Periods Beginning on or After October 1, 2023, and Payment Rates for LTCHs Effective for Discharges Occurring on or After October 1, 2023

I. Summary and Background

In this Addendum, we are setting forth a description of the methods and data we used to determine the prospective payment rates for Medicare hospital inpatient operating costs and Medicare hospital inpatient capital-related costs for FY 2024 for acute care hospitals. We also are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS for FY 2024. We note that, because certain hospitals excluded from the IPPS are paid on a reasonable cost basis subject to a rate-of-increase ceiling (and not by the IPPS), these hospitals are not affected by the figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this final rule, we are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS that will be effective for cost reporting periods beginning on or after October 1, 2023.

In addition, we are setting forth a description of the methods and data we used to determine the LTCH PPS standard Federal payment rate that would be applicable to Medicare LTCHs for FY 2024.

In general, except for SCHs and MDHs, for FY 2024, each hospital's payment per discharge under the IPPS is based on 100 percent of the Federal national rate, also known as the national adjusted standardized amount. This amount reflects the national average hospital cost per case from a base year, updated for inflation.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate (including, as discussed in section IV.G. of the preamble of this final rule, uncompensated care payments under section 1886(r)(2) of the Act); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge.

Under section 1886(d)(5)(G) of the Act, MDHs historically were paid based on the Federal national rate or, if higher, the Federal national rate plus 50 percent of the difference between the Federal national rate and the updated hospital-specific rate based on FY 1982 or FY 1987 costs per discharge, whichever was higher. However, section 5003(a)(1) of Public Law 109–171 extended and modified the MDH special payment provision that was previously set to expire on October 1, 2006, to include discharges occurring on or after October 1, 2006, but before October 1, 2011. Under section 5003(b) of Public Law 109–171, if the change results in an increase to an MDH's target amount, we must rebase an MDH's hospital specific rates based on its FY 2002 cost report.

Section 5003(c) of Public Law 109–171 further required that MDHs be paid based on the Federal national rate or, if higher, the Federal national rate plus 75 percent of the difference between the Federal national rate and the updated hospital specific rate. Further, based on the provisions of section 5003(d) of Public Law 109–171, MDHs are no longer subject to the 12-percent cap on their DSH payment adjustment factor. Under current law, the Medicare-dependent, small rural hospital (MDH) program is effective through FY 2024.

As discussed in section V.A.2. of the preamble of this final rule, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. In general, Puerto Rico hospitals are paid 100 percent of the national standardized amount and are subject to the same national standardized amount as subsection (d) hospitals that receive the full update. Accordingly, our discussion later in this section does not include references to the Puerto Rico standardized amount or the Puerto Rico-specific wage index.

As discussed in section II. of this Addendum, we are making changes in the determination of the prospective payment rates for Medicare inpatient operating costs for acute care hospitals for FY 2024. In section III. of this Addendum, we discuss our policy changes for determining the prospective payment rates for Medicare inpatient capital-related costs for FY 2024. In section IV. of this Addendum, we are setting forth the rate-of-increase percentage for determining the rate-of-increase limits for certain hospitals excluded from the IPPS for FY 2024. In section V. of this Addendum, we discuss policy changes for determining the LTCH PPS standard Federal rate for LTCHs paid under the LTCH PPS for FY 2024. The tables to which we refer in the preamble of this final rule are listed in section VI. of this Addendum and are available via the internet on the CMS website.

II. Changes to Prospective Payment Rates for Hospital Inpatient Operating Costs for Acute Care Hospitals for FY 2024

The basic methodology for determining prospective payment rates for hospital inpatient operating costs for acute care hospitals for FY 2005 and subsequent fiscal years is set forth under § 412.64. The basic methodology for determining the prospective payment rates for hospital inpatient operating costs for hospitals located in Puerto Rico for FY 2005 and subsequent fiscal years is set forth under §§ 412.211 and 412.212. In this section, we discuss the factors we are using for determining the prospective payment rates for FY 2024.

In summary, the standardized amounts set forth in Tables 1A, 1B, and 1C that are listed and published in section VI. of this Addendum (and available via the internet on the CMS website) reflect—

- Equalization of the standardized amounts for urban and other areas at the level computed for large urban hospitals during FY 2004 and onward, as provided for under section 1886(d)(3)(A)(iv)(II) of the Act.
- The labor-related share that is applied to the standardized amounts to give the hospital the highest payment, as provided for under sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act. For FY 2024, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), there are four possible applicable percentage increases that can be applied to the national standardized amount. We refer readers to section V.B. of the preamble of this final rule for a complete discussion on the FY 2024 inpatient hospital update. The table that follows shows these four scenarios:

FY 2024 APPLICABLE PERCENTAGE INCREASES FOR THE IPPS				
FY 2024	**Hospital Submitted Quality Data and is a Meaningful EHR User**	**Hospital Submitted Quality Data and is NOT a Meaningful EHR User**	**Hospital Did NOT Submit Quality Data and is a Meaningful EHR User**	**Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User**
Market Basket Rate-of-Increase	3.3	3.3	3.3	3.3
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.825	-0.825
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-2.475	0	-2.475
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.2	-0.2	-0.2	-0.2
Applicable Percentage Increase Applied to Standardized Amount	**3.1**	**0.625**	**2.275**	**-0.2**

We note that section 1886(b)(3)(B)(viii) of the Act, which specifies the adjustment to the applicable percentage increase for ''subsection (d)'' hospitals that do not submit quality data under the rules established by the Secretary, is not applicable to hospitals located in Puerto Rico.

In addition, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016, and also to apply the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022. Accordingly, the applicable percentage increase for subsection (d) Puerto Rico hospitals that are not meaningful EHR users for FY 2024 and subsequent fiscal years is adjusted by the adjustment for failure to

be a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act. The regulations at 42 CFR 412.64(d)(3)(ii) reflect the current law for the update for subsection (d) Puerto Rico hospitals for FY 2022 and subsequent fiscal years.

- An adjustment to the standardized amount to ensure budget neutrality for DRG recalibration and reclassification, as provided for under section 1886(d)(4)(C)(iii) of the Act.
- An adjustment to the standardized amount to ensure budget neutrality for the permanent 10 percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year, as discussed in section II.D.2.c. of the preamble of this final rule, consistent with our current methodology for implementing DRG recalibration and reclassification budget neutrality under section 1886(d)(4)(C)(iii) of the Act.
- An adjustment to ensure the wage index and labor-related share changes (depending on the fiscal year) are budget neutral, as provided for under section 1886(d)(3)(E)(i) of the Act (as discussed in the FY 2006 IPPS final rule (70 FR 47395) and the FY 2010 IPPS final rule (74 FR 44005)). We note that section 1886(d)(3)(E)(i) of the Act requires that when we compute such budget neutrality, we assume that the provisions of section 1886(d)(3)(E)(ii) of the Act (requiring a 62-percent labor-related share in certain circumstances) had not been enacted.
- An adjustment to ensure the effects of geographic reclassification are budget neutral, as provided for under section 1886(d)(8)(D) of the Act, by removing the FY 2023 budget neutrality factor and applying a revised factor.
- An adjustment to the standardized amount to implement in a budget neutral manner the increase in the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals (as described in section III.G.4 of the preamble of this final rule).
- An adjustment to the standardized amount to implement in a budget neutral manner the wage index cap policy (as described in section III.G.5. of the preamble of this final rule).
- An adjustment to ensure the effects of the Rural Community Hospital Demonstration program required under section 410A of Public Law 108–173 (as amended by sections 3123 and 10313 of Pub. L. 111–148, which extended the demonstration program for an additional 5 years and section 15003 of Pub. L. 114–255), are budget neutral as required under section 410A(c)(2) of Public Law 108–173.
- An adjustment to remove the FY 2023 outlier offset and apply an offset for FY 2024, as provided for in section 1886(d)(3)(B) of the Act.

For FY 2024, consistent with current law, we are applying the rural floor budget neutrality adjustment to hospital wage indexes. Also, consistent with section 3141 of the Affordable Care Act, instead of applying a State-level rural floor budget neutrality adjustment to the wage index, we are applying a uniform, national budget neutrality adjustment to the FY 2024 wage index for the rural floor.

For FY 2024, as we proposed, we are continuing to not remove the Stem Cell Acquisition Budget Neutrality Factor from the prior year's standardized amount and to not apply a new factor. If we removed the prior year's adjustment, we would not satisfy budget neutrality. We believe this approach ensures the effects of the reasonable cost-based payment for allogeneic hematopoietic stem cell acquisition costs under section 108 of the Further Consolidated Appropriations Act, 2020 (Pub. L. 116–94) are budget neutral as required under section 108 of Public Law 116–94. For a discussion of Stem Cell Acquisition Budget Neutrality Factor, we refer the reader to the FY 2021 IPPS/LTCH PPS final rule (85 FR 59032 and 59033).

A. Calculation of the Adjusted Standardized Amount

1. Standardization of Base-Year Costs or Target Amounts

In general, the national standardized amount is based on per discharge averages of adjusted hospital costs from a base period (section 1886(d)(2)(A) of the Act), updated and otherwise adjusted in accordance with the provisions of section 1886(d) of the Act. The September 1, 1983 interim final rule (48 FR 39763) contained a detailed explanation of how base-year cost data (from cost reporting periods ending during FY 1981) were established for urban and rural hospitals in the initial development of standardized amounts for the IPPS.

Sections 1886(d)(2)(B) and 1886(d)(2)(C) of the Act require us to update base-year per discharge costs for FY 1984 and then standardize the cost data to remove the effects of certain sources of cost variations among hospitals. These effects include case-mix, differences in area wage levels, cost-of-living adjustments for Alaska and Hawaii, IME costs, and costs to hospitals serving a disproportionate share of low-income patients.

For FY 2024, as we proposed, we are continuing to use the national labor-related and nonlabor-related shares (which are based on the 2018-based IPPS market basket) that were used in FY 2023. Specifically, under section 1886(d)(3)(E) of the Act, the Secretary estimates, from time to time, the proportion of payments that are labor-related and adjusts the proportion (as estimated by the Secretary from time to time) of hospitals' costs which are attributable to wages and wage-related costs of the DRG prospective payment rates. We refer to the proportion of hospitals' costs that are attributable to wages and wage-related costs as the ''labor-related share.'' For FY 2024, as discussed in section III.M. of the preamble of this final rule, as we proposed, we are using a labor-related share of 67.6 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, as proposed, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000.

The standardized amounts for operating costs appear in Tables 1A, 1B, and 1C that are listed and published in section VI. of the Addendum to this final rule and are available via the internet on the CMS website.

2. Computing the National Average Standardized Amount

Section 1886(d)(3)(A)(iv)(II) of the Act requires that, beginning with FY 2004 and thereafter, an equal standardized amount be computed for all hospitals at the level computed for large urban hospitals during FY 2003, updated by the applicable percentage update. Accordingly, as proposed, we are calculating the FY 2024 national average standardized amount irrespective of whether a hospital is located in an urban or rural location.

3. Updating the National Average Standardized Amount

Section 1886(b)(3)(B) of the Act specifies the applicable percentage increase used to update the standardized amount for payment for inpatient hospital operating costs. We note that, in compliance with section 404 of the MMA, we are using the 2018-based IPPS operating and capital market baskets for FY 2024. As discussed in section IV.B. of the preamble of this final rule, in accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are reducing the FY 2024

applicable percentage increase (which for this final rule is based on IGI's second quarter 2023 forecast of the 2018-based IPPS market basket) by the productivity adjustment, as discussed elsewhere in this final rule.

Based on IGI's second quarter 2023 forecast (as discussed in appendix B of this final rule), the forecast of the hospital market basket percentage increase for FY 2024 for this final rule is 3.3 percent and the forecast of the productivity adjustment for FY 2024 for this final rule is 0.2 percent. As discussed earlier, for FY 2024, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, there are four possible applicable percentage increases that can be applied to the standardized amount. We refer readers to section V.B. of the preamble of this final rule for a complete discussion on the FY 2024 inpatient hospital update to the standardized amount. We also refer readers to the previous table for the four possible applicable percentage increases that would be applied to update the national standardized amount. The standardized amounts shown in Tables 1A through 1C that are published in section VI. of this Addendum and that are available via the internet on the CMS website reflect these differential amounts.

Although the update factors for FY 2024 are set by law, we are required by section 1886(e)(4) of the Act to recommend, taking into account MedPAC's recommendations, appropriate update factors for FY 2024 for both IPPS hospitals and hospitals and hospital units excluded from the IPPS. Section 1886(e)(5)(A) of the Act requires that we publish our recommendations in the **Federal Register** for public comment. Our recommendation on the update factors is set forth in appendix B of this final rule.

4. Methodology for Calculation of the Average Standardized Amount

The methodology we used to calculate the FY 2024 standardized amount is as follows:

- To ensure we are only including hospitals paid under the IPPS in the calculation of the standardized amount, we applied the following inclusion and exclusion criteria: include hospitals whose last four digits fall between 0001 and 0879 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); exclude CAHs at the time of this final rule; exclude hospitals in Maryland (because these hospitals are paid under an all payer model under section 1115A of the Act); and remove PPS excluded—cancer hospitals that have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.
- As in the past, we are adjusting the FY 2024 standardized amount to remove the effects of the FY 2023 geographic reclassifications and outlier payments before applying the FY 2024 updates. We then applied budget neutrality offsets for outliers and geographic reclassifications to the standardized amount based on FY 2024 payment policies.
- We do not remove the prior year's budget neutrality adjustments for reclassification and recalibration of the DRG relative weights and for updated wage data because, in accordance with sections 1886(d)(4)(C)(iii) and 1886(d)(3)(E) of the Act, estimated aggregate payments after updates in the DRG relative weights and wage index should equal estimated aggregate payments prior to the changes. If we removed the prior year's adjustment, we would not satisfy these conditions.

Budget neutrality is determined by comparing aggregate IPPS payments before and after making changes that are required to be budget neutral (for example, changes to MS–DRG classifications, recalibration of the MS–DRG relative weights, updates to the wage index, and different geographic reclassifications). We include outlier payments in the simulations because they may be affected by changes in these parameters.

- Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50433), because IME Medicare Advantage payments are made to IPPS hospitals under section 1886(d) of the Act, we believe these payments must be part of these budget neutrality calculations. However, we note that it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation or the outlier offset to the standardized amount because the statute requires that outlier payments be not less than 5 percent nor more than 6 percent of total ''operating DRG payments,'' which does not include IME and DSH payments. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.
- Consistent with the methodology in the FY 2012 IPPS/LTCH PPS final rule, to ensure that we capture only fee-for-service claims, we are only including claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).
- Consistent with our methodology established in the FY 2017 IPPS/LTCH PPS final rule (81 FR 57277), to further ensure that we capture only FFS claims, we are excluding claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).
- Consistent with our methodology established in the FY 2011 IPPS/LTCH PPS final rule (75 FR 50422 through 50423), we examine the MedPAR file and remove pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field for the budget neutrality adjustments. We are removing organ acquisition charges, except for cases that group to MS–DRG 018, from the covered charge field for the budget neutrality adjustments because organ acquisition is a pass-through payment not paid under the IPPS. Revenue centers 081X–089X are typically excluded from ratesetting, however, we are not removing revenue center 891 charges from MS–DRG 018 claims during ratesetting because those revenue 891 charges were included in the relative weight calculation for MS–DRG 018, which is consistent with the policy finalized in FY 2021 final rule (85 FR 58600). We note that a new MedPAR variable for revenue code 891 charges was introduced in April 2020.
- For FY 2024, we are continuing to remove allogeneic hematopoietic stem cell acquisition charges from the covered charge field for budget neutrality adjustments. As discussed in the FY 2021 IPPS/LTCH PPS final rule, payment for allogeneic hematopoietic stem cell acquisition costs is made on a reasonable cost basis for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 through 58842).
- The participation of hospitals under the BPCI (Bundled Payments for Care Improvement) Advanced model started on October 1, 2018. The BPCI Advanced model, tested under the authority of section 3021 of the Affordable Care Act (codified at section 1115A of the Act), is comprised of a single payment and risk track, which bundles payments for multiple services beneficiaries receive during a Clinical Episode. Acute care hospitals may participate in the BPCI Advanced model in one of two

capacities: as a model Participant or as a downstream Episode Initiator. Regardless of the capacity in which they participate in the BPCI Advanced model, participating acute care hospitals would continue to receive IPPS payments under section 1886(d) of the Act. Acute care hospitals that are Participants also assume financial and quality performance accountability for Clinical Episodes in the form of a reconciliation payment. For additional information on the BPCI Advanced model, we refer readers to the BPCI Advanced web page on the CMS Center for Medicare and Medicaid Innovation's website at: *https://innovation.cms.gov/initiatives/bpci-advanced/*.

For FY 2024, consistent with how we treated hospitals that participated in the BPCI Advanced Model in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59029 and 59030), as we proposed, we are including all applicable data from subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations. We believe it is appropriate to include all applicable data from the subsection (d) hospitals participating in the BPCI Advanced model in our IPPS payment modeling and ratesetting calculations because these hospitals are still receiving IPPS payments under section 1886(d) of the Act. For the same reasons, as we proposed, we included all applicable data from subsection (d) hospitals participating in the Comprehensive Care for Joint Replacement (CJR) Model in our IPPS payment modeling and ratesetting calculations.

- Consistent with our methodology established in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688), we believe that it is appropriate to include adjustments for the Hospital Readmissions Reduction Program and the Hospital VBP Program (established under the Affordable Care Act) within our budget neutrality calculations.

Both the hospital readmissions payment adjustment (reduction) and the hospital VBP payment adjustment (redistribution) are applied on a claim-by-claim basis by adjusting, as applicable, the base-operating DRG payment amount for individual subsection (d) hospitals, which affects the overall sum of aggregate payments on each side of the comparison within the budget neutrality calculations.

In order to properly determine aggregate payments on each side of the comparison, consistent with the approach we have taken in prior years, for FY 2024, we are applying a proxy based on the prior fiscal year hospital readmissions payment adjustment (for FY 2024 this would be FY 2023 final adjustment factors from Table 15 of the FY 2023 IPPS/LTCH PPS final rule) and the FY 2024 proposed hospital VBP payment adjustment on each side of the comparison (we note, generally, we use the prior year VBP factors. In the proposed rule, we used an adjustment factor of 1 to reflect our policy for the FY 2023 program year to suppress measures and award each hospital a value-based payment amount that matches the reduction to the base operating DRG payment amount. For this final rule, we used the FY 2024 proposed proxy VBP factors from Table 16A of the proposed rule), consistent with the methodology that we adopted in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53687 through 53688). That is, we are applying a proxy readmissions payment adjustment factor from the prior final rule and a proxy hospital VBP payment adjustment factor on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum. We refer the reader to section V.H. of the preamble of this final rule for a complete discussion on the Hospital Readmissions Reduction Program and section V.G. of the preamble of this final rule for a complete discussion on the Hospital VBP Program.

- The Affordable Care Act also established section 1886(r) of the Act, which modifies the methodology for computing the Medicare DSH payment adjustment beginning in FY 2014. Beginning in FY 2014, IPPS hospitals receiving Medicare DSH payment adjustments receive an empirically justified Medicare DSH payment equal to 25 percent of the amount that would previously have been received under the statutory formula set forth under section 1886(d)(5)(F) of the Act governing the Medicare DSH payment adjustment. In accordance with section 1886(r)(2) of the Act, the remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured and any additional statutory adjustment, is available to make additional payments to Medicare DSH hospitals based on their share of the total amount of uncompensated care reported by Medicare DSH hospitals for a given time period. To properly determine aggregate payments on each side of the comparison for budget neutrality, prior to FY 2014, we included estimated Medicare DSH payments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

To do this for FY 2024 (as we did for the last 10 fiscal years), as we proposed, we are including estimated empirically justified Medicare DSH payments that would be paid in accordance with section 1886(r)(1) of the Act and estimates of the additional uncompensated care payments made to hospitals receiving Medicare DSH payment adjustments as described by section 1886(r)(2) of the Act. That is, we considered estimated empirically justified Medicare DSH payments at 25 percent of what would otherwise have been paid, and also the estimated additional uncompensated care payments for hospitals receiving Medicare DSH payment adjustments on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

We also are including the estimated supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals on both sides of our comparison of aggregate payments when determining all budget neutrality factors described in section II.A.4. of this Addendum.

- When calculating total payments for budget neutrality, to determine total payments for SCHs, we model total hospital-specific rate payments and total Federal rate payments and then include whichever one of the total payments is greater. As discussed in section IV.G. of the preamble to this final rule and later in this section, we are continuing to use the FY 2014 finalized methodology under which we take into consideration uncompensated care payments in the comparison of payments under the Federal rate and the hospital-specific rate for SCHs. Therefore, we are including estimated uncompensated care payments in this comparison.

Similarly, for MDHs, as discussed in section IV.G. of the preamble of this final rule, when computing payments under the Federal national rate plus 75 percent of the difference between the payments under the Federal national rate and the payments under the updated hospital-specific rate, we are continuing to take into consideration uncompensated care payments in the computation of payments under the Federal rate and the hospital-specific rate for MDHs.

- As we proposed, we included an adjustment to the standardized amount for those hospitals that are not meaningful EHR users in our modeling of aggregate payments for budget neutrality for FY 2024. Similar to FY

2023, we are including this adjustment based on data on the prior year's performance. Payments for hospitals would be estimated based on the applicable standardized amount in Tables 1A and 1B for discharges occurring in FY 2024.

• In our determination of all budget neutrality factors described in section II.A.4. of this Addendum, we used transfer-adjusted discharges.

We note, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49414 through 49415), we finalized a change to the ordering of the budget neutrality factors in the calculation so that the RCH Demonstration budget neutrality factor is applied after all wage index and other budget neutrality factors. We refer the reader to the FY 2023 IPPS/LTCH PPS final rule for further discussion.

a. Reclassification and Recalibration of MS–DRG Relative Weights Before Cap

Section 1886(d)(4)(C)(iii) of the Act specifies that, beginning in FY 1991, the annual DRG reclassification and recalibration of the relative weights must be made in a manner that ensures that aggregate payments to hospitals are not affected. As discussed in section II.D. of the preamble of this final rule, we normalized the recalibrated MS–DRG relative weights by an adjustment factor so that the average case relative weight after recalibration is equal to the average case relative weight prior to recalibration. However, equating the average case relative weight after recalibration to the average case relative weight before recalibration does not necessarily achieve budget neutrality with respect to aggregate payments to hospitals because payments to hospitals are affected by factors other than average case relative weight. Therefore, as we have done in past years, we are making a budget neutrality adjustment to ensure that the requirement of section 1886(d)(4)(C)(iii) of the Act is met.

For this FY 2024 final rule, as we proposed, to comply with the requirement that MS–DRG reclassification and recalibration of the relative weights be budget neutral for the standardized amount and the hospital-specific rates, we used FY 2022 discharge data to simulate payments and compared the following:

• Aggregate payments using the FY 2023 labor-related share percentages, the FY 2023 relative weights, and the FY 2023 pre-reclassified wage data, and applied the proxy FY 2024 hospital readmissions payment adjustments and proxy FY 2024 hospital VBP payment adjustments; and

• Aggregate payments using the FY 2023 labor-related share percentages, the FY 2024 relative weights before applying the 10 percent cap, and the FY 2023 pre-reclassified wage data, and applied the same proxy FY 2024 hospital readmissions payment adjustments and proxy FY 2024 hospital VBP payment adjustments applied previously.

Because this payment simulation uses the FY 2024 relative weights (before applying the 10 percent cap), consistent with our policy in section IV.I. of the preamble to this final rule, we applied the adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments. We note that because the simulations of payments for all of the budget neutrality factors discussed in this section also use the FY 2024 relative weights, we are applying the adjustor for certain MS–DRG 018 (Chimeric Antigen Receptor (CAR) T-cell and other immunotherapies) cases in all simulations of payments for the budget neutrality factors discussed later in this section. We refer the reader to section IV.I. of the preamble of this final rule for a complete discussion on the adjustor for certain cases that group to MS–DRG 018 and to section II.D.2.b. of the preamble of this final rule, for a complete discussion of the adjustment to the FY 2024 relative weights to account for certain cases that group to MS–DRG 018.

Based on this comparison, we computed a budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, as we proposed, we are applying the MS–DRG reclassification and recalibration budget neutrality factor to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2023. Please see the table later in this section setting forth each of the FY 2024 budget neutrality factors.

b. Budget Neutrality Adjustment for Reclassification and Recalibration of MS–DRG Relative Weights With Cap

As discussed in section II.D.2.c of this final rule, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48897 through 48900), we finalized a permanent 10-percent cap on the reduction in an MS–DRG's relative weight in a given fiscal year, beginning in FY 2023. As also discussed in section II.D.2.c of the preamble of this final rule, and consistent with our current methodology for implementing budget neutrality for MS–DRG reclassification and recalibration of the relative weights under section 1886(d)(4)(C)(iii) of the Act, we apply a budget neutrality adjustment to the standardized amount for all hospitals so that this 10-percent cap on relative weight reductions does not increase estimated aggregate Medicare payments beyond the payments that would be made had we never applied this cap. We refer the reader to the FY 2023 IPPS/LTCH PPS final rule for further discussion.

To calculate this final budget neutrality adjustment factor for FY 2024, we used FY 2022 discharge data to simulate payments and compared the following:

• Aggregate payments using the FY 2023 labor-related share percentages, the FY 2024 relative weights before applying the 10-percent cap, and the FY 2023 pre-reclassified wage data, and applied the proxy FY 2024 hospital readmissions payment adjustments and the proxy FY 2024 hospital VBP payment adjustments; and

• Aggregate payments using the FY 2023 labor-related share percentages, the FY 2024 relative weights after applying the 10-percent cap, and the FY 2023 pre-reclassified wage data, and applied the same proxy FY 2024 hospital readmissions payment adjustments and proxy FY 2024 hospital VBP payment adjustments applied previously.

Because this payment simulation uses the FY 2024 relative weights, consistent with our proposal in section IV.I. of the preamble to this final rule and our historical policy, and as discussed in the preceding section, we applied the adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments.

In addition, we applied the MS–DRG reclassification and recalibration budget neutrality adjustment factor before the cap (derived in the first step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2023 to FY 2024. Based on this comparison, we computed a budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, as we proposed, we are applying this budget neutrality factor to the hospital-specific rates that are effective for cost reporting periods beginning on or after October 1, 2023. Please see the table later in this section setting forth each of the FY 2024 budget neutrality factors.

c. Updated Wage Index—Budget Neutrality Adjustment

Section 1886(d)(3)(E)(i) of the Act requires us to update the hospital wage index on an annual basis beginning October 1, 1993. This provision also requires us to make any updates or

adjustments to the wage index in a manner that ensures that aggregate payments to hospitals are not affected by the change in the wage index. Section 1886(d)(3)(E)(i) of the Act requires that we implement the wage index adjustment in a budget neutral manner. However, section 1886(d)(3)(E)(ii) of the Act sets the labor-related share at 62 percent for hospitals with a wage index less than or equal to 1.0000, and section 1886(d)(3)(E)(i) of the Act provides that the Secretary shall calculate the budget neutrality adjustment for the adjustments or updates made under that provision as if section 1886(d)(3)(E)(ii) of the Act had not been enacted. In other words, this section of the statute requires that we implement the updates to the wage index in a budget neutral manner, but that our budget neutrality adjustment should not take into account the requirement that we set the labor-related share for hospitals with wage indexes less than or equal to 1.0000 at the more advantageous level of 62 percent. Therefore, for purposes of this budget neutrality adjustment, section 1886(d)(3)(E)(i) of the Act prohibits us from taking into account the fact that hospitals with a wage index less than or equal to 1.0000 are paid using a labor-related share of 62 percent. Consistent with current policy, for FY 2024, as we proposed, we are adjusting 100 percent of the wage index factor for occupational mix. We describe the occupational mix adjustment in section III.E. of the preamble of this final rule.

To compute a budget neutrality adjustment factor for wage index and labor-related share percentage changes, we used FY 2022 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2024 relative weights and the FY 2023 pre-reclassified wage indexes, applied the FY 2023 labor-related share of 67.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the proxy FY 2024 hospital readmissions payment adjustment and the proxy FY 2024 hospital VBP payment adjustment.
- Aggregate payments using the FY 2024 relative weights and the FY 2024 pre-reclassified wage indexes, applied the labor-related share for FY 2024 of 67.6 percent to all hospitals (regardless of whether the hospital's wage index was above or below 1.0000), and applied the same proxy FY 2024 hospital readmissions payment adjustments and proxy FY 2024 hospital VBP payment adjustments applied previously.

In addition, we applied the MS–DRG reclassification and recalibration budget neutrality adjustment factor before the cap (derived in the first step) and the 10 percent cap on relative weight reductions adjustment factor (derived from the second step) to the payment rates that were used to simulate payments for this comparison of aggregate payments from FY 2023 to FY 2024. Based on this comparison, we computed a budget neutrality adjustment factor and applied this factor to the standardized amount for changes to the wage index. Please see the table later in this section for a summary of the FY 2024 budget neutrality factors.

d. Reclassified Hospitals—Budget Neutrality Adjustment

Section 1886(d)(8)(B) of the Act provides that certain rural hospitals are deemed urban. In addition, section 1886(d)(10) of the Act provides for the reclassification of hospitals based on determinations by the MGCRB. Under section 1886(d)(10) of the Act, a hospital may be reclassified for purposes of the wage index.

Under section 1886(d)(8)(D) of the Act, the Secretary is required to adjust the standardized amount to ensure that aggregate payments under the IPPS after implementation of the provisions of sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are equal to the aggregate prospective payments that would have been made absent these provisions. We note, as discussed in section III.G.1. of the preamble of this final rule, we are finalizing as proposed, beginning with FY 2024, to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and only exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) in accordance with the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. Consistent with the previous policy, beginning with FY 2024, we will include the data of all § 412.103 hospitals (including those that have an MGCRB reclassification) in the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act. As discussed in section III.G.1. of the preamble of this final rule, we acknowledge that this policy has significant effects on wage index values. In addition, as a result of this change, the geographic reclassification budget neutrality adjustment is significantly larger than in prior years.

We refer the reader to the FY 2015 IPPS final rule (79 FR 50371 and 50372) for a complete discussion regarding the requirement of section 1886(d)(8)(C)(iii) of the Act. We further note that the wage index adjustments provided for under section 1886(d)(13) of the Act are not budget neutral. Section 1886(d)(13)(H) of the Act provides that any increase in a wage index under section 1886(d)(13) of the Act shall not be taken into account in applying any budget neutrality adjustment with respect to such index under section 1886(d)(8)(D) of the Act. To calculate the budget neutrality adjustment factor for FY 2024, we used FY 2022 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2024 labor-related share percentage, the FY 2024 relative weights, and the FY 2024 wage data prior to any reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act, and applied the proxy FY 2024 hospital readmissions payment adjustments and the proxy FY 2024 hospital VBP payment adjustments.
- Aggregate payments using the FY 2024 labor-related share percentage, the FY 2024 relative weights, and the FY 2024 wage data after such reclassifications, and applied the same proxy FY 2024 hospital readmissions payment adjustments and the proxy FY 2024 hospital VBP payment adjustments applied previously.

We note that the reclassifications applied under the second simulation and comparison are those listed in Table 2 associated with this final rule, which is available via the internet on the CMS website. This table reflects reclassification crosswalks for FY 2024 and applies the policies explained in section III. of the preamble of this final rule. Based on this comparison, we computed a budget neutrality adjustment factor and applied this factor to the standardized amount to ensure that the effects of these provisions are budget neutral, consistent with the statute. Please see the table later in this section for a summary of the FY 2024 budget neutrality factors.

The FY 2024 budget neutrality adjustment factor was applied to the standardized amount after removing the effects of the FY 2023 budget neutrality adjustment factor. We note that the FY 2024 budget neutrality adjustment reflects FY 2024 wage index reclassifications approved by the MGCRB or the Administrator at the time of development of this final rule. We finally note, in the absence of the policies discussed in section III.G.1 of this final rule (to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all

rural wage index calculations, and to only exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) in accordance with the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act), the reclassification budget neutrality factor would be 0.984000.

e. Rural Floor Budget Neutrality Adjustment

Under § 412.64(e)(4), we make an adjustment to the wage index to ensure that aggregate payments after implementation of the rural floor under section 4410 of the BBA (Pub. L. 105–33) are equal to the aggregate prospective payments that would have been made in the absence of this provision. Consistent with section 3141 of the Affordable Care Act and as discussed in section III.G. of the preamble of this final rule and codified at § 412.64(e)(4)(ii), the budget neutrality adjustment for the rural floor is a national adjustment to the wage index.

Similar to our calculation in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50369 through 50370), for FY 2024, as we proposed, we calculated a national rural Puerto Rico wage index. Because there are no rural Puerto Rico hospitals with established wage data, our calculation of the FY 2024 rural Puerto Rico wage index is based on the policy adopted in the FY 2008 IPPS final rule with comment period (72 FR 47323). That is, we use the unweighted average of the wage indexes from all CBSAs (urban areas) that are contiguous to (share a border with) the rural counties to compute the rural floor (72 FR 47323; 76 FR 51594). Under the OMB labor market area delineations, except for Arecibo, Puerto Rico (CBSA 11640), all other Puerto Rico urban areas are contiguous to a rural area. Therefore, based on our existing policy, the FY 2024 rural Puerto Rico wage index is calculated based on the average of the FY 2024 wage indexes for the following urban areas: Aguadilla-Isabela, PR (CBSA 10380); Guayama, PR (CBSA 25020); Mayaguez, PR (CBSA 32420); Ponce, PR (CBSA 38660); San German, PR (CBSA 41900); and San Juan-Carolina-Caguas, PR (CBSA 41980).

We note, as discussed in section III.G.1 of the preamble of this final rule, we are finalizing as proposed to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations and are only excluding ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) in accordance with the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. Consistent with the previous policy, beginning with FY 2024 we will include the data of all § 412.103 hospitals (including those that have an MGCRB reclassification) in the calculation of the rural floor. As discussed in section III.G.1 of this final rule, we acknowledge that these policies have significant effects on wage index values. In addition, as a result of this change, the rural floor budget neutrality adjustment is significantly larger than in prior years.

To calculate the national rural floor budget neutrality adjustment factor, we used FY 2022 discharge data to simulate payments, and the post-reclassified national wage indexes and compared the following:

- National simulated payments without the rural floor.
- National simulated payments with the rural floor.

Based on this comparison, we determined a national rural floor budget neutrality adjustment factor. The national adjustment was applied to the national wage indexes to produce rural floor budget neutral wage indexes. Please see the table later in this section for a summary of the FY 2024 budget neutrality factors. We note, in the absence of the policies discussed in section III.G.1. of this final rule (to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and to only exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) in accordance with the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act), the rural floor budget neutrality factor would be 0.985838.

As further discussed in section III.G.2. of this final rule, we note that section 9831 of the American Rescue Plan Act of 2021 (Pub. L. 117–2), enacted on March 11, 2021 amended section 1886(d)(3)(E)(i) of the Act (42 U.S.C. 1395ww(d)(3)(E)(i)) and added section 1886(d)(3)(E)(iv) of the Act to establish a minimum area wage index (or imputed floor) for hospitals in all-urban States for discharges occurring on or after October 1, 2022. Unlike the imputed floor that was in effect from FY 2005 through FY 2018, section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index shall not be applied in a budget neutral manner. Specifically, section 9831(b) of Public Law 117–2 amends section 1886(d)(3)(E)(i) of the Act to exclude the imputed floor from the budget neutrality requirement under section 1886(d)(3)(E)(i) of the Act. In the past, we budget neutralized the estimated increase in payments each year resulting from the imputed floor that was in effect from FY 2005 through FY 2018. For FY 2022 and subsequent years, in applying the imputed floor required under section 1886(d)(3)(E)(iv) of the Act, we are applying the imputed floor after the application of the rural floor and would apply no reductions to the standardized amount or to the wage index to fund the increase in payments to hospitals in all-urban States resulting from the application of the imputed floor. We refer the reader to section III.G.2. of the preamble of this final rule for a complete discussion regarding the imputed floor.

f. Continuation of the Low Wage Index Hospital Policy—Budget Neutrality Adjustment

As discussed in section III.G.3. of the preamble of this final rule, we are continuing for FY 2024 the wage index policy finalized in the FY 2020 IPPS/LTCH PPS final rule to address wage index disparities by increasing the wage index values for hospitals with a wage index value below the 25th percentile wage index value across all hospitals (the low wage index hospital policy). As discussed in section III.G.3. of this final rule, consistent with our current methodology for implementing wage index budget neutrality under section 1886(d)(3)(E) of the Act, we are making a budget neutrality adjustment to the national standardized amount for all hospitals so that the increase in the wage index for hospitals with a wage index below the 25th percentile wage index, is implemented in a budget neutral manner.

To calculate this final budget neutrality adjustment factor for FY 2024, we used FY 2022 discharge data to simulate payments and compared the following:

- Aggregate payments using the FY 2024 labor-related share percentage, the FY 2024 relative weights, and the FY 2024 wage index for each hospital before adjusting the wage indexes under the low wage index hospital policy, and applied the proxy FY 2024 hospital readmissions payment adjustments and the proxy FY 2024 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2024 labor-related share percentage, the FY 2024 relative weights, and the FY 2024 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy, and applied the same proxy FY 2024 hospital readmissions payment adjustments and the proxy FY 2024

hospital VBP payment adjustments applied previously.

This final FY 2024 budget neutrality adjustment factor was applied to the standardized amount.

g. Permanent Cap Policy for Wage Index—Budget Neutrality Adjustment

As noted previously, in section III.N. of the preamble to this final rule, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49018 through 49021) we finalized a policy to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline. That is, a hospital's wage index would not be less than 95 percent of its final wage index for the prior FY. We also finalized the application of this permanent cap policy in a budget neutral manner through an adjustment to the standardized amount to ensure that estimated aggregate payments under our wage index cap policy for hospitals that will have a decrease in their wage indexes for the upcoming fiscal year of more than 5 percent will equal what estimated aggregate payments would have been without the permanent cap policy.

To calculate a wage index cap budget neutrality adjustment factor for FY 2024, we used FY 2022 discharge data to simulate payments and compared the following:

- Aggregate payments without the 5-percent cap using the FY 2024 labor-related share percentages, the FY 2024 relative weights, the FY 2024 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy, and applied the proxy FY 2024 hospital readmissions payment adjustments and the proxy FY 2024 hospital VBP payment adjustments.
- Aggregate payments with the 5-percent cap using the FY 2024 labor-related share percentages, the FY 2024 relative weights, the FY 2024 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy, and applied the same proxy FY 2024 hospital readmissions payment adjustments and the proxy FY 2024 hospital VBP payment adjustments applied previously.

We note, Table 2 associated with this final rule contains the wage index by provider before and after applying the low wage index hospital policy and the cap.

h. Rural Community Hospital Demonstration Program Adjustment

In section V.L. of the preamble of this final rule, we discuss the Rural Community Hospital (RCH) Demonstration program, which was originally authorized for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), and extended for another 5-year period by sections 3123 and 10313 of the Affordable Care Act (Pub. L. 111–148). Subsequently, section 15003 of the 21st Century Cures Act (Pub. L. 114–255), enacted December 13, 2016, amended section 410A of Public Law 108–173 to require a 10-year extension period (in place of the 5-year extension required by the Affordable Care Act, as further discussed later in this section). Finally, Division CC, section 128(a) of the Consolidated Appropriations Act of 2021 (Pub. L. 116–260) again amended section 410A to require a 15-year extension period in place of the 10-year period. We make an adjustment to the standardized amount to ensure the effects of the RCH Demonstration program are budget neutral as required under section 410A(c)(2) of Public Law 108–173. We refer readers to section V.M. of the preamble of this final rule for complete details regarding the Rural Community Hospital Demonstration.

With regard to budget neutrality, as mentioned earlier, we make an adjustment to the standardized amount to ensure the effects of the Rural Community Hospital Demonstration are budget neutral, as required under section 410A(c)(2) of Public Law 108–173. For FY 2024, based on the latest data for this final rule, the total amount that we are applying to make an adjustment to the standardized amounts to ensure the effects of the Rural Community Hospital Demonstration program are budget neutral is $53,441,735. Accordingly, using the most recent data available to account for the estimated costs of the demonstration program, for FY 2024, we computed a factor for the Rural Community Hospital Demonstration budget neutrality adjustment that would be applied to the standardized amount. Please see the table later in this section for a summary of the FY 2024 budget neutrality factors. We refer readers to section V.L. of the preamble of this final rule on complete details regarding the calculation of the amount we are applying to make an adjustment to the standardized amounts.

The following table is a summary of the FY 2024 budget neutrality factors, as discussed in the previous sections.

Summary of FY 2024 Budget Neutrality Factors	
MS-DRG Reclassification and Recalibration Budget Neutrality Factor	1.001463
Cap Policy MS-DRG Weights Budget Neutrality Factor	0.999928
Wage Index Budget Neutrality Factor	1.000702
Reclassification Budget Neutrality Factor	0.971295
*Rural Floor Budget Neutrality Factor	0.978183
Low Wage Index Hospital Policy Budget Neutrality Factor	0.997402
Cap Policy Wage Index Budget Neutrality Factor	0.999645
Rural Demonstration Budget Neutrality Factor	0.999463

*The rural floor budget neutrality factor is applied to the national wage indexes while the rest of the budget neutrality adjustments are applied to the standardized amounts.

i. Outlier Payments

Section 1886(d)(5)(A) of the Act provides for payments in addition to the basic prospective payments for ''outlier'' cases involving extraordinarily high costs. To qualify for outlier payments, a case must have costs greater than the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, any new technology add-on payments, and the ''outlier

threshold'' or ''fixed-loss'' amount (a dollar amount by which the costs of a case must exceed payments in order to qualify for an outlier payment). We refer to the sum of the prospective payment rate for the MS–DRG, any IME and DSH payments, uncompensated care payments, supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, any new technology add-on payments, and the outlier threshold as the outlier ''fixed-loss cost threshold.'' To determine whether the costs of a case exceed the fixed-loss cost threshold, a hospital's CCR is applied to the total covered charges for the case to convert the charges to estimated costs. Payments for eligible cases are then made based on a marginal cost factor, which is a percentage of the estimated costs above the fixed-loss cost threshold. The marginal cost factor for FY 2024 is 80 percent, or 90 percent for burn MS–DRGs 927, 928, 929, 933, 934 and 935. We have used a marginal cost factor of 90 percent since FY 1989 (54 FR 36479 through 36480) for designated burn DRGs as well as a marginal cost factor of 80 percent for all other DRGs since FY 1995 (59 FR 45367).

In accordance with section 1886(d)(5)(A)(iv) of the Act, outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments (which does not include IME and DSH payments) plus outlier payments. When setting the outlier threshold, we compute the percent target by dividing the total operating outlier payments by the total operating DRG payments plus outlier payments. As discussed in the next section, for FY 2024, we are incorporating an estimate of outlier reconciliation when setting the outlier threshold. We do not include any other payments such as IME and DSH within the outlier target amount. Therefore, it is not necessary to include Medicare Advantage IME payments in the outlier threshold calculation. Section 1886(d)(3)(B) of the Act requires the Secretary to reduce the average standardized amount by a factor to account for the estimated proportion of total DRG payments made to outlier cases. More information on outlier payments may be found on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/outlier.htm*.

(1) Methodology To Incorporate an Estimate of Outlier Reconciliation in the FY 2024 Outlier Fixed-Loss Cost Threshold

The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement will be based on operating and capital cost-to-charge ratios (CCRs) calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. We have instructed MACs to identify for CMS any instances where: (1) A hospital's actual CCR for the cost reporting period fluctuates plus or minus 10 percentage points compared to the interim CCR used to calculate outlier payments when a bill is processed; and (2) the total outlier payments for the hospital exceeded $500,000.00 for that cost reporting period. If we determine that a hospital's outlier payments should be reconciled, we reconcile both operating and capital outlier payments. We refer readers to section 20.1.2.5 of Chapter 3 of the Medicare Claims Processing Manual (available on the CMS website at: *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*) for complete details regarding outlier reconciliation. The regulation at § 412.84(m) further states that at the time of any outlier reconciliation under § 412.84(i)(4), outlier payments may be adjusted to account for the time value of any underpayments or overpayments. Section 20.1.2.6 of Chapter 3 of the Medicare Claims Processing Manual contains instructions on how to assess the time value of money for reconciled outlier amounts.

If the operating CCR of a hospital subject to outlier reconciliation is lower at cost report settlement compared to the operating CCR used for payment, the hospital would owe CMS money because it received an outlier overpayment at the time of claim payment. Conversely, if the operating CCR increases at cost report settlement compared to the operating CCR used for payment, CMS would owe the hospital money because the hospital outlier payments were underpaid.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42635), we finalized a methodology to incorporate outlier reconciliation in the FY 2020 outlier fixed loss cost threshold. As discussed in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19592), we stated that rather than trying to predict which claims and/or hospitals may be subject to outlier reconciliation, we believe a methodology that incorporates an estimate of outlier reconciliation dollars based on actual outlier reconciliation amounts reported in historical cost reports would be a more feasible approach and provide a better estimate and predictor of outlier reconciliation for the upcoming fiscal year. We also stated that we believe the methodology addresses stakeholder's concerns on the impact of outlier reconciliation on the modeling of the outlier threshold. For a detailed discussion of additional background regarding outlier reconciliation, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule.

(a) Incorporating a Projection of Outlier Payment Reconciliations for the FY 2024 Outlier Threshold Calculation

Based on the methodology finalized in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42625), for FY 2024, as we proposed, we are continuing to incorporate outlier reconciliation in the FY 2024 outlier fixed loss cost threshold.

As discussed in the FY 2020 IPPS/LTCH PPS final rule, for FY 2020, we used the historical outlier reconciliation amounts from the FY 2014 cost reports (cost reports with a begin date on or after October 1, 2013, and on or before September 30, 2014), which we believed would provide the most recent and complete available data to project the estimate of outlier reconciliation. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42623 through 42625) for a discussion on the use of the FY 2014 cost report data for purposes of projecting outlier payment reconciliations for the FY 2020 outlier threshold calculation. For FY 2023, we applied the same methodology finalized in FY 2020, using the historical outlier reconciliation amounts from the FY 2017 cost reports (cost reports with a begin date on or after October 1, 2016, and on or before September 30, 2017).

Similar to the FY 2023 methodology, in this final rule, we are determining a projection of outlier payment reconciliations for the FY 2024 outlier threshold calculation, by advancing the methodology by 1 year. Specifically, we are using FY 2018 cost reports (cost reports with a begin date on or after October 1, 2017, and on or before September 30, 2018).

For FY 2024, as we proposed, we are using the same methodology from FY 2020 to incorporate a projection of operating outlier payment reconciliations for the FY 2024 outlier threshold calculation.

The following steps are the same as those finalized in the FY 2020 final rule but with updated data for FY 2024:

Step 1.—Use the Federal FY 2018 cost reports for hospitals paid under the IPPS from the most recent publicly available quarterly HCRIS extract available at the time of development of the proposed and final rules, and

exclude sole community hospitals (SCHs) that were paid under their hospital-specific rate (that is, if Worksheet E, Part A, Line 48 is greater than Line 47). We note that when there are multiple columns available for the lines of the cost report described in the following steps and the provider was paid under the IPPS for that period(s) of the cost report, then we believe it is appropriate to use multiple columns to fully represent the relevant IPPS payment amounts, consistent with our methodology for the FY 2020 final rule.

Step 2.—Calculate the aggregate amount of historical total of operating outlier reconciliation dollars (Worksheet E, Part A, Line 2.01) using the Federal FY 2018 cost reports from Step 1.

Step 3.—Calculate the aggregate amount of total Federal operating payments using the Federal FY 2018 cost reports from Step 1. The total Federal operating payments consist of the Federal payments (Worksheet E, Part A, Line 1.01 and Line 1.02, plus Line 1.03 and Line 1.04), outlier payments (Worksheet E, Part A, Line 2 and Line 2.02), and the outlier reconciliation payments (Worksheet E, Part A, Line 2.01). We note that a negative amount on Worksheet E, Part A, Line 2.01 for outlier reconciliation indicates an amount that was owed by the hospital, and a positive amount indicates this amount was paid to the hospital.

Step 4.—Divide the amount from Step 2 by the amount from Step 3 and multiply the resulting amount by 100 to produce the percentage of total operating outlier reconciliation dollars to total Federal operating payments for FY 2018. This percentage amount would be used to adjust the outlier target for FY 2023 as described in Step 5.

Step 5.—Because the outlier reconciliation dollars are only available on the cost reports, and not in the Medicare claims data in the MedPAR file used to model the outlier threshold, we are targeting 5.1 percent minus the percentage determined in Step 4 in determining the outlier threshold. Using the FY 2018 cost reports, because the aggregate outlier reconciliation dollars from Step 2 are negative, we are targeting an amount higher than 5.1 percent for outlier payments for FY 2024 under our methodology.

For the FY 2024 proposed rule, we used the December 2022 HCRIS extract of the cost report data to calculate the proposed percentage adjustment for outlier reconciliation. For the FY 2024 final rule, we proposed to use the latest quarterly HCRIS extract that is publicly available at the time of the development of that rule which, for FY 2024, would be the March 2023 extract. While in the past we have considered the use of more recent data that may become available for purposes of projecting the estimate of operating outlier reconciliation used in the calculation of the final outlier threshold, we have also noted that we generally expect historical cost reports for the applicable fiscal year to be available by March (84 FR 53609). Since the FY 2020 final rule we have worked with our Medicare Administrator Contractors (MACs) so that historical cost reports for the applicable fiscal year can be made available with the March HCRIS update for the final rule, which, as noted, would be the March 2023 HCRIS extract for purposes of projecting the estimate of operating outlier reconciliation used in the calculation of the FY 2024 outlier threshold for the final rule. Information on availability of the HCRIS cost report data can be found at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports*.

In the FY 2024 proposed rule, based on the December 2022 HCRIS, 5 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 2.01 for total operating outlier reconciliation dollars of negative $6,925,967 (Step 2). The total Federal operating payments based on the December 2021 HCRIS was $ 88,729,603,026 (Step 3). The ratio (Step 4) is a negative 0.007806 percent, which, when rounded to the second digit, is -0.01 percent. Therefore, for FY 2024, we proposed to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.11 percent [5.1 percent − (− 0.01 percent)].

When the percentage of operating outlier reconciliation dollars to total Federal operating payments rounds to a negative value (that is, when the aggregate amount of outlier reconciliation as a percent of total operating payments rounds to a negative percent), the effect is a decrease to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars. In section II.A.4.i.(2). of this Addendum, we provide the FY 2024 outlier threshold as calculated for this final rule both with and without including the final percentage estimate of operating outlier reconciliation.

As explained in the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19593), we would continue to use a 5.1 percent target (or an outlier offset factor of 0.949) in calculating the outlier offset to the standardized amount. Therefore, the proposed operating outlier offset to the standardized amount was 0.949 (1 − 0.051).

We invited public comment on our methodology for projecting an estimate of outlier reconciliation and incorporating that estimate into the modeling for the fixed-loss cost outlier threshold for FY 2024.

We did not receive any comments on the proposed methodology, and for the reasons discussed in the proposed rule and in this final rule, we are finalizing the methodology described previously for incorporating the outlier reconciliation in the outlier threshold calculation. Therefore, for this final rule we used the same steps described previously and in the proposed rule to incorporate a projection of operating outlier payment reconciliations for the calculation of the FY 2024 outlier threshold calculation.

Based on March 2023 HCRIS data, a total of 15 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 2.01 for total operating outlier reconciliation dollars of negative $15,014,533 (Step 2). The total Federal operating payments based on the March 2023 HCRIS is $ 88,747,588,563 (Step 3). The ratio (Step 4) is a negative 0.016918 percent, which, when rounded to the second digit, is negative 0.02 percent. Therefore, for FY 2024, using the finalized methodology, we incorporated a projection of operating IPPS outlier reconciliation dollars by targeting an outlier threshold at 5.12 percent [5.1 percent − (− 0.02 percent)]. As noted previously, when the percentage of operating outlier reconciliation dollars to total Federal operating payments is negative (such is the case when the aggregate amount of outlier reconciliation is negative), the effect is a decrease to the outlier threshold compared to an outlier threshold that is calculated without including this estimate of operating outlier reconciliation dollars.

(b) Reduction to the FY 2024 Capital Standard Federal Rate by an Adjustment Factor To Account for the Projected Proportion of Capital IPPS Payments Paid as Outliers

We establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital related costs (58 FR 46348). Similar to the calculation of the adjustment to the standardized amount to account for the projected proportion of operating payments paid as outlier payments, as discussed in greater detail in section III.A.2. of this Addendum, we proposed to reduce the FY 2024 capital standard Federal rate by an adjustment

factor to account for the projected proportion of capital IPPS payments paid as outliers. The regulations in 42 CFR 412.84(i)(4) state that any outlier reconciliation at cost report settlement would be based on operating and capital CCRs calculated based on a ratio of costs to charges computed from the relevant cost report and charge data determined at the time the cost report coinciding with the discharge is settled. As such, any reconciliation also applies to capital outlier payments.

For FY 2024, we proposed to use the same methodology from FY 2020 to adjust the FY 2024 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers. Similar to FY 2020, as part of our proposal for FY 2024 to incorporate into the outlier model the total outlier reconciliation dollars from the most recent and most complete fiscal year cost report data, we also proposed to adjust our estimate of FY 2024 capital outlier payments to incorporate a projection of capital outlier reconciliation payments when determining the adjustment factor to be applied to the capital standard Federal rate to account for the projected proportion of capital IPPS payments paid as outliers (that is, the capital outlier payment adjustment factor). To do so, we proposed to use the following methodology, which generally parallels the proposed methodology to incorporate a projection of operating outlier reconciliation payments for the FY 2024 outlier threshold calculation.

Step 1.—Use the Federal FY 2018 cost reports for hospitals paid under the IPPS from the most recent publicly available quarterly HCRIS extract available at the time of development of the proposed and final rules, and exclude SCHs that were paid under their hospital-specific rate (that is, if Worksheet E, Part A, Line 48 is greater than Line 47). We note that when there are multiple columns available for the lines of the cost report described in the following steps and the provider was paid under the IPPS for that period(s) of the cost report, then we believe it is appropriate to use multiple columns to fully represent the relevant IPPS payment amounts, consistent with our methodology for the FY 2020 final rule.

Step 2.—Calculate the aggregate amount of the historical total of capital outlier reconciliation dollars (Worksheet E, Part A, Line 93, Column 1) using the Federal FY 2018 cost reports from Step 1.

Step 3.—Calculate the aggregate amount of total capital Federal payments using the Federal FY 2018 cost reports from Step 1. The total capital Federal payments consist of the capital DRG payments, including capital indirect medical education (IME) and capital disproportionate share hospital (DSH) payments (Worksheet E, Part A, Line 50, Column 1) and the capital outlier reconciliation payments (Worksheet E, Part A, Line 93, Column 1). We note that a negative amount on Worksheet E, Part A, Line 93 for capital outlier reconciliation indicates an amount that was owed by the hospital, and a positive amount indicates this amount was paid to the hospital.

Step 4.—Divide the amount from Step 2 by the amount from Step 3 and multiply the resulting amount by 100 to produce the percentage of total capital outlier reconciliation dollars to total capital Federal payments for FY 2018. This percentage amount would be used to adjust the estimate of capital outlier payments for FY 2024 as described in Step 5.

Step 5.—Because the outlier reconciliation dollars are only available on the cost reports, and not in the specific Medicare claims data in the MedPAR file used to estimate outlier payments, we proposed that the estimate of capital outlier payments for FY 2024 would be determined by adding the percentage in Step 4 to the estimated percentage of capital outlier payments otherwise determined using the shared outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. (We note that this percentage is added for capital outlier payments but subtracted in the analogous step for operating outlier payments. We have a unified outlier payment methodology that uses a shared threshold to identify outlier cases for both operating and capital payments. The difference stems from the fact that operating outlier payments are determined by first setting a ''target'' percentage of operating outlier payments relative to aggregate operating payments which produces the outlier threshold. Once the shared threshold is set, it is used to estimate the percentage of capital outlier payments to total capital payments based on that threshold. Because the threshold is already set based on the operating target, rather than adjusting the threshold (or operating target), we adjust the percentage of capital outlier to total capital payments to account for the estimated effect of capital outlier reconciliation payments. This percentage is adjusted by adding the capital outlier reconciliation percentage from Step 4 to the estimate of the percentage of capital outlier payments to total capital payments based on the shared threshold.) We note, when the aggregate capital outlier reconciliation dollars from Step 2 are negative, the estimate of capital outlier payments for FY 2024 under our methodology would be lower than the percentage of capital outlier payments otherwise determined using the shared outlier threshold.

For the FY 2024 proposed rule, we used the December 2022 HCRIS extract of the cost report data to calculate the proposed percentage adjustment for outlier reconciliation. For this FY 2024 final rule, we proposed to use the latest quarterly HCRIS extract that is publicly available at the time of the development of that rule which, for FY 2024, would be the March 2023 extract. While in the past we have considered the use of more recent data that may become available for purposes of projecting the estimate of capital outlier reconciliation used in the calculation of the adjustment to the capital standard Federal rate for the final rule, we have also noted that we generally expect historical cost reports for the applicable fiscal year to be available by March (84 FR 53609). As noted previously, since the FY 2020 final rule we have worked with our Medicare Administrator Contractors (MACs) so that historical cost reports for the applicable fiscal year can be made available with the March HCRIS update for the final rule, which, as noted, would be the March 2023 HCRIS extract for purposes of projecting the estimate of capital outlier reconciliation used in the calculation of the FY 2024 adjustment to the FY 2024 capital standard Federal rate for the final rule.

For the FY 2024 proposed rule, the estimated percentage of FY 2024 capital outlier payments otherwise determined using the shared outlier threshold was 4.16 percent (estimated capital outlier payments of $280,666,342 divided by (estimated capital outlier payments of $280,666,342 plus the estimated total capital Federal payment of $6,470,989,911)). The proposed ratio in step 4 above is a negative 0.00477 percent ((−$383,169/$8,027,006,104) × 100), which, when rounded to the second digit, is 0.00 percent. Therefore, for the FY 2024 proposed rule, we stated that taking into account projected capital outlier reconciliation payments under our proposed methodology, there would be no decrease to the estimated percentage of FY 2024 aggregate capital outlier payments.

As discussed in section III.A.2. of this Addendum, we proposed to incorporate the capital outlier reconciliation dollars from Step 5 when applying the outlier adjustment factor in determining the capital Federal rate based on the

estimated percentage of capital outlier payments to total capital Federal rate payments for FY 2024.

We invited public comment on our proposed methodology for projecting an estimate of capital outlier reconciliation and incorporating that estimate into the modeling of the estimate of FY 2024 capital outlier payments for purposes of determining the capital outlier adjustment factor.

We did not receive comments about the proposed capital outlier reconciliation methodology. For the reasons discussed earlier, we are finalizing the methodology for projecting an estimate of capital outlier reconciliation as previously described. Therefore, for this final rule, we used the same steps as described in the proposed rule and this final rule to reduce the FY 2024 capital standard Federal rate by an adjustment factor to account for the projected proportion of capital IPPS payments paid as outliers.

For projecting the estimate of capital outlier reconciliation, similar to our projection of the estimate of operating outlier reconciliation, we are using cost report data from the March 2023 HCRIS. We note that a difference in the number of cost reports for the operating and capital outlier reconciliation projections is possible and may be due to new hospitals defined in the regulations at 42 CFR 412.300(b) that may receive capital cost-based payments (in lieu of Federal rate payments), and therefore would not receive capital outlier payments. As a result, capital outlier reconciliation is not applicable to such hospitals since there is no capital outlier payment.

Based on the March 2023 HCRIS data, 10 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 93 for total capital outlier reconciliation dollars of negative $1,494,671 (Step 2). The total Federal capital payments based on the March 2023 HCRIS is approximately $8,032,054,774 (Step 3). The ratio (Step 4) is a negative 0.018609 percent, which, when rounded to the second digit, is negative 0.02 percent (Step 4). Therefore, for FY 2024, taking into account projected capital outlier reconciliation payments under our methodology will decrease the estimated percentage of FY 2024 aggregate capital outlier payments by 0.02 percent.

(2) FY 2024 Outlier Fixed-Loss Cost Threshold

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50977 through 50983), in response to public comments on the FY 2013 IPPS/LTCH PPS proposed rule, we made changes to our methodology for projecting the outlier fixed-loss cost threshold for FY 2014. We refer readers to the FY 2014 IPPS/LTCH PPS final rule for a detailed discussion of the changes.

As we have done in the past, to calculate the FY 2024 outlier threshold, we simulated payments by applying FY 2024 payment rates and policies using cases from the FY 2022 MedPAR file. As noted in section II.C. of this Addendum, we specify the formula used for actual claim payment which is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the Provider-Specific File (PSF) while CMS uses an adjusted CCR (as described later in this section) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

To determine the FY 2024 outlier threshold, we inflated the charges on the MedPAR claims by 2 years, from FY 2022 to FY 2024. Consistent with the FY 2020 IPPS/LTCH PPS final rule (84 FR 42626 and 42627), we proposed to use the following methodology to calculate the charge inflation factor for FY 2024:

- Include hospitals whose last four digits fall between 0001 and 0899 (section 2779A1 of Chapter 2 of the State Operations Manual on the CMS website at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c02.pdf*); include CAHs that were IPPS hospitals for the time period of the MedPAR data being used to calculate the charge inflation factor; include hospitals in Maryland; and remove PPS-excluded cancer hospitals that have a ''V'' in the fifth position of their provider number or a ''E'' or ''F'' in the sixth position.
- Include providers that are in both periods of charge data that are used to calculate the 1-year average annual rate of-change in charges per case. We note this is consistent with the methodology used since FY 2014.
- We excluded Medicare Advantage IME claims for the reasons described in section I.A.4. of this Addendum. We refer readers to the FY 2011 IPPS/LTCH PPS final rule for a complete discussion on our methodology of identifying and adding the total Medicare Advantage IME payment amount to the budget neutrality adjustments.
- In order to ensure that we capture only FFS claims, we included claims with a ''Claim Type'' of 60 (which is a field on the MedPAR file that indicates a claim is an FFS claim).
- In order to further ensure that we capture only FFS claims, we excluded claims with a ''GHOPAID'' indicator of 1 (which is a field on the MedPAR file that indicates a claim is not an FFS claim and is paid by a Group Health Organization).
- We examined the MedPAR file and removed pharmacy charges for anti-hemophilic blood factor (which are paid separately under the IPPS) with an indicator of ''3'' for blood clotting with a revenue code of ''0636'' from the covered charge field. We also removed organ acquisition charges from the covered charge field because organ acquisition is a pass-through payment not paid under the IPPS. As noted previously, we are removing allogeneic hematopoietic stem cell acquisition charges from the covered charge field for budget neutrality adjustments. As discussed in the FY 2021 IPPS/LTCH PPS final rule, payment for allogeneic hematopoietic stem cell acquisition costs is made on a reasonable cost basis for cost reporting periods beginning on or after October 1, 2020 (85 FR 58835 through 58842).
- Because this payment simulation uses the FY 2024 relative weights, consistent with our policy discussed in section IV.I. of the preamble to this final rule, we applied the adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments.

In the FY 2023 IPPS/LTCH PPS final rule, due to the impact of the COVID–19 PHE on our ordinary ratesetting data, we finalized modifications to our usual ratesetting methodologies for FY 2023, including the methodology for calculating the FY 2023 outlier threshold. We refer the reader to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49422 through 49428) for a discussion of the FY 2023 outlier threshold and the modifications made to our usual methodologies for calculating the outlier threshold. As discussed in section I.E. of the preamble to the proposed rule, based on the information available at the time, we stated that we do not believe there is a reasonable basis for us to assume that there will be a meaningful difference in the number of COVID–19 cases treated at IPPS hospitals and LTCHs in FY 2024 relative to FY 2022, such that modifications to our usual ratesetting methodologies (including the methodology for calculating the outlier threshold) would be warranted. Therefore, we proposed to calculate the FY 2024 outlier threshold consistent with our historic

methodologies, as described further in this section, without modifications.

