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Title 3—

The President

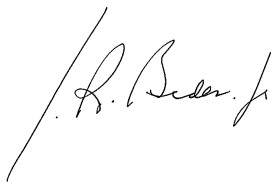
Memorandum of April 19, 2023

Delegation of Authority Under Section 506(a)(1) of the Foreign Assistance Act of 1961

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 621 of the Foreign Assistance Act of 1961 (FAA), I hereby delegate to the Secretary of State the authority under section 506(a)(1) of the FAA to direct the drawdown of up to $325 million in defense articles and services of the Department of Defense, and military education and training, to provide assistance to Ukraine and to make the determinations required under such section to direct such a drawdown.

You are authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, April 19, 2023

[FR Doc. 2023–09297
Filed 4–28–23; 8:45 am]
Billing code 4710–10–P

Presidential Documents

Memorandum of April 25, 2023

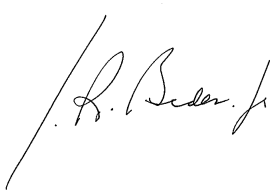
Delegation of Authority Under Section 5948(d) of the James M. Inhofe National Defense Authorization Act for Fiscal Year 2023

Memorandum for the Secretary of State

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, I hereby delegate to the Secretary of State the authority to submit to the Congress the report required by section 5948(d) of the James M. Inhofe National Defense Authorization Act for Fiscal Year 2023 (Public Law 117–263).

The delegation in this memorandum shall apply to any provision of any future public law that is the same or substantially the same as the provision referenced in this memorandum.

You are authorized and directed to publish this memorandum in the *Federal Register*.



THE WHITE HOUSE,
Washington, April 25, 2023

[FR Doc. 2023–09299
Filed 4–28–23; 8:45 am]
Billing code 4710–10–P

Presidential Documents

Executive Order 14097 of April 27, 2023

Authority To Order the Ready Reserve of the Armed Forces to Active Duty To Address International Drug Trafficking

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the National Emergencies Act (50 U.S.C. 1601 *et seq.*), and in furtherance of Executive Order 14059 of December 15, 2021 (Imposing Sanctions on Foreign Persons Involved in the Global Illicit Drug Trade), which declared a national emergency to address the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States posed by international drug trafficking, it is hereby ordered as follows:

Section 1. *Emergency Authority*. To provide additional authority to the Secretary of Defense and the Secretary of Homeland Security to respond to the national emergency declared in Executive Order 14059, the authority under section 12302 of title 10, United States Code, is invoked and made available, according to its terms, to the Secretary of Defense and the Secretary of Homeland Security. The Secretaries of the Army, Navy, and Air Force, at the direction of the Secretary of Defense, and the Secretary of Homeland Security with respect to the Coast Guard when it is not operating as a service in the Navy, are authorized to order to active duty such units and individual members of the Ready Reserve under the jurisdiction of the Secretary concerned as the Secretary concerned considers necessary, consistent with the terms of section 12302 of title 10, United States Code.

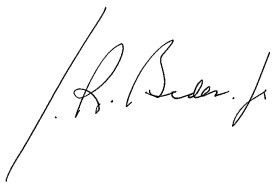
Sec. 2. *General Provisions*. (a) Nothing in this order shall be construed to impair or otherwise affect:

(i) the authority granted by law to an executive department or agency, or the head thereof; or

(ii) the functions of the Director of the Office of Management and Budget relating to budgetary, administrative, or legislative proposals.

(b) This order shall be implemented consistent with applicable law and subject to the availability of appropriations.

(c) This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.



THE WHITE HOUSE,
April 27, 2023.

[FR Doc. 2023–09318
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Presidential Documents

Proclamation 10557 of April 26, 2023

70th Anniversary of the Lavender Scare

By the President of the United States of America

A Proclamation

Our Nation has made tremendous progress in advancing the cause of equality for LGBTQI+ Americans. To keep building on that progress, we must reflect honestly on the darkest chapters of our story and on how far we have come. Seventy years ago, as the Cold War set in, President Eisenhower signed an Executive Order banning LGBTQI+ Americans from serving in the Federal Government. This action codified a shameful chapter in our Nation's history known as the ''Lavender Scare.'' It was a decades-long period when 5,000 to 10,000 LGBTQI+ Federal employees were investigated, were interrogated, and lost their jobs simply because of who they were and whom they loved.

On this anniversary, we acknowledge the importance of telling the complete history of our Nation, reflecting on the lives changed by this discrimination, honoring the courageous Americans who fought to end this injustice, and celebrating the contributions of today's proud LGBTQI+ public servants—including members of our Armed Forces.

Our Nation was founded on the sacred idea that all of us are created equal and deserve to be treated equally under our laws. But for so many members of the LGBTQI+ community, hate, discrimination, and isolation throughout our country's history have denied them the full promise of America. The Lavender Scare epitomized—and institutionalized—this injustice. As LGBTQI+ employees were forced out of the workforce, the Federal Government attempted to defend its policies by propagating false and hateful stereotypes—accusing this community of being a threat to our national security and unworthy of public trust. Employees who were fired under these policies often lost future employment, other opportunities, and even relationships with their own families. Many endured poverty and public disgrace. Some took their own lives as a result of the trauma they had to bear.

While this is a story of profound injustice, it is also a story of remarkable bravery. From seeking relief in the courts to picketing in front of the White House, activists stood up for their rights and helped lay the foundation for the modern-day LGBTQI+ civil rights movement. One such trailblazer was Franklin Kameny, an Army astronomer, who after being fired because he was gay, dedicated over 50 years of his life to activism and helping LGBTQI+ workers stand up for their rights. In 2009, I was proud to meet Frank Kameny in the Oval Office as President Obama and I officially expanded many Federal benefits to same-sex partners of Government employees.

I am equally proud to have mandated additional protections for the fundamental rights of LGBTQI+ Americans. I have appointed barrier-breaking LGBTQI+ leaders to the highest levels of Government, including the first openly gay Senate-confirmed Cabinet Secretary, the first two openly transgender Americans to be confirmed by the United States Senate, and the first open lesbian to achieve the rank of Ambassador. When Americans tune in to the daily White House press briefing, they see the first openly gay White House Press Secretary representing my Administration on the world stage.

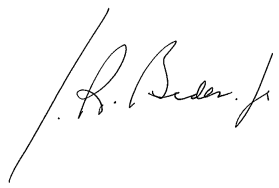
But this is just the beginning. I rescinded the discriminatory ban on transgender service members, paving the way for these brave Americans to once again serve openly in the United States military. I signed an Executive Order on Advancing Diversity, Equity, Inclusion, and Accessibility in the Federal Workforce, taking additional steps to ensure that LGBTQI+ public servants are treated with dignity and respect. I also signed a landmark Executive Order charging the Federal Government to prevent and combat discrimination on the basis of sexual orientation and gender identity. Federal agencies have since strengthened or clarified protections for LGBTQI+ Americans in housing, health care, education, employment, credit and lending services, and the criminal justice system. Just last year, I proudly signed the Respect for Marriage Act to defend the rights of LGBTQI+ and interracial couples.

The struggle for equal justice is not over. Today and in each generation, we must rededicate ourselves to ending the hatred and discrimination that LGBTQI+ Americans continue to face. That includes addressing a wave of discriminatory laws that target them—especially transgender children—and that echo the hateful stereotypes and stigma of the Lavender Scare. My Administration is standing firmly with brave LGBTQI+ Americans to push back against these injustices.

Great nations face their history openly and honestly: the good, the bad, and the truth. Today, we make our message simple to every public servant who suffered from the un-American policies and discrimination of the Lavender Scare: We see your sacrifices. We acknowledge what you lost and what you wrongfully endured. I have mandated my Administration to do all we can to write a new chapter of our American story that will demonstrate our abiding commitment to equal rights, respect for human dignity, and limitless opportunity for all.

NOW, THEREFORE, I, JOSEPH R. BIDEN JR., President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim April 27, 2023, as the 70th Anniversary of the Lavender Scare. I call upon government officials and the people of the United States of America to honor the contributions of LGBTQI+ public servants, to recognize the lives impacted by the Lavender Scare, and to celebrate the great diversity of the American people.

IN WITNESS WHEREOF, I have hereunto set my hand this twenty-sixth day of April, in the year of our Lord two thousand twenty-three, and of the Independence of the United States of America the two hundred and forty-seventh.



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CONSUMER FINANCIAL PROTECTION BUREAU

12 CFR Part 1006

Fair Debt Collection Practices Act (Regulation F); Time-Barred Debt

AGENCY: Consumer Financial Protection Bureau.

ACTION: Advisory opinion.

SUMMARY: The Consumer Financial Protection Bureau (CFPB) is issuing this advisory opinion to affirm that the Fair Debt Collection Practices Act (FDCPA) and its implementing Regulation F prohibit a debt collector, as that term is defined in the statute and regulation, from suing or threatening to sue to collect a time-barred debt. Accordingly, an FDCPA debt collector who brings or threatens to bring a State court foreclosure action to collect a time-barred mortgage debt may violate the FDCPA and Regulation F.

DATES: This advisory opinion is effective on May 1, 2023.

FOR FURTHER INFORMATION CONTACT: Seth Caffrey, Courtney Jean, or Kristin McPartland, Senior Counsels, Office of Regulations at (202) 435–7700 or *https://reginquiries.consumerfinance.gov/.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION: The CFPB is issuing this advisory opinion through the procedures for its Advisory Opinions Policy.[1] Refer to those procedures for more information.

I. Advisory Opinion

A. Background

Leading up to the 2008 financial crisis, many lenders originated mortgages to consumers without considering their ability to repay the loans.[2] These practices, which harmed millions of people, included in some cases originating products such as ''piggyback'' mortgages in which high-interest second mortgages were issued simultaneously with the origination of the first mortgage. One common piggyback mortgage product, known as an 80/20 loan, involved a first lien loan for 80 percent of the value of the home and a second lien loan for the remaining 20 percent of the valuation. Some consumers in these loans found themselves unable to make full payments on their first and second mortgages, and when housing prices began to decline in 2005, refinancing became more difficult.[3]

When a borrower defaults on a second mortgage, the mortgage holder may be able to initiate a foreclosure even if the borrower is current on the first mortgage. However, the second mortgage holder only receives proceeds from the foreclosure sale if there are any funds left after paying off the first mortgage. As a result, many second mortgage holders of piggyback loans, recognizing that a foreclosure would not generate enough money to cover even the first mortgage, charged their defaulted loans off as uncollectible and ceased communicating with the borrowers. Some sold the loans to debt buyers, often for pennies on the dollar. Such sales often occurred unbeknownst to borrowers, who continued to receive no communications regarding the loans. Many borrowers, having not received any notices or periodic statements for years, concluded that their second mortgages had been modified along with the first mortgage, discharged in bankruptcy, or forgiven.

In recent years, as home prices have increased and borrowers have paid down their first mortgages, after years of silence, some borrowers are hearing from companies that claim to own or have the right to collect on their long-dormant second mortgages.[4] These companies often demand the outstanding balance on the second mortgage, plus fees and interest, and threaten to foreclose if the borrower does not or cannot pay. The CFPB is concerned about homeowners who survived the 2008 financial crisis but who are now facing foreclosure threats and other collection activity because of long-dormant second mortgages. These borrowers are often told that they face a choice between entering into onerous payment plans or losing their homes and the equity they have diligently built since the financial crisis.

Because of the amount of time that has lapsed on these long-dormant loans, some have likely become time barred under State law. Time-barred debts are debts for which the applicable statute of limitations has expired.[5] Statutes of limitation are, typically, State laws that provide time limits for bringing suit on legal claims.[6] In most States the expiration of the applicable statute of limitations, if raised by the consumer as an affirmative defense, precludes the debt collector from recovering on the debt using judicial processes.[7] In many jurisdictions, State court (*i.e.,* judicial) foreclosure actions are subject to a statute of limitations.

The CFPB understands that some debt collectors collecting on long-dormant second mortgages may have filed or have threatened to file judicial foreclosure actions even though the underlying debt is time barred. The CFPB is issuing this advisory opinion to affirm that: (1) the FDCPA and its implementing Regulation F prohibit a debt collector, as that term is defined in the statute and regulation, from suing or threatening to sue to collect a time-barred debt; and (2) this prohibition applies even if the debt collector neither knows nor should know that the debt is time barred. Accordingly, an FDCPA debt collector who brings or threatens to bring a State court foreclosure action to collect a time-barred mortgage debt may violate the FDCPA and Regulation F.

B. Coverage

This advisory opinion applies to debt collectors as defined in section 803(6) of the FDCPA and implemented in Regulation F, 12 CFR 1006.2(i).

[1] 85 FR 77987 (Dec. 3, 2020).

[2] *See generally* 78 FR 79730, 79732–33 (Dec. 31, 2013).

[3] *Id.* at 79733.

[4] *See generally* Michael Hill, ''*Zombie Debt*'': *Homeowners face foreclosure on old mortgages,* Associated Press (Nov. 16, 2022), *https://apnews.com/article/business-mortgages-44b1ffad08a80b96a8630e091d1e96f2.*

[5] *See* 86 FR 5766, 5776–77 (Jan. 19, 2021); 12 CFR 1006.26(a)(2).

[6] *See* 86 FR at 5775–76; 12 CFR 1006.26(a)(1).

[7] *See* 86 FR at 5777.

C. Legal Analysis

The FDCPA [8] and its implementing Regulation F [9] govern the conduct of ''debt collectors'' when they collect ''debt.'' The statute and regulation generally define a debt collector as ''any person who uses any instrumentality of interstate commerce or the mails in any business the principal purpose of which is the collection of any debts, or who regularly collects or attempts to collect, directly or indirectly, debts owed or due or asserted to be owed or due another.'' [10] Many individuals and entities that seek to collect defaulted mortgage loans, and many of the attorneys that bring foreclosure actions on their behalf, are FDCPA debt collectors.

The FDCPA and Regulation F define ''debt'' as ''any obligation or alleged obligation of a consumer to pay money arising out of a transaction in which the money, property, insurance, or services which are the subject of the transaction are primarily for personal, family, or household purposes, whether or not such obligation has been reduced to judgment.'' [11] A consumer's payment obligation arising from a mortgage transaction primarily for personal, family, or household purposes, such as the purchase of the consumer's residence, falls within the plain language of this definition.[12] It follows that State court foreclosure proceedings often constitute the collection of ''debt'' under the FDCPA,[13] and debt collectors who engage in such debt collection activity are subject to the requirements and prohibitions of the FDCPA and Regulation F.

Regulation F prohibits a debt collector from suing or threatening to sue to collect a time-barred debt.[14] As the CFPB explained in finalizing this prohibition, ''a debt collector who sues or threatens to sue a consumer to collect a time-barred debt explicitly or implicitly misrepresents to the consumer that the debt is legally enforceable, and that misrepresentation is material to consumers because it may affect their conduct with regard to the collection of that debt, including whether to pay it.'' [15] Regulation F's prohibition on suits and threats of suit on time-barred debt is subject to a strict liability standard.[16] That is, a debt collector who sues or threatens to sue to collect a time-barred debt violates the prohibition ''even if the debt collector neither knew nor should have known that a debt was time barred.'' [17] Accordingly, a debt collector who brings or threatens to bring a State court foreclosure action with respect to a time-barred mortgage debt may violate the FDCPA and Regulation F. This is true even if the debt collector neither knew nor should have known that the debt was time barred.

The CFPB also notes that a broad range of non-foreclosure debt collection-related activity, such as communicating with consumers about defaulted mortgages, can be covered by the FDCPA. FDCPA debt collectors undertaking such activity are subject to the other requirements and prohibitions of the statute and Regulation F when collecting debt [18] whether or not that debt is time-barred. These include, for example, the prohibition on debt collectors: falsely representing the character, amount, or legal status of any debt; [19] threatening to take any action that cannot legally be taken or that is not intended to be taken; [20] and selling, transferring for consideration, or placing for collection a debt that the debt collector knows or should know has been paid or settled or discharged in bankruptcy.[21] They also include, for example, the requirement that debt collectors: identify themselves as a debt collector in all communications with the consumer (except formal pleadings in connection with a legal action); [22] provide the consumer with validation information in certain circumstances; [23] and respond to consumer disputes adequately before continuing to collect.[24] Finally, even if an FDCPA debt collector engages only in actions necessary to undertake a nonjudicial foreclosure action, the debt collector is still subject to FDCPA section 808(6) [25] and Regulation F, 12 CFR 1006.22(e),[26] which generally prohibit taking or threatening to take any nonjudicial action to effect dispossession or disablement of property if the debt collector has no present right or intention to do so.[27]

Although not the focus of this advisory opinion, the CFPB also notes that entities selling or collecting on these second mortgages who are mortgage servicers may also be subject to certain requirements under the Real Estate Settlement Procedures Act,[28] the Truth in Lending Act,[29] and the CFPB's mortgage servicing regulations.[30] For example, unless an exemption applies, the CFPB's mortgage servicing regulations require servicers to provide periodic statements to consumers.[31]

II. Regulatory Matters

This advisory opinion is issued under the CFPB's authority to interpret the FDCPA, including under section 1022(b)(1) of the Consumer Financial Protection Act of 2010,[32] which authorizes guidance as may be necessary or appropriate to enable the CFPB to administer and carry out the purposes and objectives of Federal consumer financial laws.[33]

An advisory opinion is a type of interpretive rule. As an interpretive rule, this advisory opinion is exempt from the notice-and-comment rulemaking requirements of the Administrative Procedure Act.[34] Because no notice of proposed rulemaking is required, the Regulatory Flexibility Act does not require an initial or final regulatory flexibility analysis.[35] The CFPB has also

[8] 15 U.S.C. 1692–1692p.

[9] 12 CFR part 1006.

[10] 15 U.S.C. 1692a(6); 12 CFR 1006.2(i). The statute and regulation also provide that, for purposes of section 808(6) and 12 CFR 1006.22(e), the term debt collector also includes any person who uses any instrumentality of interstate commerce or the mails in any business the principal purpose of which is the enforcement of security interests. *Id.*

[11] 15 U.S.C. 1692a(5); 12 CFR 1006.2(h).

[12] *See, e.g., Cohen* v. *Rosicki, Rosicki & Assocs., PC,* 897 F.3d 75, 83 (2d Cir. 2018).

[13] *Id.* at 83–84.

[14] 12 CFR 1006.26(b).

[15] 86 FR 5776, 5778 (Jan. 19, 2021).

[16] *See id.* at 5777, 5781.

[17] *Id.* at 5777.

[18] *See* 15 U.S.C. 1692a(5); 12 CFR 1006.2(h).

[19] 15 U.S.C. 1692e(2)(a); 12 CFR 1006.18(b)(2).

[20] 15 U.S.C. 1692e(5); 12 CFR 1006.18(c)(1); 15 U.S.C. 1692f(6); 12 CFR 1006.22(e).

[21] 12 CFR 1006.30(b).

[22] 15 U.S.C. 1692e(11); 12 CFR 1006.18(e).

[23] 15 U.S.C. 1692g(a); 12 CFR 1006.34.

[24] 15 U.S.C. 1692g(b); 12 CFR 1006.38(d); 85 FR 76734, 76845–48 (Nov. 30, 2020).

[25] 15 U.S.C. 1692f(6).

[26] *See* 15 U.S.C. 1692a(6); 12 CFR 1006.2(i)(1).

[27] *See Obduskey* v. *McCarthy & Holthus LLP,* 139 S.Ct. 1029 (2019) (holding that a business engaged in no more than nonjudicial foreclosure proceedings is not a debt collector under FDCPA section 803(6), except for the limited purpose of FDCPA section 808(6)).

[28] 12 U.S.C. 2601 *et seq.*

[29] 15 U.S.C. 1601 *et seq.*

[30] *See, e.g.,* 12 CFR 1024.33(b) (requiring a transferee and transferor servicer to provide a timely notice of transfer of servicing to the affected borrower), 12 CFR 1024.39 (requiring servicers to make early intervention contacts with delinquent borrowers), 12 CFR 1024.41 (requiring servicers to follow certain loss mitigation procedural requirements, including certain foreclosure-related protections). Note that small servicers, as defined in 12 CFR 1026.41(e)(4), are exempt from certain of these requirements. *See* 12 CFR 1024.30(b).

[31] *See* 12 CFR 1026.41(a); *see also, e.g.,* 12 CFR 1026.41(e)(4) (exempting small servicers from this requirement) and 12 CFR 1026.41(e)(6) (exempting servicers from periodic statement requirements for certain charged-off loans but only if, among other conditions, the servicer sends a specific notice to the consumer and does not charge additional fees or interest on the account).

[32] Dodd-Frank Wall Street Reform and Consumer Protection Act, *Public Law* 111–203, 124 Stat. 1376 (2010).

[33] 12 U.S.C. 5512(b)(1).

[34] 5 U.S.C. 553(b).

[35] 5 U.S.C. 603(a), 604(a).

determined that this advisory opinion does not impose any new or revise any existing recordkeeping, reporting, or disclosure requirements on covered entities or members of the public that would be collections of information requiring approval by the Office of Management and Budget under the Paperwork Reduction Act.[36]

Pursuant to the Congressional Review Act,[37] the CFPB will submit a report containing this interpretive rule and other required information to the United States Senate, the United States House of Representatives, and the Comptroller General of the United States prior to the rule's published effective date. The Office of Information and Regulatory Affairs has designated this interpretive rule as not a ''major rule'' as defined by 5 U.S.C. 804(2).

Rohit Chopra,

Director, Consumer Financial Protection Bureau.

[FR Doc. 2023–09171 Filed 4–28–23; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 158

[Docket ID: DOD–2020–OS–0015]

RIN 0790–AK81

Operational Contract Support (OCS) Outside the United States

AGENCY: Office of the Under Secretary of Defense for Acquisition and Sustainment, Department of Defense (DoD).

ACTION: Final rule.

SUMMARY: The DoD is updating the policies and procedures for operational contract support (OCS) outside the United States. These changes include broadening the range of applicable operational scenarios, eliminating content internal to the Department designating contractor personnel as part of the DoD total force, incorporating requirements for accountability and reporting, and clarifying responsibilities. With these updates, the Department addresses open recommendations from the Government Accountability Office (GAO).

DATES: This rule is effective May 31, 2023.

FOR FURTHER INFORMATION CONTACT: Ms. Donna M. Livingston, 703–692–3032, *donna.m.livingston.civ@mail.mil.*

SUPPLEMENTARY INFORMATION: OCS is a segment of the GAO High Risk Area of DoD Contract Management, and while the latest update in March 2021, GAO–21–119SP, ''High-Risk Series: Dedicated Leadership Needed to Address Limited Progress in Most High-Risk Areas'' (available at: *https://www.gao.gov/products/gao-21-119sp*) acknowledged progress, GAO cited the need to revise and reissue guidance to address five open recommendations.

Legal Authority

Section 861 of the *National Defense Authorization Act for Fiscal Year 2008* (Pub. L. 110–181) requires the DoD, Department of State, and the United States Agency for International Development to enter into an agreement regarding contracting matters in Iraq and Afghanistan and identify a common database to serve as a repository of information on contracts and contractor personnel supporting these operations. Section 854 of the *Duncan Hunter National Defense Authorization Act for Fiscal Year 2009* (Pub. L. 110–417) requires mechanisms for ensuring contractors are required to report specified offenses that are alleged to have been committed by or against contractor personnel to the appropriate authorities.

Discussion of Comments

The Department of Defense published a proposed rule titled ''Operational Contract Support (OCS) Outside the United States'' (32 CFR part 158) in the **Federal Register** on January 7, 2021 (86 FR 1063–1080). Fourteen comments were received from eight respondents and a summary of the comments and the Department's responses as follows.

Comment: The Department received five comments from respondents recommending the addition of requirements for defense contractor personnel to report information on gross violations of human rights (GVHRs). In general, all five comments regarding GVHR reporting recommended that the rule include a ''duty to report'' GVHRs for defense contractors. Several respondents noted that the proposed rule missed an opportunity to address the requirements of Section 888 of the National Defense Authorization Act for Fiscal Year 2020 to ''monitor and report allegations of gross violations of internationally recognized human rights.''

Response: The DoD acknowledges the requirement, however the policy and processes to support the requirements for reporting allegations of gross violations of human rights are still being developed and are not final. When those actions are completed, the DoD will initiate actions to update this rule as needed to comply with the established policy.

Comment: The Department received a comment objecting to requiring the people of the United States to provide proof of vaccination for the coronavirus disease 2019 (COVID–19) prior to any travel.

Response: The rule does not address requirements related to any specific vaccination requirement for contractor personnel. The provisions in the rule regarding immunizations and deployment health activities ensure that contractor personnel are medically ready to deploy and protect the health of the total force in deployed environments.

Comment: The DoD received a comment recognizing the significant role defense contractors play in support of military operations overseas and the costs born in terms of injury and death that have resulted. The commenter recommended DoD make a more robust effort to collect, analyze, and publicly share data with regard to contractor personnel fatalities and injuries.

Response: The Department appreciates the commenter's understanding of the key role defense contractors play in supporting the DoD. While the DoD does collect data on contractor personnel wounded and killed while performing their duties, this data is not made publicly available. The Synchronized Predeployment and Operational Tracker—Enterprise Suite (SPOT–ES) is the common joint database used to maintain accountability and visibility of contractors supporting applicable operations. In accordance with the SPOT Business Rules, referenced in this rule, it is the responsibility of the contractor's employer to close out the individual's deployment record in SPOT–ES following a death and to update the records when an injury occurs. The DoD is reviewing how to improve contractors' compliance with these procedures and to respectfully encourage more comprehensive reporting to the DoD without impacting legal and privacy issues.

Comment: The DoD received one comment regarding the types of support contractors are generally required to provide their employees while deployed. The commenter asserted that in austere environments, it is common for the U.S. Government to provide life support to contractor personnel when those personnel are located at U.S. military facilities; however, contractor personnel may need to transit through other military facilities before reaching

[36] 44 U.S.C. 3501–3521.

[37] 5 U.S.C. 801 *et seq.*

smaller or more remote military facilities. The commenter recommended that the final rule clarify, in § 158.4(d) or elsewhere, that the contract should specify who will be responsible for providing this support during transit between military facilities, and if it is the responsibility of the contractor, then the contract should include additional resources needed to support that function.

Response: The DoD appreciates the comment; however, the paragraph referenced does not delineate or specify a specific location for treatment or when or where these services might be provided by the Government. In the case of contractor personnel authorized to accompany the Military Services in deployed settings, care at MTFs may be provided consistent with DoDI 6025.23, ''Health Care Eligibility Under the Secretarial Designee (SECDES) Program and Related Special Authorities'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/602523p.pdf?ver=2019-03-22-095347-850*).

Comment: The Department received one comment specific to § 158.5(a), ''Planning considerations and requirements; requirements for publication.'' The commenter recommended management policies take into account the manner in which ''contractor personnel'' are defined in contract requirements. The rationale was that such distinctions may allow for more accurate policies to account for differences that exist within the contractor labor pool from which contractors authorized to accompany the force (CAAF) may be recruited, and also permit contractors to more readily and competitively respond to those requirements.

Response: The rule is written to be sufficiently broad to permit all Commanders, regardless of their location outside the United States and in a variety of scenarios, to tailor specific policies and procedures to best meet their operational and mission needs.

Comment: The DoD received one comment regarding emergency medical care for contractor personnel. The commenter asserted that in austere environments, there can be challenges in providing basic medical care below the ''life and limb'' medical services provided by the military. The recommendation was that the final rule require the contracting officer to evaluate whether or not to grant ''primary care'' in the letter of authorization, and that additional scope be added to the contract to address basic medical care.

Response: The rule includes provisions in § 158.4(d) regarding the contracting officer's latitude, consistent with DoDI 3020.41, ''Operational Contract Support (OCS)'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/302041p.pdf?ver=2019-02-25-133949-097*) to allow for selected life, mission, medical, logistics, and administrative support to be provided in certain austere, hostile, and/or non-permissive environments. No changes to the proposed rule were required to address this comment.

Comment: The DoD received a comment regarding the significant delays at deployment processing facilities due to the COVID–19 global pandemic and the impacts of these delays on contractor personnel deployment. The commenter noted significant wait times created staffing shortages on overseas contracts because replacement personnel could not be deployed in a timely manner. The commenter recommended the final rule clarify contracting officers have the authority to modify contracts and permit contractor-performed deployment processing when necessary to maintain continuity of services.

Response: Section 158.5(i)(1) of the rule establishes a process through which the contract can stipulate an alternative, Government-approved deployment/redeployment processing center. No changes to the proposed rule were required to address this comment.

Comment: The DoD received a comment that the proposed rule only differentiated between CAAF and non-CAAF in terms of medical and dental fitness requirements, while the U.S. Central Command medical standard ''Mod 15'' differentiates requirements for U.S. citizen, third country nationals, and local national contractor personnel. The commenter recommended that the final rule defer to any regional medical standards as the governing medical standard.

Response: The rule is purposefully written to provide sufficient latitude for Commanders to make decisions that are in the best interests of all personnel serving in the area of operation. The proposed rule addressed the requirements and procedures for communicating Command-specific policies and requirements to contractor personnel in § 158.5(a) and (b).

Comment: The DoD received one comment related to the requirement for CAAF to complete a post-deployment health assessment in the Defense Medical Surveillance System. The commenter noted that DoDI 6490.03, ''Deployment Health'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/649003p.pdf?ver=2019-06-19-134540-850*) states that post-deployment medical screenings ''are the responsibility of the contractor'' and that, unless contractor personnel re-deploy via a DoD deployment center, contractors may have little or no ability to conduct these medical screenings for personnel who are ending their employment. The commenter recommended that the final rule clarify that contractor personnel cannot be compelled to participate in post-deployment screenings.

Response: This recommendation is addressed in the proposed rule § 158.6(b) by reference to DoD Instruction 6490.03, ''Deployment Health.'' Per DoD Instruction 6490.03, ''all pre-, during-, and post-deployment medical assessments, examinations, treatments, and preventive measures are the responsibility of the contractor unless otherwise stated in the contract.'' Contracts may require post-deployment assessments for the benefit of deploying contractor personnel, and contractors should review the requirements in their contracts for such screenings.

Comment: The DoD received one comment regarding medical waivers. The commenter noted the proposed rule indicates waivers should be submitted through the contracting officer; however, within the U.S. Central Command, requests for waivers can be sent directly to the combatant commander, rather than through the contracting officer. The commenter recommends that the final rule be amended to align with the U.S. Central Command procedures.

Response: The policy described in the rule and the companion DoD Instruction 3020.41, ''Operational Contract Support,'' is meant to be applied broadly across the Military Departments and Combatant Commands. Commanders have the authority to tailor these processes to best meet the unique nature of operations in their areas of operation as stated in § 158.6(a)(2) of the proposed rule.

Changes From the Proposed Rule

Based on public comment and final internal coordination, several substantive changes were made to the rule. This final rule:

(1) broadens the types of operations when this rule applies to contracted support supporting operations beyond contingency operations;

(2) describes and clarifies contractors' responsibilities related to theater admission requirements for their

personnel deploying in support of operations outside the United States;

(3) clarifies contractors' responsibilities to provide personnel who meet specific medical and dental fitness standards;

(4) provides clarity regarding the services the U.S. Government is authorized to provide to contractors; and

(5) removes all internally facing information to promote efficiency and streamline communication with the public.

These changes are explained in detail below.

• Language was added to § 158.4(g) (Policy) during internal coordination to specify that the Under Secretary of Defense for Acquisition and Sustainment will coordinate with the Under Secretary of Defense for Intelligence and Security on requests to waive the requirements of this rule for highly sensitive, classified, cryptologic, or intelligence projects and programs.

• A new paragraph including references regarding policy and reporting procedures on combating trafficking in persons was added to § 158.5(d) as a result of internal coordination.

• Additional language was added to §§ 158.3 and 158.5(e) to support compliance with DoD Directive 2311.01, ''DoD Law of War Program'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/231101p.pdf?ver=2020-07-02-143157-007*) reissued on July 2, 2020.

• To address five GAO recommendations across four reports, GAO–16–105 ''Operational Contract Support: Additional Actions Needed to Manage, Account for, and Vet Defense Contractors in Africa'' (available at *https://www.gao.gov/products/gao-16-105*), GAO–15–243 ''Operational Contract Support: Actions Needed to Enhance the Collection, Integration, and Sharing of Lessons Learned'' (available at *https://www.gao.gov/products/gao-15-243*), GAO–15–250 ''Contingency Contracting: Contractor Personnel Tracking System Needs Better Plans and Guidance'' (available at *https://www.gao.gov/products/gao-15-250*), and GAO–17–428 ''Operational Contract Support: Actions Needed to Enhance Capabilities in the Pacific Region'' (available at *https://www.gao.gov/products/gao-17-428*), to improve the ability to account for and maintain visibility of contractor personnel in contingency and other operations, ensure DoD possesses the capability to collect and report statutorily required information, and clarify responsibilities and procedures, § 158.5(h) was updated to address SPOT–ES minimum reporting requirements, system requirements, and includes references to the SPOT–ES business rules that include area specific requirements.

Expected Impact of the Final Rule

Community Impact. The existing rule provides information relevant to contractors and their personnel who may provide contracted support to the DoD during applicable operations outside the United States. The primary stakeholder populations impacted by this rulemaking are contractor personnel and the companies or organizations that employ these personnel in support of DoD contracts. There are no impacts to State or local governments.

Contractor personnel—Provides information and describes the requirements the DoD imposes on employees of commercial industry partners who may be employed in support of DoD operations conducted outside the United States.

Companies or organizations—Provides information for commercial industry partners to understand how contractor personnel are managed and accounted for and includes deployment requirements necessary to provide support to DoD in applicable operations. A negligible burden reduction to the public may be achieved by the clarifications and increased transparency provided by this revision. Contractors may save time by having increased access to DoD policy requirements and in avoiding unnecessary duplication or providing personnel not suitable or prepared to support applicable operations outside the United States.

A negligible burden reduction to the public may be achieved by the clarifications and increased transparency provided by this revision. Contractors may save time by having increased access to DoD policy requirements and in avoiding unnecessary duplication or providing personnel not suitable or prepared to support applicable operations outside the United States.

The changes implemented by this rule are not expected to alter significantly the baseline burden that was calculated as part of the most recent SPOT–ES system collection, Control Number 0704–0460, approved by the OMB in 2019 in accordance with the Public Law 96–511, ''Paperwork Reduction Act.'' This total burden was calculated to be $1,197,077 annually.

Benefits. Operational contract support, when properly planned for and integrated into operations, can be leveraged to support the Secretary of Defense's objective of restoring military readiness and to close any gaps in fulfilling requirements associated with maintenance, material, intelligence information, or translation services, which can be filled by either short- or long-term commercial capabilities. This rule most significantly improves and refines DoD policy for planning and integrating contracted support in applicable operations. The Department has been working for more than a decade to establish OCS as a core defense capability; one that minimizes risk, increases readiness and flexibility, and improves effectiveness. This rule codifies policy that implements a programmatic approach and improves oversight of contracted support, reducing the likelihood that historical instances of waste, fraud, and abuse will be repeated. This rule furthermore ensures contractors supporting applicable operations are fully prepared to meet the requirements necessary to support operations outside the United States.

TOTAL COSTS FOR NON-GOVERNMENT

Collection instrument (SPOT database)	2016 Approved estimates	2019 Approved estimates
Estimation of Respondent Burden Hours		
Number of Respondents	1670	964.
Number of Responses per Respondent	56	77.
Number of Total Annual Responses	93,520	74,561.
Response Time (Amount of time needed to complete the collection instrument).	.5	.5.

TOTAL COSTS FOR NON-GOVERNMENT—Continued

Collection instrument (SPOT database)	2016 Approved estimates	2019 Approved estimates
Respondent Burden Hours (Total Annual Responses multiplied by Response Time) Please compute these into hours).	46,760	37,291.
Labor Cost of Respondent Burden		
Number of Responses	93,520	74,561 (decrease of 18,959).
Response Time per Response	.5	.5.
Respondent Hourly Wage	$36.00	$32.11 (reduction due to category change).
Labor Burden per Response (Response Time multiplied by Respondent Hourly Wage).	$18.00	$16.06.
Total Labor Burden (Number of Respondents multiplied by Response Time multiplied by Respondent Hourly Wage).	$1,683,360	$1,197,077 (decrease of $486,283).

Regulatory Compliance Analysis

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

These Executive orders direct agencies to assess all costs, benefits, and available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, safety effects, distributive impacts, and equity). These Executive orders emphasize the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated as significant under E.O. 12866.

B. Congressional Review Act (5 U.S.C. 801 et seq.)

Pursuant to the Congressional Review Act, this rule has not been designated a major rule, as defined by 5 U.S.C. 804(2).

C. Public Law 96–354, ''Regulatory Flexibility Act'' (5 U.S.C. 601)

The Under Secretary of Defense for Acquisition and Sustainment certifies that this rule is not subject to the Regulatory Flexibility Act (5 U.S.C. 601) because it would not, if promulgated, have a significant economic impact on a substantial number of small entities. Based on data from the Federal Procurement Data System—Next Generation for contract actions for fiscal year 2019 with a place of performance outside the United States, approximately 15,742 of 2.4 million (or 1 percent), are to small businesses. This amounts to $2,438,406,319 of $36,747,264,771 (or less than 8 percent) of contracts obligated to small businesses worldwide. Therefore, the Regulatory Flexibility Act, as amended, does not require us to prepare a regulatory flexibility analysis.

D. Sec. 202, Public Law 104–4, ''Unfunded Mandates Reform Act''

Section 202 of the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1532) requires agencies to 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. This rule will not mandate any requirements for State, local, or tribal governments, and will not affect private sector costs.

E. Public Law 96–511, ''Paperwork Reduction Act'' (44 U.S.C. Chapter 35)

This rule imposes reporting and recordkeeping requirements under the Paperwork Reduction Act of 1995 under OMB Control Number 0704–0460, *Synchronized Predeployment Operational Tracker-Enterprise Suite (SPOT–ES).* The Department does not anticipate any changes to the cost or burden associated with collection with the publication of this final rule.

The applicable System of Records Notice (SORN) and Privacy Impact Assessments (PIA) are available at *https://www.dmdc.osd.mil/appj/dwp/documents.jsp*) under SORN Identifier DMDC 18 DoD (available at *https://dpcld.defense.gov/Privacy/SORNsIndex/DOD-wide-SORN-Article-View/Article/570569/dmdc-18-dod/*), ''Synchronized Predeployment and Operational Tracker—Enterprise Suite.''

F. Executive Order 13132, ''Federalism''

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 rule will not have a substantial effect on State and local governments.

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

Executive Order 13175 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on one or more Indian Tribes, preempts Tribal law, or effects the distribution of power and responsibilities between the Federal Government and Indian Tribes. This rule will not have a substantial effect on Indian Tribal governments.

List of Subjects in 32 CFR Part 158

Accountability/visibility, Accounting, Armed forces, Combating trafficking in persons, Deployment and redeployment, Government contracts, Medical clearances, Passports and visas, Planning, Security measures, Support to contractors, Transportation.

■ Accordingly, 32 CFR part 158 is revised to read as follows:

PART 158—OPERATIONAL CONTRACT SUPPORT (OCS) OUTSIDE THE UNITED STATES

Sec.

158.1 Purpose.
158.2 Applicability.
158.3 Definitions.
158.4 Policy.
158.5 Procedures.
158.6 Guidance for contractor medical and dental fitness.
Appendix A to Part 158—Related Policies

Authority: Pub. L. 110–181; Pub. L. 110–417.

§ 158.1 Purpose.

This part establishes policy, assigns responsibilities, and provides procedures for operational contract support (OCS), including contract support integration, contracting support,

management, and deployment of defense contractor personnel in applicable operations outside the United States.

§ 158.2 Applicability.

This part applies to contracts and contractor personnel supporting DoD Components operating outside the United States in contingency operations, humanitarian assistance, or peace operations and other activities, including operations and exercises as determined by a Combatant Commander or as directed by the Secretary of Defense.

§ 158.3 Definitions.

Unless otherwise noted, the following terms and their definitions are for the purposes of this part.

Acquisition. The acquiring by contract with appropriated funds of supplies or services (including construction) by and for the use of the Federal Government through purchase or lease, whether the supplies or services are already in existence or must be created, developed, demonstrated, and evaluated. Acquisition begins at the point when agency needs are established and includes the description of requirements to satisfy agency needs, solicitation and selection of sources, award of contracts, contract financing, contract performance, contract administration, and those technical and management functions directly related to the process of fulfilling agency needs by contract.

Applicable operations. Contingency operations, humanitarian assistance, or peace operations conducted outside the United States and other activities, including operations and exercises outside the United States as determined by a combatant commander (CCDR) or as directed by the Secretary of Defense.

Austere environment. Areas where applicable operations may be conducted that are in remote, isolated locations, where access to modern comforts and resources may be limited or non-existent.

Civil augmentation program. External support contracts designed to augment Military Department logistics capabilities with contracted support in both preplanned and short-notice operations.

Contingency contract. A legally binding agreement for supplies, services, and/or construction let by a U.S. Government contracting officer in the operational area, or that has a prescribed area of performance within an operational area.

Contingency operation. A military operation that is either designated by the Secretary of Defense as a contingency operation or becomes a contingency operation as a matter of law as defined in 10 U.S.C. 101(a)(13).

Contract administration. The processes and procedures of contracting, from contract award through closeout, that includes oversight efforts by contracting professionals and designated non-contracting personnel to ensure that supplies, services, and/or construction are delivered and/or performed in accordance with the terms and conditions of the contract.

Contract support integration. The coordination and synchronization of contracted support executed in a designated operational area in support of military operations.

Contracting. Purchasing, renting, leasing, or otherwise obtaining supplies or services from nonfederal sources. Contracting includes description (but not determination) of supplies and services required, selection, and solicitation of sources, preparation and award of contracts, and all phases of contract administration. It does not include making grants or cooperative agreements.

Contracting officer. A person with the authority to enter into, administer, and/or terminate contracts and make related determinations and findings. The term includes certain authorized representatives of the contracting officer acting within the limits of their authority as delegated by the contracting officer. ''Administrative contracting officer (ACO)'' refers to a contracting officer who is administering contracts. ''Termination contracting officer (TCO)'' refers to a contracting officer who is settling terminated contracts. A single contracting officer may be responsible for duties in any or all of these areas.

Contracting Officer's Representative (COR). An individual, including a contracting officer's technical representative (COTR), designated and authorized in writing by the contracting officer to perform specific technical or administrative functions.

Contracting support. The coordination of contracts and execution of contracting authority by a warranted contracting officer that legally binds commercial entities to perform contractual requirements in support of DoD operational requirements.

Contractor management. The oversight and integration of contractor personnel and associated equipment providing support to military operations.

Contractor personnel. Any individual, employed by a firm, corporation, partnership, or association, employed under contract with the DoD to furnish services, supplies, or construction. Contractor personnel may include U.S. citizens and host nation and third country national (TCN) individuals.

Contractor personnel accountability. The process of identifying, capturing, and recording the personally identifiable information and assigned permanent duty location of an individual contractor employee through the use of a designated database.

Contractor personnel visibility. Information on the daily location, movement, status, and identity of contractor personnel.

Contractors Authorized to Accompany the Force (CAAF). Contractor personnel and all tiers of subcontractor personnel authorized to accompany U.S. Armed Forces in applicable operations outside of the United States who have been afforded this status through the issuance of a Letter of Authorization (LOA). CAAF generally include all U.S. citizen and TCN employees not normally residing within the operational area whose area of performance is in the direct vicinity of the U.S. Armed Forces and who are routinely co-located with the U.S. Armed Forces. In some cases, CCDR subordinate commanders may designate mission-essential host nation (HN) or local national (LN) contractor personnel (*e.g.,* interpreters) as CAAF. CAAF includes contractor personnel previously identified as contractors deploying with the force. CAAF status does not apply to contractor personnel within U.S. territory working in support of contingency operations outside the United States.

Defense contractor. Any individual, firm, corporation, partnership, association, or other legal non-Federal entity that enters into a contract directly with the DoD to furnish services, supplies, or construction.

DoD Components. Includes the Office of the Secretary of Defense, the Military Departments, the Office of the Chairman of the Joint Chiefs of Staff (CJCS) and the Joint Staff, the Combatant Commands (CCMDs), the Office of the Inspector General of the Department of Defense, the Defense Agencies, and the DoD Field Activities.

Essential contractor service. A service provided by a firm or an individual under contract to the DoD to support mission-essential functions, such as support of vital systems, including ships owned, leased, or operated in support of military missions or roles at sea; associated support activities, including installation, garrison, and base support services; and similar services provided to foreign military sales customers under the Security Assistance Program. Services are essential if the effectiveness

of defense systems or operations has the potential to be seriously impaired by the interruption of these services, as determined by the appropriate functional commander or civilian equivalent.

Expeditionary Contract Administration (ECA). Contract administration conducted during joint or other expeditionary operations. Formerly known as the Contingency Contract Administrative Services or CCAS.

Expeditionary operations. Activities organized to achieve a specific objective in a foreign country.

External support contracts. Contracts awarded by contracting organizations whose contracting authority does not derive directly from the theater support contracting head(s) of contracting activity or from systems support contracting authorities.

Host nation (HN). A nation that permits, either in writing or through other official provision of consent, government representatives or agencies and/or agencies of another nation to operate, under specified conditions, within its territory.

Hostile environment. Operational environment in which local government forces, whether opposed to or receptive to operations that a unit intends to conduct, do not have control of the territory and population in the intended operational area.

Isolated personnel. U.S. military, DoD civilians, and contractor personnel (and others designated by the President or Secretary of Defense) who are unaccounted for as an individual or a group while supporting an applicable operation and are, or may be, in a situation where they must survive, evade, resist, or escape.

Law of war. The treaties and customary international law binding on the United States that regulate: the resort to armed force; the conduct of hostilities and the protection of war victims in international and non-international armed conflict; belligerent occupation; and the relationships between belligerent, neutral, and non-belligerent States. Sometimes also called the ''law of armed conflict'' or ''international humanitarian law,'' the law of war is specifically intended to address the circumstances of armed conflict. Consult the DoD Law of War Manual (available at *https://dod.defense.gov/Portals/1/Documents/pubs/DoD%20Law%20of%20War%20Manual%20-%20June%202015%20Updated%20Dec%202016.pdf?ver=2016-12-13-172036-190*) for an authoritative statement on the law of war.

Letter of authorization (LOA). A document issued by a contracting officer or his or her designee that authorizes contractor personnel to accompany the force to travel to, from, and within an operational area, and outlines U.S. Government authorized support authorizations within the operational area, as agreed to under the terms and conditions of the contract. For more information, see 48 CFR subpart 225.3.

Local national (LN). An individual who is a permanent resident of the nation in which the United States is conducting operations.

Long-term care. A variety of services that help a person with comfort, personal, or wellness needs. These services assist in the activities of daily living, including such things as bathing and dressing. Sometimes known as custodial care.

Mission-essential functions. Those organizational activities that must be performed under all circumstances to achieve DoD component missions or responsibilities, as determined by the appropriate functional commander or civilian equivalent. Failure to perform or sustain these functions would significantly affect the DoD's ability to provide vital services or exercise authority, direction, and control.

Non-CAAF. Personnel who are not designated as CAAF, such as LN employees and non-LN employees who are permanent residents in the operational area or TCNs not routinely residing with the U.S. Armed Forces (and TCN expatriates who are permanent residents in the operational area), who perform support functions away from the close proximity of, and do not reside with, the U.S. Armed Forces. U.S. Government-furnished support to non-CAAF is typically limited to force protection, emergency medical care, and basic human needs (*e.g.,* bottled water, latrine facilities, security, and food when necessary) when performing their jobs in the direct vicinity of the U.S. Armed Forces.

Operational area. An overarching term encompassing more descriptive terms (such as area of responsibility and joint operations area) for geographic areas where military operations are conducted.

Operational contract support (OCS). The ability to orchestrate and synchronize the provision of integrated contract support and management of contractor personnel providing support to command-directed operations within a designated operational area.

Operationally critical support. A critical source of supply for airlift, sealift, intermodal transportation services, or logistical support that is essential to the mobilization, deployment, or sustainment of the U.S. Armed Forces in applicable operations.

Prime contractor. Any supplier, distributor, vendor, or firm that has entered into a contract with the United States government.

Replacement centers. Centers at selected installations that ensure necessary accountability, training, and processing actions are taken to prepare personnel for onward movement and deployment to a designated operational area.

Requiring activity. A military or other designated supported organization that identifies the need for and receives contracted support to meet mission requirements during military operations.

Subcontractor. Any supplier, distributor, vendor, or firm that furnishes supplies or services to or for a prime contractor or another subcontractor.

Synchronized Predeployment and Operational Tracker-Enterprise Suite (SPOT–ES). A common joint database used to maintain contractor personnel visibility and accountability in applicable operations. References to SPOT–ES in this part will refer to that system or any database system that supersedes it.

Systems support contract. Contracts awarded by Military Service acquisition program management offices that provide fielding support, technical support, maintenance support, and, in some cases, repair parts support, for selected military weapon and support systems.

Theater business clearance. A CCDR policy or process to ensure visibility of and control over systems support and external support contracts executing or delivering support in designated areas of operations.

Theater support contract. A type of contract awarded by contracting officers deployed to an operational area serving under the direct contracting authority of the Military Service component, special operations force command, or designated joint contracting authority for the designated operation.

Total force. The organizations, units, and individuals that comprise the DoD resources for implementing the National Security Strategy. It includes DoD Active and Reserve Component military personnel, military retired members, DoD civilian personnel (including foreign national direct- and indirect-hires, as well as nonappropriated fund employees), contractor personnel, and host-nation support personnel. (For source information, see paragraph (a) of appendix A to this part.)

Uncertain environment. Operational environment in which host government forces, whether opposed to or receptive to operations that a unit intends to conduct, do not have totally effective control of the territory and population in the intended operational area.

§ 158.4 Policy.

It is DoD policy that:

(a) Defense contractor personnel are part of the total force. (See paragraph (a) of appendix A of this part).

(b) DoD Components implement OCS functions, including contract support integration, contracting support, and contractor management, during applicable operations.

(c) DoD Components will use contracted support only in appropriate situations, consistent with 48 CFR subpart 7.5, 48 CFR subpart 207.5, and Office of Federal Procurement Policy (OFPP) Policy Letter 11–01 (available at *https://www.federalregister.gov/documents/2011/09/12/2011-23165/publication-of-the-office-of-federal-procurement-policy-ofpp-policy-letter-11-01-performance-of*), and paragraph (b) of appendix A to this part.

(d) Generally, contractors are responsible for providing their employees with all life, mission, medical, logistics, and administrative support necessary to perform the contract. However, in many operations, especially in those in which conditions are austere, hostile, and/or non-permissive, the decision may be made that it is in the interest of the U.S. Government to allow for selected life, mission, medical, logistics, and administrative support to be provided to contractor personnel to ensure continuation of essential contractor services, consistent with DoD regulations. Contractors authorized to accompany the force (CAAF) may receive U.S. Government-furnished support commensurate with the operational situation in accordance with the terms of the contract.

(e) A common joint database (*i.e.,* the Synchronized Predeployment and Operational Tracker-Enterprise Suite (SPOT–ES) or its successor) will be used to maintain contractor personnel visibility and accountability in applicable operations. References to SPOT–ES in this part will refer to that system or any database system that supersedes it for contractor personnel visibility and accountability.

(f) Solicitations and contracts will:

(1) Require defense contractors to provide personnel who are ready to perform contract duties in applicable operations and environments by verifying the medical, dental, and psychological fitness of their employees and, if applicable, by ensuring currency of any professional qualifications and associated certification requirements needed for employees to perform contractual duties.

(2) Incorporate contractual terms and clauses into the contract that are consistent with applicable host nation (HN) laws and agreements or designated operational area performance considerations.

(g) Contracts for highly sensitive, classified, cryptologic, or intelligence projects and programs must implement this rule to the maximum extent possible, consistent with applicable laws, Executive orders, presidential directives, and relevant DoD issuances. To the extent that contracting activities are unable to comply with this rule, they should submit a request for a waiver to the Under Secretary of Defense for Acquisition and Sustainment (USD(A&S)). Waiver requests should include specific information providing the rationale regarding the inability to comply with this rule. The USD(A&S) will consider these requests in coordination with the Under Secretary of Defense for Intelligence and Security.

§ 158.5 Procedures.

(a) *Planning considerations and requirements; requirements for publication.* CCDRs will make management policies and specific OCS requirements for contractual support available to affected contractor personnel. The Geographic Combatant Commander (GCC) OCS web page will set forth the following:

(1) Theater business clearance (TBC) requirements for contracts currently being performed and delivering contracted support in the CCDR's AOR.

(2) Restrictions imposed by applicable local laws, international law, status of forces agreements (SOFAs), and other agreements with the HN.

(3) CAAF-related deployment requirements, including, but not limited to:

(i) Pre-deployment and required individual protective equipment (IPE) training.

(ii) Physical health standards.

(iii) Immunization and medical requirements.

(iv) Deployment procedures and theater reception.

(4) Reporting requirements for accountability and visibility of contractor personnel and associated contracts.

(5) Operational security (OPSEC) plans and restrictions.

(6) Force protection policies.

(7) Personnel recovery procedures.

(8) Availability of medical and other authorized U.S. Government support (AGS).

(9) Redeployment procedures, including disposition of U.S. Government-furnished equipment.

(b) *Contractual relationships.* The contract provides the only legal basis for the contractual relationship between the DoD and the contractor. The contracting officer is the only individual with the legal authority to enter into such a binding relationship with the contractor.

(1) Commanders have the ability to restrict installation access, and contractor personnel must comply with applicable CCDR and local commander force protection policies. However, military commanders or unit personnel do not have contracting authority over contractors or contractor personnel and may not direct contractors or contractor personnel to perform contractual tasks. Moreover, the contract does not provide a basis for commanders to exercise operational control or tactical control over contractors or their personnel or to assign or attach contractors or their personnel to a command or organization.

(2) The contract must specify:

(i) The terms and conditions under which the contractor is to perform, including minimum acceptable professional and technical standards.

(ii) The method by which the contracting officer will notify the contractor of the deployment procedures to process contractor personnel who are deploying to the operational area.

(iii) The specific contractual support terms and agreement between the contractor and DoD.

(iv) The appropriate flow-down of provisions and clauses to subcontractors and state that the service performed by contractor personnel is not considered to be active duty or active service. For more information, see paragraph (c) in appendix A to this part, and 38 U.S.C. 106, ''Active Duty Service Determinations for Civilian or Contractual Groups.''

(3) The contract must contain applicable clauses to ensure efficient deployment, accountability, visibility, protection, and redeployment of contractor personnel and detail authorized levels of health service, sustainment, and other support that is authorized to be provided to contractor personnel supporting applicable operations outside the United States.

(c) *Restrictions on contractors performing inherently governmental functions.* (1) Paragraph (b) of appendix

A of this part, 48 CFR subpart 7.5, 48 CFR subpart 207.5; Public Law 105–270 and Office of Management and Budget Circular No. A–76 (available at *https://www.whitehouse.gov/sites/whitehouse.gov/files/omb/circulars/A76/a76_incl_tech_correction.pdf*) bar inherently governmental functions and duties from private sector performance.

(2) Contractor personnel may provide support during applicable operations, including, but not limited to:

(i) Transporting munitions and other supplies.

(ii) Providing communications support.

(iii) Performing maintenance functions for military equipment.

(iv) Providing force protection and private security services.

(v) Providing foreign language interpretation and translation services.

(vi) Providing logistics services, such as billeting and messing.

(vii) Intelligence surveillance and reconnaissance support.

(viii) Commercial air assets.

(3) The requiring official will review each service performed by contractor personnel in applicable operations on a case-by-case basis to ensure compliance with paragraph (b) of appendix A of this part and applicable laws and international agreements.

(4) Restrictions on use of contractor personnel for private security services. A contractor may be authorized to provide private security services only if such authorization is consistent with applicable U.S., local, and international law, including applicable agreements with the HN or other applicable international agreements, and 32 CFR part 159. For more information, see paragraph (b) of appendix A of this part and 48 CFR subpart 252.2, which provide specific procedures and guidance.

(d) *Combating trafficking in persons.* Trafficking in persons is a violation of U.S. law and internationally recognized human rights, and is incompatible with DoD core values.

(1) 48 CFR subpart 222.17 and 48 CFR 52.222–50 also known and referred to as Combating Trafficking in Persons, describe how contractors, contracting officers and their representatives, and commanders must deter activities such as prostitution, forced labor, and other related activities contributing to trafficking in persons. For more information, see paragraph (d) of appendix A to this part.

(2) Contracts in support of applicable operations will include terms and provisions that require that the contractor remove personnel from the performance of the contract and return any of its personnel who have been determined to have engaged in any of the activities mentioned in paragraph (h)(4)(v)(H) of this section from the operational area to the home of record, point of origin, or an authorized location at the end of contract performance or sooner as directed by the contracting officer. Once notified of such an incident, the contracting officer will notify the commander responsible in the AOR and provide any information required to support an investigation. For more information, see 48 CFR subpart 222.17 and 48 CFR subpart 42.15.

(e) *Law of war compliance.* Contract work statements for contractors and their subcontractors must comply with the policies in paragraph (gg) of appendix A to this part and require contractors that engage in activities governed by the law of war to implement effective programs to prevent violations of the law of war by their employees and subcontractors, including programs for law of war dissemination and periodic training commensurate with each individual's duties and responsibilities. Paragraph (gg) of appendix A includes, among others, DoD policy that ''[a]ll military and U.S. civilian employees, contractor personnel, and subcontractors assigned to or accompanying a DoD Component must report through their chain of command all reportable incidents, including those involving allegations of non-DoD personnel having violated the law of war.'' Contracts in support of applicable operations must include provisions to require contractor employees to report reportable incidents as defined in paragraph (gg) of appendix A to this part to the appropriate Commander (*e.g.,* the commander of the unit they are accompanying or the installation to which they are assigned) or command-designated office.

(f) *CAAF designation, legal status, credentialing, and security clearance requirements*—(1) *CAAF designation.* (i) CAAF designation is provided to contractor personnel, including all tiers of subcontractor personnel, through a letter of authorization (LOA). CAAF generally include all U.S. citizen and third country national (TCN) employees not normally residing within the operational area whose area of performance is in the direct vicinity of the U.S. Armed Forces and who routinely are co-located with the U.S. Armed Forces, especially in non-permissive environments. Personnel co-located with the U.S. Armed Forces will be afforded CAAF status through an LOA.

(ii) In some cases, CCDRs or subordinate commanders may designate mission-essential HN or LN contractor personnel as CAAF unless otherwise precluded by HN law, a SOFA, or other agreement. In general, LNs are only afforded CAAF status when they assume great personal risk to perform an essential function.

(iii) Personnel who do not receive a CAAF designation are referred to as non-CAAF. Individuals' CAAF status may change depending on where their employers or the provisions of their contract details them to work. CAAF designation may affect, but does not necessarily affect, a person's legal status under the law of war and the treatment to which that person is entitled under the 1949 Geneva Conventions if that person falls into the power of the enemy during international armed conflict. Although CAAF are regarded as ''persons authorized to accompany the armed forces,'' personnel who are not CAAF may also receive this status under the law of war. For more information, see section 4.15 of paragraph (e) of appendix A of this part. In addition, although CAAF designation and access to AGS often coincide, CAAF status does not determine AGS provided.

(2) *Legal status.* In implementing this part, the DoD Component heads must abide by applicable laws, regulations, international agreements, and DoD policy as they relate to contractor personnel performing contractual support in support of applicable operations.

(i) *HN and third country laws.* All contractor personnel must comply with applicable HN and third country laws. The applicability of HN and third country laws may be affected by international agreements (*e.g.,* agreements between the United States and the HN) and customary international law (*e.g.,* limits imposed by customary international law on the reach of third country laws).

(A) The United States, HN, or other countries may hire contractor personnel whose status may change (*e.g.,* from non-CAAF to CAAF) depending on where in the operational AOR their employers or the provisions of their contracts detail them to work.

(B) CCDRs, as well as subordinate commanders, Military Service Component commanders, the Directors of the Defense Agencies, and Directors of DoD Field Activities should recognize limiting factors regarding the employment of LN and TCN personnel. Limiting factors include, but are not limited to:

(*1*) Imported labor worker permits.

(*2*) Workforce and hour restrictions.

(*3*) Medical, life, and disability insurance coverage.

(*4*) Taxes, customs, and duties.
(*5*) Cost of living allowances.
(*6*) Hardship differentials.
(*7*) Access to classified information.
(*8*) Hazardous duty pay.

(ii) *U.S. laws.* U.S. citizens and CAAF, with some exceptions, are subject to U.S. laws and U.S. Government regulations.

(A) All U.S. citizen and TCN CAAF are subject to potential prosecutorial action under the criminal jurisdiction of the United States, including, but not limited to, 18 U.S.C. 3261, also known and referred to in this part as the Military Extraterritorial Jurisdiction Act of 2000 (MEJA). MEJA extends U.S. federal criminal jurisdiction to certain contractor personnel for offenses committed outside U.S. territory.

(B) The March 10, 2008, Secretary of Defense Memorandum states that contractor personnel are subject to prosecution pursuant to 10 U.S.C. Chapter 47, also known and referred to in this part as the Uniform Code of Military Justice (UCMJ), when serving overseas in support of a declared war or contingency, and provides guidance to commanders on the exercise of this UCMJ jurisdiction.

(C) Other U.S. law may allow prosecution of offenses by contractor personnel (*e.g.,* 18 U.S.C. 7).

(3) *1949 Geneva Conventions.* The 1949 Geneva Conventions, including the Geneva Convention Relative to the Treatment of Prisoners of War, may be applicable to certain contractor personnel who fall into the power of the enemy during international armed conflict.

(i) All contractor personnel may be at risk of injury or death incidental to enemy actions while supporting military operations.

(ii) Contractor personnel with CAAF status and other contractor personnel who have been authorized to accompany the U.S. Armed Forces and who are at risk of capture and detention by the enemy as prisoners of war will receive an appropriate identification card required by the Geneva Convention Relative to the Treatment of Prisoners of War, consistent with paragraph (f) of appendix A to this part.

(iii) CAAF may be used in support of applicable operations, consistent with the terms of U.S. Government authorization. If they fall into the power of the enemy during international armed conflict, contractor personnel with CAAF status are entitled to prisoner of war status.

(4) *Credentialing.* Contracts must require CAAF to receive an identification card with the Geneva Convention's category of persons authorized to accompany the armed forces. For more information, see paragraphs (f) through (h) of appendix A to this part. At the time of identification card issuance, CAAF must present their SPOT–ES-generated LOA as proof of eligibility.

(i) Sponsorship must incorporate the processes for confirming eligibility for an identification card. The sponsor is the person affiliated with the DoD or another Federal agency that takes responsibility for verifying and authorizing an applicant's need for a Geneva Convention identification card. A DoD official or employee must sponsor applicants for a common access card (CAC).

(ii) Individuals who have multiple DoD personnel category codes (*e.g.,* an individual who is both a reservist and a contractor) will receive a separate identification card in each personnel category for which they are eligible. Individuals under a single personnel category code may not hold multiple current identification cards of the same form.

(5) *Security clearance requirements.* To the extent necessary, the contract must require the contractor to provide personnel who have the appropriate security clearance or who are able to satisfy the appropriate background investigation requirements to obtain access required to perform contractual requirements in support of the applicable operation.

(g) *Considerations for support to contractors*—(1) *U.S. Government support.* Generally, contracts supporting applicable operations must require contractors to provide to their personnel all life, mission, medical, and administrative support necessary to perform the contractual requirements and meet CCDR guidance posted on the GCC OCS web page. In some operations, especially those in which conditions are austere, uncertain, or non-permissive, the CCDR may decide it is in the U.S. Government's interest for the DoD to allow contractor personnel access, consistent with DoD regulations, to selected AGS. The contract must state the level of access to AGS in its terms and conditions.

(i) In operations where conditions are austere, uncertain, or non-permissive, the contracting officer will consult with the requiring activity to determine if it is in the U.S. Government's interests to allow for selected life, mission, medical, and administrative support to certain contractor personnel.

(ii) The solicitation and contract must specify the level of AGS that the U.S. Government will provide to contractor personnel and what support provided to the contractor personnel is reimbursable to the U.S. Government.

(iii) Access to DoD benefits facilitated by the identification card may be granted to contractors under certain circumstances. For more information, see paragraph (i) of appendix A to this part.

(2) *IPE.* When necessary or directed by the CCDR, the contracting officer will include language in the contract authorizing the issuance of military IPE (*e.g.,* chemical, biological, radiological, nuclear (CBRN) protective ensemble, body armor, ballistic helmet) to contractor personnel as part of AGS.

(i) Typically, IPE will be issued by the central issue facility at the deployment center before deployment to the designated operational area and must be accounted for and returned to the U.S. Government or otherwise accounted for, in accordance with appropriate DoD Component regulations, directives, and instructions.

(ii) Contractor personnel deployment training will include training on the proper care, fitting, and maintenance of protective equipment, whether issued by the U.S. Government or provided by the contractor in accordance with the contractual requirements. This training will include practical exercises within mission-oriented protective posture levels.

(iii) When the terms and conditions of a contract require a contractor to provide IPE, such IPE must meet minimum standards as defined by the contract.

(3) *Clothing.* Contractors, or their personnel, must provide their own personal clothing, including casual and work clothing required to perform the contract requirements.