Our general methodology to inflate the charges computes the 1-year average annual rate-of-change in charges per case which is then applied twice to inflate the charges on the MedPAR claims by 2 years since we typically use claims data for the fiscal year that is 2 years prior to the upcoming fiscal year.

In the FY 2020 IPPS/LTCH PPS final rule (84 FR 42627), we modified our charge inflation methodology. We stated that we believe balancing our preference to use the latest available data from the MedPAR files and stakeholders' concerns about being able to use publicly available MedPAR files to review the charge inflation factor can be achieved by modifying our methodology to use the publicly available Federal fiscal year period (that is, for FY 2020, we used the charge data from Federal fiscal years 2017 and 2018), rather than the most recent data available to CMS which, under our prior methodology, was based on calendar year data. We refer the reader to the FY 2020 IPPS/LTCH PPS final rule for a complete discussion regarding this change.

For the same reasons discussed in that rulemaking, for FY 2024, we proposed to use the same methodology as FY 2020 to determine the charge inflation factor. That is, for FY 2023, we proposed to use the MedPAR files for the two most recent available Federal fiscal year time periods to calculate the charge inflation factor, as we did for FY 2020. Specifically, for the proposed rule we used the December 2021 MedPAR file of FY 2021 (October 1, 2020 to September 30, 2021) charge data (released for the FY 2023 IPPS/LTCH PPS proposed rule) and the December 2022 MedPAR file of FY 2022 (October 1, 2021 to September 30, 2022) charge data (released for the FY 2024 IPPS/LTCH PPS proposed rule) to compute the proposed charge inflation factor. We proposed that for the FY 2024 final rule, we would use more recently updated data, that is the MedPAR files from March 2022 for the FY 2021 time period and March 2023 for the FY 2022 time period.

For FY 2024, under this methodology, to compute the 1-year average annual rate-of-change in charges per case, we compared the average covered charge per case of $70,089.49 ($579,065,304,520/7,415,406) from October 1, 2020 through September 30, 2021, to the average covered charge per case of $ 82,583.83 ($574,783,177,187/6,959,997) from October 1, 2021 through September 30, 2022. This rate-of-change was 5.755 percent (1.05755) or 11.8412 percent (1.118412) over 2 years. The billed charges are obtained from the claims from the MedPAR file and inflated by the inflation factor specified previously.

As we have done in the past, in the FY 2024 IPPS/LTCH PPS proposed rule, we proposed to establish the FY 2024 outlier threshold using hospital CCRs from the December 2022 update to the Provider-Specific File (PSF), the most recent available data at the time of the development of the proposed rule. We proposed to apply the following edits to providers' CCRs in the PSF. We believe these edits are appropriate to accurately model the outlier threshold. We first search for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replace these CCRs with the statewide average CCR for the upcoming fiscal year. We also assign the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF or whose CCRs exceed the ceilings described later in this section (3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals). We do not apply the adjustment factors described later in this section to hospitals assigned the statewide average CCR. For FY 2024, we also proposed to continue to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained later in this section). We also proposed that, if more recent data become available, we would use that data to calculate the final FY 2024 outlier threshold.

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we adopted a new methodology to adjust the CCRs. Specifically, we finalized a policy to compare the national average case-weighted operating and capital CCR from the most recent update of the PSF to the national average case-weighted operating and capital CCR from the same period of the prior year.

Therefore, as we have done in the past, we proposed to adjust the CCRs from the December 2022 update of the PSF by comparing the percentage change in the national average case weighted operating CCR and capital CCR from the December 2021 update of the PSF to the national average case weighted operating CCR and capital CCR from the December 2022 update of the PSF. We note that, in the proposed rule, we used total transfer-adjusted cases from FY 2022 to determine the national average case weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison because this will produce the true percentage change in the average case-weighted operating and capital CCR from one year to the next without any effect from a change in case count on different sides of the comparison.

Using the proposed methodology, for the proposed rule, we calculated a December 2021 operating national average case-weighted CCR of 0.253006 and a December 2022 operating national average case-weighted CCR of 0.247389. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the December 2021 operating national average case-weighted CCR from the December 2022 operating national average case-weighted CCR and then dividing the result by the December 2021 national operating average case-weighted CCR. This resulted in a proposed one-year national operating CCR adjustment factor of 0.977799.

We used this same proposed methodology to adjust the capital CCRs. Specifically, we calculated a December 2021 capital national average case-weighted CCR of 0.0202 and a December 2022 capital national average case-weighted CCR of 0.018054. We then calculated the percentage change between the two national capital case-weighted CCRs by subtracting the December 2021 capital national average case-weighted CCR from the December 2022 capital national average case-weighted CCR and then dividing the result by the December 2021 capital national average case-weighted CCR. This resulted in a proposed one-year national capital CCR adjustment factor of 0.893762.

For purposes of estimating the proposed outlier threshold for FY 2024, we used a wage index that reflects the policies discussed in the proposed rule. This includes the following:

—Application of the proposed rural and imputed floor adjustment.

—The proposed frontier State floor adjustments in accordance with section 10324(a) of the Affordable Care Act.

—The proposed out-migration adjustment as added by section 505 of Public Law 108–173.

—Incorporating the proposed FY 2024 low wage index hospital policy (described in section III.G.4 of the preamble of this final rule) for hospitals with a wage index value below the 25th percentile, where the increase in the wage index value for these hospitals would be equal to half the difference between the otherwise applicable final wage index value for

a year for that hospital and the 25th percentile wage index value for that year across all hospitals.

—Incorporating our policy (described in section III.N. of the preamble of this final rule) to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline.

As stated earlier, if we did not take the aforementioned into account, our estimate of total FY 2024 payments would be too low, and, as a result, our outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.1 percent of total payments (which includes outlier reconciliation).

As described in sections V.K. and V.L., respectively, of the preamble of this final rule, sections 1886(q) and 1886(o) of the Act establish the Hospital Readmissions Reduction Program and the Hospital VBP Program, respectively. We do not believe that it is appropriate to include the proposed hospital VBP payment adjustments and the hospital readmissions payment adjustments in the proposed outlier threshold calculation or the outlier offset to the standardized amount. Specifically, consistent with our definition of the base operating DRG payment amount for the Hospital Readmissions Reduction Program under § 412.152 and the Hospital VBP Program under § 412.160, outlier payments under section 1886(d)(5)(A) of the Act are not affected by these payment adjustments. Therefore, outlier payments would continue to be calculated based on the unadjusted base DRG payment amount (as opposed to using the base-operating DRG payment amount adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment). Consequently, we proposed to exclude the estimated hospital VBP payment adjustments and the estimated hospital readmissions payment adjustments from the calculation of the proposed outlier fixed-loss cost threshold.

We note that, to the extent section 1886(r) of the Act modifies the DSH payment methodology under section 1886(d)(5)(F) of the Act, the uncompensated care payment under section 1886(r)(2) of the Act, like the empirically justified Medicare DSH payment under section 1886(r)(1) of the Act, may be considered an amount payable under section 1886(d)(5)(F) of the Act such that it would be reasonable to include the payment in the outlier determination under section 1886(d)(5)(A) of the Act. As we have done since the implementation of uncompensated care payments in FY 2014, for FY 2024, we proposed to allocate an estimated per-discharge uncompensated care payment amount to all cases for the hospitals eligible to receive the uncompensated care payment amount in the calculation of the outlier fixed-loss cost threshold methodology. We continue to believe that allocating an eligible hospital's estimated uncompensated care payment to all cases equally in the calculation of the outlier fixed-loss cost threshold would best approximate the amount we would pay in uncompensated care payments during the year because, when we make claim payments to a hospital eligible for such payments, we would be making estimated per-discharge uncompensated care payments to all cases equally. Furthermore, we continue to believe that using the estimated per-claim uncompensated care payment amount to determine outlier estimates provides predictability as to the amount of uncompensated care payments included in the calculation of outlier payments. Therefore, consistent with the methodology used since FY 2014 to calculate the outlier fixed-loss cost threshold, for FY 2024, we proposed to include estimated FY 2024 uncompensated care payments in the computation of the proposed outlier fixed-loss cost threshold. Specifically, we proposed to use the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

In addition, consistent with the methodology finalized in the FY 2023 final rule, we proposed to include the estimated supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals in the computation of the FY 2024 proposed outlier fixed-loss cost threshold. Specifically, we proposed to use the estimated per-discharge supplemental payments to hospitals eligible for the supplemental payment for all cases in the calculation of the proposed outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1. of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. In addition, as described in the earlier section to this Addendum, we proposed to incorporate an estimate of FY 2024 outlier reconciliation in the methodology for determining the outlier threshold. As noted previously, for the FY 2024 proposed rule, the ratio of outlier reconciliation dollars to total Federal Payments (Step 4) is a negative 0.007806 percent, which, when rounded to the second digit, is − 0.01 percent. Therefore, for FY 2024, we proposed to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.11 percent [5.1 percent − (− .01 percent)]. Under this proposed approach, we determined a proposed threshold of $40,732 and calculated total outlier payments of $4,259,029,890 and total operating Federal payments of $79,087,551,441. We then divided total outlier payments by total operating Federal payments plus total outlier payments and determined that this threshold matched with the 5.11 percent target, which reflected our proposal to incorporate an estimate of outlier reconciliation in the determination of the outlier threshold (as discussed in more detail in the previous section of this Addendum). We noted that, if calculated without applying our methodology for incorporating an estimate of outlier reconciliation in the determination of the outlier threshold, the proposed threshold would be $40,808. We proposed an outlier fixed-loss cost threshold for FY 2024 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, estimated supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, and any add-on payments for new technology, plus $40,732.

Comment: A commenter expressed appreciation for the stabilization of the outlier threshold. Another commenter stated that the fixed loss threshold remains significantly higher than the threshold prior to the COVID–19 PHE. The commenter stated that this represents a more than 55 percent increase over the pre-PHE fixed loss threshold. The commenter stated that this suggests the data to establish the threshold is abnormal and that CMS needs to adjust its process further so that the threshold will be established at a level likely to result in total outlier payments of 5.1 percent. This commenter requested that CMS model a significant reduction in COVID–19 cases compared to the volume of cases in the FY 2022 claims data to better model estimated post-PHE outlier cases. The commenter noted that this has the impact of reducing the threshold by $700. Another commenter requested that CMS maintain the outlier threshold from FY 2023 given the large increase

that took effect in FY 2023. Another commenter suggested that the increase to the fixed loss threshold should be limited to the 3 percent market basket update.

A commenter recommended suppressing COVID–19 cases from the FY 2022 MedPAR data for the first half of FY 2022 and duplicating the COVID–19 cases from the second half of the year, essentially applying an extrapolation methodology based on data from the second half of FY 2022 for COVID–19 cases. The commenter believes this approach is a rational and targeted strategy for adjusting the FY 2022 MedPAR data for use in estimating post-PHE outlier cases.

Another commenter urged CMS to undertake a thorough examination of the outlier methodology and consider further changes to address the persistent upward trend of the fixed loss threshold. Another commenter requested that CMS share more information regarding the factors driving the increase to the fixed-loss threshold to facilitate more informed comments.

A commenter stated that CMS did not explain why it is appropriate to use data from the PHE to calculate the CCR adjustment factor, and that the CCRs are expected to decrease even more than the adjustment factors included in the proposed rule.

Response: We thank the commenters for their feedback. To determine the applicable fixed-loss amount, we estimate outlier payments and total payments using claims data from the MedPAR files. As discussed in section I.E. of the preamble to this final rule, in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26670 through 26671), we proposed to use the FY 2022 MedPAR claims file and the FY 2021 HCRIS (which contains data from many cost reports ending in FY 2022 based on each hospital's cost reporting period) for purposes of the FY 2024 IPPS ratesetting without any modifications to our usual ratesetting methodologies to account for the impact of COVID–19 on the ratesetting data. One key component of our ratesetting methodologies is the determination of the outlier fixed-loss amount. In the proposed rule, we stated our belief that FY 2022 data, as the most recent available data, is the best available data for approximating the inpatient experience at both IPPS hospitals and LTCHs in FY 2024. We also stated that based on the information available at the time of the proposed rule, we believe there will continue to be COVID–19 cases treated at IPPS hospitals and LTCHs in FY 2024, such that it was appropriate to use the FY 2022 data, as the most recent available data, for purposes of the FY 2024 IPPS and LTCH PPS ratesetting. However, based on the information available at that time, we did not believe there is a reasonable basis for us to assume that there will be a meaningful difference in the number of COVID–19 cases treated at IPPS hospitals in FY 2024 relative to FY 2022, such that modifications to our usual ratesetting methodologies would be warranted. We acknowledge that COVID–19 hospitalizations have recently trended below FY 2022 levels. We believe there remains uncertainty regarding the impact that COVID–19 will have on IPPS in FY 2024 relative to FY 2022. For this final rule, for the reasons stated previously we continue to believe that the most recent available data is the best available data for approximating the inpatient experience for IPPS hospitals for FY 2024, including for purposes of determining the adjustment factors used in the outlier fixed-loss cost threshold methodology, without modifications to that methodology for COVID–19.

We also note that the final FY 2024 outlier fixed-loss cost threshold of $42,750 increased by 10 percent from the final FY 2023 outlier fixed-loss cost threshold of $38,859. This increase is in line with increases from one year to the next for fiscal years prior to the PHE. For example, the FY 2017 outlier fixed-loss cost threshold was $23,573 and increased 12.5 percent in FY 2018 to $26,537. Other prior FYs such as FY 2015 have also seen increases greater than 10 percent. Therefore, with the increase in the threshold from FY 2023 to FY 2024 in line with prior fiscal years, we do not see the need to make an adjustment to the outlier fixed-loss cost threshold due to COVID–19 for FY 2024.

With respect to the commenter who stated that the increase over the pre-PHE fixed loss threshold suggests the data to establish the threshold is abnormal, while also noting that modeling a significant reduction to the COVID–19 cases would lower the threshold by $700, as stated earlier, we acknowledge that COVID–19 hospitalizations have recently trended below FY 2022 levels. We believe there remains uncertainty regarding the impact that COVID–19 will have on IPPS in FY 2024 relative to FY 2022. For this final rule, for the reasons stated previously we continue to believe that the most recent available data is the best available data for approximating the inpatient experience for IPPS hospitals for FY 2024, including for purposes of determining the adjustment factors used in the outlier fixed-loss cost threshold methodology, without modifications to that methodology for COVID–19. Also, with respect to commenters who suggested alternative fixed loss thresholds, we note that using these alternative thresholds would mean that the fixed loss threshold for FY 2024 would not meet the requirement that outlier payments result in 5.1 percent of total payments.

Regarding the comment that the CCRs are expected to decrease even more than the adjustment factors included in the proposed rule, the commenter did not provide any evidence or data as to why it believes the CCR adjustment factors are expected to decrease even more than the adjustment factors included in the proposed rule.

With regard to the commenters that urged CMS to undertake a thorough examination of the outlier methodology, consider further changes to address the persistent upward trend of the fixed loss threshold and share more information regarding the factors driving the increase, each year we present our methodology to meet the statutory target. We believe we have thoroughly explained our proposed methodology so that commenters can review and provide meaningful comments. There are many factors that can drive the threshold to increase or decrease from one fiscal year to the next making it challenging to pinpoint which exact issue is causing the threshold to increase from one FY to the next.

We appreciate the comments and concerns from the commenters. However, after consideration of the comments received and for the reasons discussed, for FY 2024, we are finalizing to use the most recent available data without any adjustments to the outlier fixed-loss cost threshold methodology for COVID–19.

Comment: A commenter requested that CMS apply trims when calculating charge inflation as it does under the LTCH PPS to ''remove all claims from providers whose growth in average charges was a statistical outlier''.

Response: With regard to the charge inflation methodology for the LTCH PPS, in section V.D.3 of this addendum, we stated that we remove all claims from providers whose growth in average charges was a statistical outlier. We further stated that we remove these statistical outliers prior to calculating the charge inflation factor because we believe they may represent aberrations in the data that would distort the measure of average charge growth. We note, in the FY 2024 LTCH PPS final rule impact file, there are 333 providers with approximately 61,000 claims. In the FY 2024 IPPS final rule impact file,

there are 3,199 providers with approximately 6.8 million claims. There are many more providers and claims under the IPPS compared to the LTCH PPS. When we analyzed the LTCH PPS claims data, a single LTCH provider had substantial increases in its charges with average charges per case of approximately $10 million which significantly influenced the charge inflation factor. Since there are fewer hospitals and claims under the LTCH PPS, the potential for a single provider to influence the charge inflation factor is much more significant. We are not aware of a similar situation with a hospital having such high average charges under the IPPS. Therefore, we believe it is not necessary to apply the same trim to hospitals included in the IPPS charge inflation factor.

Comment: A commenter stated that the growth in the fixed loss threshold is occurring because of inadequate IPPS payment rates. The commenter urged CMS to adopt a forecast error adjustment and apply a payment adjustment under section 7(b)(1)(B) of the TMA with a positive 0.9412 percent adjustment, both of which would lower the fixed loss threshold.

Response: We refer readers to section V.A of the preamble of this final rule for our response to comments about the market basket update.

Comment: A commenter requested that CMS consider whether it is appropriate to include extreme cases when calculating the threshold. This commenter explained that high charge cases have a significant impact on the threshold. The commenter stated that it examined the data to understand the factors that drove an increase of over $15,000 between FY 2017 and FY 2023, and to propose to increase the threshold almost an additional $1,900 for FY 2024, and stated that it observed that the inclusion of extreme cases in the calculation of the threshold, the rate of which are increasing over time, significantly impacts CMS' determination of the fixed-loss threshold. If this trend continues (that is, if the number (and proportion) of extreme cases continues to increase each year), the commenter stated that the impact of this population of cases on the threshold will likewise increase. Thus, the commenter recommended that CMS carefully consider what is causing this trend, whether the inclusion of these cases in the calculation of the threshold is appropriate, or whether a separate outlier mechanism should apply to these cases that more closely hews outlier payments to marginal costs.

Response: As we explained when responding to a similar comment in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38526) and other prior rulemaking, the methodology used to calculate the outlier threshold includes all claims to account for all different types of cases, including high charge cases, to ensure that CMS meets the 5.1 percent target. As the commenter pointed out, the volume of these cases continues to rise, making their impact on the threshold significant. We believe excluding these cases would artificially lower the threshold. We believe it is important to include all cases in the calculation of the threshold no matter how high or low the charges. Including these cases with high charges lends more accuracy to the threshold, as these cases have an impact on the threshold and continue to rise in volume. Therefore, we believe the inclusion of the high-cost outlier cases in the calculation of the outlier threshold is appropriate. Also, in response to commenter recommending that CMS consider whether a separate outlier mechanism should apply to these cases that more closely hews outlier payments to marginal costs, we believe the current calculation of outlier payment meets these goals. If a case has high charges that once reduced to cost significantly exceed the payment plus the threshold, then the case will receive a larger outlier payment reflective of the higher costs. Therefore, we believe the current payment system provides such a mechanism.

Comment: A commenter stated that it believes that CMS should disclose all aspects of its edits to the most current data used for the proposed rule and commit to the same process and methods when it recalculates the threshold for purposes of the final rule. Additionally, the commenter stated CMS should commit to make public the data files it uses for the final rule, including all edits and calculations, when it publishes the final rule.

Response: We refer the reader to the FY 2022 IPPS/LTCH final rule (86 FR 45541) where we responded to a similar comment.

Comment: A commenter supported the inclusion of the impact of outlier reconciliation in setting the FY 2024 fixed-loss threshold and requested that CMS release information on the outlier reconciliation process and data showing the amounts recovered so that it can evaluate the impact of the reconciliation process on the outlier threshold.

Response: We appreciate the commenter's support. We note that the quarterly HCRIS data contains the information the commenter is requesting and is published as a public use file, available at *https://www.cms.gov/research-statistics-data-and-systems/downloadable-public-use-files/cost-reports/cost-reports-by-fiscal-year*. For the annual proposed rule we use the December HCRIS and for the annual final rule we use the March HCRIS. Quarterly updates of HCRIS are generally available by the end of the month following the quarterly cutoff date. For example, the December 2022 HCRIS update used in the FY 2024 proposed rule would generally become available towards the end of January 2023. This final rule discusses the impact of incorporating the reconciliation amounts from March 2023 HCRIS reports.

Comment: A commenter noted the final fixed-loss threshold established by CMS has consistently been lower than the threshold set forth in the proposed rule, and the variance between the proposed and final thresholds has generally exceeded 4 percent. The commenter emphasized that this demonstrates that CMS must ordinarily use the most recent data to appropriately calculate the outlier threshold.

Response: We responded to similar comments in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50378 through 50379) and refer readers to that rule for our response. We reiterate that CMS' historical policy is to use the best available data when setting the payment rates and factors in both the proposed and final rules. Sometimes there are variables that change between the proposed and final rule as result of the availability of more recent data, such as the charge inflation factor and the CCR adjustment factors that can cause fluctuations in the threshold amount. Other factors such as changes to the wage indexes and market basket increase can also cause the outlier fixed loss cost threshold to fluctuate between the proposed rule and the final rule each year. We use the latest data that is available at the time of the development of the proposed and final rules, such as the most recent update of MedPAR claims data and CCRs from the most recent update of the PSF.

After consideration of the public comments we received and for the reasons discussed, we are finalizing to use the same methodology we proposed, without modifications, to calculate the final outlier threshold for FY 2024.

For the FY 2024 final outlier threshold, we used the used the March 2022 MedPAR file of FY 2021 (October 1, 2020, through September 30, 2021) charge data (released in conjunction with the FY 2023 IPPS/LTCH PPS final rule) and the March 2023 MedPAR file

of FY 2022 (October 1, 2021 through September 30, 2022) charge data (released in conjunction with this FY 2024 IPPS/LTCH PPS final rule) to determine the charge inflation factor. To compute the 1-year average annual rate-of-change in charges per case, we compared the average covered charge per case of $78,169.74 ($581,708,955,080/7,441,613 cases) from October 1, 2020, through September 31, 2021, to the average covered charge per case of $82,691.67 ($578,217,120,322/6,992,447 cases) from October 1, 2021, through September 31, 2022. This rate-of-change was 5.8 percent (1.05785) or 11.9 percent (1.11904) over 2 years. The billed charges are obtained from the claims from the MedPAR file and inflated by the inflation factor specified previously.

As we have done in the past, we are establishing the FY 2024 outlier threshold using hospital CCRs from the March 2023 update to the Provider-Specific File (PSF)—the most recent available data at the time of the development of the final rule. We applied the following edits to providers' CCRs in the PSF. We believe these edits are appropriate to accurately model the outlier threshold. We first search for Indian Health Service providers and those providers assigned the statewide average CCR from the current fiscal year. We then replaced these CCRs with the statewide average CCR for the upcoming fiscal year. We also assigned the statewide average CCR (for the upcoming fiscal year) to those providers that have no value in the CCR field in the PSF or whose CCRs exceed the ceilings described later in this section (3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals). We did not apply the adjustment factors described later in this section to hospitals assigned the statewide average CCR. For FY 2024, we also are continuing to apply an adjustment factor to the CCRs to account for cost and charge inflation (as explained later in this section).

For this final rule, as we have done since FY 2014 (with the exception of FYs 2022 and 2023, as discussed in the FY 2022 and FY 2023 IPPS/LTCH PPS proposed and final rules), we are adjusting the CCRs from the March 2023 update of the PSF by comparing the percentage change in the national average case-weighted operating CCR and capital CCR from the March 2022 update of the PSF to the national average case-weighted operating CCR and capital CCR from the March 2023 update of the PSF. We note that we used total transfer-adjusted cases from FY 2022 to determine the national average case weighted CCRs for both sides of the comparison. As stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50979), we believe that it is appropriate to use the same case count on both sides of the comparison because this will produce the true percentage change in the average case-weighted operating and capital CCR from one year to the next without any effect from a change in case count on different sides of the comparison.

Using the methodology noted earlier, for this final rule, we calculated a March 2022 operating national average case-weighted CCR of 0.251181 and a March 2023 operating national average case-weighted CCR of 0.248881. We then calculated the percentage change between the two national operating case-weighted CCRs by subtracting the March 2022 operating national average case weighted CCR from the March 2023 operating national average case-weighted CCR and then dividing the result by the March 2022 national operating average case-weighted CCR. This resulted in a national operating CCR adjustment factor of 0.990843.

We used the same methodology earlier to adjust the capital CCRs. Specifically, for this final rule, we calculated a March 2022 capital national average case-weighted CCR of 0.019678 and a March 2023 capital national average case-weighted CCR of 0.01779. We then calculated the percentage change between the two national capital case weighted CCRs by subtracting the March 2022 capital national average case-weighted CCR from the March 2023 capital national average case-weighted CCR and then dividing the result by the March 2022 capital national average case-weighted CCR. This resulted in a national capital CCR adjustment factor of 0.904055.

As discussed previously, for purposes of estimating the final outlier threshold for FY 2024, we used a wage index that reflects the policies discussed in this final rule. This includes the following:

—Application of the rural imputed floor adjustment.

—The frontier State floor adjustments in accordance with section 10324(a) of the Affordable Care Act.

—The out-migration adjustment as added by section 505 of Public Law 108–173.

—Incorporating the FY 2024 low wage index hospital policy (described in section III.G.4 of the preamble of this final rule) for hospitals with a wage index value below the 25th percentile, where the increase in the wage index value for these hospitals would be equal to half the difference between the otherwise applicable final wage index value for a year for that hospital and the 25th percentile wage index value for that year across all hospitals.

—Incorporating our policy (described in section III.N. of the preamble of this final rule) to apply a 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY, regardless of the circumstances causing the decline.

As stated previously, if we did not take the previous into account, our estimate of total FY 2024 payments would be too low, and, as a result, our outlier threshold would be too high, such that estimated outlier payments would be less than our projected 5.12 percent of total payments (which reflects the estimate of outlier reconciliation calculated for this final rule).

- We excluded the hospital VBP payment adjustments and the hospital readmissions payment adjustments from the calculation of the outlier fixed-loss cost threshold.
- We used the estimated per-discharge uncompensated care payments to hospitals eligible for the uncompensated care payment for all cases in the calculation of the outlier fixed-loss cost threshold methodology.
- Based on the policy finalized, as previously described, we used the estimated per-discharge supplemental payments to hospitals eligible for the supplemental payment for all cases in the calculation of the outlier fixed-loss cost threshold methodology.

Using this methodology, we used the formula described in section I.C.1. of this Addendum to simulate and calculate the Federal payment rate and outlier payments for all claims. In addition, as described in the earlier section to this Addendum, we are finalizing to incorporate an estimate of FY 2024 outlier reconciliation in the methodology for determining the outlier threshold. As noted previously, for this final rule, the ratio of outlier reconciliation dollars to total Federal Payments (Step 4) is a negative 0.016918 percent, which, when rounded to the second digit, is −0.02 percent. Therefore, for FY 2024, we incorporated a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.12 percent [5.1 percent − (−.02 percent)]. Under this approach, we determined a threshold of $42,750 and calculated total outlier payments of $4,289,273,383 and total operating Federal payments of $79,484,223,474. We then divided total outlier payments by total operating Federal payments plus total outlier payments and

determined that this threshold matched with the 5.12 percent target, which incorporated an estimate of outlier reconciliation in the determination of the outlier threshold (as discussed in more detail in the previous section of this Addendum). We note that, if calculated without applying our methodology for incorporating an estimate of outlier reconciliation in the determination of the outlier threshold, the threshold would be $42,909. We are finalizing an outlier fixed-loss cost threshold for FY 2024 equal to the prospective payment rate for the MS–DRG, plus any IME, empirically justified Medicare DSH payments, estimated uncompensated care payment, estimated supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, and any add-on payments for new technology, plus $42,750.

(3) Other Changes Concerning Outliers

As stated in the FY 1994 IPPS final rule (58 FR 46348), we establish an outlier threshold that is applicable to both hospital inpatient operating costs and hospital inpatient capital-related costs. When we modeled the combined operating and capital outlier payments, we found that using a common threshold resulted in a higher percentage of outlier payments for capital-related costs than for operating costs. We project that the threshold for FY 2024 (which reflects our methodology to incorporate an estimate of operating outlier reconciliation) would result in outlier payments that would equal 5.1 percent of operating DRG payments and we estimate that capital outlier payments would equal 4.02 percent of capital payments based on the Federal rate (which reflects our methodology discussed previously to incorporate an estimate of capital outlier reconciliation).

In accordance with section 1886(d)(3)(B) of the Act and as discussed previously, we reduced the FY 2024 standardized amount by the percentage of 5.1 percent to account for the projected proportion of payments paid as outliers.

The outlier adjustment factors that would be applied to the operating standardized amount and capital Federal rate based on the FY 2024 outlier threshold are as follows:

	Operating Standardized Amounts	Capital Federal Rate*
National	0.949	0.959757

*The adjustment factor for the capital Federal rate includes an adjustment to the estimated percentage of FY 2024 capital outlier payments for capital outlier reconciliation, as discussed previously and in section III.A.2 in this Addendum.

We are applying the outlier adjustment factors to the FY 2024 payment rates after removing the effects of the FY 2023 outlier adjustment factors on the standardized amount.

To determine whether a case qualifies for outlier payments, we currently apply hospital-specific CCRs to the total covered charges for the case. Estimated operating and capital costs for the case are calculated separately by applying separate operating and capital CCRs. These costs are then combined and compared with the outlier fixed-loss cost threshold.

Under our current policy at § 412.84, we calculate operating and capital CCR ceilings and assign a statewide average CCR for hospitals whose CCRs exceed 3.0 standard deviations from the mean of the log distribution of CCRs for all hospitals. Based on this calculation, for hospitals for which the MAC computes operating CCRs greater than 1.209 or capital CCRs greater than 0.124 or hospitals for which the MAC is unable to calculate a CCR (as described under § 412.84(i)(3) of our regulations), statewide average CCRs are used to determine whether a hospital qualifies for outlier payments. Table 8A listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the statewide average operating CCRs for urban hospitals and for rural hospitals for which the MAC is unable to compute a hospital-specific CCR within the range previously specified. These statewide average ratios would be effective for discharges occurring on or after October 1, 2023, and would replace the statewide average ratios from the prior fiscal year. Table 8B listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the comparable statewide average capital CCRs. As previously stated, the CCRs in Tables 8A and 8B would be used during FY 2024 when hospital-specific CCRs based on the latest settled cost report either are not available or are outside the range noted previously. Table 8C listed in section VI. of this Addendum (and available via the internet on the CMS website) contains the statewide average total CCRs used under the LTCH PPS as discussed in section V. of this Addendum.

We finally note that section 20.1.2 of chapter three of the Medicare Claims Processing Manual (on the internet at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c03.pdf*) covers an array of topics, including CCRs, reconciliation, and the time value of money. We encourage hospitals that are assigned the statewide average operating and/or capital CCRs to work with their MAC on a possible alternative operating and/or capital CCR as explained in the manual. Use of an alternative CCR developed by the hospital in conjunction with the MAC can avoid possible overpayments or underpayments at cost report settlement, thereby ensuring better accuracy when making outlier payments and negating the need for outlier reconciliation. We also note that a hospital may request an alternative operating or capital CCR at any time as long as the guidelines of the manual are followed. In addition, the manual outlines the outlier reconciliation process for hospitals and Medicare contractors. We refer hospitals to the manual instructions for complete details on outlier reconciliation.

(4) FY 2022 Outlier Payments

Our current estimate, using available FY 2022 claims data, is that actual outlier payments for FY 2022 were approximately 6.78 percent of actual total MS–DRG payments. Therefore, the data indicate that, for FY 2022, the percentage of actual outlier payments relative to actual total payments is higher than we projected for FY 2022. Consistent with the policy and statutory interpretation we have maintained since the inception of the IPPS, we do not make retroactive adjustments to outlier payments to ensure that total outlier payments for FY 2022 are equal to 5.1 percent of total MS–DRG payments. As explained in the FY 2003 Outlier final rule (68 FR 34502), if we were to make retroactive adjustments to all outlier payments to ensure total payments are 5.1 percent of MS–DRG payments (by retroactively adjusting outlier payments), we would be removing the important aspect of the prospective nature of the IPPS. Because such an

across-the-board adjustment would either lead to more or less outlier payments for all hospitals, hospitals would no longer be able to reliably approximate their payment for a patient while the patient is still hospitalized. We believe it would be neither necessary nor appropriate to make such an aggregate retroactive adjustment. Furthermore, we believe it is consistent with the statutory language at section 1886(d)(5)(A)(iv) of the Act not to make retroactive adjustments to outlier payments. This section states that outlier payments be equal to or greater than 5 percent and less than or equal to 6 percent of projected or estimated (not actual) MS–DRG payments. We believe that an important goal of a PPS is predictability. Therefore, we believe that the fixed-loss outlier threshold should be projected based on the best available historical data and should not be adjusted retroactively. A retroactive change to the fixed-loss outlier threshold would affect all hospitals subject to the IPPS, thereby undercutting the predictability of the system as a whole.

We note that, because the MedPAR claims data for the entire FY 2023 period would not be available until after September 30, 2023, we are unable to provide an estimate of actual outlier payments for FY 2023 based on FY 2023 claims data in this final rule. We will provide an estimate of actual FY 2023 outlier payments in the FY 2025 IPPS/LTCH PPS proposed rule.

5. FY 2024 Standardized Amount

The adjusted standardized amount is divided into labor-related and nonlabor-related portions. Tables 1A and 1B listed and published in section VI. of this Addendum (and available via the internet on the CMS website) contain the national standardized amounts that we are applying to all hospitals, except hospitals located in Puerto Rico, for FY 2024. The standardized amount for hospitals in Puerto Rico is shown in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). The amounts shown in Tables 1A and 1B differ only in that the labor-related share applied to the standardized amounts in Table 1A is 67.6 percent, and the labor-related share applied to the standardized amounts in Table 1B is 62 percent. In accordance with sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act, we are applying a labor-related share of 62 percent, unless application of that percentage would result in lower payments to a hospital than would otherwise be made. In effect, the statutory provision means that we would apply a labor-related share of 62 percent for all hospitals whose wage indexes are less than or equal to 1.0000.

In addition, Tables 1A and 1B include the standardized amounts reflecting the applicable percentage increases for FY 2024.

The labor-related and nonlabor-related portions of the national average standardized amounts for Puerto Rico hospitals for FY 2024 are set forth in Table 1C listed and published in section VI. of this Addendum (and available via the internet on the CMS website). Similarly, section 1886(d)(9)(C)(iv) of the Act, as amended by section 403(b) of Public Law 108–173, provides that the labor-related share for hospitals located in Puerto Rico be 62 percent, unless the application of that percentage would result in lower payments to the hospital.

The following table illustrates the changes from the FY 2023 national standardized amounts to the FY 2024 national standardized amounts. The second through fifth columns display the changes from the FY 2023 standardized amounts for each applicable FY 2024 standardized amount. The first row of the table shows the updated (through FY 2023) average standardized amount after restoring the FY 2023 offsets for outlier payments, geographic reclassification, rural demonstration, lowest quartile, and wage index cap policy budget neutrality. The MS–DRG reclassification and recalibration wage index, and stem cell acquisition budget neutrality factors are cumulative (that is, we have not restored the offsets). Accordingly, those FY 2023 adjustment factors have not been removed from the base rate in the following table. Additionally, for FY 2024 we have applied the budget neutrality factors for the lowest quartile hospital policy, described previously.

BILLING CODE 4120–01–P

CHANGES FROM FY 2023 STANDARDIZED AMOUNTS TO THE FY 2024 STANDARDIZED AMOUNTS

	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
FY 2024 Base Rate after removing: 1. FY 2023 Geographic Reclassification Budget Neutrality (0.984399) 2. FY 2023 Operating Outlier Offset (0.949) 3. FY 2023 Rural Demonstration Budget Neutrality Factor (0.998935) 4. FY 2023 Lowest Quartile Budget Neutrality Factor (0.998146) 5. FY 2023 Cap Policy Wage Index Budget Neutrality Factor (0.999689)	If Wage Index is Greater Than 1.0000: Labor (67.6%): $4,628.54 Nonlabor (32.4%): $2,218.41	If Wage Index is Greater Than 1.0000: Labor (67.6%): $4,628.54 Nonlabor (32.4%): $2,218.41	If Wage Index is Greater Than 1.0000: Labor (67.6%): $4,628.54 Nonlabor (32.4%): $2,218.41	If Wage Index is Greater Than 1.0000: Labor (67.6%): $4,628.54 Nonlabor (32.4%): $2,218.41
	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $4,245.11 Nonlabor (38%): $2,601.84	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $4,245.11 Nonlabor (38%): $2,601.84	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $4,245.11 Nonlabor (38%): $2,601.84	If Wage Index is less Than or Equal to 1.0000: Labor (62%): $4,245.11 Nonlabor (38%): $2,601.84
FY 2024 Update Factor	1.031	1.00625	1.02275	.998
FY 2024 MS-DRG Reclassification and Recalibration Budget Neutrality Factor Before Cap	1.001463	1.001463	1.001463	1.001463
FY 2024 Cap Policy MS-DRG Weight Budget Neutrality Factor	0.999928	0.999928	0.999928	0.999928
FY 2024 Wage Index Budget Neutrality Factor	1.000702	1.000702	1.000702	1.000702
FY 2024 Reclassification Budget Neutrality Factor	0.971295	0.971295	0.971295	0.971295
FY 2024 Lowest Quartile Budget Neutrality Factor	0.997402	0.997402	0.997402	0.997402
FY 2024 Cap Policy Wage Index Budget Neutrality Factor	0.999645	0.999645	0.999645	0.999645
FY 2024 RCH Demonstration Budget Neutrality Factor	0.999463	0.999463	0.999463	0.999463
FY 2024 Operating Outlier Factor	0.949	0.949	0.949	0.949
National Standardized Amount for FY 2024 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (67.6/32.4)	**Labor: $4,392.49** **Nonlabor: $2,105.28**	**Labor: $4,287.05** **Nonlabor: $2,054.74**	**Labor: $4,357.34** **Nonlabor: $2,088.43**	**Labor: $4,251.90** **Nonlabor: $2,037.89**
National Standardized Amount for FY 2024 if Wage Index is Less Than or Equal to 1.0000; Labor/Non-Labor Share Percentage (62/38)	**Labor: $4,028.62** **Nonlabor: $2,469.15**	**Labor: $3,931.91** **Nonlabor: $2,409.88**	**Labor: $3,996.38** **Nonlabor: $2,449.39**	**Labor: $3,899.67** **Nonlabor: $2,390.12**

BILLING CODE 4120–01–C

B. Adjustments for Area Wage Levels and Cost-of-Living

Tables 1A through 1C, as published in section VI. of this Addendum (and available via the internet on the CMS website), contain the labor-related and nonlabor-related shares that we are using to calculate the prospective payment rates for hospitals located in the 50 States, the District of Columbia, and Puerto Rico for FY 2024. This section addresses two types of adjustments to the standardized amounts that are made in determining the prospective payment rates as described in this Addendum.

1. Adjustment for Area Wage Levels

Sections 1886(d)(3)(E) and 1886(d)(9)(C)(iv) of the Act require that we make an adjustment to the labor-related portion of the national prospective payment rate to account for area differences in hospital wage levels. This adjustment is made by multiplying the labor-related portion of the adjusted standardized amounts by the appropriate wage index for the area in which the hospital is located. For FY 2024, as discussed in section IV.B.3. of the preamble of this final rule, we are applying a labor-related share of 67.6 percent for the national standardized amounts for all IPPS hospitals (including hospitals in Puerto Rico) that have a wage index value that is greater than 1.0000. Consistent with section 1886(d)(3)(E) of the Act, we are applying the wage index to a labor-related share of 62 percent of the national standardized amount for all IPPS hospitals (including hospitals in Puerto Rico) whose wage index values are less than or equal to 1.0000. In section III. of the preamble of this final rule, we discuss the data and methodology for the FY 2024 wage index.

2. Adjustment for Cost-of-Living in Alaska and Hawaii

Section 1886(d)(5)(H) of the Act provides discretionary authority to the Secretary to make adjustments as the Secretary deems appropriate to take into account the unique circumstances of hospitals located in Alaska and Hawaii. Higher labor-related costs for these two States are taken into account in the adjustment for area wages described previously. To account for higher non-labor-related costs for these two States, we multiply the nonlabor-related portion of the standardized amount for hospitals in Alaska and Hawaii by an adjustment factor.

In the FY 2013 IPPS/LTCH PPS final rule, we established a methodology to update the cost of living adjustment (COLA) factors for Alaska and Hawaii that were published by the U.S. Office of Personnel Management (OPM) every 4 years (coinciding with the update to the labor related share of the IPPS market basket), beginning in FY 2014. We refer readers to the FY 2013 IPPS/LTCH PPS proposed and final rules for additional background and a detailed description of this methodology (77 FR 28145 through 28146 and 77 FR 53700 through 53701, respectively). For FY 2022, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45546 through 45547), we updated the COLA factors published by OPM for 2009 (as these are the last COLA factors OPM published prior to transitioning from COLAs to locality pay) using the methodology that we finalized in the FY 2013 IPPS/LTCH PPS final rule. Based on the policy finalized in the FY 2013 IPPS/LTCH PPS final rule, we are continuing to use the same COLA factors in FY 2024 that were used in FY 2023 to adjust the nonlabor-related portion of the standardized amount for hospitals located in Alaska and Hawaii. The following table lists the COLA factors for FY 2024.

FY 2024 Cost-of-Living Adjustment Factors (COLA): Alaska and Hawaii Hospitals

Area	FY 2022 through FY 2024
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.22
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.22
City of Juneau and 80-kilometer (50-mile) radius by road	1.22
Rest of Alaska	1.24
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.22
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

Lastly, as we finalized in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53700 and 53701), we intend to update the COLA factors based on our methodology every 4 years, at the same time as the update to the labor-related share of the IPPS market basket.

C. Calculation of the Prospective Payment Rates

1. General Formula for Calculation of the Prospective Payment Rates for FY 2024

In general, the operating prospective payment rate for all hospitals (including hospitals in Puerto Rico) paid under the IPPS, except SCHs and MDHs, for FY 2024 equals the Federal rate (which includes uncompensated care payments). Under current law, the MDH program is effective for discharges on or before September 30, 2024.

SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal national rate (which, as discussed in section VI.G. of the preamble of this final rule,

includes uncompensated care payments); the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment.

The prospective payment rate for SCHs for FY 2024 equals the higher of the applicable Federal rate, or the hospital-specific rate as described later in this section. The prospective payment rate for MDHs for FY 2024 equals the higher of the Federal rate, or the Federal rate plus 75 percent of the difference between the Federal rate and the hospital-specific rate as described in this section. For MDHs, the updated hospital-specific rate is based on FY 1982, FY 1987, or FY 2002 costs per discharge, whichever yields the greatest aggregate payment.

2. Operating and Capital Federal Payment Rate and Outlier Payment Calculation

Note: The formula specified in this section is used for actual claim payment and is also used by CMS to project the outlier threshold for the upcoming fiscal year. The difference is the source of some of the variables in the formula. For example, operating and capital CCRs for actual claim payment are from the PSF while CMS uses an adjusted CCR (as described previously) to project the threshold for the upcoming fiscal year. In addition, charges for a claim payment are from the bill while charges to project the threshold are from the MedPAR data with an inflation factor applied to the charges (as described earlier).

Step 1—Determine the MS–DRG and MS–DRG relative weight (from Table 5) for each claim primarily based on the ICD–10–CM diagnosis and ICD–10–PCS procedure codes on the claim.

Step 2—Select the applicable average standardized amount depending on whether the hospital submitted qualifying quality data and is a meaningful EHR user, as described previously.

Step 3—Compute the operating and capital Federal payment rate:

—Federal Payment Rate for Operating Costs = MS–DRG Relative Weight × [(Labor-Related Applicable Standardized Amount × Applicable CBSA Wage Index) + (Nonlabor-Related Applicable Standardized Amount × Cost-of-Living Adjustment)] × (1 + IME + (DSH * 0.25))

—Federal Payment for Capital Costs = MS–DRG Relative Weight × Federal Capital Rate × Geographic Adjustment Fact × (1 + IME + DSH)

Step 4—Determine operating and capital costs:

—Operating Costs = (Billed Charges × Operating CCR)

—Capital Costs = (Billed Charges × Capital CCR).

Step 5—Compute operating and capital outlier threshold (CMS applies a geographic adjustment to the operating and capital outlier threshold to account for local cost variation):

—Operating CCR to Total CCR = (Operating CCR)/(Operating CCR + Capital CCR)

—Operating Outlier Threshold = [Fixed Loss Threshold × ((Labor-Related Portion × CBSA Wage Index) + Nonlabor-Related portion)] × Operating CCR to Total CCR + Federal Payment with IME, DSH + Uncompensated Care Payment + supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals + New Technology Add-On Payment Amount

—Capital CCR to Total CCR = (Capital CCR)/(Operating CCR + Capital CCR)

—Capital Outlier Threshold = (Fixed Loss Threshold × Geographic Adjustment Factor × Capital CCR to Total CCR) + Federal Payment with IME and DSH

Step 6—Compute operating and capital outlier payments:

—Marginal Cost Factor = 0.80 or 0.90 (depending on the MS–DRG)

—Operating Outlier Payment = (Operating Costs − Operating Outlier Threshold) × Marginal Cost Factor

—Capital Outlier Payment = (Capital Costs − Capital Outlier Threshold) × Marginal Cost Factor

The payment rate may then be further adjusted for hospitals that qualify for a low-volume payment adjustment under section 1886(d)(12) of the Act and 42 CFR 412.101(b). The base-operating DRG payment amount may be further adjusted by the hospital readmissions payment adjustment and the hospital VBP payment adjustment as described under sections 1886(q) and 1886(o) of the Act, respectively. Payments also may be reduced by the 1-percent adjustment under the HAC Reduction Program as described in section 1886(p) of the Act. We also make new technology add-on payments in accordance with section 1886(d)(5)(K) and (L) of the Act. Finally, we add the uncompensated care payment and supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals to the total claim payment amount. As noted in the previous formula, we take uncompensated care payments, supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals, and new technology add-on payments into consideration when calculating outlier payments.

3. Hospital-Specific Rate (Applicable Only to SCHs and MDHs)

a. Calculation of Hospital-Specific Rate

Section 1886(b)(3)(C) of the Act provides that SCHs are paid based on whichever of the following rates yields the greatest aggregate payment: the Federal rate; the updated hospital-specific rate based on FY 1982 costs per discharge; the updated hospital-specific rate based on FY 1987 costs per discharge; the updated hospital-specific rate based on FY 1996 costs per discharge; or the updated hospital-specific rate based on FY 2006 costs per discharge to determine the rate that yields the greatest aggregate payment. Under current law, the MDH program has been extended for discharges occurring through September 30, 2024.

For a more detailed discussion of the calculation of the hospital-specific rates, we refer readers to the FY 1984 IPPS interim final rule (48 FR 39772); the April 20, 1990 final rule with comment period (55 FR 15150); the FY 1991 IPPS final rule (55 FR 35994); and the FY 2001 IPPS final rule (65 FR 47082).

b. Updating the FY 1982, FY 1987, FY 1996, FY 2002 and FY 2006 Hospital-Specific Rate for FY 2024

Section 1886(b)(3)(B)(iv) of the Act provides that the applicable percentage increase applicable to the hospital-specific rates for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS). Because the Act sets the update factor for SCHs and MDHs equal to the update factor for all other IPPS hospitals, the update to the hospital-specific rates for SCHs and MDHs is subject to the amendments to section 1886(b)(3)(B) of the Act made by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, the applicable percentage increases to the hospital-specific rates applicable to SCHs and MDHs are the following:

FY 2024	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	3.3	3.3	3.3	3.3
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.825	-0.825
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-2.475	0	-2.475
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.2	-0.2	-0.2	-0.2
Applicable Percentage Increase Applied to Standardized Amount	**3.1**	**0. 625**	**2.275**	**-0.2**

For a complete discussion of the applicable percentage increase applied to the hospital-specific rates for SCHs and MDHs, we refer readers to section V.B. of the preamble of this final rule.

In addition, because SCHs and MDHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, the hospital-specific rate is adjusted by a budget neutrality factor to ensure that changes to the MS–DRG classifications and the recalibration of the MS–DRG relative weights are made in a manner so that aggregate IPPS payments are unaffected. Therefore, the hospital specific-rate for an SCH or an MDH is adjusted by the MS–DRG reclassification and recalibration budget neutrality factor, as discussed in section III. of this Addendum and listed in the table in section II. of this Addendum. In addition, as discussed in section II.D.2.c. of the preamble this final rule and previously, we are applying a permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given fiscal year, as finalized in the FY 2023 IPPS/LTCH PPS final rule. Because SCHs and MDHs use the same MS–DRGs as other hospitals when they are paid based in whole or in part on the hospital-specific rate, consistent with the policy adopted in the FY 2023 IPPS/LTCH PPS final rule (87 FR 48897 through 48900 and 49432 through 49433), the hospital specific-rate for an SCH or MDH would be adjusted by the MS–DRG 10-percent cap budget neutrality factor. The resulting rate is used in determining the payment rate that an SCH or MDH would receive for its discharges beginning on or after October 1, 2023.

III. Changes to Payment Rates for Acute Care Hospital Inpatient Capital-Related Costs for FY 2024

The PPS for acute care hospital inpatient capital-related costs was implemented for cost reporting periods beginning on or after October 1, 1991. The basic methodology for determining Federal capital prospective rates is set forth in the regulations at 42 CFR 412.308 through 412.352. In this section of this Addendum, we discuss the factors that we used to determine the capital Federal rate for FY 2024, which would be effective for discharges occurring on or after October 1, 2023.

All hospitals (except ''new'' hospitals under § 412.304(c)(2)) are paid based on the capital Federal rate. We annually update the capital standard Federal rate, as provided in § 412.308(c)(1), to account for capital input price increases and other factors. The regulations at § 412.308(c)(2) also provide that the capital Federal rate be adjusted annually by a factor equal to the estimated proportion of outlier payments under the capital Federal rate to total capital payments under the capital Federal rate. In addition, § 412.308(c)(3) requires that the capital Federal rate be reduced by an adjustment factor equal to the estimated proportion of payments for exceptions under § 412.348. (We note that, as discussed in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53705), there is generally no longer a need for an exceptions payment adjustment factor.) However, in limited circumstances, an additional payment exception for extraordinary circumstances is provided for under § 412.348(f) for qualifying hospitals. Therefore, in accordance with § 412.308(c)(3), an exceptions payment adjustment factor may need to be applied if such payments are made. Section 412.308(c)(4)(ii) requires that the capital standard Federal rate be adjusted so that the effects of the annual DRG reclassification and the recalibration of DRG weights and changes in the geographic adjustment factor (GAF) are budget neutral.

Section 412.374 provides for payments to hospitals located in Puerto Rico under the IPPS for acute care hospital inpatient capital-related costs, which currently specifies capital IPPS payments to hospitals located in Puerto Rico are based on 100 percent of the Federal rate.

A. Determination of the Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update for FY 2024

In the discussion that follows, we explain the factors that we used to determine the capital Federal rate for FY 2024. In particular, we explain why the FY 2024 capital Federal rate would increase approximately 4.14 percent, compared to the FY 2023 capital Federal rate. As discussed in the impact analysis in appendix A to this final rule, we estimate that capital payments per discharge will increase approximately 6.6 percent during that same period. Because capital payments constitute approximately 10 percent of hospital payments, a 1-percent change in the capital Federal rate yields only approximately a 0.1 percent change in actual payments to hospitals.

1. Projected Capital Standard Federal Rate Update

Under § 412.308(c)(1), the capital standard Federal rate is updated on the basis of an analytical framework that takes into account changes in a capital input price index (CIPI) and several other policy adjustment factors. Specifically, we adjust the projected CIPI rate of change, as appropriate, each year for case-mix index-related changes, for intensity, and for errors in previous CIPI forecasts. The update factor for FY 2024 under that framework is 3.8 percent based on a projected 2.9 percent increase in the 2018-based CIPI, a 0.0 percentage point adjustment for intensity, a 0.0 percentage point adjustment for case-mix, a 0.0 percentage point adjustment for the

DRG reclassification and recalibration, and a forecast error correction of 0.9 percentage point. As discussed in section III.C. of this Addendum, we continue to believe that the CIPI is the most appropriate input price index for capital costs to measure capital price changes in a given year. We also explain the basis for the FY 2024 CIPI projection in that same section of this Addendum. In this final rule, we describe the policy adjustments that we applied in the update framework for FY 2024.

The case-mix index is the measure of the average DRG weight for cases paid under the IPPS. Because the DRG weight determines the prospective payment for each case, any percentage increase in the case-mix index corresponds to an equal percentage increase in hospital payments.

The case-mix index can change for any of several reasons—

- The average resource use of Medicare patient changes (''real'' case-mix change);
- Changes in hospital documentation and coding of patient records result in higher-weighted DRG assignments (''coding effects''); or
- The annual DRG reclassification and recalibration changes may not be budget neutral (''reclassification effect'').

We define real case-mix change as actual changes in the mix (and resource requirements) of Medicare patients, as opposed to changes in documentation and coding behavior that result in assignment of cases to higher-weighted DRGs, but do not reflect higher resource requirements. The capital update framework includes the same case-mix index adjustment used in the former operating IPPS update framework (as discussed in the May 18, 2004 IPPS proposed rule for FY 2005 (69 FR 28816)). (We no longer use an update framework to make a recommendation for updating the operating IPPS standardized amounts, as discussed in section II. of appendix B to the FY 2006 IPPS final rule (70 FR 47707).)

For FY 2024, we are projecting a 0.5 percent total increase in the case-mix index. We estimated that the real case-mix increase would equal 0.5 percent for FY 2024. The net adjustment for change in case-mix is the difference between the projected real increases in case mix and the projected total increase in case mix. Therefore, as proposed, the net adjustment for case-mix change in FY 2024 is 0.0 percentage point.

The capital update framework also contains an adjustment for the effects of DRG reclassification and recalibration. This adjustment is intended to remove the effect on total payments of prior year's changes to the DRG classifications and relative weights, to retain budget neutrality for all case-mix index-related changes other than those due to patient severity of illness. Due to the lag time in the availability of data, there is a 2-year lag in data used to determine the adjustment for the effects of DRG reclassification and recalibration. For example, for this final rule, we have the FY 2022 MedPAR claims data available to evaluate the effects of the FY 2022 DRG reclassification and recalibration as part of our update for FY 2024. We assume for purposes of this adjustment, that the estimate of FY 2022 DRG reclassification and recalibration would result in no change in the case-mix when compared with the case mix index that would have resulted if we had not made the reclassification and recalibration changes to the DRGs. Therefore, as proposed, we are making a 0.0 percentage point adjustment for reclassification and recalibration in the update framework for FY 2024.

The capital update framework also contains an adjustment for forecast error. The input price index forecast is based on historical trends and relationships ascertainable at the time the update factor is established for the upcoming year. In any given year, there may be unanticipated price fluctuations that may result in differences between the actual increase in prices and the forecast used in calculating the update factors. In setting a prospective payment rate under the framework, we make an adjustment for forecast error only if our estimate of the change in the capital input price index for any year is greater than 0.25 percentage point in absolute terms. There is a 2-year lag between the forecast and the availability of data to develop a measurement of the forecast error. Historically, when a forecast error of the CIPI is greater than 0.25 percentage point in absolute terms, it is reflected in the update recommended under this framework. A forecast error of 0.9 percentage point was calculated for the FY 2022 update, for which there are historical data. That is, current historical data indicate that the forecasted FY 2022 CIPI increase (1.1 percent) used in calculating the FY 2022 update factor is 0.9 percentage point lower than actual realized price increases (2.0 percent). As this exceeds the 0.25 percentage point threshold, we are making an adjustment of 0.9 percentage point for the FY 2022 forecast error in the update for FY 2024.

Under the capital IPPS update framework, we also make an adjustment for changes in intensity. Historically, we calculate this adjustment using the same methodology and data that were used in the past under the framework for operating IPPS. The intensity factor for the operating update framework reflects how hospital services are utilized to produce the final product, that is, the discharge. This component accounts for changes in the use of quality-enhancing services, for changes within DRG severity, and for expected modification of practice patterns to remove noncost-effective services. Our intensity measure is based on a 5-year average.

We calculate case-mix constant intensity as the change in total cost per discharge, adjusted for price level changes (the CPI for hospital and related services) and changes in real case-mix. Without reliable estimates of the proportions of the overall annual intensity changes that are due, respectively, to ineffective practice patterns and the combination of quality-enhancing new technologies and complexity within the DRG system, we assume that one-half of the annual change is due to each of these factors. Thus, the capital update framework provides an add-on to the input price index rate of increase of one-half of the estimated annual increase in intensity, to allow for increases within DRG severity and the adoption of quality-enhancing technology.

In this final rule, as proposed, we are continuing to use a Medicare-specific intensity measure that is based on a 5-year adjusted average of cost per discharge for FY 2024 (we refer readers to the FY 2011 IPPS/LTCH PPS final rule (75 FR 0436) for a full description of our Medicare-specific intensity measure). Specifically, for FY 2024, we are using an intensity measure that is based on an average of cost-per-discharge data from the 5-year period beginning with FY 2017 and extending through FY 2021. Based on these data, we estimated that case-mix constant intensity declined during FYs 2017 through 2021. In the past, when we found intensity to be declining, we believed a zero (rather than a negative) intensity adjustment was appropriate. Consistent with this approach, because we estimated that intensity would decline during that 5-year period, we believe it is appropriate to continue to apply a zero-intensity adjustment for FY 2024. Therefore, as proposed, we are making a 0.0 percentage point adjustment for intensity in the update for FY 2024.

Earlier, we described the basis of the components we used to develop the 3.8 percent capital update factor under the capital update framework for FY 2024, as shown in the following table.

FY 2024 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	2.9
Intensity:	0.0
Case-Mix Adjustment Factors:	
Projected Case-Mix Change	-0.5
Real Across DRG Change	0.5
Subtotal	0.0
Effect of FY 2022 Reclassification and Recalibration	0.0
Forecast Error Correction	0.9
Total Update	3.8

*The capital input price index represents the 2018-based CIPI.

2. Outlier Payment Adjustment Factor

Section 412.312(c) establishes a unified outlier payment methodology for inpatient operating and inpatient capital-related costs. A shared threshold is used to identify outlier cases for both inpatient operating and inpatient capital-related payments. Section 412.308(c)(2) provides that the standard Federal rate for inpatient capital-related costs be reduced by an adjustment factor equal to the estimated proportion of capital-related outlier payments to total inpatient capital-related PPS payments. The outlier threshold is set so that operating outlier payments are projected to be 5.1 percent of total operating IPPS DRG payments. For FY 2024, we have incorporated the estimated outlier reconciliation payment amounts into the outlier threshold model, as we did for FY 2023. (For more details on our incorporation of the estimated outlier reconciliation payment amounts into the outlier threshold model, please see section II.A. of this Addendum to this final rule.)

For FY 2023, we estimated that outlier payments for capital-related PPS payments would equal 5.51 percent of inpatient capital-related payments based on the capital Federal rate. Based on the threshold discussed in section II.A. of this Addendum, we estimate that prior to taking into account projected capital outlier reconciliation payments, outlier payments for capital-related costs will equal 4.04 percent of inpatient capital-related payments based on the capital Federal rate in FY 2024. Using the methodology outlined in section II.A. of this Addendum, we estimate that taking into account projected capital outlier reconciliation payments will decrease the estimated percentage of FY 2024 capital outlier payments by 0.02 percent. Therefore, accounting for estimated capital outlier reconciliation, the estimated outlier payments for capital-related PPS payments would equal 4.02 percent (4.04 percent − 0.02 percent) of inpatient capital-related payments based on the capital Federal rate in FY 2024. Accordingly, we applied an outlier adjustment factor of 0.9598 in determining the capital Federal rate for FY 2024. Thus, we estimate that the percentage of capital outlier payments to total capital Federal rate payments for FY 2024 would be lower than the percentage for FY 2023.

The outlier reduction factors are not built permanently into the capital rates; that is, they are not applied cumulatively in determining the capital Federal rate. The FY 2024 outlier adjustment of 0.9598 is a 1.57 percent change from the FY 2023 outlier adjustment of 0.9449. Therefore, the net change in the outlier adjustment to the capital Federal rate for FY 2024 is 1.0157 (0.9598/0.9449) so that the outlier adjustment will increase the FY 2024 capital Federal rate by approximately 1.57 percent compared to the FY 2023 outlier adjustment.

3. Budget Neutrality Adjustment Factor for Changes in DRG Classifications and Weights and the GAF

Section 412.308(c)(4)(ii) requires that the capital Federal rate be adjusted so that aggregate payments for the fiscal year based on the capital Federal rate, after any changes resulting from the annual DRG reclassification and recalibration and changes in the GAF, are projected to equal aggregate payments that would have been made on the basis of the capital Federal rate without such changes.

As discussed in section III.G.3. of the preamble of this final rule, in the FY 2020 IPPS/LTCH PPS final rule (84 FR 42325 through 42339), we finalized a policy to help reduce wage index disparities between high and low wage index hospitals by increasing the wage index values for hospitals with a wage index value below the 25th percentile wage index. We stated that this policy will be effective for at least 4 years, beginning in FY 2020. As discussed in section III.G.3. of the preamble of this final rule, this policy was applied in FYs 2020 through 2023, and will continue to apply in FY 2024 as we proposed. In addition, beginning in FY 2023, we finalized a permanent 5-percent cap on any decrease to a hospital's wage index from its wage index in the prior FY regardless of the circumstances causing the decline. That is, under this policy, a hospital's wage index value would not be less than 95 percent of its prior year value (87 FR 49018 through 49021).

We have established a 2-step methodology for computing the budget neutrality factor for changes in the GAFs in light of the effect of those wage index changes on the GAFs. In the first step, we first calculate a factor to ensure budget neutrality for changes to the GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy, consistent with our historical GAF budget neutrality factor methodology. In the second step, we calculate a factor to ensure budget neutrality for changes to the GAFs due to our policy to increase the wage index for hospitals with a wage index value below the 25th percentile wage index, which we are finalizing to continue in FY 2024, and our policy to place a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in the prior fiscal year. In this section, we refer to the policy that we applied in FYs 2020 through FY 2023 and are finalizing to continue to apply in FY 2024, of increasing the wage index for hospitals with a wage index value below the 25th percentile wage index, as the lowest quartile hospital wage index adjustment (also known as low wage index hospital policy). We refer to our policy to place a 5-percent cap on any decrease in a hospital's wage index from the hospital's final wage index in the prior fiscal year as the 5-percent cap on wage index decreases policy.

The budget neutrality factors applied for changes to the GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy are built permanently into the capital Federal rate; that is, they are applied cumulatively in determining the capital Federal rate. However, the budget neutrality factor for the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy is not permanently built into the capital Federal rate. This is because the GAFs with the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy applied from the previous year are not used in the budget neutrality factor calculations for the current year. Accordingly, and consistent with this approach, prior to calculating the GAF budget neutrality factors for FY 2024, we removed from the capital Federal rate the budget neutrality factor applied in FY 2023 for the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy. Specifically, we divided the capital Federal rate by the FY 2023 budget neutrality factor of 0.9972 (87 FR 49463). We refer the reader to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45552) for additional discussion on our policy of removing the prior year budget neutrality factor for the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases from the capital Federal rate.

In light of the changes to the wage index and other wage index policies for FY 2024 discussed previously, which directly affect the GAF, we continue to compute a budget neutrality adjustment for changes in the GAFs in two steps. We discuss our 2-step calculation of the GAF budget neutrality factors for FY 2024 as follows.