(i) Generally, CCDRs will not authorize the issuance of military clothing to contractor personnel or will not allow the wearing of military or military look-alike uniforms. Contractor personnel are prohibited from wearing military clothing unless specifically authorized in writing by the CCDR. However, a CCDR or subordinate joint force commander (JFC) deployed forward may authorize contractor personnel to wear standard uniform items for operational reasons. Contracts must include terms and clauses that require that this authorization be provided in writing by the CCDR and that the uniforms are maintained in the possession of authorized contractor personnel at all times.

(ii) When commanders issue any type of standard uniform item to contractor personnel, care must be taken to ensure that contractor personnel are distinguishable from military personnel

through the use of distinctive patches, arm bands, nametags, or headgear, consistent with force protection measures, and that contractor personnel carry the CCDR's written authorization with them at all times.

(4) *Weapons.* Contractor personnel are not authorized to possess or carry firearms or ammunition during applicable operations, except as provided in paragraph (h)(2)(ii) of this section and 32 CFR part 159. The contract will provide the terms and conditions governing the possession of firearms by contractor personnel. Information on all weapons authorized for contractors and their personnel will be entered into the SPOT–ES database.

(5) *Mortuary affairs.* The DoD Mortuary Affairs Program, as described in paragraph (j) of appendix A to this part, covers all CAAF who die while performing contractual requirements in support of the U.S. Armed Forces. Mortuary affairs support and transportation will be provided on a reimbursable basis for the recovery, identification, and disposition of remains and personal effects of CAAF.

(i) Every effort must be made to identify remains and account for un-recovered remains of contractor personnel and their dependents who die in military operations, training accidents, and other incidents. The remains of contractor personnel who die as the result of an incident in support of military operations are afforded the same dignity and respect afforded to remains of service members. For more information, see paragraph (k) of appendix A to this part.

(ii) The DoD may provide mortuary affairs support and transportation on a reimbursable basis for the recovery, identification, and disposition of remains and personal effects of non-CAAF at the request of the Department of State (DOS) and in accordance with this rule, applicable agreements with the HN, and applicable contract provisions. The Under Secretary of Defense for Personnel and Readiness (USD(P&R)) will coordinate this support with the DOS, including for cost reimbursement to the DoD Component for the provision of this support.

(iii) The responsibility for coordinating the transfer of non-CAAF remains to the HN or affected nation resides with the GCC in coordination with the DOS, through the respective embassies, or through the International Committee of the Red Cross, the International Federation of the Red Cross or Red Crescent Societies, as appropriate, and in accordance with applicable contract clauses.

(6) *Medical support and evacuation.* Generally, the DoD will provide only resuscitative care, stabilization, and hospitalization at military medical treatment facilities (MTFs) and assistance with patient movement in emergencies where loss of life, limb, or eyesight could occur. The DoD Foreign Clearance Guide (FCG) and the GCC OCS web pages contain theater-specific contract language to provide contract terms to clarify available healthcare for contractor personnel. During operations in austere, uncertain, or hostile environments, CAAF may encounter situations in which they cannot access adequate medical support in the local area.

(i) All costs associated with the treatment and transportation of contractor personnel to the selected civilian facility are reimbursable to the U.S. Government and are the responsibility of contractor personnel, their employers, or their health insurance providers. For more information, see paragraph (l) of appendix A to this part. Nothing in this paragraph is intended to affect the allowability of costs incurred under a contract.

(ii) Medical support and evacuation procedures:

(A) All CAAF will normally be afforded emergency medical and dental care if injured while supporting applicable operations. Additionally, non-CAAF who are injured while in the vicinity of the U.S. Armed Forces while supporting applicable operations also normally will receive emergency medical and dental care. Emergency medical and dental care includes medical care situations in which life, limb, or eyesight is jeopardized. Examples of emergency medical and dental care include:

(*1*) Examination and initial treatment of victims of sexual assault.

(*2*) Refills of prescriptions for life-dependent drugs.

(*3*) Repair of broken bones, lacerations, and infections.

(*4*) Traumatic injuries to the teeth.

(B) MTFs normally will not authorize or provide primary medical or dental care to CAAF. When required and authorized by the CCDR or subordinate JFC, this support must be specifically authorized under the terms and conditions of the contract and detailed in the corresponding LOA. Primary care is not authorized for non-CAAF. Primary care includes:

(*1*) Routine inpatient and outpatient services.

(*2*) Non-emergency evacuation.

(*3*) Pharmaceutical support (with the exception of emergency refills of prescriptions for life-dependent drugs).

(*4*) Non-emergency dental services.

(*5*) Other medical support, as determined by the CCDR or JFC based on recommendations from the cognizant medical authority and the existing capabilities of the forward-deployed MTFs.

(C) The DoD will not provide long-term care to contractor personnel.

(D) The CCDR or subordinate commander has the authority to quarantine or restrict movement of contractor personnel. For more information, see paragraph (m) of appendix A to this part.

(E) When CAAF are evacuated for medical reasons from the designated operational area to MTFs funded by the Defense Health Program, normal reimbursement policies will apply for services rendered by the facility. If CAAF require medical evacuation outside the United States, the sending MTF staff will assist the CAAF in making arrangements for transfer to a civilian facility of the CAAF's choice. When U.S. forces provide emergency medical care to LN contractor personnel, these patients will use HN transportation means, when possible, for evacuation or transportation to their local medical systems. For more information, see paragraph (n) of appendix A to this part.

(7) *Other AGS.* 48 CFR subpart 225.3 lists types of support that may be authorized for contractor personnel who are deployed with or otherwise provide support to applicable operations, which may include transportation to and within the operational area, mess operations, quarters, phone service, religious support, and laundry.

(i) Contractor personnel of U.S. owned-contractors who are supporting DoD activities may be authorized the use of the military postal service. For more information, see paragraph (o) of appendix A to this part. The extent of postal support will be set forth in the contract. The provisions for postal support in such contracts must be reviewed and approved by the applicable CCDR, or the designated representative, and the Military Department concerned before execution of the contract.

(ii) Morale, welfare, and recreation and exchange services are authorized for contractor personnel who are U.S. citizens supporting DoD activities outside the United States. For more information, see paragraphs (p) and (q) of appendix A to this part.

(h) *Accountability and visibility of contracts and contractor personnel.* (1)

During applicable operations, contractors will use SPOT–ES as follows:

(i) All CAAF will register in SPOT–ES by name.

(ii) Non-CAAF will be registered in SPOT–ES by name if they are performing on a DoD contract for at least 30 consecutive days unless a lesser number of days is requested by the CCDR or if they require access to a U.S. or coalition-controlled installation. Contracting officers will ensure non-CAAF who require access to U.S. or coalition-controlled installations are registered in SPOT–ES before requesting or receiving installation access.

(iii) All private security contractor personnel and all other contractor personnel authorized to carry weapons, regardless of the length of the performance or contract value, will register in SPOT–ES by name.

(iv) During operations other than contingency operations, humanitarian assistance, or peace operations, contractors will use SPOT–ES in situations required by the CCDR and as follows:

(2) To account for:

(i) All U.S. citizen and TCN contractor personnel.

(ii) All private security contractor personnel and all other contractor personnel authorized to carry weapons, where the designated area and place of performance are outside the United States, regardless of the length of performance or contract value.

(3) The contracting officer will account for an estimated total number of LNs employed under the contract, by country or on a monthly basis.

(4) Contract linguists will register in SPOT–ES in the same manner as other contractor personnel and will also be tracked using the Contract Linguist Enterprise-wide Database. For more information, see paragraph (r) of appendix A to this part.

(5) LNs should be registered in SPOT–ES by name to improve data quality and reduce confusion during a transition to accountability requirements during a contingency operation, which will require by-name accountability.

(6) The DoD has designated SPOT–ES as the joint web-based database to assist the CCDRs in maintaining awareness of the nature, extent, and potential risks and capabilities associated with contracted support for contingency operations, humanitarian assistance, and peacekeeping operations, or military exercises designated by the CCDR. To facilitate integration of contractors and other personnel, as directed by the USD(A&S) or the CCDR, and to ensure the accurate forecasting and provision of accountability, visibility, force protection, medical support, personnel recovery, and other related support, the following procedures will help establish, maintain, and validate the accuracy of information in the database.

(i) SPOT–ES will:

(A) Serve as the central repository for deployment status and reporting on the contractor personnel as well as other U.S. Government agency contractor personnel, as applicable. For additional information, see paragraph (s) of appendix A to this part.

(B) Track information for all DoD contracts that are awarded in support of applicable operations outside of the United States, in accordance with the SPOT Business Rules and as directed by the USD(A&S), 48 CFR subpart 225.3, or the CCDR. SPOT–ES will collect and report on:

(*1*) The total number of contractor personnel working under contracts entered into as of the end of each calendar quarter.

(*2*) The total number of contractor personnel performing security functions under contracts entered into with the DoD.

(*3*) The total number of contractor personnel killed or wounded who were performing under any contracts entered into with the DoD.

(C) Provide personnel accountability via unique identifier (*e.g.,* Electronic Data Interchange Personnel Identifier or Foreign Identification Number) of contractor personnel and other personnel, as directed by the USD(A&S), 48 CFR subpart 225.3, or the CCDR.

(D) Contain, or link to, minimum contract information necessary to:

(*1*) Establish and maintain accountability of the personnel in paragraph (g) of this section.

(*2*) Maintain information on specific equipment related to the performance of private security contracts.

(*3*) Maintain oversight information on the contracted support in applicable operations.

(E) Comply with:

(*1*) The personnel identity protection program requirements found in paragraphs (t) and (u) of appendix A to this part.

(*2*) The DoD Information Enterprise architecture. For more information, see paragraph (v) of appendix A to this part.

(*3*) The interoperability and secure sharing of information requirements found in paragraphs (w) through (y) of appendix A to this part.

(ii) Before registering in SPOT–ES, contracting officers, company administrators, and U.S. Government administrators or authorities must meet minimum training requirements in the SPOT Business Rules.

(iii) The contractor must enter all required data into SPOT–ES before its employees may deploy to or enter a theater of operations, and maintain such data, as directed by the USD(A&S), 48 CFR subpart 225.3, or the CCDR.

(iv) The contracting officer will enter the DoD contract services or capabilities for all contracts that are awarded in support of applicable operations, including theater support, external support, and systems support contracts, into SPOT–ES consistent with 48 CFR 252.225–7040.

(v) In accordance with applicable acquisition policy and regulations and under the terms and conditions of each affected contract, all contractors awarded contracts that support applicable operations must input employee data and maintain accountability, by name, of designated contractor personnel in SPOT–ES as required by 48 CFR 252.225–7040.

(A) Contractors must maintain current status of the daily location of their employees and, when requested, submit to the COR up-to-date, real-time information reflecting all personnel deployed or to be deployed in support of applicable operations.

(B) Prime contractors must enter up-to-date information regarding their subcontractors at all tiers into SPOT–ES.

(vi) In all cases, users providing classified information in response to the requirements of this part must report and maintain that information on systems approved for the level of classification of the information provided.

(7) The contracting officer or his or her designee will ensure a SPOT–ES-generated LOA has been issued to all CAAF who are approved to deploy, as required by 48 CFR 252.225–7040, and selected non-CAAF (*e.g.,* LN and non-LN employees who are permanent residents in the operational area, or TCNs not routinely residing with the U.S. Armed Forces who perform support functions away from the close proximity of, and do not reside with, the U.S. Armed Forces, and private security contractors), pursuant to 48 CFR subpart 225.3, or as otherwise designated by the CCDR.

(i) The contract will require that all contractor personnel issued an LOA carry the LOA with them at all times.

(ii) [Reserved].

(i) *Theater admission requirements.* Special area, country, and theater personnel clearance documents must be current, in accordance with the DoD FCG, and coordinated with affected agencies to ensure that entry

requirements do not adversely affect accomplishment of mission requirements.

(1) CAAF employed in support of DoD missions are considered DoD-sponsored personnel for DoD FCG purposes.

(2) Contracting officers must ensure contracts include a requirement for contractor personnel to meet theater personnel clearance requirements and obtain personnel clearances through the Aircraft and Personnel Automated Clearance System before entering a designated theater of operations. For more information, see paragraph (z) of appendix A to this part.

(3) Contracts must require contractor personnel to obtain proper identification credentials, such as passports, visas, and other documents required to enter and exit a designated operational area, and have a required Geneva Conventions identification card, or other appropriate DoD credential from the deploying center.

(j) *Deployment procedures.* Contracts must contain terms and conditions that detail the need for contractors to follow these credentialing requirements, as required by 48 CFR subpart 225.3, 48 CFR 252.225–7040, and as outlined in the DoD FCG. At a minimum, contracting officers must ensure that contracts address operational area-specific contract requirements and the means by which the DoD will inform contractor personnel of the requirements and procedures applicable to their deployment.

(1) *Deployment center designation.* A formally designated group, joint, or Military Department deployment center will be used to conduct deployment and redeployment processing for CAAF, unless contractor-performed theater admission preparation is authorized or waived by the CCDR or designee pursuant to DoDI 3020.41, ''Operational Contract Support (OCS).'' If the contract contains clauses that specify another U.S. Government-authorized process that incorporates all the functions of a deployment center, such process may also be used by a contractor to conduct deployment and redeployment processing for CAAF.

(2) *Medical preparation.* (i) In accordance with § 158.6, contracts must require that contractors provide medically and physically qualified contractor personnel to perform duties in applicable operations, as outlined in the contract.

(A) Any CAAF deemed unsuitable to deploy during the deployment process due to medical or dental reasons will not be authorized to deploy.

(B) The Secretary of Defense may direct immunizations as mandatory for CAAF performing essential contractor services.

(C) For contracts that employ CAAF who are U.S. citizens, the contract must require that contractors make available the medical and dental records of deploying employees who authorize release for this purpose based on this section, applicable cognizant medical authority guidance, and relevant Military Department policy. These records should include current panographic x-rays. For more information, see paragraph (aa) of appendix A to this part.

(ii) U.S. Government personnel may not involuntarily immunize contractor personnel or require contractor personnel to involuntarily disclose their medical records. Therefore, the contracting officer will provide contractors time to notify and/or hire employees who voluntarily consent to U.S. Government medical requirements, including to receiving U.S. Government-required immunizations and disclosing their private medical information to the U.S. Government.

(iii) All CAAF will receive medical threat pre-deployment briefings at the deployment center to communicate health risks and countermeasures in the designated operational area. For more information, see paragraph (bb) of appendix A to this part.

(A) In accordance with GCC or JFC plans and orders, contracts must include terms and conditions that fully specify health readiness and force health protection capability, either as a responsibility of the contractor or the DoD Components, to ensure appropriate medical staffing in the operational area.

(B) Health surveillance activities must include plans for CAAF. For more information, see paragraphs (bb) and (cc) of appendix A to this part. Section 158.6 of this rule further addresses deoxyribonucleic acid (DNA) collection and other medical requirements.

(3) *Training.* Joint training policy and guidance applies to both members of the Military Services and contractor personnel. For more information, see paragraph (dd) of appendix A to this part. CCDRs will place standing training requirements on the GCC OCS web pages for reference by contractors. Other training requirements that are specific to an applicable operation will be placed on the GCC OCS web pages shortly after identifying the requirement so that contracting officers can incorporate the training requirement into the appropriate contracts as soon as possible. Training requirements:

(i) Must be included, or incorporated by reference, in contracts employing contractor personnel supporting applicable operations.

(ii) Include specific requirements established by the CCDR and training required in accordance with this rule, 32 CFR part 159, and paragraphs (ee) through (hh) of appendix A to this part.

(4) *Deployment center procedures.* Affected contracts must require that all CAAF deploying from outside the operational area process through a designated deployment center or a U.S. Government-authorized, contractor-performed deployment processing facility before deploying to an applicable operation and redeploy in the same manner. Upon receiving the contracted company's certification that employees meet deployability requirements, the contracting officer or representative will digitally sign the LOA, which CAAF will then present to officials at the deployment center. The deployment process includes, but is not limited to:

(i) Verifying registration in SPOT–ES.

(ii) Issuing applicable U.S. Government-furnished equipment.

(iii) Verifying the completion of medical and dental screening before arrival.

(iv) Administering required theater-specific immunizations and medications not available through healthcare providers in the general public.

(v) Verifying and, when necessary, providing required training, country and cultural awareness briefings, and other training and briefings, as required by the CCDR. Examples of required training include, but are not limited to:

(A) Law of war, including the 1949 Geneva Conventions and DoD policy to implement the law of war.

(B) Law and policy applicable to detainee operations and intelligence interrogation operations, as appropriate.

(C) General orders.

(D) Standards of conduct.

(E) Force protection.

(F) Personnel recovery.

(G) First aid.

(H) Combating trafficking in persons.

(I) OPSEC.

(J) Anti-terrorism.

(K) Counterintelligence reporting.

(L) The use of CBRN protective ensemble.

(M) Deployment health threats briefing.

(5) *Certification.* Contracts supporting applicable operations must include terms and conditions requiring contractors to certify to the authorized U.S. Government representative, before deployment, that each individual has completed all required deployment processing actions.

(6) *Legal.* Contractor personnel are not entitled to military legal assistance in-

theater or at the deployment center. Individual contractor personnel must have their personal legal affairs in order (*e.g.,* preparing and completing powers of attorney, wills, trusts, and estate plans) before reporting to deployment centers.

(7) *Waivers.* For required contracted support of 17 days or less in an operational area, the CCDR or designee may waive a portion of the formal procedural requirements pursuant to DoDI 3020.41, ''Operational Contract Support (OCS),'' which may include the CCDR or designee waiving the requirement in writing for processing through a deployment center. However, the CCDR or designee may not waive the requirements to possess proper identification cards and to establish and maintain accountability for all contractor personnel, or any medical requirement without the prior approval of the cognizant medical authority or their designee. If a contract authorizes contractor personnel to be armed, the requirements of paragraphs (c)(4) and (k)(2) of this section may not be waived.

(k) *Reception*—(1) *Designated reception site.* In applicable operations, all CAAF must enter into the operational area through a designated reception site.

(i) Based upon a visual inspection of the LOA, the site will verify that contractor personnel are entered in SPOT–ES and meet theater-specific entry requirements.

(ii) Contractor personnel already in the designated operational area when a contingency is declared must report to the designated reception site as soon as it is operational based on the terms and conditions of the contract.

(iii) When entering a designated reception site for theater entry processing, if any CAAF does not have the proper documentation to perform in an area, he or she will be refused entry into the theater, and the contracting officer will notify the contractor to take the necessary action to resolve the issue. Should the contractor fail to take action, the CAAF individual will be sent back to his or her departure point, or directed to report to the Military Service Component command or Defense Agency responsible for that specific contract, for theater entrance processing.

(2) *Contractor integration.* It is critical that CAAF brought into an operational area are properly integrated into the military operation through a formal reception process. At a minimum, they will:

(i) Meet theater entry requirements and be authorized to enter the theater.

(ii) Be accounted for in SPOT–ES.

(iii) Possess any required IPE, including CBRN protective ensemble.

(iv) Be authorized any contractually required AGS and force protection.

(l) *In-theater management*—(1) *Conduct and discipline.* Contract terms and conditions must require that CAAF comply with CCDR theater orders, applicable directives, laws, and regulations. Non-CAAF who require base access to perform contractual requirements must follow base force protection and security-related procedures, as applicable.

(i) The contracting officer may appoint a designee (usually a COR) as a liaison between the contracting officer and the contractor and requiring activity. This designee monitors and reports contractor performance and requiring activity concerns to the contracting officer. In emergency situations (*e.g.,* enemy or terrorist actions or natural disaster), the cognizant military commander may recommend or issue warnings or messages urging contractor personnel to take emergency actions to remove themselves from harm's way or to take other appropriate self-protective measures. During armed conflict, contractor personnel are not exempt from the authority that commanders may exercise to control the movement of persons and vehicles within the immediate vicinity of operations. For more information, see sections 5.2.2.1, 13.8, and 14.6 of paragraph (e) of appendix A to this part.

(ii) The contractor is responsible for disciplining contractor personnel, as necessary and appropriate. However, in accordance with 48 CFR 252.225–7040(h)(1), the contracting officer may direct the contractor, at its own expense, to remove and replace any contractor personnel who jeopardize or interfere with mission accomplishment, who threaten force protection measures, or who fail to comply with or violate applicable requirements of the contract. Such action may:

(A) Include contractor personnel whose actual field performance (certification or professional standard) is below the contractual requirement.

(B) Be taken at U.S. Government discretion without prejudice to the contractor's rights under any other provision of the contract. A commander also has the authority to take certain actions affecting contractor personnel, such as the ability to revoke or suspend security access or impose restrictions from access to military installations or specific worksites.

(iii) CAAF, or individuals employed by or accompanying the Military Services outside the United States, are subject to potential prosecutorial action under the criminal jurisdiction of the United States, pursuant to sections 7, 2441, 2442, or 3261 of Title 18, U.S.C., or other provisions of U.S. law, including the UCMJ.

(A) Commanders possess significant authority to act whenever criminal acts are committed by anyone subject to the MEJA and UCMJ that relates to or affects the commander's responsibilities. This includes situations in which the alleged offender's precise identity or actual affiliation is undetermined. The March 10, 2008, Secretary of Defense Memorandum provides guidance to commanders on the exercise of this UCMJ jurisdiction over DoD contractor personnel serving with or accompanying the U.S. Armed Forces overseas during declared war and in contingency operations.

(B) Contracting officers will ensure that contractors are aware of their employees' status and liabilities as CAAF and the required training associated with this status.

(C) CCDRs retain authority to respond to an incident, restore safety and order, investigate, apprehend suspected offenders, and otherwise address the immediate needs of the situation.

(iv) The Department of Justice may prosecute misconduct under applicable Federal laws, including MEJA and 18 U.S.C. 2441. Contractor personnel also are normally subject to the domestic criminal law of the local country. When confronted with disciplinary problems involving contractor personnel, commanders should seek the assistance of their legal staff, the contracting officer responsible for the contract, and the contractor's management team.

(v) In the event of an investigation of reported offenses allegedly committed by or against contractor personnel, appropriate investigative authorities will keep the contracting officer informed, to the extent possible without compromising the investigation, if the alleged offense has a potential contract performance implication.

(2) *Force protection and weapons issuance.* CCDRs must include contractor personnel in their force protection planning and communicate the results to contracting activities and contractors via the GCC OCS web page. In general, contractors are responsible for the security of their own personnel. Contractor personnel working within a U.S. military facility or in close proximity to the U.S. Armed Forces may receive incidentally the benefits of measures taken to protect the U.S. Armed Forces. For more information, see paragraph (ee) of appendix A to this part. However, where additional

security is needed to achieve force protection, and it is not operationally or cost effective for contractors to do so individually, the commander may determine it is in the interests of the U.S. Government to provide security for contractor personnel. When security is provided through military means, contractor personnel should receive a level of force protection equal to that of DoD civilian employees.

(i) When the CCDR deems military force protection and legitimate civil authority are unavailable or insufficient, he or she may authorize, in writing, contractor personnel to be armed for self-defense purposes only. In authorizing contractor personnel to be armed, the contractor, the armed contractor personnel, and the U.S. military must adhere to:

(A) Applicable U.S., HN, and international law;

(B) Relevant SOFAs and other agreements;

(C) Other arrangements with local authorities; and

(D) The rules for the use of force, and guidance and orders regarding the possession, use, safety, accountability of weapons and ammunition that are issued by the CCDR.

(ii) Depending on the operational situation and the specific circumstances of contractor personnel, the contractor may apply for its personnel to be armed for self-defense purposes on a case-by-case basis. The appropriate Staff Judge Advocate (or their designee) to the CCDR will review all applications to ensure there is a legal basis for approval. In reviewing applications, CCDRs will apply the criteria mandated for arming contractor personnel for private security services consistent with 32 CFR part 159.

(A) In such cases, the contractor will validate to the contracting officer, or designee, that the contractor personnel have received weapons familiarization, qualification, and briefings regarding the rules for the use of force, in accordance with CCDR policies.

(B) Acceptance of weapons by contractor personnel is voluntary. In accordance with paragraph (j) of 48 CFR 252.225–7040, the contract must require contractors to ensure that applicable U.S. law does not prohibit personnel from possessing firearms.

(C) Contracts must require all contractor personnel to comply with applicable CCDR and local commander force protection policies. When armed for personal protection, the contract may only authorize contractor personnel to use force for self-defense and must require contractors to ensure that U.S. law does not prohibit its personnel from possessing firearms, in accordance with 48 CFR 252.225–7040(j). Unless not subject to local laws or HN jurisdiction by virtue of an international agreement or customary international law, the contract must include terms and conditions setting forth that the inappropriate use of force could subject contractor personnel to U.S. and/or local or HN prosecution and civil liability.

(3) *Personnel recovery, missing persons, and casualty reporting.* (i) The DoD personnel recovery program applies to all CAAF regardless of their citizenship. For more information, see paragraph (ii) of appendix A to this part. If a CAAF individual becomes isolated or unaccounted for, the contractor must promptly file a search and rescue incident report to the theater's personnel recovery architecture (*e.g.,* the component personnel recovery coordination cell or the CCMD joint personnel recovery center).

(ii) Upon recovery following an isolating event, a CAAF returnee must enter the first of the three phases of reintegration. For more information, see paragraph (jj) of appendix A to this part. The contractor must offer the additional phases of reintegration to the returnee to ensure his or her physical and psychological well-being while adjusting to the post-captivity environment.

(iii) The contractor must report all CAAF and non-CAAF casualties. For more information, see paragraph (s) of appendix A to this part.

(m) *Redeployment procedures.* The considerations in this section apply during the redeployment of CAAF. At the end of the performance period of a contract, or in cases of early redeployment, CAAF must complete the redeployment process to adjust AGS requirements and turn in U.S. Government-provided equipment.

(1) *Preparation for redeployment.* CAAF must complete intelligence out-briefs and customs and immigration briefings and inspections in accordance with CCDR policy and applicable HN law. CAAF are subject to customs and immigration processing procedures at all designated stops and their final destination during their redeployment. CAAF returning to the United States are subject to U.S. reentry customs requirements in effect at the time of reentry.

(2) *Transportation out of theater.* The terms and conditions of the contract will state whether the U.S. Government will provide transportation out of theater.

(i) Upon completion of the deployment or other authorized release, the U.S. Government must provide contractor personnel transportation from the theater of operations to the location from which they deployed, in accordance with each individual's LOA and unless otherwise directed. If commercial transportation is not available, it should be stated in the LOA in accordance with paragraph (l) of appendix A to this part. CAAF are also required to depart from the operational area through the designated reception site.

(ii) Before redeployment, the contractor personnel, through his or her contractor, will coordinate exit times and transportation with the continental U.S. replacement center or designated reception site.

(3) *Redeployment center procedures.* In most instances, the deployment center or site that prepared the CAAF for deployment will serve as the return processing center. As part of CAAF redeployment processing, the designated reception site personnel will screen contractor records, recover U.S. Government-issued identification cards and equipment, and conduct debriefings, as appropriate. The returning CAAF will spend the minimum amount of time possible at the return processing center in order to complete the necessary administrative procedures.

(i) Contractor personnel must return all U.S. Government-issued identification and access badges (*e.g.,* badges, key cards, and other access devices, including CACs).

(ii) Contractor personnel must return any issued clothing and equipment and report any lost, damaged, or destroyed clothing and equipment in accordance with procedures of the issuing facility. Contractor personnel also will receive a post-deployment medical briefing on signs and symptoms of potential diseases (*e.g.,* tuberculosis (TB)). As some countries hosting an intermediate staging base may not permit certain items to enter their territory, certain clothing and equipment, whether issued by the contractor, purchased by the employee, or provided by the DoD, may not be permitted to be removed from the AOR. In this case, CCDR or JFC guidance and contract terms and conditions will provide alternate methods of accounting for U.S. Government-issued equipment and clothing.

(4) *Update to SPOT–ES.* Contracting officers or their designated representatives must verify that contractors have updated SPOT–ES to reflect their employee's change in status within three days of a contractor employee's redeployment, close out the

deployment, and collect or revoke the LOA.

(5) *Transportation to home destination.* Transportation of CAAF from the deployment center or site to their home destinations is the employer's responsibility.

§ 158.6 Guidance for contractor medical and dental fitness.

(a) *General.* (1) DoD contracts requiring the deployment of CAAF must include medical and dental fitness standards as specified in this section. Under the terms and conditions of their contracts, contractors will employ personnel who meet such medical and dental fitness standards. With respect to contractor personnel covered by the Rehabilitation Act of 1973, as amended, 29 U.S.C. 791, *et seq.* or the Americans with Disabilities Act of 1990, as amended, 29 U.S.C. 12101, *et seq.,* these medical and dental fitness standards do not alter the legal obligations of DoD Components and contractors (as employers). Replacement of non-medically qualified contractor personnel already deployed to theater will be at the contractor's cost.

(2) The GCC concerned will establish force health protection policies and programs for the protection of all forces assigned or attached to the command in accordance with applicable force health protection (FHP) requirements and medical and dental fitness standards in order to promote and sustain a healthy and ready force. For more information, see paragraph (kk) of appendix A to this part. The GCC concerned will establish a process for reviewing requests for exceptions to such requirements, on an individualized basis, and will ensure that a mechanism is in place to appropriately maintain records related to all approved and denied waivers, including any medical records.

(3) The GCC concerned will ensure that medical fitness processes and procedures, to include those pertaining to removal of contractor personnel from the theater who are no longer medically qualified, at the contractor's expense, are posted on the GCC OCS web page. Contracting officers will incorporate the language concerning these processes and procedures into clauses for all contracts for performance in the AOR.

(4) Unless otherwise stated in the contract terms and conditions, all medical evaluations and treatment are the contractor's responsibility.

(b) *Medical and dental evaluations.* (1) All CAAF deploying in support of an applicable operation are subject to medical and dental fitness standards pursuant to paragraph (kk) of appendix A to this part and CCDR guidance. Fitness standards pertain to the individual's ability to accomplish the tasks and duties unique to a particular operation and the ability to tolerate the environmental and operational conditions of the deployed location.

(2) All CAAF must undergo a screening medical and dental assessment within 12 months before arrival at the designated deployment center or U.S. Government-authorized contractor-performed deployment processing facility. This screening assessment, conducted by the contractor's medical health provider, should emphasize diagnosing system disease conditions (*e.g.,* cardiovascular, pulmonary, orthopedic, neurologic, endocrinologic, dermatologic, psychological, visual, auditory, dental) that may preclude the CAAF from performing the functional requirements of the contract, especially in the austere work environments encountered in some applicable operations.

(3) CAAF will receive a health threat and countermeasures briefing from the applicable Military Service before deployment to the operational area. For more information, see paragraph (bb) of appendix A to this part.

(4) CAAF whose initial screening assessment or subsequent medical evaluation identifies any of the medical conditions listed in paragraph (j) of this section or identifies a requirement for extensive preventive dental case (see paragraph (j)(2)(xxv) of this section) are considered ''not medically fit'' for deployment unless their deployment is approved by a waiver.

(5) Individuals who are deemed ''not medically fit,'' including those whose request for a waiver has been denied, following an individual assessment by a licensed medical provider are not authorized to deploy.

(6) Non-CAAF shall be medically screened by a U.S. Government designee when required by the requiring activity and the contract, for the class of labor under consideration (*e.g.,* LNs working in a dining facility).

(7) Contracts will require contractors to replace individuals who develop conditions that cause them to become medically unqualified to perform contractual requirements at any time during contract performance.

(8) Contracts will require that CAAF complete a post-deployment health assessment in the Defense Medical Surveillance System at the end of their deployment or within 30 days of redeployment. For more information, see paragraph (bb) of appendix A to this part.

(c) *Glasses and contact lenses.* (1) If contractor personnel require vision correction, they must have two pairs of glasses, and if applicable, eyeglass inserts for a chemical protective mask. The contractor personnel may also provide a written prescription to the supporting military medical component in order to prepare eyeglass inserts for use in a compatible chemical protective mask. If the type of protective mask to be issued is known and time permits, the military medical component should attempt to complete the preparation of eyeglass inserts before deployment.

(2) Wearing contact lenses in a field environment is not recommended and is at the contractor personnel's own risk due to the potential for irreversible eye damage caused by debris, chemical or other hazards present, and the lack of ophthalmologic care in a field environment.

(d) *Medications.* Other than those force health protection prescription products provided by the U.S. Government to CAAF and selected non-CAAF, contracts must require that contractor personnel deploy with a minimum 90-day supply of any required medications obtained at their own expense. For more information, see paragraph (bb) of appendix A to this part.

(1) Contractor personnel must be informed that deployed medical units are equipped and staffed to provide emergency care to healthy adults and are unable to provide or replace many medications required for routine treatment of chronic medical conditions, such as high blood pressure, heart conditions, and arthritis.

(2) The contract must require contractor personnel to review both the amount of the medication and its suitability in the foreign area with their personal physician and make any necessary adjustments before deploying. The contract must also hold the contractor personnel responsible for the re-supply of required medications.

(e) *Comfort items.* The contract must require that contractor personnel take spare hearing-aid batteries, sunglasses, insect repellent, sunscreen, and any other supplies related to their individual physical requirements. DoD sources will not provide these items.

(f) *Immunizations.* A list of immunizations, including those required for entry into the designated area of operations and those recommended by medical authorities, will be produced by the cognizant medical authority for each deployment; posted to the GCC OCS web page and DoD FCG; and incorporated in contracts for performance in the designated AOR.

(1) The GCC, upon the recommendation of the cognizant

medical authority, will provide contractor personnel who are deploying to the applicable theater of operation a list of the immunizations necessary to protect against the communicable diseases assessed to be a potential hazard in the applicable theater. The cognizant medical authority will prepare and maintain this list.

(2) The contract must require that CAAF complete any mandatory immunizations, subject to any legally required exemptions, to complete the pre-deployment process.

(3) During pre-deployment processing, the DoD will provide contractor personnel, at no cost to the contractor, any theater-specific immunizations and medications not available to the general public. Contractor personnel must obtain all other immunizations before arrival at the deployment center, documented on the International Certificate of Vaccinations of Prophylaxis as approved by the World Health Organization or the Department of Health and Human Services Centers for Disease Control and Prevention Form 731. However, the contract must stipulate that CAAF and selected non-CAAF obtain all other necessary immunizations before their arrival at the deployment center. The TB skin test is required for all contractor personnel within three months before they are deployed.

(4) The DoD will provide theater-specific medical supplies and force health protection prescription products to CAAF and selected non-CAAF. Additionally, these personnel will receive deployment medication information sheets for all vaccines or deployment-related medications that are to be dispensed or administered.

(5) Contractors will ensure that individuals with a positive TB skin test be evaluated for targeted diagnosis and treatment of latent TB infection in accordance with the procedures outlined in the World Health Organization Guidelines on the Management of Latent Tuberculosis Infection.

(6) The contract must stipulate that CAAF and selected non-CAAF bring a current copy of the International Certificate of Vaccination or Prophylaxis to the pre-deployment processing center and to the operational area.

(g) *Human Immunodeficiency Virus (HIV) Testing.* HIV testing is not mandatory for contractor personnel unless specified by the GCC CCDR or by host nation requirements. HIV testing, if required, must occur within one year before deployment.

(h) *Armed Forces Repository of Specimen Samples for the Identification of Remains (AFRSSIR).* For identification of remains purposes, contractors whose CAAF members are U.S. citizens will obtain a dental panograph and will forward a specimen sample suitable for DNA analysis to, and ensure it is on file with, the AFRSSIR before or during deployment processing and recorded in SPOT–ES. The DoD Components must ensure that all contracts require CAAF who are U.S. citizens to provide DNA specimen samples for AFRSSIR as a condition of deployment. For more information, see paragraph (ll) of appendix A to this part.

(1) All CAAF who are U.S. citizens processing through a deployment center will have a DNA specimen sample collected and forwarded to the AFRSSIR for storage. Contracts must require contractors to verify in SPOT–ES or its successor that AFRSSIR has received the DNA specimen sample or that the contractor has collected the DNA specimen sample.

(2) If CAAF who are U.S. citizens do not process through a deployment center, or the contractor is authorized to process its own personnel, the contract must require that the contractor collect and forward DNA specimen samples for all contractor personnel who are deployed as CAAF to the AFRSSIR. Regardless of what specimen collection and storage arrangements are made, all contractors deploying CAAF who are U.S. citizens must provide the CAAF's name and Social Security number, location of the DNA specimen sample, facility contact information, and retrieval plan to AFRSSIR. If the AFRSSIR is not used and a CAAF who is a U.S. citizen becomes a casualty, the contractor must be able to retrieve identification media for use by the Armed Forces Medical Examiner (AFME) or other competent authority to conduct a medical-legal investigation of the incident and identification of the victim or victims. These records must be retrievable within 24 hours for forwarding to the AFME when there is a reported incident that would necessitate their use for identifying human remains. The contractor shall have access to the location of its employees' fingerprint, medical, and dental records, including panographs.

(3) AFRSSIR is responsible for implementing special rules and procedures to ensure the protection of privacy interests in regards to the specimen samples and any DNA analysis of those samples. Specimen samples shall only be used for the purposes outlined in paragraph (ll) of appendix A to this part.

(i) *Waivers related to medical and dental fitness standards.* Based on an individualized assessment, waivers may be appropriate for contractor personnel who have potentially disqualifying medical conditions if, with or without a reasonable accommodation:

(1) The condition is not of such a nature it is likely to have a medically grave outcome or a negative impact on mission execution if it unexpectedly worsens.

(2) The condition is stable and reasonably anticipated by the medical evaluator not to worsen during the deployment under contractor-provided medical care in-theater in light of the physical, physiological, psychological, environmental, and nutritional effects of the duties and location.

(3) Any required ongoing health care or medications must be available or accessible to contractor personnel, independent of the military health system, and not be subject to special handling, storage, or other requirements (*e.g.,* refrigeration requirements and/or cold chain, electrical power requirements) that cannot be met in the specific theater of operations.

(4) The condition does not and is not anticipated to require duty limitations that would preclude performance of contractual requirements or to require accommodation by the DoD component or requiring activity. When necessary, the cognizant medical authority (or delegated representative) is the appropriate authority to evaluate the suitability of an individual's limitations in theater.

(5) There is no need for routine out-of-theater evacuation for continuing diagnostics or other evaluations.

(j) *Conditions usually precluding medical clearance.* This section is not intended to be comprehensive. A list of all possible diagnoses would be too expansive to list in this part. These are minimum requirements. Contractor personnel may have additional medical clearance requirements based on their occupation and local laws. It is the responsibility of the contractor to ensure that its employees' medical clearances comply with any applicable local occupation-specific medical requirements.

(1) In general, the conditions in paragraph (b) of this section, based on an individual assessment pursuant to paragraph (bb) of appendix A to this part, are disqualifying. The medical evaluator will carefully consider whether climate; altitude; the nature of available food and housing available; the nature of medical, behavioral health, and dental services; or other environmental or operational factors

may prove hazardous to the deploying person's heath because of a known physical or mental condition.

(2) Medical clearance for deployment of persons with any of the conditions in this section may be granted by the contracting officer only after consultation with and approval of a waiver by the appropriate cognizant medical authority on behalf of the CCDR. The cognizant medical authority makes recommendations and serves as the CCDR's advisor on conditions precluding the medial clearance of deploying personnel; however, the CCDR is the final approval or disapproval authority except as provided in paragraph (k)(3) of this section. The cognizant medical authority or designated representative may determine if adequate treatment facilities and specialist support are available at the duty station for:

(i) Physical or psychological conditions resulting in the inability to wear IPE effectively, if wearing IPE may be reasonably anticipated or required in the deployed location.

(ii) Conditions that prevent safe administration of applicable immunizations, prescription products, or other health protection measures, including atropine, epinephrine, and/or 2-pam chloride auto-injectors, certain antimicrobials, antimalarials, and/or pyridostigmine bromide.

(iii) Any chronic medical conditions that require frequent clinical visits, fail to respond to adequate conservative treatment, or necessitate significant limitation of physical activity.

(iv) Any medical conditions that require durable medical equipment or appliances or periodic evaluation or treatment by medical specialists not readily available in theater (*e.g.,* Continuous Positive Airway Pressure (CPAP) machine for sleep apnea).

(v) Any unresolved acute or chronic illness or injuries that would impair duty performance in a deployed environment during the duration of the deployment.

(vi) Active TB or known blood-borne diseases that may be transmitted to others in a deployed environment. (For HIV infections, see paragraph (j)(2)(xvii) of this section.)

(vii) An acute exacerbation of a physical or mental health condition that could affect duty performance.

(viii) Recurrent loss of consciousness for any reason.

(ix) Any medical condition that could result in sudden incapacitation including a history of stroke within the last 24 months, seizure disorders, and diabetes mellitus type I or II, treated with insulin or oral hypoglycemic agents.

(x) Hypertension not controlled with medication or that requires frequent monitoring to achieve control.

(xi) Pregnancy.

(xii) Cancers for which individuals are receiving continuing treatment or that require periodic specialty medical evaluations during the anticipated duration of the deployment.

(xiii) Precancerous lesions that have not been treated or evaluated and that require treatment or evaluation during the anticipated duration of the deployment.

(xiv) Any medical conditions that require surgery or for which surgery has been performed that requires rehabilitation or additional surgery to remove devices.

(xv) Asthma that has a Forced Expiratory Volume-1 (FEV–1) of less than or equal to 50 percent of predicted FEV–1 despite appropriate therapy, that has required hospitalization at least two times in the last 12 months, or that requires daily systemic oral or injectable steroids.

(xvi) Any musculoskeletal conditions that significantly impair performance of duties in a deployed environment.

(xvii) HIV antibody positive with the presence of progressive clinical illness or immunological deficiencies. The contracting officer should consult the cognizant medical authority in all instances of HIV seropositivity before medical clearance for deployment.

(xviii) Hearing loss. The requirement for use of a hearing aid does not necessarily preclude deployment. However, the individual must have sufficient unaided hearing to perform duties safely.

(xix) Loss of vision. Best corrected visual acuity must meet job requirements to perform duties safely.

(xx) Symptomatic coronary artery disease.

(xxi) History of myocardial infarction within one year of deployment.

(xxii) History of coronary artery bypass graft, coronary artery angioplasty, carotid endarterectomy, other arterial stenting, or aneurysm repair within one year of deployment.

(xxiii) Cardiac dysrhythmias or arrhythmias, either symptomatic or requiring medical or electrophysiologic control, such as the presence of an implanted defibrillator and/or pacemaker.

(xxiv) Heart failure.

(xxv) Individuals without a dental exam within the last 12 months or who are likely to require dental treatment or reevaluation for oral conditions that are likely to result in dental emergencies within 12 months.

(xxvi) Psychotic and/or bipolar disorders. For detailed guidance on deployment-limiting psychiatric conditions or psychotropic medications, see paragraph (mm) of appendix A to this part.

(xxvii) Psychiatric disorders under treatment with fewer than three months of demonstrated stability.

(xxviii) Clinical psychiatric disorders with residual symptoms that impair duty performance.

(xxix) Mental health conditions that pose a substantial risk for deterioration or recurrence of impairing symptoms in the deployed environment.

(xxx) Chronic medical conditions that require ongoing treatment with antipsychotics, lithium, or anticonvulsants.

(k) *Exceptions to medical standards (waivers).* If a contractor believes an individual CAAF with one of the conditions listed in paragraphs (j)(2)(i) through (xxx) of this section can, with or without reasonable accommodation, accomplish the essential duties of his or her tasks and duties and tolerate the environmental and operational conditions of the deployed location, the contractor may request a waiver for that individual through the contracting officer, using the process and procedures established by the GCC.

(1) Contractors will include a summary of a detailed medical evaluation or consultation concerning the medical condition or conditions in the requests for waivers. Since maximization of mission accomplishment and the protection of the health of personnel are the ultimate goals, justification for the waiver will include:

(i) Statement indicating the CAAF individual's qualifications and experience.

(ii) The position the CAAF individual will occupy and the nature and scope of contractual duties assigned.

(iii) Any known specific hazards of the position.

(iv) Anticipated availability and need for care while deployed.

(2) Waivers to deploy or permit continued service in a deployed environment by persons with any of the conditions in paragraphs (j)(2)(i) through (xxx) of this section require an individualized assessment and a recommendation from a cognizant medical authority. The GCC, or designee, is the final decision authority for medical waiver requests, except as provided in paragraph (k)(3) of this section.

(3) For CAAF individuals working with Special Operations Forces personnel, the Theater Special

Operations Command Commander is the final decision authority for medical waiver requests.

Appendix A to Part 158—Related Policies

The Operational Contract Support Outside the United States Program is supported by the following policies:

(a) DoD Directive 5124.02, ''Under Secretary of Defense for Personnel and Readiness (USD(P&R))'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/512402p.pdf*).

(b) DoD Instruction 1100.22, ''Policy and Procedures for Determining Workforce Mix'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/110022p.pdf*).

(c) DoD Directive 1000.20, ''Active Duty Service Determinations for Civilian or Contractual Groups'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/100020p.pdf*).

(d) DoD Instruction 2200.01, ''Combating Trafficking in Persons (CTIP)'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/220001p.pdf*).

(e) DoD Law of War Manual (June 2015, Updated Dec. 2016) (available at *https://dod.defense.gov/Portals/1/Documents/pubs/DoD%20Law%20of%20War%20Manual%20-%20June%202015%20Updated%20Dec%202016.pdf?ver=2016-12-13-172036-190*).

(f) DoD Instruction 1000.01, ''Identification (ID) Cards Required by the Geneva Conventions'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/100001p.pdf*).

(g) DoD Instruction 1000.13, ''Identification (ID) Cards for Members of the Uniformed Services, Their Dependents, and Other Eligible Individuals'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/100013p.pdf*).

(h) DoD Manual 1000.13, ''DoD Identification (ID) Cards: ID Card Life-Cycle'' Volume 1 (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodm/100013_vol1.pdf*).

(i) DoD Manual 1000.13, ''DoD Identification (ID) Cards: ID Card Life-Cycle'', Volume 2 (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodm/100013_vol2.pdf*).

(j) DoD Directive 1300.22, ''Mortuary Affairs Policy'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/130022p.pdf*).

(k) DoD Instruction 1300.18, ''Department of Defense (DoD) Personnel Casualty Matters, Policies, and Procedures'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/130018p.pdf*).

(l) DoD Instruction 4515.13, ''Air Transportation Eligibility'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/451513p.PDF*).

(m) DoD Instruction 6200.03, ''Public Health Emergency Management (PHEM) within the DoD'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/620003p.pdf*).

(n) DoD Instruction 6000.11, ''Patient Movement (PM)'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/600011p.pdf*).

(o) DoD Instruction 4525.09, ''Military Postal Service'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/452509p.pdf*).

(p) DoD Instruction 1015.10, ''Military Morale, Welfare, and Recreation (MWR) Programs'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/101510p.pdf*).

(q) DoD Instruction 1330.21, ''Armed Services Exchange Regulations'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/133021p.pdf*).

(r) DoD Directive 5160.41E, ''Defense Language, Regional Expertise, and Culture (LREC) Program'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/516041Ep.pdf*).

(s) Synchronized Predeployment and Operational Tracker (SPOT) Business Rules (available at *https://www.acq.osd.mil/log/LOG_CSD/spot.html*).

(t) DoD 5400.11–R, ''Department of Defense Privacy Program'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodm/540011r.pdf*).

(u) DoD Manual 6025.18, ''Implementation of the Health Insurance Portability and Accountability Act (HIPPA) Privacy Rule in DoD Health Care Programs'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodm/602518m.pdf*).

(v) DoD Directive 8000.01, ''Management of the Department of Defense Information Enterprise (DoD IE)'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/800001p.pdf*).

(w) DoD Instruction 8320.02, ''Sharing Data, Information, and Information Technology (IT) Services in the Department of Defense'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/832002p.pdf*).

(x) DoD Instruction 8330.01, ''Interoperability of Information Technology, Including National Security Systems'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/833001p.pdf*).

(y) DoD Instruction 8500.01, ''Cybersecurity'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/850001_2014.pdf*).

(z) DoD Directive 4500.54E, ''DoD Foreign Clearance Program'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/450054E.pdf*).

(aa) DoD Directive 6485.02E, ''DoD Human Immunodeficiency Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS) Prevention Program (DHAPP) to Support Foreign Militaries'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/648502E.pdf*).

(bb) DoD Instruction 6490.03, ''Deployment Health'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/649003p.pdf*).

(cc) DoD Directive 6490.02E, ''Comprehensive Health Surveillance'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/649002Ep.pdf*).

(dd) CJCS Instruction 3500.01J, ''Joint Training Policy for the Armed Forces of the United States'' (available at *https://www.jcs.mil/Portals/36/Documents/Library/Instructions/CJCSI%203500.01J.pdf?ver=_ah_rbO2yB6Uw6QbvzC8pw%3d%3d*).

(ee) DoD Instruction 2000.12, ''DoD Antiterrorism (AT) Program'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/200012p.pdf*).

(ff) DoD Directive 2310.01E, ''DoD Detainee Program'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/231001e.pdf*).

(gg) DoD Directive 2311.01, ''DoD Law of War Program'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/231101p.pdf?ver=2020-07-02-143157-007*).

(hh) DoD Directive 3115.09, ''DoD Intelligence Interrogations, Detainee Debriefings, and Tactical Questioning'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/311509p.pdf*).

(ii) DoD Directive 3002.01, ''Personnel Recovery in the Department of Defense'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/300201p.pdf*).

(jj) DoD Instruction 3002.03, ''DoD Personnel Recovery—Reintegration of Recovered Personnel'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/300203p.pdf*).

(kk) DoD Directive 6200.04, ''Force Health Protection (FHP)'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodd/620004p.pdf*).

(ll) DoD Instruction 5154.30, ''Armed Forces Medical Examiner System (AFMES) Operations'' (available at *https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/515430p.pdf*).

(mm) Assistant Secretary of Defense for Health Affairs Memorandum, Clinical Practice Guidance for Deployment-Limiting Mental Disorders and Psychotropic Medications'' October 7, 2013 (available at *https://health.mil/Reference-Center/Policies?query=deployment&isDateRange=0&broadVector=000&newsVector=00000000&refVector=0000000000100000&refSrc=1.*

Dated: April 25, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2022–0596; FRL–10910–01–OCSPP]

Poly (oxy-1,2-ethanediyl), α,α′-[[[4-[2-(4-methyl-2-benzothiazolyl)diazenyl] phenyl]imino]di-2,1-ethanediyl]bis[ω-hydroxy- in Pesticide Formulations; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of poly (oxy-1,2-ethanediyl), α,α′-[[[4-[2-(4-methyl-2-benzothiazolyl)diazenyl] phenyl]imino]di-2,1-ethanediyl]bis[ω-hydroxy- (CAS Reg. No. 158172–12–4), herein referred to as polymeric red, when used as an inert ingredient (colorant) on growing crops and raw agricultural commodities pre- and post-harvest. Milliken Chemical submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of polymeric red, when used in accordance with the terms of the exemption.

DATES: This regulation is effective May 1, 2023. Objections and requests for hearings must be received on or before June 30, 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–2022–0596, 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) 566–2427; 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 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–2022–0596 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 June 30, 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–2022–0596, 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#express.*

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

II. Petition for Exemption

In the **Federal Register** of August 30, 2022 (87 FR 52868) (FRL–9410–04), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (PP IN–11672) by Milliken Chemical, 920 Milliken Road, M–209, Spartanburg, South Carolina 29303. The petition requested that 40 CFR 180.910 be amended by establishing an exemption from the requirement of a tolerance for residues of polymeric red (CAS Reg. No. 158172–12–4) when used as an inert ingredient (colorant) in pesticide formulations applied to growing crops or raw agricultural commodities pre- and post-harvest. That document referenced a summary of the petition prepared by Milliken Chemical, which is available in the docket, *https://www.regulations.gov.* A comment was received on the notice of filing. EPA's response to the comment is discussed in Unit V.B.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not

intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for 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(c)(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. When making a safety determination for an exemption from the requirement of a tolerance, FFDCA section 408(c)(2)(B) directs EPA to take into account the considerations in section 408(b)(2)(C) and (D). 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. . . .'' Section 408(b)(2)(D) lists other factors for EPA's consideration in making safety determinations, *e.g.,* the validity, completeness, and reliability of available data, nature of toxic effects, available information concerning the cumulative effects of the pesticide chemical and other substances with a common mechanism of toxicity, and available information concerning aggregate exposure levels to the pesticide chemical and other related substances, among other factors.

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no harm to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), 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 polymeric red, including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with polymeric red follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by polymeric red as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Polymeric red exhibits low levels of acute toxicity via the oral route of exposure. Based on physical and chemical properties, it is not expected to be of concern via the acute dermal and inhalation routes of exposure. It is not a skin or eye irritant and it is not expected to be a dermal sensitizer. No adverse effects were reported in the combined 28-day oral with reproduction/developmental toxicity screening study in rats. No adverse maternal, reproduction or offspring effects were found in this study. No oral chronic or carcinogenicity studies are available for review, and structural alerts for potential carcinogenicity due to the formation of aromatic amines were identified. However, the concern is low for carcinogenicity based on negative results in a modified Ames test designed to identify mutagenicity due to the formation of aromatic amines, and the lack of toxicity in the available studies. No evidence of neurotoxicity or immunotoxicity was seen in the database.

B. Toxicological Points of Departure/ Levels of Concern

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

The hazard profile of polymeric red is adequately defined. Overall, polymeric red is of low acute, subchronic, and developmental toxicity. No systemic toxicity is observed up to 1,000 mg/kg/day. Since signs of toxicity were not observed, no toxicological endpoints of concern or PODs were identified. Therefore, a qualitative risk assessment for polymeric red can be performed.

C. Exposure Assessment

1. *Dietary exposure.* In evaluating dietary exposure to polymeric red, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from polymeric red in food and drinking water as follows:

Dietary exposure (food and drinking water) to polymeric red may occur following ingestion of drinking water or foods with residues of this chemical from their use in accordance with this exemption. However, a quantitative dietary exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

2. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables).

Polymeric red may be present in pesticide products that may be used in and around the home. However, a quantitative residential exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

3. *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.''

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

D. Additional Safety Factor for the Protection of Infants and Children

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

Based on an assessment of polymeric red, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children. Because there are no threshold effects associated with polymeric red, EPA conducted a qualitative assessment. As part of that assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

E. Aggregate Risks and Determination of Safety

Because no toxicological endpoints of concern were identified, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to polymeric red residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. Response to Comment

EPA received one comment in response to the notice of filing. The comment concerns pesticide use generally and advocates for ''natural'' alternatives to chemicals. While the Agency recognizes that some people oppose the use of chemicals in or on food commodities, the FFDCA allows EPA to establish tolerances and exemptions for residues of pesticides in or on food as long as the Agency can determine they are safe. The Agency has evaluated the aggregate exposures of polymeric red and has determined that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to polymeric red residues. The commenter has provided no information to support a conclusion that the exemption from the requirement of a tolerance is not safe.

VI. Conclusions

Therefore, an exemption from the requirement of a tolerance is established for residues of poly (oxy-1,2-ethanediyl), α,α′-[[[4-[2-(4-methyl-2-benzothiazolyl)diazenyl] phenyl]imino]di-2,1-ethanediyl]bis[ω-hydroxy- (CAS Reg. No. 158172–12–4) when used as an inert ingredient (colorant) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest under 40 CFR 180.910.

VII. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance 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 exemption 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).

VIII. 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: April 25, 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 § 180.910, amend table 1 to 180.910 by adding, in alphabetical order, an entry for ''Poly (oxy-1,2-ethanediyl), α,α′-[[[4-[2-(4-methyl-2-benzothiazolyl)diazenyl] phenyl]imino]di-2,1-ethanediyl]bis[ω-hydroxy- (CAS Reg. No. 158172–12–4)'' to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

* * * * *

TABLE 1 TO 180.910

Inert ingredients	Limits	Uses
* * * * *	*	*
Poly (oxy-1,2-ethanediyl), α,α′-[[[4-[2-(4-methyl-2-benzothiazolyl)diazenyl]phenyl]imino]di-2,1-ethanediyl]bis[ω-hydroxy- (CAS Reg. No. 158172–12–4).	.....	Colorant.
* * * * *	*	*

[FR Doc. 2023–09121 Filed 4–28–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2021–0273, EPA–HQ–OPP–2022–0841 and EPA–HQ–OPP–2022–0844; FRL–10877–01–OCSPP]

Starch, 1-Octenylbutanedioate, Aluminum Salt; Dextrin, Hydrogen 1-Octenylbutanedioate; and Amylopectin, 2-Hydroxypropyl Ether, Acid-; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of starch, 1-octenylbutanedioate, aluminum salt; dextrin, hydrogen 1-octenylbutanedioate; and amylopectin, 2-hydroxypropyl ether, acid- when used as inert ingredients (for seed treatment only) in pesticide formulations applied pre-harvest. Ingredion Incorporated submitted petitions to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of exemptions from the requirement of a tolerance. This regulation eliminates the need to establish maximum permissible levels for residues of starch, 1-octenylbutanedioate, aluminum salt; dextrin, hydrogen 1-octenylbutanedioate; and amylopectin, 2-hydroxypropyl ether, acid- when used in accordance with the terms of the exemptions.

DATES: This regulation is effective May 1, 2023. Objections and requests for hearings must be received on or before June 30, 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 dockets for these actions, identified by docket identification (ID) numbers EPA–HQ–OPP–2021–0273, EPA–HQ–OPP–2022–0841 and EPA–HQ–OPP–2022–0844, are 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 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 numbers EPA–HQ–OPP–2021–0273, EPA–HQ–OPP–2022–0841 and EPA–HQ–OPP–2022–0844 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 June 30, 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 numbers EPA–HQ–OPP–2021–0273, EPA–HQ–OPP–2022–0841 and EPA–HQ–OPP–2022–0844, 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. Petitions for Exemption

In the **Federal Register** of June 1, 2021 (86 FR 29229) (FRL–10023–95), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of pesticide petition PP IN–11458 by Ingredion Incorporated, 5 Westbrook Corporate Center, Westchester, IL 60154. The petition requested that 40 CFR 180.920 be amended by establishing an exemption from the requirement of a tolerance for residues of starch, 1-octenylbutanedioate, aluminum salt (CAS Reg. No. 9087–61–0) when used as an inert ingredient in pesticide formulations applied ''in or on raw agricultural commodities pre-harvest and as a seed treatment.'' A summary of the petition prepared by Ingredion Incorporated is available in the docket at *https://www.regulations.gov*. Ingredion Incorporated subsequently clarified that the word ''and'' should not have been included in the request and that they were requesting an exemption under 40 CFR 180.920 for seed treatment use only. Therefore, a use pattern limitation for seed treatment use is being established for this exemption.

In the **Federal Register** of November 17, 2022 (87 FR 68959) (FRL–9410–07–OCSPP), EPA issued documents pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of pesticide petitions PP IN–11699 and PP IN–11715 by Ingredion Incorporated, 5 Westbrook Corporate Center, Westchester, IL 60154. The petitions requested that 40 CFR 180.920 be amended by establishing exemptions from the requirement of a tolerance for residues of dextrin, hydrogen 1-octenylbutanedioate (CAS Reg. No. 68070–94–0) and amylopectin, 2-hydroxypropyl ether, acid- (CAS Reg. No. 2756130–86–4) when used as inert ingredients (for seed treatment only) in pesticide formulations applied pre-harvest. Summaries of the petitions prepared by Ingredion Incorporated are available in the dockets at *https://www.regulations.gov*.

There were no comments received in response to the notices of filing.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for 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(c)(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. When making a safety determination for an exemption from the requirement of a tolerance, FFDCA section 408(c)(2)(B) directs EPA to account for the considerations in section 408(b)(2)(C) and (D). 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 an exemption 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. . . .'' Section 408(b)(2)(D) lists other factors for EPA's consideration in making safety determinations, *e.g.,* the validity, completeness, and reliability of available data, nature of toxic effects, available information concerning the cumulative effects of the pesticide chemical and other substances with a common mechanism of toxicity, and available information concerning aggregate exposure levels to the pesticide chemical and other related substances, among other factors.

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no harm to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients,

the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of these actions. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for starch, 1-octenylbutanedioate, aluminum salt; dextrin, hydrogen 1-octenylbutanedioate; and amylopectin, 2-hydroxypropyl ether, acid-, including exposure resulting from the exemptions established by this action. EPA's assessment of exposures and risks associated with starch, 1-octenylbutanedioate, aluminum salt; dextrin, hydrogen 1-octenylbutanedioate; and amylopectin, 2-hydroxypropyl ether, acid- follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by starch, 1-octenylbutanedioate, aluminum salt; dextrin, hydrogen 1-octenylbutanedioate; and amylopectin, 2-hydroxypropyl ether, acid- as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

The toxicological database for starch, 1-octenylbutanedioate, aluminum salt; dextrin, hydrogen 1-octenylbutanedioate; and amylopectin, 2-hydroxypropyl ether, acid-, all of which are modified starches, is supported by data regarding amylopectin, acid-hydrolyzed, 1-octenylbutanedioate (CAS Reg. No. 113894–85–2); amylopectin, hydrogen 1-octadecenylbutanedioate (CAS Reg. No. 125109–81–1); and 2-hydroxypropyl starch (CAS Reg. No. 9049–76–7), which are three other modified starches previously reviewed by the Agency. EPA has determined that it is appropriate to bridge amylopectin, acid-hydrolyzed, 1-octenylbutanedioate; amylopectin, hydrogen 1-octadecenylbutanedioate; and 2-hydroxypropyl starch data to assess starch, 1-octenylbutanedioate, aluminum salt; dextrin, hydrogen 1-octenylbutanedioate; and amylopectin, 2-hydroxypropyl ether, acid- due to similarities in the manufacturing processes, functional groups/structure, composition, and physical/chemical properties of these modified starches.

In acute studies, the oral lethal dose, LD_{50} of the modified starches was > 7,000 milligrams/kilogram (mg/kg). Various modified starches were tested in repeat dose studies, and no toxicity was observed at doses as high as 9,000 mg/kg/day. No fetal, parental, or reproductive toxicity was seen in any of the multi-generational reproduction toxicity studies at dietary levels up to 62% (*i.e.,* 31,000 mg/kg/day).

B. Toxicological Points of Departure/Levels of Concern

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

The hazard profile of these modified starches is adequately defined. Overall, they show low acute, subchronic, and developmental toxicity. No systemic toxicity is observed up to the limit dose of 1,000 mg/kg/day and as high as 31,000 mg/kg/day. Since signs of toxicity were not observed, no toxicological endpoints of concern or PODs were identified. Therefore, a qualitative risk assessment for starch, 1-octenylbutanedioate, aluminum salt; dextrin, hydrogen 1-octenylbutanedioate; and amylopectin, 2-hydroxypropyl ether, acid- can be performed.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to starch, 1-octenylbutanedioate, aluminum salt; dextrin, hydrogen 1-octenylbutanedioate; and amylopectin, 2-hydroxypropyl ether, acid-, EPA considered exposure under the proposed exemptions from the requirement of a tolerance and from existing uses. EPA assessed dietary exposures from starch, 1-octenylbutanedioate, aluminum salt; dextrin, hydrogen 1-octenylbutanedioate; and amylopectin, 2-hydroxypropyl ether, acid- in food as follows:

Modified food starches are approved (21 CFR 172.892) by the U.S. Food and Drug Administration (FDA) as food additives and are used in a wide range of food products. In addition, dietary (food and drinking water) exposure is possible from the use of modified starches when used as food use inert ingredients in pesticide products. However, a quantitative dietary exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

2. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, tables). Starch, 1-octenylbutanedioate, aluminum salt; dextrin, hydrogen 1-octenylbutanedioate; and amylopectin, 2-hydroxypropyl ether, acid- are not currently proposed for pesticide residential uses; however, future uses may include uses in and around the home. Residential exposure is also possible from the use of modified starches in non-pesticidal products such as cosmetics. However, a quantitative residential exposure assessment was not conducted since a toxicological

endpoint for risk assessment was not identified.

3. *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.'' Based on the lack of toxicity in the available database, EPA has not found starch, 1-octenylbutanedioate, aluminum salt; dextrin, hydrogen 1-octenylbutanedioate; and amylopectin, 2-hydroxypropyl ether, acid- to share a common mechanism of toxicity with any other substances, and these modified starches do not appear to produce a toxic metabolite produced by other substances. For the purposes of these tolerance exemptions, therefore, EPA has assumed that starch, 1-octenylbutanedioate, aluminum salt; dextrin, hydrogen 1-octenylbutanedioate; and amylopectin, 2-hydroxypropyl ether, acid- do not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides.*

D. Additional Safety Factor for the Protection of Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act safety factor. In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor. Based on an assessment of starch, 1-octenylbutanedioate, aluminum salt; dextrin, hydrogen 1-octenylbutanedioate; and amylopectin, 2-hydroxypropyl ether, acid-, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children. Because there are no threshold effects associated with these chemicals, EPA conducted a qualitative assessment. As part of that assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children.

E. Aggregate Risks and Determination of Safety

Because no toxicological endpoints of concern were identified, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children, from aggregate exposure to starch, 1-octenylbutanedioate, aluminum salt; dextrin, hydrogen 1-octenylbutanedioate; and amylopectin, 2-hydroxypropyl ether, acid- residues.

V. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing exemptions from the requirement of a tolerance without any numerical limitation.