To determine the GAF budget neutrality factors for FY 2024, we first compared estimated aggregate capital Federal rate payments based on the FY 2023 MS–DRG classifications and relative weights and the FY 2023 GAFs to estimated aggregate capital Federal rate payments based on the FY 2023 MS–DRG classifications and relative weights and the FY 2024 GAFs without incorporating the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy. To achieve budget neutrality for these changes in the GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 0.9869 for FY 2024. Next, we compared estimated aggregate capital Federal rate payments based on the FY 2024 GAFs with and without the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy. For this calculation, estimated aggregate capital Federal rate payments were calculated using the FY 2024 MS–DRG classifications and relative weights (after application of the 10-percent cap discussed later in this section) and the FY 2024 GAFs (both with and without the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy). (We note, for this calculation the GAFs included the imputed floor, out-migration, and Frontier state adjustments.) To achieve budget neutrality for the effects of the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy on the FY 2024 GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 0.9964. As discussed earlier in this section, the budget neutrality factor for the lowest quartile hospital wage index adjustment factor and the 5-percent cap on wage index decreases policy is not permanently built into the capital Federal rate. Consistent with this, we present the budget neutrality factor for the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy calculated under the second step of this 2-step methodology separately from the other budget neutrality factors in the discussion that follows, and this factor is not included in the calculation of the combined GAF/DRG adjustment factor described later in this section. (We note that the FY 2024 GAFs reflect the changes to the rural wage index methodology finalized in section III.G.1. of the preamble to this final rule.) As discussed, beginning in FY 2024, we are including hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and are only excluding ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) in accordance with the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. We also are including the data of all § 412.103 hospitals (including those that have an MGCRB reclassification when appropriate) in the calculation of the rural floor and the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act.

In the FY 2023 IPPS/LTCH PPS final rule, we finalized a permanent 10-percent cap on the reduction in an MS–DRG's relative weight in a given fiscal year, beginning in FY 2023. Consistent with our historical methodology for adjusting the capital standard Federal rate to ensure that the effects of the annual DRG reclassification and the recalibration of DRG weights are budget neutral under § 412.308(c)(4)(ii), we finalized to apply an additional budget neutrality factor to the capital standard Federal rate so that the 10-percent cap on decreases in an MS–DRG's relative weight is implemented in a budget neutral manner (87 FR 49436). Specifically, we augmented our historical methodology for computing the budget neutrality factor for the annual DRG reclassification and recalibration by computing a budget neutrality adjustment for the annual DRG reclassification and recalibration in two steps. We first calculate a budget neutrality factor to account for the annual DRG reclassification and recalibration prior to the application of the 10-percent cap on MS–DRG relative weight decreases. Then we calculate an additional budget neutrality factor to account for the application of the 10-percent cap on MS–DRG relative weight decreases.

To determine the DRG budget neutrality factors for FY 2024, we first compared estimated aggregate capital Federal rate payments based on the FY 2023 MS–DRG classifications and relative weights to estimated aggregate capital Federal rate payments based on the FY 2024 MS–DRG classifications and relative weights prior to the application of the 10-percent cap. For these calculations, estimated aggregate capital Federal rate payments were calculated using the FY 2024 GAFs without the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy. The incremental adjustment factor for DRG classifications and changes in relative weights prior to the application of the 10-percent cap is 1.0017. Next, we compared estimated aggregate capital Federal rate payments based on the FY 2024 MS–DRG classifications and relative weights prior to the application of the 10-percent cap to estimated aggregate capital Federal rate payments based on the FY 2024 MS–DRG classifications and relative weights after the application of the 10-percent cap. For these calculations, estimated aggregate capital Federal rate payments were also calculated using the FY 2024 GAFs without the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy. The incremental adjustment factor for the application of the 10-percent cap on relative weight decreases is 0.9999. Therefore, to

achieve budget neutrality for the FY 2024 MS–DRG reclassification and recalibration (including the 10-percent cap), based on the calculations described previously, we are applying an incremental budget neutrality adjustment factor of 1.0016 (1.0017 × 0.9999) for FY 2024 to the capital Federal rate. We note that all the values are calculated with unrounded numbers.

The incremental adjustment factor for the FY 2024 MS–DRG reclassification and recalibration (1.0016) and for changes in the FY 2024 GAFs due to the update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy (0.9869) is 0.9885 (1.0016 × 0.9869). This incremental adjustment factor is built permanently into the capital Federal rates. To achieve budget neutrality for the effects of the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy on the FY 2024 GAFs, as described previously, we calculated a budget neutrality adjustment factor of 0.9964 for FY 2024. We refer to this budget neutrality factor for the remainder of this section as the lowest quartile/cap adjustment factor.

We applied the budget neutrality adjustment factors described previously to the capital Federal rate. This follows the requirement under § 412.308(c)(4)(ii) that estimated aggregate payments each year be no more or less than they would have been in the absence of the annual DRG reclassification and recalibration and changes in the GAFs.

The methodology used to determine the recalibration and geographic adjustment factor (GAF/DRG) budget neutrality adjustment is similar to the methodology used in establishing budget neutrality adjustments under the IPPS for operating costs. One difference is that, under the operating IPPS, the budget neutrality adjustments for the effect of updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy are determined separately. Under the capital IPPS, there is a single budget neutrality adjustment factor for changes in the GAF that result from updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy. In addition, there is no adjustment for the effects that geographic reclassification, the lowest quartile hospital wage index adjustment, or the 5-percent cap on wage index decreases policy described previously have on the other payment parameters, such as the payments for DSH or IME.

The incremental GAF/DRG adjustment factor of 0.9885 accounts for the MS–DRG reclassifications and recalibration (including application of the 10-percent cap on relative weight decreases) and for changes in the GAFs that result from updates to the wage data, the effects on the GAFs of FY 2024 geographic reclassification decisions made by the MGCRB compared to FY 2023 decisions, and the application of the rural floor policy. The lowest quartile/cap adjustment factor of 0.9964 accounts for changes in the GAFs that result from our policy to increase the wage index values for hospitals with a wage index value below the 25th percentile wage index and the 5-percent cap on wage index decreases policy. However, these factors do not account for changes in payments due to changes in the DSH and IME adjustment factors.

4. Capital Federal Rate for FY 2024

For FY 2023, we established a capital Federal rate of $483.79 (87 FR 49436, as corrected in 87 FR 66563). We are establishing an update of 3.8 percent in determining the FY 2024 capital Federal rate for all hospitals. As a result of this update and the budget neutrality factors discussed earlier, we are establishing a national capital Federal rate of $503.83 for FY 2024. The national capital Federal rate for FY 2024 was calculated as follows:

- The FY 2024 update factor is 1.0380; that is, the update is 3.8 percent.
- The FY 2024 GAF/DRG budget neutrality adjustment factor that is applied to the capital Federal rate for changes in the MS–DRG classifications and relative weights (including application of the 10-percent cap on relative weight decreases) and changes in the GAFs that result from updates to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy is 0.9885.
- The FY 2024 lowest quartile/cap budget neutrality adjustment factor that is applied to the capital Federal rate for changes in the GAFs that result from our policy to increase the wage index values for hospitals with a wage index value below the 25th percentile wage index and the 5-percent cap on wage index decreases policy is 0.9964.
- The FY 2024 outlier adjustment factor is 0.9598.

We are providing the following chart that shows how each of the factors and adjustments for FY 2024 affects the computation of the FY 2024 national capital Federal rate in comparison to the FY 2023 national capital Federal rate. The FY 2024 update factor has the effect of increasing the capital Federal rate by 3.8 percent compared to the FY 2023 capital Federal rate. The GAF/DRG budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 1.15 percent. The FY 2024 lowest quartile/cap budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.08 percent compared to the FY 2023 capital Federal rate. The FY 2024 outlier adjustment factor has the effect of increasing the capital Federal rate by 1.57 percent compared to the FY 2023 capital Federal rate. The combined effect of all the changes will increase the national capital Federal rate by approximately 4.14 percent, compared to the FY 2023 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2023 CAPITAL FEDERAL RATE AND THE FY 2024 CAPITAL FEDERAL RATE

	FY 2023	FY 2024	Change	Percent Change
Update Factor[1]	1.0250	1.0380	1.0380	3.80
GAF/DRG Adjustment Factor[1]	1.0012	0.9885	0.9885	-1.15
Quartile/Cap Adjustment Factor[2]	0.9972	0.9964	0.9992	-0.08
Outlier Adjustment Factor[3]	0.9449	0.9598	1.0157	1.57
Capital Federal Rate	$483.79	$503.83	1.0414	4.14[4]

[1] The update factor and the GAF/DRG budget neutrality adjustment factors are built permanently into the capital Federal rate. Thus, for example, the incremental change from FY 2023 to FY 2024 resulting from the application of the 0.9885 GAF/DRG budget neutrality adjustment factor for FY 2024 is a net change of 0.9885 (or -1.15 percent).

[2] The lowest quartile/cap budget neutrality adjustment factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the FY 2024 lowest quartile/cap budget neutrality adjustment factor is 0.9964/0.9972 or 0.9992 (or -0.08 percent).

[3] The outlier reduction factor is not built permanently into the capital Federal rate; that is, the factor is not applied cumulatively in determining the capital Federal rate. Thus, for example, the net change resulting from the application of the FY 2024 outlier adjustment factor is 0.9598/0.9449 or 1.0157 (or 1.57 percent).

[4] Percent change may not sum due to rounding.

B. Calculation of the Inpatient Capital-Related Prospective Payments for FY 2024

For purposes of calculating payments for each discharge during FY 2024, the capital Federal rate is adjusted as follows: (Standard Federal Rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH Adjustment Factor + IME Adjustment Factor, if applicable). The result is the adjusted capital Federal rate.

Hospitals also may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. Section 412.312(c) provides for a shared threshold to identify outlier cases for both inpatient operating and inpatient capital-related payments. The outlier threshold for FY 2024 is in section II.A. of this Addendum. For FY 2024, a case will qualify as a cost outlier if the cost for the case is greater than the prospective payment rates for the MS–DRG plus IME and DSH payments (including the empirically justified Medicare DSH payment and the estimated uncompensated care payment), estimated supplemental payment for eligible IHS/Tribal hospitals and Puerto Rico hospitals, and any add-on payments for new technology, plus the fixed-loss amount of $42,750.

Currently, as provided under § 412.304(c)(2), we pay a new hospital 85 percent of its reasonable costs during the first 2 years of operation, unless it elects to receive payment based on 100 percent of the capital Federal rate. Effective with the third year of operation, we pay the hospital based on 100 percent of the capital Federal rate (that is, the same methodology used to pay all other hospitals subject to the capital PPS).

C. Capital Input Price Index

1. Background

Like the operating input price index, the capital input price index (CIPI) is a fixed-weight price index that measures the price changes associated with capital costs during a given year. The CIPI differs from the operating input price index in one important aspect—the CIPI reflects the vintage nature of capital, which is the acquisition and use of capital over time. Capital expenses in any given year are determined by the stock of capital in that year (that is, capital that remains on hand from all current and prior capital acquisitions). An index measuring capital price changes needs to reflect this vintage nature of capital. Therefore, the CIPI was developed to capture the vintage nature of capital by using a weighted-average of past capital purchase prices up to and including the current year.

We periodically update the base year for the operating and capital input price indexes to reflect the changing composition of inputs for operating and capital expenses. For this final rule, we are using the IPPS operating and capital market baskets that reflect a 2018 base year. For a complete discussion of this rebasing, we refer readers to section IV. of the preamble of the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45213).

2. Forecast of the CIPI for FY 2024

Based on IHS Global Inc.'s second quarter 2023 forecast, for this final rule, we are forecasting the 2018-based CIPI to increase 2.9 percent in FY 2024. This reflects a projected 3.4 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 5.4 percent increase in other capital expense prices in FY 2024, partially offset by a projected 1.6 percent decline in vintage-weighted interest expense prices in FY 2024. The weighted average of these three factors produces the forecasted 2.9 percent increase for the 2018-based CIPI in FY 2024. As proposed in the FY 2024 IPPS/LTCH proposed rule (88 FR 27232), we are using the more recent data available for this final rule to determine the FY 2024 increase in the 2018-based CIPI for this final rule.

IV. Changes to Payment Rates for Excluded Hospitals: Rate-of-Increase Percentages for FY 2024

Payments for services furnished in children's hospitals, 11 cancer hospitals, and hospitals located outside the 50 States, the District of Columbia and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) that are excluded from the IPPS are paid on the basis of reasonable costs based on the hospital's own historical cost experience, subject to a rate-of-increase ceiling. A per discharge limit (the target amount, as defined in § 413.40(a) of the regulations) is set for each hospital, based on the hospital's own cost experience in its base year, and updated annually by a rate-of-increase percentage specified in § 413.40(c)(3). In addition, as specified in the FY 2018 IPPS/LTCH PPS final rule (82 FR 38536), effective for cost reporting periods beginning during FY 2018, the annual update to the target amount for extended neoplastic disease care hospitals (hospitals described in § 412.22(i) of the regulations) also is the

rate-of-increase percentage specified in § 413.40(c)(3). (We note that, in accordance with § 403.752(a), religious nonmedical health care institutions (RNHCIs) are also subject to the rate-of-increase limits established under § 413.40 of the regulations.)

For the FY 2024 IPPS/LTCH PPS proposed rule, based on IGI's 2022 fourth quarter forecast, we estimated that the 2018-based IPPS operating market basket percentage increase for FY 2024 would be 3.0 percent (that is, the estimate of the market basket rate-of-increase). However, we proposed that if more recent data became available for the FY 2024 IPPS/LTCH PPS final rule, we would use such data, if appropriate, to calculate the final IPPS operating market basket update for FY 2024. As proposed, we used more recent data for this FY 2024 IPPS/LTCH PPS final rule, based on IGI's 2023 second quarter forecast, we estimate that the 2018-based IPPS operating market basket update for FY 2024 is 3.3 percent. Based on this estimate, the FY 2024 rate-of-increase percentage that will be applied to the FY 2023 target amounts in order to calculate the FY 2024 target amounts for children's hospitals, the 11 cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa will be 3.3 percent, in accordance with the applicable regulations at 42 CFR 413.40.

IRFs and rehabilitation distinct part units, IPFs and psychiatric units, and LTCHs are excluded from the IPPS and paid under their respective PPSs. The IRF PPS, the IPF PPS, and the LTCH PPS are updated annually. We refer readers to section VIII. of the preamble and section V. of the Addendum of this final rule for the changes to the Federal payment rates for LTCHs under the LTCH PPS for FY 2024. The annual updates for the IRF PPS and the IPF PPS are issued by the agency in separate **Federal Register** documents.

V. Changes to the Payment Rates for the LTCH PPS for FY 2024

A. LTCH PPS Standard Federal Payment Rate for FY 2024

1. Overview

In section VIII. of the preamble of this final rule, we discuss our annual updates to the payment rates, factors, and specific policies under the LTCH PPS for FY 2024.

Under § 412.523(c)(3) of the regulations, for FY 2012 and subsequent years, we updated the standard Federal payment rate by the most recent estimate of the LTCH PPS market basket at that time, including additional statutory adjustments required by sections 1886(m)(3) (citing sections 1886(b)(3)(B)(xi)(II) and 1886(m)(4) of the Act as set forth in the regulations at § 412.523(c)(3)(viii) through (xvii)). (For a summary of the payment rate development prior to FY 2012, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38310 through 38312) and references therein.)

Section 1886(m)(3)(A) of the Act specifies that, for rate year 2012 and each subsequent rate year, any annual update to the standard Federal payment rate shall be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act as discussed in section VIII.C.2. of the preamble of this final rule. This section of the Act further provides that the application of section 1886(m)(3)(B) of the Act may result in the annual update being less than zero for a rate year, and may result in payment rates for a rate year being less than such payment rates for the preceding rate year. (As noted in section VIII.C.2. of the preamble of this final rule, the annual update to the LTCH PPS occurs on October 1 and we have adopted the term ''fiscal year'' (FY) rather than ''rate year'' (RY) under the LTCH PPS beginning October 1, 2010. Therefore, for purposes of clarity, when discussing the annual update for the LTCH PPS, including the provisions of the Affordable Care Act, we use the term ''fiscal year'' rather than ''rate year'' for 2011 and subsequent years.)

For LTCHs that fail to submit the required quality reporting data in accordance with the LTCH QRP, the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

2. Development of the FY 2024 LTCH PPS Standard Federal Payment Rate

Consistent with our historical practice and § 412.523(c)(3)(xvii), for FY 2024, as we proposed, we are applying the annual update to the LTCH PPS standard Federal payment rate from the previous year. Furthermore, in determining the LTCH PPS standard Federal payment rate for FY 2024, we also are making certain regulatory adjustments, consistent with past practices. Specifically, in determining the FY 2024 LTCH PPS standard Federal payment rate, as we proposed, we are applying a budget neutrality adjustment factor for the changes related to the area wage level adjustment (that is, changes to the wage data and labor-related share) as discussed in section V.B.6.of this Addendum.

In this final rule, we are establishing an annual update to the LTCH PPS standard Federal payment rate of 3.3 percent (that is, the most recent estimate of the LTCH PPS market basket increase of 3.5 percent less the productivity adjustment of 0.2 percentage point). Therefore, in accordance with § 412.523(c)(3)(xvii), we are applying an update factor of 1.033 to the FY 2023 LTCH PPS standard Federal payment rate of $46,432.77 to determine the FY 2024 LTCH PPS standard Federal payment rate. Also, in accordance with § 412.523(c)(3)(xvii) and (c)(4), we are required to reduce the annual update to the LTCH PPS standard Federal payment rate by 2.0 percentage points for LTCHs that fail to submit the required quality reporting data for FY 2024 as required under the LTCH QRP. Therefore, for LTCHs that fail to submit quality reporting data under the LTCH QRP, we are establishing an annual update to the LTCH PPS standard Federal payment rate of 1.3 percent (or an update factor of 1.013). This update amount reflects the 0.2 percentage point productivity adjustment to the annual market basket update of 3.5 percent, as required by section 1886(m)(3)(A)(i) of the Act, minus 2.0 percentage points for LTCHs failing to submit quality data under the LTCH QRP, as required by section 1886(m)(5) of the Act. Consistent with § 412.523(d)(4), we are applying an area wage level budget neutrality factor to the FY 2024 LTCH PPS standard Federal payment rate of 1.0031599, based on the best available data at this time, to ensure that any changes to the area wage level adjustment (that is, the annual update of the wage index (including application of the 5-percent cap on wage index decreases, discussed later in this section), and labor-related share) will not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. Accordingly, we are establishing an LTCH PPS standard Federal payment rate of $48,116.62 (calculated as $46,432.77 × 1.033 × 1.0031599) for FY 2024. For LTCHs that fail to submit quality reporting data for FY 2024, in accordance with the requirements of the LTCH QRP under section 1866(m)(5) of the Act, we are establishing an LTCH PPS standard Federal payment rate of $47,185.03 (calculated as $46,432.77 × 1.013 × 1.0031599) for FY 2024.

B. Adjustment for Area Wage Levels Under the LTCH PPS for FY 2024

1. Background

Under the authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, we established an adjustment to the LTCH PPS standard

Federal payment rate to account for differences in LTCH area wage levels under § 412.525(c). The labor-related share of the LTCH PPS standard Federal payment rate is adjusted to account for geographic differences in area wage levels by applying the applicable LTCH PPS wage index. The applicable LTCH PPS wage index is computed using wage data from inpatient acute care hospitals without regard to reclassification under section 1886(d)(8) or section 1886(d)(10) of the Act.

The FY 2024 LTCH PPS standard Federal payment rate wage index values that will be applicable for LTCH PPS standard Federal payment rate discharges occurring on or after October 1, 2023, through September 30, 2024, are presented in Table 12A (for urban areas) and Table 12B (for rural areas), which are listed in section VI. of this Addendum and available via the internet on the CMS website.

2. Geographic Classifications (Labor Market Areas) for the LTCH PPS Standard Federal Payment Rate

In adjusting for the differences in area wage levels under the LTCH PPS, the labor-related portion of an LTCH's Federal prospective payment is adjusted by using an appropriate area wage index based on the geographic classification (labor market area) in which the LTCH is located. Specifically, the application of the LTCH PPS area wage level adjustment under existing § 412.525(c) is made based on the location of the LTCH—either in an ''urban area,'' or a ''rural area,'' as defined in § 412.503. Under § 412.503, an ''urban area'' is defined as a Metropolitan Statistical Area (MSA) (which includes a Metropolitan division, where applicable), as defined by the Executive OMB, and a ''rural area'' is defined as any area outside of an urban area (75 FR 37246).

The geographic classifications (labor market area definitions) currently used under the LTCH PPS, effective for discharges occurring on or after October 1, 2014, are based on the Core Based Statistical Areas (CBSAs) established by OMB, which are based on the 2010 decennial census data. In general, the current statistical areas (which were implemented beginning with FY 2015) are based on revised OMB delineations issued on February 28, 2013, in OMB Bulletin No. 13–01. (We note we have adopted minor revisions and updates in the years between the decennial censuses.) We adopted these labor market area delineations because they were at that time based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas. We also believed that these OMB delineations would ensure that the LTCH PPS area wage level adjustment most appropriately accounted for and reflected the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level. We noted that this policy was consistent with the IPPS policy adopted in FY 2015 under § 412.64(b)(1)(ii)(D) (79 FR 49951 through 49963). (For additional information on the CBSA-based labor market area (geographic classification) delineations currently used under the LTCH PPS and the history of the labor market area definitions used under the LTCH PPS, we refer readers to the FY 2015 IPPS/LTCH PPS final rule (79 FR 50180 through 50185).)

In general, it is our historical practice to update the CBSA-based labor market area delineations annually based on the most recent updates issued by OMB. Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. However, OMB occasionally issues minor updates and revisions to statistical areas in the years between the decennial censuses. OMB Bulletin No. 17–01, issued August 15, 2017, established the delineations for the Nation's statistical areas, and the corresponding changes to the CBSA-based labor market areas were adopted in the FY 2019 IPPS/LTCH PPS final rule (83 FR 41731). A copy of this bulletin may be obtained on the website at: *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/bulletins/2017/b-17-01.pdf*.

On April 10, 2018, OMB issued OMB Bulletin No. 18–03, which superseded OMB Bulletin No. 17–01 (August 15, 2017). On September 14, 2018, OMB issued OMB Bulletin No. 18–04, which superseded OMB Bulletin No. 18–03 (April 10, 2018). Historically OMB bulletins issued between decennial censuses have only contained minor modifications to CBSA delineations based on changes in population counts. However, OMB's 2010 Standards for Delineating Metropolitan and Micropolitan Standards created a larger mid-decade redelineation that takes into account commuting data from the American Commuting Survey. As a result, OMB Bulletin No. 18–04 (September 14, 2018) included more modifications to the CBSAs than are typical for OMB bulletins issued between decennial censuses. We adopted the updates set forth in OMB Bulletin No. 18–04 in the FY 2021 IPPS/LTCH PPS final rule (85 FR 59050 through 59051). A copy of OMB Bulletin No. 18–04 (September 14, 2018) may be obtained at *https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf*.

On March 6, 2020, OMB issued Bulletin No. 20–01, which provided updates to and superseded OMB Bulletin No. 18–04, which was issued on September 14, 2018. The attachments to OMB Bulletin No. 20–01 provided detailed information on the update to statistical areas since September 14, 2018. (For a copy of this bulletin, we refer readers to the following website: *https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf*.) In OMB Bulletin No. 20–01, OMB announced one new Micropolitan Statistical Area and one new component of an existing Combined Statistical Area. After reviewing OMB Bulletin No. 20–01, we determined that the changes in OMB Bulletin 20–01 encompassed delineation changes that would not affect the CBSA-based labor market area delineations used under the LTCH PPS. Therefore, we adopted the updates set forth in OMB Bulletin No. 20–01 in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45556 through 45557) consistent with our general policy of adopting OMB delineation updates; however, the LTCH PPS area wage level adjustment was not altered as a result of adopting the updates because the CBSA-based labor market area delineations were the same as the CBSA-based labor market area delineations adopted in the FY 2021 IPPS/LTCH PPS final rule based on OMB Bulletin No. 18–04 (85 FR59050 through 59051).

We believe the CBSA-based labor market area delineations, as established in OMB Bulletin 20–01, ensure that the LTCH PPS area wage level adjustment most appropriately accounts for and reflects the relative hospital wage levels in the geographic area of the hospital as compared to the national average hospital wage level based on the best available data that reflect the local economies and area wage levels of the hospitals that are currently located in these geographic areas (81 FR 57298). Therefore, for FY 2024, we did not propose any changes to the CBSA-based labor market area delineations as established in OMB Bulletin 20–01 and adopted in the FY 2022 IPPS/LTCH final rule.

CBSAs are made up of one or more constituent counties. For FY 2024, we are continuing to use the Federal Information Processing Standard (FIPS) county codes, maintained by the U.S. Census Bureau, for purposes of crosswalking counties to CBSAs. The current county-to-CBSA crosswalk was adopted under the LTCH PPS in the FY

2023 IPPS/LTCH PPS final rule (87 FR 49439) and is located on the CMS website at *https://www.cms.gov/medicare/medicare-fee-for-service-payment/longtermcarehospitalpps/download*.

3. Labor-Related Share for the LTCH PPS Standard Federal Payment Rate

Under the payment adjustment for the differences in area wage levels under § 412.525(c), the labor-related share of an LTCH's standard Federal payment rate is adjusted by the applicable wage index for the labor market area in which the LTCH is located. The LTCH PPS labor-related share currently represents the sum of the labor-related portion of operating costs and a labor-related portion of capital costs using the applicable LTCH market basket. Additional background information on the historical development of the labor-related share under the LTCH PPS can be found in the RY 2007 LTCH PPS final rule (71 FR 27810 through 27817 and 27829 through 27830) and the FY 2012 IPPS/LTCH PPS final rule (76 FR 51766 through 51769 and 51808).

For FY 2013, we rebased and revised the market basket used under the LTCH PPS by adopting a 2009-based LTCH market basket. In addition, for FY 2013 through FY 2016, we determined the labor-related share annually as the sum of the relative importance of each labor-related cost category of the 2009-based LTCH market basket for the respective fiscal year based on the best available data. (For more details, we refer readers to the FY 2013 IPPS/LTCH PPS final rule (77 FR 53477 through 53479).) For FY 2017, we rebased and revised the 2009-based LTCH market basket to reflect a 2013 base year. In addition, for FY 2017 through FY 2020, we determined the labor-related share annually as the sum of the relative importance of each labor-related cost category of the 2013-based LTCH market basket for the respective fiscal year based on the best available data. (For more details, we refer readers to the FY 2017 IPPS/LTCH PPS final rule (81 FR 57085 through 57096).) Then, effective for FY 2021, we rebased and revised the 2013-based LTCH market basket to reflect a 2017 base year and determined the labor-related share annually as the sum of the relative importance of each labor-related cost category in the 2017-based LTCH market basket using the most recent available data. (For more details, we refer readers to the FY 2021 IPPS/LTCH PPS final rule (85 FR 58909 through 58926).)

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27235), consistent with our historical practice, we proposed that the LTCH PPS labor-related share for FY 2024 would be the sum of the FY 2024 relative importance of each labor-related cost category in the LTCH market basket using the most recent available data. Specifically, we proposed that the labor-related share for FY 2024 would continue to include the sum of the labor-related portion of operating costs from the 2017-based LTCH market basket (that is, the sum of the FY 2024 relative importance shares of Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, and Repair Services; All Other: Labor-Related Services) and a portion of the relative importance of Capital-Related cost weight from the 2017-based LTCH market basket. The relative importance reflects the different rates of price change for these cost categories between the base year (2017) and FY 2024. Based on IHS Global Inc.'s fourth quarter 2022 forecast of the 2017-based LTCH market basket, the sum of the FY 2024 relative importance for Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, & Repair Services; and All Other: Labor-Related Services was 64.2 percent. The portion of capital-related costs that is influenced by the local labor market is estimated to be 46 percent (that is, the same percentage applied to the 2009-based and 2013-based LTCH market basket capital-related costs relative importance). Since the FY 2024 relative importance for capital-related costs was 9.2 percent based on IHS Global Inc.'s fourth quarter 2022 forecast of the 2017-based LTCH market basket, we took 46 percent of 9.2 percent to determine the labor-related share of capital-related costs for FY 2024 of 4.2 percent. Therefore, in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27235), we proposed a total labor-related share for FY 2024 of 68.4 percent (the sum of 64.2 percent for the labor-related share of operating costs and 4.2 percent for the labor-related share of capital-related costs). We also proposed that if more recent data became available after the publication of the proposed rule and before the publication of the final rule (for example, a more recent estimate of the relative importance of each labor-related cost category of the 2017-based LTCH market basket), we would use such data, if appropriate, to determine the FY 2024 LTCH PPS labor-related share.

Comment: A commenter stated that they do not support the increase in the labor-related share from 68.0 percent in FY 2023 to 68.4 percent in FY 2024. They claimed that any increase to the labor-related share percentage penalizes any facility that has a wage index less than 1.0. They further stated that there is a growing disparity between high-wage and low-wage states that harms hospitals in many rural and underserved communities. The commenter stated that limiting the increase in the labor-related share helps mitigate that growing disparity.

Response: We appreciate the commenter's concern over the proposed increase in the labor-related share and the impact to payments for facilities with a wage index less than 1.0; however, we believe it is technically accurate and appropriate to use the sum of the FY 2024 relative importance values for the labor-related cost categories, based on the most recent forecast of the 2017-based LTCH market basket, in order to determine the final labor-related share for FY 2024, as it accounts for more recent data regarding price pressures and cost structure of LTCHs.

After consideration of public comments, we are finalizing the FY 2024 labor-related share using the most recently available data. Based on IHS Global Inc.'s second quarter 2023 forecast of the 2017-based LTCH market basket, the sum of the FY 2024 relative importance for Wages and Salaries; Employee Benefits; Professional Fees: Labor-Related; Administrative and Facilities Support Services; Installation, Maintenance, & Repair Services; and All Other: Labor-Related Services is 64.3 percent. The portion of capital-related costs that is influenced by the local labor market is estimated to be 46 percent (that is, the same percentage applied to the 2009- based and 2013-based LTCH market basket capital-related costs relative importance). Since the FY 2024 relative importance for capital-related costs is 9.2 percent based on IHS Global Inc.'s second quarter 2023 forecast of the 2017-based LTCH market basket, we took 46 percent of 9.2 percent to determine the labor-related share of capital-related costs for FY 2024 of 4.2 percent. Therefore, we are finalizing a total labor-related share for FY 2024 of 68.5 percent (the sum of 64.3 percent for the labor-related share of operating costs and 4.2 percent for the labor-related share of capital-related costs).

4. Wage Index for FY 2024 for the LTCH PPS Standard Federal Payment Rate

Historically, we have established LTCH PPS area wage index values calculated from acute care IPPS hospital

wage data without taking into account geographic reclassification under sections 1886(d)(8) and 1886(d)(10) of the Act (67 FR 56019). The area wage level adjustment established under the LTCH PPS is based on an LTCH's actual location without regard to the ''urban'' or ''rural'' designation of any related or affiliated provider. As with the IPPS wage index, wage data for multicampus hospitals with campuses located in different labor market areas (CBSAs) are apportioned to each CBSA where the campus (or campuses) are located. We also employ a policy for determining area wage index values for areas where there are no IPPS wage data.

Consistent with our historical methodology, to determine the applicable area wage index values for the FY 2024 LTCH PPS standard Federal payment rate, under the broad authority of section 123 of the BBRA, as amended by section 307(b) of the BIPA, as we proposed, we are continuing to employ our historical practice of using the same data we used to compute the FY 2024 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this final rule (that is, wage data collected from cost reports submitted by IPPS hospitals for cost reporting periods beginning during FY 2020) because these data are the most recent complete data available.

In addition, as we proposed, we computed the FY 2024 LTCH PPS standard Federal payment rate area wage index values consistent with the ''urban'' and ''rural'' geographic classifications (that is, the proposed labor market area delineations as previously discussed in section V.B. of this Addendum) and our historical policy of not taking into account IPPS geographic reclassifications under sections 1886(d)(8) and 1886(d)(10) of the Act in determining payments under the LTCH PPS. As we proposed, we also continued to apportion the wage data for multicampus hospitals with campuses located in different labor market areas to each CBSA where the campus or campuses are located, consistent with the IPPS policy. Lastly, consistent with our existing methodology for determining the LTCH PPS wage index values, for FY 2024, as we proposed, we continued to use our existing policy for determining area wage index values for areas where there are no IPPS wage data. Under our existing methodology, the LTCH PPS wage index value for urban CBSAs with no IPPS wage data is determined by using an average of all of the urban areas within the State, and the LTCH PPS wage index value for rural areas with no IPPS wage data is determined by using the unweighted average of the wage indices from all of the CBSAs that are contiguous to the rural counties of the State.

Based on the FY 2020 IPPS wage data that we used to determine the FY 2024 LTCH PPS area wage index values in this final rule, there are no IPPS wage data for the urban area of Hinesville, GA (CBSA 25980). Consistent with our existing methodology, we calculated the FY 2024 wage index value for CBSA 25980 as the average of the wage index values for all of the other urban areas within the State of Georgia (that is, CBSAs 10500, 12020, 12060, 12260, 15260, 16860, 17980, 19140, 23580, 31420, 40660, 42340, 46660 and 47580), as shown in Table 12A, which is listed in section VI. of this Addendum.

Based on the FY 2020 IPPS wage data that we used to determine the FY 2024 LTCH PPS standard Federal payment rate area wage index values in this final rule, there are no rural areas without IPPS hospital wage data. Therefore, it is not necessary to use our established methodology to calculate a LTCH PPS wage index value for rural areas with no IPPS wage data for FY 2024. We note that, as IPPS wage data are dynamic, it is possible that the number of rural areas without IPPS wage data will vary in the future.

5. Permanent Cap on Wage Index Decreases

a. Permanent Cap on LTCH PPS Wage Index Decreases

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49440 through 49442), we finalized a policy that applies a permanent 5-percent cap on any decrease to an LTCH's wage index from its wage index in the prior year. Consistent with the requirement at § 412.525(c)(2) that changes to area wage level adjustments are made in a budget neutral manner, we include the application of this policy in the determination of the area wage level budget neutrality factor that is applied to the standard Federal payment rate, as is discussed later in section V.B.6. of this Addendum.

Under this policy, an LTCH's wage index will not be less than 95 percent of its wage index for the prior fiscal year. An LTCH's wage index cap adjustment is determined based on the wage index value applicable to the LTCH on the last day of the prior Federal fiscal year. LTCHs that became operational during the prior Federal fiscal year are subject to the LTCH PPS wage index cap. However, for newly opened LTCHs that become operational on or after the first day of the fiscal year to which this final rule would apply, these LTCHs are not subject to the LTCH PPS wage index cap since they were not paid under the LTCH PPS in the prior year. These LTCHs would receive the calculated wage index for the area in which they are geographically located, even if other LTCHs in the same geographic area are receiving a wage index cap. The cap on wage index decreases policy is reflected at § 412.525(c)(1).

For each LTCH we identify in our rulemaking data, we are including in a supplemental data file the wage index values from both fiscal years used in determining its capped wage index. This includes the LTCH's final prior year wage index value, the LTCH's uncapped current year wage index value, and the LTCH's capped current year wage index value. Due to the lag in rulemaking data, a new LTCH may not be listed in this supplemental file for a few years. For this reason, a newly opened LTCH could contact their MAC to ensure that its wage index value is not less than 95 percent of the value paid to it for the prior Federal fiscal year. This supplemental data file for public use will be posted on the CMS website for this final rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

Comment: A commenter stated that while they support the permanent cap on LTCH PPS wage index decreases policy, they urge CMS to implement this policy in a non-budget-neutral manner. The commenter believes this would both stabilize provider reimbursement and avoid further unexpected reductions for other providers.

Response: Implementation of this policy in a budget neutral manner is consistent with the requirement at § 412.525(c)(2) that changes to area wage level adjustments are made in a budget neutral manner. Consistent with this requirement, we continue to believe that changes to area wage level adjustments, including the 5-percent cap on the decrease on an LTCH's wage index, should not result in any change in estimated aggregate LTCH PPS payments. Furthermore, we anticipate that, in the absence of wage index policy changes beyond an annual update of the wage data, most LTCHs will experience year-to-year wage index declines less than 5 percent in any given year, and that the overall budget neutrality adjustments associated with the cap on wage index decreases will therefore be relatively small and will not create volatility in LTCH PPS payments.

b. Permanent Cap on IPPS Comparable Wage Index Decreases

Determining LTCH PPS payments for short-stay-outlier cases (reflected in § 412.529) and site neutral payment rate cases (reflected in § 412.522(c)) requires calculating an ''IPPS comparable amount.'' For information on this ''IPPS comparable amount'' calculation, we refer the reader to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49608 through 49610). Determining LTCH PPS payments for LTCHs that do not meet the applicable discharge payment percentage (reflected in § 412.522(d)) requires calculating an ''IPPS equivalent amount.'' For information on this ''IPPS equivalent amount'' calculation, we refer the reader to the FY 2020 IPPS/LTCH PPS final rule (84 FR 42439 through 42445).

Calculating both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' requires adjusting the IPPS operating and capital standardized amounts by the applicable IPPS wage index for nonreclassified IPPS hospitals. That is, the standardized amounts are adjusted by the IPPS wage index for nonreclassified IPPS hospitals located in the same geographic area as the LTCH. In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49442 through 49443), we finalized a policy that applies a permanent 5-percent cap on decreases in an LTCH's applicable IPPS comparable wage index from its applicable IPPS comparable wage index in the prior year. Historically, we have not budget neutralized changes to LTCH PPS payments that result from the annual update of the IPPS wage index for nonreclassified IPPS hospitals. Consistent with this approach, the cap on decreases in an LTCH's applicable IPPS comparable wage index is not applied in a budget neutral manner.

Under this policy, an LTCH's applicable IPPS comparable wage index will not be less than 95 percent of its applicable IPPS comparable wage index for the prior fiscal year. An LTCH's applicable IPPS comparable wage index cap adjustment is determined based on the wage index value applicable to the LTCH on the last day of the prior Federal fiscal year. LTCHs that became operational during the prior Federal fiscal year are subject to the applicable IPPS comparable wage index cap. However, for newly opened LTCHs that become operational on or after the first day of the fiscal year to which this final rule would apply, these LTCHs are not subject to the applicable IPPS comparable wage index cap since they were not paid under the LTCH PPS in the prior year. This means that these LTCHs would receive the calculated applicable IPPS comparable wage index for the area in which they are geographically located, even if other LTCHs in the same geographic area are receiving a wage cap. The cap on IPPS comparable wage index decreases policy is reflected at § 412.529(d)(4)(ii)(B) and (d)(4)(iii)(B).

Similar to the information we are making available for the cap on the LTCH PPS wage index values (described previously), for each LTCH we identify in our rulemaking data, we are including in a supplemental data file the wage index values from both fiscal years used in determining its capped applicable IPPS comparable wage index. Due to the lag in rulemaking data, a new LTCH may not be listed in this supplemental file for a few years. For this reason, a newly opened LTCH could contact its MAC to ensure that its applicable IPPS comparable wage index value is not less than 95 percent of the value paid to them for the prior Federal fiscal year. This supplemental data file for public use will be posted on the CMS website for this final rule at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

6. Budget Neutrality Adjustments for Changes to the LTCH PPS Standard Federal Payment Rate Area Wage Level Adjustment

Historically, the LTCH PPS wage index and labor-related share are updated annually based on the latest available data. Under § 412.525(c)(2), any changes to the area wage index values or labor-related share are to be made in a budget neutral manner such that estimated aggregate LTCH PPS payments are unaffected; that is, will be neither greater than nor less than estimated aggregate LTCH PPS payments without such changes to the area wage level adjustment. Under this policy, we determine an area wage level adjustment budget neutrality factor that is applied to the standard Federal payment rate to ensure that any changes to the area wage level adjustments are budget neutral such that any changes to the area wage index values or labor-related share would not result in any change (increase or decrease) in estimated aggregate LTCH PPS payments. Accordingly, under § 412.523(d)(4), we have applied an area wage level adjustment budget neutrality factor in determining the standard Federal payment rate, and we also established a methodology for calculating an area wage level adjustment budget neutrality factor. (For additional information on the establishment of our budget neutrality policy for changes to the area wage level adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771 through 51773 and 51809).)

For FY 2024, in accordance with § 412.523(d)(4), we are applying an area wage level budget neutrality factor to adjust the LTCH PPS standard Federal payment rate to account for the estimated effect of the adjustments or updates to the area wage level adjustment under § 412.525(c)(1) on estimated aggregate LTCH PPS payments, consistent with the methodology we established in the FY 2012 IPPS/LTCH PPS final rule (76 FR 51773). As discussed in section V.B.6. of this Addendum, consistent with, § 412.525(c)(2), we include the application of the 5-percent cap on wage index decreases in the determination of the area wage level budget neutrality factor. Specifically, as we proposed, we determined an area wage level adjustment budget neutrality factor that is applied to the LTCH PPS standard Federal payment rate under § 412.523(d)(4) for FY 2024 using the following methodology:

Step 1—Simulate estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2023 wage index values and the FY 2023 labor-related share of 68.0 percent.

Step 2—Simulate estimated aggregate LTCH PPS standard Federal payment rate payments using the FY 2024 wage index values (including application of the 5 percent cap on wage index decreases) and the FY 2024 labor-related share of 68.5 percent. (As noted previously, the changes to the wage index values based on updated hospital wage data are discussed in section V.B.4. of this Addendum and the labor-related share is discussed in section V.B.3. of this Addendum.)

Step 3—Calculate the ratio of these estimated total LTCH PPS standard Federal payment rate payments by dividing the estimated total LTCH PPS standard Federal payment rate payments using the FY 2023 area wage level adjustments (calculated in Step 1) by the estimated total LTCH PPS standard Federal payment rate payments using the FY 2024 updates to the area wage level adjustment (calculated in Step 2) to determine the budget neutrality factor for updates to the area wage level adjustment for FY 2024 LTCH PPS standard Federal payment rate payments.

Step 4—Apply the FY 2024 updates to the area wage level adjustment budget neutrality factor from Step 3 to determine the FY 2024 LTCH PPS standard Federal payment rate after the

application of the FY 2024 annual update.

In section I.E., of the preamble of this final rule, we finalized our proposal to use the most recent data available for the FY 2024 LTCH PPS ratesetting, including the FY 2022 MedPAR file. Therefore, we used claims from the FY 2022 MedPAR file in calculating the FY 2024 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor. We note that, because the area wage level adjustment under § 412.525(c) is an adjustment to the LTCH PPS standard Federal payment rate, consistent with historical practice, we only used data from claims that qualified for payment at the LTCH PPS standard Federal payment rate under the dual rate LTCH PPS to calculate the FY 2024 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49448), we discussed an LTCH (CCN 312024) whose abnormal charging practices in FY 2021 led to the LTCH receiving an excessive amount of high cost outlier payments. In that rule, we stated our belief, based on information we received from the provider, that these abnormal charging practices would not persist into FY 2023. Therefore, we did not include its cases in our model for determining the FY 2023 outlier fixed-loss amount. The FY 2022 MedPAR claims also reflect the abnormal charging practices of this LTCH. In the March 2023 update of the FY 2022 MedPAR file, we identified 166 LTCH PPS standard Federal payment rate cases for this LTCH. Of these 166 cases, 118 of the cases had charges that were exactly or within ten dollars of $10 million. We do not believe these abnormal charging practices will persist into FY 2024. As such, simulating FY 2023 and FY 2024 payments for this LTCH based on their FY 2022 claims results in simulated payment amounts that we do not believe are reasonable approximations of the payment amounts this LTCH will actually receive in FY 2023 and FY 2024. For this reason, we do not believe it would be appropriate to use these claims in determining the FY 2024 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor. Therefore, as we proposed, we removed claims from CCN 312024 when determining the FY 2024 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor.

For this final rule, using the steps in the methodology previously described, we determined a FY 2024 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 1.0031599. Accordingly, in section V.A. of this Addendum, we applied the area wage level adjustment budget neutrality factor of 1.0031599 to determine the FY 2024 LTCH PPS standard Federal payment rate, in accordance with § 412.523(d)(4).

C. Cost-of-Living Adjustment (COLA) for LTCHs Located in Alaska and Hawaii

Under § 412.525(b), a cost-of-living adjustment (COLA) is provided for LTCHs located in Alaska and Hawaii to account for the higher costs incurred in those States. Specifically, we apply a COLA to payments to LTCHs located in Alaska and Hawaii by multiplying the nonlabor-related portion of the standard Federal payment rate by the applicable COLA factors established annually by CMS. Higher labor-related costs for LTCHs located in Alaska and Hawaii are taken into account in the adjustment for area wage levels previously described. The methodology used to determine the COLA factors for Alaska and Hawaii is based on a comparison of the growth in the Consumer Price Indexes (CPIs) for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as published by the Bureau of Labor Statistics (BLS). It also includes a 25-percent cap on the CPI-updated COLA factors. Under our current policy, we have updated the COLA factors using the methodology as previously described every 4 years (at the same time as the update to the labor-related share of the IPPS market basket) and we last updated the COLA factors for Alaska and Hawaii published by OPM for 2009 in FY 2022 (86 FR 45559 through 45560).

We continue to believe that determining updated COLA factors using this methodology would appropriately adjust the nonlabor-related portion of the LTCH PPS standard Federal payment rate for LTCHs located in Alaska and Hawaii. Therefore, in this final rule, for FY 2024, under the broad authority conferred upon the Secretary by section 123 of the BBRA, as amended by section 307(b) of the BIPA, to determine appropriate payment adjustments under the LTCH PPS, as we proposed, we are continuing to use the COLA factors based on the 2009 OPM COLA factors updated through 2020 by the comparison of the growth in the CPIs for Anchorage, Alaska, and Honolulu, Hawaii, relative to the growth in the CPI for the average U.S. city as established in the FY 2022 IPPS/LTCH PPS final rule. (For additional details on our current methodology for updating the COLA factors for Alaska and Hawaii and for a discussion on the FY 2022 COLA factors, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45559 through 45560).)

COST-OF-LIVING ADJUSTMENT FACTORS (COLA): ALASKA AND HAWAII UNDER THE LTCH PPS FOR FY 2024

Area	FY 2024
Alaska:	
City of Anchorage and 80-kilometer (50-mile) radius by road	1.22
City of Fairbanks and 80-kilometer (50-mile) radius by road	1.22
City of Juneau and 80-kilometer (50-mile) radius by road	1.22
Rest of Alaska	1.24
Hawaii:	
City and County of Honolulu	1.25
County of Hawaii	1.22
County of Kauai	1.25
County of Maui and County of Kalawao	1.25

D. Adjustment for LTCH PPS High Cost Outlier (HCO) Cases

1. HCO Background

From the beginning of the LTCH PPS, we have included an adjustment to account for cases in which there are extraordinarily high costs relative to the costs of most discharges. Under this policy, additional payments are made based on the degree to which the estimated cost of a case (which is calculated by multiplying the Medicare allowable covered charge by the hospital's overall hospital CCR) exceeds a fixed-loss amount. This policy results in greater payment accuracy under the LTCH PPS and the Medicare program, and the LTCH sharing the financial risk for the treatment of extraordinarily high-cost cases.

We retained the basic tenets of our HCO policy in FY 2016 when we implemented the dual rate LTCH PPS payment structure under section 1206 of Public Law 113–67. LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid at the LTCH PPS standard Federal payment rate, which includes, as applicable, HCO payments under § 412.523(e). LTCH discharges that do not meet the criteria for exclusion are paid at the site neutral payment rate, which includes, as applicable, HCO payments under § 412.522(c)(2)(i). In the FY 2016 IPPS/LTCH PPS final rule, we established separate fixed-loss amounts and targets for the two different LTCH PPS payment rates. Under this bifurcated policy, the historic 8-percent HCO target was retained for LTCH PPS standard Federal payment rate cases, with the fixed-loss amount calculated using only data from LTCH cases that would have been paid at the LTCH PPS standard Federal payment rate if that rate had been in effect at the time of those discharges. For site neutral payment rate cases, we adopted the operating IPPS HCO target (currently 5.1 percent) and set the fixed-loss amount for site neutral payment rate cases at the value of the IPPS fixed-loss amount. Under the HCO policy for both payment rates, an LTCH receives 80 percent of the difference between the estimated cost of the case and the applicable HCO threshold, which is the sum of the LTCH PPS payment for the case and the applicable fixed-loss amount for such case.

To maintain budget neutrality, consistent with the budget neutrality requirement at § 412.523(d)(1) for HCO payments to LTCH PPS standard Federal rate payment cases, we also adopted a budget neutrality requirement for HCO payments to site neutral payment rate cases by applying a budget neutrality factor to the LTCH PPS payment for those site neutral payment rate cases. (We refer readers to § 412.522(c)(2)(i) of the regulations for further details.) We note that, during the 4-year transitional period, the site neutral payment rate HCO budget neutrality factor did not apply to the LTCH PPS standard Federal payment rate portion of the blended payment rate at § 412.522(c)(3) payable to site neutral payment rate cases. (For additional details on the HCO policy adopted for site neutral payment rate cases under the dual rate LTCH PPS payment structure, including the budget neutrality adjustment for HCO payments to site neutral payment rate cases, we refer readers to the FY 2016 IPPS/LTCH PPS final rule (80 FR 49617 through 49623).)

2. Determining LTCH CCRs Under the LTCH PPS

a. Background

As noted previously, CCRs are used to determine payments for HCO adjustments for both payment rates under the LTCH PPS and are also used to determine payments for site neutral payment rate cases. As noted earlier, in determining HCO and the site neutral payment rate payments (regardless of whether the case is also an HCO), we generally calculate the estimated cost of the case by multiplying the LTCH's overall CCR by the Medicare allowable charges for the case. An overall CCR is used because the LTCH PPS uses a single prospective payment per discharge that covers both inpatient operating and capital-related costs. The LTCH's overall CCR is generally computed based on the sum of LTCH operating and capital costs (as described in section 150.24, Chapter 3, of the Medicare Claims Processing Manual (Pub. 100–4)) as compared to total Medicare charges (that is, the sum of its operating and capital inpatient routine and ancillary charges), with those values determined from either the most recently settled cost report or the most recent tentatively settled cost report, whichever is from the latest cost reporting period. However, in certain instances, we use an alternative CCR, such as the statewide average CCR, a CCR that is specified by CMS, or one that is requested by the hospital. (We refer readers to § 412.525(a)(4)(iv) of the regulations for further details regarding CCRs and HCO adjustments for either LTCH PPS payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate.)

The LTCH's calculated CCR is then compared to the LTCH total CCR

ceiling. Under our established policy, an LTCH with a calculated CCR in excess of the applicable maximum CCR threshold (that is, the LTCH total CCR ceiling, which is calculated as 3 standard deviations from the national geometric average CCR) is generally assigned the applicable statewide CCR. This policy is premised on a belief that calculated CCRs in excess of the LTCH total CCR ceiling are most likely due to faulty data reporting or entry, and CCRs based on erroneous data should not be used to identify and make payments for outlier cases.

b. LTCH Total CCR Ceiling

Consistent with our historical practice, as we proposed, we used the best available data to determine the LTCH total CCR ceiling for FY 2024 in this final rule. Specifically, in this final rule, we used our established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the March 2023 update of the Provider Specific File (PSF), which is the most recent data available. Accordingly, we are establishing an LTCH total CCR ceiling of 1.289 under the LTCH PPS for FY 2024 in accordance with § 412.525(a)(4)(iv)(C)(*2*) for HCO cases under either payment rate and § 412.522(c)(1)(ii) for the site neutral payment rate. (For additional information on our methodology for determining the LTCH total CCR ceiling, we refer readers to the FY 2007 IPPS final rule (71 FR 48117 through 48119).)

We did not receive any public comments on our proposals and are finalizing our proposals as described previously, without modification.

c. LTCH Statewide Average CCRs

Our general methodology for determining the statewide average CCRs used under the LTCH PPS is similar to our established methodology for determining the LTCH total CCR ceiling because it is based on ''total'' IPPS CCR data. (For additional information on our methodology for determining statewide average CCRs under the LTCH PPS, we refer readers to the FY 2007 IPPS final rule (71 FR 48119 through 48120).) Under the LTCH PPS HCO policy at § 412.525(a)(4)(iv)(C), the SSO policy at § 412.529(f)(4)(iii), and the site neutral payment rate at § 412.522(c)(1)(ii), the MAC may use a statewide average CCR, which is established annually by CMS, if it is unable to determine an accurate CCR for an LTCH in one of the following circumstances: (1) New LTCHs that have not yet submitted their first Medicare cost report (a new LTCH is defined as an entity that has not accepted assignment of an existing hospital's provider agreement in accordance with § 489.18); (2) LTCHs whose calculated CCR is in excess of the LTCH total CCR ceiling; and (3) other LTCHs for whom data with which to calculate a CCR are not available (for example, missing or faulty data). (Other sources of data that the MAC may consider in determining an LTCH's CCR include data from a different cost reporting period for the LTCH, data from the cost reporting period preceding the period in which the hospital began to be paid as an LTCH (that is, the period of at least 6 months that it was paid as a short-term, acute care hospital), or data from other comparable LTCHs, such as LTCHs in the same chain or in the same region.)

Consistent with our historical practice of using the best available data, in this final rule, as we proposed, we are using our established methodology for determining the LTCH PPS statewide average CCRs, based on the most recent complete IPPS ''total CCR'' data from the March 2023 update of the PSF. As we proposed, we are establishing LTCH PPS statewide average total CCRs for urban and rural hospitals that will be effective for discharges occurring on or after October 1, 2023, through September 30, 2024, in Table 8C listed in section VI. of this Addendum (and available via the internet on the CMS website).

Under the current LTCH PPS labor market areas, all areas in Delaware, the District of Columbia, New Jersey, and Rhode Island are classified as urban. Therefore, there are no rural statewide average total CCRs listed for those jurisdictions in Table 8C. This policy is consistent with the policy that we established when we revised our methodology for determining the applicable LTCH statewide average CCRs in the FY 2007 IPPS final rule (71 FR 48119 through 48121) and is the same as the policy applied under the IPPS. In addition, although Connecticut has areas that are designated as rural, in our calculation of the LTCH statewide average CCRs, there were no short-term, acute care IPPS hospitals classified as rural or LTCHs located in these rural areas as of March 2023. Therefore, consistent with our existing methodology, we used the national average total CCR for rural IPPS hospitals for rural Connecticut in Table 8C. While Massachusetts also has rural areas, the statewide average CCR for rural areas in Massachusetts is based on one IPPS provider whose CCR is an atypical 1.105. Because this is much higher than the statewide urban average (0.46) and furthermore implies costs greater than charges, as with Connecticut, we used the national average total CCR for rural IPPS hospitals for rural Massachusetts in Table 8C. Furthermore, consistent with our existing methodology, in determining the urban and rural statewide average total CCRs for Maryland LTCHs paid under the LTCH PPS, as we proposed, we are continuing to use, as a proxy, the national average total CCR for urban IPPS hospitals and the national average total CCR for rural IPPS hospitals, respectively. We are using this proxy because we believe that the CCR data in the PSF for Maryland hospitals may not be entirely accurate (as discussed in greater detail in the FY 2007 IPPS final rule (71 FR 48120)).

We did not receive any public comments on our proposals. We are finalizing our proposals as described previously, without modification.

d. Reconciliation of HCO Payments

Under the HCO policy at § 412.525(a)(4)(iv)(D), the payments for HCO cases are subject to reconciliation (regardless of whether payment is based on the LTCH standard Federal payment rate or the site neutral payment rate). Specifically, any such payments are reconciled at settlement based on the CCR that was calculated based on the cost report coinciding with the discharge. For additional information on the reconciliation policy, we refer readers to sections 150.26 through 150.28 of the Medicare Claims Processing Manual (Pub. 100–4), as added by Change Request 7192 (Transmittal 2111; December 3, 2010), and the RY 2009 LTCH PPS final rule (73 FR 26820 through 26821).

3. High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

a. High-Cost Outlier Payments for LTCH PPS Standard Federal Payment Rate Cases

Under the regulations at § 412.525(a)(2)(ii) and as required by section 1886(m)(7) of the Act, the fixed-loss amount for HCO payments is set each year so that the estimated aggregate HCO payments for LTCH PPS standard Federal payment rate cases are 99.6875 percent of 8 percent (that is, 7.975 percent) of estimated aggregate LTCH PPS payments for LTCH PPS standard Federal payment rate cases. (For more details on the requirements for high-cost outlier payments in FY 2018 and subsequent years under section 1886(m)(7) of the Act and additional information regarding high-cost outlier payments prior to FY 2018, we refer readers to the FY 2018 IPPS/LTCH PPS final rule (82 FR 38542 through 38544).)

b. Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2024

To determine the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases, we estimate outlier payments and total LTCH PPS payments using claims data from the MedPAR files. As discussed in section I.E. of the preamble to this final rule, in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 26670 through 26671), we proposed to use the FY 2022 MedPAR claims file and the FY 2021 HCRIS (which contains data from many cost reports ending in FY 2022 based on each hospital's cost reporting period) for purposes of the FY 2024 LTCH PPS ratesetting without any modifications to our usual ratesetting methodologies to account for the impact of COVID–19 on the ratesetting data. One key component of our LTCH ratesetting methodologies is the determination of the outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases. In the proposed rule, we stated our belief that FY 2022 data, as the most recent available data, is the best available data for approximating the inpatient experience at both IPPS hospitals and LTCHs in FY 2024. We also stated that based on the information available at the time of the proposed rule, we believe there will continue to be COVID–19 cases treated at IPPS hospitals and LTCHs in FY 2024, such that it was appropriate to use the FY 2022 data, as the most recent available data, for purposes of the FY 2024 IPPS and LTCH PPS ratesetting. However, based on the information available at that time, we did not believe there was a reasonable basis for us to assume that there will be a meaningful difference in the number of COVID–19 cases treated at LTCHs in FY 2024 relative to FY 2022, such that modifications to our usual ratesetting methodologies would be warranted. We received several comments on our proposal to use FY 2022 data for purposes of the FY 2024 LTCH PPS ratesetting, nearly all focused on the specific use of FY 2022 MedPAR claims data when determining the FY 2024 outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases. Therefore, we summarize and respond to all of these comments in this section.

As discussed in greater detail later in this section, in addition to the claims data, the charge inflation factor and CCR adjustment factors are key components of our methodology for determining the outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases. In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27240 through 27242), we presented our proposed methodology for determining the outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases and proposed an outlier fixed-loss amount of $94,378. This proposed amount was significantly higher than the fixed-loss amount we finalized for FY 2023. For this reason, in the proposed rule (88 FR 27242), we solicited comments on our proposed methodology and the assumptions underlying it, and stated that we would consider these comments when finalizing our methodology in the final rule. As noted previously, we summarize and respond to the comments received in response to that solicitation later in this section. Later in this section of the Addendum, we present the detailed application of our finalized methodology based on consideration of the comments and our responses that are presented later in the section.

Comment: We received several comments expressing concern with our proposal to use FY 2022 data for purposes of the FY 2024 LTCH PPS ratesetting without any modifications to our usual ratesetting methodologies that would account for the impact of COVID–19 on the ratesetting data. Several commenters disagreed with our statement in the proposed rule that we do not believe there is a reasonable basis for us to assume that there will be a meaningful difference in the number of COVID–19 cases treated at LTCHs in FY 2024 relative to FY 2022, such that modifications to our usual ratesetting methodologies would be warranted.

Some commenters found this statement to be unsupported by the most recent data on COVID–19 hospitalizations. These commenters found that FY 2022 was the ''worst'' year for COVID–19 hospitalizations, citing surges in hospitalizations that occurred in January 2022 and again during the summer of 2022. The commenters pointed out, however, that since FY 2022 there has been a sustained decline in COVID–19 hospitalizations. The commenters believe the most recent hospitalization data provide a reasonable basis to assume that the number of COVID–19 cases treated at LTCHs in FY 2024 will be lower relative to FY 2022. Some commenters also cited the CDC's most recent monthly COVID–19 hospitalization forecast, which predicts that trends in numbers of future hospitalizations are uncertain or predicted to remain stable in all states and territories over the next four weeks, as evidence that the number of COVID–19 cases treated at LTCHs will be lower in FY 2024 relative to FY 2022.

Some commenters stated that the U.S. population's immunity to COVID–19 is higher than it was in FY 2022 due to increases in COVID–19 vaccination rates and increases in natural immunity from prior infection. These commenters believe this increase in immunity supports the assumption that there will be a decrease in the number of COVID–19 cases treated at LTCHs in FY 2024 relative to FY 2022. A few commenters stated that certain declarations (such as the World Health Organization (WHO) declaring an end to the COVID–19 global pandemic on May 5, 2023), certain measures (such as HHS allowing the COVID–19 PHE to expire on May 11, 2023), and other actions (such as the removal of the health care personnel vaccination requirements from the hospital conditions of participation), are inconsistent with CMS's stated belief that there is not a reasonable basis to assume that there will be a meaningful difference in the number of COVID–19 cases treated at LTCHs in FY 2024 relative to FY 2022.

Commenters cited several ways the COVID–19 PHE impacted the FY 2022 LTCH data that we proposed to use for FY 2024 ratesetting. For example, some commenters discussed how they believe the FY 2022 claims data reflect the significant number of patients treated at LTCHs in FY 2022 who were positive with COVID–19 or were suffering from varying diseases that resulted from a previous COVID–19 infection. Other commenters stated that the case-mix index and average length of stay for LTCHs rose significantly during the COVID–19 PHE, which resulted in major cost anomalies in the FY 2022 data. Since these commenters believe that there will be a decrease in the number of COVID–19 cases treated at LTCHs in FY 2024 relative to FY 2022, they argued CMS must make modifications to our usual LTCH PPS ratesetting methodologies to account for the effect of the COVID–19 PHE on the FY 2022 data ratesetting data.

Some commenters suggested that CMS use FY 2019 LTCH claims (the last fiscal year prior to the PHE) to determine the outlier fixed-loss amount. These commenters stated that given the COVID–19 impacts on hospitals and other providers have diminished and the PHE waivers have expired, it would be reasonable to assume that LTCH utilization in FY 2024 would more closely resemble pre-pandemic times. A commenter suggested blending FY 2019 and FY 2021 LTCH claims data for purposes of determining the outlier fixed-loss amount.

Several commenters expressed that during FY 2022, many IPPS hospitals

were operating beyond capacity and could not always offer an ICU placement to critical patients for a full three days. Due to the CARES Act waiver of the site neutral payment rate, which was in effect for all of FY 2022 and expired on May 11, 2023, commenters stated that there was no financial disincentive to LTCHs for admitting these types of patients (that is, patients that did not meet the statutory patient criteria to be excluded from the site-neutral payment rate in section 1886(m)(6) of the Act). Commenters stated that CMS is treating these types of cases in the FY 2022 MedPAR as site neutral payment rate cases and excluding them from the calculations of the FY 2024 outlier fixed-loss amount. However, commenters believe that in the absence of the COVID–19 PHE and the CARES Act waiver, these types of cases would have met the statutory patient criteria to be paid the standard Federal payment rate. Commenters admitted that there is not an easy way to identify these types of cases in the FY 2022 MedPAR file. Therefore, for purposes of determining the FY 2024 outlier fixed-loss amount, commenters stated that CMS should use all FY 2022 cases regardless of whether the case would have met the statutory patient criteria to be excluded from the site-neutral payment rate. Some commenters urged CMS to exclude dialysis patients from the FY 2022 claims data when determining the outlier fixed-loss amount. Commenters discussed the rising cost of treating dialysis patients at LTCHs in FY 2022 and the difficulties LTCHs faced in discharging dialysis patients into outpatient dialysis or home care, which commenters stated led to longer lengths of stay and resulted in higher charges. In describing the challenges and increased costs faced by LTCHs in providing dialysis services, some commenters noted that they have made modifications to their procurement of dialysis services provided to their patients, such as updating their dialysis vendor contracts with third party companies, hiring additional clinical staff to be able to provide the service ''in-house'' rather than under arrangements by third party companies, and making capital investments to purchase the necessary equipment. Some commenters stated that these issues are abating in their justification for why it would be appropriate for CMS to exclude claims for dialysis patients when calculating the fixed-loss threshold for FY 2024.

Numerous commenters made specific suggestions for modifying the proposed methodology for determining the FY 2024 outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases. Many of these comments objected to the charge inflation factor we proposed to apply under our methodology when determining the FY 2024 fixed-loss amount. Commenters stated that the proposed 1-year charge inflation factor of 13.56 percent was too high and is reflective of pandemic era inflationary trends. Some commenters stated the proposed charge inflation factor reflects the increase in patient complexity that occurred during the pandemic. Commenters believe it is unreasonable to assume that charges will continue to increase at this rate and therefore provided several modifications they believe CMS should adopt regarding the charge inflation factor.

A commenter stated that CMS should modify the statistical outlier trim used in our usual methodology for determining the charge inflation factor. The commenter believes that CMS should modify this trim by removing claims for providers with a calculated charge growth factor that exceeds 1 standard deviation from the mean provider charge growth factor during the FY 2021 and FY 2022 period. Some commenters requested that CMS exclude claims for dialysis patients from the calculation of the charge inflation factor.

Many commenters urged CMS to not base the charge inflation factor on the growth in charges that occurred from FY 2021 to FY 2022. Many commenters cited an AHA analysis that found that the average covered charge per case for LTCH PPS standard Federal payment rate cases during the first six months of FY 2023 only increased 2.5 percent compared to data from FY 2022. Many commenters supported setting the charge inflation factor based on this more recent data as they believe it would provide a more accurate indication of LTCH charges levels in FY 2024. Other commenters recommended that CMS return to the methodology employed prior to FY 2022 in which the charge inflation factor was set equal to the market basket update. A commenter suggested that CMS continue to use a charge inflation factor based on data prior to the COVID–19 PHE.

Response: We thank the commenters for their feedback. We acknowledge that COVID–19 hospitalizations have recently trended below FY 2022 levels, that a significant portion of the U.S. population has received at least one dose of the COVID–19 vaccination, and that certain COVID–19-related actions have subsequently been discontinued (such as the national COVID–19 PHE). We continue to believe there remains uncertainty regarding the impact that COVID–19 will have on LTCHs in FY 2024 relative to FY 2022.

We also acknowledge that it is likely that some LTCH cases in the FY 2022 MedPAR file would have met the site neutral exclusion criteria but for extenuating circumstances involving the COVID–19 PHE and the CARES Act waiver. However, we do not believe the number of these types of cases is significant enough to justify including all cases in our calculation of the outlier fixed-loss amount. In the FY 2022 MedPAR file, we found approximately 32 percent of cases did not meet the statutory patient criteria for exclusion from the site neutral payment rate (that is, were treated as site neutral payment rate cases for the FY 2024 ratesetting in the proposed rule). This percentage of cases is not significantly different than the percentage of a site neutral payment rate cases we identified in years prior to the PHE. For example, in the FY 2018 and FY 2019 MedPAR files, respectively, we found approximately 29 percent and 25 percent of cases did not meet the statutory patient criteria for exclusion from the site neutral payment rate. Furthermore, the commenters did not describe why these types of cases differ significantly enough from the cases we treat as standard payment rate cases for the FY 2024 ratesetting such that including them in the calculation of the outlier fixed-loss amount would have a material effect on the resulting outlier fixed-loss amount. For these reasons, we disagree with commenters that it would be appropriate to include all cases in the FY 2022 MedPAR claims data in the determination of the FY 2024 outlier fixed-loss amount.

We thank the commenters for the suggestion to exclude dialysis claims when calculating the fixed-loss threshold. However, as discussed in greater detail later in the section, we are required by section 1886(m)(7) of the Act to establish a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2024 that would result in total estimated outlier payments being equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases. We acknowledge that the factors that led to increased costs to treat dialysis patients in FY 2022 may be lessening for some LTCHs. However, we expect LTCHs will continue to treat such patients, and as such, those cases would continue to be eligible for high cost outlier payments. For example, some commenters stated that LTCHs are transitioning back to their prior admissions practices, and a commenter indicated that the ''in-hospital'' dialysis

issues that contributed to the increases in dialysis costs experienced in the last 2 years are not limited to COVID–19 surge periods. Although commenters provided evidence on why dialysis cases were costly in FY 2022, we do not believe the commenters provided sufficient evidence to support why costs for these types of patients would differ significantly from FY 2022 to FY 2024, such that it would be appropriate to exclude them from our calculations. Therefore, we believe it would not be appropriate to completely exclude certain high cost cases from our payment model for determining the outlier fixed-loss amount. For these reasons, we are not adopting commenters' suggestion to exclude dialysis claims when calculating the fixed-loss threshold for FY 2024.

We appreciate feedback and suggestions commenters provided on the proposed charge inflation factor. In light of these comments, we examined the increase in LTCHs' charges between FY 2022 and FY 2023 using the most recent available data for those years. Specifically, we calculated a charge inflation factor based on the average covered charge in the March 2023 update of the FY 2023 MedPAR claims compared to the average covered charge in the March 2022 update of the FY 2022 MedPAR claims using our established charge inflation methodology. Based on this analysis, we found that charges for LTCH PPS standard Federal payment rate cases have increased approximately 6 percent during the first six months of FY 2023 compared to the first six months of FY 2022. After reviewing this more recently available data on LTCH charges and considering the broader economic slowdown in inflation, we agree with commenters that it is not likely that charges will continue to increase at the rates observed during the FY 2021 to FY 2022 period. For this reason, in this final rule and under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of the BIPA, we are modifying our proposed methodology for determining the charge inflation factor for FY 2024 by setting the charge inflation factor based on data prior to the COVID–19 PHE, as suggested by a commenter. Specifically, we are modifying our methodology to determine the FY 2024 outlier fixed-loss amount by applying the same charge inflation factor that we utilized in both the FY 2022 final rule (86 FR 45565) and the FY 2023 final rule (87 FR 49446). This 2-year charge inflation factor of 1.125133 is based on the 6.0723 percent growth in charges that occurred between FY 2018 and FY 2019, which is the last 1-year period prior to the COVID–19 PHE. We note that this charge inflation factor would be similar to a charge inflation factor based on the percentage growth in charges for the first six months of FY 2023 (discussed previously). We believe it is most appropriate to use the factor of 1.125133 because it is based on two full years of publicly available claims data.

To be consistent with this modification to the charge inflation factor, we believe it is also appropriate to use a CCR adjustment factor based on data prior to the COVID–19 PHE. (As explained later in this section, our methodology for determining the outlier fixed-loss amount includes a charge inflation factor, and a CCR adjustment factor.) Therefore, under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of the BIPA, we are also modifying our methodology in this final rule to apply the same CCR adjustment factor that we utilized in both the FY 2022 final rule (86 FR 45565) and the FY 2023 final rule (87 FR 49447) to determine the FY 2024 outlier fixed-loss amount. This CCR adjustment factor of 0.961554 is based on the change in CCRs that occurred between the March 2019 PSF and the March 2020 PSF, which is the last 1-year period prior to the COVID–19 PHE. We note that this CCR adjustment factor is considerably lower than CCR adjustment factor of 0.996923 calculated using the most recently available data and our usual methodology.

Therefore, in this final rule, after consideration of public comments and for the reasons discussed previously, we are using the FY 2022 MedPAR claims file and the FY 2021 HCRIS for purposes of the FY 2024 LTCH PPS ratesetting, as proposed. However, we are making modifications to our usual ratesetting methodology for determining the FY 2024 outlier fixed-loss amount for LTCH PPS standard Federal payment rate cases by modifying the charge inflation factor and the CCR adjustment factor (as described earlier). As stated previously, later in this section of the Addendum, we present the detailed application of our finalized methodology based on consideration of the comments and our responses.

Comment: Some commenters stated that CMS needs to better account for the impact of the dual rate payment structure on its methodology for determining the outlier fixed-loss amount for standard Federal rate cases. These commenters stated that the number of LTCH cases used in determining the fixed-loss amount has decreased since the implementation of the dual payment rate structure due to LTCH closures and because only standard Federal payment rate cases are used in the calculations. The commenter believes utilizing these relatively smaller datasets has led to fluctuations in the fixed-loss amount that CMS needs to address.

Some commenters also stated that the ICU criterion and ventilator criterion exceptions to site neutral payment rate have resulted in a high concentration of LTCH discharges assigned to only a few MS–LTC–DRGs. A commenter stated their belief that this concentration is one of the main factors causing the increase in the fixed-loss amount. The commenter explained that when there is a significant concentration of cases in an MS–LTC–DRG, there is a wider range of costs among the cases assigned to the MS–LTC–DRG. The commenter stated that when this occurs it is more likely that there will be high cost outlier cases in that MS–LTC–DRG. The commenter proposed a technically complex modification to the CMS methodology for determining the FY 2024 outlier amount that the commenter believes would address this. The modification involved regrouping cases with relatively long length of stays to a new temporary MS–LTC–DRG, calculating an alternative set of relative weights for all MS–LTC–DRGs using these regrouped cases, and then modelling payments for purposes of determining the high-cost outlier threshold using these alternative relative weights.

A commenter stated that CMS should consider setting the FY 2024 fixed-loss amount by looking at the previous three years high-cost outlier cases and developing a formula that adjusts with population health demographics, medical technology advancements, and cost variables.

Response: We thank the commenters for this feedback. We note that comments did not provide specific recommendations on how CMS could address the decreasing number of cases available for LTCH PPS ratesetting or provide specific details on how CMS could develop a formula to adjust for the various factors noted. Without this information, we are unable to fully evaluate these suggested modifications to our methodology for this final rule; however, we may consider these comments for future rulemaking.

We also acknowledge the commenters' concern regarding the potential impact that the high concentration of LTCH discharges in certain MS–LTC–DRGs may have on LTCH PPS outlier payments. We may also consider this issue for future rulemaking. With regards to the specific

modification presented by the commenter, we do not believe it would be appropriate to use an alternative set of relative weights for purposes of calculating the FY 2024 outlier fixed-loss amount that differ from the relative weights that will be used to make payments. We are required by statute to establish an outlier fixed-loss amount that we project will result in total estimated outlier payments being equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases. We do not believe we can accurately model FY 2024 LTCH PPS payments without using the relative weights that we are finalizing for FY 2024.

Comment: Many commenters stated that the proposed increase to the outlier fixed-loss amount would have devastating financial impacts on LTCHs and lead to LTCH closures. Commenters also stated that the proposed outlier fixed-loss amount would lead to LTCHs avoiding high-cost cases and consequently creating an access barrier for the sickest of patients and leading to overcrowding at IPPS hospital ICUs. Some commenters stated that the proposed increase to the outlier fixed-loss amount violates CMS's principle for stability and predictability in reimbursement rates. A commenter stated that to the extent increases in the fixed-loss threshold are necessary, they should be limited to no more than the market basket percent increase in any given year. Another commenter stated that CMS should uses its regulatory authority to set the FY 2024 outlier fixed-loss amount equal to the FY 2023 outlier fixed-loss amount. Another commenter expressed that CMS should phase in the increase to the fixed-loss amount over a multi-year period.

Response: We thank the commenters for their feedback. We acknowledged in the proposed rule that the proposed increase to the fixed-loss amount was substantial and sought comments on our proposed methodology and the assumptions underlying it to take into consideration when finalizing our methodology in the final rule. However, we are required by section 1886(m)(7) of the Act to establish a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2024 that would result in total estimated outlier payments being equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Therefore, we do not agree with commenters that CMS should use its regulatory authority to establish an alternative outlier fixed-loss amount that would not be projected to result in total estimated outlier payments being equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases. After consideration of all comments that discussed approaches that commenters believe would result in more accurate estimations of the total outlier payments and/or the total LTCH PPS payments for LTCH PPS standard Federal payment rate cases in FY 2024, as described in greater detail later in this section, we are finalizing a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2024 that is notably lower than in the proposed rule. Although this fixed-loss amount for FY 2024 is still considerably higher than the current fixed-loss amount, we believe this increase will meet the 7.975 percent target required by section 1886(m)(7) of the Act. As we discussed in the IPPS/LTCH PPS proposed rule (88 FR 27242), we estimate that high cost outlier payments significantly exceeded the statutory 7.975 percent target in both FY 2021 and FY 2022. Using the FY 2021 and FY 2022 MedPAR files, we currently estimate that actual high cost outlier payments accounted for 11.1 and 11.9 percent of total LTCH PPS standard Federal payment rate payments in FY 2021 and FY 2022, respectively. We also currently project that in FY 2023, high cost outlier payments will be approximately 10.9 percent of the estimated total LTCH PPS standard Federal payment rate payments.

In summary, we are finalizing our proposed methodology for determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2024, with modifications. In this section of this Addendum, we present the detailed application of our finalized methodology, including the modifications discussed earlier.

When we implemented the LTCH PPS, we established a fixed-loss amount so that total estimated outlier payments are projected to equal 8 percent of total estimated payments (that is, the target percentage) under the LTCH PPS (67 FR 56022 through 56026). When we implemented the dual rate LTCH PPS payment structure beginning in FY 2016, we established that, in general, the historical LTCH PPS HCO policy would continue to apply to LTCH PPS standard Federal payment rate cases. That is, the fixed-loss amount for LTCH PPS standard Federal payment rate cases would be determined using the LTCH PPS HCO policy adopted when the LTCH PPS was first implemented, but we limited the data used under that policy to LTCH cases that would have been LTCH PPS standard Federal payment rate cases if the statutory changes had been in effect at the time of those discharges.

To determine the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases, we estimate outlier payments and total LTCH PPS payments for each LTCH PPS standard Federal payment rate case (or for each case that would have been an LTCH PPS standard Federal payment rate case if the statutory changes had been in effect at the time of the discharge) using claims data from the MedPAR files. In accordance with § 412.525(a)(2)(ii), the applicable fixed-loss amount for LTCH PPS standard Federal payment rate cases results in estimated total outlier payments being projected to be equal to 7.975 percent of projected total LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49448), we discussed an LTCH (CMS certification number (CCN) 312024) whose abnormal charging practices in FY 2021 led to the LTCH receiving an excessive amount of high cost outlier payments. In that rule, we stated our belief, based on information we received from the provider, that these abnormal charging practices would not persist into FY 2023. Therefore, we did not include its cases in our model for determining the FY 2023 outlier fixed-loss amount. The FY 2022 MedPAR claims also reflect the abnormal charging practices of this LTCH. In the March 2023 update of the FY 2022 MedPAR file, we identified 166 LTCH PPS standard Federal payment rate cases for this LTCH. Of these 166 cases, 118 of the cases had charges that were exactly or within ten dollars of $10 million. Due to the abnormal charges reflected in this LTCH's FY 2022 claims, we do not believe it would be appropriate to use these claims in determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2024. Therefore, as we proposed, we removed claims from CCN 312024 when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2024.

(1) Charge Inflation Factor for Use in Determining the Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2024

Under the LTCH PPS, the cost of each claim is estimated by multiplying the charges on the claim by the provider's CCR. Due to the lag time in the availability of claims data, when estimating costs for the upcoming payment year we typically inflate the charges from the claims data by a uniform factor.

For greater accuracy in calculating the fixed-loss amount, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45562 through 45566), we finalized a technical change to our methodology for determining the charge inflation factor. Similar to the method used under the IPPS hospital payment methodology (as discussed in section II.A.4.i.(2). of this Addendum), our methodology determines the LTCH charge inflation factor based on the historical growth in charges for LTCH PPS standard Federal payment rate cases, calculated using historical MedPAR claims data.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27240 through 27241) we described our methodology for computing the charge inflation factor in detail. Using this methodology and the most recently available data, we computed a proposed 2-year charge inflation factor of 1.289703. We proposed to inflate the billed charges obtained from the FY 2022 MedPAR file by this 2-year charge inflation factor of 1.289703 when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2024.

As we discussed earlier in this section, many commenters objected to this proposed charge inflation factor. After considering these comments, we are modifying our proposed methodology for determining the charge inflation factor by setting the charge inflation factor based on data prior to the COVID–19 PHE. Specifically, to determine the FY 2024 outlier fixed-loss amount we applied the same charge inflation factor determined in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45565), which was based on the growth in charges that occurred between FY 2018 and FY 2019 (the last 1-year period prior to the COVID–19 PHE). The rate of LTCH charge growth determined in the FY 2022 IPPS/LTCH PPS final rule, based on the growth in charges that occurred between FY 2018 and FY 2019, was 6.0723 percent. This results in a 1-year charge inflation factor of 1.060723, and a 2-year charge inflation factor of 1.125133 (calculated by squaring the 1-year factor). Therefore, for this final rule, we inflated the billed charges obtained from the FY 2022 MedPAR file by this 2-year charge inflation factor of 1.125133 when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2024.

We note that, using data we would ordinarily use for purposes of determining the charge inflation factor for this final rule, which is FY 2021 MedPAR claims data from the March 2022 update and FY 2022 MedPAR claims data from the March 2023 update, we calculated a 2-year charge inflation factor of 1.29349.

(2) CCRs for Use in Determining the Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2024

For greater accuracy in calculating the fixed-loss amount, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45562 through 45566), we finalized a technical change to our methodology for determining the CCRs used to calculate the fixed-loss amount. Similar to the methodology used for IPPS hospitals (as discussed in section II.A.4.i.(2). of this Addendum), our methodology adjusts CCRs obtained from the best available PSF data by an adjustment factor that is calculated based on historical changes in the average case-weighted CCR for LTCHs. We believe these adjusted CCRs more accurately reflect CCR levels in the upcoming payment year because they account for historical changes in the relationship between costs and charges for LTCHs.

In the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27241 through 27242) we described our methodology for computing the CCR adjustment factor in detail. Using this methodology and the most recently available data, we computed a proposed 1-year national CCR adjustment factor of 0.975513. When calculating the proposed fixed-loss amount for FY 2024, we proposed to assign the statewide average CCR for the upcoming fiscal year to all providers who were assigned the statewide average in the December 2022 PSF or whose CCR was missing in the December 2022 PSF. For all other providers, we proposed to multiply their CCR from the December 2022 PSF by the proposed 1-year national CCR adjustment factor of 0.975513.

As we discussed earlier in this section, after consideration of comments received, we are modifying our methodology for determining the charge inflation factor for this final rule by setting the charge inflation factor based on data prior to the COVID–19 PHE. As discussed previously, to be consistent with this modification, we believe it is also appropriate to use a CCR adjustment factor based on data prior to the COVID–19 PHE. Therefore, we are modifying our methodology in this final rule to apply the same CCR adjustment factor that we utilized in both the FY 2022 final rule (86 FR 45565) and the FY 2023 final rule (87 FR 49447) to determine the FY 2024 outlier fixed-loss amount. This CCR adjustment factor of 0.961554 is based on the change in CCRs that occurred between the March 2019 PSF and the March 2020 PSF, which is the last 1-year period prior to the COVID–19 PHE.

Therefore, for this final rule, when calculating the fixed-loss amount for FY 2024, we assigned the statewide average CCR for the upcoming fiscal year to all providers who were assigned the statewide average in the March 2023 PSF or whose CCR was missing in the March 2023 PSF. For all other providers, we multiplied their CCR from the March 2023 PSF by the 1-year national CCR adjustment factor of 0.961554.

We note that, using the data we would ordinarily use for purposes of determining the CCR for this final rule, which is the March 2022 PSF and the March 2023 PSF, we calculated a 1-year national CCR adjustment factor of 0.996923.

(3) Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2024

In this final rule, for FY 2024, using the best available data and the steps described previously, we calculated a fixed-loss amount that would maintain estimated HCO payments at the projected 7.975 percent of total estimated LTCH PPS payments for LTCH PPS standard Federal payment rate cases as required by section 1886(m)(7) of the Act and in accordance with § 412.525(a)(2)(ii) (based on the payment rates and policies for these cases presented in this final rule). Consistent with our historical practice, we use the best available LTCH claims data and CCR data, if applicable, when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2024 in the final rule. Therefore, based on LTCH claims data from the March 2023 update of the FY 2022 MedPAR file adjusted for charge inflation and adjusted CCRs from the March 2023 update of the PSF, under the broad authority of section 123(a)(1) of the BBRA and section 307(b)(1) of the BIPA, we are establishing a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2024 of $59,873 that will result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2024 payments for such cases. We are continuing, as proposed, to make an additional HCO payment for the cost of an LTCH PPS standard Federal payment rate case that exceeds the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the adjusted LTCH PPS standard Federal payment rate payment and the fixed-

loss amount for LTCH PPS standard Federal payment rate cases of $59,873).

4. High-Cost Outlier Payments for Site Neutral Payment Rate Cases

When we implemented the application of the site neutral payment rate in FY 2016, in examining the appropriate fixed-loss amount for site neutral payment rate cases issue, we considered how LTCH discharges based on historical claims data would have been classified under the dual rate LTCH PPS payment structure and the CMS' Office of the Actuary projections regarding how LTCHs will likely respond to our implementation of policies resulting from the statutory payment changes. We again relied on these considerations and actuarial projections in FY 2017 and FY 2018 because the historical claims data available in each of these years were not all subject to the LTCH PPS dual rate payment system. Similarly, for FYs 2019 through 2023, we continued to rely on these considerations and actuarial projections because, due to the transitional blended payment policy for site neutral payment rate cases and the provisions of section 3711(b)(2) of the CARES Act, the historical claims data available in each of these years were not subject to the full effect of the site neutral payment rate.

For FYs 2016 through 2023, our actuaries projected that the proportion of cases that would qualify as LTCH PPS standard Federal payment rate cases versus site neutral payment rate cases under the statutory provisions would remain consistent with what is reflected in the historical LTCH PPS claims data. Although our actuaries did not project an immediate change in the proportions found in the historical data, they did project cost and resource changes to account for the lower payment rates. Our actuaries also projected that the costs and resource use for cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and would likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what is found based on the historical data. As discussed in the FY 2016 IPPS/LTCH PPS final rule (80 FR 49619), this actuarial assumption is based on our expectation that site neutral payment rate cases would generally be paid based on an IPPS comparable per diem amount under the statutory LTCH PPS payment changes that began in FY 2016, which, in the majority of cases, is much lower than the payment that would have been paid if these statutory changes were not enacted. In light of these projections and expectations, we discussed that we believed that the use of a single fixed-loss amount and HCO target for all LTCH PPS cases would be problematic. In addition, we discussed that we did not believe that it would be appropriate for comparable LTCH PPS site neutral payment rate cases to receive dramatically different HCO payments from those cases that would be paid under the IPPS (80 FR 49617 through 49619 and 81 FR 57305 through 57307). For those reasons, we stated that we believed that the most appropriate fixed-loss amount for site neutral payment rate cases for FYs 2016 through 2023 would be equal to the IPPS fixed-loss amount for that particular fiscal year. Therefore, we established the fixed-loss amount for site neutral payment rate cases as the corresponding IPPS fixed-loss amounts for FYs 2016 through 2023. In particular, in FY 2023, we established the fixed-loss amount for site neutral payment rate cases as the FY 2023 IPPS fixed-loss amount of $38,788 (87 FR 49450, as corrected in 87 FR 66564).

As discussed in section I.E. of the preamble of this final rule, we are finalizing our proposal to use FY 2022 data in the FY 2024 LTCH PPS ratesetting. Section 3711(b)(2) of the CARES Act, which provided a waiver of the application of the site neutral payment rate for LTCH cases admitted during the COVID–19 PHE period, was in effect for the entirety of FY 2022. Therefore, all LTCH PPS cases in FY 2022 were paid the LTCH PPS standard Federal rate regardless of whether the discharge met the statutory patient criteria. Because not all FY 2022 claims in the data used for this final rule were subject to the site neutral payment rate, we continue to rely on the same considerations and actuarial projections used in FYs 2016 through 2023 when developing a fixed-loss amount for site neutral payment rate cases for FY 2024. Our actuaries continue to project that the costs and resource use for FY 2024 cases paid at the site neutral payment rate would likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG, regardless of whether the proportion of site neutral payment rate cases in the future remains similar to what was found based on the historical data. (Based on the FY 2022 LTCH claims data used in the development of this final rule, if the provisions of the CARES Act had not been in effect, approximately 68 percent of LTCH cases would have been paid the LTCH PPS standard Federal payment rate and approximately 32 percent of LTCH cases would have been paid the site neutral payment rate for discharges occurring in FY 2022.)

For these reasons, we continue to believe that the most appropriate fixed-loss amount for site neutral payment rate cases for FY 2024 is the IPPS fixed-loss amount for FY 2024. Therefore, for FY 2024, as we proposed, we are establishing that the applicable HCO threshold for site neutral payment rate cases is the sum of the site neutral payment rate for the case and the IPPS fixed-loss amount. That is, we are establishing a fixed-loss amount for site neutral payment rate cases of $42,750, which is the same FY 2024 IPPS fixed-loss amount discussed in section II.A.4.i.(2). of this Addendum. Accordingly, under this policy, for FY 2024, we will calculate an HCO payment for site neutral payment rate cases with costs that exceed the HCO threshold amount that is equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold (the sum of the site neutral payment rate payment and the fixed-loss amount for site neutral payment rate cases of $42,750).

In establishing an HCO policy for site neutral payment rate cases, we established a budget neutrality adjustment under § 412.522(c)(2)(i). We established this requirement because we believed, and continue to believe, that the HCO policy for site neutral payment rate cases should be budget neutral, just as the HCO policy for LTCH PPS standard Federal payment rate cases is budget neutral, meaning that estimated site neutral payment rate HCO payments should not result in any change in estimated aggregate LTCH PPS payments.

To ensure that estimated HCO payments payable to site neutral payment rate cases in FY 2024 would not result in any increase in estimated aggregate FY 2024 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce site neutral payment rate payments by 5.1 percent to account for the estimated additional HCO payments payable to those cases in FY 2024. Consistent with our historical practice, as we proposed, we are continuing this policy.

As discussed earlier, consistent with the IPPS HCO payment threshold, we estimate the fixed-loss threshold would

result in FY 2024 HCO payments for site neutral payment rate cases to equal 5.1 percent of the site neutral payment rate payments that are based on the IPPS comparable per diem amount. As such, to ensure estimated HCO payments payable for site neutral payment rate cases in FY 2024 would not result in any increase in estimated aggregate FY 2024 LTCH PPS payments, under the budget neutrality requirement at § 412.522(c)(2)(i), it is necessary to reduce the site neutral payment rate amount paid under § 412.522(c)(1)(i) by 5.1 percent to account for the estimated additional HCO payments payable for site neutral payment rate cases in FY 2024. To achieve this, for FY 2024, as we proposed, we are applying a budget neutrality factor of 0.949 (that is, the decimal equivalent of a 5.1 percent reduction, determined as 1.0 − 5.1/100 = 0.949) to the site neutral payment rate for those site neutral payment rate cases paid under § 412.522(c)(1)(i). We note that, consistent with our current policy, this HCO budget neutrality adjustment will not be applied to the HCO portion of the site neutral payment rate amount (81 FR 57309).

We did not receive any public comments on our proposals and are finalizing our proposals as described previously, without modification.

E. Update to the IPPS Comparable Amount to Reflect the Statutory Changes to the IPPS DSH Payment Adjustment Methodology

In the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766), we established a policy to reflect the changes to the Medicare IPPS DSH payment adjustment methodology made by section 3133 of the Affordable Care Act in the calculation of the ''IPPS comparable amount'' under the SSO policy at § 412.529 and the ''IPPS equivalent amount'' under the site neutral payment rate at § 412.522. Historically, the determination of both the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' includes an amount for inpatient operating costs ''for the costs of serving a disproportionate share of low-income patients.'' Under the statutory changes to the Medicare DSH payment adjustment methodology that began in FY 2014, in general, eligible IPPS hospitals receive an empirically justified Medicare DSH payment equal to 25 percent of the amount they otherwise would have received under the statutory formula for Medicare DSH payments prior to the amendments made by the Affordable Care Act. The remaining amount, equal to an estimate of 75 percent of the amount that otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured and any additional statutory adjustment, is made available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has uncompensated care. The additional uncompensated care payments are based on the hospital's amount of uncompensated care for a given time period relative to the total amount of uncompensated care for that same time period reported by all IPPS hospitals that receive Medicare DSH payments.

To reflect the Medicare DSH payment adjustment methodology statutory changes in section 3133 of the Affordable Care Act in the calculation of the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS, we stated in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50766) that we will include a reduced Medicare DSH payment amount that reflects the projected percentage of the payment amount calculated based on the statutory Medicare DSH payment formula prior to the amendments made by the Affordable Care Act that will be paid to eligible IPPS hospitals as empirically justified Medicare DSH payments and uncompensated care payments in that year (that is, a percentage of the operating Medicare DSH payment amount that has historically been reflected in the LTCH PPS payments that are based on IPPS rates). We also stated, in the FY 2014 IPPS/LTC PPS final rule (78 FR 50766), that the projected percentage will be updated annually, consistent with the annual determination of the amount of uncompensated care payments that will be made to eligible IPPS hospitals. We believe that this approach results in appropriate payments under the LTCH PPS and is consistent with our intention that the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS closely resemble what an IPPS payment would have been for the same episode of care, while recognizing that some features of the IPPS cannot be translated directly into the LTCH PPS (79 FR 50766 through 50767).

As discussed in the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27244), for FY 2024, based on the most recent data available at that time, we proposed to establish that the calculation of the ''IPPS comparable amount'' under § 412.529 would include an applicable operating Medicare DSH payment amount that is equal to 74.28 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula absent the amendments made by the Affordable Care Act. Furthermore, consistent with our historical practice, we proposed that, if more recent data became available, we would use that data to determine the applicable operating Medicare DSH payment amount used to calculate the ''IPPS comparable amount'' in the final rule.

We did not receive any public comments in response to our proposal, and as such are finalizing this proposal. However, as we proposed, we are determining the applicable operating Medicare DSH payment amount used to calculate the ''IPPS comparable amount'' in this final rule using more recent data. For FY 2024, as discussed in greater detail in section IV.E.2.b. of the preamble of this final rule, based on the most recent data available, our estimate of 75 percent of the amount that would otherwise have been paid as Medicare DSH payments (under the methodology outlined in section 1886(r)(2) of the Act) is adjusted to 59.29 percent of that amount to reflect the change in the percentage of individuals who are uninsured. The resulting amount is then used to determine the amount available to make uncompensated care payments to eligible IPPS hospitals in FY 2024. In other words, the amount of the Medicare DSH payments that would have been made prior to the amendments made by the Affordable Care Act is adjusted to 44.47 percent (the product of 75 percent and 59.29 percent) and the resulting amount is used to calculate the uncompensated care payments to eligible hospitals. As a result, for FY 2024, we project that the reduction in the amount of Medicare DSH payments pursuant to section 1886(r)(1) of the Act, along with the payments for uncompensated care under section 1886(r)(2) of the Act, will result in overall Medicare DSH payments of 69.47 percent of the amount of Medicare DSH payments that would otherwise have been made in the absence of the amendments made by the Affordable Care Act (that is, 25 percent + 44.47 percent = 69.47 percent).

Therefore, for FY 2024, consistent with our proposal, we are establishing that the calculation of the ''IPPS comparable amount'' under § 412.529 will include an applicable operating Medicare DSH payment amount that is equal to 69.47 percent of the operating Medicare DSH payment amount that would have been paid based on the statutory Medicare DSH payment formula absent the amendments made by the Affordable Care Act.

F. Computing the Adjusted LTCH PPS Federal Prospective Payments for FY 2024

Section 412.525 sets forth the adjustments to the LTCH PPS standard Federal payment rate. Under the dual rate LTCH PPS payment structure, only LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate are paid based on the LTCH PPS standard Federal payment rate. Under § 412.525(c), the LTCH PPS standard Federal payment rate is adjusted to account for differences in area wages by multiplying the labor-related share of the LTCH PPS standard Federal payment rate for a case by the applicable LTCH PPS wage index (the final FY 2024 values are shown in Tables 12A through 12B listed in section VI. of this Addendum and are available via the internet on the CMS website). The LTCH PPS standard Federal payment rate is also adjusted to account for the higher costs of LTCHs located in Alaska and Hawaii by the applicable COLA factors (the final FY 2024 factors are shown in the chart in section V.C. of this Addendum) in accordance with § 412.525(b). In this final rule, we are establishing an LTCH PPS standard Federal payment rate for FY 2024 of $48,116.62, as discussed in section V.A. of this Addendum. We illustrate the methodology to adjust the LTCH PPS standard Federal payment rate for FY 2024, applying our finalized LTCH PPS amounts for the standard Federal payment rate, MS–LTC–DRG relative weights, and wage index in the following example:

Example:

During FY 2024, a Medicare discharge that meets the criteria to be excluded from the site neutral payment rate, that is, an LTCH PPS standard Federal payment rate case, is from an LTCH that is located in CBSA 16984, which has a FY 2024 LTCH PPS wage index value of 1.0419 (as shown in Table 12A listed in section VI. of this Addendum). The Medicare patient case is classified into MS–LTC–DRG 189 (Pulmonary Edema & Respiratory Failure), which has a relative weight for FY 2024 of 0.9416 (as shown in Table 11 listed in section VI. of this Addendum). The LTCH submitted quality reporting data for FY 2024 in accordance with the LTCH QRP under section 1886(m)(5) of the Act.

To calculate the LTCH's total adjusted Federal prospective payment for this Medicare patient case in FY 2024, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted FY 2024 LTCH PPS standard Federal payment rate ($48,116.62) by the labor-related share (68.5 percent) and the wage index value (1.0419). This wage-adjusted amount was then added to the nonlabor-related portion of the unadjusted LTCH PPS standard Federal payment rate (31.5 percent; adjusted for cost of living, if applicable) to determine the adjusted LTCH PPS standard Federal payment rate, which is then multiplied by the MS–LTC–DRG relative weight (0.9416) to calculate the total adjusted LTCH PPS standard Federal prospective payment for FY 2024 ($46,606.98). The table illustrates the components of the calculations in this example.

Unadjusted LTCH PPS Standard Federal Prospective Payment Rate	$48,116.62
Labor-Related Share	x 0.685
Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate	= $32,959.88
Wage Index (CBSA 16984)	x 1.0419
Wage-Adjusted Labor Share of the LTCH PPS Standard Federal Payment Rate	= $34,340.90
Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate ($48,116.62 x 0.315)	+ $15,156.74
Adjusted LTCH PPS Standard Federal Payment Amount	= $49,497.64
MS-LTC-DRG 189 Relative Weight	x 0.9416
Total Adjusted LTCH PPS Standard Federal Prospective Payment	= $46,606.98

VI. Tables Referenced in This Final Rule Generally Available Through the internet on the CMS website

This section lists the tables referred to throughout the preamble of this final rule and in the Addendum. In the past, a majority of these tables were published in the **Federal Register** as part of the annual proposed and final rules. However, similar to FYs 2012 through 2023, for the FY 2024 rulemaking cycle, the IPPS and LTCH PPS tables will not be published in the **Federal Register** in the annual IPPS/LTCH PPS proposed and final rules and will be on the CMS website. Specifically, all IPPS tables listed in the final rule, with the exception of IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E, will generally be available on the CMS website. IPPS Tables 1A, 1B, 1C, and 1D, and LTCH PPS Table 1E are displayed at the end of this section and will continue to be published in the **Federal Register** as part of the annual proposed and final rules. For additional discussion of the information included in the IPPS and LTCH PPS tables associated with the IPPS/LTCH PPS proposed and final rules, as well as prior changes to the information included in these tables, we refer readers to the FY 2023 IPPS/LTCH PPS final rule (87 FR 49451 through 49453).

Tables 7A and 7B historically contained the Medicare prospective payment system selected percentile lengths of stay for the MS–DRGs for the prior year and upcoming fiscal year. We note, in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49452), we finalized beginning with FY 2023, to provide the percentile length of stay information previously included in Tables 7A and 7B in the supplemental AOR/BOR data file. The AOR/BOR files can be found on the FY 2024 IPPS final rule home page on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

As discussed in section II.E. of the preamble to this final rule, we made available separate tables listing the ICD–10–CM codes, ICD–10–PCS codes, and/or MS–DRGs related to the analyses of the cost criterion for the FY 2024 new technology add-on payment applications in Table 10 associated with the proposed rule. For this final rule, we have not updated these tables and therefore are not issuing Table 10 with this final rule.

After hospitals have been given an opportunity to review and correct their calculations for FY 2024, we will post Table 15 (which will be available via the CMS website) to display the final FY 2024 readmissions payment adjustment factors that will be applicable to discharges occurring on or after October 1, 2023. We expect Table 15 will be posted on the CMS website in the Fall 2023.

Readers who experience any problems accessing any of the tables that are posted on the CMS websites identified

in this final rule should contact Michael Treitel at (410) 786–4552.

The following IPPS tables for this final rule are generally available on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*. Click on the link on the left side of the screen titled ''FY 2024 IPPS Final Rule Home Page'' or ''Acute Inpatient-Files-for Download.''

Table 2.—Case-Mix Index and Wage Index Table by CCN—FY 2024 Final Rule

Table 3.—Wage Index Table by CBSA—FY 2024 Final Rule

Table 4A.—List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2024 Final Rule

Table 4B.—Counties Redesignated under Section 1886(d)(8)(B) of the Act (LUGAR Counties)—FY 2024 Final Rule

Table 5.—List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2024 Final Rule

Table 6A.—New Diagnosis Codes—FY 2024

Table 6B.—New Procedure Codes—FY 2024

Table 6C.—Invalid Diagnosis Codes—FY 2024

Table 6D.—Invalid Procedure Codes—FY 2024

Table 6E.—Revised Diagnosis Code Titles—FY 2024

Table 6F.—Revised Procedure Code Titles—FY 2024

Table 6G.1.—Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2024

Table 6G.2.—Principal Diagnosis Order Additions to the CC Exclusions List—FY 2024

Table 6H.1.—Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2024

Table 6H.2.—Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2024

Table 6I.—Complete MCC List—FY 2024

Table 6I.1.—Additions to the MCC List—FY 2024

Table 6I.2.—Deletions to the MCC List—FY 2024

Table 6J.—Complete CC List—FY 2024

Table 6J.1.—Additions to the CC List—FY 2024

Table 6J.2.—Deletions to the CC List—FY 2024

Table 6K.—Complete List of CC Exclusions—FY 2024

Table 8A.—Final FY 2024 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)

Table 8B.—Final FY 2024 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals

Table 16A.—Updated Proxy Hospital Value-Based Purchasing (VBP) Program Adjustment Factors for FY 2024

Table 18.—FY 2024 Final Rule Medicare DSH Uncompensated Care Payment Factor 3 (Final Methodology)

The following LTCH PPS tables for this FY 2024 final rule are available through the internet on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/LongTermCareHospitalPPS/index.html* under the list item for Regulation Number CMS–1785–F:

Table 8C.—Final FY 2024 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)

Table 11.—MS–LTC–DRGs, Relative Weights, Geometric Average Length of Stay, and Short-Stay Outlier (SSO) Threshold for LTCH PPS Discharges Occurring from October 1, 2023, through September 30, 2024

Table 12A.—LTCH PPS Wage Index for Urban Areas for Discharges Occurring from October 1, 2023, through September 30, 2024

Table 12B.—LTCH PPS Wage Index for Rural Areas for Discharges Occurring from October 1, 2023, through September 30, 2024

TABLE 1A.— NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (67.6 PERCENT LABOR SHARE/32.4 PERCENT NONLABOR SHARE IF WAGE INDEX IS GREATER THAN 1)--FY 2024

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 3.1 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0. 625 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 2.275 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.2 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$4,392.49	$2,105.28	$4,287.05	$2,054.74	$4,357.34	$2,088.43	$4,251.90	$2,037.89

TABLE 1B.— NATIONAL ADJUSTED OPERATING STANDARDIZED AMOUNTS, LABOR/NONLABOR (62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE IF WAGE INDEX IS LESS THAN OR EQUAL TO 1)—FY 2024

Hospital Submitted Quality Data and is a Meaningful EHR User (Update = 3.1 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.625 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 2.275 Percent)		Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User (Update = -0.2 Percent)	
Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
$4,028.62	$2,469.15	$3,931.91	$2,409.88	$3,996.38	$2,449.39	$3,899.67	$2,390.12

TABLE 1C.— ADJUSTED OPERATING STANDARDIZED AMOUNTS FOR HOSPITALS IN PUERTO RICO, LABOR/NONLABOR (NATIONAL: 62 PERCENT LABOR SHARE/38 PERCENT NONLABOR SHARE BECAUSE WAGE INDEX IS LESS THAN OR EQUAL TO 1);—FY 2024

	Rates if Wage Index Greater Than 1		Hospital is a Meaningful EHR User and Wage Index Less Than or Equal to 1 (Update = 3.1)		Hospital is NOT a Meaningful EHR User and Wage Index Less Than or Equal to 1 (Update = 0.625)	
	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
National[1]	Not Applicable	Not Applicable	$4,028.62	$2,469.15	$3,931.91	$2,409.88

[1] For FY 2024, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

TABLE 1D.— CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2024

	Rate
National	$503.83

TABLE 1E.— LTCH PPS STANDARD FEDERAL PAYMENT RATE--FY 2024

	Full Update (3.3 Percent)	Reduced Update* (1.3 Percent)
Standard Federal Rate	$48,116.62	$47,185.03

* For LTCHs that fail to submit quality reporting data for FY 2024 in accordance with the LTCH Quality Reporting Program (LTCH QRP), the annual update is reduced by 2.0 percentage points as required by section 1886(m)(5) of the Act.

Appendix A—Economic Analyses

I. Regulatory Impact Analysis

A. Statement of Need

This final rule is necessary to make payment and policy changes under the IPPS for Medicare acute care hospital inpatient services for operating and capital-related costs as well as for certain hospitals and hospital units excluded from the IPPS. This final rule also is necessary to make payment and policy changes for Medicare hospitals under the LTCH PPS. Also, as we note later in this appendix, the primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their legitimate costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the changes in this final rule, such as the updates to the IPPS and LTCH PPS rates, and the final policies and discussions relating to applications for new technology add-on payments, are needed to further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries.

We expect that these changes will ensure that the outcomes of the prospective payment systems are reasonable and provide equitable payments, while avoiding or minimizing unintended adverse consequences.

1. Acute Care Hospital Inpatient Prospective Payment System (IPPS)

a. Update to the IPPS Payment Rates

In accordance with section 1886(b)(3)(B) of the Act and as described in section V.B. of the preamble to this final rule, we are updating the national standardized amount for inpatient hospital operating costs by the applicable percentage increase of 3.1 percent (that is, a 3.3 percent market basket update with a reduction of 0.2 percentage point for the productivity adjustment). We are also applying the applicable percentage increase (including the market basket update and the productivity adjustment) to the hospital-specific rates.

Subsection (d) hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act will receive an applicable percentage increase of 2.275 percent. Hospitals that are identified as not meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act will receive an applicable percentage increase of 0.625 percent.

Hospitals that are identified as not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act will receive an applicable percentage increase of -0.2 percent, which reflects a one-quarter percent reduction of the market basket update for failure to submit quality data and a three-quarter percent reduction of the market basket update for being identified as not a meaningful EHR user.

b. Changes for the Add-On Payments for New Services and Technologies

Consistent with sections 1886(d)(5)(K) and (L) of the Act, we review applications for new technology add-on payments based on the eligibility criteria at 42 CFR 412.87. As set forth in 42 CFR 412.87(e)(1), we consider whether a technology meets the criteria for the new technology add-on payment and announce the results as part of the annual updates and changes to the IPPS.

As discussed in section II.E.9. of this final rule, beginning with new technology add-on payment applications for FY 2025, for technologies that are not already market authorized, we are finalizing our policy to require applicants to have a complete and active FDA market authorization request at the time of new technology add-on payment application submission and to provide documentation of FDA acceptance or filing to CMS at the time of application submission. We are also finalizing our policy that, beginning with FY 2025 applications, to be eligible for consideration for the new technology add-on payment for the upcoming fiscal year, an applicant for new technology add-on payments must have received FDA marketing authorization by May 1 rather than July 1 of the year prior to the beginning of the fiscal year for which the application is being considered.

c. Continuation of the Low Wage Index Hospital Policy

To help mitigate wage index disparities between high wage and low wage hospitals, in the FY 2020 IPPS/LTCH PPS rule (84 FR 42326 through 42332), we adopted a policy to increase the wage index values for certain

hospitals with low wage index values (the low wage index hospital policy). This policy was adopted in a budget neutral manner through an adjustment applied to the standardized amounts for all hospitals. We also indicated our intention that this policy would be effective for at least 4 years, beginning in FY 2020, to allow employee compensation increases implemented by these hospitals sufficient time to be reflected in the wage index calculation. As discussed in section III.G.4. of the preamble of this final rule, as we only have one year of relevant data at this time that we could use to evaluate any potential impacts of this policy, we believe it is necessary to wait until we have useable data from additional fiscal years before making any decision to modify or discontinue the policy. Therefore, for FY 2024, we are continuing the low wage index hospital policy and the related budget neutrality adjustment.

d. Modification to the Rural Wage Index Calculation Methodology

As discussed in section III.G.1. of the preamble of this final rule, CMS has taken the opportunity to revisit the case law, prior public comments, and the relevant statutory language with regard to its policies involving the treatment of hospitals that have reclassified as rural under section 1886(d)(8)(E) of the Act, as implemented in the regulations under 42 CFR 412.103. After doing so, CMS now agrees that the best reading of section 1886(d)(8)(E) of the Act is that it instructs CMS to treat § 412.103 hospitals the same as geographically rural hospitals for the wage index calculation. Therefore, we believe it is proper to include these hospitals in all iterations of the rural wage index calculation methodology included in section 1886(d) of the Act, including all hold harmless calculations in that provision. Beginning with FY 2024, we are finalizing the proposal to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and to exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. Changes to the rural wage index which affect the rural floor would be implemented in a budget neutral manner.

e. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs)

In this final rule, as required by section 1886(r)(2) of the Act, we are updating our estimates of the 3factors used to determine uncompensated care payments for FY 2024. Beginning with FY 2023, we adopted a multiyear averaging methodology to determine Factor 3 of the uncompensated care payment methodology, which will help to mitigate against large fluctuations in uncompensated care payments from year to year. Under this methodology, for FY 2024 and subsequent fiscal years, we will determine Factor 3 for all eligible hospitals using a 3-year average of the data on uncompensated care costs from Worksheet S–10 for the 3 most recent fiscal years for which audited data are available. Specifically, we will use a 3-year average of audited data on uncompensated care costs from Worksheet S–10 from the FY 2018, FY 2019, and FY 2020 cost reports to calculate Factor 3 for FY 2024 for all eligible hospitals.

Beginning with FY 2023, we established a supplemental payment for Indian Health Service (IHS) and Tribal hospitals and hospitals located in Puerto Rico to help prevent undue long-term financial disruption to these hospitals due to the discontinuation of the use of the low-income insured days proxy in the uncompensated care payment methodology for these providers.

In this final rule, beginning with FY 2024, we are revising our regulations governing the treatment of certain section 1115 demonstration days in the calculation of the Medicaid fraction in the Medicare DSH disproportionate patient percentage. Specifically, we are to revising our regulations at § 412.106(b)(4) to explicitly reflect our interpretation of the language ''regarded as'' ''eligible for medical assistance under a State plan approved under title XIX'' ''because they receive benefits under a demonstration project approved under title XI'' in section 1886(d)(5)(F)(vi) of the Act to mean patients—(1) who receive health insurance through a section 1115 demonstration itself; or (2) who purchase health insurance with the use of premium assistance provided by a section 1115 demonstration, where State expenditures to provide the insurance or premium assistance may be matched with funds from title XIX and to explicitly state that we will not regard as Medicaid- eligible patients whose costs are paid to hospitals from uncompensated/undercompensated care pool funds authorized by a section 1115 demonstration; and we are similarly excluding the days of such patients from being counted in the DPP Medicaid fraction numerator. Thus, we are explicitly excluding from counting in the DPP Medicaid fraction numerator any days of patients for which hospitals are paid from demonstration-authorized uncompensated/undercompensated care pools. Our revised regulation will be effective for discharges occurring on or after October 1, 2023. As has been our practice for more than two decades, we have made our periodic revisions to the counting of certain section 1115 patient days in the Medicare DSH calculation effective based on patient discharge dates. Doing so again here treats all providers similarly and does not impact providers differently depending on their cost reporting periods.

f. Effects of Implementation of the Rural Community Hospital Demonstration Program in FY 2024

The Rural Community Hospital Demonstration (RCHD) was authorized originally for a 5-year period by section 410A of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L 108–173), and it was extended for another 5-year period by section 3123 and 10313 of the Affordable Care Act (Pub. L 111–148). Section 15003 of the 21st Century Cures Act (Cures Act) (Pub. L. 114–255) extended the demonstration for an additional 5-year period, and section 128 of the Consolidated Appropriations Act of 2021(Pub. L. 116–159) included an additional 5-year re-authorization. CMS has conducted the demonstration since 2004, which allows enhanced, cost-based payment for Medicare inpatient services for up to 30 small rural hospitals.

The authorizing legislation imposes a strict budget neutrality requirement. In this final rule, we summarize the status of the demonstration program, and the ongoing methodologies for implementation and budget neutrality.

2. Frontier Community Health Integration Project (FCHIP) Demonstration

The Frontier Community Health Integration Project (FCHIP) demonstration was authorized under section 123 of the Medicare Improvements for Patients and Providers Act of 2008 (Pub. L 110–275), as amended by section 3126 of the Affordable Care Act of 2010 (Pub. L 114–158), and most recently re-authorized and extended by the Consolidated Appropriations Act of 2021 (Pub. L 116–159). The legislation authorized a demonstration project to allow eligible entities to develop and test new models for the delivery of health care to improve access to and better integrate the delivery of acute care, extended care and other health care services to Medicare beneficiaries in certain rural areas. The FCHIP demonstration initial period was conducted in 10 critical access hospitals (CAHs) from August 1, 2016, to July 31, 2019, and the demonstration ''extension period'' began on January 1, 2022, to run through June 30, 2027.

The authorizing legislation requires the FCHIP demonstration to be budget neutral. In this final rule, we proposed to continue with the budget neutrality approach used in the demonstration initial period for the demonstration extension period—to offset payments across CAHs nationally—should the demonstration incur costs to Medicare.

3. Update to the LTCH PPS Payment Rates

As described in section VIII.C.2. of the preamble of this final rule, to update payments to LTCHs using the best available data, we are updating the LTCH PPS standard Federal payment rate by 3.3 percent (that is, a 3.5 percent market basket update with a reduction of 0.2 percentage point for the productivity adjustment, as required by section 1886(m)(3)(A)(i) of the Act). LTCHs that failed to submit quality data, as required by 1886(m)(5)(A)(i) of the Act and described in section VIII.C.2. of the preamble of this final rule, would receive an update of 1.3 percent, which reflects a 2.0 percentage point reduction for failure to submit quality data.

4. Hospital Quality Programs

Section 1886(b)(3)(B)(viii) of the Act requires subsection (d) hospitals to report data in accordance with the requirements of the Hospital IQR Program for purposes of measuring and making publicly available information on health care quality. This provision links the submission of quality data to the annual applicable percentage increase. Sections 1886(b)(3)(B)(ix), 1886(n), and 1814(l) of the Act require eligible hospitals and CAHs to demonstrate they are meaningful users of certified EHR technology for purposes of electronic exchange of health information to improve the quality of health

care; these provisions link the submission of information demonstrating meaningful use to the annual applicable percentage increase for eligible hospitals and the applicable percent for CAHs. Section 1886(m)(5) of the Act requires each LTCH to submit quality measure data in accordance with the requirements of the LTCH QRP for purposes of measuring and making publicly available information on health care quality, and to avoid a 2-percentage point reduction in their annual payment. Section 1886(o) of the Act requires the Secretary to establish a value-based purchasing program under which value-based incentive payments are made in a fiscal year to hospitals that meet the performance standards established on an announced set of quality and efficiency measures for the fiscal year. The purposes of the Hospital VBP Program include measuring the quality of hospital inpatient care, linking hospital measure performance to payment, and making publicly available information on hospital quality of care. Section 1886(p) of the Act requires a reduction in payment for subsection (d) hospitals that rank in the worst-performing 25 percent with respect to measures of hospital-acquired conditions under the HAC Reduction Program for the purpose of measuring HACs linking measure performance to payment, and making publicly available information on health care quality. Section 1886(q) of the Act requires a reduction in payment for subsection (d) hospitals for excess readmissions based on measures for applicable conditions under the Hospital Readmissions Reduction Program for the purpose of measuring readmissions, linking measure performance to payment, and making publicly available information on health care quality. Section 1866(k) of the Act applies to hospitals described in section 1886(d)(1)(B)(v) of the Act (referred to as ''PPS-Exempt Cancer Hospitals'' or ''PCHs'') and requires PCHs to report data in accordance with the requirements of the PCHQR Program for purposes of measuring and making publicly available information on the quality of care furnished by PCHs, however, there is no reduction in payment to a PCH that does not report data.

5. Other Provisions

a. Rural Emergency Hospitals

Section 125 of Division CC of the CAA was signed into law on December 27, 2020, and establishes REHs as a new Medicare provider-type that receives Medicare payment for services furnished on or after January 1, 2023. Section 125 of the CAA added section 1861(kkk) to the Act, which sets forth the requirements for REHs.

Sections 1861(kkk)(4)(A)(i) through (iv) of the Act requires that an eligible facility that submits an application for enrollment as an REH under section 1866(j) of the Act, must also submit additional information that must include an action plan containing: (1) a plan for initiating REH services (which must include the provision of emergency department services and observation care); (2) a detailed transition plan that lists the specific services that the provider will retain, modify, add, and discontinue as an REH; (3) a detailed description of other outpatient medical and health services that it intends to furnish on an outpatient basis as an REH; and (4) information regarding how the provider intends to use the additional facility payment provided under section 1834(x)(2) of the Act, including a description of the services that the additional facility payment would be supporting, such as the operation and maintenance of the facility and the furnishing of covered services (for example, telehealth services and ambulance services).

On January 26, 2023, CMS issued QSO–23–07–REH (*https://www.cms.gov/files/document/qso-23-07-reh.pdf*) that provided the additional information requirements specified by section 1861(kkk)(4)(A)(i) through (iv) of the Act as well as guidance regarding the REH enrollment and conversion process for eligible facilities. We proposed to codify those requirements at 42 CFR 488.70. We also proposed to update the definition of a ''participating hospital'' to include REHs, and to add REHs to the other applicable provisions contained in 42 CFR parts 488 and 489: §§ 488.1, ''Definitions''; 488.2, ''Statutory basis''; 488.18, ''Documentation of findings''; and 489.102, ''Requirements for providers.''

b. Physician-Owned Hospitals

As discussed in section X.B. of the preamble of this final rule, we recently reviewed the expansion exception process for hospitals that wish to expand beyond the number of operating rooms, procedure rooms, and beds for which they were licensed at the time of enactment of the Affordable Care Act. To clarify our interpretation of the statutory authority, ensure that approval of a request to expand a hospital's facility capacity occurs only in appropriate circumstances, and provide transparency to facilitate compliance with the process for requesting an expansion exception, we are revising the regulations to clarify that CMS will only consider expansion exception requests from eligible hospitals, clarify the data and information that must be included in an expansion exception request, identify factors that CMS will consider when making a decision on an expansion exception request, and revise certain aspects of the process for requesting an expansion exception.

Also, we recently reconsidered whether CY 2021 OPPS/ASC regulatory revisions that removed program integrity restrictions regarding the frequency of expansion exception requests, maximum aggregate expansion of a hospital, and location of expansion facility capacity for high Medicaid facilities currently present a risk of the types of program or patient abuse that the physician self-referral law is intended to thwart. Following this review, we believe that not applying these program integrity restrictions poses a significant risk of program or patient abuse. Therefore, we are reinstating, with respect to high Medicaid facilities, the program integrity restrictions on the frequency of expansion exception requests, maximum aggregate expansion of a hospital, and location of expansion facility capacity that were removed in the CY 2021 OPPS/ASC final rule.

B. Overall Impact

We have examined the impacts of this final 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), Executive Order 14094 on Modernizing Regulatory Review (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the 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 (CRA) (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). Executive Order 14094 amends section 3(f) of Executive Order 12866 to define a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year, or adversely affect in a material way of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities; (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 legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) of $200 million or more in any 1 year. Based on our estimates, OMB'S Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) as measured by the $200 million or more in any 1 year. We have prepared a regulatory impact analysis that to the best of our ability presents the costs and benefits of the rulemaking. OMB has reviewed these regulations, and the Departments have provided the following assessment of their impact.

We estimate that the changes for FY 2024 acute care hospital operating and capital payments would redistribute amounts in excess of $200 million to acute care hospitals. The applicable percentage increase to the IPPS rates required by the statute, in conjunction with other payment changes in this final rule, would result in an estimated $2.2 billion increase in FY 2024 payments, primarily driven by: (a) a combined $2.6 billion increase in FY 2024 operating payments, including uncompensated care payments, and FY 2024 capital payments and (b) a decrease of $ 0.364 million resulting from estimated changes in new technology add-on payments. These changes are relative

to payments made in FY 2023. The impact analysis of the capital payments can be found in section I.I. of this appendix. In addition, as described in section I.J. of this appendix, LTCHs are expected to experience an increase in payments by approximately $6 million in FY 2024 relative to FY 2023.

Our operating payment impact estimate includes the 3.1 percent hospital update to the standardized amount (reflecting the 3.3 percent market basket update reduced by the 0.2 percentage point for the productivity adjustment). The estimates of IPPS operating payments to acute care hospitals do not reflect any changes in hospital admissions or real case-mix intensity, which will also affect overall payment changes.

The analysis in this appendix, in conjunction with the remainder of this document, demonstrates that this final rule is consistent with the regulatory philosophy and principles identified in Executive Orders 12866 and 13563, the RFA, and section 1102(b) of the Act. This final rule would affect payments to a substantial number of small rural hospitals, as well as other classes of hospitals, and the effects on some hospitals may be significant. Finally, in accordance with the provisions of Executive Order 12866, the Office of Management and Budget has reviewed this final rule.

C. Objectives of the IPPS and the LTCH PPS

The primary objective of the IPPS and the LTCH PPS is to create incentives for hospitals to operate efficiently and minimize unnecessary costs, while at the same time ensuring that payments are sufficient to adequately compensate hospitals for their costs in delivering necessary care to Medicare beneficiaries. In addition, we share national goals of preserving the Medicare Hospital Insurance Trust Fund.

We believe that the changes in this final rule would further each of these goals while maintaining the financial viability of the hospital industry and ensuring access to high quality health care for Medicare beneficiaries. We expect that these changes would ensure that the outcomes of the prospective payment systems are reasonable and equitable, while avoiding or minimizing unintended adverse consequences.

Because this final rule contains a range of policies, we refer readers to the section of the final rule where each policy is discussed. These sections include the rationale for our decisions, including the need for the policy.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our policy changes, as well as statutory changes effective for FY 2024, on various hospital groups. We estimate the effects of individual policy changes by estimating payments per case, while holding all other payment policies constant. We use the best data available, but, generally unless specifically indicated, we do not attempt to make adjustments for future changes in such variables as admissions, lengths of stay, case mix, changes to the Medicare population, or incentives. In addition, we discuss limitations of our analysis for specific policies in the discussion of those policies as needed.

E. Hospitals Included in and Excluded From the IPPS

The prospective payment systems for hospital inpatient operating and capital related- costs of acute care hospitals encompass most general short-term, acute care hospitals that participate in the Medicare program. There were 24 Indian Health Service hospitals in our database, which we excluded from the analysis due to the special characteristics of the prospective payment methodology for these hospitals. Among other short term, acute care hospitals, hospitals in Maryland are paid in accordance with the Maryland Total Cost of Care Model, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, 6 short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa) receive payment for inpatient hospital services they furnish on the basis of reasonable costs, subject to a rate-of-increase ceiling.

As of March 2023, there were 3,131 IPPS acute care hospitals included in our analysis. This represents approximately 53 percent of all Medicare-participating hospitals. The majority of this impact analysis focuses on this set of hospitals. There also are approximately 1,429 CAHs. These small, limited service hospitals are paid on the basis of reasonable costs, rather than under the IPPS. IPPS-excluded hospitals and units, which are paid under separate payment systems, include IPFs, IRFs, LTCHs, RNHCIs, children's hospitals, cancer hospitals, extended neoplastic disease care hospital, and short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa. Changes in the prospective payment systems for IPFs and IRFs are made through separate rulemaking. Payment impacts of changes to the prospective payment systems for these IPPS-excluded hospitals and units are not included in this final rule. The impact of the update and policy changes to the LTCH PPS for FY 2024 is discussed in section I.J. of this appendix.

F. Quantitative Effects of the Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this final rule, we are announcing policy changes and payment rate updates for the IPPS for FY 2024 for operating costs of acute care hospitals. The FY 2024 updates to the capital payments to acute care hospitals are discussed in section I.I. of this appendix.

Based on the overall percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2024 operating payments would increase by 3.1 percent, compared to FY 2023. The impacts do not reflect changes in the number of hospital admissions or real case-mix intensity, which would also affect overall payment changes.

We have prepared separate impact analyses of the changes to each system. This section deals with the changes to the operating inpatient prospective payment system for acute care hospitals. Our payment simulation model relies on the best available claims data to enable us to estimate the impacts on payments per case of certain changes in this final rule. As discussed in section I.E. of the preamble to this final rule, we believe that the FY 2022 claims data is the best available data for purposes of the FY 2024 ratesetting and this impact analysis reflects the use of that data. However, there are other changes for which we do not have data available that would allow us to estimate the payment impacts using this model. For those changes, we have attempted to predict the payment impacts based upon our experience and other more limited data.

The data used in developing the quantitative analyses of changes in payments per case presented in this section are taken from the FY 2022 MedPAR file, as discussed previously in this final rule, and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the changes to the operating PPS do not incorporate cost data, data from the best available hospital cost reports were used to categorize hospitals, as also discussed previously in this final rule. Our analysis has several qualifications. First, in this analysis, we do not adjust for future changes in such variables as admissions, lengths of stay, or underlying growth in real case-mix. Second, due to the interdependent nature of the IPPS payment components, it is very difficult to precisely quantify the impact associated with each change. Third, we use various data sources to categorize hospitals in the tables. In some cases, particularly the number of beds, there is a fair degree of variation in the data from the different sources. We have attempted to construct these variables with the best available source overall. However, for individual hospitals, some miscategorizations are possible.

Using cases from the FY 2022 MedPAR file, we simulate payments under the operating IPPS given various combinations of payment parameters. As described previously, Indian Health Service hospitals and hospitals in Maryland were excluded from the simulations. The impact of payments under the capital IPPS, and the impact of payments for costs other than inpatient operating costs, are not analyzed in this section. Estimated payment impacts of the capital IPPS for FY 2024 are discussed in section I.I. of this appendix.

We discuss the following changes:

- The effects of the application of the applicable percentage increase of 3.1 percent (that is, a 3.3 percent market basket update with a reduction of 0.2 percentage point for the productivity adjustment), and the applicable percentage increase (including the market basket update and the productivity adjustment) to the hospital-specific rates.
- The effects of the changes to the relative weights and MS–DRG GROUPER.
- The effects of the changes in hospitals' wage index values reflecting updated wage data from hospitals' cost reporting periods beginning during FY 2020, compared to the FY 2019 wage data, to calculate the FY 2024 wage index.
- The effects of the geographic reclassifications by the MGCRB (as of publication of this final rule) that will be effective for FY 2024.
- The effects of the rural floor with the application of the national budget neutrality

factor to the wage index and the change to the rural wage index and rural floor methodology.

- The effects of the imputed floor wage index adjustment. This provision is not budget neutral.
- The effects of the frontier State wage index adjustment under the statutory provision that requires hospitals located in States that qualify as frontier States to not have a wage index less than 1.0. This provision is not budget neutral.
- The effects of the implementation of section 1886(d)(13) of the Act, which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes for FY 2024. This provision is not budget neutral.
- The total estimated change in payments based on the FY 2024 policies relative to payments based on FY 2023 policies.

To illustrate the impact of the FY 2024 changes, our analysis begins with a FY 2023 baseline simulation model using: the FY 2023 applicable percentage increase of 3.8 percent; the 0.5 percentage point adjustment required under section 414 of the MACRA applied to the IPPS standardized amount; the FY 2023 MS–DRG GROUPER (Version 40); the FY 2023 CBSA designations for hospitals based on the OMB definitions from the 2010 Census; the FY 2023 wage index; and no MGCRB reclassifications. Outlier payments are set at 5.1 percent of total operating MS–DRG and outlier payments for modeling purposes.