VI. Conclusions

Therefore, exemptions from the requirement of a tolerance are established for residues of starch, 1-octenylbutanedioate, aluminum salt (CAS Reg. No. 9087–61–0); dextrin, hydrogen 1-octenylbutanedioate (CAS Reg. No. 68070–94–0); and amylopectin, 2-hydroxypropyl ether, acid- (CAS Reg. No. 2756130–86–4) when used as inert ingredients (for seed treatment only) in pesticide formulations applied pre-harvest under 40 CFR 180.920.

VII. Statutory and Executive Order Reviews

This action establishes exemptions from the requirement of a tolerance 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 exemptions 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).

VIII. 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: April 25, 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 § 180.920, amend table 1 to the section by adding, in alphabetical order, entries for ''Amylopectin, 2-hydroxypropyl ether, acid- (CAS Reg. No. 2756130–86–4)''; ''Dextrin, hydrogen 1-octenylbutanedioate (CAS Reg. No. 68070–94–0)''; and ''Starch, 1-octenylbutanedioate, aluminum salt (CAS Reg. No. 9087–61–0)'' to read as follows:

§ 180.920 Inert ingredients used pre-harvest; exemptions from the requirement of a tolerance.

* * * * *

TABLE 1 TO 180.920

Inert ingredients	Limits	Uses
* * *	* *	* *
Amylopectin, 2-hydroxypropyl ether, acid- (CAS Reg. No. 2756130–86–4).	For seed treatment use only	Binder, carrier, film-former.
* * *	* *	* *
Dextrin, hydrogen 1-octenylbutanedioate (CAS Reg. No. 68070–94–0)	For seed treatment use only	Binder, carrier, film-former.
* * *	* *	* *
Starch, 1-octenylbutanedioate, aluminum salt (CAS Reg. No. 9087–61–0).	For seed treatment use only	Flow aid, flow enhancer, anti-caking agent
* * *	* *	* *

[FR Doc. 2023–09090 Filed 4–28–23; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 230425–0113]

RTID 0648–XC579

Magnuson-Stevens Act Provisions; Fisheries of the Northeastern United States; Northeast Multispecies Fishery; Approval of 2023 and 2024 Sector Operations Plans and Allocation of 2023 Northeast Multispecies Annual Catch Entitlements

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

ACTION: Final rule.

SUMMARY: This final rule approves sector operations plans and contracts, including 18 regulatory exemptions for fishing years 2023 and 2024. This final rule also allocates Northeast multispecies annual catch entitlements to approved groundfish sectors for fishing year 2023; this includes default specifications for nine stocks. This action is intended to allow limited access permit holders to continue to operate sectors, as authorized under the Northeast Multispecies Fishery Management Plan, and to exempt sectors from certain effort control regulations to improve the efficiency and economics of sector vessels. Approval of sector operations plans and contracts is necessary to allocate annual catch entitlements to the sectors in order for sectors to operate.

DATES: Sector operations plans and regulatory exemptions are effective May 1, 2023, through April 30, 2025. Northeast multispecies annual catch entitlements for sectors are effective May 1, 2023, through April 30, 2024. Default catch limits are effective May 1, 2023, through October 31, 2023, or until the final rule for Framework 65 is implemented, if that final rule is implemented prior to October 31, 2023. If Framework 65 is not implemented on or before October 31, 2023, all fishing for these stocks would be prohibited beginning November 1, 2023.

ADDRESSES: Copies of each sector's operations plan and contract are available from the NMFS Greater Atlantic Regional Fisheries Office (GARFO): Contact Samantha Tolken at *Samantha.Tolken@noaa.gov.* These documents are also accessible via the GARFO website. To view these documents and the **Federal Register** documents referenced in this rule, you can visit: *https://www.fisheries.noaa.gov/management-plan/northeast-multispecies-management-plan.*

FOR FURTHER INFORMATION CONTACT: Samantha Tolken, Fishery Management Specialist, (978) 675–2176.

SUPPLEMENTARY INFORMATION:

Background

The Northeast Multispecies Fishery Management Plan (FMP) defines a sector as a group of persons holding limited access Northeast multispecies permits that has voluntarily entered into a contract and agree to certain fishing restrictions for a specified period of time, and that has been granted a portion of the total allowable catch (TAC) in order to achieve objectives consistent with applicable FMP goals and objectives. A sector must be comprised of at least three Northeast multispecies permits issued to at least three different persons, none of whom have any common ownership interest in the permits, vessels, or businesses associated with the permits issued to the other two or more persons in that sector. Sectors are self-selecting, meaning each sector can choose its members.

The Northeast multispecies sector management system allocates a portion of the Northeast multispecies stocks to each sector. These annual sector allocations are known as annual catch entitlements (ACE) and are based on the collective fishing history of a sector's members. Sectors may receive

allocations of large-mesh Northeast multispecies stocks with the exception of Atlantic halibut, windowpane flounder, Atlantic wolffish, and ocean pout, which are non-allocated species managed under separate effort controls. ACEs are portions of a stock's annual catch limit (ACL) available to commercial Northeast multispecies vessels. A sector determines how to harvest its ACE.

Because sectors elect to receive an allocation under a quota-based system, the FMP grants sector vessels several universal exemptions (*i.e.,* exemptions from certain Northeast multispecies regulations that are granted to all sectors) from the FMP's effort controls. These universal exemptions apply to: Trip limits on allocated stocks; Northeast multispecies days-at-sea (DAS) restrictions; the requirement to use a 6.5-inch (16.5-cm) mesh codend when fishing with selective gear on Georges Bank (GB); and portions of the Gulf of Maine (GOM) Cod Protection Closures. The FMP prohibits sectors from requesting exemptions from permitting restrictions, gear restrictions designed to minimize habitat impacts, and most reporting requirements.

In addition to the approved sectors, there are several state-operated permit banks, which receive allocations based on the history of the permits owned by the states. The final rule implementing Amendment 17 to the FMP allowed a state-operated permit bank to receive an allocation without needing to comply with the administrative and procedural requirements for sectors (77 FR 16942; March 23, 2012). Instead, permit banks are required to submit a list of participating permits to us, as specified in the permit bank's Memorandum of Agreement, to determine the ACE allocated to the permit bank. These allocations may be leased to fishermen enrolled in sectors. State-operated permit banks are no longer approved through the sector approval process, but current state-operated permit banks contribute to the total allocation under the sector system.

We received operations plans and preliminary contracts for fishing years 2023 and 2024 from 15 sectors. One additional sector that was active in fishing year 2022 submitted an initial operations plan, but later notified us that it does not intend to operate in fishing year 2023. This sector did not submit a final operations plan for approval. The operations plans for the 15 sectors included 18 exemptions previously requested by sectors, and approved by NMFS, in fishing years 2021 and 2022. These sectors did not request any new regulatory exemptions. We have determined that the 15 sector operations plans and contracts that we received, and that the 18 previously approved regulatory exemptions requested, are consistent with the FMP's goals and objectives and meet sector requirements outlined in the regulations at 50 CFR 648.87. Consequently, in this final rule we are approving the 15 sector operations plans, as well as the 18 previously approved regulatory exemptions requested. No new regulatory exemptions are approved as none were requested for fishing year 2023. Copies of the operations plans and contracts, and the environmental assessment (EA), are available at: *http://www.regulations.gov* and from NMFS (see **ADDRESSES**).

Catch Limits for Fishing Year 2023

Previously Established Catch Limits

Last year, Framework Adjustment 63 (Framework 63) (87 FR 42375; July 15, 2022) set fishing years 2022–2023 catch limits for two groundfish stocks: GOM cod and GB yellowtail flounder. Additionally, Framework 61 (86 FR 33191; July 9, 2021) set fishing years 2021–2023 catch limits for nine groundfish stocks: GB winter flounder; GOM Winter flounder; Southern New England/Mid-Atlantic (SNE/MA) winter flounder; redfish; northern windowpane flounder; southern windowpane flounder; ocean pout; Atlantic halibut; and wolffish. Frameworks 61 and 63 did not, however, specify a 2023 catch limit for nine stocks: GB cod; GB haddock; GOM haddock; SNE/MA yellowtail flounder; Cape Cod/GOM yellowtail flounder; American plaice; witch flounder; white hake; and pollock. Framework 65 would set catch limits for these nine stocks (and seven other stocks). However, Framework 65 will not be in place by the May 1, 2023, start of the fishing year. To prevent disruption to the groundfish fishery while Framework 65 is finalized, this final rule announces default catch limits that will be in effect for these nine stocks until Framework 65 is finalized and goes into effect.

As a result, the sector and common pool allocations in this rule are based on the 2023 catch limits set in Framework 61, Framework 63 or default catch limits that will be effective on May 1, 2023, and preliminary 2023 fishing year rosters (Table 1). If we approve Framework 65, the 2023 catch limits for 16 (out of 20) groundfish stocks announced in this rule will change when Framework 65 measures become effective.

Default Catch Limits

This rule announces default catch limits for GB cod; GB haddock; GOM haddock; SNE/MA yellowtail flounder; Cape Cod/GOM yellowtail flounder; American plaice; witch flounder; white hake; and pollock (Table 1). These stocks do not already have a catch limit in place for fishing year 2023. The groundfish regulations implement default catch limits for any stock for which final specifications are not in place by the beginning of the fishing year on May 1. The FMP's default specifications provision in the regulations sets catch limits at 75 percent of the previous year's (2022) catch limits, except in instances where the default catch limit would exceed the Council's recommendation for the final specifications. The default catch limits are effective from May 1 through October 31, or until the final rule for Framework 65 is implemented if that final rule is implemented prior to October 31. We are announcing these default specifications to comply with the FMP as set out in these regulations and to minimize impacts on the fishery that would occur if no catch limits are specified. If Framework 65 is not implemented on or before October 31, all fishing for these stocks would be prohibited beginning November 1.

TABLE 1—NORTHEAST MULTISPECIES CATCH LIMITS FOR 2023

Stock	Total U.S. ABC (mt)	Commercial groundfish sub-ACL (mt)
GB Cod #	257	182.9
GOM Cod *	551	269.9
GB Haddock #	11,901	11,079.8
GOM Haddock #	1,936	1,148.6
GB Yellowtail Flounder *	122	97.0

TABLE 1—NORTHEAST MULTISPECIES CATCH LIMITS FOR 2023—Continued

Stock	Total U.S. ABC (mt)	Commercial groundfish sub-ACL (mt)
SNE/MA Yellowtail Flounder #	17	11.7
CC/GOM Yellowtail Flounder #	617	518.9
American Plaice #	2,119	1,972.6
Witch Flounder #	1,112	988.0
GB Winter Flounder *	608	563.2
GOM Winter Flounder *	497	280.9
SNE/MA Winter Flounder *	456	288.1
Redfish *	9,967	9,468.7
White Hake #	1,587	1,492.6
Pollock #	12,609	10,601.0
N. Windowpane Flounder *	160	107.9
S. Windowpane Flounder *	384	42.9
Ocean Pout *	87	49.8
Atlantic Halibut *	101	73.4
Atlantic Wolffish *	92	85.6

* These catch limits are based on fishing year 2023 Frameworks 61 or 63 and will be replaced when the final rule for Framework 65 becomes effective, if approved.

These catch limits are based on default specifications and will be replaced when the final rule for Framework 65 becomes effective, if approved. If Framework 65 is not implemented on or before October 31, all fishing for these stocks would be prohibited beginning November 1.

Sector Allocations

This rule allocates ACE to sectors based on the preliminary fishing year 2023 sector rosters and the 2023 catch limits established in Framework 61, Framework 63, or default specifications, as shown in Table 1. Any permits that change ownership after the enrollment deadline established by the Regional Administrator (April 3 for fishing year 2023) retain the ability to join a sector through April 30, 2023. All permit holders who have joined a sector for fishing year 2023 have until April 30, 2023, to withdraw and elect to fish in the common pool, although sectors may specify a more restrictive withdrawal date for their members. As a result, the total permits enrolled in sectors for fishing year 2023 could change from the preliminary rosters, although such changes are expected to be minimal based on past fishing years. For fishing year 2024, we will set similar roster deadlines, notify permit holders of the fishing year 2024 deadlines, and allow permit holders to change sectors separate from the annual sector operations plans approval process.

We calculate a sector's allocation for each stock by summing its members' potential sector contributions (PSC) for a stock and then multiplying that total percentage by the available commercial sub-ACL for that stock. Table 2 shows the preliminary total PSCs for each sector for fishing year 2023. Tables 3 and 4 show the initial allocations that each sector is allocated, in pounds and metric tons, respectively, for fishing year 2023 based on their preliminary fishing year 2023 rosters and the fishing year 2023 catch limits established in Framework 61, Framework 63, or default specifications. At the start of the 2023 fishing year, we provide final allocations, to the nearest pound, to each sector based on their final May 1 rosters. We use these final allocations, along with later adjustments for ACE transfers, reductions for overages, or increases for carryover from fishing year 2022, to monitor sector catch. We have included the preliminary common pool sub-ACLs in tables 2 through 4 for comparison.

These tables do not represent the final allocations for the 2023 fishing year. One additional sector, Northeast Fishery Sector VII (NEFS 7), that was active in fishing year 2022, did not submit a final operations plan and will not operate in fishing year 2023. As a result, NEFS 7 is not included in tables 2 through 4. We expect the permits initially enrolled in NEFS 7 for fishing year 2023 to enroll in a different sector or join the common pool for fishing year 2023. ACE attributable to those permits will be allocated to whichever sector(s) those permits enroll in for 2023, or to the common pool.

We do not assign each permit separate PSCs for Eastern GB cod or Eastern GB haddock; instead, we assign each permit a PSC for the GB cod stock and GB haddock stock. Each sector's GB cod and GB haddock allocations are then divided into an Eastern ACE and a Western ACE, based on each sector's percentage of the GB cod and GB haddock ACLs. For example, if a sector is allocated 4 percent of the GB cod ACL and 6 percent of the GB haddock ACL, the sector is allocated 4 percent of the commercial Eastern U.S./Canada Area GB cod TAC and 6 percent of the commercial Eastern U.S./Canada Area GB haddock TAC as its Eastern GB cod and haddock ACEs. These amounts are then subtracted from the sector's overall GB cod and haddock allocations to determine its Western GB cod and haddock ACEs. A sector may only harvest its Eastern GB cod and haddock ACEs in the Eastern U.S./Canada Area, but may ''convert,'' or transfer, its Eastern GB cod or haddock allocation into Western GB allocation and fish that converted ACE outside the Eastern GB area.

We expect to finalize 2022 catch information in summer 2023. We allow sectors to trade fishing year 2022 ACE for 2 weeks upon our completion of year-end catch accounting to reduce or eliminate any fishing year 2022 overages. If necessary, we reduce any sector's fishing year 2023 allocation to account for a remaining overage in fishing year 2022. Each year of the operations plans, we notify the Council and sector managers of this deadline in writing and announce our final ACE determination on our website at: *https://www.greateratlantic.fisheries.noaa.gov/ro/fso/reports/h/groundfish_catch_accounting.*

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Table 2 -- Preliminary Cumulative PSC (percentage) Each Sector Would Receive by Stock for Fishing Year 2023*

Sector Name	MRI Count	GB Cod	GOM Cod	GB Haddock	GOM Haddock	GB Yellowtail Flounder	SNE/MA Yellowtail Flounder	CC/GOM Yellowtail Flounder	Plaice	Witch Flounder	GB Winter Flounder	GOM Winter Flounder	SNE/MA Winter Flounder	Redfish	White Hake	Pollock
Fixed Gear Sector	61	11.57986499	0.63266494	1.55709587	0.17782891	0.00406226	0.19072868	1.56837644	0.43174061	1.06929398	0.02017520	1.76433338	0.97813195	0.53443731	1.02810850	3.10014146
Maine Coast Community Sector	107	2.25872338	15.77695646	3.39860872	12.23265710	1.94946469	2.52105226	6.24820292	15.59255291	12.31331703	0.80739011	7.86800590	2.22916131	9.20710231	13.81791663	12.66325657
Maine Permit Bank	11	0.13433240	1.16132981	0.04453264	1.12518663	0.01387769	0.03207060	0.31964827	1.16764266	0.72913817	0.00021875	0.42733160	0.01820574	0.82280483	1.65671798	1.69621727
Mooncusser Sector	50	12.21207657	6.36850801	3.92352145	3.79196735	1.23244264	0.86275027	3.03294081	0.91306647	1.83458249	0.95258019	2.85243127	2.52636501	4.91308407	11.18619853	11.05573652
NEFS 2	114	6.42825249	24.13859747	10.61172726	20.61383546	1.63968415	1.23668481	23.10232143	9.60519865	12.94806752	3.21989291	22.04608759	4.12456871	14.91808881	8.17134810	13.77522197
NEFS 4	57	7.44182724	11.17474122	5.84423897	8.86143242	2.17753304	2.28300499	6.41878000	9.43778040	8.82208019	0.69764780	7.42336800	1.00862116	6.64654117	8.24718969	6.85834879
NEFS 5	19	0.47149877	0.32931400	0.69353736	0.11153396	0.96582476	15.83291422	0.92575781	0.30952689	0.50529332	0.32057976	0.84564416	10.01866915	0.01278743	0.06955800	0.07519106
NEFS 6	21	3.17006017	2.71824028	3.70430689	4.38577536	3.59916811	5.11414456	3.97330741	4.56862983	6.00979246	1.86779590	4.42270572	1.91331185	6.81156513	4.52758411	3.66493820
NEFS 8	67	15.45781499	2.72279254	14.23112169	7.12601424	27.65164455	11.46256002	8.88351106	10.09984910	8.69323561	38.08255616	4.20645961	16.29546939	7.64776369	6.57566090	6.07784450
NEFS 10	29	0.53059111	2.48774096	0.17754905	1.32502399	0.00115685	0.57051305	4.14466839	1.20285919	2.12677255	0.01091121	9.11147909	0.61624860	0.33718022	0.65893852	0.77238161
NEFS 11	42	0.39868824	11.36618893	0.03379860	2.73738311	0.00147256	0.01232208	2.28956997	1.51568211	1.54445027	0.00310767	2.00546780	0.02573956	1.86957706	4.01717694	8.76970929
NEFS 12	18	0.49689927	2.85999449	0.09383689	1.00316208	0.00042837	0.03278811	7.79068228	0.50382892	0.57283757	0.00044221	9.04712407	0.26242952	0.22773747	0.27471192	0.70794807
NEFS 13	67	12.42581344	0.64815143	20.35989584	0.90719096	35.69975739	22.94096330	6.48201064	8.58789891	8.81654744	19.26342385	1.81825768	17.44476423	4.35072387	2.20494996	2.67670424
New Hampshire Permit Bank	4	0.00082660	1.15152380	0.00003421	0.03236669	0.00002041	0.00001803	0.02192452	0.02856510	0.00617879	0.00000326	0.06080509	0.00003694	0.01942366	0.08147900	0.11142826
Sustainable Harvest Sector 1	50	6.78013931	5.94227322	9.64423085	12.67012829	4.44827137	2.60383435	3.60914781	16.80461955	13.81559835	10.29166596	2.93321238	4.50042687	17.77418284	18.16731342	10.38203747
Sustainable Harvest Sector 2	24	2.55865401	1.91547867	2.88873257	4.40959622	2.84272472	2.72846562	5.31596012	3.54963283	3.36537604	2.71017433	4.63543304	5.10781614	4.57851646	3.44227274	3.07644866
Sustainable Harvest Sector 3	44	15.02324149	4.80760938	20.80489387	16.31924540	14.05896255	7.69574599	10.06005305	12.84075445	13.48850779	19.42849745	2.92793175	20.84919617	18.28435712	14.84613393	13.60902668
Common Pool	486	2.63069553	3.79789437	1.98833726	2.16967183	3.71350387	23.87943908	5.81313708	2.84017141	3.33893045	2.32293728	15.60392187	12.08083768	1.04412655	1.02674112	0.92741938
All Sectors	785	97.37	96.20	98.01	97.83	96.29	76.12	94.19	97.16	96.66	97.68	84.40	87.92	98.96	98.97	99.07

* The data in this table are based on preliminary fishing year 2023 sector rosters.

Table 3 -- Preliminary ACE (in 1,000 lbs), by Stock, for Each Sector for Fishing Year 2023*#^

Sector Name	GB Cod East	GB Cod West	GOM Cod	GB Haddock East	GB Haddock West	GOM Haddock	GB Yellowtail Flounder	SNE/MA Yellowtail Flounder	CC/GOM Yellowtail Flounder	Plaice	Witch Flounder	GB Winter Flounder	GOM Winter Flounder	SNE/MA Winter Flounder	Redfish	White Hake	Pollock
FGS	41	6	4	227	153	5	0	0	18	19	23	0	11	6	112	34	725
MCCS	8	1	94	497	334	310	4	1	71	678	268	10	49	14	1,922	455	2,960
MPB	0	0	7	7	4	28	0	0	4	51	16	0	3	0	172	55	396
Mooncusser	43	6	38	573	385	96	3	0	35	40	40	12	18	16	1,026	368	2,584
NEFS 2	23	3	144	1,550	1,042	522	4	0	264	418	282	40	137	26	3,114	269	3,219
NEFS 4	26	4	66	854	574	224	5	1	73	410	192	9	46	6	1,387	271	1,603
NEFS 5	2	0	2	101	68	3	2	4	11	13	11	4	5	64	3	2	18
NEFS 6	11	2	16	541	364	111	8	1	45	199	131	23	27	12	1,422	149	857
NEFS 8	55	8	16	2,079	1,397	180	59	3	102	439	189	473	26	103	1,596	216	1,420
NEFS 10	2	0	15	26	17	34	0	0	47	52	46	0	56	4	70	22	181
NEFS 11	1	0	68	5	3	69	0	0	26	66	34	0	12	0	390	132	2,050
NEFS 12	2	0	17	14	9	25	0	0	89	22	12	0	56	2	48	9	165
NEFS 13	44	6	4	2,975	1,999	23	76	6	74	373	192	239	11	111	908	73	626
NHPB	0	0	7	0	0	1	0	0	0	1	0	0	0	0	4	3	26
SHS 1	24	3	35	1,409	947	321	10	1	41	731	301	128	18	29	3,710	598	2,426
SHS 2	9	1	11	422	284	112	6	1	61	154	73	34	29	32	956	113	719
SHS 3	53	8	29	3,040	2,042	413	30	2	115	558	294	241	18	132	3,817	489	3,181
Common Pool	9	1	23	290	195	55	8	6	67	124	73	29	97	77	218	34	217
Sector Total	343	49	572	14,320	9,622	2,477	206	20	1,078	4,225	2,105	1,213	523	558	20,657	3,257	23,155

* The data in this table are based on preliminary fishing year 2023 sector rosters.

Numbers are rounded to the nearest thousand pounds. In some cases, this table shows an allocation of 0, but that sector may be allocated a small amount of that stock in tens or hundreds pounds.

^ The data in the table represent the preliminary total allocations to each sector. Final allocations will be determined using final fishing year 2023 rosters.

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Table 4 -- Preliminary ACE (in metric tons), by Stock, for Each Sector for Fishing Year 2023*#^

Sector Name	GB Cod East	GB Cod West	GOM Cod	GB Haddock East	GB Haddock West	GOM Haddock	GB Yellowtail Flounder	SNE/MA Yellowtail Flounder	CC/GOM Yellowtail Flounder	Plaice	Witch Flounder	GB Winter Flounder	GOM Winter Flounder	SNE/MA Winter Flounder	Redfish	White Hake	Pollock
FGS	19	3	2	103	69	2	0	0	8	9	11	0	5	3	51	15	329
MCCS	4	1	43	225	151	141	2	0	32	308	122	5	22	6	872	206	1,342
MPB	0	0	3	3	2	13	0	0	2	23	7	0	1	0	78	25	180
Mooncusser	20	3	17	260	175	44	1	0	16	18	18	5	8	7	465	167	1,172
NEFS 2	10	1	65	703	473	237	2	0	120	189	128	18	62	12	1,413	122	1,460
NEFS 4	12	2	30	387	260	102	2	0	33	186	87	4	21	3	629	123	727
NEFS 5	1	0	1	46	31	1	1	2	5	6	5	2	2	29	1	1	8
NEFS 6	5	1	7	245	165	50	3	1	21	90	59	11	12	6	645	68	389
NEFS 8	25	4	7	943	634	82	27	1	46	199	86	214	12	47	724	98	644
NEFS 10	1	0	7	12	8	15	0	0	22	24	21	0	26	2	32	10	82
NEFS 11	1	0	31	2	2	31	0	0	12	30	15	0	6	0	177	60	930
NEFS 12	1	0	8	6	4	12	0	0	40	10	6	0	25	1	22	4	75
NEFS 13	20	3	2	1,349	907	10	35	3	34	169	87	108	5	50	412	33	284
NHPB	0	0	3	0	0	0	0	0	0	1	0	0	0	0	2	1	12
SHS 1	11	2	16	639	429	146	4	0	19	331	136	58	8	13	1,683	271	1,101
SHS 2	4	1	5	191	129	51	3	0	28	70	33	15	13	15	434	51	326
SHS 3	24	3	13	1,379	926	187	14	1	52	253	133	109	8	60	1,731	222	1,443
Common Pool	4	1	10	132	89	25	4	3	30	56	33	13	44	35	99	15	98
Sector Total	156	22	260	6,495	4,364	1,124	93	9	489	1,917	955	550	237	253	9,370	1,477	10,503

* The data in this table are based on preliminary fishing year 2023 sector rosters.

Numbers are rounded to the nearest metric ton, but allocations are made in pounds. In some cases, this table shows a sector allocation of 0 metric tons, but that sector may be allocated a small amount of that stock in pounds.

^ The data in the table represent the preliminary total allocations to each sector. Final allocations will be determined using final fishing year 2023 rosters.

Sector Operations Plans and Contracts

We are approving 15 sector operations plans and contracts for fishing years 2023 and 2024. All 15 sectors were active in fishing years 2021 and 2022. One sector, NEFS 7, submitted an initial operations plan, but later notified us that they would not be operating in fishing year 2023, and did not submit a final operations plan for approval. In order to approve a sector's operations plan for fishing years 2023 and 2024, we consider whether a sector's plan is consistent with regulatory requirements and FMP objectives, and whether it has been compliant with reporting requirements from previous years, including the year-end reporting requirements found at § 648.87(b)(1)(v). Approved operations plans contain the rules under which each sector will fish, and also provide the legal contract that binds each member to the sector for the length of the sector's operations plan. Each sector's operations plan, and each sector's members, must comply with the regulations governing sectors, found at § 648.87. In addition, each sector must conduct fishing activities as detailed in its approved operations plan.

Participating vessels are required to comply with all pertinent Federal fishing regulations, except as specifically exempted in the letter of authorization (LOA) issued by the Regional Administrator, which details any approved sector exemptions from the regulations. If, during a fishing year, or between fishing years 2023 and 2024, a sector requests an exemption that we have already granted, or proposes a change to administrative provisions, we may amend the sector operations plans. Should any such amendments require modifications to LOAs, we will include these changes in updated LOAs and provide them to the appropriate sectors.

We may revoke exemptions in-season if: We determine that the exemption jeopardizes management measures, FMP objectives, or rebuilding efforts; the exemption results in unforeseen negative impacts on other managed fish stocks, habitat, or protected resources; the exemption causes enforcement concerns; catch from trips using the exemption cannot be adequately monitored; or a sector is not meeting certain administrative or operational requirements. If it becomes necessary to revoke an exemption, we will do so through a process consistent with the existing regulations or in a separate rulemaking action, as appropriate.

Each sector is required to ensure that it does not exceed its ACE during the fishing year. Sector vessels are required to retain all legal-sized allocated Northeast multispecies stocks, unless a sector is granted an exemption allowing its member vessels to discard legal-sized unmarketable fish at sea. Catch (defined as landings and discards) of all allocated Northeast multispecies stocks by a sector's vessels count against the sector's allocation. Groundfish catch from a sector trip targeting non-groundfish species will be deducted from the sector's ACE because these are groundfish trips using gear capable of catching groundfish. Catch from a non-sector trip in an exempted fishery does not count against a sector's allocation and is assigned to a separate ACL sub-component to account for any groundfish bycatch that occurs in non-groundfish fisheries.

Each sector operations plan submitted for fishing years 2023 and 2024 states that the sector may withhold an initial reserve from the sector's ACE sub-allocation to each individual member to prevent the sector from exceeding its ACE. A sector and sector members can be held jointly and severally liable for ACE overages, discarding legal-sized fish, and/or misreporting catch (landings or discards). Each sector contract provides procedures for sector enforcement of its rules, explains sector monitoring and reporting requirements, provides sector managers with the authority to issue stop fishing orders to sector members who violate provisions of the operations plan and contract, and presents a schedule of penalties that managers may levy on members for sector plan violations.

Sectors are required to monitor their allocations and catch. To help ensure that a sector does not exceed its ACE, each sector operations plan explains sector monitoring and reporting requirements, including a requirement to submit weekly catch reports to us. If a sector reaches an ACE threshold (specified in the operations plan), the sector must provide us with sector allocation usage reports on a daily basis. Once a sector's allocation for a particular stock is caught, that sector is required to cease all sector fishing operations in that stock area until it acquires more ACE, likely by an ACE transfer between sectors. Within 60 days of when we complete year-end catch accounting, each sector is required to submit an annual report detailing the sector's catch (landings and discards), sector enforcement actions, and pertinent information necessary to evaluate the biological, economic, and social impacts of each sector.

Industry-Funded Monitoring Programs

Sectors are responsible for developing and implementing a monitoring program that must be approved by NMFS as both sufficient to monitor catch, discards, and use of ACE, and consistent with the sector monitoring program goals and objectives. Amendment 23 (87 FR 75852; December 9, 2022) replaced the previous method for determining the at-sea monitoring (ASM) coverage target with a fixed coverage target as a percentage of trips, dependent on Federal funding. Each year, NMFS will evaluate available Federal funding. NMFS will determine how much Federal funding is available for the groundfish sector monitoring program and then use that in conjunction with other available information (*e.g.,* recent monitoring costs, estimate of the number of vessels choosing electronic monitoring (EM)) to calculate the human ASM coverage target between 40 and 100 percent for the coming fishing year. This funding-based determination replaces the former annual process for determining the ASM coverage target for the sector monitoring program.

For fishing year 2023, sector vessels may choose to use ASM, the audit model EM, or the maximized retention EM program to meet monitoring requirements, provided that the sector has a corresponding monitoring program approved as part of its operations plan. On March 16, 2023, we announced a preliminary monitoring coverage level of 90 percent of all sector groundfish trips for the 2023 fishing year. The preliminary coverage level was announced to facilitate preparations by industry members and monitoring companies ahead of the 2023 fishing year. The final ASM coverage level will be announced when the ASM spend plan is approved. Vessels that choose to use ASM to meet monitoring requirements will be assigned monitors based on the target coverage level set for all sector groundfish trips. Vessels that choose to use EM to meet monitoring coverage requirements must use cameras and adhere to catch handling protocols as described in their vessel monitoring plans for all groundfish trips. Only a subset of the submitted trips will be selected for review to monitor groundfish discards for catch accounting. A subset of the selected EM trips will also undergo editing by NMFS to monitor the third-party service provider's performance. The vessel owner or operator and the third-party service provider must provide the EM data for any given trip to NMFS, and its authorized officers and designees, upon request including, but not limited to, trips selected for NMFS review. For fishing year 2023, the audit model EM

video footage review rate will be calculated for each active EM vessel based on each vessel's performance in 2022. The minimum possible EM video footage review rate will be 35 percent of sector trips for audit model vessels. The EM video footage review rate remains at 50 percent for all maximized retention EM vessels in fishing year 2023. Vessels that are new to EM will have a 50-percent video footage review rate in 2023 to allow more opportunities for feedback on their catch handling and reporting performance.

The operations plans submitted by sectors include industry-funded monitoring plans for fishing year 2023. As in previous years, we gave sectors the option to design their own monitoring program(s) in compliance with regulations or elect to adopt the NMFS-designed ASM and/or EM audit model and maximized retention program(s). In the event that we cannot approve a proposed monitoring program, we asked all sectors to include an option to select a current NMFS-designed monitoring program as a fail-safe.

All active sectors submitted an ASM plan as part of their operations plans. Sectors that operate only as permit banks, and explicitly prohibit fishing in their operations plans, are not required to include provisions for an ASM program. Similar to previous years, some sectors chose to use the NMFS-designed ASM program while others proposed programs of their own design. The NMFS-designed ASM program is the same program that we have used in previous fishing years. Sector-designed ASM programs for fishing years 2023 and 2024 were materially the same as those approved in past years. We reviewed all sector-proposed ASM programs for consistency with ASM requirements.

Sustainable Harvest Sectors 1, 2, and 3; the GB Cod Fixed Gear Sector; the Maine Coast Community Sector; and NEFS 5, 10, 11, and 13 will use the NMFS-designed ASM program. NEFS 2, 6, 8, and 12 will use a sector-designed ASM program, which states that they will: Contract with a NMFS-approved ASM provider; meet the specified coverage level; and utilize the Pre-Trip Notification System for random selection of monitored trips and notification to providers. These ASM programs also include additional protocols for ASM coverage waivers, incident reporting, and safety requirements for their sector managers and members. We are approving these programs because they are consistent with the goals and objectives of ASM and regulatory requirements.