Section 1886(b)(3)(B)(viii) of the Act provides that, for FY 2007 and each subsequent year through FY 2014, the update factor will include a reduction of 2.0 percentage points for any subsection (d) hospital that does not submit data on measures in a form and manner, and at a time specified by the Secretary. Beginning in FY 2015, the reduction is one-quarter of such applicable percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act, or one-quarter of the market basket rate-of-increase. Therefore, hospitals that do not submit quality information under rules established by the Secretary and that are meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act would receive an applicable percentage increase of 2.275 percent. At the time this impact was prepared, 65 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2024 because they failed the quality data submission process or did not choose to participate, but are meaningful EHR users. For purposes of the simulations shown later in this section, we modeled the payment changes for FY 2024 using a reduced update for these hospitals.

For FY 2024, in accordance with section 1886(b)(3)(B)(ix) of the Act, a hospital that has been identified as not a meaningful EHR user will be subject to a reduction of three-quarters of such applicable market basket rate-of-increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act. Therefore, hospitals that are identified as not meaningful EHR users and do submit quality information under section 1886(b)(3)(B)(viii) of the Act would receive an applicable percentage increase of 0.625 percent. At the time this impact analysis was prepared, 110 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2024 because they are identified as not meaningful EHR users that do submit quality information under section 1886(b)(3)(B)(viii) of the Act. For purposes of the simulations shown in this section, we modeled the payment changes for FY 2024 using a reduced update for these hospitals.

Hospitals that are identified as not meaningful EHR users under section 1886(b)(3)(B)(ix) of the Act and also do not submit quality data under section 1886(b)(3)(B)(viii) of the Act would receive a applicable percentage increase of −0.2 percent, which reflects a one-quarter reduction of the market basket rate-of-increase for failure to submit quality data and a three-quarter reduction of the market basket rate-of-increase for being identified as not a meaningful EHR user. At the time this impact was prepared, 31 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2024 because they are identified as not meaningful EHR users that do not submit quality data under section 1886(b)(3)(B)(viii) of the Act.

Each policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2024 model incorporating all of the changes. This simulation allows us to isolate the effects of each change.

Our comparison illustrates the percent change in payments per case from FY 2023 to FY 2024. Two factors not discussed separately have significant impacts here. The first factor is the update to the standardized amount. In accordance with section 1886(b)(3)(B)(i) of the Act, we are updating the standardized amounts for FY 2024 using a applicable percentage increase of 3.1 percent. This includes the FY 2024 IPPS operating hospital market basket increase of 3.3 percent with a 0.2 percentage point reduction for the productivity adjustment. Hospitals that fail to comply with the quality data submission requirements and are meaningful EHR users would receive an update of 2.275 percent. This update includes a reduction of one-quarter of the market basket rate-of-increase for failure to submit these data. Hospitals that do comply with the quality data submission requirements but are not meaningful EHR users would receive an update of 0.625 percent, which includes a reduction of three-quarters of the market basket rate-of-increase. Furthermore, hospitals that do not comply with the quality data submission requirements and are not meaningful EHR users would receive an update of −0.2 percent. Under section 1886(b)(3)(B)(iv) of the Act, the update to the hospital-specific amounts for SCHs and MDHs is also equal to the applicable percentage increase, or 3.1 percent, if the hospital submits quality data and is a meaningful EHR user.

A second significant factor that affects the changes in hospitals' payments per case from FY 2023 to FY 2024 is the change in hospitals' geographic reclassification status from one year to the next. That is, payments may be reduced for hospitals reclassified in FY 2023 that are no longer reclassified in FY 2024. Conversely, payments may increase for hospitals not reclassified in FY 2023 that are reclassified in FY 2024.

2. Analysis of Table I

Table I displays the results of our analysis of the changes for FY 2024. The table categorizes hospitals by various geographic and special payment consideration groups to illustrate the varying impacts on different types of hospitals. The top row of the table shows the overall impact on the 3,131 acute care hospitals included in the analysis.

The next two rows of Table I contain hospitals categorized according to their geographic location: urban and rural. There are 2,416 hospitals located in urban areas and 715 hospitals in rural areas included in our analysis. The next two groupings are by bed-size categories, shown separately for urban and rural hospitals. The last groupings by geographic location are by census divisions, also shown separately for urban and rural hospitals.

The second part of Table I shows hospital groups based on hospitals' FY 2024 payment classifications, including any reclassifications under section 1886(d)(10) of the Act. For example, the rows labeled urban and rural show that the numbers of hospitals paid based on these categorizations after consideration of geographic reclassifications (including reclassifications under sections 1886(d)(8)(B) and 1886(d)(8)(E) of the Act that have implications for capital payments) are 1,811 and 1,320, respectively.

The next three groupings examine the impacts of the changes on hospitals grouped by whether or not they have GME residency programs (teaching hospitals that receive an IME adjustment) or receive Medicare DSH payments, or some combination of these two adjustments. There are 1,900 nonteaching hospitals in our analysis, 953 teaching hospitals with fewer than 100 residents, and 278 teaching hospitals with 100 or more residents.

In the DSH categories, hospitals are grouped according to their DSH payment status, and whether they are considered urban or rural for DSH purposes. The next category groups together hospitals considered urban or rural, in terms of whether they receive the IME adjustment, the DSH adjustment, both, or neither.

The next six rows examine the impacts of the changes on rural hospitals by special payment groups (SCHs, MDHs, and RRCs) and reclassification status from urban to rural in accordance with section 1886(d)(8)(E) of the Act. Of the hospitals that are not reclassified from urban to rural, there are 133 RRCs, 256 SCHs, 116 MDHs, 121 hospitals that are both SCHs and RRCs, and 18 hospitals that are both MDHs and RRCs. Of the hospitals that are reclassified from urban to rural, there are 491 RRCs, 45 SCHs, 30 MDHs, 43 hospitals that are both SCHs and RRCs, and 13 hospitals that are both MDHs and RRCs.

The next series of groupings are based on the type of ownership and the hospital's Medicare and Medicaid utilization expressed as a percent of total inpatient days. These

data were taken from the most recent available Medicare cost reports.

The next grouping concerns the geographic reclassification status of hospitals. The first subgrouping is based on whether a hospital is reclassified or not. The second and third subgroupings are based on whether urban and rural hospitals were reclassified by the MGCRB for FY 2024 or not, respectively. The fourth subgrouping displays hospitals that reclassified from urban to rural in accordance with section 1886(d)(8)(E) of the Act. The fifth subgrouping displays hospitals deemed urban in accordance with section 1886(d)(8)(B) of the Act.

TABLE I.—IMPACT ANALYSIS OF CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2024

	Number of Hospitals[1]	Hospital Rate Update (1)[2]	FY 2024 Weights and DRG Changes with Application of Budget Neutrality (2)[3]	FY 2024 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2024 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Imputed Floor, Frontier State Wage Index and Outmigration Adjustment (6)[7]	All FY 2024 Changes (7)[8]
All Hospitals	3,131	3.1	0.0	0.0	0.0	0.0	0.4	3.1
By Geographic Location:								
Urban hospitals	2,416	3.1	0.0	0.0	-0.1	0.0	0.4	3.1
Rural hospitals	715	3.0	0.2	-0.3	1.8	-0.6	0.1	3.5
Bed Size (Urban):								
0-99 beds	650	3.0	-0.2	-0.1	-1.6	0.9	0.5	2.5
100-199 beds	696	3.1	0.2	0.0	-0.6	0.8	0.4	3.2
200-299 beds	414	3.1	0.1	0.0	-0.1	0.5	0.5	3.4
300-499 beds	404	3.1	0.0	0.1	0.6	0.2	0.3	3.8
500 or more beds	250	3.0	-0.1	0.0	-0.3	-0.6	0.4	2.4
Bed Size (Rural):								0.0
0-49 beds	363	2.9	0.1	-0.1	1.1	-0.5	0.2	3.1
50-99 beds	188	3.0	0.3	0.0	1.7	-0.4	0.1	4.0
100-149 beds	87	3.0	0.4	-0.2	2.0	-0.5	0.1	3.7
150-199 beds	46	3.1	0.2	-0.5	1.9	-0.7	0.0	3.2
200 or more beds	31	3.1	0.1	-0.7	2.5	-0.7	0.3	3.1
Urban by Region:								
New England	108	3.1	0.0	-0.5	4.0	0.0	0.6	0.5
Middle Atlantic	292	3.1	0.1	0.9	-0.1	-0.5	1.0	3.9
East North Central	372	3.1	0.0	-0.6	-1.1	-1.0	0.1	1.2
West North Central	156	3.1	-0.2	-0.1	-1.4	-0.9	0.6	1.3
South Atlantic	403	3.1	0.0	0.0	-0.6	-0.2	0.4	3.3
East South Central	138	3.1	0.0	0.0	-1.3	-0.9	0.1	2.2
West South Central	359	3.1	0.0	0.0	-1.5	-1.0	0.1	1.6
Mountain	177	3.1	-0.1	-0.4	0.5	1.4	0.4	3.1
Pacific	360	3.0	0.0	0.1	1.0	2.7	0.1	6.4
Puerto Rico	51	3.0	0.3	-1.9	-2.5	-0.2	0.1	1.9
Rural by Region:								
New England	19	3.1	0.0	-1.2	0.9	-0.7	0.1	2.0
Middle Atlantic	47	3.1	0.2	-0.1	5.6	-0.8	0.4	7.2
East North Central	113	3.1	0.1	-0.3	1.1	-0.4	0.0	2.9
West North Central	84	3.0	0.2	-0.1	0.4	-0.3	0.3	3.1
South Atlantic	108	3.1	0.4	0.2	2.0	-0.7	0.1	3.4
East South Central	140	3.0	0.3	-0.7	1.9	-0.8	0.1	3.1
West South Central	134	3.0	0.2	-0.1	2.1	-0.7	0.0	3.1
Mountain	46	2.8	0.0	0.0	0.1	-0.2	0.8	2.6
Pacific	24	3.1	0.4	-0.2	3.6	-0.5	0.0	5.4
By Payment Classification:								
Urban hospitals	1,811	3.1	0.0	0.0	-1.8	1.1	0.6	3.3
Rural areas	1,320	3.1	0.0	0.0	1.8	-1.1	0.1	2.8
Teaching Status:								
Nonteaching	1,900	3.1	0.1	-0.1	-0.2	0.9	0.3	3.5

	Number of Hospitals[1]	Hospital Rate Update (1)[2]	FY 2024 Weights and DRG Changes with Application of Budget Neutrality (2)[3]	FY 2024 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2024 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Imputed Floor, Frontier State Wage Index and Outmigration Adjustment (6)[7]	All FY 2024 Changes (7)[8]
Fewer than 100 residents	953	3.1	0.0	0.0	0.0	0.0	0.5	3.2
100 or more residents	278	3.0	0.0	0.1	0.1	-0.7	0.4	2.6
Urban DSH:								
Non-DSH	353	3.1	-0.4	0.2	-1.8	-0.2	0.9	2.0
100 or more beds	1,099	3.1	0.1	0.0	-1.8	1.2	0.6	3.5
Less than 100 beds	359	3.1	0.2	-0.1	-1.8	1.7	0.4	3.1
Rural DSH:								
Non-DSH	108	3.0	-0.3	0.1	2.6	-1.0	0.2	2.3
SCH	257	3.0	0.3	0.0	0.3	-0.1	0.0	3.4
RRC	712	3.1	0.0	-0.1	2.0	-1.1	0.1	2.8
100 or more beds	32	3.1	-0.2	0.5	-1.1	-1.2	0.1	3.7
Less than 100 beds	211	3.0	0.3	-0.1	1.9	-0.8	0.2	3.9
Urban teaching and DSH:								
Both teaching and DSH	637	3.1	0.1	0.1	-1.8	0.8	0.7	3.2
Teaching and no DSH	57	3.1	-0.3	0.6	-1.8	-0.5	1.1	2.4
No teaching and DSH	821	3.1	0.1	-0.1	-1.7	2.2	0.3	4.1
No teaching and no DSH	296	3.1	-0.4	-0.1	-1.7	-0.1	0.8	1.8
Special Hospital Types:								
RRC	133	3.2	0.0	-0.4	1.8	-0.3	0.4	3.1
RRC with Section 401 Rural Reclassification	491	3.1	-0.1	0.0	2.1	-1.3	0.1	2.7
SCH	256	3.0	0.2	0.0	0.3	-0.2	0.1	3.3
SCH with Section 401 Rural Reclassification	45	3.1	0.3	0.0	0.1	-0.1	0.0	3.4
SCH and RRC	121	3.1	0.2	-0.2	0.9	-0.3	0.1	3.4
SCH and RRC with Section 401 Rural Reclassification	43	3.1	-0.1	0.0	0.3	-0.1	0.0	2.9
MDH	116	3.0	0.1	-0.2	1.3	-0.6	0.6	3.6
MDH with Section 401 Reclassification	30	3.1	0.3	-0.2	0.6	-0.3	0.0	3.7
MDH and RRC	18	3.0	0.3	0.0	1.2	-0.4	0.1	3.5
MDH and RRC with Section 401 Reclassification	13	3.1	0.3	-0.1	0.7	-0.3	0.0	3.3
Type of Ownership:								
Voluntary	1,920	3.1	0.0	0.0	0.2	-0.2	0.4	3.0
Proprietary	778	3.1	0.0	-0.2	-0.4	1.3	0.2	3.8
Government	432	3.0	0.1	0.0	-0.6	-0.1	0.1	3.0
Medicare Utilization as a Percent of Inpatient Days:								
0-25	995	3.0	0.1	0.1	-0.5	0.3	0.2	3.6
25-50	1,945	3.1	0.0	-0.1	0.3	-0.2	0.5	2.8
50-65	138	3.0	0.1	0.1	-0.6	1.6	0.6	3.5
Over 65	25	2.7	0.7	0.3	0.3	-0.2	0.0	4.1
Medicaid Utilization as a Percent of Inpatient Days:								
0-25	2,038	3.1	-0.1	0.0	0.1	-0.4	0.4	2.7
25-50	974	3.1	0.1	0.0	-0.1	0.3	0.4	3.4
50-65	91	2.9	0.8	0.5	-0.7	2.7	0.1	6.4
Over 65	28	2.9	1.1	0.3	-1.9	7.6	0.0	11.7
FY 2024 Reclassifications:								
All Reclassified Hospitals	1,054	3.1	0.0	0.0	1.9	-0.8	0.1	2.9
Non-Reclassified Hospitals	2,077	3.1	0.0	0.0	-2.0	0.8	0.6	3.2
Urban Hospitals Reclassified	869	3.1	-0.1	0.0	1.8	-0.8	0.2	2.9
Urban Non-Reclassified Hospitals	1,561	3.1	0.0	0.1	-2.4	1.0	0.7	3.2
Rural Hospitals Reclassified Full Year	298	3.1	0.3	-0.3	2.3	-0.6	0.0	3.3

	Number of Hospitals[1]	Hospital Rate Update (1)[2]	FY 2024 Weights and DRG Changes with Application of Budget Neutrality (2)[3]	FY 2024 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2024 MGCRB Reclassifications (4)[5]	Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Imputed Floor, Frontier State Wage Index and Outmigration Adjustment (6)[7]	All FY 2024 Changes (7)[8]
Rural Non-Reclassified Hospitals Full Year	403	3.0	0.2	-0.3	1.0	-0.5	0.4	3.7
All Section 401 Rural Reclassified Hospitals	659	3.1	-0.1	0.0	1.8	-1.1	0.1	2.7
Other Reclassified Hospitals (Section 1886(d)(8)(B))	54	3.1	0.2	-0.4	4.0	-0.9	0.0	3.9

[1] Because data necessary to classify some hospitals by category were missing, the total number of hospitals in each category may not equal the national total. Discharge data are from FY 2022, and hospital cost report data are from the latest available reporting periods.

[2] This column displays the payment impact of the hospital rate update, including the 3.1 percent update to the national standardized amount and the hospital-specific rate (the 3.3 percent market basket rate-of-increase reduced by 0.2 percentage point for the productivity adjustment).

[3] This column displays the payment impact of the changes to the Version 41 GROUPER, the changes to the relative weights and the recalibration of the MS-DRG weights based on FY 2022 MedPAR data as the best available data, and the permanent 10-percent cap where the relative weight for a MS-DRG would decrease by more than ten percent in a given fiscal year. This column displays the application of the recalibration budget neutrality factors of 1.001463 and 0.999928.

[4] This column displays the payment impact of the update to wage index data using FY 2020 cost report data and the OMB labor market area delineations based on 2010 Decennial Census data. This column displays the payment impact of the application of the wage budget neutrality factor. The wage budget neutrality factor is 1.000702.

[5] Shown here are the effects of geographic reclassifications by the Medicare Geographic Classification Review Board (MGCRB). The effects demonstrate the FY 2024 payment impact of going from no reclassifications to the reclassifications scheduled to be in effect for FY 2024. Reclassification for prior years has no bearing on the payment impacts shown here. This column reflects the geographic budget neutrality factor of 0.971295.

[6] This column displays the effects of the rural floor and the change to the rural wage index methodology. The Affordable Care Act requires the rural floor budget neutrality adjustment to be a 100 percent national level adjustment. The rural floor budget neutrality factor applied to the wage index is 0.978183.

[7] This column shows the combined impact of (1) the imputed floor for all-urban states; (2) the policy that requires hospitals located in frontier States have a wage index no less than 1.0; and (3) the policy which provides for an increase in a hospital's wage index if a threshold percentage of residents of the county where the hospital is located commute to work at hospitals in counties with higher wage indexes. These are not budget neutral policies.

[8] This column shows the estimated change in payments from FY 2023 to FY 2024.

a. Effects of the Hospital Update (Column 1)

As discussed in section V.A. of the preamble of this final rule, this column includes the hospital update, including the 3.3 percent market basket rate-of-increase reduced by the 0.2 percentage point for the productivity adjustment. As a result, we are making a 3.1 percent update to the national standardized amount. This column also includes the update to the hospital-specific rates which includes the 3.3 percent market basket rate-of-increase reduced by 0.2 percentage point for the productivity adjustment. As a result, we are making a 3.1 percent update to the hospital-specific rates.

Overall, hospitals would experience a 3.1 percent increase in payments primarily due to the combined effects of the hospital update to the national standardized amount and the hospital update to the hospital-specific rate.

b. Effects of the Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 2)

Column 2 shows the effects of the changes to the MS–DRGs and relative weights with the application of the recalibration budget neutrality factor to the standardized amounts. Section 1886(d)(4)(C)(i) of the Act requires us annually to make appropriate classification changes to reflect changes in treatment patterns, technology, and any other factors that may change the relative use of hospital resources. Consistent with section 1886(d)(4)(C)(iii) of the Act, we calculated a recalibration budget neutrality factor to account for the changes in MS–DRGs and relative weights to ensure that the overall payment impact is budget neutral. We also applied the permanent 10-percent cap on the reduction in a MS–DRG's relative weight in a given year and an associated recalibration cap budget neutrality factor to account for the 10-percent cap on relative weight reductions to ensure that the overall payment impact is budget neutral.

As discussed in section II.D. of the preamble of this final rule, for FY 2024, we calculated the MS–DRG relative weights using the FY 2022 MedPAR data grouped to the Version 41 (FY 2024) MS–DRGs. The reclassification changes to the GROUPER are described in more detail in section II.C. of the preamble of this final rule.

The ''All Hospitals'' line in Column 2 indicates that changes due to the MS–DRGs and relative weights would result in a 0.0 percent change in payments with the application of the recalibration budget neutrality factor of 1.001463 and the recalibration cap budget neutrality factor of 0.999928to the standardized amount.

c. Effects of the Wage Index Changes (Column 3)

Column 3 shows the impact of the updated wage data, with the application of the wage budget neutrality factor. The wage index is calculated and assigned to hospitals on the basis of the labor market area in which the hospital is located. Under section 1886(d)(3)(E) of the Act, beginning with FY 2005, we delineate hospital labor market areas based on the Core Based Statistical Areas (CBSAs) established by OMB. The current statistical standards (based on OMB standards) used in FY 2024 are discussed in section III.A.2. of the preamble of this final rule.

Section 1886(d)(3)(E) of the Act requires that, beginning October 1, 1993, we annually update the wage data used to calculate the wage index. In accordance with this requirement, the wage index for acute care hospitals for FY 2024 is based on data submitted for hospital cost reporting periods, beginning on or after October 1, 2019 and before October 1, 2020. The estimated impact of the updated wage data and the OMB labor market area delineations on hospital payments is isolated in Column 3 by holding the other payment parameters constant in this simulation. That is, Column 3 shows the percentage change in payments when going from a model using the FY 2023 wage index, the labor-related share of 67.6 percent, under the OMB delineations and having a 100-percent occupational mix adjustment applied, to a model using the FY 2024 pre-reclassification wage index with the labor-related share of 67.6 percent, under the OMB delineations, also having a 100-percent occupational mix adjustment applied, while holding other payment parameters, such as use of the Version 41 MS–DRG GROUPER constant. The FY 2024 occupational mix adjustment is based on the CY 2019 occupational mix survey.

In addition, the column shows the impact of the application of the wage budget neutrality to the national standardized amount. In FY 2010, we began calculating separate wage budget neutrality and recalibration budget neutrality factors, in accordance with section 1886(d)(3)(E) of the Act, which specifies that budget neutrality to account for wage index changes or updates made under that subparagraph must be made without regard to the 62 percent labor-related share guaranteed under section 1886(d)(3)(E)(ii) of the Act. Therefore, for FY 2024, we are calculating the wage budget neutrality factor to ensure that payments under updated wage data and the labor-related share of 67.6 percent are budget neutral, without regard to the lower labor-related share of 62 percent applied to hospitals with a wage index less than or equal to 1.0. In other words, the wage budget neutrality is calculated under the assumption that all hospitals receive the higher labor-related share of the standardized amount. The FY 2024 wage budget neutrality factor is 1.000702 and the overall payment change is 0 percent.

Column 3 shows the impacts of updating the wage data. Overall, the new wage data and the labor-related share, combined with the wage budget neutrality adjustment, would lead to no change for all hospitals, as shown in Column 3.

In looking at the wage data itself, the national average hourly wage would increase 5.2 percent compared to FY 2023. Therefore, the only manner in which to maintain or exceed the previous year's wage index was to match or exceed the 5.2 percent increase in the national average hourly wage.

The following chart compares the shifts in wage index values for hospitals due to changes in the average hourly wage data for FY 2024 relative to FY 2023. These figures reflect proposed changes in the ''pre-reclassified, occupational mix-adjusted wage index,'' that is, the wage index before the application of geographic reclassification, the rural floor, the out-migration adjustment, and other wage index exceptions and adjustments. We note that the ''post-reclassified wage index'' or ''payment wage index,'' which is the wage index that includes all such exceptions and adjustments (as reflected in Tables 2 and 3 associated with this final rule) is used to adjust the labor-related share of a hospital's standardized amount, either 67.6 percent (as proposed) or 62 percent, depending upon whether a hospital's wage index is greater than 1.0 or less than or equal to 1.0. Therefore, the pre-reclassified wage index figures in the following chart may illustrate a somewhat larger or smaller change than would occur in a hospital's payment wage index and total payment.

The following chart shows the projected impact of changes in the area wage index values for urban and rural hospitals based on the wage data used for this final rule.

FY 2024 Percentage Change in Area Wage Index Values	Number of Hospitals	
	Urban	Rural
Increase 10 percent or more	3	1
Increase greater than or equal to 5 percent and less than 10 percent	80	0
Increase or decrease less than 5 percent	2,226	689
Decrease greater than or equal to 5 percent and less than 10 percent	79	10
Decrease 10 percent or more	7	0
Unchanged	0	0

d. Effects of MGCRB Reclassifications (Column 4)

Our impact analysis to this point has assumed acute care hospitals are paid on the basis of their actual geographic location (with the exception of ongoing policies that provide that certain hospitals receive payments on bases other than where they are geographically located, such as hospitals with a § 412.103 reclassification). The changes in Column 4 reflect the per case payment impact of moving from this baseline to a simulation incorporating the MGCRB decisions for FY 2024.

By spring of each year, the MGCRB makes reclassification determinations that will be effective for the next fiscal year, which begins on October 1. The MGCRB may approve a hospital's reclassification request for the purpose of using another area's wage index value. Hospitals may appeal denials by the MGCRB of reclassification requests to the CMS Administrator. Further, hospitals have 45 days from the date the IPPS proposed rule is issued in the **Federal Register** to decide whether to withdraw or terminate an approved geographic reclassification for the following year.

As discussed in section III.G.1. of this final rule, this column also reflects the change to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and to only exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) in accordance with the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. Consistent with this change, beginning with FY 2024 we are including the data of all § 412.103 hospitals (including those that have an MGCRB reclassification where appropriate) in the calculation of ''the wage index for rural areas in the State in which the county is located,'' as referred to in section 1886(d)(8)(C)(iii) of the Act.

The overall effect of geographic reclassification is required by section 1886(d)(8)(D) of the Act to be budget neutral. Therefore, for purposes of this impact analysis, we are applying an adjustment of 0.971295 to ensure that the effects of the reclassifications under sections 1886(d)(8)(B) and (C) and 1886(d)(10) of the Act are budget neutral (section II.A. of the Addendum to this final rule).

Geographic reclassification generally benefits hospitals in rural areas. We estimate that the geographic reclassification would increase payments to rural hospitals by an average of 1.8 percent. By region, rural hospital categories would experience increases in payments due to MGCRB reclassifications.

Table 2 listed in section VI. of the Addendum to this final rule and available via the internet on the CMS website reflects the reclassifications for FY 2024.

e. Effects of the Rural Floor, Including Application of National Budget Neutrality (Column 5)

As discussed in section III.G.1. of the preamble of this FY 2024 IPPS/LTCH PPS final rule, section 4410 of Pub. L. 105–33 established the rural floor by requiring that the wage index for a hospital in any urban area cannot be less than the wage index applicable to hospitals located in rural areas in the same state. We apply a uniform budget neutrality adjustment to the wage index. Column 5 shows the effects of the rural floor.

As discussed in section III.G.1 of this final rule, this column also reflects the change to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and to only exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) in accordance with the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. Consistent with this change, beginning with FY 2024, we are including the data of all § 412.103 hospitals (including those that have an MGCRB reclassification where appropriate) in the calculation of the rural floor.

The Affordable Care Act requires that we apply one rural floor budget neutrality factor to the wage index nationally. We have calculated a FY 2024 rural floor budget neutrality factor to be applied to the wage index of 0.978183, which would reduce wage indexes by 2.2 percent compared to the rural floor provision not being in effect.

Column 5 shows the projected impact of the rural floor with the national rural floor budget neutrality factor applied to the wage index based on the OMB labor market area delineations and the projected impact of the change to the rural floor and rural wage index methodology. The column compares the post-reclassification FY 2024 wage index of providers before the rural floor adjustment and the post-reclassification FY 2024 wage index of providers with the rural floor adjustment based on the OMB labor market area delineations and with the change to the rural floor and the rural wage index methodology applied.

We estimate that 646 hospitals would receive the rural floor in FY 2024. All IPPS hospitals in our model would have their wage indexes reduced by the rural floor budget neutrality adjustment of 0.978183. We project that, in aggregate, rural hospitals would experience a 0.6 percent decrease in payments as a result of the application of the rural floor budget neutrality adjustment because the rural hospitals do not benefit from the rural floor, but have their wage indexes downwardly adjusted to ensure that the application of the rural floor is budget neutral overall. We project that, in the aggregate, hospitals located in urban areas would experience no change in payments, because increases in payments to hospitals benefitting from the rural floor offset decreases in payments to non-rural floor urban hospitals whose wage index is downwardly adjusted by the rural floor budget neutrality factor. Urban hospitals in the Pacific region would experience a 2.7 percent increase in payments primarily due to the application of the rural floor in California.

f. Effects of the Application of the Imputed Floor, Frontier State Wage Index and Out-Migration Adjustment (Column 6)

This column shows the combined effects of the application of the following: (1) the imputed floor under section 1886(d)(3)(E)(iv)(I) and (II) of the Act, which provides that for discharges occurring on or after October 1, 2021, the area wage index applicable to any hospital in an all-urban State may not be less than the minimum area wage index for the fiscal year for hospitals in that State established using the methodology described in § 412.64(h)(4)(vi) as in effect for FY 2018; (2) section 10324(a) of the Affordable Care Act, which requires that we establish a minimum post-reclassified wage index of 1.00 for all hospitals located in ''frontier States;'' and (3) the effects of section 1886(d)(13) of the Act, which provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county, but work in a different area with a higher wage index.

These three wage index provisions are not budget neutral and would increase payments overall by 0.4 percent compared to the provisions not being in effect.

Section 1886(d)(3)(E)(iv)(III) of the Act provides that the imputed floor wage index for all-urban States shall not be applied in a budget neutral manner. Therefore, the imputed floor adjustment is estimated to increase IPPS operating payments by approximately $230 million. There are an estimated 65 providers in Connecticut, Delaware, Washington DC, New Jersey, and Rhode Island that will receive the imputed floor wage index.

The term ''frontier States'' is defined in the statute as States in which at least 50 percent of counties have a population density less than 6 persons per square mile. Based on these criteria, 5 States (Montana, Nevada, North Dakota, South Dakota, and Wyoming) are considered frontier States, and an estimated 42 hospitals located in Montana, North Dakota, South Dakota, and Wyoming would receive a frontier wage index of 1.0000. We note, the rural floor for Nevada exceeds the frontier state wage index of 1.000, and therefore no hospitals in Nevada receive the frontier state wage index. Overall, this provision is not budget neutral and is estimated to increase IPPS operating payments by approximately $60 million.

In addition, section 1886(d)(13) of the Act provides for an increase in the wage index for hospitals located in certain counties that have a relatively high percentage of hospital employees who reside in the county but work in a different area with a higher wage index. Hospitals located in counties that qualify for the payment adjustment would receive an increase in the wage index that is equal to a weighted average of the difference between the wage index of the resident county, post-reclassification and the higher wage index work area(s), weighted by the overall percentage of workers who are employed in an area with a higher wage index. There are an estimated 173 providers that would receive the out-migration wage adjustment in FY 2024. This out-migration wage adjustment

is not budget neutral, and we estimate the impact of these providers receiving the out-migration increase would be approximately $52 million.

g. Effects of All FY 2024 Changes (Column 7)

Column 7 shows our estimate of the changes in payments per discharge from FY 2023 and FY 2024, resulting from all changes reflected in this final rule for FY 2024. It includes combined effects of the year-to-year change of the previous columns in the table.

The average increase in payments under the IPPS for all hospitals is approximately 3.1 percent for FY 2024 relative to FY 2023 and for this row is primarily driven by the changes reflected in Column 1. Column 7 includes the annual hospital update of 3.1 percent to the national standardized amount. This annual hospital update includes the 3.3 percent market basket rate-of-increase reduced by the 0.2 percentage point productivity adjustment. Hospitals paid under the hospital-specific rate would receive a 3.1 percent hospital update. As described in Column 1, the annual hospital update for hospitals paid under the national standardized amount, combined with the annual hospital update for hospitals paid under the hospital-specific rates, combined with the other adjustments described previously and shown in Table I, would result in a 3.1 percent increase in payments in FY 2024 relative to FY 2023.

This column also reflects the estimated effect of outlier payments returning to their targeted levels in FY 2024 as compared to the estimated outlier payments for FY 2023 produced from our payment simulation model. As discussed in section II.A.4.j. of the Addendum to this final rule, the statute requires that outlier payments for any year are projected to be not less than 5 percent nor more than 6 percent of total operating DRG payments plus outlier payments, and also requires that the average standardized amount be reduced by a factor to account for the estimated proportion of total DRG payments made to outlier cases. We continue to use a 5.1 percent target (or an outlier offset factor of 0.949) in calculating the outlier offset to the standardized amount, just as we did for FY 2023. Therefore, our estimate of payments per discharge for FY 2024 from our payment simulation model reflects this 5.1 percent outlier payment target. Our payment simulation model shows that estimated outlier payments for FY 2023 exceed that target by approximately 0.3 percent. Therefore, our estimate of the changes in payments per discharge from FY 2023 and FY 2024 in Column 7 reflects the estimated −0.3 percent change in outlier payments produced by our payment simulation model when returning to the 5.1 percent outlier target for FY 2024. There are also interactive effects among the various factors comprising the payment system that we are not able to isolate, which may contribute to our estimate of the changes in payments per discharge from FY 2023 and FY 2024 in Column 7.

Overall payments to hospitals paid under the IPPS due to the applicable percentage increase and changes to policies related to MS–DRGs, geographic adjustments, and outliers are estimated to increase by 3.1 percent for FY 2024. Hospitals in urban areas would experience a 3.1 percent increase in payments per discharge in FY 2024 compared to FY 2023. Hospital payments per discharge in rural areas are estimated to increase by 3.5 percent in FY 2024.

3. Impact Analysis of Table II

Table II presents the projected impact of the changes for FY 2024 for urban and rural hospitals and for the different categories of hospitals shown in Table I. It compares the estimated average payments per discharge for FY 2023 with the estimated average payments per discharge for FY 2024, as calculated under our models. Therefore, this table presents, in terms of the average dollar amounts paid per discharge, the combined effects of the changes presented in Table I. The estimated percentage changes shown in the last column of Table II equal the estimated percentage changes in average payments per discharge from Column 7 of Table I.

TABLE II.--IMPACT ANALYSIS OF CHANGES FOR FY 2024 ACUTE CARE HOSPITAL OPERATING PROSPECTIVE PAYMENT SYSTEM (PAYMENTS PER DISCHARGE)

	Number of Hospitals (1)	Estimated Average FY 2023 Payment Per Discharge (2)	Estimated Average FY 2024 Payment Per Discharge (3)	FY 2024 Changes (4)
All Hospitals	3,131	15,741	16,226	3.1
By Geographic Location:				
Urban hospitals	2,416	16,127	16,619	3.1
Rural hospitals	715	11,736	12,144	3.5
Bed Size (Urban):				
0-99 beds	650	12,051	12,355	2.5
100-199 beds	696	12,843	13,254	3.2
200-299 beds	414	14,388	14,871	3.4
300-499 beds	404	15,896	16,498	3.8
500 or more beds	250	20,094	20,578	2.4
Bed Size (Rural):				
0-49 beds	363	9,901	10,212	3.1
50-99 beds	188	11,569	12,030	4.0
100-149 beds	87	11,371	11,790	3.7
150-199 beds	46	12,690	13,096	3.2
200 or more beds	31	13,853	14,285	3.1
Urban by Region:				
New England	108	17,955	18,041	0.5
Middle Atlantic	292	18,824	19,553	3.9
East North Central	372	15,377	15,560	1.2
West North Central	156	15,447	15,642	1.3
South Atlantic	403	13,823	14,280	3.3
East South Central	138	13,363	13,657	2.2
West South Central	359	14,105	14,337	1.6
Mountain	177	16,223	16,729	3.1
Pacific	360	20,337	21,644	6.4
Puerto Rico	51	9,146	9,318	1.9
Rural by Region:				
New England	19	17,495	17,840	2.0
Middle Atlantic	47	11,703	12,551	7.2

	Number of Hospitals (1)	Estimated Average FY 2023 Payment Per Discharge (2)	Estimated Average FY 2024 Payment Per Discharge (3)	FY 2024 Changes (4)
East North Central	113	11,904	12,250	2.9
West North Central	84	12,168	12,549	3.1
South Atlantic	108	10,759	11,126	3.4
East South Central	140	10,501	10,830	3.1
West South Central	134	9,808	10,108	3.1
Mountain	46	13,806	14,160	2.6
Pacific	24	16,169	17,039	5.4
By Payment Classification:				
Urban hospitals	1,811	14,687	15,176	3.3
Rural areas	1,320	16,977	17,456	2.8
Teaching Status:				
Nonteaching	1,900	12,201	12,633	3.5
Fewer than 100 residents	953	14,464	14,929	3.2
100 or more residents	278	23,163	23,757	2.6
Urban DSH:				
Non-DSH	353	12,630	12,886	2.0
100 or more beds	1,099	15,218	15,750	3.5
Less than 100 beds	359	11,052	11,393	3.1
Rural DSH:				
Non-DSH	108	15,340	15,687	2.3
SCH	257	12,903	13,345	3.4
RRC	712	17,607	18,093	2.8
100 or more beds	32	17,548	18,189	3.7
Less than 100 beds	211	9,629	10,000	3.9
Urban teaching and DSH:				
Both teaching and DSH	637	16,590	17,121	3.2
Teaching and no DSH	57	13,880	14,219	2.4
No teaching and DSH	821	12,358	12,859	4.1
No teaching and no DSH	296	11,947	12,157	1.8
Special Hospital Types:				
RRC	133	12,423	12,804	3.1
RRC with Section 401 Rural Reclassification	491	18,490	18,981	2.7
SCH	256	12,156	12,561	3.3
SCH with Section 401 Rural Reclassification	45	15,004	15,516	3.4
SCH and RRC	121	13,819	14,286	3.4
SCH and RRC with Section 401 Rural Reclassification	43	16,466	16,944	2.9
MDH	116	10,065	10,431	3.6
MDH with Section 401 Reclassification	30	12,929	13,410	3.7
MDH and RRC	18	11,080	11,469	3.5
MDH and RRC with Section 401 Reclassification	13	13,926	14,385	3.3
Type of Ownership:				
Voluntary	1,920	15,799	16,266	3.0
Proprietary	778	13,749	14,266	3.8
Government	432	18,052	18,602	3.0
Medicare Utilization as a Percent of Inpatient Days:				
0-25	995	17,920	18,568	3.6
25-50	1,945	14,967	15,385	2.8
50-65	138	12,459	12,895	3.5
Over 65	25	8,593	8,950	4.1
Medicaid Utilization as a Percent of Inpatient Days:				
0-25	2,038	14,256	14,635	2.7
25-50	974	18,011	18,629	3.4
50-65	91	21,156	22,514	6.4
Over 65	28	19,730	22,029	11.7
FY 2024 Reclassifications:				
All Reclassified Hospitals	1,054	16,846	17,340	2.9
Non-Reclassified Hospitals	2,077	14,731	15,207	3.2
Urban Hospitals Reclassified	869	17,458	17,969	2.9
Urban Nonreclassified Hospitals	1,561	14,794	15,268	3.2
Rural Hospitals Reclassified Full Year	298	11,792	12,185	3.3
Rural Non-Reclassified Hospitals Full Year	403	11,652	12,085	3.7
All Section 401 Reclassified Hospitals:	659	18,109	18,604	2.7

	Number of Hospitals (1)	Estimated Average FY 2023 Payment Per Discharge (2)	Estimated Average FY 2024 Payment Per Discharge (3)	FY 2024 Changes (4)
Other Reclassified Hospitals (Section 1886(d)(8)(B))	54	11,086	11,518	3.9

4. Impact Analysis of Table III: Provider Deciles by Beneficiary Characteristics

Advancing health equity is the first pillar of CMS's 2022 Strategic Framework.[1] To gain insight into how the IPPS policies could affect health equity, we have added Table III, Provider Deciles by Beneficiary Characteristics, for informational purposes. Table III details providers in terms of the beneficiaries they serve, and shows differences in estimated average payments per case and changes in estimated average payments per case relative to other providers.

As noted in section I.C. of this appendix, this final rule contains a range of policies and there is a section of the final rule where each policy is discussed. Each section includes the rationale for our decisions, including the need for the final policy. The information contained in Table III is provided solely to demonstrate the quantitative effects of our policies across a number of health equity dimensions and does not form the basis or rationale for the policies.

Patient populations that have been disadvantaged or underserved by the healthcare system may include patients with the following characteristics, among others: members of racial and ethnic minorities; members of federally recognized Tribes, people with disabilities; members of the lesbian, gay, bisexual, transgender, and queer (LGBTQ+) community; individuals with limited English proficiency, members of rural communities, and persons otherwise adversely affected by persistent poverty or inequality. The CMS Framework for Health Equity was developed with particular attention to disparities in chronic and infectious diseases; as an example of a chronic disease associated with significant disparities, we therefore also detail providers in terms of the percentage of their claims for beneficiaries receiving ESRD Medicare coverage.

Because we do not have data for all characteristics that may identify disadvantaged or underserved patient populations, we use several proxies to capture these characteristics, based on claims data from the FY 2022 MedPAR file and Medicare enrollment data from Medicare's Enrollment Database (EDB), including: race/ethnicity, dual eligibility for Medicaid and Medicare, Medicare low income subsidy (LIS) enrollment, a joint indicator for dual or LIS enrollment, presence of an ICD–10–CM Z code indicating a ''social determinant of health'' (SDOH), presence of a behavioral health diagnosis code, receiving ESRD Medicare coverage, qualifying for Medicare due to disability, living in a rural area, and living in an area with an area deprivation index (ADI) greater than or equal to 85. We refer to each of these proxies as characteristics in Table III and the discussion that follows.

a. Race

The first health equity-relevant grouping presented in Table III is race/ethnicity. To assign the race/ethnicity variables used in Table III, we utilized the Medicare Bayesian Improved Surname Geocoding (MBISG) data in conjunction with the MedPAR data. The method used to develop the MBISG data involves estimating a set of six racial and ethnic probabilities (White, Black, Hispanic, American Indian or Alaskan Native, Asian or Pacific Islander, and multiracial) from the surname and address of beneficiaries by using previous self-reported data from a national survey of Medicare beneficiaries, post-stratified to CMS enrollment files. The MBISG method is used by the CMS Office of Minority Health in its reports analyzing Medicare Advantage plan performance on Healthcare Effectiveness Data and Information Set (HEDIS) measures, and is being considered by CMS for use in other CMS programs. To estimate the percentage of discharges for each specified racial/ethnic category for each hospital, the sum of the probabilities for that category for that hospital was divided by the hospital's total number of discharges.

b. Income

The two main proxies for income available in the Medicare claims and enrollment data are dual eligibility for Medicare and Medicaid and Medicare LIS status. Dual-enrollment status is a powerful predictor of poor outcomes on some quality and resource use measures even after accounting for additional social and functional risk factors.[2] Medicare LIS enrollment refers to a beneficiary's enrollment in the low-income subsidy program for the Part D prescription drug benefit. This program covers all or part of the Part D premium for qualifying Medicare beneficiaries and gives them access to reduced copays for Part D drugs. (We note that beginning on January 1, 2024, eligibility for the full low-income subsidy will be expanded to include individuals currently eligible for the partial low-income subsidy.) Because Medicaid eligibility rules and benefits vary by state/territory, Medicare LIS enrollment identifies beneficiaries who are likely to have low income but may not be eligible for Medicaid. Not all beneficiaries who qualify for the duals or LIS programs actually enroll. Due to differences in the dual eligibility and LIS qualification criteria and less than complete participation in these programs, sometimes beneficiaries were flagged as dual but not LIS or vice versa. Hence this analysis also used a ''dual or LIS'' flag as a third proxy for low income. The dual and LIS flags were constructed based on enrollment/eligibility status in the EDB during the month of the hospital discharge.

c. Social Determinants of Health (SDOH)

Social determinants of health (SDOH) are the conditions in the environments where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.[3] These circumstances or determinants influence an individual's health status and can contribute to wide health disparities and inequities. ICD–10–CM contains Z-codes that describe a range of issues related—but not limited—to education and literacy, employment, housing, ability to obtain adequate amounts of food or safe drinking water, and occupational exposure to toxic agents, dust, or radiation. The presence of ICD–10–CM Z-codes in the range Z55–Z65 identifies beneficiaries with these SDOH characteristics. The SDOH flag used for this analysis was turned on if one of these Z-codes was recorded on the claim for the hospital stay itself (that is, the beneficiary's prior claims were not examined for additional Z-codes). Since these codes are not required for Medicare FFS patients and do not currently impact payment under the IPPS, we believe they may be underreported in current claims data and not reflect the actual rates of SDOH. In 2019, 0.11% of all Medicare FFS claims were Z code claims and 1.59% of continuously enrolled Medicare FFS beneficiaries had claims with Z codes.[4] However, we expect the reporting of Z codes on claims may increase over time, because of newer quality measures in the Hospital Inpatient Quality Reporting (IQR) Program that capture screening and identification of patient-level, health-related social needs (MUC21–134 and MUC21–136) (*see* 87 FR 49201 through 49220). We also refer the reader to section II.C.12.c. of the preamble of this final rule, where we discuss our final policy to change the severity level designation for ICD–10–CM diagnosis codes Z59.00 (Homelessness, unspecified), Z59.01 (Sheltered homelessness) and Z59.02 (Unsheltered homelessness) from a non-CC to a CC for FY 2024.

[1] Available at: *https://www.cms.gov/files/document/2022-cms-strategic-framework.pdf.*

[2] *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195046/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report-Executive-Summary.pdf.*

[3] *Available at: https://health.gov/healthypeople/priority-areas/social-determinants-health.*

[4] See ''Utilization of Z Codes for Social Determinants of Health among Medicare Fee-for-Service Beneficiaries, 2019,'' available at *https://www.cms.gov/files/document/z-codes-data-highlight.pdf.*

d. Behavioral Health

Beneficiaries with behavioral health diagnoses often face co-occurring physical illnesses, but often experience difficulty accessing care.[5] The combination of physical and behavioral health conditions can exacerbate both conditions and result in poorer outcomes than one condition alone.[6] Additionally, the intersection of behavioral health and health inequities is a core aspect of CMS' Behavioral Health Strategy.[7] We used the presence of one or more ICD–10–CM codes in the range of F01–F99 to identify beneficiaries with a behavioral health diagnosis.

e. Disability

Beneficiaries are categorized as disabled because of medically determinable physical or mental impairment(s) that has lasted or is expected to last for a continuous period of at least 12 months or is expected to result in death.[8] Disabled beneficiaries often have complex healthcare needs and difficulty accessing care. Beneficiaries were classified as disabled for the purposes of this analysis if their original reason for qualifying for Medicare was disability; this information was obtained from Medicare's EDB. We note that this is likely an underestimation of disability because it does not account for beneficiaries who became disabled after becoming entitled to Medicare. This metric also does not capture all individuals who would be considered to have a disability under 29 U.S.C. 705(9)(B).

f. ESRD

Beneficiaries with ESRD have high healthcare needs and high medical spending, and often experience comorbid conditions and poor mental health. Beneficiaries with ESRD also experience significant disparities, such as a limited life expectancy.[9] Beneficiaries were classified as ESRD for the purposes of this analysis if they were receiving Medicare ESRD coverage during the month of the discharge; this information was obtained from Medicare's EDB.

g. Geography

Beneficiaries in some geographic areas—particularly rural areas or areas with concentrated poverty—often have difficulty accessing care.[10] [11] For this impact analysis, beneficiaries were classified on two dimensions: from a rural area and from an area with an area deprivation index (ADI) greater than or equal to 85.

Rural status is defined for purposes of this analysis using the primary Rural-Urban Commuting Area (RUCA) codes 4–10 (including micropolitan, small town, and rural areas) corresponding to each beneficiary's zip code. RUCA codes are defined at the census tract level based on measures of population density, urbanization, and daily commuting. The ADI is obtained from a publicly available dataset designed to capture socioeconomic disadvantage at the neighborhood level.[12] It utilizes data on income, education, employment, housing quality, and 13 other factors from the American Community Survey and combines them into a single raw score, which is then used to rank neighborhoods (defined at various levels), with higher scores reflecting greater deprivation. The version of the ADI used for this analysis is at the Census Block Group level and the ADI corresponds to the Census Block Group's percentile nationally. Living in an area with an ADI score of 85 or above, a validated measure of neighborhood disadvantage, is shown to be a predictor of 30-day readmission rates, lower rates of cancer survival, poor end of life care for patients with heart failure, and longer lengths of stay and fewer home discharges post-knee surgery even after accounting for individual social and economic risk factors.[13] [14] [15] [16] [17] The MedPAR discharge data was linked to the RUCA using beneficiaries' five-digit zip code and to the ADI data using beneficiaries' 9-digit zip codes, both of which were derived from Common Medicare Enrollment (CME) files. Beneficiaries with no recorded zip code were treated as being from an urban area and as having an ADI less than 85.

For each of these characteristics, the hospitals were classified into groups as follows. First, all discharges at IPPS hospitals (excluding Maryland and IHS hospitals) in the FY 2022 MedPAR file were flagged for the presence of the characteristic, with the exception of race/ethnicity, for which probabilities were assigned instead of binary flags, as described further in this section. Second, the percentage of discharges at each hospital for the characteristic was calculated. Finally, the hospitals were divided into four groups based on the percentage of discharges for each characteristic: decile group 1 contains the 10% of hospitals with the lowest rate of discharges for that characteristic; decile group 2 to 5 contains the hospitals with less than or equal to the median rate of discharges for that characteristic, excluding those in decile group 1; decile group 6 to 9 contains the hospitals with greater than the median rate of discharges for that characteristic, excluding those in decile group 10; and decile group 10 contains the 10% of hospitals with the highest rate of discharges for that characteristic. These decile groups provide an overview of the ways in which the average estimated payments per discharge vary between the providers with the lowest and highest percentages of discharges for each characteristic, as well as those above and below the median.

We note that a supplementary provider-level dataset containing the percentage of discharges at each hospital for each of the characteristics in Table III is available on our website.

- Column 1 of Table III specifies the beneficiary characteristic;
- Column 2 specifies the decile group;
- Column 3 specifies the percentiles covered by the decile group; and
- Column 4 specifies the percentage range of discharges for each decile group specified in the first column.
- Columns 5 and 6 present the average estimated payments per discharge for FY 2023 and average estimated payments per discharge for FY 2024, respectively.
- Column 7 shows the percentage difference between these averages.

The average payment per discharge, as well as the percentage difference between the average payment per discharge in FY 2023 and FY 2024, can be compared across decile groups. For example, providers with the lowest decile of discharges for Dual(All) or LIS Enrolled beneficiaries have an average FY 2023 payment per discharge of $13,500.03, while providers with the highest decile of discharges for Dual(All) or LIS Enrolled beneficiaries have an average FY 2023 payment per discharge of $19,779.23.

---

[5] Viron M, Zioto K, Schweitzer J, Levine G. Behavioral Health Homes: an opportunity to address healthcare inequities in people with serious mental illness. Asian J Psychiatr. 2014 Aug; 10:10–6. doi: 10.1016/j.ajp.2014.03.009.

[6] Cully, J.A., Breland, J.Y., Robertson, S. et al. Behavioral health coaching for rural veterans with diabetes and depression: a patient randomized effectiveness implementation trial. BMC Health Serv Res 14, 191 (2014). *https://doi.org/10.1186/1472-6963-14-191*.

[7] *https://www.cms.gov/cms-behavioral-health-strategy*.

[8] *https://www.ssa.gov/disability/professionals/bluebook/general-info.htm*.

[9] Smart NA, Titus TT. Outcomes of early versus late nephrology referral in chronic kidney disease: a systematic review. Am J Med. 2011 Nov;124(11):1073–80.e2. doi: 10.1016/j.amjmed.2011.04.026. PMID: 22017785.

[10] National Healthcare Quality and Disparities Report chartbook on rural health care. Rockville, MD: Agency for Healthcare Research and Quality; October 2017. AHRQ Pub. No. 17(18)-0001–2–EF, available at *https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/nhqrdr/chartbooks/qdr-ruralhealthchartbook-update.pdf*.

[11] Muluk, S, Sabik, L, Chen, Q, Jacobs, B, Sun, Z, Drake, C. Disparities in geographic access to medical oncologists. *Health Serv Res.* 2022; 57(5): 1035–1044. doi:10.1111/1475–6773.13991.

[12] *https://www.neighborhoodatlas.medicine.wisc.edu/*.

[13] 7 U.S. Department of Health & Human Services, ''Executive Summary: Report to Congress: Social Risk Factors and Performance in Medicare's Value-Based Purchasing Program,'' Office of the Assistant Secretary for Planning and Evaluation, March 2020. Available at *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195046/Social-Risk-inMedicare%E2%80%99s-VBP-2nd-Report-Executive-Summary.pdf*.

[14] Kind AJ, et al., ''Neighborhood socioeconomic disadvantage and 30-day rehospitalization: a retrospective cohort study.'' Annals of Internal Medicine. No. 161(11), pp 765–74, doi: 10.7326/M13–2946 (December 2, 2014), available at *https://www.acpjournals.org/doi/epdf/10.7326/M13-2946*.

[15] Jencks SF, et al., ''Safety-Net Hospitals, Neighborhood Disadvantage, and Readmissions Under Maryland's All-Payer Program.'' Annals of Internal Medicine. No. 171, pp 91–98, doi:10.7326/M16–2671 (July 16, 2019), available athttps://*www.acpjournals.org/doi/epdf/10.7326/M16-2671*.

[16] Cheng E, et al., ''Neighborhood and Individual Socioeconomic Disadvantage and Survival Among Patients With Nonmetastatic Common Cancers.'' JAMA Network Open Oncology. No. 4(12), pp 1–17, doi: 10.1001/jamanetworkopen.2021.39593 (December 17, 2021), available at *https://online library.wiley.com/doi/epdf/10.1111/jrh.12597*.

[17] Khlopas A, et al., ''Neighborhood Socioeconomic Disadvantages Associated With Prolonged Lengths of Stay, Nonhome Discharges, and 90-Day Readmissions After Total Knee Arthroplasty.'' The Journal of Arthroplasty. No. 37(6), pp S37–S43, doi: 10.1016/j.arth.2022.01.032 (June 2022), available at *https://www.sciencedirect.com/science/article/pii/* S0883540322000493.

This pattern is also seen in the average FY 2024 payment per discharge.

Comment: A few commenters supported the addition of the 15 new health equity hospital categorizations as presented in the proposed rule.

Response: We appreciate commenters' support. We are providing an updated Table III using the more recent data available for this final rule.

BILLING CODE 4120–01–P

TABLE III. PROVIDER DECILES BY BENEFICIARY CHARACTERISTICS

Beneficiary Characteristics (1)	Decile Group* (2)	Percentile Range of Group (3)	Decile Value Range (4)	Average Payment Per Discharge - FY 2023 (5)	Average Payment Per Discharge - FY 2024 (6)	Percent Change (7)
All Hospitals				15,741.05	16,225.71	3.1%
% Of Discharges for Beneficiaries Who Are American Indian or Alaska Native	1	0 to 10	0.1% - 0.2%	12,244.26	12,473.69	1.9%
	2 to 5	>10 to 50	0.2% - 0.3%	15,144.88	15,519.39	2.5%
	6 to 9	>50 to 90	0.3% - 1.3%	17,095.17	17,754.18	3.9%
	10	>90 to 100	1.3% - 48.6%	15,487.81	15,974.98	3.1%
% Of Discharges for Beneficiaries Who Are Asian or Pacific Islander	1	0 to 10	0.0% - 0.2%	10,391.59	10,687.12	2.8%
	2 to 5	>10 to 50	0.2% - 0.8%	12,895.49	13,257.00	2.8%
	6 to 9	>50 to 90	0.8% - 4.9%	16,411.50	16,853.16	2.7%
	10	>90 to 100	4.9% - 95.1%	21,502.44	22,538.97	4.8%
% Of Discharges for Beneficiaries Who Are Black	1	0 to 10	0.0% - 0.4%	13,055.75	13,376.97	2.5%
	2 to 5	>10 to 50	0.4% - 4.3%	14,424.23	14,891.48	3.2%
	6 to 9	>50 to 90	4.3% - 24.4%	16,460.05	16,972.70	3.1%
	10	>90 to 100	24.4% - 95.9%	18,430.40	18,895.95	2.5%
% Of Discharges for Beneficiaries Who Are Hispanic	1	0 to 10	0.3% - 1.1%	12,163.17	12,515.36	2.9%
	2 to 5	>10 to 50	1.1% - 2.6%	13,955.81	14,269.57	2.2%
	6 to 9	>50 to 90	2.6% - 21.0%	17,154.62	17,689.06	3.1%
	10	>90 to 100	21.0% - 98.5%	18,050.92	19,254.78	6.7%

Beneficiary Characteristics (1)	Decile Group* (2)	Percentile Range of Group (3)	Decile Value Range (4)	Average Payment Per Discharge - FY 2023 (5)	Average Payment Per Discharge - FY 2024 (6)	Percent Change (7)
% Of Discharges for Beneficiaries Who Are Multiracial	1	0 to 10	0.1% - 1.5%	13,462.81	13,909.00	3.3%
	2 to 5	>10 to 50	1.5% - 2.1%	15,229.28	15,669.77	2.9%
	6 to 9	>50 to 90	2.1% - 3.1%	16,460.05	16,981.96	3.2%
	10	>90 to 100	3.1% - 10.5%	16,923.21	17,499.33	3.4%
% Of Discharges for Beneficiaries Who Are White	1	0 to 10	0.1% - 45.9%	20,281.36	21,244.51	4.7%
	2 to 5	>10 to 50	45.9% - 84.8%	17,142.48	17,657.02	3.0%
	6 to 9	>50 to 90	84.8% - 95.0%	13,832.43	14,231.39	2.9%
	10	>90 to 100	95.0% - 98.2%	11,680.89	11,994.14	2.7%
% Of Discharges for Beneficiaries Who Are Dual(All) Enrolled During The Month Of Discharge	1	0 to 10	0.0% - 11.2%	13,498.58	13,767.90	2.0%
	2 to 5	>10 to 50	11.2% - 25.8%	14,551.16	14,899.75	2.4%
	6 to 9	>50 to 90	25.8% - 50.1%	17,042.97	17,633.84	3.5%
	10	>90 to 100	50.1% - 100.0%	20,031.32	21,241.33	6.0%
% Of Discharges for Beneficiaries Who Are LIS Enrolled During The Month Of Discharge	1	0 to 10	0.0% - 13.2%	13,514.17	13,801.82	2.1%
	2 to 5	>10 to 50	13.2% - 28.3%	14,669.68	15,022.90	2.4%
	6 to 9	>50 to 90	28.3% - 53.5%	17,011.32	17,611.03	3.5%
	10	>90 to 100	53.5% - 100.0%	19,776.30	20,944.75	5.9%
% Of Discharges for Beneficiaries Who Are Dual(All) or LIS Enrolled During The Month Of Discharge	1	0 to 10	0.0% - 13.2%	13,500.03	13,786.41	2.1%
	2 to 5	>10 to 50	13.2% - 28.3%	14,665.75	15,019.20	2.4%
	6 to 9	>50 to 90	28.3% - 53.5%	17,015.22	17,614.13	3.5%

Beneficiary Characteristics (1)	Decile Group* (2)	Percentile Range of Group (3)	Decile Value Range (4)	Average Payment Per Discharge - FY 2023 (5)	Average Payment Per Discharge - FY 2024 (6)	Percent Change (7)
	10	>90 to 100	53.5% - 100.0%	19,779.23	20,950.62	5.9%
% Of Discharges for Beneficiaries With a Z code reported related to SDOH **	1	0 to 10	0%	11,658.11	11,934.99	2.4%
	2 to 5	>10 to 50	0.0% - 1.2%	14,865.94	15,320.40	3.1%
	6 to 9	>50 to 90	1.2% - 4.7%	16,200.33	16,677.74	2.9%
	10	>90 to 100	4.7% - 59.5%	18,017.60	18,733.66	4.0%
% Of Discharges for Beneficiaries With a Behavioral Health Diagnosis	1	0 to 10	0.0% - 35.3%	18,016.70	18,607.22	3.3%
	2 to 5	>10 to 50	35.3% - 46.6%	16,533.82	17,059.74	3.2%
	6 to 9	>50 to 90	46.6% - 57.4%	14,743.11	15,138.56	2.7%
	10	>90 to 100	57.4% - 100.0%	13,943.19	14,675.89	5.3%
% Of Discharges for Beneficiaries who come from rural areas	1	0 to 10	0.0% - 0.8%	16,650.86	17,119.01	2.8%
	2 to 5	>10 to 50	0.8% - 14.0%	16,187.97	16,715.39	3.3%
	6 to 9	>50 to 90	14.0% - 93.9%	15,309.77	15,749.46	2.9%
	10	>90 to 100	93.9% - 100.0%	11,813.81	12,235.97	3.6%
% Of Discharges for Beneficiaries With ESRD coverage **	1	0 to 10	0%	11,124.30	11,388.98	2.4%
	2 to 5	>10 to 50	0.0% - 4.2%	13,179.54	13,552.31	2.8%
	6 to 9	>50 to 90	4.2% - 9.8%	16,290.82	16,769.89	2.9%
	10	>90 to 100	9.8% - 87.5%	19,906.33	20,735.97	4.2%
	1	0 to 10	0.0% - 17.0%	14,180.96	14,567.66	2.7%

Beneficiary Characteristics (1)	Decile Group* (2)	Percentile Range of Group (3)	Decile Value Range (4)	Average Payment Per Discharge - FY 2023 (5)	Average Payment Per Discharge - FY 2024 (6)	Percent Change (7)
% Of Discharges for Beneficiaries with Disability	2 to 5	>10 to 50	17.0% - 27.4%	15,250.58	15,644.53	2.6%
	6 to 9	>50 to 90	27.4% - 39.7%	16,433.79	17,012.19	3.5%
	10	>90 to 100	39.7% - 100.0%	17,788.32	18,573.66	4.4%
% Of Discharges for Beneficiaries who live in an area with ADI >= 85	1	0 to 10	0.0% - 0.6%	18,272.11	18,748.63	2.6%
	2 to 5	>10 to 50	0.6% - 12.4%	16,379.17	16,914.52	3.3%
	6 to 9	>50 to 90	12.4% - 45.8%	14,524.77	14,958.59	3.0%
	10	>90 to 100	45.8% - 100.0%	12,173.03	12,553.29	3.1%

* Decile group 1 contains the 10% of hospitals with the lowest rate of discharges for that characteristic; decile group 2 to 5 contains the hospitals with less than or equal to the median rate of discharges for that characteristic, excluding those in decile group 1; decile group 6 to 9 contains the hospitals with greater than the median rate of discharges for that characteristic, excluding those in group 10; and decile group 10 contains the 10% of hospitals with the highest rate of discharges for that characteristic.

** Greater than 10 percent of providers did not report discharges associated with this characteristic. Therefore, we have randomly allocated those providers to decile groups 1 and 2.

G. Effects of Other Policy Changes

In addition to those policy changes discussed previously that we can model using our IPPS payment simulation model, we are making various other changes in this final rule. As noted in section I.D. of this appendix, our payment simulation model uses the most recent available claims data to estimate the impacts on payments per case of certain changes in this final rule. Generally, we have limited or no specific data available with which to estimate the impacts of these changes using that payment simulation model. For these changes, we have attempted to predict the payment impacts based upon our experience and other more limited data. Our estimates of the likely impacts associated with these other changes are discussed in this section.

1. Effects of Policy Changes Relating to New Medical Service and Technology Add-On Payments

In addition to those proposed policy changes discussed previously that we are able to model using our IPPS payment simulation model, we are making various other changes in this final rule. As noted in section I.D. of this appendix, our payment simulation model uses the most recent available claims data to estimate the impacts on payments per case of certain proposed changes in this final rule. Generally, we have limited or no specific data available with which to estimate the impacts of these changes using that payment simulation model. For those changes, we have attempted to predict the payment impacts based upon our experience and other more limited data. Our estimates of the likely impacts associated with these other changes are discussed in this section.

1. Effects of Policy Changes Relating to New Medical Service and Technology Add-On Payments

a. FY 2024 Status of Technologies Approved for FY 2023 New Technology Add-On Payments

As discussed in section II.E.5. of the preamble of this final rule, we are continuing new technology add-on payments in FY 2024 for 11 technologies that are still within their newness period. Under § 412.88(a)(2), the new technology add-on payment for each case involving use of an approved technology would be limited to the lesser of: (1) 65 percent of the costs of the new technology (or 75 percent of the costs for technologies designated as Qualified Infectious Disease Products (QIDPs) or approved under the Limited Population Pathway for Antibacterial and Antifungal Drugs (LPAD) pathway); or (2) 65 percent of the amount by which the costs of the case exceed the standard MS–DRG payment for the case (or 75 percent of the amount for technologies designated as QIDPs or approved under the LPAD pathway). Because it is difficult to predict the actual new technology add-on payment for each case, the estimated total payments in this final rule are based on the applicant's estimated cost and volume projections at the time they submitted their application (or based on updated figures provided during the public comment period) and the assumption that every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment.