Thirteen sectors also submitted an EM plan as part of their operations plans. Sustainable Harvest Sectors 1, 2, and 3; the GB Cod Fixed Gear Sector; the Maine Coast Community Sector; and NEFS 2, 5, 6, 8, 10, 11, 12, and 13 included the NMFS-designed audit model EM program in their operations plans. Sustainable Harvest Sectors 1, 2, and 3; the GB Cod Fixed Gear Sector; the Maine Coast Community Sector; and NEFS 2, 6, 8, 10, 12, and 13 also included the NMFS-designed maximized retention EM program in their operations plans.

Approved Exemptions for Fishing Years 2023 and 2024

We are granting exemptions from the following requirements for fishing years 2023 and 2024, all of which have been requested and granted in previous years:

(1) 120-day block out of the fishery required for Day gillnet vessels;

(2) 20-day spawning block out of the fishery required for all vessels;

(3) Limits on the number of gillnets for Day gillnet vessels outside the GOM;

(4) Prohibition on a vessel hauling another vessel's gillnet gear;

(5) Limits on the number of gillnets that may be hauled on GB when fishing under a Northeast multispecies/monkfish DAS;

(6) Limits on the number of hooks that may be fished;

(7) DAS Leasing Program length and horsepower restrictions;

(8) Prohibition on discarding;

(9) Gear requirements in the Eastern U.S./Canada Management Area;

(10) Prohibition on a vessel hauling another vessel's hook gear;

(11) The requirement to declare an intent to fish in the Eastern U.S./Canada Special Access Program (SAP) and the Closed Area (CA) II Yellowtail Flounder/Haddock SAP prior to leaving the dock;

(12) Seasonal restrictions for the Eastern U.S./Canada Haddock SAP;

(13) Seasonal restrictions for the CA II Yellowtail Flounder/Haddock SAP;

(14) Sampling exemption;

(15) Prohibition on combining small-mesh exempted fishery and sector trips in southern New England (SNE);

(16) Extra-large mesh requirement to target dogfish on trips excluded from ASM in SNE and Inshore GB;

(17) Requirement that Handgear A vessels carry a Vessel Monitoring System (VMS) unit when fishing in a single broad stock area; and

(18) Limits on the number of gillnets for Day gillnet vessels in the GOM.

Exemption Requests in Fishing Year 2023

For fishing year 2023, sectors did not request any novel exemptions.

Comments and Responses

We received no comments on the proposed rule.

Changes From the Proposed Rule

The 16 sector operations plans published in the proposed rule were based on sectors' submissions of initial operations plans for fishing years 2023 and 2024. NEFS 7 was approved for operation in fishing year 2022. However, NEFS 7 did not submit a final operations plan and will not operate in fishing year 2023. Therefore, the final rule approves 15 sector operations plans for fishing years 2023 and 2024.

The allocations published in the proposed rule were based on final fishing year 2022 sector rosters because we had not yet processed preliminary rosters for the 2023 fishing year. The deadline for preliminary sector roster submissions was April 3, 2023. The ACE allocated to each sector is updated in this final rule to reflect preliminary sector enrollment for fishing year 2023. ACE attributable to those permits enrolled in NEFS 7 for fishing year 2022 will be allocated to whichever sector(s) those permits enroll in for 2023, or to the common pool.

Sector ACEs published in the proposed rule were based on the New England Fishery Management Council's preferred catch limits in Framework 65. Framework 65 would set catch limits for 16 (out of 20) groundfish stocks. However, Framework 65 will not be in place by the May 1, 2023, start of the fishing year. As a result, to authorize fishing at the beginning of this fishing year, this rule implements allocations based on catch limits previously set in Frameworks 61 and 63 to the FMP. In addition, ACE is based on default specifications for the following stocks which do not already have catch limits set for fishing year 2023: GB cod; GB haddock; GOM haddock; SNE/MA yellowtail flounder; Cape Cod/GOM yellowtail flounder; American plaice; witch flounder; white hake; and pollock. The final rule for Framework 65 will include updated sector allocations for relevant stocks, and account for any changes from preliminary sector rosters if needed.

No other changes from the proposed action were made in this final rule.

Classification

NMFS is issuing this rule pursuant to section 305(d) of the Magnuson-Stevens Fishery Conservation and Management

Act (Magnuson-Stevens Act). Consistent with Magnuson-Stevens Act section 305(d), this action is necessary to carry out the Northeast Multispecies FMP in accordance with the FMP's implementing regulations. These regulations require Regional Administrator approval of operations plans for sectors to receive their ACE for specific groundfish stocks. The NMFS Assistant Administrator has determined that this final rule is consistent with the Northeast Multispecies FMP, other provisions of the Magnuson-Stevens Act, and other applicable law.

There is good cause pursuant to 5 U.S.C. 553(d)(3) to waive the 30-day delay in effective date for this final rule. This action approves fishing years 2023 and 2024 operations plans for 15 groundfish sectors in the Northeast multispecies fishery and allocates ACE for fishing year 2023. This rulemaking was required to be delayed to accommodate the sector roster deadline (April 3, 2023). We must have preliminary sector rosters for the upcoming fishing year in order to allocate preliminary ACE to sectors. Sectors are prohibited from fishing without an approved operations plan and ACE allocations; as such, timely implementation is necessary to ensure that sectors may fish at the start of the 2023 fishing year on May 1, 2023. If sectors were prohibited from fishing while waiting for the rule to take effect, there would be significant disruption to the fishery along with negative economic impacts, thus undermining the intent of the rule. The approval of sector operations plans occurs annually. Industry members and other stakeholders are aware of and familiar with these proceedings and expect them to occur in a timely manner.

This final rule is exempt from review under Executive Order 12866 because it contains no implementing regulations. This final rule contains no information collection requirements under the Paperwork Reduction Act of 1995.

The Chief Counsel for Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration at the proposed rule stage that this action would not have a significant economic impact on a substantial number of small entities. No comments were received regarding this certification. In addition, the changes from the proposed rule do not affect the factual basis for the certification. The factual basis for the certification was published in the proposed rule and is not repeated here. As a result, a final regulatory flexibility analysis was not required and none was prepared.

Dated: April 25, 2023

Samuel D. Rauch, III,

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

[FR Doc. 2023–09143 Filed 4–28–23; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 88, No. 83
Monday, May 1, 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 ENERGY

10 CFR Part 430

[EERE–2017–BT–STD–0014]

RIN 1904–AD98

Energy Conservation Program: Energy Conservation Standards for Residential Clothes Washers; Extension of Public Comment Period

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of proposed rulemaking; extension of public comment period.

SUMMARY: On March 3, 2023, the U.S. Department of Energy (''DOE'') published a notice of proposed rulemaking (''NOPR'') and announcement of public meeting proposing amended energy conservation standards for residential clothes washers (''RCWs'') and announcing a public meeting to receive comment on the proposed standards and associated analyses and results. (''March 2023 NOPR'') The notice provided an opportunity for submitting written comments, data, and information by May 2, 2023. On April 15, 2023, DOE received a request from the Association of Home Appliance Manufacturers (''AHAM'') to extend the written comment period. DOE has reviewed this request and is granting a 15-day extension of the public comment period to allow comments to be submitted until May 17, 2023.

DATES: The comment period for the NOPR published on March 3, 2023 (88 FR 13520) is extended. Written comments and information regarding the NOPR will be accepted on or before May 17, 2023.

ADDRESSES: Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *www.regulations.gov* under docket number EERE–2017–BT–STD–0014. Follow the instructions for submitting comments. Alternatively, interested persons may submit comments, identified by docket number EERE–2017–BT–STD–0014, by any of the following methods:

Email: ConsumerClothesWasher2017STD0014@ee.doe.gov. Include the docket number EERE–2017–BT–STD–0014 in the subject line of the message.

Postal Mail: Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. If possible, please submit all items on a compact disc (''CD''), in which case it is not necessary to include printed copies.

Hand Delivery/Courier: Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW, 6th Floor, Washington, DC 20024. Telephone: (202) 287–1445. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimiles (''faxes'') will be accepted.

Docket: The docket for this activity, which includes **Federal Register** notices, public meeting attendee lists and transcripts (if a public meeting is held), comments, and other supporting documents/materials, is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

The docket web page can be found at *www.regulations.gov/docket/EERE-2017-BT-STD-0014.* The docket web page contains instructions on how to access all documents, including public comments, in the docket.

FOR FURTHER INFORMATION CONTACT:

Dr. Carl Shapiro, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 287–5649. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Ms. Melanie Lampton, U.S. Department of Energy, Office of the General Counsel, Mail Stop GC–33, Forrestal Building, 1000 Independence Avenue SW, Washington, DC 20585–0103. Telephone: (240) 751–5157. Email: *Melanie.Lampton@hq.doe.gov.*

For further information on how to submit a comment, review other public comments and the docket, or participate in the public meeting, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: On September 29, 2021, DOE published a notification of the availability of a preliminary technical support document for RCWs (''September 2021 Preliminary Analysis''). 86 FR 53886. In that notification, DOE sought comment on the analytical framework, models, and tools that DOE used to evaluate potential standards for RCWs. *Id.* On October 29, 2021, DOE extended the comment period for the September 2021 Preliminary Analysis by an additional 45 days. 86 FR 59889. DOE subsequently published a notification of data availability (''NODA'') on April 13, 2022, presenting the results of additional testing conducted in furtherance of the development of the translations between the current test procedure and the proposed new test procedure. 87 FR 21816 (''April 2022 NODA''). On May 19, 2022, DOE reopened the comment period for the April 2022 NODA and provided additional information in response to stakeholder questions. 87 FR 30433. On March 3, 2023, the DOE published a NOPR proposing amended energy conservation standards for residential clothes washers. 88 FR 13520. The March 2023 NOPR announced a public meeting to receive comment on the proposed standards and provided for the written submission of comments by May 2, 2023. *Id.*

On April 15, 2023, DOE received a request from AHAM to extend the written comment period on the March 2023 NOPR by 20 days. AHAM stated that it was reviewing DOE's responses to other stakeholders' comments, including comments requesting that DOE consider an equation-based approach for energy conservation standards. AHAM noted that while DOE did not propose such an approach, DOE indicated a willingness to consider it, and AHAM requires additional time to review and analyze how such an approach could work and provide DOE

with substantive feedback. (AHAM, No. 89).

In response to the September 2021 Preliminary Analysis, the California investor-owned utilities (''CA IOUs'') stated that they were supportive of an equation-based metric that can account for the efficiency differences related to capacity. (CA IOUs, No. 43 at pp. 3–4). In the March 2023 NOPR, DOE did not propose equation-based standards, but noted that given the close relationship between efficiency and capacity, DOE continues to consider whether to specify an equation-based standard for the top-loading standard-size product class. 88 FR 13540.

DOE has reviewed the request and considered the benefit of allowing interested parties additional time to submit comments regarding the March 2023 NOPR, including feedback on an equation-based approach for energy conservation standards, for DOE's consideration. Accordingly, DOE has determined that an extension of the public comment period is appropriate, and is hereby extending the comment period by 15 days, until May 17, 2023.

Signing Authority

This document of the Department of Energy was signed on April 25, 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 April 25, 2023.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

[FR Doc. 2023–09019 Filed 4–28–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 52

[REG–105954–22]

RIN 1545–BQ40

Superfund Chemical Taxes; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking; correction.

SUMMARY: This document contains corrections to a notice of proposed rulemaking (REG–105954–22) that was published in the **Federal Register** on Wednesday, March 29, 2023. The proposed rulemaking published in March contains proposed regulations relating to the excise taxes imposed on certain chemicals and certain imported substances, effective July 1, 2022. Such taxes are known as the Superfund chemical taxes.

DATES: Written or electronic comments and requests for a public hearing are still being accepted and must be received by May 30, 2023.

ADDRESSES: Commenters are strongly encouraged to submit public comments electronically. Submit electronic submissions via the Federal eRulemaking Portal at *www.regulations.gov* (indicate IRS and REG–105954–22) by following the online instructions for submitting comments. Once submitted to the Federal eRulemaking Portal, comments cannot be edited or withdrawn. The Department of the Treasury (Treasury Department) and the IRS will publish for public availability any comment submitted electronically and on paper, to its public docket. Send paper submissions to: CC:PA:LPD:PR (REG–120653–22), Room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Stephanie Bland or Amanda Dunlap at (202) 317–6855 (not a toll-free number); concerning submissions of comments and requests for a public hearing, call Vivian Hayes (202) 317–5306 (not a toll-free number) or by email to *publichearings@irs.gov* (preferred).

SUPPLEMENTARY INFORMATION:

Background

The notice of proposed rulemaking that is the subject of this document is under sections 4661, 4662, 4671 and 4672 of the Internal Revenue Code.

Need for Correction

As published, the notice of proposed rulemaking (REG–105954–22) (FR 2023–06278), beginning on page 18446 in the issue of March 29, 2023, contains errors that need to be corrected.

■ 1. On page 18453, in the second column, the heading ''*VII. Definitions Relating to Sections 4671*'' is corrected to read ''*VII. Definitions Relating to Sections 4671 and 4672*''.

§ 52.4662–2 [Corrected]

■ 2. On page 18462, in the first column, in paragraph (g)(3)(iii) of § 52.4662–2, the language ''refinery grade'' is corrected to read ''refinery-grade'', wherever it appears.

Oluwafunmilayo A. Taylor,

Branch Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel (Procedure and Administration).

[FR Doc. 2023–09003 Filed 4–28–23; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG–2023–0342]

RIN 1625–AA00

Safety Zone; Graduate Boat Parade, Sturgeon Bay, WI

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard is proposing to establish a temporary safety zone for certain waters of Sturgeon Bay, WI. This action is necessary to provide for the safety of life on these navigable waters during the boat parade for the Graduates of Sturgeon Bay High School on June 3, 2023. This proposed rulemaking would restrict usage by persons and vessels within the safety zone. At no time during the effective period may non-parade vessels transit the waters of Sturgeon Bay between the Highway 42 Bridge and Michigan Street Bridge. These restrictions would apply to all vessels during the effective period unless authorized by the Captain of the Port Lake Michigan or a designated representative. We invite your comments on this proposed rulemaking.

DATES: Comments and related material must be received by the Coast Guard on or before May 16, 2023.

ADDRESSES: You may submit comments identified by docket number USCG–

2023–0342 using the Federal eRulemaking Portal at *https://www.regulations.gov.* See the ''Public Participation and Request for Comments'' portion of the **SUPPLEMENTARY INFORMATION** section for further instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: If you have questions about this proposed rulemaking, call or email Chief Petty Officer Jeromy Sherrill, Sector Lake Michigan Waterways Management Division, U.S. Coast Guard; telephone 414–747–7148, email *Jeromy.N.Sherrill@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, Purpose, and Legal Basis

On April 10, 2023, the principal of Sturgeon Bay High School notified the Coast Guard that they will be conducting a boat parade for graduates of the Class of 2023 on June 3, 2023 from 11:15 a.m. through 1 p.m. The boat parade will begin at Madelyn Marine, NW of Highway 42 bridge, proceed NW to the Michigan Street Bridge, cross the channel towards the Maritime Museum, then proceed SE, crossing back across the channel and ending at Madelyn Marine. The Captain of the Port has determined that potential hazards associated with the boat parade would be a safety concern for anyone within the safety zone that is not participating in the boat parade.

The purpose of this rulemaking is to ensure the safety of vessels and the navigable waters of Sturgeon Bay between the Highway 42 Bridge and Michigan Street Bridge during the event. The Coast Guard is proposing this rulemaking under authority in 46 U.S.C. 70034 (previously 33 U.S.C. 1231).

III. Discussion of Proposed Rule

The Captain of the Port is proposing to establish a safety zone from 10 a.m. through 2 p.m. on June 3, 2023. The safety zone would cover all navigable waters of Sturgeon Bay between the Highway 42 Bridge and Michigan Street Bridge. The duration of the zone is intended to ensure the safety of vessels and these navigable waters before, during, and after the boat parade event. No vessels or person would be permitted to enter the safety zone without obtaining permission from the Captain of the Port or a designated representative. The regulatory text we are proposing appears at the end of this document.

IV. Regulatory Analyses

We developed this proposed 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 NPRM has not been designated a ''significant regulatory action,'' under Executive Order 12866. Accordingly, the NPRM has not been reviewed by the Office of Management and Budget (OMB).

This regulatory action determination is based on the characteristics of the safety zone. The safety zone created by this proposed rule will relatively small and is designed to minimize its impact on navigable waters. This proposed rule will prohibit entry into certain navigable waters of Sturgeon Bay, WI, and it is not anticipated to exceed 2 hours in duration. Thus, restrictions on vessel movement within that particular area are expected to be minimal. Moreover, under certain conditions vessels may still transit through the safety zone when permitted by the Captain of the Port Lake Michigan.

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 proposed rule would 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 IV.A above, this proposed rule would not have a significant economic impact on any vessel owner or operator.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this proposed rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this proposed rule would economically affect it.

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 proposed rule. If the rulemaking 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. The Coast Guard will not retaliate against small entities that question or complain about this proposed rule or any policy or action of the Coast Guard.

C. Collection of Information

This proposed rule would 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 proposed 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 proposed rule does not have tribal implications under Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments) because it would 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. If you believe this proposed rule has implications for federalism or Indian tribes, please call or email the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

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 proposed rule would not result in such an expenditure, we do discuss the effects of this rulemaking elsewhere in this preamble.

F. Environment

We have analyzed this proposed 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 made a preliminary determination 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 proposed rule involves a safety zone lasting 4 hours that would prohibit entry within a relatively small portion of Sturgeon Bay. Normally such actions are categorically excluded from further review under paragraph L60(a) of Appendix A, Table 1 of DHS Instruction Manual 023–01–001–01, Rev. 1. A preliminary Record of Environmental Consideration supporting this determination is available in the docket. For instructions on locating the docket, see the **ADDRESSES** section of this preamble. We seek any comments or information that may lead to the discovery of a significant environmental impact from this proposed rule.

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.

V. Public Participation and Request for Comments

We view public participation as essential to effective rulemaking, and will consider all comments and material received during the comment period. Your comment can help shape the outcome of this rulemaking. If you submit a comment, please include the docket number for this rulemaking, indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation.

We encourage you to submit comments through the Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the person in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions.

We accept anonymous comments. All comments received will be posted without change to *https://www.regulations.gov* and will include any personal information you have provided. For more about privacy and submissions in response to this document, see DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020).

Documents mentioned in this NPRM as being available in the docket, and all public comments, will be in our online docket at *https://www.regulations.gov* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign up for email alerts, you will be notified when comments are posted or a final rule is published.

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.T09–0342 to read as follows:

§ 165.T09–0342 Safety Zone; Graduate Boat Parade, Sturgeon Bay, WI

(a) *Location.* All navigable waters of Sturgeon Bay between the Highway 42 Bridge and Michigan Street Bridge.

(b) *Enforcement Period.* The safety zone described in paragraph (a) would be effective on June 3, 2023 from 10 a.m. through 2 p.m.

(c) *Regulations.*

(1) In accordance with the general regulations in section 165.23, entry into, transiting, or anchoring within this safety zone is prohibited unless authorized by the Captain of the Port Lake Michigan (COTP) or a designated representative.

(2) This safety zone is closed to all vessel traffic, except as may be permitted by the COTP or a designated representative.

(3) The ''designated representative'' of the COTP is any Coast Guard commissioned, warrant, or petty officer who has been designated by the COTP to act on his or her behalf.

(4) Persons and vessel operators desiring to enter or operate within the safety zone during the boat parade must contact the COTP or an on-scene representative to obtain permission to do so. The COTP or an on-scene representative may be contacted via VHF Channel 16. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP or an on-scene representative.

Dated: April 25, 2023.

Doreen McCarthy,

Commander, U.S. Coast Guard, Alternate Captain of the Port Lake Michigan.

[FR Doc. 2023–09155 Filed 4–28–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 181

46 CFR Parts 25, 28, 108, 117, 133, 141, 160, 169, 180 and 199

[Docket No. USCG–2022–0120]

RIN 1625–AC62

Lifejacket Approval Harmonization

Correction

In proposed rule document 2023–06504, appearing on pages 21016–21058 in the issue of Friday, April 7, 2023, make the following correction:

§ 160.060–15 [Corrected]

■ On page 21050, in the second column, in paragraph (e)(2), in the third and fourth lines, ''not less than 151 2044;2 pounds of buoyancy in fresh water'' is corrected to read ''not less than 15½ pounds of buoyancy in fresh water''.

[FR Doc. C1–2023–06504 Filed 4–28–23; 8:45 am]

BILLING CODE 0099–10–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 90

[WP Docket No. 07–100; Report No. 3194; FR ID 138356]

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 Federal Communications Commission's (Commission) proceeding the American Association of State Highway and Transportation Officials.

DATES: Oppositions to the Petition must be filed on or before May 16, 2023. Replies to oppositions must be filed on or before May 26, 2023.

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

FOR FURTHER INFORMATION CONTACT: For additional information on this proceeding, contact Jon Markman of the Wireless Telecommunications Bureau, Mobility Division, at (202) 418–7090 or *Jonathan.Markman@fcc.gov* or Brian Marenco of the Public Safety and Homeland Security Bureau at (202) 418–0838 or *Brian.Marenco@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's document, Report No. 3194, released April 19, 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: Improving Public Safety Communications in the 4.9 GHz Band (WP Docket No. 07–100).

Number of Petitions Filed: 1.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–09035 Filed 4–28–23; 8:45 am]

BILLING CODE 6712–01–P

Notices

Federal Register
Vol. 88, No. 83
Monday, May 1, 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.

AGENCY FOR INTERNATIONAL DEVELOPMENT

Notice of Advisory Committee Public Meeting

AGENCY: Agency for International Development (USAID).

ACTION: Notice of advisory committee public meeting and request for public comment.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), notice is hereby given of Advisory Committee on Voluntary Foreign Aid (ACVFA) public meeting on Wednesday, May 24, 2023.

ADDRESSES: To view additional information related to ACVFA please visit *http://www.usaid.gov/who-we-are/organization/advisory-committee.*

This event will feature remarks by the USAID Administrator and the ACVFA Chair, as well as two discussion panels featuring ACVFA members on key Agency priorities such as food security, climate change, democratic governance, private sector engagement, and inclusive development.

You may submit comments regarding the work of ACVFA to *acvfa@usaid.gov* OR the committee's public comment form at: *https://www.usaid.gov/who-we-are/organization/advisory-committee/acvfa-contact-us.* Include ''Public Comment, ACVFA Meeting, May 24 2023'' in the subject line. All public comments and questions will be included in the official record of the meeting and posted publicly on the USAID website.

American Sign Language interpretation will be provided during the public meeting. If you require a reasonable accommodation, please email *reasonableaccommodations@usaid.gov.* Include ''Request for Reasonable Accommodation, ACVFA Meeting, May 24'' in the subject line.

The entirety of this meeting is open to the public. You may register to watch the live public meeting at this link: *https://usaid.zoomgov.com/webinar/register/WN_4DaAIfWTTgG5x0Tof8G8YA.*

FOR FURTHER INFORMATION CONTACT: Sophia Lajaunie, Designated Federal Officer for ACVFA, at *slajaunie@usaid.gov* or 202–531–9819.

SUPPLEMENTARY INFORMATION: ACVFA is USAID's external advisory committee, bringing together representatives from private voluntary organizations, nongovernmental organizations (NGOs), academia, civil society, and the private sector. Its membership of internationally recognized leaders represent a broad range of sectors who support the Agency's mission and goals by advising on key development challenges and priorities.

Pursuant to its charter, ACVFA is holding an annual public meeting on May 24, 2023, from 9:00 a.m.–10:30 a.m. ET. This meeting is free and open to the public. The Committee welcomes public participation and comment before, during, and after the meeting via the web and/or email addresses provided above.

Sophia Lajaunie,

ACVFA Designated Federal Officer.

[FR Doc. 2023–09172 Filed 4–28–23; 8:45 am]

BILLING CODE 6116–01–P

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 this information collection received by May 31, 2023 will be considered. 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.

Animal and Plant Health Inspection Service

Title: Plum Pox Compensation.

OMB Control Number: 0579–0159.

Summary of Collection: Under the Plant Protection Act (7 U.S.C. 7701 *et seq.*), the Secretary of Agriculture is authorized to prohibit or restrict the importation, entry, or movement of plants and plant pests to prevent the introduction of plant pests into the United States or their dissemination within the United States. The regulations in 7 CFR 301.74–5 permit owners of commercial stone fruit orchards to receive compensation for losses associated with trees destroyed to control plum pox pursuant to an emergency action notification (EAN) issued by the Animal & Plant Health Inspection Service (APHIS). Plum Pox is an extremely serious viral disease of plants that can affect many stone fruit species, including plum, peach, apricot, almond, and nectarine. Owners of fruit tree nurseries may receive compensation for net revenue losses associated with movement or sale of nursery stock prohibited under an EAN issued by APHIS with respect to regulated articles within the nursery in order to control plum pox.

Need and Use of the Information: Compensation applications include information about the business such as

name and address, a description of the property, and a certification statement that the trees removed from the owner's property were stone fruit trees from commercial fruit orchards or fruit tree nurseries. For claims made by owners of stone fruit orchards, the completed application must be accompanied by a copy of the EAN ordering the destruction of their trees, the notification's accompanying inventory describing the acreage and ages of trees removed and documentation verifying that the destruction of the trees have been completed and the date of that completion. For claims made by owners of fruit tree nurseries, the completed application must be accompanied by a copy of the EAN prohibiting the same or movement of the nursery stock, the notification's accompanying inventory describing the total number of trees covered by the EAN, their age and variety, and documentation indicating the final disposition of the nursery stock. Applicants may also need to apply for a DUNS number and provide direct deposit information for payments. Without the information APHIS would be unable to compensate eligible grove and nursery owners for their losses.

Description of Respondents: State Plant Health Officials; Business or other for-profit; Farm.

Number of Respondents: 2.

Frequency of Responses: Reporting, Recordkeeping: On occasion.

Total Burden Hours: 5.

Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2023–09125 Filed 4–28–23; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2023–0023]

Notice of Availability of a Pest Risk Analysis for the Importation of Fresh Ginseng Roots (Panax ginseng C.A. Mey.) From the Republic of Korea Into the 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 ginseng roots (*Panax ginseng* C.A. Mey.) from the Republic of Korea into the 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 ginseng roots (*Panax ginseng* C.A. Mey.) from the Republic of Korea. 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 June 30, 2023.

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

- *Federal eRulemaking Portal:* Go to *www.regulations.gov*. Enter APHIS–2023–0023 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–2023–0023, 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, 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., 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 (NPPO) of the Republic of Korea to allow the importation of fresh ginseng roots (*Panax ginseng* C.A. Mey.) from the Republic of Korea into the United States. As part of our evaluation of the Republic of Korea's request, we have prepared a pest risk assessment to identify the pests of quarantine significance that could follow the pathway of the importation of fresh ginseng roots into the United States from the Republic of Korea. Based on the pest risk assessment, a risk management document (RMD) was prepared to identify phytosanitary measures that could be applied to the fresh ginseng roots to mitigate the pest risk.

Therefore, in accordance with § 319.56–4(c), we are announcing the availability of our pest risk assessment and RMD for public review and comment. Those documents, as well as a description of the economic considerations associated with the importation of fresh ginseng roots from the Republic of Korea, 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 pest risk assessment 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 ginseng roots from the Republic of Korea 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 ginseng roots from the Republic of Korea into the 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 24th day of April 2023.

Michael Watson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2023–09136 Filed 4–28–23; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS–2023–0027]

Notice of Request for Revision to and Extension of Approval of an Information Collection; National Veterinary Services Laboratories; Bovine Spongiform Encephalopathy Surveillance Program

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Revision to and extension of approval of an information collection; comment request.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Animal and Plant Health Inspection Service's intention to request a revision to and extension of approval of an information collection associated with National Veterinary Services Laboratories diagnostic support for the bovine spongiform encephalopathy surveillance program.

DATES: We will consider all comments that we receive on or before June 30, 2023.

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

- *Federal eRulemaking Portal:* Go to *www.regulations.gov.* Enter APHIS–2023–0027 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–2023–0027, 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, 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., 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: For information on the regulations to prevent the introduction of bovine spongiform encephalopathy into the United States, contact Dr. Christina Loiacono, Coordinator, National Animal Health Laboratory Network, Veterinary Services, APHIS, USDA, 1920 Dayton Road, Ames, IA 50010; (515) 231–2515; *christina.m.loiacono@usda.gov.* For information on the information collection process, contact Mr. Joseph Moxey, APHIS' Paperwork Reduction Act Coordinator, at (301) 851–2483; *joseph.moxey@usda.gov.*

SUPPLEMENTARY INFORMATION:

Title: National Veterinary Services Laboratories; Bovine Spongiform Encephalopathy Surveillance Program.

OMB Control Number: 0579–0409.

Type of Request: Revision to and extension of approval of an information collection.

Abstract: Under the Animal Health Protection Act (7 U.S.C. 8301 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) of the U.S. Department of Agriculture (USDA) is authorized, among other things, to carry out activities to detect, control, and eradicate pests and diseases of livestock within the United States. APHIS' National Veterinary Services Laboratories (NVSL) safeguard U.S. animal health and contribute to public health by ensuring that timely and accurate laboratory support is provided by their nationwide animal health diagnostic system.

USDA complies with the standard set by the World Organization for Animal Health (WOAH) for bovine spongiform encephalopathy (BSE) surveillance. This compliance is critical for maintaining our BSE-risk status with the WOAH. Our BSE surveillance program requires information collection activities, such as completing the USDA BSE Surveillance Submission form and the USDA BSE Surveillance Data Collection form.

We are asking the Office of Management and Budget (OMB) to approve our use of these information collection activities, as described, for an additional 3 years.

The purpose of this notice is to solicit comments from the public (as well as affected agencies) concerning our information collection. These comments will help us:

(1) Evaluate 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;

(2) Evaluate the accuracy of our estimate of the burden of the collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, through use, as appropriate, of automated, electronic, mechanical, and other collection technologies; *e.g.,* permitting electronic submission of responses.

Estimate of burden: The public burden for this collection of information is estimated to average 0.159 hours per response.

Respondents: Slaughter establishments, offsite collection facilities for condemned slaughter cattle, rendering 3D/4D facilities, State animal health personnel, veterinary diagnostic laboratories, and accredited veterinarians.

Estimated annual number of respondents: 178.

Estimated annual number of responses per respondent: 121.

Estimated annual number of responses: 21,568.

Estimated total annual burden on respondents: 3,421 hours. (Due to averaging, the total annual burden hours may not equal the product of the annual number of responses multiplied by the reporting burden per response.)

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record.

Done in Washington, DC, this 24th day of April 2023.

Michael Watson,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2023–09140 Filed 4–28–23; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2023–0014]

National Advisory Committee on Microbiological Criteria for Foods; Notice of Public Meeting

AGENCY: Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA).

ACTION: Notice of public meeting.

SUMMARY: The National Advisory Committee on Microbiological Criteria for Foods (NACMCF) will hold a public meeting of the full Committee and Subcommittees from May 16, 2023 to May 18, 2023. The Committee will provide updates on the charges *related to Cyclospora cayetanensis* in produce and *Cronobacter* spp. in Powdered Infant Formula.

DATES: The full Committee will hold an in-person and virtual public meeting on Tuesday, May 16, 2023, from 10 a.m. to 12 p.m. The Subcommittees on *Cyclospora cayetanensis* in produce and on *Cronobacter* spp. in Powdered Infant Formula will hold concurrent Subcommittee meetings on Tuesday,

May 16, 2023, from 1 to 5 p.m., as well as on Wednesday, May 17, 2023, and Thursday, May 18, 2023, from 9 a.m. to 5 p.m., respectively. The deadline to register to provide verbal comments is May 8, 2023.

FSIS invites interested persons to submit written comments on the *Cyclospora cayetanensis* in produce and on the *Cronobacter* spp. in Powdered Infant Formula charges. The deadline to submit comments is May 8, 2023.

ADDRESSES: The meetings will be held in the USDA South Building, 1400 Independence Ave. SW, Washington, DC 20250. Room locations will be provided the day of the meeting. Virtual attendees will be provided details on how to access the full Committee and Subcommittee meetings upon registration.

In-person attendees must show valid photo identification and will be required to pass through the security screening systems and escorted to the respective conference rooms. Please allow adequate time for this process.

Attendance is free. Attendees must pre-register at *https://ems8.intellor.com/?do=register&t=1&p=847719.* FSIS requests that those interested in providing public comments at the May 16, 2023, full Committee session indicate this when registering. Comments will be limited to three minutes per speaker. FSIS will do its best to accommodate all registered persons who request to provide verbal comments at the plenary meeting.

Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal:* This website provides the ability to type short comments directly into the comment field on this web page or attach a file for lengthier comments. Go to *https://www.regulations.gov.* Follow the on-line instructions at that site for submitting comments.
- *Mail:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250–3700.
- *Hand- Or Courier-Delivered Submittals:* Deliver to 1400 Independence Avenue SW, Jamie L. Whitten Building, Room 350–E, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2023–0014. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *https://www.regulations.gov.*

Docket: For access to background documents or comments received, call (202) 937–4272 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250–3700.

Agenda: FSIS will finalize an agenda on or before the meeting date and post it on FSIS' website at *https://www.fsis.usda.gov/news-events/events-meetings.*

Please note that the meeting agenda is subject to change and sessions could end earlier or later than anticipated. Please plan accordingly if you would like to attend this meeting or participate in the public comment period.

The official transcript of the May 16, 2023 Committee meeting, when it becomes available, will also be posted on FSIS' website at *https://www.fsis.usda.gov/news-events/events-meetings.*

FOR FURTHER INFORMATION CONTACT: Dr. Kristal Southern, USDA, FSIS, Office of Public Health Science, 1400 Independence Avenue SW, Room 1128, Washington, DC 20250; Phone: (202) 937–4171 or Email: *NACMCF@usda.gov.*

Persons requiring a sign language interpreter or other special accommodations should notify Dr. Southern by May 5, 2023.

SUPPLEMENTARY INFORMATION:

Background

The NACMCF was established in 1988, in response to a recommendation of the National Academy of Sciences for an interagency approach to microbiological criteria for foods, and in response to a recommendation of the U.S. House of Representatives Committee on Appropriations, as expressed in the Rural Development, Agriculture, and Related Agencies Appropriation Bill for fiscal year 1988. The charter for the NACMCF is available on FSIS' website at *https://www.fsis.usda.gov/policy/advisory-committees/national-advisory-committee-microbiological-criteria-foods-nacmcf.* The NACMCF provides scientific advice and recommendations to the Secretary of Agriculture and the Secretary of Health and Human Services on public health issues relative to the safety and wholesomeness of the U.S. food supply, including development of microbiological criteria and review and evaluation of epidemiological and risk assessment data and methodologies for assessing microbiological hazards in foods. The Committee also provides scientific advice and recommendations to the Departments of Commerce and Defense. The Committee reports to the Secretary of Agriculture through the Under Secretary for Food Safety, the Committee's Chair, and to the Secretary of Health and Human Services through the Assistant Secretary for Health, the Committee's Vice-Chair. Currently, Dr. José Emilio Esteban, Under Secretary for Food Safety, USDA, is the Committee Chair; Dr. Susan T. Mayne, Director of the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN), is the Vice-Chair; and Dr. Kristal Southern, FSIS, is the Director of the NACMCF Secretariat and Designated Federal Officer.

NACMCF documents and comments posted on the FSIS website are electronic conversions from a variety of source formats. In some cases, document conversion may result in character translation or formatting errors. The original document is the official, legal copy. To meet the electronic and information technology accessibility standards in Section 508 of the Rehabilitation Act, NACMCF may add alternate text descriptors for non-text elements (graphs, charts, tables, multimedia, etc.). These modifications only affect the internet copies of the documents. Copyrighted documents will not be posted on FSIS' website but will be available for inspection in the FSIS Docket Room.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication through the FSIS website located at *https://www.fsis.usda.gov/policy/federal-register-rulemaking/federal-register-notices.* FSIS also will make copies of this publication available through the FSIS *Constituent Update,* which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at *https://www.fsis.usda.gov/news-events/news-press-releases/news-feeds-subscriptions.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the

option to password protect their accounts.

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Program information may be made available in languages other than English. Persons with disabilities who require alternative means of communication to obtain program information (*e.g.,* Braille, large print, audiotape, American Sign Language) should contact the responsible Mission Area, agency, or staff office; the USDA TARGET Center at (202) 720–2600 (voice and TTY); or the Federal Relay Service at (800) 877–8339.

To file a program discrimination complaint, a complainant should complete a Form, AD–3027, *USDA Program Discrimination Complaint Form,* which can be obtained online at *https://www.usda.gov/forms/electronic-forms,* from any USDA office, by calling (866) 632–9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights about the nature and date of an alleged civil rights violation. The completed AD–3027 form or letter must be submitted to USDA by: (1) Mail: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; (2) Fax: (833) 256–1665 or (202) 690–7442; or (3) Email: *program.intake@usda.gov.*

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Dated: April 25 2023.

Cikena Reid,

Committee Management Officer, United States Department of Agriculture.

[FR Doc. 2023–09111 Filed 4–28–23; 8:45 am]

BILLING CODE 3410–DM–P

CHEMICAL SAFETY AND HAZARD INVESTIGATION BOARD

Agency Information Collection Activities; Accidental Release Reporting Form

AGENCY: U.S. Chemical Safety and Hazard Investigation Board (CSB).

ACTION: 30-Day notice of submission of information collection request (ICR) renewal approval and request for comments.

SUMMARY: The proposed information collection request (ICR) renewal described below will be submitted to the Office of Management and Budget (OMB) for review and approval, as required by the Paperwork Reduction Act of 1995. The Chemical Safety Board (CSB) is soliciting public comments on this proposed collection renewal. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: Comments should be sent no later than 5 p.m. EDT on Tuesday, May 30, 2023.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions within 30 days of publication of this notice: OMB, Office of Information and Regulatory Affairs, Attention: Chemical Safety Board Desk Officer, Fax Number: (202) 395–5806 *OR,* Email: *OIRA_submission@omb.eop.gov.*

Additionally, written comments and recommendations for the proposed information collection can be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* To find this particular information collection request, select ''Currently under 30-day Review—Open for Public Comments'' or use the search function.

Requests for information, including copies of the information collection proposed and supporting documentation should be directed to: Tamara Qureshi, Assistant General Counsel, U.S. Chemical Safety and Hazard Investigation Board, at *report@csb.gov.*

FOR FURTHER INFORMATION CONTACT: Tamara Qureshi, Assistant General Counsel, U.S. Chemical Safety and Hazard Investigation Board, 1750 Pennsylvania Ave. NW, Suite 910, Washington, DC 20006, *report@csb.gov* or 202–261–7600.

SUPPLEMENTARY INFORMATION:

Title: CSB Accidental Release Reporting Form.

OMB Control Number: 3301–0001.

Expiration Date of Approval: 04–30–2023.

Type of Request: Renewal.

Abstract: The enabling statute of the Chemical Safety and Hazard Investigation Board (CSB) provides that the CSB shall establish by regulation requirements binding on persons for reporting accidental releases into the ambient air subject to the Board's investigative jurisdiction. The CSB published its Accidental Release Reporting Rule (40 CFR part 1604) on February 21, 2020. This final rule is intended to satisfy the CSB's statutory requirement. The rule describes when an owner or operator is required to file a report of an accidental release, and the required content of such a report. The purpose of the rule is to ensure that the CSB receives rapid, accurate reports of any accidental release that meets established statutory criteria.

In conjunction with the Accidental Release Reporting Rule, the CSB also developed a form to capture the information necessary to initially assess an accidental release. The form is located on CSB's website: *https://www.csb.gov/news/incident-report-rule-form-/.*

Type of Respondents: The vast majority of respondents will be private sector businesses involved in the production, storage or handling of regulated substances or extremely hazardous substances.

Estimate Annual Number of Respondents: 100.

Frequency of Use: On occasion. Most respondents will only submit a response if an accidental release within the scope of the rule occurs during a given year. For the vast majority of potential respondents, the frequency of responses will likely be ''none'' in a given year.

Small Businesses or Organizations Affected: No. At the time of the rulemaking, the CSB determined that the rule would not have an impact on businesses, including small businesses. Furthermore, there have been even less reports than originally predicted.

Estimated Number of Annual Responses: 100.

Estimated Average Burden Hours per Response: 0.25 hour. The CSB acknowledges that there may be additional burdens on the public that are not quantifiable.

Estimated Total Annual Burden Hours: 25 hours.

Need for and Use of Information: The CSB is required by law to issue an accidental release reporting rule. The

CSB intends to use the information to learn of any accidental release within its jurisdiction and to plan how to respond to that accidental release.

Comment is Invited: Comment is invited on: (1) Whether this collection of information is necessary for the stated purposes and the proper performance of the functions of the Agency, including whether the information will have practical or scientific utility; (2) the accuracy of the Agency's estimate of the burden of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

All comments received in response to this notice, including names and addresses when provided, will be a matter of public record. Comments will be summarized and included in the submission request toward Office of Management and Budget approval.

The CSB is still accepting comments under its 60-day notice at *report@csb.gov* or 202–261–7600 until 5 p.m. EDT April 28, 2023.

Dated: April 26, 2023.

Tamara Qureshi,

Assistant General Counsel, Chemical Safety and Hazard Investigation Board.

[FR Doc. 2023–09177 Filed 4–27–23; 11:15 am]

BILLING CODE 6350–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Colorado Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: U.S. Commission on Civil Rights.

ACTION: Notice of public 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, that the Colorado Advisory Committee (Committee) to the U.S. Commission on Civil Rights will hold a public briefing in Boulder. The purpose of the briefing is to hear testimony from experts, government officials, advocates, academics and others on public school attendance zones in Colorado. There will be an opportunity for the public to comment at the conclusion of the scheduled testimony.

DATES: Monday, May 15, 2023; from 10 a.m. to 5 p.m. Mountain Time.

ADDRESSES: The briefing will be held at the Colorado University of Colorado Law School, Wolf Law Building, Wittemeyer Court Room, 2450 Kittredge Loop Drive, Boulder, CO 80309.

FOR FURTHER INFORMATION CONTACT: Barbara Delaviez, Designated Federal Official at *ero@usccr.gov.*

SUPPLEMENTARY INFORMATION: The briefing is free of charge and is open to the public. Interested members of the public may sign up any time during the briefing and may make comments on the topic towards the end of the briefing. Per the Federal Advisory Committee Act, public minutes of the briefing will include a list of persons who are present at the briefing. Persons with hearing impairments, please request accommodations at least 10 business days prior to the briefing at: *ebohor@usccr.gov.*

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following the briefing. Written comments may be emailed to Barbara Delaviez at *ero@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at 1–312–353–8311.

Records generated from this briefing may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the briefing. Records of all committee meetings will be available via the *www.facadatabase.gov* under the Commission on Civil Rights, Colorado Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at 1–312–353–8311.

Agenda

I. Welcome & Chair Remarks
II. Briefing on Public School Attendance Zones in Colorado
III. Public Comment
IV. Next Steps
V. Adjournment

Dated: April 25, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–09073 Filed 4–28–23; 8:45 am]

BILLING CODE 6335–01–P

COMMISSION ON CIVIL RIGHTS

Notice of Public Meeting of the Puerto Rico Advisory Committee to the U.S. Commission on Civil Rights

AGENCY: Commission on Civil Rights.

ACTION: Announcement of 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 a meeting of the Puerto Rico Advisory Committee to the Commission will convene by virtual web conference on Monday, May 22, 2023, at 3:30 p.m. Atlantic Time/Eastern Time. The purpose is to continue discussion on their project on the civil rights impacts of the Insular Cases in Puerto Rico.

DATES: May 22, 2023, Monday, at 3:30 p.m. (AT and ET)

ADDRESSES: Meeting will be held via Zoom.

Registration Link (Audio/Visual): https://tinyurl.com/2s434xas.

Join by Phone (Audio Only): 1–551–285–1373; Meeting ID: 161 620 4980#.

FOR FURTHER INFORMATION CONTACT: Email Victoria Moreno, Designated Federal Officer at *vmoreno@usccr.gov,* or by phone at 434–515–0204.

SUPPLEMENTARY INFORMATION: This meeting will take place in Spanish with English interpretation. This committee meeting is available to the public through the registration 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. Callers will incur no charge for calls they initiate over land-line connections to the toll-free telephone number. 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 *ebohor@usccr.gov* at least 10 business days prior to the meeting.

Members of the public are entitled to submit written comments; the comments must be received in the regional office within 30 days following

the meeting. Written comments may be emailed to Victoria Moreno at *vmoreno@usccr.gov.* Persons who desire additional information may contact the Regional Programs Coordination Unit at 1–312–353–8311.

Records generated from this meeting may be inspected and reproduced at the Regional Programs Coordination Unit Office, as they become available, both before and after the meeting. Records of the meetings will be available via *www.facadatabase.gov* under the Commission on Civil Rights, Puerto Rico Advisory Committee link. Persons interested in the work of this Committee are directed to the Commission's website, *http://www.usccr.gov,* or may contact the Regional Programs Coordination Unit at *ebohor@usccr.gov.*

Agenda

1. Welcome & Roll Call
2. Committee Discussion on Project Regarding the Civil Rights Impacts of the Insular Cases in Puerto Rico
3. Next Steps
4. Public Comment
5. Other Business
6. Adjourn

Dated: April 25, 2023.

David Mussatt,

Supervisory Chief, Regional Programs Unit.

[FR Doc. 2023–09116 Filed 4–28–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

Initiation of Five-Year (Sunset) Reviews

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: In accordance with the Tariff Act of 1930, as amended (the Act), the Department of Commerce (Commerce) is automatically initiating the five-year reviews (Sunset Reviews) of the antidumping and countervailing duty (AD/CVD) order(s) and suspended investigation(s) listed below. The International Trade Commission (ITC) is publishing concurrently with this notice its notice of *Institution of Five-Year Reviews* which covers the same order(s) and suspended investigation(s).

DATES: Applicable May 1, 2023.

FOR FURTHER INFORMATION CONTACT: Commerce official identified in the *Initiation of Review* section below at AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Washington, DC 20230. For information from the ITC, contact Mary Messer, Office of Investigations, U.S. International Trade Commission at (202) 205–3193.

SUPPLEMENTARY INFORMATION:

Background

Commerce's procedures for the conduct of Sunset Reviews are set forth in its *Procedures for Conducting Five-Year (Sunset) Reviews of Antidumping and Countervailing Duty Orders,* 63 FR 13516 (March 20, 1998) and 70 FR 62061 (October 28, 2005). Guidance on methodological or analytical issues relevant to Commerce's conduct of Sunset Reviews is set forth in *Antidumping Proceedings: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Duty Proceedings; Final Modification,* 77 FR 8101 (February 14, 2012).

Initiation of Review

In accordance with section 751(c) of the Act and 19 CFR 351.218(c), we are initiating the Sunset Reviews of the following antidumping and countervailing duty order(s) and suspended investigation(s):

DOC case No.	ITC case No.	Country	Product	Commerce contact
A–570–806	731–TA–472	China	Silicon Metal (5th Review)	Thomas Martin, (202) 482–3936.
A–570–064	731–TA–1383	China	Stainless Steel Flanges (1st Review)	Thomas Martin, (202) 482–3936.
A–533–877	731–TA–1384	India	Stainless Steel Flanges (1st Review)	Thomas Martin, (202) 482–3936.
C–570–065	701–TA–585	China	Stainless Steel Flanges (1st Review)	Thomas Martin, (202) 482–3936.
C–533–878	701–TA–586	India	Stainless Steel Flanges (1st Review)	Thomas Martin, (202) 482–3936.

Filing Information

As a courtesy, we are making information related to sunset proceedings, including copies of the pertinent statute and Commerce's regulations, Commerce's schedule for Sunset Reviews, a listing of past revocations and continuations, and current service lists, available to the public on Commerce's website at the following address: *https://enforcement.trade.gov/sunset/.* All submissions in these Sunset Reviews must be filed in accordance with Commerce's regulations regarding format, translation, and service of documents. These rules, including electronic filing requirements via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS), can be found at 19 CFR 351.303.

In accordance with section 782(b) of the Act, any party submitting factual information in an AD/CVD proceeding must certify to the accuracy and completeness of that information. Parties must use the certification formats provided in 19 CFR 351.303(g). Commerce intends to reject factual submissions if the submitting party does not comply with applicable revised certification requirements.

Letters of Appearance and Administrative Protective Orders

Pursuant to 19 CFR 351.103(d), Commerce will maintain and make available a public service list for these proceedings. Parties wishing to participate in any of these five-year reviews must file letters of appearance as discussed at 19 CFR 351.103(d). To facilitate the timely preparation of the public service list, it is requested that those seeking recognition as interested parties to a proceeding submit an entry of appearance within 10 days of the publication of the Notice of Initiation. Because deadlines in Sunset Reviews can be very short, we urge interested parties who want access to proprietary information under administrative protective order (APO) to file an APO application immediately following publication in the **Federal Register** of this notice of initiation. Commerce's regulations on submission of proprietary information and eligibility to receive access to business proprietary information under APO can be found at 19 CFR 351.304–306. Note that Commerce has temporarily modified certain of its requirements for serving documents containing business

proprietary information, until further notice.[1]

Information Required From Interested Parties

Domestic interested parties, as defined in section 771(9)(C), (D), (E), (F), and (G) of the Act and 19 CFR 351.102(b), wishing to participate in a Sunset Review must respond not later than 15 days after the date of publication in the **Federal Register** of this notice of initiation by filing a notice of intent to participate. The required contents of the notice of intent to participate are set forth at 19 CFR 351.218(d)(1)(ii). In accordance with Commerce's regulations, if we do not receive a notice of intent to participate from at least one domestic interested party by the 15-day deadline, Commerce will automatically revoke the order without further review.[2]

If we receive an order-specific notice of intent to participate from a domestic interested party, Commerce's regulations provide that *all parties* wishing to participate in a Sunset Review must file complete substantive responses not later than 30 days after the date of publication in the **Federal Register** of this notice of initiation. The required contents of a substantive response, on an order-specific basis, are set forth at 19 CFR 351.218(d)(3). Note that certain information requirements differ for respondent and domestic parties. Also, note that Commerce's information requirements are distinct from the ITC's information requirements. Consult Commerce's regulations for information regarding Commerce's conduct of Sunset Reviews. Consult Commerce's regulations at 19 CFR part 351 for definitions of terms and for other general information concerning antidumping and countervailing duty proceedings at Commerce.

This notice of initiation is being published in accordance with section 751(c) of the Act and 19 CFR 351.218(c).

Dated: April 17, 2023.

James Maeder,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2023–09221 Filed 4–28–23; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Temporary Rule Modifying AD/CVD Service Requirements Due to COVID–19; Extension of Effective Period,* 85 FR 41363 (July 10, 2020).

[2] *See* 19 CFR 351.218(d)(1)(iii).

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC965]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a joint public meeting of its Monkfish and Dogfish Advisory Panels 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 Tuesday, May 16, 2023, at 3 p.m. Webinar registration URL information: *https://attendee.gotowebinar.com/register/5909621442701126236.*

ADDRESSES:

Council address: New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Monkfish and Dogfish Advisory Panels will meet to discuss recommendations from the Sturgeon Bycatch Fishery Management Action Team/Plan Development Team. They will also discuss potential measures to reduce bycatch of Atlantic sturgeon in the monkfish and spiny dogfish gillnet fisheries, developed from the recommendations in NOAA's Action Plan to Reduce Atlantic Sturgeon Bycatch in Federal Large-Mesh Gillnet Fisheries. The panels will discuss the range of alternatives recommended to the Joint Monkfish and Dogfish Committee to be considered for reducing bycatch of Atlantic sturgeon in the monkfish and spiny dogfish gillnet fisheries. Other business may 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: April 26, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–09147 Filed 4–28–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC967]

Endangered Species; File No. 24016–01

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

ACTION: Notice; receipt of application for a permit modification.

SUMMARY: Notice is hereby given that Jason Kahn, Ph.D., National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910, has applied in due form for a permit modification to take Atlantic (*Acipenser oxyrinchus*) and shortnose (*A. brevirostrum*) sturgeon for purposes of scientific research.

DATES: Written, telefaxed, or emailed comments must be received on or before May 31, 2023.

ADDRESSES: The application request and related documents are available for review by selecting ''Records Open for Public Comment'' from the Features box on the Applications and Permits for Protected Species (APPS) home page, *https://apps.nmfs.noaa.gov,* and then selecting File No. 20416–01 from the list of available applications. These documents are also available upon written request via email to *NMFS.Pr1Comments@noaa.gov.*

Written comments on this application should be submitted via email to *NMFS.Pr1Comments@noaa.gov.* Please include File No. 20416–01 in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request via email to *NMFS.Pr1Comments@noaa.gov.* The request should set forth the specific reasons why a hearing on this application would be appropriate.

FOR FURTHER INFORMATION CONTACT: Malcolm Mohead or Erin Markin, Ph.D. at (301) 427–8401.

SUPPLEMENTARY INFORMATION: The subject permit modification to Permit No. 24016, issued on January 28, 2021 (86 FR 13700, March 10, 2021), is requested under the authority of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*) and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226).

Permit No. 24016 currently authorizes the permit holder to conduct scientific research on Atlantic and shortnose sturgeon in freshwater and estuary areas of the Chesapeake Bay and other coastal rivers, assessing sturgeon population and reproductive capacity, as well as monitoring spawning activity, movement, and habitat through telemetry. Atlantic and shortnose sturgeon life stages may be captured using gill or trammel nets, trawls, and trapping nets (*e.g.,* fyke, or other trap nets). All animals are marked with passive integrated transponder (PIT) and Floy tags, genetic tissue sampled, measured, weighed, photographed and released. Subsets of animals are also anesthetized, and internally or externally acoustically tagged, biologically sampled (*i.e.,* fin ray, blood, gametes), endoscoped and ultrasounded. Larvae and eggs are currently collected with D-nets, trawls (*i.e.,* epibenthic sleds), and egg mats. The applicant anticipates that up to one adult/sub-adult and one juvenile Atlantic sturgeon may be killed annually. The proposed modification focuses on activities designed to stage the reproductive status of eggs collected from female sturgeon captured from the York River (Virginia) and its tributaries. To understand sturgeon egg development and spawning characteristics in the York River, the Permit Holder is requesting to directly sample an additional 800 eggs using an approved egg extraction device. The permit is valid through January 31, 2031.

Dated: April 25, 2023.

Amy Sloan,

Deputy Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2023–09075 Filed 4–28–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC930]

Fisheries of the South Atlantic; Southeast Data, Assessment, and Review (SEDAR); Public Meeting

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

ACTION: Notice of SEDAR 82 South Atlantic Gray Triggerfish Assessment Webinar 2.

SUMMARY: The SEDAR 82 assessment of the South Atlantic stock of gray triggerfish will consist of a data workshop, a series of assessment webinars, and a review workshop. A SEDAR 82 Assessment Webinar 2 is scheduled for May 18, 2023. See **SUPPLEMENTARY INFORMATION**.

DATES: The SEDAR 82 South Atlantic Gray Triggerfish Assessment Webinar 2 is scheduled for May 18, 2023, from 9 a.m. to 12 p.m., Eastern. 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 meeting will be held via webinar. The webinar is open to members of the public. Registration for the webinar is available by contacting the SEDAR coordinator via email at *Kathleen.Howington@safmc.net.*

SEDAR address: South Atlantic Fishery Management Council, 4055 Faber Place Drive, Suite 201, N Charleston, SC 29405; *www.sedarweb.org.*

FOR FURTHER INFORMATION CONTACT: Kathleen Howington, SEDAR Coordinator, 4055 Faber Place Drive, Suite 201, North Charleston, SC 29405; phone: (843) 571–4371; email: *Kathleen.Howington@safmc.net.*

SUPPLEMENTARY INFORMATION: The Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils, in conjunction with NOAA Fisheries and the Atlantic and Gulf States Marine Fisheries Commissions, have implemented the Southeast Data, Assessment and Review (SEDAR) process, a multi-step method for determining the status of fish stocks in the Southeast Region. SEDAR is a three-step process including: (1) Data Workshop; (2) Assessment Process utilizing webinars; and (3) Review Workshop. The product of the Data Workshop is a data report which compiles and evaluates potential datasets and recommends which datasets are appropriate for assessment analyses. The product of the Assessment Process is a stock assessment report which describes the fisheries, evaluates the status of the stock, estimates biological benchmarks, projects future population conditions, and recommends research and monitoring needs. The assessment is independently peer reviewed at the Review Workshop. The product of the Review Workshop is a Summary documenting panel opinions regarding the strengths and weaknesses of the stock assessment and input data. Participants for SEDAR Workshops are appointed by the Gulf of Mexico, South Atlantic, and Caribbean Fishery Management Councils and NOAA Fisheries Southeast Regional Office, Highly Migratory Species Management Division, and Southeast Fisheries Science Center. Participants include: data collectors and database managers; stock assessment scientists, biologists, and researchers; constituency representatives including fishermen, environmentalists, and non-governmental organizations (NGOs); international experts; and staff of Councils, Commissions, and state and federal agencies.

The items of discussion at the SEDAR 82 South Atlantic Gray Triggerfish Assessment Webinar 2 are as follows: Discuss any leftover data issues that were not cleared up during the data process, answer any questions that the analysts have, and introduce/discuss model development and model setup.

Although non-emergency issues not contained in this agenda may come before this group for discussion, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically identified in this notice and any issues arising after publication of this notice that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

This meeting is accessible to people with disabilities. Requests for auxiliary aids should be directed to the South Atlantic Fishery Management Council office (see **ADDRESSES**) at least 10 business days prior to the meeting.

Note: The times and sequence specified in this agenda are subject to change.

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

Dated: April 26, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–09145 Filed 4–28–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[RTID 0648–XC957]

New England Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The New England Fishery Management Council (Council) is scheduling a joint public meeting of its Monkfish and Dogfish Committees 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, May 17, 2023, at 9:30 a.m. Webinar registration URL information: *https://attendee.gotowebinar.com/register/3037065951232152662.*

ADDRESSES: *Council address:* New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950.

FOR FURTHER INFORMATION CONTACT: Thomas A. Nies, Executive Director, New England Fishery Management Council; telephone: (978) 465–0492.

SUPPLEMENTARY INFORMATION:

Agenda

The Monkfish and Dogfish Committees will meet to discuss recommendations from the Sturgeon Bycatch Fishery Management Action Team/Plan Development Team and the Joint Monkfish and Dogfish Advisory Panel. They will discuss potential measures to reduce bycatch of Atlantic sturgeon in the monkfish and spiny dogfish gillnet fisheries, developed from the recommendations in NOAA's Action Plan to Reduce Atlantic Sturgeon Bycatch in Federal Large-Mesh Gillnet Fisheries. They will also discuss the range of alternatives recommended to the Councils (New England and Mid-Atlantic) to be considered for reducing bycatch of Atlantic sturgeon in the monkfish and spiny dogfish gillnet fisheries. Other business may 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: April 26, 2023.

Rey Israel Marquez,

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

[FR Doc. 2023–09146 Filed 4–28–23; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Solicitation for Members of the NOAA Science Advisory Board

AGENCY: Office of Oceanic and Atmospheric Research (OAR), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce (DOC).

ACTION: Notice of solicitation for members of the NOAA Science Advisory Board.

SUMMARY: NOAA is soliciting nominations for members of the NOAA Science Advisory Board (SAB). The SAB is the only Federal Advisory Committee with the responsibility to advise the Under Secretary of Commerce for Oceans, Atmosphere, and NOAA Administrator on long and short range strategies for research, education, and application of science to resource management and environmental assessment and prediction. The SAB consists of approximately fifteen members reflecting the full breadth of NOAA's areas of responsibility and assists NOAA in maintaining a complete and accurate understanding of scientific issues critical to the agency's missions.

DATES: Nominations should be sent to the web address specified below and must be received by June 15, 2023.

ADDRESSES: Applications should be submitted electronically to *noaa.scienceadvisoryboard@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Dr. Cynthia Decker, Executive Director, Science Advisory Board, NOAA, Rm. 11230, 1315 East-West Highway, Silver Spring, Maryland 20910. (Phone: 301–734–1156), Fax: 301–713–1459, Email: *Cynthia.Decker@noaa.gov*); or visit the NOAA SAB website at *http://www.sab.noaa.gov.*

SUPPLEMENTARY INFORMATION: At this time, individuals are sought with expertise in an artificial intelligence and machine learning in the fields of weather and climate; environmental remote sensing; engineering for coastal resilience; social and behavioral sciences; and tropical cyclones. Individuals with expertise in other NOAA mission areas are also welcome to apply.

NOAA is also interested in expanding the diversity of expertise represented on the SAB in order to reflect better the viewpoints of the United States population. The agency welcomes scientists in the listed areas of expertise and can also provide insights and experiences derived from their ethnic, gender, and racial backgrounds and races, native- and tribal-based traditions, and experiences of those who are differently abled. Composition and Points of View: The board will consist of approximately fifteen members including a Chair, designated by the Under Secretary in accordance with FACA requirements.

Members will be appointed for three-year terms, renewable once, and serve at the discretion of the Under Secretary.

Members will be appointed as special government employees (SGEs) and will be subject to the ethical standards applicable to SGEs. Members are reimbursed for actual and reasonable travel and per diem expenses incurred in performing such duties but will not

be reimbursed for their time. As a Federal Advisory Committee, the Board's membership is required to be balanced in terms of viewpoints represented and the functions to be performed as well as the interests of geographic regions of the country and the diverse sectors of U.S. society.

The SAB meets in person three times each year, exclusive of teleconferences or subcommittee, task force, and working group meetings. Board members must be willing to serve as liaisons to SAB working groups and/or participate in periodic reviews of the NOAA Cooperative Institutes and overarching reviews of NOAA's research enterprise.

Nominations: Interested persons may nominate themselves or third parties.

Applications: An application is required to be considered for board membership, regardless of whether a person is nominated by a third party or self-nominated. The application package must include: (1) the nominee's full name, title, institutional affiliation, and contact information, including mailing address; (2) the nominee's area(s) of expertise; (3) a short description of their qualifications relative to the kinds of advice being solicited by NOAA in this Notice; and (4) a current resume (maximum length four [4] pages).

David Holst,

Chief Financial Officer/Administrative Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2023–09156 Filed 4–28–23; 8:45 am]

BILLING CODE 3510–KD–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

[Docket Number: 230412–0099]

RIN 0660–XC058

Introduction of Accountable Measures Regarding Access to Personal Information of .us Registrants

AGENCY: National Telecommunications and Information Administration, Department of Commerce.

ACTION: Request for comments.

SUMMARY: The United States Department of Commerce's (Department) National Telecommunications and Information Administration (NTIA) administers the contract for the country code top-level domain (ccTLD) for the United States, ''.us'' (usTLD). NTIA seeks input from interested parties on the introduction of accountability measures regarding access to the personal information of usTLD registrants. NTIA's policy goal regarding access to domain registration data is to ensure that the usTLD protects the privacy of its usTLD registrants while also enabling third parties to access usTLD domain registration data for legitimate purposes.

DATES: Submit comments on or before May 31, 2023.

ADDRESSES: You may submit comments, identified by docket number and/or RIN number, by any of the following methods:

Federal Rulemaking website: Go to *https://www.regulations.gov* and search for Docket ID NTIA–2023–0006.

Email comments to: usTLD@ntia.gov.

Mail comments to: National Telecommunications and Information Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW, Room 4701, Attn: Susan Chalmers, Washington, DC 20230. Comments submitted by mail may be in hard copy (paper) or electronic (*e.g.,* CD–ROM, disk, or thumb drive).

FOR FURTHER INFORMATION CONTACT: Please direct questions regarding this Notice to Susan Chalmers, Telecommunications Policy Specialist, at the address listed in the **ADDRESSES** section of this notice by electronic or regular mail as listed above, or by telephone (202) 281–5218. Please direct media inquiries to NTIA's Office of Public Affairs, *press@ntia.gov* or (202) 482–7002.

SUPPLEMENTARY INFORMATION: The usTLD serves as an online home for American business, individuals, and localities for the benefit of the nation's internet community. NTIA administers the contract governing the operation of the usTLD, the most recent of which was awarded in 2019 to Registry Services, LLC (the Contractor).

NTIA requires the Contractor to maintain a publicly accessible registration database of usTLD domain name registrations.[1] The Contractor currently provides a WHOIS directory service [2] that allows users to retrieve usTLD domain name registration data directly and without any form of authentication from its comprehensive central usTLD registrant database of real usTLD registrant data.[3] This data includes important contact information: individual names, physical addresses, telephone numbers, and email addresses of all usTLD registrants.