In the following table, we present estimated payment for the 11 technologies for which we are continuing to make new technology add-on payments in FY 2024:

FY 2024 ESTIMATES FOR NEW TECHNOLOGY ADD-ON PAYMENTS TO CONTINUE FOR FY 2024

Technology Name	Estimated Cases	FY 2024 NTAP Amount (65 % or 75 %)	Estimated Total FY 2024 Impact
Intercept® (PRCFC)	2,296	$2,535.00	$5,820,360.00
Rybrevant™	349	$6,405.89	$2,235,655.61
StrataGraft®	261	$44,200.00	$11,536,200.00
Hemolung Respiratory Assist System (RAS) *(excluding use related to COVID-19)*	161	$6,500.00	$1,046,500.00
aprevo® Intervertebral Body Fusion Device *(TLIF indication)*	1,261	$40,950.00	$51,637,950.00
Livtencity™	129.5	$32,500.00	$4,208,750.00
Thoraflex Hybrid Device	800	$22,750.00	$18,200,000.00
ViviStim	135	$23,400.00	$3,159,000.00
GORE TAG Thoracic Branch Endoprosthesis	386	$27,807.00	$10,733.502.00
Cerament® G	1,610	$4,918.55	$7,918,865.50
iFuse Bedrock Granite Implant System	1,480	$9,828.00	$14,545,440.00
Aggregate Estimated Total FY 2024 Impact			**$131,042,223.11**

b. FY 2024 Applications for New Technology Add-On Payments

In sections II.E.6. and 7. of the preamble to this final rule, we discussed 25 technologies for which we received applications for add-on payments for new medical services and technologies for FY 2024. We noted that of the 54 applications (27 alternative and 27 traditional) we received, 26 applicants withdrew their application (14 alternative and 12 traditional) prior to the issuance of this final rule, and 3 technologies (1 alternative and 2 traditional) did not meet the July 1 deadline for FDA approval or clearance of the technology and are therefore ineligible for consideration for new technology add-on payments for FY 2024. Of the 25 technologies discussed in the preamble of this final rule, we are not approving 3, and 4 other applications are considered as 2 technologies due to substantial similarity. This results in a total of 20 new approvals or conditional approvals (8 traditional and 12 alternative) for new technology add-on payments for FY 2024. As explained in the preamble to this final rule, add-on payments for new medical services and technologies under section 1886(d)(5)(K) of the Act are not required to be budget neutral.

As discussed in section II.E.7. of the preamble of this final rule, under the alternative pathway for new technology add-on payments, new technologies that are medical products with a QIDP designation, approved through the FDA LPAD pathway, or are designated under the Breakthrough Device program will be considered not substantially similar to an existing technology for purposes of the new technology add-on payment under the IPPS, and will not need to demonstrate that the technology represents a substantial clinical improvement. These technologies must still be within the 2 to 3-year newness period, as discussed in section II.E.1.a.(1). of the preamble this final rule, and must also still meet the cost criterion.

As fully discussed in section II.E.7. of the preamble of this final rule, we are approving or conditionally approving 12 alternative pathway applications submitted for FY 2024 new technology add-on payments, including 9 technologies that received a Breakthrough Device designation from FDA and 3 that were designated as a QIDP by FDA. We did not receive any LPAD applications for add-on payments for new technologies for FY 2024.

Based on information from the applicants at the time of this final rule, we estimate that total payments for the 12 technologies approved under the alternative pathway will be approximately $305 million for FY 2024. Total estimated FY 2024 payments for new technologies that are designated as a QIDP are approximately $218 million, and the total estimated FY 2024 payments for new technologies that are part of the Breakthrough Device program are approximately $87 million.

In the following table, we present detailed estimates for the 12 technologies for which we are approving or conditionally approving new technology add-on payments under the alternative pathway in FY 2024:

FY 2024 ESTIMATES FOR NEW TECHNOLOGY ADD-ON PAYMENTS FOR TECHNOLOGIES UNDER THE ALTERNATIVE PATHWAY FOR FY 2024				
Technology Name	**Pathway (QIDP, LPAD, or Breakthrough Device)**	**Estimated Cases**	**FY 2024 NTAP Amount (65 % or 75 %)**	**Estimated Total FY 2024 Impact**
taurolidine/heparin*	QIDP	12,000	$17,111.25	$205,335,000.00
REZZAYO™	QIDP	795	$4,387.50	$3,488,062.50
XACDURO®	QIDP	654	$13,680.00	$8,946,720.00
Aveir™ AR Leadless Pacemaker	Breakthrough Device	245	$10,725.00	$2,627,625.00
Aveir™ Leadless Pacemaker (Dual-Chamber)	Breakthrough Device	2,250	$15,600.00	$35,100,000.00
Canary Tibial Extension (CTE) with Canary Health Implanted Reporting Processor (CHIRP) System	Breakthrough Device	3,157	$850.85	$2,686,133.45
Ceribell Status Epilepticus Monitor	Breakthrough Device	2,477	$913.90	$2,263,730.30
EchoGo Heart Failure 1.0	Breakthrough Device	19,656	$1,023.75	$20,122,830.00
Phagenyx® System	Breakthrough Device	294	$3,250.00	$955,500.00
SAINT Neuromodulation System	Breakthrough Device	25	$12,675.00	$316,875.00
DETOUR System	Breakthrough Device	600	$16,250.00	$9,750,000.00
TOPS™ System	Breakthrough Device	1,200	$11,375.00	$13,650,000.00
Estimated Total FY 2024 Impact				**$305,242,476.25**

*Conditional approval; Payments will only be made if the technology receives FDA approval, beginning the quarter after approval is received.

As fully discussed in section II.E.6. of the preamble of this final rule, we are approving 8 new technology add-on payments for 10 technologies that applied under the traditional pathway for new technology add-on payments for FY 2024. Based on information from the applicants at the time of rulemaking, we estimate that total payments for the technologies for which we are making new technology add-on payments is approximately $59 million for FY 2024.

In the following table, we present detailed estimates for the 10 technologies for which we are providing 8 new technology add-on payments under the traditional pathway in FY 2024:

FY 2024 ESTIMATES FOR NEW TECHNOLOGY ADD-ON PAYMENTS FOR TECHNOLOGIES UNDER THE TRADITIONAL PATHWAY FOR FY 2024			
Technology Name	**Estimated Cases**	**FY 2024 NTAP Amount (65 % or 75 %)**	**Estimated Total FY 2024 Impact**
CYTALUX® (lung)	300	$2,762.50	$828,750.00
CYTALUX® (ovarian)	50	$2,762.50	$138,125.00
EPKINLY™ and COLUMVI™*	157	$6,504.07	$1,021,138.83
Lunsumio™	40	$17,492.10	$699,683.92
REBYOTA™ and VOWST™*	2,628	$6,789.25	$17,842,149.00
SPEVIGO®	76	$33,236.45	$2,525,970.20
TECVAYLI™	1906	$8,940.54	$17,040,660.66
TERLIVAZ®	1146	$16,672.50	$19,106,685.00
Aggregate Estimated Total FY 2024 Impact			**$59,203,162.61**

* These two technologies were determined to be substantially similar to each other and were therefore evaluated as one application for new technology add-on payments under the IPPS.

c. Total Estimated Costs for NTAP in FY 2024

In the following table, we present summary estimates for all technologies approved for new technology add-on payments for FY 2024:

FY 2024 ESTIMATES FOR NEW TECHNOLOGY ADD-ON PAYMENTS FOR FY 2024	
Category	**Estimated Total FY 2024 Impact**
Technologies Continuing New Technology Add-on Payments in FY 2024	$131,042,223.11
Alternative Pathway Applications	$305,242,476.25
Traditional Pathway Applications	$59,203,162.61
Aggregate Estimated Total FY 2024 Impact	**$495,487,861.97**

2. Effects of the Changes to Medicare DSH and Uncompensated Care Payments and Supplemental Payments for Indian Health Service Hospitals and Tribal Hospitals and Hospitals Located in Puerto Rico for FY 2024

a. Effects of the Changes to Medicare DSH Payments of Counting Certain Days Associated With Section 1115 Demonstrations in the Medicaid Fraction

In February 2023 we issued a proposed rule (88 FR 12623) to revise our regulations on the counting of days associated with individuals eligible for certain benefits provided by section 1115 demonstrations in the Medicaid fraction of a hospital's disproportionate patient percentage (DPP). In section IV.F. of the preamble to this final rule, we discuss our finalized policies related to counting certain days associated with section 1115 demonstrations in the Medicaid fraction. Specifically, we are revising our regulations to explicitly reflect our interpretation of the statutory language ''patients . . . regarded as'' ''eligible for medical assistance under a State plan approved under title XIX'' ''because they receive benefits under a demonstration project approved under title XI'' in section 1886(d)(5)(F)(vi) of the Act to mean patients who receive health insurance authorized by a section 1115 demonstration or patients who pay for health insurance with premium assistance authorized by a section 1115 demonstration, where State expenditures to provide the health insurance or premium assistance may be matched with funds from title XIX. Alternatively, we are using the statutory discretion provided the Secretary to regard as eligible for Medicaid only these same groups of patients. Moreover, of individuals who are ''regarded as'' Medicaid eligible, the Secretary is exercising his discretion to include in the DPP Medicaid fraction numerator only the days of those patients who receive from a section 1115 demonstration (1) health insurance that covers inpatient hospital services or (2) premium assistance that covers 100 percent of the premium cost to the patient, which the patient uses to buy health insurance that covers inpatient hospital services, provided in either case that the patient is not also entitled to Medicare Part A.

Eight states currently have section 1115 demonstrations that explicitly include premium assistance programs that we believe include providing assistance that covers 100 percent of the premium cost to patients: Arkansas, Connecticut, Massachusetts, Oklahoma, Rhode Island, Tennessee, Utah, and Vermont. In the preamble of this final rule, we summarized a comment that Connecticut recently received demonstration approval for a premium assistance program that pays through the health insurance exchange to cover low-income individuals ineligible for Medicaid. For this final rule, we are including Connecticut in the list of states that have section 1115 waivers, bringing the total to eight from the seven we noted in the February 2023 proposal (88 FR 12634). We also summarized in the preamble of this final rule a comment that Massachusetts' demonstration, in addition to providing 100 percent premium assistance to some patients, also provides premium assistance to some Medicaid-ineligible patients at less than 100 percent of the premium cost to the patients. We note in the finalized policy in this final rule that patient days of patients receiving this type of premium assistance are not includable in the DPP Medicaid fraction numerator.

Hospitals in States that have section 1115 demonstrations that explicitly include premium assistance programs that provide 100 percent of the premium cost to the patient will be allowed to continue to include days of those patients receiving 100 percent premium assistance in the DPP Medicaid fraction numerator, provided the patient is not also entitled to Medicare Part A. Therefore, there will be no change to these hospitals reporting these days as Medicaid days and no impact on their Medicaid fraction as a result of our revisions to the regulations regarding the counting of patient days associated with these section 1115 demonstrations. However, to the extent any state's demonstration includes a premium assistance program that provides assistance that covers less than 100 percent of the premium cost to the patient (such as Massachusetts's program), days of the patients receiving less than 100 percent premium assistance cannot be included in the DPP Medicaid fraction numerator. This is a change to how some hospitals may report Medicaid days for purposes of the DSH calculation and may have some impact on their Medicaid fraction and DSH payment adjustment.

To estimate the impact of the policy to exclude days of the patients receiving less than 100 percent premium assistance, we would need to know the number of these section 1115 demonstration days per hospital for the hospitals potentially impacted. As we explained in the February 2023 proposed rule, the Medicare cost report does not include lines for section 1115 demonstration days to be reported separately from other types of days that providers report for Medicare payment purposes. Days associated with individuals eligible for certain benefits provided by section 1115 demonstrations are counted in the Medicaid fraction of a hospital's DPP, along with days associated with Medicaid State plans. Because the cost report does not collect the number of section 1115 demonstration days separately from Medicaid State plan days, and we do not have a mechanism to disaggregate section 1115 demonstration days from the Medicaid days reported by hospitals on the cost report, we do not currently possess data to estimate an impact of this aspect of our policy.

For States that have section 1115 demonstrations that include uncompensated/undercompensated care pools, the patients whose care is subsidized by these section 1115 demonstration funding pools will not be ''regarded as'' ''eligible for medical assistance under a State plan approved under title XIX'' in section 1886(d)(5)(F)(vi) of the Act because the demonstration does not provide them with health insurance benefits. Even if they could be regarded as Medicaid eligible, the Secretary is using his authority to not so regard such patients and to exclude the days of those patients from being counted in the DPP Medicaid fraction numerator. Therefore, hospitals in the following six States can no longer report days of patients for which they receive payments from uncompensated/undercompensated care pools authorized by the States' section 1115 demonstration as Medicaid days in the DPP Medicaid fraction numerator: Florida, Kansas, Massachusetts, New Mexico, Tennessee, and Texas.

As discussed in the February 2023 proposed rule (88 FR 12623) and in section IV.F. of this final rule, to estimate the impact of the policy to exclude uncompensated/undercompensated care pool days, we would need to know the number of these section 1115 demonstration days per hospital for the hospitals potentially impacted. As described previously, we do not currently possess such data because the Medicare cost report does not include lines for section 1115 demonstration days to be reported separately from other types of days that providers report for Medicare payment purposes. Therefore, the number of demonstration-authorized uncompensated/undercompensated care pool days per hospital and the net overall savings of our proposal were (and continue to be) especially challenging to estimate.

However, in light of public comments received in prior rulemakings recommending that we use plaintiff data to help inform this issue, in the February 2023 proposed rule, we examined the unaudited figures claimed by plaintiffs in the most recent of the series of court cases on this issue, *Bethesda Health, Inc.* v. *Azar,* 980 F.3d 121 (D.C. Cir. 2020), as reflected in the System for Tracking Audit and Reimbursement (STAR or the STAR system) as of the time of the development of the February 2023 proposed rule. (We note, there were no changes in these figures in the STAR system at the time of this final

rulemaking.) Of the Bethesda Health plaintiff data in the STAR system that listed reported section 1115 demonstration-approved uncompensated/undercompensated care pool days for purposes of implementing the judgment in that case, we used the reported unaudited amounts in controversy claimed by the plaintiffs for the more recent of their cost reports ending in FY 2016 or FY 2017 ($6,167,193). We then used the total number of beds (2,490) reported in the March 2022 Provider Specific File to determine the average unaudited amount in controversy per bed for these plaintiffs. Based on the data as shown in Table I.G.–1, the average unaudited amount in controversy per bed for these plaintiffs is $2,477 (= $6,167,193/2,490). We note that there are Bethesda Health plaintiffs that do not have section 1115 demonstration program days listed in STAR, and one plaintiff that has section 1115 demonstration program days listed in STAR, but the most recent cost report with this data ends in FY 2012; therefore, these plaintiffs are not included in the calculation reflected in Table I.G.–1.

TABLE I.G.1: AVERAGE UNAUDITED AMOUNT IN CONTROVERSY PER BED (A/B)

Unaudited Amount in Controversy by Plaintiff (A)	Beds (B)	Average unaudited amount in controversy per bed (A/B)
$2,174,897	382	
$1,342,081	512	
$253,404	210	
$1,301,024	717	
$505,899	310	
$318,984	181	
$270,905	178	
Total $6,167,193	**Total 2,490**	**$2,477**

In Table I.G.–2, we used the number of beds in DSH eligible hospitals in the six States currently with section 1115 demonstration programs that include uncompensated/undercompensated care pools and the average unaudited per bed amount derived in Table I.G.–1 to extrapolate an unaudited amount in controversy for all DSH eligible hospitals in those States. The result is $348,749,215 (= 140,795 × $2,477).

TABLE I.G.-2: EXTRAPOLATED UNAUDITED AMOUNT IN CONTROVERSY

State	DSH Hospital Beds (A)	Unaudited average amount in controversy per bed from Table 1 (B)	Extrapolated unaudited amount in controversy (A x B)
Florida	50,352	$2,477	$124,721,904
Kansas	5,881	$2,477	$14,567,237
Massachusetts	13,099	$2,477	$32,446,223
New Mexico	3,405	$2,477	$8,434,185
Tennessee	15,718	$2,477	$38,933,486
Texas	52,340	$2,477	$128,646,180
Total	**140,795**	**$2,477**	**$348,749,215**

BILLING CODE 4120–01–C

Note, we caution against considering the extrapolated unaudited amount in controversy to be the estimated Trust Fund savings that would result from our proposal. As we explained in the February 2023 proposed rule, for the reasons described earlier, the savings from our proposal are highly uncertain. The savings may be higher or lower than the extrapolated amount. However, in the proposed rule we provided the transfer calculations earlier in response to the public comments received on prior rulemaking on this issue, requesting that we use plaintiff data in some manner to help inform this issue.

Comment: A commenter noted that CMS stated in the regulatory impact analysis in the February 2023 proposed rule that ''The financial viability of the hospital industry and access to high quality health care for Medicare beneficiaries will be maintained.'' The commenter asserted that the proposed rule provides no quantitative assurances or analyses to back up this assertion. If CMS were to finalize this proposal, the commenter stated that CMS must include a more detailed impact analysis that will help guarantee that the payment cuts do not contribute to even more hospital closures or reductions in critical, life-saving services.

Response: We do not believe our proposed and finalized policy would cause harm to hospitals, especially to the point that would cause hospital closures. We also disagree that we provided no quantitative analysis; we provided the analysis described earlier in Tables 1 and 2. While we do not provide a quantitative analysis beyond this due to the agency's lack of data on the number of days for which hospitals receive payment from demonstration-approved uncompensated/undercompensated care pools and for which patients receive less than 100 percent of their premium cost in premium assistance from a demonstration, the extrapolated unaudited amount in controversy of $348,749,215 is approximately 0.3 percent (less than half of one percent) of total IPPS payments. Therefore, we continue to believe that the financial viability of the hospital industry and access to high quality health care for Medicare beneficiaries will be maintained in light of our proposed and final policy.

Comment: A commenter concluded that the proposal, in violation of the Administrative Procedure Act (APA) and the Regulatory Flexibility Act (RFA), inadequately considers the financial impact of the policy changes on safety-net hospitals nationwide. A commenter stated that CMS' proposal is ''fatally flawed'' because it fails to consider the impact of its policy on low-income patients and the hospitals that care for them. The commenter explained that CMS identifies in the proposed rule the states that have currently approved 1115 demonstration projects that include uncompensated care pools or premium assistance programs, but they fall short in determining what the patient and hospital impacts would be for those hospitals in the affected states. The commenter further stated that for states with premium assistance programs, CMS makes a modest attempt to estimate hospital burden but does not estimate the potential loss of DSH payments, and for states with uncompensated care pools, CMS states that it cannot estimate the impact because the Medicare cost report does not have information on 1115 demonstration days by hospital. The commenter stated that, in reality, the impacts would be devastating to low-income individuals and the providers who care for them in many states. Another commenter was concerned that CMS remains unable to sufficiently account for the potential financial implications and burdens on hospitals by excluding these section 1115 demonstration days. The commenter believes that the estimates in the proposed rule vastly understate the likely financial impacts on hospitals, which the commenter believes would exceed $1 billion.

Response: We respectfully disagree that our proposal (88 FR 12623), which we finalize here, inadequately considers the financial impact of the policy changes on hospitals or patients. As stated in the proposed rule, to estimate the impact of the proposal to exclude uncompensated/undercompensated care pool days, we would need to know the number of these section 1115 demonstration days per hospital for the hospitals potentially impacted. Similarly, to estimate the impact of demonstrations that provide less than 100 percent of the patient's premium cost in premium assistance, we would need to know the number of these section 1115 demonstration days per hospital for the hospitals potentially impacted. We do not currently possess such data because the Medicare cost report does not include lines for section 1115 demonstration days to be reported separately from other types of days that providers report for Medicare payment purposes, and we do not have a mechanism to disaggregate section 1115 demonstration days from the aggregate Medicaid days reported by hospitals on the cost report. Therefore, the number of demonstration-authorized uncompensated/undercompensated care pool days and premium assistance days that provide less than 100 percent of the patient's premium cost per hospital and the net overall savings of this proposal are especially challenging to estimate. However, to mitigate concerns, we provided an estimate in the proposed rule in light of public comments received in prior rulemakings recommending that we utilize plaintiff data in some manner to help inform this issue. Specifically, we examined the unaudited figures claimed by plaintiffs in the most recent of the series of court cases on this issue, *Bethesda Health, Inc.* v. *Azar,* 980 F.3d 121 (D.C. Cir. 2020), as currently reflected in the STAR system. While

commenters may not agree with CMS regarding the source of data used in the estimate or the total of the estimate, we believe the estimate we provided responds to commenters concerns on the impact of the proposal by using unaudited figures claimed by plaintiffs in the most recent of the series of court cases on this issue, which we believe is the best information currently available upon which to estimate the net overall savings of the proposal.

With regard to hospital burden concerns, we note we respond to similar comments in section IV.F. of the preamble of this final rule. In that section, in particular, we explain that we are unsure why some commenters have significant concerns with verifying an individual's 1115 eligibility and premium assistance when hospitals are already communicating with their state Medicaid office to verify an individual's eligibility. In addition, as we noted in the February 2023 proposed rule (88 FR 12634), there would be no change to how these hospitals report Medicaid days and no impact on their Medicaid fraction as a result of our proposed revisions to the regulations regarding the counting of patient days associated with patients receiving 100 percent of the cost of their premium from premium assistance provided under a section 1115 demonstration. To the extent a demonstration provides patients with premium assistance that covers less than 100 percent of a patient's premium costs, as stated above, we do not possess data upon which to estimate the economic impact of excluding days of those patients from the DPP Medicaid fraction numerator. We also note, we have updated our burden estimate as discussed in section XII.B.2. of the preamble to this final rule, and refer readers to that section for complete details on the development of this estimate.

While we appreciate commenters' concerns for low-income patients, we also do not understand or agree with comments that suggest our proposal will adversely affect low-income patients. Nothing in the proposal that we are finalizing diminishes or eliminates any benefit low-income patients receive from section 1115 demonstrations, including any ''benefit'' a patient might receive by having some part of their hospital bill paid for by an uncompensated care pool authorized by a demonstration or by receiving some portion of the cost of their premium paid for with premium assistance authorized by a demonstration; such patient will remain in the same position whether or not a hospital is permitted to include their patient day in the hospital's DPP Medicaid fraction numerator. The policies we are finalizing here merely seek to clarify which days patients provided certain benefits under a Medicaid section 1115 demonstration *may also* be counted in calculating the Medicare DSH payment adjustment. And because the purpose of the DSH payment adjustment is not to provide as much money as possible to hospitals, but to reflect payment for a hospital's provision of a disproportionate share of care to low-income patients, we believe we have properly considered the effects of the proposal on such patients. Therefore, we do not agree that we have ignored an important factor in issuing our proposal, considering the comments we received, or that by finalizing the rule as proposed we would be in violation of the APA. We further note that the commenter did not provide any data or analyze how our proposal would adversely impact low-income individuals and providers.

Similarly, the February 2023 proposed rule we are finalizing has not ignored or violated the requirements of the RFA. We said in the February 2023 proposed rule, HHS's practice in interpreting the RFA is to consider the effects of a proposed policy economically significant'' if a proposal affects greater than five percent of providers in the amount of three to five percent or more of total revenue or total costs. We based our belief that the requirements in the proposed rule would not reach this threshold using data from the FY 2023 IPPS/LTCH PPS final rule (87 FR 49051). We estimated that DSH payments were approximately 2.8 percent of all payments under the IPPS for FY 2023. Therefore, the Secretary certified that the impact of the February 2023 proposed rule, which we are finalizing here and could result in a reduction in total DSH payments to some hospitals, will not have a significant economic impact on a substantial number of small entities, which the Secretary considers the great majority of hospitals to be. (88 FR 12636)

Comment: Another commenter asserted that CMS's estimate of the financial impact is arbitrary and capricious because the agency fails to consider other available sources of data in arriving at its estimate. The commenter explained that CMS does not take into account that many hospitals across the country have protested this issue on their cost reports or appealed the issue to the Provider Reimbursement Review Board and have submitted calculations of the protested amounts to the agency. The commenter believes that CMS could have collected the data that it needs to determine the true impact on those hospitals. The commenter asserted that the agency's failure to do so renders its proposed rule arbitrary and capricious under the APA, and cited several court cases. Other commenters further asserted that CMS's estimate is also arbitrary and unreasonable because the agency entirely failed to account for the adverse effect of its proposal on safety-net hospitals in particular, which is problematic given the purpose of the 2000 DSH regulation and the DSH adjustment.

Response: We disagree that the agency has acted arbitrarily or capriciously in estimating the financial impact of the proposed rule by failing to consider other available sources of data in arriving at its estimate. As explained previously, the Medicare cost report does not provide a way for hospitals to indicate the number of days they want treated as Medicaid days in the DPP calculation because they received demonstration-authorized uncompensated/undercompensated care pool payments for treatment they provided to the uninsured or for days of patients who purchase health insurance using premium assistance provided through a demonstration. Thus, we concluded that an estimate of the savings created by the proposal was highly uncertain because hospitals do not provide the necessary data on their Medicare cost report. When urged by commenters on previous rulemakings in which we also acknowledged the difficulty and uncertainty in estimating the savings from the proposal, they suggested we use data provided by plaintiff hospitals in effectuating a recent litigation judgment on this issue. We did so and provided what we think is the best estimate of the savings, given the lack of available audited information. We do not believe that using more unaudited data from hospitals with pending administrative appeals or who have protested amounts on their cost reports will produce a more accurate estimate of the total savings than what we have included in the February 2023 proposed rule.

We also do not understand comments that the estimate we have provided is arbitrary and unreasonable because it fails to address safety-net hospitals, and that this is problematic given the purpose of the 2000 DSH regulation and the DSH adjustment. It is not clear exactly what types of hospitals the commenters are considering to be safety-net hospitals. In this context we believe the commenters are referring to DSH hospitals, and the February 2023 proposed rule included our best estimate of the reduction in DSH payments under our proposal. Given that we do not have individual hospital data on the number of section 1115 demonstration days, and in light of public comments received in prior rulemakings recommending that we use plaintiffs' data to help inform this issue, we extrapolated unaudited amounts in controversy, estimating approximately $350 million. We further note that individual hospitals report their patient days for inclusion in the Medicaid fraction, which includes 1115 demonstration days, on the cost report, and we believe they are in the best position to understand how their individual payments would change under our proposal. Regarding the 2000 DSH regulation, we note that regulation has not been effective since the beginning of FY 2004, when we modified the regulation through rulemaking to limit the types of patient days that could be included in the Medicare DSH DPP Medicaid fraction numerator.

Comment: A commenter asserted that CMS' failure to consider adequately the significant financial impact of the policy change also violates the RFA, which requires an agency to evaluate the negative impact of its rules on small businesses, including hospitals. The commenter explained that the agency's RFA assessment that the financial impact is not ''significant'' contradicts its statements elsewhere in the rule that its proposal would reduce hospitals' DSH payments by over nearly $350 million annually. This commenter stated that the internal inconsistency between the RFA assessment that the proposal's impact would not be ''significant,'' on the one hand, and its determination that the proposal would be ''economically significant'' and cost hospitals nearly $350 million per year, on the other hand, is unreasonable and unexplained. By failing to make a proper financial assessment, the commenter stated that the agency has

ignored the RFA, and its proposed rule is invalid as a result, citing several court cases.

Response: As noted earlier, we disagree that we have failed to make a proper financial assessment of the proposed rule's impact or that the agency has ignored the RFA. The commenters are confusing the requirement of section 3(f) of Executive Order 12866, which defines a ''significant regulatory action'' as an action that is likely to result in a rule having an annual effect on the economy of $100 million or more in any one year, with the RFA, which requires agencies to analyze options for regulatory relief of small entities if a rule has a significant impact on a substantial number of small entities. As discussed in the February 2023 proposed rule and reiterated earlier, HHS's practice in interpreting the RFA is to consider the effects of a policy to be economically ''significant'' under the RFA if the policy affects greater than five percent of providers in the amount of three to five percent or more of total revenue or total costs. We have followed the regulations for each of these requirements (Executive Order 12866 and the RFA), estimating the overall impact under the Executive order, and determining under the separate RFA standard for what is ''significant'' that the agency did not need to analyze options for regulatory relief of small entities because the finalized rule will not have a significant impact on a substantial number of small entities.

Comment: One commenter noted that the agency bases its policy changes on the Federal fiscal year and not according to a hospital's cost reporting year, making such changes administratively challenging for hospitals.

Response: As we stated in the February 2023 proposed rule and reiterated in the preamble to this final rule, as has been our practice for more than two decades, we have made our periodic revisions to the counting of certain section 1115 patient days in the Medicare DSH calculation effective based on patient discharge dates. Thus, doing so again here treats all providers similarly and does not impact providers differently depending on their cost reporting periods. All hospitals will equally be able to include or not include certain section 1115 demonstration days in the DPP Medicaid fraction numerator, as permitted under this final rule, based on discharge dates of October 1, 2023, or later. We therefore disagree that the changes being finalized here will present administrative challenges or administratively impact hospitals differently depending on their cost reporting year.

Comment: One commenter stated that the exclusion of uncompensated care pool patient days from the Medicaid fraction would significantly reduce hospitals' empirical Medicare DSH payments in states that use an uncompensated care pool to cover inpatient hospital care under a section 1115 demonstration. The commenter also noted the proposed policy would also have the follow-on effect of significantly reducing national Medicare uncompensated care payments under section 1886(r) of the Act, and that CMS's cost estimate does not address or account for the impact of the proposed rule on Medicare uncompensated care payments. Therefore, the commenter stated that the February 2023 proposed rule's estimated impact of approximately $350 million likely represents only a portion of the aggregate financial impact of the proposal on IPPS hospitals nationally.

Response: As stated in the proposed rule, to estimate the impact of the proposal to exclude uncompensated/undercompensated care pool days, we would need to know the number of these section 1115 demonstration days per hospital for the hospitals potentially impacted. We do not currently possess such data because the Medicare cost report does not include lines for section 1115 demonstration days separately from other types of days. Therefore, the number of demonstration-authorized uncompensated/undercompensated care pool days per hospital and the net overall savings of this proposal are especially challenging to estimate. We did use extrapolated unaudited amount in controversy data from plaintiffs to help inform the issue, but we cautioned against considering the extrapolated amount in controversy to be the estimated Trust Fund savings that would result from our proposal (88 FR 12634 through 12635). Given this lack of data and level of uncertainty, we do not believe it would be appropriate to explicitly reduce Factor 1 of the FY 2024 Medicare uncompensated care payments by the extrapolated unaudited amount in controversy and did not propose to do so, nor are we doing so in this final rule. Please see section IV.E. of the preamble to this final rule for a discussion of the components of Factor 1 for the FY 2024 Medicare uncompensated care payments. Therefore, our proposal had no impact on Factor 1 of the FY 2024 Medicare uncompensated care payments in the proposed rule and our final policy has no impact on Factor 1 of the FY 2024 Medicare uncompensated care payments in this final rule.

b. Medicare DSH Uncompensated Care Payments and Supplemental Payment for Indian Health Service Hospitals and Tribal Hospitals and Hospitals Located in Puerto Rico

As discussed in section IV.E. of the preamble of this final rule, under section 3133 of the Affordable Care Act, hospitals that are eligible to receive Medicare DSH payments will receive 25 percent of the amount they previously would have received under the statutory formula for Medicare DSH payments under section 1886(d)(5)(F) of the Act. The remainder, equal to an estimate of 75 percent of what formerly would have been paid as Medicare DSH payments (Factor 1), reduced to reflect changes in the percentage of uninsured individuals (Factor 2), is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has reported uncompensated care. Each hospital eligible for Medicare DSH payments will receive an additional payment based on its estimated share of the total amount of uncompensated care for all hospitals eligible for Medicare DSH payments. The uncompensated care payment methodology has redistributive effects based on the proportion of a hospital's amount of uncompensated care relative to the aggregate amount of uncompensated care of all hospitals eligible for Medicare DSH payments (Factor 3). The change to Medicare DSH payments under section 3133 of the Affordable Care Act is not budget neutral.

In this final rule, we are establishing the amount to be distributed as uncompensated care payments (UCP) to DSH eligible hospitals for FY 2024, which is $5,938,006,756.87. This figure represents 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 59.29 percent. For FY 2023, the amount available to be distributed for uncompensated care was $6,874,403,459.42 or 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a Factor 2 of 65.71 percent. In addition, eligible IHS/Tribal hospitals and hospitals located in Puerto Rico are estimated to receive approximately $83.2 million in supplemental payments in FY 2024, as determined based on the difference between each hospital's FY 2022 UCP (reduced by negative 13.6 percent, which is the projected change between the FY 2024 total uncompensated care payment amount and the total uncompensated care payment amount for FY 2022) and its FY 2024 UCP as calculated using the methodology for FY 2024. If this difference is less than or equal to zero, the hospital will not receive a supplemental payment. For this final rule, the total uncompensated care payments and supplemental payments equal approximately $6.021 billion. For FY 2024, we are using 3 years of data on uncompensated care costs from Worksheet S–10 of the FYs 2018, 2019, and 2020 cost reports to calculate Factor 3 for all DSH-eligible hospitals, including IHS/Tribal hospitals and Puerto Rico hospitals. For a complete discussion regarding the methodology for calculating Factor 3 for FY 2024, we refer readers to section IV.E. of the preamble of this final rule. For a discussion regarding the methodology for calculating the supplemental payments, we refer readers to section IV.D. of the preamble of this final rule.

To estimate the impact of the combined effect of the changes in Factors 1 and 2, as well as the changes to the data used in determining Factor 3, on the calculation of Medicare uncompensated care payments along with changes to supplemental payments for IHS/Tribal hospitals and hospitals located in Puerto Rico, we compared total uncompensated care payments and supplemental payments estimated in the FY 2023 IPPS/LTCH PPS final rule to the combined total of the uncompensated care payments and the supplemental payments estimated in this FY 2024 IPPS/LTCH PPS final rule. For FY 2023, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments absent section 3133 of the Affordable Care Act, adjusted by a Factor 2 of 65.71 percent and multiplied by a Factor 3 calculated using the methodology described in the FY 2023 IPPS/LTCH PPS final rule. For FY 2024, we calculated 75 percent of the estimated amount that would be paid as Medicare DSH payments during FY 2024 absent section 3133 of the Affordable Care Act, adjusted by a Factor 2

of 59.29 percent and multiplied by a Factor 3 calculated using the methodology described previously. For this final rule, the supplemental payments for IHS/Tribal hospitals and Puerto Rico hospitals are calculated as the difference between the hospital's adjusted base year amount (as determined based on the hospital's FY 2022 uncompensated care payment) and the hospital's FY 2024 uncompensated care payment.

Our analysis included 2,384 hospitals that are projected to be eligible for DSH in FY 2024. Our analysis did not include hospitals that had terminated their participation in the Medicare program as of June 13, 2023, Maryland hospitals, new hospitals, and SCHs that are expected to be paid based on their hospital-specific rates. The 26 hospitals that are anticipated to be participating in the Rural Community Hospital Demonstration Program were also excluded from this analysis, as participating hospitals are not eligible to receive empirically justified Medicare DSH payments and uncompensated care payments. In addition, the data from merged or acquired hospitals were combined under the surviving hospital's CMS certification number (CCN), and the non-surviving CCN was excluded from the analysis. The estimated impact of the changes in Factors 1, 2, and 3 on uncompensated care payments and supplemental payments for eligible IHS/Tribal hospitals and Puerto Rico hospitals across all hospitals projected to be eligible for DSH payments in FY 2024, by hospital characteristic, is presented in the following table:

BILLING CODE 4120–01–P

MODELED UNCOMPENSATED CARE PAYMENTS* AND SUPPLEMENTAL PAYMENTS FOR ESTIMATED FY 2024 DSHS BY HOSPITAL TYPE

	Number of Estimated DSHs (1)	FY 2023 Final Rule Estimated Uncompensated Care Payments and Supplemental Payments ($ in millions) (2)	FY 2024 Uncompensated Care Payments and Supplemental Payments** ($ in millions) (3)	Dollar Difference: FY 2023 - FY 2024 ($ in millions) (4)	Percent Change*** (5)
Total	**2,384**	**$6,971**	**$6,021**	**-$950**	**-13.62%**
By Geographic Location					
Urban Hospitals	1,926	6,592	5,694	-898	-13.62
Large Urban Areas	1,009	4,073	3,529	-544	-13.35
Other Urban Areas	917	2,519	2,165	-354	-14.05
Rural Hospitals	458	379	327	-52	-13.65
Bed Size (Urban)					
0 to 99 Beds	362	260	231	-29	-11.06
100 to 249 Beds	794	1,497	1,305	-192	-12.81
250+ Beds	770	4,835	4,158	-677	-14.01
Bed Size (Rural)					
0 to 99 Beds	354	207	182	-26	-12.33
100 to 249 Beds	92	127	108	-19	-15.21
250+ Beds	12	44	38	-7	-15.38
Urban by Region					
New England	89	176	154	-22	-12.39
Middle Atlantic	231	765	660	-105	-13.77
South Atlantic	317	762	642	-119	-15.66
East North Central	101	357	305	-53	-14.70
East South Central	332	1,713	1,478	-235	-13.71
West North Central	123	428	364	-64	-15.04
West South Central	236	1,401	1,236	-165	-11.77
Mountain	138	292	254	-38	-12.87
Pacific	314	611	525	-86	-14.03
Puerto Rico	45	87	75	-12	-13.36
Rural by Region					
New England	7	11	9	-2	-18.09
Middle Atlantic	28	12	11	-1	-4.96
South Atlantic	68	43	39	-4	-8.70
East North Central	29	25	20	-5	-18.61

MODELED UNCOMPENSATED CARE PAYMENTS* AND SUPPLEMENTAL PAYMENTS FOR ESTIMATED FY 2024 DSHS BY HOSPITAL TYPE

	Number of Estimated DSHs (1)	FY 2023 Final Rule Estimated Uncompensated Care Payments and Supplemental Payments ($ in millions) (2)	FY 2024 Uncompensated Care Payments and Supplemental Payments** ($ in millions) (3)	Dollar Difference: FY 2023 - FY 2024 ($ in millions) (4)	Percent Change*** (5)
East South Central	77	107	93	-14	-13.17
West North Central	116	81	68	-13	-16.20
West South Central	107	81	71	-9	-11.42
Mountain	20	14	10	-3	-24.31
Pacific	6	6	5	-1	-17.17
By Payment Classification					
Urban Hospitals	1,422	4,038	3,499	-539	-13.34
Large Urban Areas	812	2,720	2,359	-361	-13.27
Other Urban Areas	610	1,317	1,140	-178	-13.49
Rural Hospitals	962	2,933	2,522	-411	-14.01
Teaching Status					
Nonteaching	1,311	1,824	1,598	-225	-12.35
Fewer than 100 residents	800	2,476	2,106	-369	-14.91
100 or more residents	273	2,672	2,316	-355	-13.29
Type of Ownership					
Voluntary	1,499	4,015	3,452	-563	-14.02
Proprietary	528	1,005	878	-127	-12.66
Government	357	1,950	1,691	-259	-13.30
Medicare Utilization Percent****					
0 to 25	874	3,985	3,431	-554	-13.89
25 to 50	1,432	2,951	2,555	-396	-13.41
50 to 65	70	33	33	0	-0.12
Greater than 65	8	2	2	0	-11.92
Medicaid Utilization Percent****					
0 to 25	1,365	2,903	2,547	-356	-12.25
25 to 50	898	3,347	2,839	-509	-15.20
50 to 65	92	538	481	-57	-10.50
Greater than 65	29	183	154	-29	-15.67

Source: Dobson | DaVanzo analysis of 2018, 2019, and 2020 Hospital Cost Reports.

*Dollar uncompensated care payments calculated by [0.75 * estimated section 1886(d)(5)(F) payments * Factor 2 * Factor 3]. When summed across all hospitals projected to receive DSH payments, uncompensated care payments and supplemental payments are estimated to be $6,971 million in FY 2023 and uncompensated care payments and supplemental payments are estimated to be $6,021 million in FY 2024.

** For IHS/Tribal hospitals and Puerto Rico hospitals, this impact table reflects the supplemental payments.

*** Percentage change is determined as the difference between Medicare uncompensated care payments and supplemental payments modeled for this FY 2024 IPPS/LTCH PPS final rule (column 3) and Medicare uncompensated care payments and supplemental payments modeled for the FY 2023 IPPS/LTCH PPS final rule correction notice (column 2) divided by Medicare uncompensated care payments and supplemental payments modeled for the FY 2023 IPPS/LTCH PPS final rule correction notice (column 2) times 100 percent.

****Hospitals with missing or unknown Medicare utilization or Medicaid utilization are not shown in the table.

BILLING CODE 4120–01–C

The changes in projected FY 2024 uncompensated care payments and supplemental payments compared to the total of uncompensated care payments and supplemental payments in FY 2023 are driven by decreases in Factor 1 and Factor 2. The final Factor 1 has decreased from the FY 2023 final rule's Factor 1 of $10.461 billion to this final rule's Factor 1 of $10.015 billion. The final Factor 2 has decreased from FY 2023 final rule's Factor 2 of 65.71 percent to this final rule's Factor 2 of 59.29 percent. In addition, we note that there is a slight increase in the number of projected DSH eligible hospitals to 2,384 at the time of the development for this final rule compared to the projected 2,368 DSHs in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49472). Based on the changes, the impact analysis found that, across all projected DSH eligible hospitals, FY 2024 uncompensated care payments and supplemental payments are estimated at approximately $6.021 billion, or

a decrease of approximately 13.62 percent from FY 2023 uncompensated care payments and supplemental payments (approximately $6.971 billion). While the changes result in a net decrease in the total amount available to be distributed in uncompensated care payments and supplemental payments, the projected payment decreases vary by hospital type. This redistribution of payments is caused by changes in Factor 3 and the amount of the supplemental payment for DSH-eligible IHS/Tribal hospitals and Puerto Rico hospitals. As seen in the previous table, a percent change of less than negative 13.62 percent indicates that hospitals within the specified category are projected to experience a larger decrease in payments, on average, compared to the universe of projected FY 2024 DSH hospitals. Conversely, a percentage change greater than negative 13.62 percent indicates that a hospital type is projected to have a smaller decrease compared to the overall average. The variation in the distribution of overall payments by hospital characteristic is largely dependent on a given hospital's uncompensated care costs as reported on the Worksheet S–10 and used in the Factor 3 computation and whether the hospital is eligible to receive the supplemental payment.

Rural hospitals, in general, are projected to experience a slightly larger decrease in uncompensated care payments compared to the decrease their urban counterparts are projected to experience. Overall, rural hospitals are projected to receive a 13.65 percent decrease in payments, while urban hospitals are projected to receive a 13.62 percent decrease in payments, which is equal to the overall hospital average.

By bed size, rural hospitals with 100 to 249 beds and rural hospitals with 250+ beds are projected to receive larger than average decreases of a 15.21 percent and 15.38 percent, respectively, while rural hospitals with 0 to 99 beds are projected to receive a smaller than average decrease of 12.33 percent. Among urban hospitals, the largest urban hospitals, those with 250+ beds, are projected to receive a decrease in payments that is greater than the overall hospital average, at 14.01 percent. In contrast, smaller urban hospitals with 0–99 beds and urban hospitals with 100–249 beds are projected to receive a 11.06 and 12.81 percent decrease in payments, respectively.

By region, rural hospitals are projected to receive a varied range of payment changes. Rural hospitals in the New England, East North Central, West North Central, Mountain, and Pacific regions are projected to receive larger than average decreases in payments. Rural hospitals in the Middle Atlantic, South Atlantic, East South Central, and West South Central regions are projected to receive smaller than average decreases in payments. Urban hospitals are projected to receive larger than average decreases in uncompensated care payments and supplemental payments in most regions. Urban hospitals in the Middle Atlantic, South Atlantic, East North Central, East South Central, West North Central, and Pacific regions are projected to receive larger than average decreases in payments, while urban hospitals in New England, West South Central, and Mountain regions, as well as hospitals in Puerto Rico, are projected to receive smaller than average decreases in payments.

By payment classification, although hospitals in urban payment areas overall are expected to receive a 13.34 percent decrease in uncompensated care payments and supplemental payments, hospitals in large urban payment areas are projected to receive a decrease in payments of 13.27 percent. In contrast, hospitals in rural payment areas are projected to receive a larger than average decrease in payments of 14.01 percent.

Teaching hospitals with fewer than 100 residents are projected to receive a larger than average payment decrease of 14.91 percent. Nonteaching hospitals and teaching hospitals with 100+ residents are projected to receive smaller than average payment decreases of 12.35 percent and 13.29 percent, respectively. Proprietary and government owned hospitals are projected to receive smaller than average decreases of 12.66 and 13.30 percent respectively, while voluntary hospitals are expected to receive a larger than average payment decrease of 14.02 percent. Hospitals with less than 25 percent Medicare utilization are projected to receive larger than average decreases of 13.89 percent, while hospitals with Medicare utilization of 25 percent or more are projected to receive smaller than average payment decreases. Hospitals with less than 25 percent Medicaid utilization and those with 50–65 percent Medicaid utilization are projected to receive lower than average decreases in payments of 12.25 and 10.50 percent respectively, while hospitals with 25–50 percent Medicaid utilization and those with greater than 65 percent Medicaid utilization are projected to receive a larger than average decrease of 15.20 percent and 15.67 percent, respectively.

The impact table reflects the modeled FY 2024 uncompensated care payments and supplemental payments for IHS/Tribal and Puerto Rico hospitals. We note that the supplemental payments to IHS/Tribal hospitals and Puerto Rico hospitals are estimated to be approximately $83.2 million in FY 2024.

3. Effects of the Changes to Indirect Medical Education and Direct Graduate Medical Education Payments

a. Calculation of Prior Year IME Resident to Bed Ratio When There Is a Medicare GME Affiliation Agreement

Under section V.G.2. of the preamble of this final rule, we are finalizing a proposed clarification to the Medicare cost report, CMS-Form-2552–10, Worksheet E, Part A, line 20, with regard to the IME calculation. As described in existing § 412.105(a)(1)(i), the numerator of the prior year resident-to bed ratio may be adjusted to reflect an increase in the current cost reporting period's resident-to-bed ratio due to residents in a Medicare GME affiliation agreement (among other limited reasons). We explain how to measure the net increase in FTEs in the ''current year numerator'' as compared to the prior year's numerator when there is a Medicare GME affiliation agreement. We are clarifying how to determine if the hospital increased its current year allowable FTE count, and are clarifying that the phrase ''current year numerator'' on Worksheet E, Part A line 20 refers to line 15 from Worksheet E, Part A. See section II.F.2. of the preamble of this final rule for more details on this policy. An increase to one hospital's FTE cap is offset by a decrease to another hospital's FTE cap under the terms of a Medicare GME affiliation agreement. We estimate that there is no impact for this policy clarification, as there continues to be no net change in the overall number of FTEs under the combined caps of the hospitals participating in the affiliation agreement.

b. Training in New REH Facility Type

As discussed in section V.G.3. of the preamble of this final rule, section 125 of Division CC of the Consolidated Appropriations Act, 2021 (CAA) added a new section 1861(kkk) of the Act to establish REHs as a new Medicare provider type, effective January 1, 2023. As part of the comments received in response to the CY 2023 OPPS proposed rule (87 FR 44502) and the proposed rule establishing REH CoPs (87 FR 40350), CMS received the request to designate REHs as graduate medical education (GME) eligible facilities similar to the GME designation for critical access hospitals (CAHs) (87 FR 72164).

As we note in this final rule, given the flexibility provided under section 1861(e) of the Act and the fact that an REH is a facility primarily engaged in patient care (see the definition of ''nonprovider setting that is primarily engaged in furnishing patient care'' at section 1886(h)(5)(K) of the Act), we believe that similarly to CAHs, statutory flexibility also exists for REHs to be considered nonprovider settings for GME payment purposes. We believe that increasing access to physicians in rural areas can be supported by a flexible policy which would allow for residency training to continue at CAHs that convert to REHs and begin at other newly designated REHs, which may have not previously trained residents.

Therefore, we proposed that effective for portions of cost reporting periods beginning on or after October 1, 2023, an REH may be considered a nonprovider site and a hospital may include FTE residents training at an REH in its direct GME and IME FTE counts as long as it meets the nonprovider setting requirements included at 42 CFR 412.105(f)(1)(ii)(E) and 413.78(g) and any succeeding regulations. As an alternative to being considered a nonprovider site, we proposed under the authority of section 1886(k)(2)(D) of the Act, that REHs may decide to incur the costs of training residents in an approved residency training program(s) and receive payment at 100 percent of the reasonable costs for those training costs consistent with section 1861(v)(1)(A) of the Act. In response to comments, we are finalizing these policies as proposed.

If a hospital or CAH converts to an REH, Medicare would continue paying for residency training occurring at the REH as long as the residents continue to train in an approved program. GME payments would be made either directly to the REH or to a hospital if the REH is functioning as a nonprovider setting consistent with the

regulations at 42 CFR 412.105(f)(1)(ii)(E) and 413.78(g) and any succeeding regulations. To the extent that a CAH that converts to an REH was receiving direct GME payments at 101 percent of reasonable costs, or a new REH would have received those payments had it become a CAH instead, we estimate the impact of this proposal to be negligible.

4. Effects of Changes for Reasonable Cost Payments for Nursing and Allied Health Programs

Under section V.H. of the preamble of this final rule, we finalize our proposal to implement section 4143 of the CAA 2023 (enacted December 29, 2022), called ''Waiver of Cap on Annual Payments for Nursing and Allied Health Education Payments,'' to state that for portions of cost reporting periods occurring in each of CYs 2010 through 2019, the $60 million payment limit, or payment ''pool,'' shall not apply to the ''total amount of additional payments for nursing and allied health education to be distributed to hospitals'' that, ''as of the date of enactment of this clause, are operating a school of nursing, a school of allied health, or a school of nursing and allied health.'' Section 4143 of the CAA 2023 also provides that in not applying the $60 million limit ''for each of 2010 through 2019, the Secretary shall not take into account any increase in the total amount of such additional payment amounts for such nursing and allied health education for portions of cost reporting periods occurring in the year. . . .'' We have estimated that the impact of this provision for FY 2024 to be approximately $1.8 billion.

5. Effects of Requirements Under the Hospital Readmissions Reduction Program for FY 2024

In section V.J. of the preamble of the FY 2024 IPPS/LTCH PPS proposed rule, we did not propose to add, modify, or remove any policies for the FY 2024 Hospital Readmissions Reduction Program (88 FR 27024); the policies finalized in FY 2023 IPPS/LTCH PPS final rule (87 FR 49081 through 49094) continue to apply. This program requires a reduction to a hospital's base operating DRG payment to account for excess readmissions of selected applicable conditions and procedures. Table I.G.-01 and the analysis in this final rule illustrate the estimated financial impact of the Hospital Readmissions Reduction Program payment adjustment methodology by hospital characteristic for the FY 2024 program year. Hospitals are sorted into quintiles based on the proportion of dual-eligible stays among Medicare fee-for-service (FFS) and managed care stays between July 1, 2019, and June 30, 2022 (that is, the FY 2024 Hospital Readmissions Reduction Program's applicable period).[18] Hospitals' excess readmission ratios (ERRs) are assessed relative to their peer group median and a neutrality modifier is applied in the payment adjustment factor calculation to maintain Medicare budget neutrality. In this FY 2024 IPPS/LTCH PPS final rule, we are providing an updated estimate of the financial impact using the proportion of dually-eligible beneficiaries, ERRs, and aggregate payments for each condition/procedure and all discharges for applicable hospitals from the FY 2024 Hospital Readmissions Reduction Program applicable period.

The results in Table I.G.-03 include 2,855 non-Maryland hospitals estimated as eligible to receive a penalty during the performance period. Hospitals are eligible to receive a penalty if they have 25 or more eligible discharges for at least one measure during the FY 2024 applicable period. The second column in Table I.G.-01 indicates the total number of non-Maryland hospitals with available data for each characteristic that have an estimated payment adjustment factor less than 1 (that is, penalized hospitals).

The third column in Table I.G.-03 indicates the percentage of penalized hospitals among those eligible to receive a penalty by hospital characteristic. For example, 78.53 percent of eligible hospitals characterized as non-teaching hospitals are expected to be penalized. Among teaching hospitals, 87.63 percent of eligible hospitals with fewer than 100 residents and 90.29 percent of eligible hospitals with 100 or more residents are expected to be penalized. The fourth column in Table I.G.-03 estimates the financial impact on hospitals by hospital characteristic. Table I.G.-03 shows the share of penalties as a percentage of all base operating DRG payments for hospitals with each characteristic. This is calculated as the sum of penalties for all hospitals with that characteristic over the sum of all base operating DRG payments for those hospitals between October 1, 2021, through September 30, 2022 (FY 2022). For example, the penalty as a share of payments for non-teaching hospitals is 0.49 percent. This means that total penalties for all non-teaching hospitals are 0.49 percent of total payments for non-teaching hospitals. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments accounts for differences in the amount of base operating DRG payments for hospitals with the characteristic when comparing the financial impact of the program on different groups of hospitals.

In the FY 2022 IPPS/LTCH PPS final rule, we finalized suppression of the CMS 30-Day Pneumonia Readmissions measure for the FY 2023 program year (86 FR 45254 through 45256) due to significant impacts of the COVID–19 PHE on the measure. In the FY 2023 IPPS/LTCH PPS final rule (87 FR 49083 through 49086), we finalized that beginning with the FY 2024 program year, the Pneumonia Readmission measure will no longer be suppressed under the Hospital Readmissions Reduction Program, and we will resume the use of the measure for FY 2024. Therefore, the CMS 30-Day Pneumonia Readmission measure is included in the data in Table I.G.–03.

BILLING CODE 4120–01–P

[18] Although the FY 2024 performance period is July 1, 2019, through June 30, 2022, we note that first and second quarter data from CY 2020 is excluded from program calculations due to the nationwide ECE that was granted in response to the COVID–19 PHE. Taking into consideration the 30-day window to identify readmissions, the period for calculating DRG payments will be adjusted to July 1, 2019, through December 1, 2019, and July 1, 2020, through June 30, 2022.

TABLE I.G.-03: ESTIMATED PERCENTAGE OF HOSPITALS PENALIZED AND PENALTY AS SHARE OF PAYMENTS FOR FY 2024 HOSPITAL READMISSIONS REDUCTION PROGRAM BY HOSPITAL CHARACTERISTIC

Hospital Characteristic	Number of Eligible Hospitals[a]	Number of Penalized Hospitals[b]	Percentage of Hospitals Penalized[c] (%)	Penalty as a Share of Payments[d] (%)
All Hospitals	2,855	2,356	82.52	0.44
By Geographic Location[e] (n= 2,852)				
Urban hospitals	2,172	1,836	84.53	0.44
1-99 beds	499	329	65.93	0.45
100-199 beds	630	556	88.25	0.49
200-299 beds	394	359	91.12	0.49
300-399 beds	279	257	92.11	0.47
400-499 beds	118	105	88.98	0.49
500 or more beds	252	230	91.27	0.36
Rural hospitals	680	518	76.18	0.42
1-49 beds	325	225	69.23	0.30
50-99 beds	192	150	78.13	0.39
100-149 beds	85	73	85.88	0.50
150-199 beds	45	40	88.89	0.39
200 or more beds	33	30	90.91	0.51
By Teaching Status[f] (n= 2,852)				
Non-teaching	1,677	1,317	78.53	0.49
Fewer than 100 residents	897	786	87.63	0.45
100 or more residents	278	251	90.29	0.39
By Ownership Type (n= 2,852)				
Government	399	313	78.45	0.33
Proprietary	663	527	79.49	0.55
Voluntary	1,790	1,514	84.58	0.44
By Safety-net Status[g] (n= 2,852)				
Safety-net hospitals	557	469	84.20	0.37
Non-safety-net hospitals	2,295	1,885	82.14	0.46
By Disproportionate Share Hospital (DSH) Patient Percentage[h] (n= 2,852)				
0-24	1,148	901	78.48	0.52
25-49	1,412	1,208	85.55	0.41
50-64	182	157	86.26	0.31
65 and over	110	88	80.00	0.40
By Medicare Cost Report (MCR) Percentage[i] (n= 2,849)				
0-24	816	691	84.68	0.35
25-49	1,884	1,551	82.32	0.47
50-64	134	98	73.13	0.83
65 and over	15	12	80.00	0.27

By Region (n= 2,854)				
New England	122	111	90.98	0.70
Middle Atlantic	317	276	87.07	0.51
East North Central	454	386	85.02	0.45
West North Central	231	175	75.76	0.25
South Atlantic	484	430	88.84	0.48
East South Central	250	204	81.60	0.49
West South Central	440	348	79.09	0.40
Mountain	212	154	72.64	0.32
Pacific	344	271	78.78	0.34

Source: The table results are based on the data used to calculate the FY 2024 payment adjustment factors of open, non-Maryland, subsection (d) hospitals only. The FY 2024 payment adjustment factors are based on discharges from July 1, 2019, through December 1, 2019, and July 1, 2020, through June 30, 2022. The shortened data period is due to the COVID-19 public health emergency (PHE) nationwide Extraordinary Circumstances Exception (ECE) which excluded data from January 1, 2020, through June 30, 2020, from the Hospital Readmissions Reduction Program calculations. Although data from all subsection (d) and Maryland hospitals are used in calculations of each hospital's ERR, this table does not include results for Maryland hospitals and hospitals that are not open as of the October 2023 public reporting open hospital list because these hospitals are not eligible for a penalty under the program. Hospitals are sorted into five peer groups based on the proportion of FFS and managed care dual-eligible stays for the multi-year performance period. Hospital characteristics are from the FY 2024 IPPS Proposed Rule Impact File.

For the FY 2024 applicable period, CMS will only be assessing data from July 1, 2019, through December 1, 2019, and July 1, 2020, through June 30, 2022, due to the COVID-19 PHE nationwide ECE which excluded data from January 1, 2020, through June 30, 2020, from the Hospital Readmissions Reduction Program calculations.

[a] This column is the number of applicable hospitals within the characteristic that are eligible for a penalty (that is, they have 25 or more eligible discharges for at least one measure).

[b] This column is the number of applicable hospitals that are penalized (that is, they have 25 or more eligible discharges for at least one measure and an estimated payment adjustment factor less than 1) within the characteristic.

[c] This column is the percentage of applicable hospitals that are penalized among hospitals that are eligible to receive a penalty by characteristic.

[d] This column is calculated as the sum of all penalties for the group of hospitals with that characteristic divided by total base operating DRG payments for all those hospitals. Measuring the financial impact on hospitals as a percentage of total base operating DRG payments in this way allows for comparisons across hospital characteristics that accounts for differences in the amount of base operating DRG payments for different groups of hospitals. MedPAR data from October 1, 2021, through September 31, 2022 (FY 2022), are used to estimate the total base operating DRG payments.

[e] The total number of hospitals with hospital characteristics data may not add up to the total number of hospitals because not all hospitals have data for all characteristics. Not all hospitals had data for geographic location, teaching status, ownership type, safety net status, and DSH patient percentage (n=2,852; missing=3), region (n=2,854; missing=1), and MCR percentage (n=2,849; missing=6).

[f] A hospital is considered a teaching hospital if it has an Indirect Medical Education adjustment factor for Operation PPS (TCHOP) greater than zero.

[g] A hospital is considered a safety-net hospital if it is in the top DSH quintile.

[h] DSH patient percentage is the sum of the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income (SSI), and the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.

[i] MCR (Medicare Cost Report) percentage is the percentage of total inpatient stays from Medicare patients.

6. Effects of Changes Under the Hospital Value-Based Purchasing (VBP) Program

a. Effects for the FY 2024 Program Year

In section V.K. of the preamble of this final rule, we discuss the Hospital VBP Program under which the Secretary makes value-based incentive payments to hospitals based on their performance on measures during the performance period with respect to a fiscal year. These incentive payments will be funded for FY 2024 through a reduction to the FY 2024 base operating DRG payment amount for hospital discharges for such fiscal year, as required by section 1886(o)(7)(B) of the Act. The applicable percentage for FY 2024 and subsequent years is 2 percent. The total amount available for value-based incentive payments must be equal to the total amount of reduced payments for all hospitals for the fiscal year, as estimated by the Secretary. In section V.K.1.b. of the preamble of this final rule, we estimate the available pool of funds for value-based incentive payments in the FY 2024 program year, which, in accordance with section 1886(o)(7)(C)(v) of the Act, will be 2.00 percent of base operating DRG payments, or a total of approximately $1.7 billion. This estimated available pool for FY 2024 is based on the historical pool of hospitals that were eligible to participate in the FY 2023 program year and the payment information from the March 2023 update to the FY 2022 MedPAR file.

The estimated impacts of the FY 2024 program year by hospital characteristic, found in Table V.G.-05, are based on historical Total Performance Scores. We used the FY 2022 program year's TPSs to calculate the proxy adjustment factors used for this impact analysis. These are the most recently available scores that hospitals were given an opportunity to review and correct. The proxy adjustment factors use estimated annual base operating DRG payment amounts derived from the March 2023 update to the FY 2022 MedPAR file. The proxy adjustment factors can be found in Table 16A associated with this final rule (available via the internet on the CMS website).

The impact analysis shows that, for the FY 2024 program year, the number of hospitals with a positive percent change in base operating DRG (46.2 percent) is lower than the number of hospitals with a negative percentage change (53.8 percent). On average, urban hospitals in the West North Central region and rural hospitals in the East South Central region have the highest positive

percent change in base operating DRG. Urban hospitals in the New England, South Atlantic, East South Central and Pacific regions and rural hospitals in the Middle Atlantic region experience an average negative percent change in base operating DRG. All other regions (both urban and rural) experience an average positive percent change in base operating DRG. With respect to hospitals' Medicare utilization as a percent of inpatient days (MCR), as the MCR percent increases, the average percent change in base operating DRG generally increases, except for those hospitals of more than 50 percent MCR. As DSH percent increases, the average percent change in base operating DRG generally stays the same. On average, non-teaching hospitals have a lower percent change in base operating DRG compared to teaching hospitals; both non-teaching hospitals and teaching hospitals have a positive percent change in base operating DRG.

TABLE I.G.-04 IMPACT ANALYSIS of BASE OPERATING DRG PAYMENT AMOUNTS RESULTING FROM THE FY 2024 HOSPITAL VBP PROGRAM

		Number of Hospitals	Average Net Percentage Payment Adjustment
BY GEOGRAPHIC LOCATION:			
	All Hospitals	**2,523**	**0.025%**
	Urban Area	1,977	0.012%
	Rural Area	546	0.073%
	Missing		.
	Urban Hospitals	**1,977**	**0.012%**
	0-99 beds	344	0.036%
	100-199 beds	617	0.010%
	200-299 beds	396	0.017%
	300-499 beds	381	0.032%
	500 or more beds	239	-0.054%
	Rural Hospitals	**546**	**0.073%**
	0-49 beds	210	0.080%
	50-99 beds	182	0.004%
	100-149 beds	80	0.071%
	150-199 beds	42	0.210%
	200 or more beds	32	0.249%
BY REGION:			
	Urban By Region	**1,977**	**0.012%**
	New England	100	-0.006%
	Middle Atlantic	255	0.015%
	South Atlantic	365	-0.080%
	East North Central	321	0.060%
	East South Central	110	-0.008%
	West North Central	127	0.178%
	West South Central	243	0.030%
	Mountain	148	0.065%
	Pacific	308	-0.025%
	Rural By Region	**546**	**0.073%**
	New England	18	0.113%
	Middle Atlantic	43	-0.075%

	South Atlantic	85	0.014%
	East North Central	96	0.035%
	East South Central	97	0.186%
	West North Central	70	0.062%
	West South Central	78	0.176%
	Mountain	35	0.015%
	Pacific	24	0.003%
BY MCR PERCENT:			
	0-25	763	-0.010%
	25-50	1,673	0.045%
	50-65	86	-0.055%
	Over 65	1	-0.462%
	Missing	.	.
BY DSH PERCENT:			
	0-25	959	0.031%
	25-50	1,311	0.027%
	50-65	154	0.030%
	Over 65	99	-0.050%
	Missing	.	.
BY TEACHING STATUS:			
	Non-Teaching	1,387	0.024%
	Teaching	1,136	0.028%

The actual FY 2024 program year's TPSs will not be reviewed and corrected by hospitals until after the FY 2024 IPPS/LTCH PPS final rule has been published. Therefore, the same historical universe of eligible hospitals and corresponding TPSs from the FY 2023 program year have been used for the updated impact analysis in this final rule.

b. Estimated Effects for the FY 2026 Program Year Applying Finalized Scoring Methodology Change

The estimated effects of the finalized Health Equity Adjustment (HEA) bonus points include larger mean changes in payments for both hospitals that receive bonus payments and for those that incur penalties. In a simulated analysis of the impacts of HEA bonus points in the Hospital VBP Program using FY 2023 program year data, the average bonus payment with the HEA bonus points would be $3,724 and the average penalty would be −$4,246. Our analysis finds that the finalized HEA scoring option increases the number of hospitals gaining compared to the existing scoring methodology. ''Gaining'' in this analysis means both those who are receiving a larger bonus and those who are receiving a smaller penalty under the health equity scoring change than they would receive in the existing scoring methodology. Through these analyses, we found that the average hospital-weighted payment adjustment is positive even though the Hospital VBP Program remains budget neutral. The increase in the number of hospitals gaining occurs primarily among safety net hospitals compared to non-safety net. Additionally, the distribution of TPSs would be higher after the HEA bonus points are incorporated. These impacts are described further in section V.K.6.b. of the preamble of this final rule.

7. Effects of Requirements Under the HAC Reduction Program for FY 2024

We are presenting the estimated impact of the FY 2024 Hospital-Acquired Condition (HAC) Reduction Program on hospitals by hospital characteristic based on previously adopted policies for the program. In the FY 2024 IPPS/LTCH PPS proposed rule, we did not propose to add or remove any measures from the HAC Reduction Program, nor did we propose any changes to reporting or submission requirements which would have any significant economic impact for the FY 2024 program year or future years. The table in this section presents the estimated proportion of hospitals in the worst-performing quartile of Total HAC Scores by hospital characteristic. Hospitals' CMS Patient Safety and Adverse Events Composite (CMS PSI 90) measure results are based on Medicare fee-for-service (FFS) discharges from July 1, 2019, through December 31, 2019, and January 1, 2021, through June 30, 2021, and version 12.0 of the PSI software. Not all data from the FY 2024 HAC Reduction Program CMS PSI 90 performance period (January 1, 2021 through June 30, 2022) were available at the publication of the final rule. Hospitals' measure results for Centers for Disease Control and Prevention (CDC) Central Line-Associated Bloodstream Infection (CLABSI), Catheter-Associated Urinary Tract Infection (CAUTI), Colon and Abdominal Hysterectomy Surgical Site Infection (SSI), Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia, and *Clostridium difficile* Infection (CDI) are derived from standardized infection ratios (SIRs) calculated with hospital surveillance data reported to the CDC's National Healthcare Safety Network (NHSN) for infections occurring between January 1, 2022, and December 31, 2022. Hospital characteristics are based on the FY 2024 IPPS Proposed Rule Impact File. We do not believe the proposals to establish a reconsideration process for data validation as discussed in section V.L.6.a.(2) of the preamble of the FY 2024 IPPS/LTCH PPS proposed rule (88 FR 27054 through 27055) and finalized in this rule will result in any significant economic impacts because the reconsideration request form will not be filled out by hospitals on a regular basis and information collection requirements imposed subsequent to an administrative action are not subject to the PRA under 5 CFR 1320.4(a)(2) (75 FR 50411). This form is intended to be submitted by a

hospital only in the event a hospital did not meet the HAC Reduction Program data validation requirement and seeks reconsideration from CMS on their data validation results for chart-abstracted measures. We anticipate receiving a small number of reconsideration requests annually as we expect very few, if any, hospitals selected for validation will not have their data successfully validated.

This table includes 2,997 non-Maryland hospitals with an estimated FY 2024 Total HAC Score. Maryland hospitals and hospitals without a Total HAC Score are excluded from the table. The first column presents a breakdown of each characteristic and the second column indicates the number of hospitals for the respective characteristic.

The third column in the table indicates the number of hospitals for each characteristic that would be in the worst-performing quartile of Total HAC Scores. These hospitals would receive a payment reduction under the FY 2024 HAC Reduction Program. For example, with regard to teaching status, 566 hospitals out of 1,767 hospitals characterized as non-teaching hospitals would be subject to a payment reduction. Among teaching hospitals, 123 out of 931 hospitals with fewer than 100 residents and 43 out of 279 hospitals with 100 or more residents would be subject to a payment reduction.

The fourth column in the table indicates the proportion of hospitals for each characteristic that would be in the worst performing quartile of Total HAC Scores and thus receive a payment reduction under the FY 2024 HAC Reduction Program. For example, 32.0 percent of the 1,767 hospitals characterized as non-teaching hospitals, 13.2 percent of the 931 teaching hospitals with fewer than 100 residents, and 15.4 percent of the 279 teaching hospitals with 100 or more residents would be subject to a payment reduction.

Estimated Proportion of Hospitals in the Worst-Performing Quartile (>75th percentile) of the Total HAC Scores for the FY 2024 HAC Reduction Program (by Hospital Characteristic)			
Hospital Characteristic	**Number of Hospitals**	**Number of Hospitals in the Worst-performing Quartile[a]**	**Percent of Hospitals in the Worst-Performing Quartile[b]**
Total[c]	2,997	749	25.0
By Geographic Location (n = 2,977)[d]			
Urban hospitals	2,295	450	19.6
1-99 beds	579	222	38.3
100-199 beds	655	121	18.5
200-299 beds	408	40	9.8
300-399 beds	282	23	8.2
400-499 beds	118	17	14.4
500 or more beds	253	27	10.7
Rural hospitals	682	282	41.3
1-49 beds	326	179	54.9
50-99 beds	193	71	36.8
100-149 beds	85	15	17.6
150-199 beds	45	11	24.4
200 or more beds	33	6	18.2
By Safety-Net Status[e] (n = 2,977)			
Non-safety net	2,364	565	23.9
Safety-net	613	167	27.2
By DSH Percent[f] (n = 2,977)			
0-24	1,208	308	25.5
25-49	1,428	311	21.8
50-64	198	65	32.8
65 and over	143	48	33.6
By Teaching Status[g] (n =2,977)			
Non-teaching	1,767	566	32.0
Fewer than 100 residents	931	123	13.2
100 or more residents	279	43	15.4
By Ownership (n = 2,977)			
Voluntary	1,843	377	20.5
Proprietary	716	187	26.1
Government	418	168	40.2
By MCR Percent[h] (n = 2,975)			
0-24	917	207	22.6
25-49	1,911	462	24.2
50-64	128	48	37.5
65 and over	19	13	68.4
By Region[i] (n= 2,997)			
New England	129	27	20.9
Mid-Atlantic	323	73	22.6
South Atlantic	496	99	20.0
East North Central	473	113	23.9
East South Central	260	90	34.6
West North Central	236	51	21.6
West South Central	473	155	32.8
Mountain	228	62	27.2
Pacific	379	79	20.8

Source: FY 2024 HAC Reduction Program estimated final rule results are based on CMS PSI 90 data from July 1, 2019, through December 31, 2019, and January 1, 2021, through June 30, 2021, and CDC NHSN HAI results from January 1, 2022, through December 31, 2022. Hospital Characteristics are based on the FY 2024 IPPS Proposed Rule Impact File.

[a] This column is the number of non-Maryland hospitals with a Total HAC Score within the corresponding characteristic that are estimated to be in the worst-performing quartile.
[b] This column is the percent of non-Maryland hospitals within each characteristic that are estimated to be in the worst-performing quartile. The percentages are calculated by dividing the number of non-Maryland hospitals with a Total HAC Score in the worst-performing quartile by the total number of non-Maryland hospitals with a Total HAC Score within that characteristic.
[c] The number of non-Maryland hospitals with a FY 2024 Total HAC Score (N = 2,997). Note that not all hospitals have data for all hospital characteristics.
[d] The number of hospitals that had information for geographic location with bed size, Safety-net status, DSH percent, teaching status, and Ownership (n = 2,977).
[e] A hospital is considered a Safety-net hospital if it is in the top quintile for DSH percent.
[f] The DSH patient percentage is equal to the sum of: (1) the percentage of Medicare inpatient days attributable to patients eligible for both Medicare Part A and Supplemental Security Income; and (2) the percentage of total inpatient days attributable to patients eligible for Medicaid but not Medicare Part A.
[g] A hospital is considered a teaching hospital if it has an IME adjustment factor for Operation PPS (TCHOP) greater than zero.
[h] Not all hospitals had data for MCR percent (n = 2,975).
[i] All hospitals had data for Region (n = 2,997). For the 11 hospitals that were not in the FY 2024 IPPS Proposed Rule Impact File, region data were identified using the hospital CCN.

BILLING CODE 4120–01–C

In section V.L.6.a.(3) of the preamble of the FY 2024 IPPS/LTCH PPS proposed rule, we proposed to update our targeting criteria for validation of hospitals granted an extraordinary circumstances exception (ECE) in the HAC Reduction Program (88 FR 27055). Specifically, we proposed to modify the validation targeting criteria to include any hospital with a two-tailed confidence interval that is less than 75 percent and received an ECE for one or more quarters beginning with the FY 2027 program year. In section V.L.6.a.(3). of the preamble of this final rule, we are finalizing this modification. We do not believe this modification of targeting criteria will have any economic impact on the hospitals selected for validation but will only increase the number of hospitals which are subject to being targeted for validation. Any increase will not exceed the total maximum number of hospitals that will be selected for targeted validation as previously finalized.

8. Effects of Implementation of the Rural Community Hospital Demonstration Program in FY 2024

In section V.K. of the preamble of this final rule for FY 2023, we discussed our implementation and budget neutrality methodology for section 410A of Public Law 108–173, as amended by sections 3123 and 10313 of Public Law 111–148, by section 15003 of Public Law 114–255, and most recently, by section 128 of Public Law 116–260, which requires the Secretary to conduct a demonstration that would modify payments for inpatient services for up to 30 rural hospitals.

Section 128 of Public Law 116–255 requires the Secretary to conduct the Rural Community Hospital Demonstration for a 15-year extension period (that is, for an additional 5 years beyond the previous extension period). In addition, the statute provides for continued participation for all hospitals participating in the demonstration program as of December 30, 2019.

Section 410A(c)(2) of Public Law 108–173 requires that in conducting the demonstration program under this section, the Secretary shall ensure that the aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration program under this section was not implemented (budget neutrality). We propose to adopt the general methodology used in previous years, whereby we estimated the additional payments made by the program for each of the participating hospitals as a result of the demonstration, and then adjusted the national IPPS rates by an amount sufficient to account for the added costs of this demonstration. In other words, we have applied budget neutrality across the payment system as a whole rather than across the participants of this demonstration. The language of the statutory budget neutrality requirement permits the agency to implement the budget neutrality provision in this manner. The statutory language requires that aggregate payments made by the Secretary do not exceed the amount which the Secretary would have paid if the demonstration was not implemented, but does not identify the range across which aggregate payments must be held equal.

For this final rule, the resulting amount applicable to FY 2024 is $37,766,716, which we are including in the budget neutrality offset adjustment for FY 2024. This estimated amount is based on the specific assumptions regarding the data sources used, that is, recently available ''as submitted'' cost reports and historical and currently finalized update factors for cost and payment.

In previous years, we have incorporated a second component into the budget neutrality offset amounts identified in the final IPPS rules. As finalized cost reports became available, we determined the amount by which the actual costs of the demonstration for an earlier, given year differed from the estimated costs for the demonstration set forth in the final IPPS rule for the corresponding fiscal year, and we incorporated that amount into the budget neutrality offset amount for the upcoming fiscal year. We have calculated this difference for FYs 2005 through 2017 between the actual costs of the demonstration as determined from finalized cost reports once available, and estimated costs of the demonstration as identified in the applicable IPPS final rules for these years.

With the extension of the demonstration for another 5-year period, as authorized by section 128 of Public Law 116–260, we continue this general procedure. At this time, for the FY 2024 final rule, all of the finalized cost reports are available for the 29 hospitals that completed cost report periods beginning in FY 2019 under the demonstration payment methodology; these cost reports show the actual costs of the demonstration for this fiscal year to be $46,745,899. This amount exceeds the amount that was estimated for FY 2018 in the FY 2019 IPPS final rule ($31,070,880) by $15,675,019. (Following upon the selection of new hospitals for the demonstration in 2017, the estimated costs of the demonstration for FYs 2018 and 2019 were included in the FY 2019 IPPS final rule). (83 FR 41054). Thus, keeping with past practice, we are adding this difference to the estimated cost for FY 2024 in determining the budget neutrality offset amount for the FY 2024 IPPS final rule.

Therefore, for this FY 2024 IPPS/LTCH PPS final rule, the budget neutrality offset amount for FY 2024 is based on the sum of two amounts:

- The amount representing the difference applicable to FY 2024 between the sum of the estimated reasonable cost amounts that would be paid under the demonstration for covered inpatient services to the 26 hospitals participating in the fiscal year and the sum of the estimated amounts that would generally be paid if the demonstration had not been implemented. This estimated amount is $37,766,716.
- The amount by which the actual costs of the demonstration in FY 2018 (as shown by finalized cost reports from that fiscal year) differ from the amount determined for FY 2018. The amount of this difference is for FY 2018 is $15,675,019.

We are thus subtracting the sum of these amounts ($53,441,735) from the national IPPS rates for FY 2024.

9. Effects of Continued Implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration

In section VII.B.2. of the preamble of this final rule, we discuss the implementation of the FCHIP Demonstration, which allows eligible entities to develop and test new models for the delivery of health care services in eligible counties to improve access to and better integrate the delivery of acute care, extended care, and other health care services to Medicare beneficiaries in no more than four States. Section 123 of Public Law 110–275 initially required a 3-year period of performance. The FCHIP Demonstration began on August 1, 2016, and concluded on July 31, 2019 (referred to in

this section as the ''initial period''). Section 129 of the Consolidated Appropriations Act (Pub. L. 116–159) extended the FCHIP Demonstration by 5 years (referred to in this section as the ''extension period'' of the demonstration). CAHs participating in the demonstration project during the extension period began such participation in their cost reporting year that began on or after January 1, 2022. Budget neutrality estimates for the demonstration described in the preamble of this final rule are based on the demonstration extension period.

As described in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49144 through 49147), CMS waived certain Medicare rules for CAHs participating in the demonstration extension period to allow for alternative reasonable cost-based payment methods in the three distinct intervention service areas: telehealth services, ambulance services, and skilled nursing facility/nursing facility services. These waivers were implemented with the goal of increasing access to care with no net increase in costs. As we explained in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49144 through 49147), section 129 of Public Law 116–159 stipulates that only the 10 CAHs that participated in the initial period of the FCHIP Demonstration are eligible to participate during the extension period. Among the eligible CAHs, five elected to participate in the extension period. The selected CAHs are in two states—Montana and North Dakota—and are implementing the three intervention services.

As explained in the FY 2023 IPPS/LTCH PPS final rule, we based our selection of CAHs for participation in the demonstration with the goal of maintaining the budget neutrality of the demonstration on its own terms meaning that the demonstration would produce savings from reduced transfers and admissions to other health care providers, offsetting any increase in Medicare payments as a result of the demonstration. However, because of the small size of the demonstration and uncertainty associated with the projected Medicare utilization and costs, the policy we finalized for the demonstration extension period of performance in the FY 2023 IPPS/LTCH PPS final rule provides a contingency plan to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met.

In the FY 2023 IPPS/LTCH PPS final rule, we adopted the same budget neutrality policy contingency plan used during the demonstration initial period to ensure that the budget neutrality requirement in section 123 of Public Law 110–275 is met during the demonstration extension period. If analysis of claims data for Medicare beneficiaries receiving services at each of the participating CAHs, as well as from other data sources, including cost reports for the participating CAHs, shows that increases in Medicare payments under the demonstration during the 5-year extension period is not sufficiently offset by reductions elsewhere, we will recoup the additional expenditures attributable to the demonstration through a reduction in payments to all CAHs nationwide.

As explained in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49144 through 49147), because of the small scale of the demonstration, we indicated that we did not believe it would be feasible to implement budget neutrality for the demonstration extension period by reducing payments to only the participating CAHs. Therefore, in the event that this demonstration extension period is found to result in aggregate payments in excess of the amount that would have been paid if this demonstration extension period were not implemented, CMS policy is to comply with the budget neutrality requirement finalized in the FY 2023 IPPS/LTCH PPS final rule, by reducing payments to all CAHs, not just those participating in the demonstration extension period.

In the FY 2023 IPPS/LTCH PPS final rule, we stated that we believe it is appropriate to make any payment reductions across all CAHs because the FCHIP Demonstration was specifically designed to test innovations that affect delivery of services by the CAH provider category. As we explained in the FY 2023 IPPS/LTCH PPS final rule, we believe that the language of the statutory budget neutrality requirement at section 123(g)(1)(B) of Public Law 110–275 permits the agency to implement the budget neutrality provision in this manner. The statutory language merely refers to ensuring that aggregate payments made by the Secretary do not exceed the amount which the Secretary estimates would have been paid if the demonstration project was not implemented, and does not identify the range across which aggregate payments must be held equal.

In the FY 2022 IPPS/LTCH PPS final rule (86 FR 45323 through 45328), CMS concluded that the initial period of the FCHIP Demonstration had satisfied the budget neutrality requirement described in section 123(g)(1)(B) of Public Law 110–275. Therefore, CMS did not apply a budget neutrality payment offset policy for the initial period of the demonstration. As explained in the FY 2022 IPPS/LTCH PPS final rule, we finalized a policy to address the demonstration budget neutrality methodology and analytical approach for the initial period of the demonstration. As stated in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49144 through 49147), our policy for implementing the 5-year extension period for section 129 of Public Law 116–260 follows same budget neutrality methodology and analytical approach as the demonstration initial period methodology. While we expect to use the same methodology that was used to assess the budget neutrality of the FCHIP Demonstration during initial period of the demonstration to assess the financial impact of the demonstration during this extension period, upon receiving data for the extension period, we may update and/or modify the FCHIP budget neutrality methodology and analytical approach to ensure that the full impact of the demonstration is appropriately captured. Therefore, we did not propose to apply a budget neutrality payment offset to payments to CAHs in FY 2024. This policy will have no impact for any national payment system for FY 2024.

10. Effects of Changes for Rural Emergency Hospitals

Section X.A. of the preamble of this final rule would address the special requirements for REHs that would require an eligible facility (a CAH or a small rural hospital with not more than 50 beds) to submit additional information that must include an action plan containing four specific elements when the facility submits an application for enrollment as an REH. An eligible facility that submits an application for enrollment as an REH under section 1866(j) of the Act must also submit additional information as specified in this final rule. In accordance with section 1861(kkk)(4)(A)(i) through (iv) of the Act, we specifically propose to require an eligible facility to submit additional information that must include an action plan containing: (1) a plan for initiating REH services (as those services are defined in 42 CFR 485.502, and which must include the provision of emergency department services and observation care); (2) a detailed transition plan that lists the specific services that the provider will retain, modify, add, and discontinue as an REH; (3) a detailed description of other outpatient medical and health services that it intends to furnish on an outpatient basis as an REH; and (4) information regarding how the provider intends to use the additional facility payment provided under section 1834(x)(2) of the Act, including a description of the services that the additional facility payment would be supporting, such as the operation and maintenance of the facility and the furnishing of covered services (for example, telehealth services and ambulance services).

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other healthcare providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $8.0 million to $41.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We estimate that almost all of the new REH facilities are or would be small entities based on legal status, revenues, or both. The North American Industry Classification System Code for the converting hospitals is 622110 (General Medical and Surgical Hospitals), and for the REHs to which they convert the closest Code is 621493 (Freestanding Ambulatory Surgical and Emergency Centers). HHS uses an increase in costs or decrease in revenues of more than 3 percent as its threshold for ''significant economic impact''. Our collection of information (COI) estimate is that the 68 facilities converting to REH status would face a one-time cost of about $460 each ($68 \times 460 = $31,280 (COI burden estimate)). The North Carolina Rural Health Research Program estimated that the 68 hospitals it thought most likely to convert to REH status had average patient revenues of $7.3 million.[19]

[19] ''How Many Hospitals Might Convert to a Rural Emergency Hospital (REH)?'' July 2021. Pink, GH et

For these facilities, the 3 percent threshold would be about $219,000, nearly 500 times our estimated cost of information collection. These relationships between revenues and costs would not be substantially different if the number of conversions was substantially fewer or substantially greater in number. More importantly, these facilities would be converting voluntarily to the new program. We expect that the costs any facility faces would be less than the anticipated gains of conversion, or it would not convert. For these reasons, an Initial Regulatory Flexibility Analysis is not required for the proposed Special Requirements for REHs.

11. Effects of Changes for Physician-Owned Hospitals

Provisions related to hospitals that have physician ownership or investment are discussed in section X.B. of the preamble of this final rule. Section X.B.2.a. of the preamble of this final rule describes our changes to the regulations to clarify that CMS will only consider expansion exception requests from eligible hospitals, clarify the data and information that must be included in an expansion exception request and the information that a requesting hospital may submit at its option, identify factors that CMS will consider when deciding whether to approve or deny an expansion exception request, and revise certain aspects of the process for requesting an expansion exception. We expect that the clarifications and revisions, as finalized, along with the description of the factors we will consider when deciding whether to approve or deny an expansion exception request, will increase transparency, allow for greater community input, ensure that approval of a request to expand a hospital's facility capacity occurs only in appropriate circumstances, and facilitate compliance with the process for requesting an expansion exception. The use of HCRIS data for all comparison calculations, as required under the final rule, will have little practical impact on whether a requesting hospital meets the criteria for an applicable hospital or a high Medicaid facility, nor will a requesting hospital be prejudiced by this requirement.

Section X.B.2.b. of the preamble of this final rule describes our reinstatement, with respect to high Medicaid facilities, of the program integrity restrictions on the frequency of expansion exception requests, maximum aggregate expansion of a hospital, and location of expansion capacity that were removed in the CY 2021 OPPS/ASC final rule. We believe that not applying these program integrity restrictions poses a significant risk of program or patient abuse that must be addressed despite any potential perceived burden on high Medicaid facilities. We anticipate that treating both applicable and high Medicaid hospitals the same will create consistency in the expansion exception process and protect the Medicare program and its beneficiaries, as well as Medicaid beneficiaries, uninsured patients, and other underserved populations, from harms such as overutilization, patient steering, cherry-picking, and lemon-dropping.

More information on the comments received on the physician-owned hospital provisions can be found in section X.B. of the preamble of this final rule.

H. Effects on Hospitals and Hospital Units Excluded From the IPPS

As of July 2023, there were 91 children's hospitals, 11 cancer hospitals, 6 short term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, 1 extended neoplastic disease care hospital, and 9 RNHCIs being paid on a reasonable cost basis subject to the rate-of-increase ceiling under § 413.40. (In accordance with § 403.752(a) of the regulation, RNHCIs are paid under § 413.40.) Among the remaining providers, the rehabilitation hospitals and units, and the LTCHs, are paid the Federal prospective per discharge rate under the IRF PPS and the LTCH PPS, respectively, and the psychiatric hospitals and units are paid the Federal per diem amount under the IPF PPS. As stated previously, IRFs and IPFs are not affected by the rate updates discussed in this final rule. The impacts of the changes on LTCHs are discussed in section I.J. of this appendix.

For the children's hospitals, cancer hospitals, short-term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the extended neoplastic disease care hospital, and RNHCIs, the update of the rate-of-increase limit (or target amount) is the estimated FY 2024 percentage increase in the 2018-based IPPS operating market basket, consistent with section 1886(b)(3)(B)(ii) of the Act, and §§ 403.752(a) and 413.40 of the regulations. Consistent with current law, based on IGI's second quarter 2023 forecast of the 2018-based IPPS market basket increase, we are estimating the FY 2024 update to be 3.3 percent (that is, the estimate of the market basket rate-of-increase), as discussed in section V.A. of the preamble of this final rule. We proposed that if more recent data become available for the final rule, we would use such data, if appropriate, to calculate the final IPPS operating market basket update for FY 2024. The Affordable Care Act requires a productivity adjustment (0.2 percentage point reduction for FY 2024), resulting in a 3.1 percent applicable percentage increase for IPPS hospitals that submit quality data and are meaningful EHR users, as discussed in section V.A. of the preamble of this final rule. Children's hospitals, cancer hospitals, short term acute care hospitals located in the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, the extended neoplastic disease care hospital, and RNHCIs that continue to be paid based on reasonable costs subject to rate-of-increase limits under § 413.40 of the regulations are not subject to the reductions in the applicable percentage increase required under the Affordable Care Act. Therefore, for those hospitals paid under § 413.40 of the regulations, the update is the percentage increase in the 2018-based IPPS operating market basket for FY 2024, estimated at 3.3 percent.

The impact of the update in the rate-of-increase limit on those excluded hospitals depends on the cumulative cost increases experienced by each excluded hospital since its applicable base period. For excluded hospitals that have maintained their cost increases at a level below the rate-of-increase limits since their base period, the major effect is on the level of incentive payments these excluded hospitals receive. Conversely, for excluded hospitals with cost increases above the cumulative update in their rate-of-increase limits, the major effect is the amount of excess costs that would not be paid.

We note that, under § 413.40(d)(3), an excluded hospital that continues to be paid under the TEFRA system and whose costs exceed 110 percent of its rate-of-increase limit receives its rate-of-increase limit plus the lesser of: (1) 50 percent of its reasonable costs in excess of 110 percent of the limit; or (2) 10 percent of its limit. In addition, under the various provisions set forth in § 413.40, hospitals can obtain payment adjustments for justifiable increases in operating costs that exceed the limit.

I. Effects of Changes in the Capital IPPS

1. General Considerations

For the impact analysis presented in this section of this final rule, we used data from the March 2023 update of the FY 2022 MedPAR file and the March 2023 update of the Provider-Specific File (PSF) that was used for payment purposes. Although the analyses of the changes to the capital prospective payment system do not incorporate cost data, we used the March 2023 update of the most recently available hospital cost report data to categorize hospitals. Our analysis has several qualifications and uses the best data available, as described later in this section of this final rule.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each change. In addition, we draw upon various sources for the data used to categorize hospitals in the tables. In some cases (for instance, the number of beds), there is a fair degree of variation in the data from different sources. We have attempted to construct these variables with the best available sources overall. However, it is possible that some individual hospitals are placed in the wrong category.

Using cases from the March 2023 update of the FY 2022 MedPAR file, we simulated payments under the capital IPPS for FY 2023 and the payments for FY 2024 for a comparison of total payments per case. Short-term, acute care hospitals not paid under the general IPPS (for example, hospitals in Maryland) are excluded from the simulations.

The methodology for determining a capital IPPS payment is set forth at § 412.312. The basic methodology for calculating the capital IPPS payments in FY 2024 is as follows:

(Standard Federal rate) × (DRG weight) × (GAF) × (COLA for hospitals located in Alaska and Hawaii) × (1 + DSH adjustment factor + IME adjustment factor, if applicable).

In addition to the other adjustments, hospitals may receive outlier payments for those cases that qualify under the threshold established for each fiscal year. We modeled

al. Findings Brief—NC Rural Health Research Program.

payments for each hospital by multiplying the capital Federal rate by the geographic adjustment factor (GAF) and the hospital's case-mix. Then we added estimated payments for indirect medical education, disproportionate share, and outliers, if applicable. For purposes of this impact analysis, the model includes the following assumptions:

- The capital Federal rate was updated, beginning in FY 1996, by an analytical framework that considers changes in the prices associated with capital-related costs and adjustments to account for forecast error, changes in the case-mix index, allowable changes in intensity, and other factors. As discussed in section III.A.1. of the Addendum to this final rule, the update to the capital Federal rate is 3.8 percent for FY 2024.
- In addition to the FY 2024 update factor, the FY 2024 capital Federal rate was calculated based on a GAF/DRG budget neutrality adjustment factor of 0.9885, a budget neutrality factor for the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy of 0.9964, and a outlier adjustment factor of 0.9598.

2. Results

We used the payment simulation model previously described in section I.I. of appendix A of this final rule to estimate the potential impact of the changes for FY 2024 on total capital payments per case, using a universe of 3,131 hospitals. As previously described, the individual hospital payment parameters are taken from the best available data, including the March 2023 update of the FY 2022 MedPAR file, the March 2023 update to the PSF, and the most recent available cost report data from the March 2023 update of HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2023 and estimated total payments per case for FY 2024 based on the FY 2024 payment policies. Column 2 shows estimates of payments per case under our model for FY 2023. Column 3 shows estimates of payments per case under our model for FY 2024. Column 4 shows the total percentage change in payments from FY 2023 to FY 2024. The change represented in Column 4 includes the 3.80 percent update to the capital Federal rate and other changes in the adjustments to the capital Federal rate. The comparisons are provided by: (1) geographic location; (2) region; and (3) payment classification.

The simulation results show that, on average, capital payments per case in FY 2024 are expected to increase 6.6 percent compared to capital payments per case in FY 2023. This expected increase is primarily due to the 3.80 percent update to the capital Federal rate and an estimated increase in capital DSH payments. As discussed in section VI.D of the preamble to this final rule, we are finalizing that beginning in FY 2024, hospitals reclassified as rural under § 412.103 will no longer be considered rural for purposes of determining eligibility for capital DSH payments. As such, under this policy, geographically urban hospitals with 100 or more beds reclassified as rural under § 412.103 will be eligible for capital DSH payments beginning in FY 2024. The CMS' Office of the Actuary estimates this change in policy will increase capital payments $170 million in FY 2024.

In general, regional variations in estimated capital payments per case in FY 2024 as compared to capital payments per case in FY 2023 are primarily due to the changes in GAFs, and are generally consistent with the projected changes in payments due to changes in the wage index (and policies affecting the wage index), as shown in Table I in section I.F. of this appendix. We note that the FY 2024 GAFs reflect the changes to the rural wage index methodology finalized in section III.G.1. of the preamble to this final rule. As discussed, beginning in FY 2024, we are including hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and are only excluding ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) in accordance with the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. We also are including the data of all § 412.103 hospitals (including those that have an MGCRB reclassification when appropriate) in the calculation of the rural floor and the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act.

The net impact of these changes is an estimated 6.6 percent increase in capital payments per case from FY 2023 to FY 2024 for all hospitals (as shown in Table III).

The geographic comparison shows that, on average, hospitals in both urban and rural classifications will experience an increase in capital IPPS payments per case in FY 2024 as compared to FY 2023. Capital IPPS payments per case will increase by an estimated 6.7 percent for hospitals in urban areas while payments to hospitals in rural areas will increase by 5.8 percent in FY 2023 to FY 2024.

The comparisons by region show that the change in capital payments per case from FY 2023 to FY 2024 for urban areas range from a 3.5 percent increase for Puerto Rico to a 9.6 percent increase for the Pacific region. Meanwhile, the change in capital payments per case from FY 2023 to FY 2024 for rural areas range from a 2.4 percent increase for the New England rural region to a 16.8 percent increase for the Middle Atlantic region. These regional differences are primarily due to the changes in the GAFs, which reflect the changes to the rural wage index methodology. We note that the changes to the rural wage index methodology are significantly contributing to the larger than average increase in capital payments per case for the rural Middle Atlantic region.

The comparison by hospital type of ownership (Voluntary, Proprietary, and Government) shows that voluntary hospitals are expected to experience the highest increase in capital payments per case from FY 2023 to FY 2024 of 6.6 percent. Meanwhile, proprietary and government hospitals are expected to experience an increase in capital payments per case from FY 2023 to FY 2024 of 6.4 percent.

Section 1886(d)(10) of the Act established the MGCRB. Hospitals may apply for reclassification for purposes of the wage index for FY 2024. Reclassification for wage index purposes also affects the GAFs because that factor is constructed from the hospital wage index. To present the effects of the hospitals being reclassified as of the publication of this final rule for FY 2024, we show the average capital payments per case for reclassified hospitals for FY 2024. Urban reclassified hospitals are expected to experience an increase in capital payments of 8.5 percent; urban nonreclassified hospitals are expected to experience an increase in capital payments of 4.6 percent. The higher expected increase in payments for urban reclassified hospitals compared to urban nonreclassified hospitals is primarily due to an estimated increase in capital DSH payments to urban reclassified hospitals. As discussed previously, we are finalizing a change to our capital DSH policy under which geographically urban hospitals with 100 or more beds reclassified as rural under § 412.103 will be eligible for capital DSH payments beginning in FY 2024. Rural reclassified hospitals are expected to experience an increase in capital payments of 5.4 percent; rural nonreclassified hospitals are expected to experience an increase in capital payments of 6.6 percent.

TABLE III.-- COMPARISON OF TOTAL PAYMENTS PER CASE

[FY 2023 PAYMENTS COMPARED TO FY 2024 PAYMENTS]	Number of Hospitals	Average FY 2023 Payments/ Case	Average FY 2024 Payments/ Case	Change
All Hospitals	3,131	1,088	1,160	6.6
By Geographic Location:				
Urban hospitals	2,416	1,119	1,194	6.7
Rural hospitals	715	763	807	5.8
Bed Size (Urban):				
0-99 beds	650	881	912	3.5
100-199 beds	696	942	1,000	6.2
200-299 beds	414	1,030	1,102	7.0
300-499 beds	404	1,108	1,193	7.7
500 or more beds	250	1,332	1,416	6.3
Bed Size (Rural):				
0-49 beds	363	648	686	5.9
50-99 beds	188	734	786	7.1
100-149 beds	87	746	789	5.8
150-199 beds	46	838	882	5.3
200 or more beds	31	901	948	5.2
Urban by Region:				
New England	108	1,199	1,259	5.0
Middle Atlantic	292	1,250	1,349	7.9
East North Central	372	1,048	1,101	5.1
West North Central	156	1,077	1,124	4.4
South Atlantic	403	972	1,038	6.8
East South Central	138	944	993	5.2
West South Central	359	1,025	1,075	4.9
Mountain	177	1,131	1,208	6.8
Pacific	360	1,451	1,590	9.6
Puerto Rico	51	606	627	3.5
Rural by Region:				
New England	19	1,051	1,076	2.4
Middle Atlantic	47	744	869	16.8
East North Central	113	757	792	4.6
West North Central	84	774	810	4.7
South Atlantic	108	705	747	6.0
East South Central	140	725	760	4.8
West South Central	134	684	717	4.8
Mountain	46	860	885	2.9
Pacific	24	982	1,084	10.4
By Payment Classification:				

[FY 2023 PAYMENTS COMPARED TO FY 2024 PAYMENTS]	Number of Hospitals	Average FY 2023 Payments/ Case	Average FY 2024 Payments/ Case	Change
Urban hospitals	1,811	1,070	1,122	4.9
Rural areas	1,320	1,109	1,204	8.6
Teaching Status:				
Nonteaching	1,900	902	959	6.3
Fewer than 100 residents	953	1,026	1,096	6.8
100 or more residents	278	1,470	1,566	6.5
Urban DSH:				
Non-DSH	353	963	997	3.5
100 or more beds	1,099	1,102	1,158	5.1
Less than 100 beds	359	817	846	3.5
Rural DSH:				
Non-DSH	108	1,022	1,074	5.1
SCH	257	777	842	8.4
RRC	712	1,154	1,256	8.8
100 or more beds	32	1,159	1,236	6.6
Less than 100 beds	211	647	687	6.2
Urban teaching and DSH:				
Both teaching and DSH	637	1,166	1,221	4.7
Teaching and no DSH	57	1,019	1,062	4.2
No teaching and DSH	821	953	1,007	5.7
No teaching and no DSH	296	931	961	3.2
Special Hospital Types:				
RRC	133	905	958	5.9
RRC with Section 401 Rural Reclassification	491	1,220	1,331	9.1
SCH	256	742	787	6.1
SCH with Section 401 Rural Reclassification	45	876	966	10.3
SCH and RRC	121	844	891	5.6
SCH and RRC with Section 401 Rural Reclassification	43	1,027	1,108	7.9
MDH	116	653	698	6.9
MDH with Section 401 Reclassification	30	728	785	7.8
MDH and RRC	18	705	745	5.7
MDH and RRC with Section 401 Reclassification	13	822	885	7.7
Type of Ownership:				
Voluntary	1,920	1,091	1,163	6.6
Proprietary	778	1,003	1,067	6.4
Government	432	1,186	1,262	6.4
Medicare Utilization as a Percent of Inpatient Days:				
0-25	995	1,196	1,284	7.4
25-50	1,945	1,051	1,117	6.3
50-65	138	897	948	5.7
Over 65	25	582	628	7.9
Medicaid Utilization as a Percent of Inpatient Days:				
0-25	2,038	1,009	1,067	5.7
25-50	974	1,208	1,300	7.6
50-65	91	1,395	1,532	9.8
Over 65	28	1,341	1,564	16.6
FY 2024 Reclassifications:				
All Reclassified Hospitals	1,054	1,121	1,214	8.3
Non-Reclassified Hospitals	2,077	1,058	1,110	4.9
Urban Hospitals Reclassified	869	1,161	1,260	8.5
Urban Non-Reclassified Hospitals	1,561	1,077	1,127	4.6
Rural Hospitals Reclassified Full Year	298	775	817	5.4
Rural Non-Reclassified Hospitals Full Year	403	745	794	6.6
All Section 401 Rural Reclassified Hospitals	659	1,185	1,291	8.9
Other Reclassified Hospitals (Section 1886(d)(8)(B))	54	761	819	7.6

J. Effects of Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VII. of the preamble of this final rule and section V. of the Addendum to this final rule, we set forth the annual update to the payment rates for the LTCH PPS for FY 2024. In the preamble of this final rule, we specify the statutory authority for the provisions that are presented, identify the policies for FY 2024, and present rationales for our provisions as well as alternatives that were considered. In this section, we discuss the impact of the changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this final rule in terms of their estimated fiscal impact on the Medicare budget and on LTCHs.

There are 333 LTCHs included in this impact analysis. We note that, although there are currently approximately 341 LTCHs, for purposes of this impact analysis, we excluded the data of all-inclusive rate providers consistent with the development of the FY 2024 MS–LTC–DRG relative weights (discussed in section VII.B.3. of the preamble of this final rule). We have also excluded data for CCN 312024 from this impact

analysis due to their abnormal charging practices. We note this is consistent with our removal of this LTCH from the calculation of the FY 2024 MS–LTC–DRG relative weights, the area wage level adjustment budget neutrality factor, and the fixed-loss amount for LTCH PPS standard Federal payment rate cases (discussed in section VII.B.3. of the preamble of this final rule). Moreover, in the claims data used for this final rule, one of these 333 LTCHs only have claims for site neutral payment rate cases and, therefore, do not affect our impact analysis for LTCH PPS standard Federal payment rate cases.

In the impact analysis, we used the payment rate, factors, and policies presented in this final rule, the 3.3 percent annual update to the LTCH PPS standard Federal payment rate, the update to the MS–LTC–DRG classifications and relative weights, the update to the wage index values and labor-related share, and the best available claims and CCR data to estimate the change in payments for FY 2024.

Under the dual rate LTCH PPS payment structure, payment for LTCH discharges that meet the criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) is based on the LTCH PPS standard Federal payment rate. Consistent with the statute, the site neutral payment rate is the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4), including any applicable outlier payments as specified in § 412.525(a), reduced by 4.6 percent for FYs 2018 through 2026; or 100 percent of the estimated cost of the case as determined under § 412.529(d)(2). In addition, there are two separate high cost outlier targets—one for LTCH PPS standard Federal payment rate cases and one for site neutral payment rate cases. We note that section 3711(b)(2) of the CARES Act provided a waiver of the application of the site neutral payment rate for LTCH cases admitted during the COVID–19 PHE period. The COVID–19 PHE expired on May 11, 2023. As a result, all FY 2023 cases with admission dates on or before the PHE expiration date will be paid the LTCH PPS standard Federal rate regardless of whether the discharge met the statutory patient criteria. However, all FY 2023 and FY 2024 cases with admission dates after the PHE expiration date (that is, admissions occurring on or after May 12, 2023) that do not meet the criteria for exclusion from the site neutral payment rate will be paid the site neutral payment rate determined under § 412.522(c). For purposes of this impact analysis, estimates of total LTCH PPS payments for site neutral payment rate cases in FYs 2023 and 2024 were calculated using the site neutral payment rate determined under § 412.522(c) for all cases and the provisions of the CARES Act were not considered.

Based on the best available data for the 333 LTCHs in our database that were considered in the analyses used for this final rule, we estimate that overall LTCH PPS payments in FY 2024 will increase by approximately 0.2 percent (or approximately $6 million) based on the rates and factors presented in section VII. of the preamble and section V. of the Addendum to this final rule.

Based on the FY 2022 LTCH cases that were used for the analysis in this final rule, approximately 32 percent of those cases were classified as site neutral payment rate cases (that is, 32 percent of LTCH cases would not meet the statutory patient-level criteria for exclusion from the site neutral payment rate). Our Office of the Actuary currently estimates that the percent of LTCH PPS cases that will be classified as site neutral payment rate cases in FY 2024 will not change significantly from the most recent historical data. We estimate IPPS comparable per diem amounts using the prior year's IPPS rates and factors, updated to reflect estimated changes to the IPPS rates and payments finalized for FY 2024. Taking this into account along with other changes that will apply to the site neutral payment rate cases in FY 2024, we estimate that aggregate LTCH PPS payments for these site neutral payment rate cases will increase by approximately 3.2 percent (or approximately $10 million). This projected increase in payments to LTCH PPS site neutral payment rate cases is primarily due to the finalized updates to the IPPS rates and payments reflected in our estimate of the IPPS comparable per diem amount. We note that we estimate payments to site neutral payment rate cases in FY 2024 will represent approximately 12 percent of estimated aggregate FY 2024 LTCH PPS payments.

Based on the FY 2022 LTCH cases that were used for the analysis in this final rule, approximately 68 percent of LTCH cases will meet the patient-level criteria for exclusion from the site neutral payment rate in FY 2024, and will be paid based on the LTCH PPS standard Federal payment rate for the full year. We estimate that total LTCH PPS payments for these LTCH PPS standard Federal payment rate cases in FY 2024 will decrease approximately 0.2 percent (or approximately $4 million). This estimated decrease in LTCH PPS payments for LTCH PPS standard Federal payment rate cases in FY 2024 is primarily due to the projected 2.9 percent decrease in high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments, which is discussed later in this section of the final rule.

Based on the 333 LTCHs that were represented in the FY 2022 LTCH cases that were used for the analyses in this final rule presented in this appendix, we estimate that aggregate FY 2023 LTCH PPS payments will be approximately $2.603 billion, as compared to estimated aggregate FY 2024 LTCH PPS payments of approximately $2.609 billion, resulting in an estimated overall increase in LTCH PPS payments of approximately $6 million. We note that the estimated $6 million increase in LTCH PPS payments in FY 2024 does not reflect changes in LTCH admissions or case-mix intensity, which will also affect the overall payment effects of the policies in this final rule.

The LTCH PPS standard Federal payment rate for FY 2023 is $46,432.77. For FY 2024, we are establishing an LTCH PPS standard Federal payment rate of $48,116.62 which reflects the 3.3 percent annual update to the LTCH PPS standard Federal payment rate and the budget neutrality factor for updates to the area wage level adjustment of 1.0031599 (discussed in section V.B.6. of the Addendum to this final rule). For LTCHs that fail to submit data for the LTCH QRP, in accordance with section 1886(m)(5)(C) of the Act, we are establishing an LTCH PPS standard Federal payment rate of $47,185.03. This LTCH PPS standard Federal payment rate reflects the updates and factors previously described, as well as the required 2.0 percentage point reduction to the annual update for failure to submit data under the LTCH QRP.

Table IV shows the estimated impact for LTCH PPS standard Federal payment rate cases. The estimated change attributable solely to the annual update of 3.3 percent to the LTCH PPS standard Federal payment rate is projected to result in an increase of 3.2 percent in payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2023 to FY 2024, on average, for all LTCHs (Column 6). The estimated increase of 3.2 percent shown in Column 6 of Table IV also includes estimated payments for short-stay outlier (SSO) cases, a portion of which are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the annual update for LTCHs that do not submit the required LTCH QRP data. For most hospital categories, the projected increase in payments based on the LTCH PPS standard Federal payment rate to LTCH PPS standard Federal payment rate cases also rounds to approximately 3.2 percent.

For FY 2024, we are updating the wage index values based on the most recent available data (data from cost reporting periods beginning during FY 2020 which is the same data used for the FY 2024 IPPS wage index). In addition, we are establishing a labor-related share of 68.5 percent for FY 2024, based on the most recent available data (IGI's second quarter 2023 forecast) of the relative importance of the labor-related share of operating and capital costs of the 2017-based LTCH market basket. We also are applying an area wage level budget neutrality factor of 1.0031599 to ensure that the changes to the area wage level adjustment will not result in any change in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases.

For LTCH PPS standard Federal payment rate cases, we currently estimate high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments will decrease from FY 2023 to FY 2024. Based on the FY 2022 LTCH cases that were used for the analyses in this final rule, we estimate that the FY 2023 high cost outlier threshold of $38,518 (as established in the FY 2023 IPPS/LTCH PPS final rule) will result in estimated high cost outlier payments for LTCH PPS standard Federal payment rate cases in FY 2023 that are projected to exceed the 7.975 percent target. Specifically, we currently estimate that high cost outlier payments for LTCH PPS standard Federal payment rate cases will be approximately 10.9 percent of the estimated total LTCH PPS standard Federal payment rate payments in FY 2023. Combined with our estimate that FY 2024 high cost outlier payments for LTCH PPS standard Federal payment rate cases will be 7.975 percent of

estimated total LTCH PPS standard Federal payment rate payments in FY 2024, this will result in an estimated decrease in high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments of approximately 2.9 percent between FY 2023 and FY 2024. We note that, in calculating these estimated high cost outlier payments, we inflated charges reported on the FY 2022 claims by the charge inflation factor described in section V.D.3.b. of the Addendum to this final rule. We also note that, in calculating these estimated high cost outlier payments, we estimated the cost of each case by multiplying the inflated charges by the adjusted CCRs that we determined using our finalized methodology described in section V.D.3.b. of the Addendum to this final rule.

Table IV shows the estimated impact of the payment rate and policy changes on LTCH PPS payments for LTCH PPS standard Federal payment rate cases for FY 2024 by comparing estimated FY 2023 LTCH PPS payments to estimated FY 2024 LTCH PPS payments. (As noted earlier, our analysis does not reflect changes in LTCH admissions or case-mix intensity.) We note that these impacts do not include LTCH PPS site neutral payment rate cases as discussed in section I.J.3. of this appendix.

Comment: We received comments expressing concern about the 2.5 percent decrease in payments to LTCH PPS standard Federal payment rate cases that we projected in the proposed rule. Some commenters stated that this decrease would jeopardize the ability of LTCHs to continue caring for their patients and would lead to LTCH closures. Some commenters stated that Medicare reimbursements already do not cover hospital costs and therefore they found the projected payment reduction especially concerning.

Response: We appreciate commenters' concerns about the proposed 2.5 percent decrease in payments to LTCH PPS standard Federal payment rate cases. As explained in the proposed rule (88 FR 27286), that estimated decrease of approximately 2.5 percent was primarily due to the projected decrease in high cost outlier payments. Specifically, we explained that we estimated high cost outlier payments in FY 2023 would account for approximately 12.7 percent of total LTCH PPS standard Federal payment rate payments. Because this exceeds the statutory 7.975 percent target, it resulted in an estimated decrease in high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments of approximately 4.7 percent between FY 2023 and FY 2024.

Based on the finalized payment rates and factors in this final rule, we now project a 0.2 percent decrease in payments to LTCH PPS standard Federal payment rate cases for FY 2024. This change in projected payments is primarily being driven by a downward revision in this final rule to our estimate of FY 2023 high cost outlier payments to LTCH PPS standard Federal payment rate cases. In this final rule, after incorporating into our payment model the modified charge inflation and CCR adjustment factors discussed in section V.D.3.b. of the Addendum to this final rule, we now estimate that high cost outlier payments for LTCH PPS standard Federal payment rate cases will be approximately 10.9 percent of the estimated total LTCH PPS standard Federal payment rate payments in FY 2023 (as compared to 12.7 percent in the proposed rule as noted previously). In addition, this change in projected payments is partially being driven by the annual update factor of 3.3 percent (which is 0.4 percentage point higher than the proposed annual update factor). As discussed in section VIII.C.2. of the preamble to this final rule, we believe this LTCH market basket increase appropriately reflects the input price growth that LTCHs will incur providing medical services in FY 2024.

As we discuss in detail throughout this final rule, based on the best available data, we believe that the provisions of this final rule relating to the LTCH PPS, which are projected to result in an overall increase in estimated aggregate LTCH PPS payments (for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases), and the resulting LTCH PPS payment amounts will result in appropriate Medicare payments that are consistent with the statute.

2. Impact on Rural Hospitals

For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. As shown in Table IV, we are projecting a 0.3 percent increase in estimated payments for LTCH PPS standard Federal payment rate cases for LTCHs located in a rural area. This estimated impact is based on the FY 2022 data for the 18 rural LTCHs (out of 333 LTCHs) that were used for the impact analyses shown in Table IV.

3. Anticipated Effects of the LTCH PPS Payment Rate Changes and Policy Changes

a. Budgetary Impact

Section 123(a)(1) of the BBRA requires that the PPS developed for LTCHs ''maintain budget neutrality.'' We believe that the statute's mandate for budget neutrality applies only to the first year of the implementation of the LTCH PPS (that is, FY 2003). Therefore, in calculating the FY 2003 standard Federal payment rate under § 412.523(d)(2), we set total estimated payments for FY 2003 under the LTCH PPS so that estimated aggregate payments under the LTCH PPS were estimated to equal the amount that would have been paid if the LTCH PPS had not been implemented.

Section 1886(m)(6)(A) of the Act establishes a dual rate LTCH PPS payment structure with two distinct payment rates for LTCH discharges beginning in FY 2016. Under this statutory change, LTCH discharges that meet the patient-level criteria for exclusion from the site neutral payment rate (that is, LTCH PPS standard Federal payment rate cases) are paid based on the LTCH PPS standard Federal payment rate. LTCH discharges paid at the site neutral payment rate are generally paid the lower of the IPPS comparable per diem amount, reduced by 4.6 percent for FYs 2018 through 2026, including any applicable high cost outlier (HCO) payments, or 100 percent of the estimated cost of the case, reduced by 4.6 percent.

As discussed in section I.J.1. of this appendix, we project an increase in aggregate LTCH PPS payments in FY 2024 of approximately $6 million. This estimated increase in payments reflects the projected decrease in payments to LTCH PPS standard Federal payment rate cases of approximately $4 million and the projected increase in payments to site neutral payment rate cases of approximately $10 million under the dual rate LTCH PPS payment rate structure required by the statute beginning in FY 2016.

As discussed in section V.D. of the Addendum to this final rule, our actuaries project cost and resource changes for site neutral payment rate cases due to the site neutral payment rates required under the statute. Specifically, our actuaries project that the costs and resource use for cases paid at the site neutral payment rate will likely be lower, on average, than the costs and resource use for cases paid at the LTCH PPS standard Federal payment rate, and will likely mirror the costs and resource use for IPPS cases assigned to the same MS–DRG. While we are able to incorporate this projection at an aggregate level into our payment modeling, because the historical claims data that we are using in this final rule to project estimated FY 2024 LTCH PPS payments (that is, FY 2022 LTCH claims data) do not reflect this actuarial projection, we are unable to model the impact of the change in LTCH PPS payments for site neutral payment rate cases at the same level of detail with which we are able to model the impacts of the changes to LTCH PPS payments for LTCH PPS standard Federal payment rate cases. Therefore, Table IV only reflects changes in LTCH PPS payments for LTCH PPS standard Federal payment rate cases and, unless otherwise noted, the remaining discussion in section I.J.3. of this appendix refers only to the impact on LTCH PPS payments for LTCH PPS standard Federal payment rate cases. In the following section, we present our provider impact analysis for the changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

b. Impact on Providers

The basic methodology for determining a per discharge payment for LTCH PPS standard Federal payment rate cases is currently set forth under §§ 412.515 through 412.533 and 412.535. In addition to adjusting the LTCH PPS standard Federal payment rate by the MS–LTC–DRG relative weight, we make adjustments to account for area wage levels and SSOs. LTCHs located in Alaska and Hawaii also have their payments adjusted by a COLA. Under our application of the dual rate LTCH PPS payment structure, the LTCH PPS standard Federal payment rate is generally only used to determine payments for LTCH PPS standard Federal payment rate cases (that is, those LTCH PPS cases that meet the statutory criteria to be excluded from the site neutral payment rate). LTCH discharges that do not meet the patient-level criteria for exclusion are paid the site neutral payment rate, which we are calculating as the lower of the IPPS comparable per diem amount as determined under § 412.529(d)(4),

reduced by 4.6 percent for FYs 2018 through 2026, including any applicable outlier payments, or 100 percent of the estimated cost of the case as determined under existing § 412.529(d)(2). In addition, when certain thresholds are met, LTCHs also receive HCO payments for both LTCH PPS standard Federal payment rate cases and site neutral payment rate cases that are paid at the IPPS comparable per diem amount.

To understand the impact of the changes to the LTCH PPS payments for LTCH PPS standard Federal payment rate cases presented in this final rule on different categories of LTCHs for FY 2024, it is necessary to estimate payments per discharge for FY 2023 using the rates, factors, and the policies established in the FY 2023 IPPS/LTCH PPS final rule and estimate payments per discharge for FY 2024 using the rates, factors, and the policies in this final rule (as discussed in section VII. of the preamble of this final rule and section V. of the Addendum to this final rule). As discussed elsewhere in this final rule, these estimates are based on the best available LTCH claims data and other factors, such as the application of inflation factors to estimate costs for HCO cases in each year. The resulting analyses can then be used to compare how our policies applicable to LTCH PPS standard Federal payment rate cases affect different groups of LTCHs.

For the following analysis, we group hospitals based on characteristics provided in the OSCAR data, cost report data in HCRIS, and PSF data. Hospital groups included the following:

- Location: large urban/other urban/rural.
- Participation date.
- Ownership control.
- Census region.
- Bed size.

c. Calculation of LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases

For purposes of this impact analysis, to estimate the per discharge payment effects of our policies on payments for LTCH PPS standard Federal payment rate cases, we simulated FY 2023 and FY 2024 payments on a case-by-case basis using historical LTCH claims from the FY 2022 MedPAR files that met or would have met the criteria to be paid at the LTCH PPS standard Federal payment rate if the statutory patient-level criteria had been in effect at the time of discharge for all cases in the FY 2022 MedPAR files. For modeling FY 2023 LTCH PPS payments, we used the FY 2023 standard Federal payment rate of $46,432.77 (or $45,538.11 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). Similarly, for modeling payments based on the FY 2024 LTCH PPS standard Federal payment rate, we used the finalized FY 2024 standard Federal payment rate of $48,116.62 (or $47,185.03 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). In each case, we applied the applicable adjustments for area wage levels and the COLA for LTCHs located in Alaska and Hawaii. Specifically, for modeling FY 2023 LTCH PPS payments, we used the current FY 2023 labor-related share (68.0 percent), the wage index values established in the Tables 12A and 12B listed in the Addendum to the FY 2023 IPPS/LTCH PPS final rule (which are available via the internet on the CMS website), the FY 2023 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $38,518 (as reflected in the FY 2023 IPPS/LTCH PPS final rule), and the FY 2023 COLA factors (shown in the table in section V.C. of the Addendum to that final rule) to adjust the FY 2023 nonlabor-related share (32.0 percent) for LTCHs located in Alaska and Hawaii. Similarly, for modeling FY 2024 LTCH PPS payments, we used the FY 2024 LTCH PPS labor-related share (68.5 percent), the FY 2024 wage index values from Tables 12A and 12B listed in section VI. of the Addendum to this final rule (which are available via the internet on the CMS website), the FY 2024 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $59,873 (as discussed in section V.D.3. of the Addendum to this final rule), and the FY 2024 COLA factors (shown in the table in section V.C. of the Addendum to this final rule) to adjust the FY 2024 nonlabor-related share (31.5 percent) for LTCHs located in Alaska and Hawaii. We note that in modeling payments for HCO cases for LTCH PPS standard Federal payment rate cases, we inflated charges reported on the FY 2022 claims by the charge inflation factors in section V.D.3.b. of the Addendum to this final rule. We also note that in modeling payments for HCO cases for LTCH PPS standard Federal payment rate cases, we estimated the cost of each case by multiplying the inflated charges by the adjusted CCRs that we determined using our finalized methodology described in section V.D.3.b. of the Addendum to this final rule.

The impacts that follow reflect the estimated ''losses'' or ''gains'' among the various classifications of LTCHs from FY 2023 to FY 2024 based on the payment rates and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this final rule. Table IV illustrates the estimated aggregate impact of the change in LTCH PPS payments for LTCH PPS standard Federal payment rate cases among various classifications of LTCHs. (As discussed previously, these impacts do not include LTCH PPS site neutral payment rate cases.)

- The first column, LTCH Classification, identifies the type of LTCH.
- The second column lists the number of LTCHs of each classification type.
- The third column identifies the number of LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria.
- The fourth column shows the estimated FY 2023 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The fifth column shows the estimated FY 2024 payment per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria (as described previously).
- The sixth column shows the percentage change in estimated payments per discharge for LTCH cases expected to meet the LTCH PPS standard Federal payment rate criteria from FY 2023 to FY 2024 due to the annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this final rule).
- The seventh column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2023 to FY 2024 for changes to the area wage level adjustment (that is, the updated hospital wage data and labor-related share) and the application of the corresponding budget neutrality factor (as discussed in section V.B.6. of the Addendum to this final rule).
- The eighth column shows the percentage change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2023 (Column 4) to FY 2024 (Column 5) for all changes.

TABLE IV: IMPACT OF PAYMENT RATE AND POLICY CHANGES TO LTCH PPS PAYMENTS FOR LTCH PPS STANDARD FEDERAL PAYMENT RATE CASES FOR FY 2024 (ESTIMATED FY 2023 PAYMENTS COMPARED TO ESTIMATED FY 2024 PAYMENTS)

LTCH Classification (1)	No. of LTCHS (2)	Number of LTCH PPS Standard Payment Rate Cases (3)	Average FY 2023 LTCH PPS Payment Per Standard Payment Rate (4)	Average FY 2024 LTCH PPS Payment Per Standard Payment Rate[1] (5)	Change Due to Change to the Annual Update to the Standard Federal Rate[2] (6)	Percent Change Due to Changes to Area Wage Adjustment with Wage Budget Neutrality[3] (7)	Percent Change Due to All Standard Payment Rate Changes[4] (8)
ALL PROVIDERS	332	41,552	55,109	55,022	3.2	0.0	-0.2
BY LOCATION:							
RURAL	18	1,550	43,038	43,157	3.1	-0.5	0.3
URBAN	314	40,002	55,577	55,482	3.2	0.0	-0.2
BY PARTICIPATION DATE:							
BEFORE OCT. 1983	10	889	51,487	50,344	3.3	0.0	-2.2
OCT. 1983 - SEPT. 1993	36	5,180	63,155	63,317	3.1	0.4	0.3
OCT. 1993 - SEPT. 2002	132	16,865	54,398	54,368	3.2	-0.1	-0.1
AFTER OCTOBER 2002	154	18,618	53,687	53,530	3.2	-0.1	-0.3
BY OWNERSHIP TYPE:							
VOLUNTARY	54	4,738	58,953	57,920	3.2	0.1	-1.8
PROPRIETARY	269	36,271	54,329	54,372	3.2	0.0	0.1
GOVERNMENT	9	543	73,665	73,126	3.1	1.2	-0.7
BY REGION:							
NEW ENGLAND	10	1,178	46,952	46,155	3.3	-0.1	-1.7
MIDDLE ATLANTIC	19	2,605	65,336	65,882	3.2	0.4	0.8
SOUTH ATLANTIC	61	8,558	53,413	53,193	3.2	0.2	-0.4
EAST NORTH CENTRAL	47	5,870	57,030	56,359	3.2	-0.4	-1.2
EAST SOUTH CENTRAL	31	3,071	50,921	50,560	3.2	-0.4	-0.7
WEST NORTH CENTRAL	22	2,329	54,179	52,745	3.3	-0.2	-2.6
WEST SOUTH CENTRAL	92	10,635	46,573	46,938	3.2	0.2	0.8
MOUNTAIN	27	2,291	54,250	54,767	3.1	-0.7	1.0
PACIFIC	23	5,015	73,846	74,068	3.0	0.3	0.3
BY BED SIZE:							
BEDS: 0-24	28	1,770	53,280	53,176	3.2	-0.1	-0.2
BEDS: 25-49	162	16,088	50,021	50,060	3.2	-0.2	0.1
BEDS: 50-74	74	10,213	54,689	54,639	3.2	0.1	-0.1
BEDS: 75-124	48	8,757	62,822	62,598	3.1	0.0	-0.4
BEDS: 125-199	17	4,294	60,993	60,646	3.1	0.4	-0.6
BEDS: 200+	3	430	47,123	46,882	3.2	-0.1	-0.5

[1] Estimated FY 2024 LTCH PPS payments for LTCH PPS standard Federal payment rate criteria based on the finalized payment rate and factor changes applicable to such cases presented in the preamble of and the Addendum to this final rule.

[2] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2023 to FY 2024 for the annual update to the LTCH PPS standard Federal payment rate.

[3] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2023 to FY 2024 for changes due to the changes to the area wage level adjustment under § 412.525(c) (that is, updated hospital wage data and the labor related share).

[4] Percent change in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2023 (shown in Column 4) to FY 2024 (shown in Column 5), including all of the changes to the rates and factors applicable to such cases presented in the preamble and the Addendum to this final rule. We note that this column, which shows the percent change in estimated payments per discharge for all changes, does not equal the sum of the percent changes in estimated payments per discharge for the annual update to the LTCH PPS standard Federal payment rate (Column 6) and the changes due to the changes to the area wage level adjustment with budget neutrality (Column 7) due to the effect of estimated changes in estimated payments to aggregate HCO payments for LTCH PPS standard Federal payment rate cases (as discussed in this impact analysis), as well as other interactive effects that cannot be isolated.

d. Results

Based on the FY 2022 LTCH cases (from 333 LTCHs) that were used for the analyses in this final rule, we have prepared the following summary of the impact (as shown in Table IV) of the LTCH PPS payment rate and policy changes for LTCH PPS standard Federal payment rate cases presented in this final rule. The impact analysis in Table IV shows that estimated payments per discharge for LTCH PPS standard Federal payment rate cases are projected to decrease 0.2 percent, on average, for all LTCHs from FY 2023 to FY 2024 as a result of the payment rate and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this final rule. This estimated 0.2 percent decrease in LTCH PPS payments per discharge was determined by comparing estimated FY 2024 LTCH PPS payments (using the finalized payment rates and factors discussed in this final rule) to estimated FY 2023 LTCH PPS payments for LTCH discharges which will be LTCH PPS standard Federal payment rate cases if the dual rate LTCH PPS payment structure was or had been in effect at the time of the discharge (as described in section I.J.3. of this appendix).

As stated previously, we are finalizing an annual update to the LTCH PPS standard Federal payment rate for FY 2024 of 3.3 percent. For LTCHs that fail to submit quality data under the requirements of the LTCH QRP, as required by section 1886(m)(5)(C) of the Act, a 2.0 percentage point reduction is applied to the annual update to the LTCH PPS standard Federal payment rate. Consistent with § 412.523(d)(4), we also are applying a budget neutrality factor for changes to the area wage level adjustment of 1.0031599 (discussed in section V.B.6. of the Addendum to this final rule), based on the best available data at this time, to ensure that any changes to the area wage level adjustment will not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. As we also explained earlier in this section of the final rule, for most categories of LTCHs (as shown in Table IV, Column 6), the estimated payment increase due to the 3.3 percent annual update to the LTCH PPS standard Federal payment rate is projected to result in approximately a 3.2 percent increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases for all LTCHs from FY 2023 to FY 2024. We note our estimate of the changes in payments due to the update to the LTCH PPS standard Federal payment rate also includes estimated payments for short-stay outlier (SSO) cases, a portion of which are not affected by the annual update to the LTCH PPS standard Federal payment rate, as well as the reduction that is applied to the annual update for LTCHs that do not submit data under the requirements of the LTCH QRP.

(1) Location

Based on the most recent available data, the vast majority of LTCHs are located in urban areas. Only approximately 5 percent of the LTCHs are identified as being located in a rural area, and approximately 4 percent of all LTCH PPS standard Federal payment rate cases are expected to be treated in these rural hospitals. The impact analysis presented in Table IV shows that the overall average percent decrease in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2023 to FY 2024 for all hospitals is 0.2 percent. Urban LTCHs are also projected to experience a decrease of 0.2 percent. Meanwhile, rural LTCHs are projected to experience an increase of 0.3 percent.

(2) Participation Date

LTCHs are grouped by participation date into four categories: (1) before October 1983; (2) between October 1983 and September 1993; (3) between October 1993 and September 2002; and (4) October 2002 and after. Based on the best available data, the categories of LTCHs with the largest expected percentage of LTCH PPS standard Federal payment rate cases (approximately 41 percent and 45 percent, respectively) are in LTCHs that began participating in the Medicare program between October 1993 and September 2002 and after October 2002. These LTCHs are expected to experience a decrease in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2023 to FY 2024 of 0.1 percent and 0.3 percent, respectively. LTCHs that began participating in the Medicare program between October 1983 and September 1993 are projected to experience an increase in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2023 to FY 2024 of 0.3 percent, as shown in Table IV. Approximately 3 percent of LTCHs began participating in the Medicare program before October 1983, and these LTCHs are projected to experience a decrease in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2023 to FY 2024 of 2.2 percent.

(3) Ownership Control

LTCHs are grouped into three categories based on ownership control type: voluntary, proprietary, and government. Based on the best available data, approximately 16 percent of LTCHs are identified as voluntary (Table IV). The majority (approximately 81 percent) of LTCHs are identified as proprietary, while government owned and operated LTCHs represent approximately 3 percent of LTCHs. Based on ownership type, proprietary LTCHs are expected to experience an increase in payments to LTCH PPS standard Federal payment rate cases of 0.1 percent. Voluntary LTCHs are expected to experience a decrease in payments to LTCH PPS standard Federal payment rate cases from FY 2023 to FY 2024 of 1.8 percent. Meanwhile, government owned and operated LTCHs are expected to experience a decrease in payments to LTCH PPS standard Federal payment rate cases from FY 2023 to FY 2024 of 0.7 percent.

(4) Census Region

The comparisons by region show that the changes in estimated payments per discharge for LTCH PPS standard Federal payment rate cases from FY 2023 to FY 2024 are projected to range from a decrease of 2.6 percent in the West North Central region to an increase of 1.0 percent in the Mountain region. These regional variations are primarily due to the changes to the area wage adjustment and estimated changes in outlier payments.

(5) Bed Size

LTCHs are grouped into six categories based on bed size: 0–24 beds; 25–49 beds; 50–74 beds; 75–124 beds; 125–199 beds; and greater than 200 beds. We project that LTCHs with 125–199 beds will experience a decrease in payments for LTCH PPS standard Federal payment rate cases of 0.6 percent. LTCHs with 25–49 beds are projected to experience an increase in payments of 0.1 percent. The remaining bed size categories are projected to experience a decrease in payments in the range of 0.1 to 0.5 percent.

4. Effect on the Medicare Program

As stated previously, we project that the provisions of this final rule will result in a decrease in estimated aggregate LTCH PPS payments to LTCH PPS standard Federal payment rate cases in FY 2024 relative to FY 2023 of approximately $4 million (or approximately 0.2 percent) for the 333 LTCHs in our database. Although, as stated previously, the hospital-level impacts do not include LTCH PPS site neutral payment rate cases, we estimate that the provisions of this final rule will result in an increase in estimated aggregate LTCH PPS payments to site neutral payment rate cases in FY 2024 relative to FY 2023 of approximately $10 million (or approximately 3.2 percent) for the 333 LTCHs in our database. (As noted previously, we estimate payments to site neutral payment rate cases in FY 2024 represent approximately 12 percent of total estimated FY 2024 LTCH PPS payments.) Therefore, we project that the provisions of this final rule will result in an increase in estimated aggregate LTCH PPS payments for all LTCH cases in FY 2024 relative to FY 2023 of approximately 6 million (or approximately 0.2 percent) for the 333 LTCHs in our database.

5. Effect on Medicare Beneficiaries

Under the LTCH PPS, hospitals receive payment based on the average resources consumed by patients for each diagnosis. We do not expect any changes in the quality of care or access to services for Medicare beneficiaries as a result of this final rule, but we continue to expect that paying prospectively for LTCH services will enhance the efficiency of the Medicare program. As discussed previously, we do not expect the continued implementation of the site neutral payment system to have a negative impact on access to or quality of care, as demonstrated in areas where there is little or no LTCH presence, general short-term acute care hospitals are effectively providing treatment for the same types of patients that are treated in LTCHs.

K. Effects of Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

In section IX.C. of the preamble of this final rule, we discuss requirements for hospitals reporting quality data under the Hospital IQR Program to receive the full annual percentage increase for the FY 2024 payment determination and subsequent years.

In this final rule, we are: (1) removing the Elective Delivery measure beginning with the CY 2024 reporting period/FY 2026 payment determination; (2) adopting the Hospital Harm-Pressure Injury electronic clinical quality measure (eCQM) beginning with the CY 2025 reporting period/FY 2027 payment determination; (3) adopting the Hospital Harm—Acute Kidney Injury eCQM beginning with the CY 2025 reporting period/FY 2027 payment determination; (4) adopting the Excessive Radiation eCQM beginning with CY 2025 reporting period/FY 2027 payment determination; (5) modifying the Hybrid Hospital-Wide All-Cause Risk Standardized Mortality measure beginning with the performance data from July 1, 2024 through June 30, 2025, impacting the FY 2027 payment determination; (6) modifying the Hybrid Hospital-Wide All-Cause Risk Standardized Readmission measure beginning with the performance data from July 1, 2024 through June 30, 2025, impacting the FY 2027 payment determination; (7) modifying the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the Q4 CY 2023 reporting period/FY 2025 payment determination; (8) removing the Risk-Standardized Complication Rate Following Elective Primary Total Hip Arthroplasty and/or Total Knee Arthroplasty measure beginning with the April 1, 2025 through March 31, 2028 reporting period impacting the FY 2030 payment determination; (9) removing the Medicare Spending per Beneficiary Hospital measure beginning with the CY 2026 reporting period/FY 2028 payment determination; (10) modifying the validation targeting criteria to include any hospital with a two-tailed confidence interval that is less than 75 percent and which submitted less than four quarters of data due to receiving an extraordinary circumstances exception (ECE) for one or more quarters beginning with the FY 2027 payment determination; and (11) modifying data collecting and reporting requirements for the Hospital Consumer Assessment of Healthcare providers and Systems (HCAHPS) survey beginning with the FY 2027 payment determination.

As shown in the summary tables in section XII.B.6. of the preamble of this final rule, we estimate a total information collection burden decrease for 3,150 IPPS hospitals of 144,836 hours at a savings of $6,834,886 annually associated with the policies we are finalizing across a 4-year period from the CY 2024 reporting period/FY 2026 payment determination through the CY 2028 reporting period/FY 2030 payment determination, compared to our currently approved information collection burden estimates.

We note that in sections IX.C.5.a., b., and c. of the preamble of this final rule, we are adopting three new eCQMs. Similar to the FY 2019 IPPS/LTCH PPS final rule regarding removal of eCQMs, while there is no change in information collection burden related to the finalized policies with regard to submission of measure data, we believe that costs associated with adopting three new eCQMs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining all of the eCQMs available for use in the Hospital IQR Program in hospitals' EHR systems (83 FR 41771). For the Excessive Radiation eCQM, hospitals will be required to create a secure account through the measure developer's website and link their EHR and PACS data to the Alara Imaging Software for CMS Measure Compliance. We estimate this one-time activity will require no more than one hour to complete and therefore estimate a total of 3,150 hours (1 hour × 3,150 hospitals) at a cost of $141,309 (3,150 hours × $44.86) for all IPPS hospitals.

In section IX.B. of this final rule, we are modifying the COVID–19 Vaccination Coverage among HCP measure to utilize the term ''up to date'' in the HCP vaccination definition and update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID–19 vaccines. Although we anticipate this modification may require some facilities to update IT systems or workflow related to maintaining accurate vaccination records for HCP, we assume most facilities are currently recording all necessary information for HCP such that this modification will not require additional information to be collected, therefore, the financial impact of any required updates would be minimal. Finally, we do not estimate any changes to the effects previously discussed in the FY 2022 IPPS/LTCH PPS final rule for the Hospital IQR Program (86 FR 45607 and 45608).

Regarding the remaining policies to remove or modify existing measures, we do not believe any of these policies will result in any additional economic impact beyond those discussed in section XII.B.6. (Collection of Information). Similarly, we do not believe the finalized policy to modify targeting criteria will have any economic impact on the IPPS hospitals selected for validation, but will only increase the number of IPPS hospitals which are subject to being targeted for validation. Any increase will not exceed the total maximum number of hospitals that would be selected for targeted validation as previously finalized.

Historically, 100 hospitals, on average, that participate in the Hospital IQR Program do not receive the full annual percentage increase in any fiscal year due to the failure to meet all requirements of the Hospital IQR Program. We anticipate that the number of hospitals not receiving the full annual percentage increase will be approximately the same as in past years based on review of previous performance.

L. Effects of Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In section IX.D. of the preamble of this final rule, we discuss our policies for the quality data reporting program for PPS-exempt cancer hospitals (PCHs), which we refer to as the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program. The PCHQR Program is authorized under section 1866(k) of the Act. There is no financial impact to PCH Medicare reimbursement if a PCH does not submit data.

In section IX.D of the preamble of this final rule, we are: (1) adopting the Documentation of Goals of Care Discussions Among Cancer Patients measure beginning with the FY 2026 program year; (2) adopting the Facility Commitment to Health Equity measure beginning with the FY 2026 program year; (3) adopting the Screening for Social Drivers of Health measure with voluntary reporting in the FY 2026 program year and mandatory reporting beginning with the FY 2027 program year; (4) adopting the Screen Positive Rate for Social Drivers of Health measure with voluntary reporting for the FY 2026 program year and mandatory reporting beginning with the FY 2027 program year; (5) updating the data collection and reporting for the HCAHPS Survey Measure (NQF #0166) beginning with the FY 2027 program year; (6) modifying the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the FY 2025 program year; and (7) beginning public reporting of the Surgical Treatment Complications for Localized Prostate Cancer (PCH–37) measure. As shown in the summary table in section XII.B.7. of the preamble of this final rule, we estimate a total information collection burden increase for 11 PCHs of 188 hours at a cost of $4,088 annually associated with our finalized policies and updated burden estimates beginning with the FY 2027 program year compared to our currently approved information collection burden estimates. We refer readers to section XII.B.7. of the preamble of this final rule (Collection of Information) for a detailed discussion of the calculations estimating the changes to the information collection burden for submitting data to the PCHQR Program.

In section IX.D.6. of the preamble of this final rule, we are adopting the Documentation of Goals of Care Discussions Among Cancer Patients measure beginning with the FY 2026 program year. This measure will focus on the essential process of documenting goals of care conversations in the EHR. The intent of this measure is for PCHs to track and improve this documentation to ensure that that such conversations have taken place, have been properly documented in a manner that is retrievable by all members of the healthcare team, and to facilitate the delivery of care that aligns with patients' and families' values and unique priorities. Ideally, these conversations will occur with patients with serious illness, however, definitions of and the means of identifying serious illness may vary widely. This measure is intended to focus on cancer patients who died in the reporting PCH in the measurement period, had a diagnosis of cancer, and had at least 2 eligible contacts at the reporting hospital in the 6 months prior to death. Since we are unable to determine either an exact number of patients who meet these criteria or the extent to which the conversations currently take place, as a maximum, we estimate an average of 275 patients for each of the 11 PCHs, for a total of 3,025 patients for all PCHs. We estimate the time required for this discussion to be approximately 30 minutes (0.5 hours).

To estimate the cost per patient, we use the same methodology as in the Collection of Information section (section XII.B.7.c. of the preamble of this final rule) and estimate a

post-tax hourly wage rate of $20.71/hour. The most recent data from the Bureau of Labor Statistics reflects a median hourly wage of $121.38 per hour for a Physician. We calculate the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in publicly available literature. Nonetheless, we believe that doubling the hourly wage rate ($121.38 × 2 = $242.76) to estimate total cost is a reasonably accurate estimation method and is consistent with OMB guidance. We therefore estimate the total cost associated with a patient and physician discussing goals of care to be $131.74 per patient (0.5 hours × ($20.71/hour + $242.76/hour)). For all 3,025 patients, we estimate a total cost of $398,514 (3,025 patients × $131.74/patient).

In section IX.D.3. of the preamble of this final rule, we are adopting the Facility Commitment to Health Equity measure. In order for PCHs to receive credit for all of the five domains in the measure, affirmative attestations are required for all of those domains. For PCHs that are unable to attest affirmatively for a domain, there are likely to be additional costs associated with activities which could include updating hospital policies, engaging senior leadership, participating in new quality improvement activities, performing additional data analysis, or training staff. The extent of these costs will vary from PCH to PCH depending on what activities the PCH is already performing, size, and the individual choices each PCH makes to meet the criteria necessary to attest affirmatively.

In section IX.D.4. of the preamble of this final rule, we are adopting the Screening for Social Drivers of Health measure with voluntary reporting with the FY 2026 program year and mandatory reporting beginning with the FY 2027 program year. For PCHs that are not currently administering some screening mechanism and elect to begin doing so as a result of this policy, there will be some non-recurring costs associated with changes in workflow and information systems to collect the data. The extent of these costs is difficult to quantify as different PCHs may utilize different modes of data collection (for example, paper-based, electronically patient-directed, clinician-facilitated, etc.). In addition, depending on the method of data collection utilized, the time required to complete the survey may add a negligible amount of time to patient visits.

In section IX.B. of the preamble of this final rule, we are modifying the COVID–19 Vaccination Coverage among HCP Measure to utilize the term ''up to date'' in the HCP vaccination definition and update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID–19 vaccines, including booster doses, beginning with the FY 2025 program year. Although we anticipate this modification may require some PCHs to update IT systems or workflow related to maintaining accurate vaccination records for HCP, we assume most PCHs are currently recording all necessary information for HCP such that this modification will not require additional information to be collected, therefore the financial impact of any required updates would be minimal. However, due to the unique nature of each PCH, we are unable to estimate the financial impact for each PCH. We do not estimate any changes to the effects previously discussed in the FY 2022 IPPS/LTCH PPS final rule for the PCHQR Program (86 FR 45608).

We do not believe the remaining policies will result in any additional economic impact.

M. Effects of Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In section IX.G. of the preamble of this final rule, we proposed to modify one measure, adopt two measures and remove two measures from the LTCH QRP. Specifically, we proposed to modify the HCP COVID–19 Vaccine measure and adopt the DC Function measure beginning with the FY 2025 LTCH QRP, as well as the Patient/Resident COVID–19 Vaccine measure beginning with the FY 2026 LTCH QRP. We also proposed to remove two measures, the Application of Functional Assessment/Care Plan and the Functional Assessment/Care Plan measures beginning with the FY 2025 LTCH QRP. We proposed to begin publicly displaying data for the quality measures TOH-Patient, TOH–Provider, DC Function, and Patient/Resident COVID–19 Vaccine measures. We proposed to increase the LTCH QRP data completion thresholds for the LCDS items beginning with the FY 2026 LTCH QRP. Finally, we sought information on principles for selecting and prioritizing LTCH QRP quality measures and concepts for measure development and provided an update on CMS continued efforts to close the health equity gap.

We note that the CDC would account for the burden associated with the COVID–19 Vaccination Coverage among HCP measure collection under OMB control number 0920–1317 (expiration January 31, 2024). Additionally, because we did not propose any updates to the form, manner, and timing of data submission for this measure, there will be no increase in burden associated with the proposal.

The effect of the remaining proposals for the LTCH QRP will be an overall decrease in burden for LTCHs participating in the LTCH QRP. As shown in summary table XII.B.8–1 in section XII.B.8. of the preamble of this final rule, we estimate a total information collection burden decrease for 330 eligible LTCHs of 1,301 hours for a total cost reduction of $127,048 annually associated with our finalized policies and updated burden estimates across the FY 2025 and FY 2026 LTCH QRPs compared to our currently approved information collection burden estimates. We refer readers to section XII.B.8. of the preamble of this final rule, where CMS has provided an estimate of the burden and cost to LTCHs, and note that it will be included in a revised information collection request for 0938–1163.

N. Effects of Requirements Regarding the Medicare Promoting Interoperability Program

In section IX.F of this final rule, we are finalizing the following changes for eligible hospitals and critical access hospitals (CAHs) that attest to CMS under the Medicare Promoting Interoperability Program: (1) adoption of the Hospital Harm—Pressure Injury eCQM beginning with the CY 2025 reporting period; (2) adoption of the Hospital Harm—Acute Kidney Injury eCQM beginning with the CY 2025 reporting period; (3) adoption of the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Inpatient) eCQM beginning with the CY 2025 reporting period; (4) modification of the SAFER Guides measure to require eligible hospitals and CAHs to submit a ''yes'' attestation to fulfill the measure beginning with the EHR reporting period in CY 2024; and (5) establishment of an EHR reporting period of a minimum of any continuous 180-day period in CY 2025. As discussed in section XII.B.9 of the preamble of this final rule, we do not estimate a change in total information collection burden associated with our finalized policies.

In section IX.F.7.a.(2). of the preamble of this final rule, we are adopting three new eCQMs. Similar to the FY 2019 IPPS/LTCH PPS final rule regarding removal of eCQM measures, while there is no change in information collection burden related to the finalized policies with regard to submission of measure data, we believe that costs associated with adopting three new eCQMs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining all of the eCQMs available for use in the Medicare Promoting Interoperability Program in hospitals' and CAHs' EHR systems (83 FR 41771).

In section IX.F.3. of the preamble of this final rule, we are modifying the SAFER Guides measure to require eligible hospitals and CAHs to submit a ''yes'' attestation to fulfill the measure beginning with the EHR reporting period in CY 2024. In the FY 2022 IPPS/LTCH PPS final rule, we adopted the SAFER Guides measure and required eligible hospitals and CAHs to attest ''yes'' or ''no'' as to whether they completed an annual self-assessment on each of the nine SAFER Guides during the calendar year in which their EHR reporting period occurs (86 FR 45479 through 45481). As a result of this finalized policy, eligible hospitals and CAHs will be required to complete an annual self-assessment on each of the nine SAFER Guides. Because each eligible hospital and CAH is unique and may conduct these self-assessments with varying degrees of rigor, we are unable to accurately estimate the time each eligible hospital or CAH will spend performing each self-assessment or the staff they would utilize. Therefore, we estimate the time required to conduct each self-assessment will range from approximately 30 minutes per guide to approximately 20 minutes per recommendation.[20] Across the

[20] Toward More Proactive Approaches to Safety in the Electronic Health Record Era. Available at

nine SAFER Guides and 165 recommendations within them, the estimated time to complete all nine self-assessments will range from a minimum of 4.5 hours to a maximum of 55 hours. Based on the suggested sources of input provided in the SAFER Guides, we assume that eligible hospitals and CAHs will form multi-disciplinary teams composed of 1.0 FTE of a clinical administrator and 0.75 FTE each of a clinician, support staff, EHR developer, and health IT support staff to conduct the self-assessments. The following table provides the detail of our calculated cost to conduct SAFER Guide self-assessments.

COST PER ELIGIBLE HOSPITAL AND CAH TO CONDUCT SAFER GUIDES SELF-ASSESSMENT				
Eligible Hospital/CAH Staff Title	**BLS Labor Category (Occupation Code)[21]**	**Wage Rate***	**FTE**	**Labor Cost**
Clinicians	Physicians	$242.76	0.75	$182.07
Support Staff	Medical Record Specialists	$44.86	0.75	$33.65
Clinical Administration	Medical and Health Services Managers	$97.44	1.0	$97.44
EHR Developer	Web Developers	$116.10	0.75	$87.08
Health IT Support Staff	Health Information Technologists and Medical Registrars	$53.42	0.75	$40.07
Total Cost Per Hour of Self-Assessment Team				$440.31
Minimum Cost to Conduct Self-Assessment (4.5 hours x $440.31/hour)				**$1,981**
Maximum Cost to Conduct Self-Assessment (55 hours x $440.31/hour)				**$24,217**

* We calculated the cost of overhead, including fringe benefits, at 100 percent of the median hourly wage, consistent with previous years. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly by employer and methods of estimating these costs vary widely in the literature. Nonetheless, we believe that doubling the hourly wage rate to estimate total cost is a reasonably accurate estimation method.

Using the cost to complete all nine self-assessments from Table XX, we estimate all 4,500 eligible hospitals and CAHs would require between 20,250 hours (4.5 hours per hospital/CAHs × 4,500 hospitals/CAHs) and 247,500 hours (55 hours per hospital/CAHs × 4,500 hospitals/CAHs) at a cost between $8,916,278 (20,250 hours × $440.31/hour) and $108,976,725 (247,500 hours × $440.31/hour) to attest ''yes'' to the measure. We did not receive any public comments regarding our assumptions or estimate of economic impact associated with the modification to the SAFER Guides measure.

While the cost to conduct a SAFER Guides self-assessment can be high, we believe the cost is outweighed by the potential for improved healthcare outcomes, increased efficiency, reduced risk of data breaches and ransomware attacks, and decreased malpractice premiums.[22]

O. Alternatives Considered

This final rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the finalized policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

1. Alternatives Considered to the Hospital Wage Index Calculations

As discussed in section III.G.1. of the preamble of this final rule, we are finalizing our proposal to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and to only exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) in accordance with the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. Consistent with the previous proposal, beginning with FY 2024 we are including the data of all § 412.103 hospitals (including those that have an MGCRB reclassification when appropriate) in the calculation of the rural floor and the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act. As also discussed in section III.G.1. of the preamble of this final rule, we acknowledge that these policies will have significant effects on wage index values. In addition, as a result of this change, both the geographic reclassification budget neutrality adjustment and the rural floor budget neutrality adjustment are significantly larger than in prior years.

Considering past concerns with hospitals' use of § 412.103 reclassification to increase the rural wage index and rural floor (as discussed in prior rulemaking (72 FR 47371 through 47373, 84 FR 42332, and 85 FR 58788) and in this rule), as well as the significant redistributive effects, we therefore considered maintaining our current methodology for calculating the rural wage index, which would not require any modification to the rural floor or the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act''. However, after revisiting the case law, prior public comments, and the relevant statutory language, along with public comments on the proposed rule, we now agree that the best reading of section 1886(d)(8)(E) of the Act is that it instructs CMS to treat § 412.103 hospitals the same as geographically rural hospitals for the wage index calculation. We are influenced by the fact that courts have largely adopted this interpretation of section 1886(d)(8)(E) of the Act, and that it requires considerable resources to unwind a wage index policy after adverse judicial decisions—often requiring an IFC outside the usual IPPS rulemaking schedule, and further note that such unwindings may have budget neutrality implications. Therefore, after consideration of public comments, we determined that it was necessary to finalize our proposal to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and to exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act, with the resulting changes to the rural floor and the calculation of ''the wage index for rural areas in the State in which the county is located'' as referred to in section 1886(d)(8)(C)(iii) of the Act.

2. Alternatives Considered to the HCP COVID–19 Vaccine Measure

With regard to the proposal to modify the HCP COVID–19 Vaccine measure and to add the Patient/Resident COVID–19 Vaccine measure to the LTCH QRP Program, the COVID–19 pandemic has exposed the importance of implementing infection prevention strategies, including the promotion of COVID–19 vaccination for healthcare personnel and patients. We believe this measure will encourage healthcare personnel to get up to date with the COVID–19 vaccine and increase vaccine uptake in patients/residents resulting in fewer cases, less hospitalizations, and lower mortality associated with the SARS–CoV–2 virus, but we were unable to identify any alternative methods for collecting the data. An overwhelming public need exists to target quality improvement among LTCHs, as well

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8136246/. Accessed July 13, 2023.

[21] *https://www.bls.gov/oes/current/oes_nat.htm*. Accessed December 14, 2022.

[22] *https://www.eisneramper.com/safer-guides-healthcare-organizations-0822/*. Accessed December 14, 2022.

as provide data to patients and caregivers through transparency of data. Therefore, these measures have the potential to generate actionable data on COVID–19 vaccination rates.

3. Alternatives Considered to the LTCH QRP Reporting Requirements

With regard to the proposal to increase the data completion threshold for LCDS data submitted to meet the LTCH QRP reporting requirements, the proposed threshold of 90 percent was based on the need for substantially complete records, which allows appropriate analysis of quality measure data for the purposes of updating quality measure specifications. This data is ultimately reported to the public, allowing our beneficiaries to gain a more complete understanding of LTCH performance related to these quality metrics, and helping them to make informed healthcare choices. We considered the alternative of not increasing the data completion threshold, but our data suggest that LTCHs are already in compliance with, or exceeding this proposed threshold. However, after consideration of the public comments we received, we are finalizing our proposal to require LTCHs to report 100 percent of the required quality measures data and standardized patient assessment data collected using the LCDS on at least 85 percent of all assessments submitted beginning with the FY 2026 payment determination and subsequent years.

4. Alternatives Considered for the Replacement of the Application of Functional Assessment/Care Plan Process Measure

The proposal to replace the topped-out Application of Functional Assessment/Care Plan process measure with the proposed DC Function measure, which has strong scientific acceptability, satisfies the requirement that there be at least one cross-setting function measure in the Post-Acute Care (PAC) QRPs, including the IRF QRP, that uses standardized functional assessment data elements from standardized patient assessment instruments. We considered the alternative of delaying the proposal of adopting the DC Function measure. However, given the proposed DC Function measure's strong scientific acceptability, the fact that it provides an opportunity to replace the current Application of Functional Assessment/Care Plan process measure, and uses standardized functional assessment data elements that are already collected, we believe further delay of the DC Function measure is unwarranted. Further, the proposed removal of the Application of Functional Assessment/Care Plan and Functional Assessment measures meets measure removal factors one and six,[23] and no longer provide meaningful distinctions in improvements in performance. Therefore, no alternatives were considered.

As discussed previously, these changes to the LTCH QRP will result in an overall decrease in burden for LTCHs, and we believe the importance of the information necessitates these provisions.

P. Overall Conclusion

1. Acute Care Hospitals

Acute care hospitals are estimated to experience an increase of approximately $2.2 billion in FY 2024, including operating, capital, and new technology changes. The estimated change in operating payments is approximately $2.1 billion (discussed in section I.F. and I.G. of this appendix). The estimated change in capital payments is approximately $0.474 billion (discussed in section I.I. of this appendix). The estimated change in new technology add-on payments is approximately −$0.364 billion as discussed in section I.G. of this appendix. Total may differ from the sum of the components due to rounding.

Table I. of section I.F. of this appendix also demonstrates the estimated redistributional impacts of the IPPS budget neutrality requirements for the proposed MS–DRG and wage index changes, and for the wage index reclassifications under the MGCRB.

We estimate that hospitals will experience a 6.6 percent increase in capital payments per case, as shown in Table III. of section I.I. of this appendix. We project that there will be a $474 million increase in capital payments in FY 2024 compared to FY 2023.

The discussions presented in the previous pages, in combination with the remainder of this final rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience an increase in estimated payments in FY 2024. In the impact analysis, we are using the rates, factors, and policies presented in this final rule based on the best available claims and CCR data to estimate the change in payments under the LTCH PPS for FY 2024. Accordingly, based on the best available data for the 333 LTCHs included in our analysis, we estimate that overall FY 2024 LTCH PPS payments would increase approximately $6 million relative to FY 2023, primarily due to the annual update to the LTCH PPS standard Federal rate offset by an estimated decrease in high cost outlier payments.

Q. Regulatory Review Cost Estimation

If regulations impose administrative costs on private entities, such as the time needed to read and interpret a rule, we should estimate the cost associated with regulatory review. Due to the uncertainty involved with accurately quantifying the number of entities that would review the final rule, we assumed that the total number of timely pieces of correspondence on this year's proposed rule would be the number of reviewers of the final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing the rule. It is possible that not all commenters reviewed this year's rule in detail, and it is also possible that some reviewers chose not to comment on the proposed rule. For these reasons, we believe that the number of past commenters would be a fair estimate of the number of reviewers of the final rule. We recognize that different types of entities are in many cases affected by mutually exclusive sections of the rule. Thus, for the purposes of our estimate we assume that each reviewer read approximately 50 percent of the proposed rule. Finally, in our estimates, we have used the 3,274 number of timely pieces of correspondence on the FY 2024 IPPS/LTCH PPS proposed rule as our estimate for the number of reviewers of the final rule. We continue to acknowledge the uncertainty involved with using this number, but we believe it is a fair estimate due to the variety of entities affected and the likelihood that some of them choose to rely (in full or in part) on press releases, newsletters, fact sheets, or other sources rather than the comprehensive review of preamble and regulatory text. Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing the final rule is $115.22 per hour, including overhead and fringe benefits (*https://www.bls.gov/oes/current/oes_nat.htm*). Assuming an average reading speed, we estimate that it would take approximately 24.35 hours for the staff to review half of this final rule. For each IPPS hospital or LTCH that reviews this final rule, the estimated cost is $2,805.61 (24.35 hours × $115.22). Therefore, we estimate that the total cost of reviewing this final rule is $9,185,567 ($2,805.61 × 3,274 reviewers).

II. Accounting Statements and Tables

A. Acute Care Hospitals

As required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), in Table V. of this appendix, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule as they relate to acute care hospitals. This table provides our best estimate of the change in Medicare payments to providers as a result of the changes to the IPPS presented in this final rule. All expenditures are classified as transfers to Medicare providers.

As shown in Table V. of this appendix, the net costs to the Federal Government associated with the policies in this final rule are estimated at $2.2 billion.

[23] Code of Federal Regulations, § 412.560(b)(3). Available at: *https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-412/subpart-O/section-412.560.*

TABLE V.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2023 TO FY 2024

Category	Transfers
Annualized Monetized Transfers	$2.2 billion
From Whom to Whom	Federal Government to IPPS Medicare Providers

B. LTCHs

As discussed in section I.J. of this appendix, the impact analysis of the payment rates and factors presented in this final rule under the LTCH PPS is projected to result in an increase in estimated aggregate LTCH PPS payments in FY 2024 relative to FY 2023 of approximately $6 million based on the data for 333 LTCHs in our database that are subject to payment under the LTCH PPS. Therefore, as required by OMB Circular A–4 (available at *https://www.whitehouse.gov/wp-content/uploads/legacy_drupal_files/omb/circulars/A4/a-4.pdf*), in Table VI. of this appendix, we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule as they relate to the changes to the LTCH PPS. Table VI. of this appendix provides our best estimate of the estimated change in Medicare payments under the LTCH PPS as a result of the payment rates and factors and other provisions presented in this final rule based on the data for the 333 LTCHs in our database. All expenditures are classified as transfers to Medicare providers (that is, LTCHs).

As shown in Table VI. of this appendix, the net cost to the Federal Government associated with the policies for LTCHs in this final rule are estimated at $6 million.

TABLE VI.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES FROM THE FY 2023 LTCH PPS TO THE FY 2024 LTCH PPS

Category	Transfers
Annualized Monetized Transfers	$6 million
From Whom to Whom	Federal Government to LTCH Medicare Providers

III. Regulatory Flexibility Act (RFA) Analysis

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. We estimate that most hospitals and most other providers and suppliers are small entities as that term is used in the RFA. The great majority of hospitals and most other health care providers and suppliers are small entities, either by being nonprofit organizations or by meeting the SBA definition of a small business (having revenues of less than $8.0 million to $41.5 million in any 1 year). (For details on the latest standards for health care providers, we refer readers to page 38 of the Table of Small Business Size Standards for NAIC 622 found on the SBA website at *https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*.)

For purposes of the RFA, all hospitals and other providers and suppliers are considered to be small entities. Because all hospitals are considered to be small entities for purposes of the RFA, the hospital impacts described in this final rule are impacts on small entities. Individuals and States are not included in the definition of a small entity. MACs are not considered to be small entities because they do not meet the SBA definition of a small business.

HHS's practice in interpreting the RFA is to consider effects economically ''significant'' if greater than 5 percent of providers reach a threshold of 3 to 5 percent or more of total revenue or total costs. We believe that the provisions of this final rule relating to IPPS hospitals would have an economically significant impact on small entities as explained in this appendix. Therefore, the Secretary has certified that this final rule would have a significant economic impact on a substantial number of small entities. For example, the majority of the 3,131 IPPS hospitals included in the impact analysis shown in ''Table I.—Impact Analysis of Changes to the IPPS for Operating Costs for FY 2024,'' on average are expected to see increases in the range of 3.1 percent, primarily due to the hospital rate update, as discussed in section I.G. of this appendix. On average, the rate update for these hospitals is estimated to be 3.1 percent.

The 333 LTCH PPS hospitals included in the impact analysis shown in ''Table IV: Impact of Payment Rate and Policy Changes to LTCH PPS Payments for LTCH PPS Standard Federal Payment Rate Cases for FY 2024 (Estimated FY 2023 Payments Compared to Estimated FY 2024 Payments)'' on average are expected to see a decrease of approximately 0.2 percent, primarily due to the 2.9 percent decrease in high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments, as discussed in section I.J. of this appendix.

This final rule contains a range of final policies. It provides descriptions of the statutory provisions that are addressed, identifies the finalized policies, and presents rationales for our decisions and, where relevant, alternatives that were considered. The analyses discussed in this appendix and throughout the preamble of this final rule constitutes our regulatory flexibility analysis. We solicited public comments on our estimates and analysis of the impact of our proposals on small entities.

IV. Impact on Small Rural Hospitals

Section 1102(b) of the Act requires us to prepare a regulatory impact analysis for any proposed or final rule that may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. With the exception of hospitals located in certain New England counties, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of an urban area and has fewer than 100 beds. Section 601(g) of the Social Security Amendments of 1983 (Pub. L. 98–21) designated hospitals in certain New England counties as belonging to the adjacent urban area. Thus, for purposes of the IPPS and the LTCH PPS, we continue to classify these hospitals as urban hospitals.

As shown in Table I. in section I.G. of this appendix, rural IPPS hospitals with 0–49 beds (363 hospitals) and 50–99 beds (188 hospitals) are expected to experience an increase in payments from FY 2023 to FY 2024 of 3.1 percent and 4.0 percent, respectively, primarily driven by the hospital rate update and the change to the calculation of the rural wage index, as discussed in section I.G of this appendix. We refer readers to Table I. in section I.G. of this appendix for additional information on the quantitative effects of the policy changes under the IPPS for operating costs.

All rural LTCHs (18 hospitals) shown in Table IV. in section I.J. of this appendix have less than 100 beds. These hospitals are expected to experience an increase in payments from FY 2023 to FY 2024 of 0.3 percent. This increase is primarily due to the 3.3 percent annual update to the LTCH PPS standard Federal payment rate for FY 2024

and the projected 2.9 percent decrease in high cost outlier payments as a percentage of total LTCH PPS standard Federal payment rate payments, as discussed in section I.J. of this appendix.

V. Unfunded Mandates Reform Act Analysis

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4) 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 2023, that threshold level is approximately $177 million. This final rule would not mandate any requirements that meet the threshold for State, local, or tribal governments, nor would it affect private sector costs.

VI. Executive Order 13132

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. This final rule would not have a substantial direct effect on state or local governments, preempt states, or otherwise have a federalism implication.

VII. Executive Order 13175

Executive Order 13175 directs agencies to consult with Tribal officials prior to the formal promulgation of regulations having tribal implications. Section 1880(a) of the Act states that a hospital of the Indian Health Service, whether operated by such Service or by an Indian tribe or tribal organization, is eligible for Medicare payments so long as it meets all of the conditions and requirements for such payments which are applicable generally to hospitals. Consistent with section 1880(a) of the Act, this final rule contains general provisions also applicable to hospitals and facilities operated by the Indian Health Service or Tribes or Tribal organizations under the Indian Self-Determination and Education Assistance Act. We continue to engage in consultations with Tribal officials on IPPS issues of interest. We will use input received from these consultations, as well as the comments on the proposed rule, to inform this rulemaking.

VIII. Executive Order 12866

In accordance with the provisions of Executive Order 12866, the Office of Management and Budget reviewed this final rule.

Appendix B—Recommendation of Update Factors for Operating Cost Rates of Payment for Inpatient Hospital Services

I. Background

Section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Under section 1886(e)(5) of the Act, we are required to publish update factors recommended by the Secretary in the proposed and final IPPS rules. Accordingly, this appendix provides the recommendations for the update factors for the IPPS national standardized amount, the hospital-specific rate for SCHs and MDHs, and the rate-of-increase limits for certain hospitals excluded from the IPPS, as well as LTCHs. In prior years, we made a recommendation in the IPPS proposed rule and final rule for the update factors for the payment rates for IRFs and IPFs. However, for FY 2024, consistent with our approach for FY 2023, we are including the Secretary's recommendation for the update factors for IRFs and IPFs in separate **Federal Register** documents at the time that we announce the annual updates for IRFs and IPFs. We also discuss our response to MedPAC's recommended update factors for inpatient hospital services.

II. Inpatient Hospital Update for FY 2024

A. FY 2024 Inpatient Hospital Update

As discussed in section IV.A. of the preamble to this final rule, for FY 2024, consistent with section 1886(b)(3)(B) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act, we are setting the applicable percentage increase by applying the following adjustments in the following sequence. Specifically, the applicable percentage increase under the IPPS is equal to the rate-of-increase in the hospital market basket for IPPS hospitals in all areas, subject to a reduction of one-quarter of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals that fail to submit quality information under rules established by the Secretary in accordance with section 1886(b)(3)(B)(viii) of the Act and a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments; also referred to as the market basket update or rate-of-increase (with no adjustments)) for hospitals not considered to be meaningful electronic health record (EHR) users in accordance with section 1886(b)(3)(B)(ix) of the Act, and then subject to an adjustment based on changes in economy-wide productivity (the productivity adjustment). Section 1886(b)(3)(B)(xi) of the Act, as added by section 3401(a) of the Affordable Care Act, states that application of the productivity adjustment may result in the applicable percentage increase being less than zero.

We note that, in compliance with section 404 of the MMA, in the FY 2022 IPPS/LTCH PPS final rule (86 FR 45194 through 45204), we replaced the 2014-based IPPS operating and capital market baskets with the rebased and revised 2018-based IPPS operating and capital market baskets beginning in FY 2022.

In the FY 2024 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we proposed to base the proposed FY 2024 market basket update used to determine the applicable percentage increase for the IPPS on IGI's fourth quarter 2022 forecast of the 2018-based IPPS market basket rate-of-increase with historical data through third quarter 2022, which was estimated to be 3.0 percent. In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, in section IV.B. of the preamble of the FY 2024 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2022 forecast, we proposed a productivity adjustment of 0.2 percentage point for FY 2024. We also proposed that if more recent data subsequently became e available, we would use such data, if appropriate, to determine the FY 2024 market basket update and productivity adjustment for the FY 2024 IPPS/LTCH PPS final rule.

In the FY 2024 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2022 forecast of the 2018-based IPPS market basket update and the productivity adjustment, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act (hereafter referred to as a hospital that submits quality data) and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act (hereafter referred to as a hospital that is a meaningful EHR user), we presented 4 possible applicable percentage increases that could be applied to the standardized amount.

In accordance with section 1886(b)(3)(B) of the Act, as amended by section 3401(a) of the Affordable Care Act, we are establishing the applicable percentages increase for the FY 2024 updates based on IGI's second quarter 2023 forecast of the 2018-based IPPS market basket of 3.3 percent and the productivity adjustment of 0.2 percentage point, as discussed in section V.A of the preamble of this final rule, depending on whether a hospital submits quality data under the rules established in accordance with section 1886(b)(3)(B)(viii) of the Act and is a meaningful EHR user under section 1886(b)(3)(B)(ix) of the Act, as shown in the table in this section.

FY 2024	Hospital Submitted Quality Data and is a Meaningful EHR User	Hospital Submitted Quality Data and is NOT a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is a Meaningful EHR User	Hospital Did NOT Submit Quality Data and is NOT a Meaningful EHR User
Market Basket Rate-of-Increase	3.3	3.3	3.3	3.3
Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	-0.825	-0.825
Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	-2.475	0.0	-2.475
Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.2	-0.2	-0.2	-0.2
Applicable Percentage Increase Applied to Standardized Amount	**3.1**	**0.625**	**2.275**	**-0.2**

B. FY 2024 SCH and MDH Update

Section 1886(b)(3)(B)(iv) of the Act provides that the FY 2024 applicable percentage increase in the hospital-specific rate for SCHs and MDHs equals the applicable percentage increase set forth in section 1886(b)(3)(B)(i) of the Act (that is, the same update factor as for all other hospitals subject to the IPPS).

Division FF, section 4102 of the Consolidated Appropriations Act, 2023 (Public Law 117–328), enacted on December 29, 2022, extended the MDH program through FY 2024 (that is, for discharges occurring on or before September 30, 2024). We refer readers to section V.F. of the preamble of this final rule for further discussion of the MDH program.

As previously stated, the update to the hospital specific rate for SCHs and MDHs is subject to section 1886(b)(3)(B)(i) of the Act, as amended by sections 3401(a) and 10319(a) of the Affordable Care Act. Accordingly, depending on whether a hospital submits quality data and is a meaningful EHR user, we are establishing the same four possible applicable percentage increases in the previous table for the hospital-specific rate applicable to SCHs and MDHs.

C. FY 2024 Puerto Rico Hospital Update

Because Puerto Rico hospitals are no longer paid with a Puerto Rico-specific standardized amount under the amendments to section 1886(d)(9)(E) of the Act, there is no longer a need for us to make an update to the Puerto Rico standardized amount. Hospitals in Puerto Rico are now paid 100 percent of the national standardized amount and, therefore, are subject to the same update to the national standardized amount discussed under section IV.A.1. of the preamble of this final rule.

In addition, as discussed in section IV.A.2. of the preamble of this final rule, section 602 of Public Law 114–113 amended section 1886(n)(6)(B) of the Act to specify that subsection (d) Puerto Rico hospitals are eligible for incentive payments for the meaningful use of certified EHR technology, effective beginning FY 2016. In addition, section 1886(n)(6)(B) of the Act was amended to specify that the adjustments to the applicable percentage increase under section 1886(b)(3)(B)(ix) of the Act apply to subsection (d) Puerto Rico hospitals that are not meaningful EHR users, effective beginning FY 2022.

Accordingly, section 1886(b)(3)(B)(ix) of the Act in conjunction with section 602(d) of Public Law 114–113 requires that for FY 2024 and subsequent fiscal years, any subsection (d) Puerto Rico hospital that is not a meaningful EHR user as defined in section 1886(n)(3) of the Act and not subject to an exception under section 1886(b)(3)(B)(ix) of the Act will have a reduction of three-quarters of the applicable percentage increase (prior to the application of other statutory adjustments).

Based on IGI's fourth quarter 2022 forecast of the 2018-based IPPS market basket update with historical data through third quarter 2022, in the FY 2024 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as previously discussed, for Puerto Rico hospitals, we proposed a market basket update of 3.0 percent and a productivity adjustment of 0.2 percentage point. Therefore, for FY 2024, depending on whether a Puerto Rico hospital is a meaningful EHR user, we stated that there are two possible applicable percentage increases that can be applied to the standardized amount. Based on these data, we determined the following proposed applicable percentage increases to the standardized amount for FY 2024 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, we proposed an applicable percentage increase to the FY 2024 operating standardized amount of 2.8 percent (that is, the FY 2024 estimate of the proposed market basket rate-of-increase of 3.0 percent less an adjustment of 0.2 percentage point for the proposed productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, we proposed an applicable percentage increase to the operating standardized amount of 0.55 percent (that is, the FY 2024 estimate of the proposed market basket rate-of-increase of 3.0 percent, less an adjustment of 2.25 percentage point (the proposed market basket rate-of-increase of 3.0 percent $\times$ 0.75 for failure to be a meaningful EHR user), and less an adjustment of 0.2 percentage point for the proposed productivity adjustment).

As noted previously, we proposed that if more recent data subsequently became available, we would use such data, if appropriate, to determine the FY 2024 market basket update and the productivity adjustment for the FY 2024 IPPS/LTCH PPS final rule.

As discussed in section V.A.1. of the preamble of this final rule, based on more recent data available for this FY 2024 IPPS/LTCH PPS final rule (that is, IGI's second quarter 2023 forecast of the 2018-based IPPS market basket rate-of-increase with historical data through the first quarter of 2023), we estimate that the FY 2024 market basket update used to determine the applicable percentage increase for the IPPS is 3.3 percent less a productivity adjustment of 0.2 percentage point. Therefore, in accordance with section 1886(b)(3)(B) of the Act, for this final rule, for Puerto Rico hospitals the more recent update of the market basket update is 3.3 percent less a productivity adjustment of 0.2 percentage point. For FY 2024, depending on whether a Puerto Rico hospital is a meaningful EHR user, there are two possible applicable percentage increases that can be applied to the standardized amount. Based on these data, we determined the following applicable percentage increases to the standardized amount for FY 2024 for Puerto Rico hospitals:

- For a Puerto Rico hospital that is a meaningful EHR user, an applicable percentage increase to the FY 2024 operating standardized amount of 3.1 percent (that is, the FY 2024 estimate of the market basket rate-of-increase of 3.3 percent less 0.2 percentage point for the productivity adjustment).
- For a Puerto Rico hospital that is not a meaningful EHR user, an applicable percentage increase to the operating standardized amount of 0.625 percent (that is, the FY 2024 estimate of the market basket rate-of-increase of 3.3 percent, less an adjustment of 2.475 percentage point (the market basket rate-of-increase of 3.3 percent $\times$ 0.75 for failure to be a meaningful EHR user), and less 0.2 percentage point for the productivity adjustment).

D. Update for Hospitals Excluded From the IPPS for FY 2024

Section 1886(b)(3)(B)(ii) of the Act is used for purposes of determining the percentage increase in the rate-of-increase limits for children's hospitals, cancer hospitals, and hospitals located outside the 50 States, the District of Columbia, and Puerto Rico (that is, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and America Samoa).

Section 1886(b)(3)(B)(ii) of the Act sets the percentage increase in the rate-of-increase limits equal to the market basket percentage increase. In accordance with § 403.752(a) of the regulations, religious nonmedical health care institutions (RNHCIs) are paid under the provisions of § 413.40, which also use section 1886(b)(3)(B)(ii) of the Act to update the percentage increase in the rate-of-increase limits.

Currently, children's hospitals, PPS-excluded cancer hospitals, RNHCIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa are among the remaining types of hospitals still paid under the reasonable cost methodology, subject to the rate-of-increase limits. In addition, in accordance with § 412.526(c)(3) of the regulations, extended neoplastic disease care hospitals (described in § 412.22(i) of the regulations) also are subject to the rate-of-increase limits. As discussed in section VI. of the preamble of this final rule, we are finalizing our proposal to use the percentage increase in the 2018-based IPPS operating market basket to update the target amounts for children's hospitals, PPS-excluded cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa, and extended neoplastic disease care hospitals for FY 2024 and subsequent fiscal years. Accordingly, for FY 2024, the rate-of-increase percentage to be applied to the target amount for these children's hospitals, cancer hospitals, RNHCIs, extended neoplastic disease care hospitals, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is the FY 2024 percentage increase in the 2018-based IPPS operating market basket. For this final rule, the current estimate of the IPPS operating market basket percentage increase for FY 2024 is 3.3 percent.

E. Update for LTCHs for FY 2024

Section 123 of Public Law 106–113, as amended by section 307(b) of Public Law 106–554 (and codified at section 1886(m)(1) of the Act), provides the statutory authority for updating payment rates under the LTCH PPS.

As discussed in section V.A. of the Addendum to this final rule, we are updating the LTCH PPS standard Federal payment rate for FY 2024 by 3.3 percent, consistent with section 1886(m)(3) of the Act which provides that any annual update be reduced by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act (that is, the productivity adjustment). Furthermore, in accordance with the LTCH QR Program under section 1886(m)(5) of the Act, we are reducing the annual update to the LTCH PPS standard Federal rate by 2.0 percentage points for failure of a LTCH to submit the required quality data. Accordingly, we are establishing an update factor of 1.033 in determining the LTCH PPS standard Federal rate for FY 2024. For LTCHs that fail to submit quality data for FY 2024, we are establishing an annual update to the LTCH PPS standard Federal rate of 1.3 percent (that is, the annual update for FY 2024 of 3.3 percent less 2.0 percentage points for failure to submit the required quality data in accordance with section 1886(m)(5)(C) of the Act and our rules) by applying an update factor of 1.013 in determining the LTCH PPS standard Federal rate for FY 2024. (We note that, as discussed in section VII.D. of the preamble of this final rule, the update to the LTCH PPS standard Federal payment rate of 3.3 percent for FY 2024 does not reflect any budget neutrality factors.)

III. Secretary's Recommendations

MedPAC is recommending inpatient hospital rates be updated by the amount specified in current law plus one percent. MedPAC's rationale for this update recommendation is described in more detail in this section. As previously stated, section 1886(e)(4)(A) of the Act requires that the Secretary, taking into consideration the recommendations of MedPAC, recommend update factors for inpatient hospital services for each fiscal year that take into account the amounts necessary for the efficient and effective delivery of medically appropriate and necessary care of high quality. Consistent with current law, depending on whether a hospital submits quality data and is a meaningful EHR user, we are recommending the four applicable percentage increases to the standardized amount listed in the table under section II. of this appendix. We are recommending that the same applicable percentage increases apply to SCHs and MDHs.

In addition to making a recommendation for IPPS hospitals, in accordance with section 1886(e)(4)(A) of the Act, we are recommending update factors for certain other types of hospitals excluded from the IPPS. Consistent with our policies for these facilities, we are recommending an update to the target amounts for children's hospitals, cancer hospitals, RNHCIs, short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa and extended neoplastic disease care hospitals of 3.3 percent.

For FY 2024, consistent with policy set forth in section VII. of the preamble of this final rule, for LTCHs that submit quality data, we are recommending an update of 3.3 percent to the LTCH PPS standard Federal rate. For LTCHs that fail to submit quality data for FY 2024, we are recommending an annual update to the LTCH PPS standard Federal rate of 1.3 percent.

IV. MedPAC Recommendation for Assessing Payment Adequacy and Updating Payments in Traditional Medicare

In its March 2023 Report to Congress, MedPAC assessed the adequacy of current payments and costs, and the relationship between payments and an appropriate cost base. MedPAC recommended that the Congress update the hospital inpatient rates by the amount specified in current law plus 1 percent. MedPAC anticipates that their recommendation to update the IPPS payment rate by the amount specified under current law plus 1 percent in 2024 would generally be adequate to maintain beneficiaries' access to hospital inpatient and outpatient care and keep IPPS payment rates close to, if somewhat below, the cost of delivering high-quality care efficiently.

MedPAC stated that their recommended update to IPPS and OPPS payment rates of current law plus 1 percent may not be sufficient to ensure the financial viability of some Medicare safety-net hospitals with a poor payer mix. MedPAC recommends redistributing the current Medicare safety-net payments (disproportionate share hospital and uncompensated care payments) using the MedPAC-developed Medicare Safety-Net Index (MSNI) for hospitals. In addition, MedPAC recommends adding $2 billion to this MSNI pool of funds to help maintain the financial viability of Medicare safety-net hospitals and recommended to Congress transitional approaches for a MSNI policy.

We refer readers to the March 2023 MedPAC report, which is available for download at *www.medpac.gov*, for a complete discussion on these recommendations.

In light of these recommendations, and in particular those concerning safety net hospitals, we look forward to working with Congress and we sought comments on approaches CMS could take. We are establishing an applicable percentage increase for FY 2024 of 3.1 percent as described in section 1886(b)(3)(B) of the Act, provided the hospital submits quality data and is a meaningful EHR user consistent with these statutory requirements. We note that, because the operating and capital payments in the IPPS remain separate, we are continuing to use separate updates for operating and capital payments in the IPPS. The update to the capital rate is discussed in section III. of the Addendum to this final rule.

With regard to MedPAC's recommendation for a MSNI policy, we note that a discussion is in section X.C. of the preamble of this final rule. We note that section 1886(d)(5)(F) of the Act provides for additional Medicare payments, called Medicare disproportionate share hospital (DSH) payments, to subsection (d) hospitals that serve a significantly disproportionate number of low-income patients. Section 1886(r) of the Act provides that, for FY 2014 and each subsequent fiscal year, the Secretary shall pay each such subsection (d) hospital that is eligible for DSH an empirically justified DSH payment equal to 25 percent of the Medicare DSH adjustment they otherwise would have received. The remaining amount, equal to an estimate of 75 percent of what otherwise would have been paid as Medicare DSH payments, reduced to reflect changes in the percentage of individuals who are uninsured, is available to make additional payments to each hospital that qualifies for Medicare DSH payments and has uncompensated care. We refer readers to section IV. of this final rule for a further discussion of Medicare DSH and uncompensated care payments.

[FR Doc. 2023–16252 Filed 8–1–23; 4:15 pm]

BILLING CODE 4120–01–P

Reader Aids

Federal Register

Vol. 88, No. 165

Monday, August 28, 2023

CUSTOMER SERVICE AND INFORMATION

ELECTRONIC RESEARCH

World Wide Web

Full text of the daily Federal Register, CFR and other publications is located at: **www.govinfo.gov.**

Federal Register information and research tools, including Public Inspection List and electronic text are located at: **www.federalregister.gov.**

E-mail

FEDREGTOC (Daily Federal Register Table of Contents Electronic Mailing List) is an open e-mail service that provides subscribers with a digital form of the Federal Register Table of Contents. The digital form of the Federal Register Table of Contents includes HTML and PDF links to the full text of each document.

To join or leave, go to **https://public.govdelivery.com/accounts/USGPOOFR/subscriber/new**, enter your email address, then follow the instructions to join, leave, or manage your subscription.

PENS (Public Law Electronic Notification Service) is an e-mail service that notifies subscribers of recently enacted laws.

To subscribe, go to **http://listserv.gsa.gov/archives/publaws-l.html and select** *Join or leave the list (or change settings);* then follow the instructions.

FEDREGTOC and **PENS** are mailing lists only. We cannot respond to specific inquiries.

Reference questions. Send questions and comments about the Federal Register system to: **fedreg.info@nara.gov**

The Federal Register staff cannot interpret specific documents or regulations.

FEDERAL REGISTER PAGES AND DATE, AUGUST

CFR PARTS AFFECTED DURING AUGUST

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

71 .....50018, 50764, 54225, 54227, 54228, 54229, 54230, 54231, 54232, 54233, 55553, 58071
93.....54873
97 .....56760, 56761, 58945, 58946
382.....50020
1204.....50765

Proposed Rules:
21.....53815
25.....55941
27.....55941
29.....55941
39 .....50067, 51739, 51742, 51745, 52055, 53402, 53406, 53823, 54500, 54933, 54935, 54939, 54941, 54944, 54946, 54949, 55953, 55956, 57012, 57902, 57904, 57907, 58114, 58116, 58120
61.....55959
71 .....54248, 54249, 54251, 54252, 54254, 54503, 54952, 54955, 54956, 54959
91.....55941, 55959
121.....55941
125.....55941
135.....55941
401.....56546
413.....56546
415.....56546
431.....56546
435.....56546
437.....56546
440.....56546
450.....56546
460.....56546

15 CFR

30.....54234
738.....54875, 56763
742.....54875
744.....57002
774.....56462
902.....53704
950.....56465

Proposed Rules:
705.....58525
922.....58123

16 CFR

310.....57333
1309.....54878
1310.....55554

Proposed Rules:
432.....56780
801.....54256
803.....54256

17 CFR

39.....53664
140.....53664
229.....51896
232.....51896
239.....51896
240.....51896
249.....51896
270.....51404
274.....51404
279.....51404

Proposed Rules:
23.....53409, 58145
37.....58145
240.....53960
275.....50076, 53960
279.....50076

20 CFR

404.....55366, 57004
416.....55366, 57004

Proposed Rules:
404.....51747
416.....51747, 57910
422.....51747

21 CFR

Ch.I 58498
161.....53764
164.....53764
184.....53764
186.....53764
500.....55559
510.....55559
516.....55559
520.....55559
522.....55559
524.....55559
526.....55559
529.....55559
556.....55559
558.....55559
1300.....50036
1302.....50036
1306.....53377
1308.....50036, 56466

Proposed Rules:
146.....55607
161.....53827, 58157
164.....53827
184.....53827
186.....53827

22 CFR

171.....58072

24 CFR

880.....56764
888.....56764
903.....56764
905.....56764
964.....56764
970.....56764
983.....56764

25 CFR

2.....53774
502.....55366
556.....55366
558.....55366

26 CFR

1.....50041, 55506

Proposed Rules:
1 .....51756, 52057, 57916
5.....52057
54.....51552
301.....52057
602.....52057

27 CFR

Proposed Rules:
555.....57370

28 CFR

Proposed Rules:
35.....51948
105.....58167

29 CFR

1.....57526
3.....57526
5.....57526
102.....58075, 58076
1614.....57879

Proposed Rules:
1636.....54714
2510.....54511
2520.....54511
2550.....54511
2590.....51552
4022.....56583
4044.....56583
4050.....56583
4262.....56583
4281.....56583

30 CFR

250.....57334
285.....54880
1206.....53790, 57881
1208.....53790
1217.....53790, 55571
1220.....53790

Proposed Rules:
56.....54961
57.....54961
60.....54961
70.....54961
71.....54961
72.....54961
75.....54961
90.....54961
550.....58173
556.....58173
590.....58173
926 .....52082, 52084, 52086

31 CFR

515.....58102
555.....52026
587.....52038
591.....52038, 52039
802.....57348

Proposed Rules:
Ch. VIII.....54961

32 CFR

1700.....51234

33 CFR

100 .....54487, 55572, 56469, 56766, 58102
117 .....54487, 54488, 56470, 58102
165 .....50042, 50765, 51699, 51701, 54237, 54489, 54880, 55371, 55373, 55375, 55572, 55913, 55915, 56768, 56770, 57004, 57006, 57352, 57354, 57356, 57882, 58104, 58106, 58108, 58110, 58112, 58500
207.....51234
326.....51234

Proposed Rules:
100.....51763, 57374
117.....58174, 58176
165.....57378

34 CFR

Ch. II 54882
165.....58112

36 CFR

1190.....53604
1280.....58502

Proposed Rules:
1195.....50096

37 CFR

6.....50767
201.....54491
205.....54491
385.....54406

38 CFR

38.....51236

Proposed Rules:
17.....54972

39 CFR

111.....54239

40 CFR

52 .....50770, 50773, 51702, 51711, 51713, 53793, 53795, 53798, 53800, 53802, 54240, 54899, 55377, 55379, 55383, 55576, 57358, 57361, 57882
60.....58442
70.....53802
80.....51239
180 .....52040, 53806, 54244, 55578, 56772, 56773, 57887, 57891, 57894, 57898, 58503, 58506
260.....54086
261.....54086
262.....54086
264.....54086
265.....54086
266.....54086
270.....54086
271 .....54086, 55387, 55394
272.....55394
300.....55582
441.....54086

Proposed Rules:
2.....54118
51.....54118
52 .....53431, 54257, 54259, 54534, 54975, 54983, 54996, 54998, 55428, 56787, 57014, 57018, 57020, 58178, 58202, 58538
62.....56787
63.....55858, 57381
98.....50282
123.....55276
124.....55276
147.....55610
180.....57026
232.....55276
233.....55276
257.....55220
260.....53836, 54537
261.....53836, 54537
262.....53836, 54537
263.....54537
264.....53836, 54537
265.....53836, 54537
266.....53836, 54537
267.....54537
268.....54537
270.....53836, 54537
271.....53836, 55429
272.....55429
300.....55611
441.....53836
745.....50444

41 CFR

60–1.....51717

60–2.....51717
60–4.....51717
60–20.....51717
60–30.....51717
60–40.....51717
60–50.....51717
60–300.....51717, 57009
60–741.....51717, 57009

42 CFR

73.....54247
405.....57901
410.....57901
411 .....53200, 57901, 58640
412 .....50986, 51054, 57901, 58640
413.....53200, 57901
416.....57901
417.....50043
418.....51164
419.....57901, 58640
422.....50043
423.....50043
424.....51164, 57901
455.....50043
460.....50043
485.....57901
488.....53200, 58640
489 .....53200, 57901, 58640
495.....58640

Proposed Rules:

405.....52262, 57029
410.....52262, 57029
411.....52262
414.....52262
415.....52262
416.....57029
418.....52262
419.....57029
422.....52262
423.....52262
424.....52262, 57029
425.....52262
455.....52262
485.....57029
488.....57029
489.....52262, 57029
491.....52262
495.....52262
498.....52262
600.....52262

45 CFR

620.....50044
1110.....53810

Proposed Rules:

101.....55613
146.....51552
147.....51552
180.....57029

46 CFR

169.....51737

Proposed Rules:

401.....55629

47 CFR

7.....55584
8.....52043
14.....50053
54 .....55401, 55918, 57363, 58509
64.....51240
73.....51249

Proposed Rules:

Ch. I.....58211
1 .....50486, 55961, 57030
2.....55961
14.....52088
15.....55961
25.....55961, 58540
27.....55961
54 .....53837, 56579, 57383
63.....50486
64.....52088, 53850
73 .....57031, 57032, 57033, 58210
74.....55961
78.....55961
101.....55961

48 CFR

Ch. 1.....53748, 53756
1.....53748
2.....53751
9.....53754
11.....53754
12.....53748
19.....53751
23.....53754
26.....53748
52 .....53748, 53751, 53754, 53756
53.....53754
203.....55937
204.....55937
206.....55937
212.....55937
215.....55937, 55940
225.....55940
234.....55940
235.....55937
252.....55940
501.....53811

Proposed Rules:

1.....51672, 52102
2.....51672
4.....51672
5.....51672
7.....51672
9.....51672
10.....51672
11.....51672
12.....51672, 52102
13.....51672
15.....51672
16.....53855
18.....51672
22.....52102
23.....51672
26.....51672
36.....51672
37.....51672
39.....51672
42.....51672
47.....52102
52.....51672, 52102

49 CFR

192.....50056
195.....50056

Proposed Rules:

171.....55430
174.....55430
180.....55430
245.....57043
246.....57044
531 .....56128, 58229, 58232
533 .....56128, 58229, 58232
535 .....56128, 58229, 58232
537 .....56128, 58229, 58232
1500.....57044
1530.....57044
1570.....57044
1572.....57044
1580.....57044
1582.....57044
1584.....57044

50 CFR

17.....56471, 57046
20.....54830, 56489
223.....54026, 58511
226.....54026
300.....53383
622 .....50063, 50806, 55585, 56527
635 .....50807, 53812, 56777
648 .....50065, 50808, 51737, 54495, 54899, 55411, 56527, 56544, 58113, 58521
660 .....51250, 52046, 53813, 58522
679 .....52053, 53704, 55419, 56778, 57009

Proposed Rules:

17 .....54263, 54548, 55962, 55991, 57060, 57180, 57224, 57292, 57388
223.....55431
622.....51255, 57916
635.....50822, 50829
660.....50830, 57400
679.....50097

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List August 9, 2023

Public Laws Electronic Notification Service (PENS)

PENS is a free email notification service of newly enacted public laws. To subscribe, go to *https://portalguard.gsa.gov/—layouts/PG/register.aspx*.

Note: This service is strictly for email notification of new laws. The text of laws is not available through this service. **PENS** cannot respond to specific inquiries sent to this address.