Historically, NTIA has authorized public access to the usTLD registration data (WHOIS service) permitting internet users to retrieve the usTLD registrant data for legitimate purposes (*e.g.,* law enforcement investigations, consumer protection, cybersecurity research, intellectual property rights protection and enforcement). In addition, the usTLD registrant data is accessible on an anonymous basis. The data (especially the personal information) may be accessed and used for abusive purposes (*e.g.,* to spam, phish, harass, dox, or otherwise cause the registrant harm).[4]

In response to concerns about the potential for abuse of usTLD registrant data, NTIA is considering a proposal from its Contractor to create an Accountable WHOIS Gateway System (the System) to provide public access to usTLD registrant information. This proposal was created based upon recommendations developed by the usTLD community. Under the Contractor's proposal, the System would be designed to reduce the potential for abuse by eliminating anonymous and unaccountable access to usTLD registrant data. The System would require those seeking access to the usTLD registration data to provide their name, an email address, and to accept the Terms of Service (TOS). The TOS would require the user to agree not to misuse the data. Users would also be required to identify, from a pre-selected list, a legitimate, non-marketing purpose for accessing the information. This list would be developed according to industry best practice in consultation with the usTLD community and approved by NTIA. Unredacted WHOIS data would then automatically be returned in near-real-time to the user via email. Queries would be rejected only if the user did not provide a name and email address or failed to select (or provide) a legitimate purpose and accept the TOS.

The System would also permit users to identify a legitimate purpose outside of the pre-selected list. The Contractor using usTLD community developed and NTIA approved standards would manually review these requests and deliver, via email, unredacted data within two (2) business days for any non-abusive purpose unrelated to

[1] .us Contract, C.4.2(iv), page 11, available at: *https://ntia.gov/files/ntia/publications/us_contract_june_28_2019.pdf.*

[2] A WHOIS directory is a database of all the registered domains in a particular zone. It contains information about the domain name registrant including the registrant contact information such as address, email, phone number, etc.

[3] Under this proposal privacy and proxy services would remain prohibited under the usTLD as currently required by the .us contract.

[4] *See e.g.,* Andrew Alleman, *Reminder: there's no Whois privacy for .us domain names—Domain Name Wire | Domain Name News*at. The Contractor has also received a number of complaints outlining these issues.

marketing. The System would also provide a mechanism to expedite emergency requests.

The Contractor would maintain auditable records of its receipt of and response to WHOIS access requests for personal data, including the number of access requests received, and the declared legitimate purposes. The Contractor would also maintain records to audit complaints of technical abuse or TOS violations. These audit records would be made publicly available in fully de-identified and aggregated form for analysis, enabling additional data driven policy development by NTIA and the usTLD community.

Non-personal information relating to the domain name would remain available for retrieval via anonymous query. This information includes domain name and ID, registrar WHOIS server, registrar URL, updated date, creation date, registry expiry date, registrar, registrar IANA ID, and registrar abuse contact (email and phone number).

To address the unique needs of law enforcement and other similarly situated entities, the Contractor would establish a portal for authenticated law enforcement users, which would grant such users near real-time access to personal information. The Contractor would continue to work with law enforcement authorities and others to ensure that investigatory confidentiality and unique other needs with respect to access and confidentiality are fully met.

Request for Comment

NTIA seeks public comments regarding the proposed Accountable WHOIS Gateway System (System). Comments that contain references, studies, research, or other empirical evidence or data that are not widely published should include copies of the referenced materials with the submitted comments. While the public is welcome to submit comments regarding the questions below and other issues relating to the proposal, we ask that comments generally be limited to issues regarding access to WHOIS in the usTLD. Specifically, NTIA seeks input on the following questions:

1. In general, what are your views on the public availability of the usTLD domain name registration data to anonymous users? Has public access by anonymous users to usTLD registration data, especially personal information, resulted in exposing registrants to spam, phishing, doxxing, identity theft and other online/offline harms? If such abuses have occurred, please provide illustrative examples. And, whether or not you are aware of examples of such abuse, do you believe that there is a significant risk of such abuse occurring in the future, if the current system remains unchanged (and if so, why)?

2. Do you believe the current system of anonymous access to usTLD domain name registration data should remain unchanged? If so, why?

3. What legitimate purposes for access to usTLD domain name registration data should be included in the System's pre-defined list? Please provide a rationale for each category recommended.

4. Are there policies and practices developed or employed by other ccTLDs regarding WHOIS access that could be incorporated into the usTLD space? Please be specific in your response.

5. Should the System distinguish between personal and non-personal registration data, and if so, how?

6. Should usTLD registrants be notified when their data is accessed through the System? If so, why, when or in what circumstances?

7. Under what circumstances, if any, should the Contractor require certain requestors to furnish a warrant when requesting access to usTLD registration data?

8. The Contractor has proposed that the System provide special access to recognized and authenticated law enforcement and similar entities. Please provide feedback on this concept. If this proposal is adopted, how should it work? Are there best practices in other similar situations or other TLDs that could be used for such a special access portal? What steps should be taken, if any, to ensure the confidentiality of law enforcement requests through the System?

9. What entities in addition to law enforcement, if any, should have special access to usTLD registration data through an authenticated portal? Why?

10. What accountability and/or enforcement mechanisms should be put in place in the case of breach of the System's TOS by those that access the registration data?

11. Do you foresee any challenges to implementation of the System, or elements thereof, for example in distinguishing between personal and non-personal registration data, enforcement of System misuse, etc? If so, how might these challenges be addressed?

12. Should the Accountable WHOIS Gateway System be offered as an opt-in or opt-out service for current and new usTLD domain name registrants?

Stephanie Weiner,

Acting Chief Counsel.

[FR Doc. 2023–09180 Filed 4–28–23; 8:45 am]

BILLING CODE 3510–60–P

CONSUMER FINANCIAL PROTECTION BUREAU

Combined Community Bank Advisory Council and Credit Union Advisory Council Meeting

AGENCY: Consumer Financial Protection Bureau.

ACTION: Notice of public meeting.

SUMMARY: Under the Federal Advisory Committee Act (FACA), this notice sets forth the announcement of a public combined meeting of the Community Bank Advisory Council (CBAC or Council) and the Credit Union Advisory Council (CUAC or Council) of the Consumer Financial Protection Bureau (CFPB or Bureau). The notice also describes the functions of the Councils.

DATES: The meeting date is Wednesday, May 17, 2023, from approximately 1:00 p.m. to 2:30 p.m., eastern daylight time. This meeting will be held virtually and is open to the general public. Members of the public will receive the agenda and dial-in information when they RSVP.

FOR FURTHER INFORMATION CONTACT: Kim George, Outreach and Engagement Associate, Section for Advisory Board and Councils, Office of Stakeholder Management, at 202–450–8617, or email: *CFPB_CABandCouncilsEvents@cfpb.gov*. If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

Section 2 of the CBAC and CUAC charters provides that pursuant to the executive and administrative powers conferred on the CFPB by Section 1012 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), the Director of the CFPB renews the discretionary Community Bank Advisory Council and the Credit Union Advisory Council under agency authority in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. 10.

Section 3 of the CBAC and CUAC charters states that the purpose of the CBAC and the CUAC is to advise the CFPB in the exercise of its functions under the Federal consumer financial laws as they pertain to community banks and credit unions with total assets of $10 billion or less.

II. Agenda

The CBAC and the CUAC will discuss broad policy matters related to the

Bureau's Unified Regulatory Agenda and general scope of authority.

If you require any additional reasonable accommodation(s) in order to attend this event, please contact the Reasonable Accommodations team at *CFPB_ReasonableAccommodations@cfpb.gov,* 48 business hours prior to the start of this event.

Written comments will be accepted from interested members of the public and should be sent to *CFPB_CABandCouncilsEvents@cfpb.gov,* a minimum of seven (7) days in advance of the meeting. The comments will be provided to the CBAC and CUAC members for consideration. Individuals who wish to join this meeting must RSVP via this link *https://surveys.consumerfinance.gov/jfe/form/SV_bwnwpzsDsARDZxY.*

III. Availability

The Councils' agenda will be made available to the public on Monday, May 1, 2023, via *consumerfinance.gov.*

A recording and summary of this combined meeting will be available after the meeting on the Bureau's website *consumerfinance.gov.*

Emily Ross,

Acting Deputy Chief of Staff, Consumer Financial Protection Bureau.

[FR Doc. 2023–08797 Filed 4–28–23; 8:45 am]

BILLING CODE 4810–AM–P

CONSUMER FINANCIAL PROTECTION BUREAU

Consumer Advisory Board Meeting

AGENCY: Consumer Financial Protection Bureau.

ACTION: Notice of public meeting.

SUMMARY: Under the Federal Advisory Committee Act (FACA), this notice sets forth the announcement of a public meeting of the Consumer Advisory Board (CAB or Board) of the Consumer Financial Protection Bureau (CFPB or Bureau). The notice also describes the functions of the Board.

DATES: The meeting date is Tuesday, May 16, 2023, from approximately 1:45 p.m. to 3:30 p.m., eastern daylight time. This meeting will be held virtually and is open to the general public. Members of the public will receive the agenda and dial-in information when they RSVP.

FOR FURTHER INFORMATION CONTACT: Kim George, Outreach and Engagement Associate, Section for Advisory Board and Councils, Office of Stakeholder Management, at 202–450–8617, or email: *CFPB_CABandCouncilsEvents@cfpb.gov.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 3 of the Charter of the Board states that: The purpose of the CAB is outlined in section 1014(a) of the Dodd-Frank Act, which states that the CAB shall ''advise and consult with the Bureau in the exercise of its functions under the Federal consumer financial laws'' and ''provide information on emerging practices in the consumer financial products or services industry, including regional trends, concerns, and other relevant information.''

To carry out the CAB's purpose, the scope of its activities shall include providing information, analysis, and recommendations to the CFPB. The CAB will generally serve as a vehicle for trends and themes in the consumer finance marketplace for the CFPB. Its objectives will include identifying and assessing the impact on consumers and other market participants of new, emerging, and changing products, practices, or services.

II. Agenda

The CAB will discuss broad policy matters related to the Bureau's Unified Regulatory Agenda and general scope of authority.

If you require any additional reasonable accommodation(s) in order to attend this event, please contact the Reasonable Accommodations team at *CFPB_ReasonableAccommodations@cfpb.gov* 48 hours prior to the start of this event.

Written comments will be accepted from interested members of the public and should be sent to *CFPB_CABandCouncilsEvents@cfpb.gov,* a minimum of seven (7) days in advance of the meeting. The comments will be provided to the CAB members for consideration. Individuals who wish to join this meeting must RSVP via this link *https://surveys.consumerfinance.gov/jfe/form/SV_9nW7knutk20UH8G.*

III. Availability

The Board's agenda will be made available to the public on May 1, 2023, via *consumerfinance.gov.*

A recording and summary of this meeting will be available after the meeting on the Bureau's website *consumerfinance.gov.*

Emily Ross,

Acting Deputy Chief of Staff, Consumer Financial Protection Bureau.

[FR Doc. 2023–08796 Filed 4–28–23; 8:45 am]

BILLING CODE 4810–AM–P

CONSUMER FINANCIAL PROTECTION BUREAU

Academic Research Council Meeting

AGENCY: Consumer Financial Protection Bureau.

ACTION: Notice of public meeting.

SUMMARY: Under the Federal Advisory Committee Act (FACA), this notice sets forth the announcement of a public meeting of the Academic Research Council (ARC or Council) of the Consumer Financial Protection Bureau (CFPB or Bureau). The notice also describes the functions of the Council.

DATES: The meeting date is Friday, May 19, 2023, from approximately 1 to 3:15 p.m., eastern daylight time. This meeting will be held virtually and is open to the general public. Members of the public will receive the agenda and dial-in information when they RSVP.

FOR FURTHER INFORMATION CONTACT: Kim George, Outreach and Engagement Associate, Section for Advisory Board and Councils, Office of Stakeholder Management, at 202–450–8617, or email: *CFPB_CABandCouncilsEvents@cfpb.gov.* If you require this document in an alternative electronic format, please contact *CFPB_Accessibility@cfpb.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 2 of the of the ARC Charter provides that pursuant to the executive and administrative powers conferred on the CFPB by section 1012 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), the Director of the CFPB renews the discretionary Academic Research Council under agency authority in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. 10.

Section 3 of the ARC Charter states: ''The committee will (1) provide the CFPB with advice about its strategic research planning process and research agenda, including views on the research that the CFPB should conduct relating to consumer financial products or services, consumer behavior, cost-benefit analysis, or other topics to enable the agency to further its statutory

purposes and objectives; and (2) provide the Office of Research with technical advice and feedback on research methodologies, data collection strategies, and methods of analysis, including methodologies and strategies for quantifying the costs and benefits of regulatory actions; and (3) serve as peer reviewers of policy-determinative research conducted by the CFPB.''

II. Agenda

The ARC will discuss broad policy matters related to the Bureau's Research Agenda and general scope of authority.

If you require any additional reasonable accommodations(s) in order to attend this event, please contact the Reasonable Accommodations team at *CFPB_ReasonableAccommodations@cfpb.gov* 48 hours prior to the start of this event.

Written comments will be accepted from interested members of the public and should be sent to *CFPB_CABandCouncilsEvents@cfpb.gov,* a minimum of seven (7) days in advance of the meeting. The comments will be provided to the ARC members for consideration. Individuals who wish to attend this meeting must RSVP via this link *https://surveys.consumerfinance.gov/jfe/form/SV_cIvDn6CqQQWh2zI.*

III. Availability

The Council's agenda will be available on Monday, May 1, 2023, and meeting presentations will be made available to the public on Friday, May 19, 2023, at noontime, both via *consumerfinance.gov.*

A recording and summary of this meeting will be available after the meeting on the Bureau's website, *consumerfinance.gov.*

Emily Ross,

Acting Deputy Chief of Staff, Consumer Financial Protection Bureau.

[FR Doc. 2023–08798 Filed 4–28–23; 8:45 am]

BILLING CODE 4810–AM–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 Wednesday, May 10, 2023 from 8:15 a.m. to 5:00 p.m. and Thursday, May 11, 2023 from 8:15 a.m. to 4:00 p.m.

ADDRESSES: The address of the closed meeting is the Executive Conference Center, 4075 Wilson Blvd., Floor 3, Arlington, VA 22203.

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 title 5 United States Code (U.S.C.) chapter 10 (commonly known as the ''Federal Advisory Committee Act (FACA)''), 5 U.S.C. 552b(c) (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).

Due to circumstances beyond the control of the Designated Federal Officer, the Defense Science Board was unable to provide public notification required by 41 CFR 102–3.150(a) concerning its May 10–11, 2023 meeting. Accordingly, the Advisory Committee Management Officer for the Department of Defense, pursuant to 41 CFR 102–3.150(b), waives the 15-calendar day notification requirement.

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 Wednesday, May 10, 2023 at 8:15 a.m. with administrative opening remarks from Mr. Kevin Doxey, DFO and Executive Director, and a classified overview of the objectives of the Summer Study from Dr. Eric Evans, the DSB Chair. Next, the DSB members will meet in a plenary session to discuss classified strategies for anticipating the global stresses and possible conflict due to climate change. Following break, the DSB members will meet in a plenary session to discuss classified strategies for anticipating the global stresses and possible conflict due to climate change. Next, members will meet in a breakout session to discuss classified strategies for anticipating the global stresses and possible conflict due to climate change. The meeting will adjourn at 5:00 p.m. On Thursday, May 11, 2023, the DSB members will meet in a breakout session to discuss classified strategies for anticipating the global stresses and possible conflict due to climate change. Next, the DSB members will meet in a plenary session to discuss classified strategies for anticipating the global stresses and possible conflict due to climate change. Following break, the DSB members will meet in a plenary session to discuss classified strategies for anticipating the global stresses and possible conflict due to climate change. The meeting will adjourn at 4:00 p.m.

Meeting Accessibility: In accordance with 5 U.S.C. 1009(d) and 41 CFR 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 meetings. 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: April 26, 2023.

Aaron T. Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2023–09174 Filed 4–28–23; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

National Assessment Governing Board; Meeting

AGENCY: National Assessment Governing Board, Department of Education.

ACTION: Notice of open and closed meetings.

SUMMARY: This notice sets forth the agenda, time, and instructions to access or participate in the National Assessment Governing Board (hereafter referred to as Governing Board or Board) meetings scheduled for May 18–19, 2023, in Los Angeles, CA. This is a hybrid meeting, accessible both in person and virtually by advance registration 5 working days prior to each meeting via *www.nagb.gov.* This notice provides information about the meetings to members of the public who may be interested in attending the meetings and/or providing written comments related to the work of the Governing Board. Notice of the meetings is required under section 1009(a)(2) of 5 U.S.C. chapter 10 (Federal Advisory Committees).

ADDRESSES: Doubletree by Hilton Los Angeles Downtown, 120 South Los Angeles Street, Los Angeles, CA 90012.

DATES: The Quarterly Board Meeting will be held on the following dates:

- May 18, 2023, from 12:30 p.m. to 5:45 p.m., PDT
- May 19, 2023, from 8:45 a.m. to 2:45 p.m., PDT

FOR FURTHER INFORMATION CONTACT: Munira Mwalimu, Executive Officer/Designated Federal Official for the Governing Board, 800 North Capitol Street NW, Suite 825, Washington, DC 20002, telephone: (202) 357–6906, fax: (202) 357–6945, email: *Munira.Mwalimu@ed.gov.*

SUPPLEMENTARY INFORMATION:

Statutory Authority and Function: The Governing Board is established under the National Assessment of Educational Progress Authorization Act, Title III of Public Law 107–279 (20 U.S.C. 9621). Information on the Governing Board and its work can be found at *www.nagb.gov.* The Governing Board formulates policy for the National Assessment of Educational Progress (NAEP) administered by the National Center for Education Statistics (NCES). The Governing Board's responsibilities include:

''(1) selecting the subject areas to be assessed; (2) developing appropriate student achievement levels; (3) developing assessment objectives and testing specifications that produce an assessment that is valid and reliable, and are based on relevant widely accepted professional standards; (4) developing a process for review of the assessment which includes the active participation of teachers, curriculum specialists, local school administrators, parents, and concerned members of the public; (5) designing the methodology of the assessment to ensure that assessment items are valid and reliable, in consultation with appropriate technical experts in measurement and assessment, content and subject matter, sampling, and other technical experts who engage in large scale surveys; (6) measuring student academic achievement in grades 4, 8, and 12 in the authorized academic subjects; (7) developing guidelines for reporting and disseminating results; (8) developing standards and procedures for regional and national comparisons; (9) taking appropriate actions needed to improve the form, content use, and reporting of results from an assessment; and (10) planning and executing the initial public release of NAEP reports.''

Standing Committee Meetings

The Governing Board's standing committees will meet to conduct regularly scheduled work planned for the quarterly Board meeting and any items undertaken by standing committees for consideration by the full Governing Board. (Please see standing committee meeting minutes for previous meetings, available at *https://www.nagb.gov/governing-board/quarterly-board-meetings.html).* Standing committees will meet in advance of the May 2023 quarterly Board meeting. Standing committee meeting agendas and meeting materials will be posted on the Governing Board's website, *www.nagb.gov,* no later than five business days prior to the committee meetings.

Standing Committee Meetings

Tuesday, May 2, 2023

Nominations Committee (Closed Session)

5 p.m.–6 p.m. (ET), Virtual Meeting.

The Nominations Committee will meet virtually in closed session on Tuesday, May 2, 2023, from 5 p.m. to 6 p.m. to receive an update on nominations for Board terms beginning on October 1, 2023. The committee will discuss the internal nominations process and plans for the 2024 nominations cycle. These discussions pertain solely to internal personnel rules and practices of an agency and information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy. As such, the discussions are protected by exemptions 2 and 6 of the Government Sunshine Act, 5 U.S.C. 552b(c).

Thursday, May 4, 2023

Executive Committee Meeting (Closed Session)

3 p.m.–4:30 p.m. (ET), Virtual Meeting.

The Executive Committee will meet virtually in closed session on Thursday, May 4, 2023, from 3:00 p.m. until 4:30 p.m. to discuss the NAEP and Governing Board's budgets, planned procurements and the NAEP Assessment Schedule. These discussions must be kept confidential to maintain the integrity of the federal budgeting and acquisition processes. Public disclosure of this confidential information would significantly impede implementation of the NAEP assessment program if conducted in open session. Such matters are protected by exemption 9(B) of the Government Sunshine Act, 5 U.S.C. 552b(c).

Monday, May 8, 2023

Reporting and Dissemination Committee (Open Session)

12:30 p.m.–2:30 p.m. (ET), Virtual Meeting.

The Reporting and Dissemination Committee will meet virtually on Monday, May 8, 2023, to receive a debriefing on the NAEP Civics and U.S. History release; results are planned to be released on May 3. The Committee will discuss the release plan for the Long-Term Trend results and how NAEP conducts and reports tests of statistical significance.

Wednesday, May 17, 2023

Assessment Development Committee (Hybrid Meeting)

10:30 a.m.–4:45 p.m. (PDT)
10:30 a.m.–11:45 a.m. (Open Session, hybrid session)
11:45 a.m.–12:15 p.m. (Closed Session, in person meeting)
1:30 p.m.–2:15 p.m. (Open Session, hybrid meeting)
2:15 p.m.–4:45 p.m. (Closed Session, in person meeting)

The Assessment Development Committee will meet in open session on Wednesday, May 17, 2023, at the Doubletree by Hilton Los Angeles Downtown from 10:30 a.m. to 4:45 p.m. From 10:30 a.m. to 11:45 a.m., the committee will meet in open session to discuss commissioned papers on the 2030 NAEP Writing Assessment Framework and potential updates to the Assessment Framework Development Policy.

From 11:45 a.m. until 12:15 p.m. the committee will meet in closed session to discuss independent cost estimates and budget matters related to framework updates. These discussions must be kept confidential to maintain the integrity of the federal budgeting and acquisition processes. Public disclosure of this confidential information would significantly impede implementation of the NAEP assessment program if conducted in open session. Such matters are protected by exemption 9(B) of the Government Sunshine Act, 5 U.S.C. 552b(c).

Following a break, the committee will reconvene in open session from 1:30 p.m. until 2:15 p.m. to discuss feedback from public comment on the NAEP Science Assessment Framework. From 2:15 p.m. until 4:45 p.m. the committee will meet in closed session to review secure and confidential pilot assessment items for 2024 Mathematics and Reading at grades 4 and 8. Public disclosure of this confidential information would significantly impede implementation of the NAEP assessment program if conducted in open session. Such matters are protected by exemption 9(B) of the Government Sunshine Act, 5 U.S.C. 552b(c).

Thursday, May 25, 2023

Committee on Standards, Design and Methodology (Open Session)

10 a.m.–12 p.m. (ET), Virtual

The Committee on Standards, Design and Methodology will meet virtually in open session on Thursday, May 25, 2023, from 10:00 a.m. until 12:00 p.m. to receive general updates on the committee's ongoing work, discuss Effect Sizes on NAEP, and responses to the Achievement Levels Communications Plans.

Quarterly Governing Board Meeting

The plenary sessions of the Governing Board's May 2023 quarterly meeting will be held on the following dates and times (PDT):

Thursday, May 18, 2023:

Open Meeting: 12:30 p.m.–3:30 p.m.;
Closed Meeting: 3:45 p.m.–5:45 p.m.

Friday, May 19, 2023

Closed Meeting: 8:45 a.m.–9:45 a.m.;
Open Meeting: 9:45 a.m.–11:45 a.m.;
Closed Meeting: 11:45 a.m.–1:15 p.m.;
Open Meeting: 1:15 p.m.–2:45 p.m.

Thursday, May 18, 2023

Plenary Session (Hybrid)

12:30–5:45 p.m. (PDT)
12:30–3:30 p.m. (Open Session)
3:45 p.m.–5:45 p.m. (Closed Session)

On Friday, May 18, 2023, the plenary session of the Governing Board meeting will convene in open session from 12:30 p.m. to 3:30 p.m. in open session. Governing Board Chair Beverly Perdue, will welcome members, followed by motions to approve the meeting agenda for the May 18–19, 2023, and meeting minutes from the March 2–3, 2023, Governing Board meeting. Thereafter, from 12:45 p.m. to 1:15 p.m., Lesley Muldoon, Executive Director of the Governing Board, will update members on ongoing work followed by an update from Mark Schneider, Director, Institute of Education Sciences (IES) from 1:15 p.m. until 1:45 p.m. From 1:45 p.m. until 2:15 p.m. the Board will receive updates from Peggy Carr, Commissioner, NCES, on NAEP activities. From 2:15 p.m. to 3:30 p.m. the Board will receive a briefing on Measuring Socioeconomic Status.

After a 15 minutes break, the meeting will re-convene in closed session from 3:45 p.m. to 5:45 p.m. to receive an update on the NAEP Budget and Assessment Schedule from NCES Commissioner Peggy Carr. These discussions must be kept confidential to maintain the integrity of the federal budgeting and acquisition processes. Public disclosure of this confidential information would significantly impede implementation of the NAEP assessment program if conducted in open session. Such matters are protected by exemption 9(B) of the Government Sunshine Act, 5 U.S.C. 552b(c). The May 18, 2023, session of the Board meeting will adjourn at 5:45 p.m.

Friday, May 19, 2023

Plenary Session (Hybrid)—8:45 a.m.–2:45 p.m. (PDT)

8:45 a.m.–9:45 a.m. (Closed Session)
9:45 a.m.–11:45 a.m. (Open Session)
11:45 a.m.–1:15 p.m. (Closed Session)
1:15 p.m.–2:45 p.m. (Open Session)

On May 19, 2023, the Governing Board will meet in closed session from 8:45 a.m. to 9:45 a.m. to continue discussion on the NAEP Budget and Assessment Schedule. These discussions must be kept confidential to maintain the integrity of the federal budgeting and acquisition processes. Public disclosure of this confidential information would significantly impede implementation of the NAEP assessment program if conducted in open session. Such matters are protected by exemption 9(B) of the Government Sunshine Act, 5 U.S.C. 552b(c).

The meeting will then transition to an open session from 9:45 a.m. to 11:15 a.m. to discuss public comment and recommendations on the Science Assessment Framework Update. From 11:15 a.m. until 11:45 a.m. the Board will engage in open discussion on future topics for consideration and ongoing work.

From 11:45 a.m. until 1:15 p.m., the Board will receive a briefing in a closed session on the embargoed results from the 2022 Long-Term Trend—age 13 assessment. These results have not been released to the public. Disclosure of this confidential information would significantly impede implementation of the NAEP assessment program if conducted in open session. Such matters are protected by exemption 9(B) of the Government Sunshine Act, 5 U.S.C. 552b(c).

Members then will then convene in open session from 1:15 p.m. until 2:45 p.m. to discuss the release plan for NAEP Long-Term Trend and Linking Studies. The May 19, 2023, session of the Governing Board meeting will adjourn at 2:45 p.m.

The quarterly Board meeting and standing committee meeting agendas, along with the meeting materials, will be posted on the Governing Board's website at *www.nagb.gov* no later than five working days prior to each meeting.

Instructions for Participating in the Meetings

Registration: Members of the public may attend all open sessions of the Governing Board's May 18–19, 2023, meetings in-person or virtually. A link to register for both the in-person and virtual attendance for the open sessions and instructions for how to register will be posted on the Governing Board's website at *www.nagb.gov* no later than 5 business days prior to each meeting. Registration is required to join the meeting virtually.

Public Comment: Written comments related to the work of the Governing Board and its committees may be submitted electronically or in hard copy to the attention of the Executive Officer/Designated Federal Official (DFO) via email at *Munira.Mwalimu@ed.gov* no later than 10 business days prior to the meeting. Written comments should be directed to the DFO as they relate to committee and Board meeting work and

should reference the relevant agenda item.

Access to Records of the Meeting: Pursuant to 5 U.S.C. 1009(b), the public may inspect the meeting materials at *www.nagb.gov,* which will be made available no later than five business days prior to each meeting. The public may also inspect the meeting materials and other Governing Board records at 800 North Capitol Street NW, Suite 825, Washington, DC 20002, by emailing *Munira.Mwalimu@ed.gov* to schedule an appointment. The official verbatim transcripts of the open meeting sessions will be available for public inspection no later than 30 calendar days following each meeting and will be posted on the Governing Board's website. Requests for the verbatim transcriptions may be made via email to the DFO noted above.

Reasonable Accommodations: The meeting location is accessible to individuals with disabilities. If you will need an auxiliary aid or service to participate in the meeting (*e.g.,* interpreting service, assistive listening device, or materials in an alternate format), notify the DFO listed in this notice no later than ten working days prior to each meeting date.

Electronic Access to this Document: The official version of this document is the document published in the **Federal Register**. 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 Adobe website. You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Authority: Public Law 107–279, Title III, 301—National Assessment of Educational Progress Authorization Act (20 U.S.C. 9621).

Lesley Muldoon,

Executive Director, National Assessment Governing Board (NAGB), U.S. Department of Education.

[FR Doc. 2023–09114 Filed 4–28–23; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2023–SCC–0074]

Agency Information Collection Activities; Comment Request; HEERF No Cost Extension (NCE) Request Form

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, ED is requesting the Office of Management and Budget (OMB) to conduct an emergency review of a new information collection.

DATES: The Department requested emergency processing from OMB for this information collection request on ED–2023–SCC–0074 by May 3, 2023. As a result, the Department is providing the public with the opportunity to comment under the full comment period. Interested persons are invited to submit comments on or before June 30, 2023.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2023–SCC–0074. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. If the *regulations.gov* site is not available to the public for any reason, the Department will temporarily accept comments at *ICDocketMgr@ed.gov.* Please include the docket ID number and the title of the information collection request when requesting documents or submitting comments. Please note that comments submitted after the comment period will not be accepted. Written requests for information or comments submitted by postal mail or delivery should be addressed to the Manager of the Strategic Collections and Clearance Governance and Strategy Division, U.S. Department of Education, 400 Maryland Ave. SW, LBJ, Room 6W203, Washington, DC 20202–8240.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Karen Epps, 202–453–6337.

SUPPLEMENTARY INFORMATION: The Department, in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. The Department is soliciting comments on the proposed information collection request (ICR) that is described below. 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: HEERF No Cost Extension (NCE) Request Form.

OMB Control Number: 1840–NEW.

Type of Review: A new ICR.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 720.

Total Estimated Number of Annual Burden Hours: 360.

Abstract: The Higher Education Emergency Relief Fund (HEERF) authorizes the Secretary of Education to allocate formula grant funds to participating institutions of higher education (IHEs) to address impacts of COVID–19. To date, the Department has made over 18,000 awards to over 5,100 IHEs totaling $76.3 billion. In both volume of grants and amount of funding, HEERF is one of the largest grant programs in agency history. On June 30, 2023, the project period for most HEERF grants will end and any remaining unliquidated grant funds will be returned to Treasury. Pursuant to 2 CFR 200.308(e)(2) and 34 CFR 75.261(a), grantees have the option to receive up to a twelve-month No-Cost Extension (NCE) of their grant project periods. The Department is requesting emergency approval of a new information collection to allow for HEERF grantees to request an extension beyond June 30, 2023 and ensure that grantees have a thought-out plan for using their remaining HEERF grant funds to address the lingering effects and impacts related

to COVID–19. In addition, the Department is requesting emergency clearance and OMB approval by May 3, 2023 in order to streamline the review and approval process as well as ensure that the reasons for requesting an extension of the HEERF project period beyond June 30, 2023 meet the applicable legal requirements. As such, the Department has created a data collection form for HEERF grantees to provide the information required to request NCEs for up to an additional twelve months to spend their remaining HEERF grant balances. The form requests information that is required under 2 CFR 200.308(e)(2) and 34 CFR 75.261(a) to grant NCEs. The Department has attempted to reduce burden on grantees by requesting, prospectively, much of the same information that grantees report on in their HEERF annual performance reports. Providing a streamlined process for NCE requests will speed the process of reviewing and approving NCE requests and help ensure grantees are able to spend down their funds in a reasonable timeframe while focusing on the pressing needs of their students and institutions.

Dated: April 26, 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. 2023–09185 Filed 4–28–23; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2023–SCC–0017]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Evaluation of Full-Service Community Schools: Early Implementation Data Collection

AGENCY: Institute of Education Sciences (IES), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act (PRA) of 1995, the Department is proposing a new information collection request (ICR).

DATES: Interested persons are invited to submit comments on or before May 31, 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 Erica Johnson, (202) 245–7676.

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: Evaluation of Full-Service Community Schools: Early Implementation Data Collection.

OMB Control Number: 1850–NEW.

Type of Review: New ICR.

Respondents/Affected Public: State, Local, and Tribal Governments.

Total Estimated Number of Annual Responses: 14.

Total Estimated Number of Annual Burden Hours: 4.

Abstract: The Full-Service Community Schools program seeks to improve student outcomes by helping schools expand and enrich learning opportunities, provide integrated student support services, strengthen family and community engagement, and adopt collaborative leadership practices that include families and community organizations. Congress has invested $180 million in Full-Service Community Schools grants and mandated an evaluation of the program.

This package requests approval to conduct a survey of Full-Service Community Schools 2022 grantees. These data will be used to study the early implementation of the Full-Service Community Schools program.

Dated: April 25, 2023.

Juliana Pearson,

PRA Coordinator, Strategic Collections and Clearance Governance and Strategy Division, Office of Chief Data Officer, Office of Planning, Evaluation and Policy Development.

[FR Doc. 2023–09091 Filed 4–28–23; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

[Docket No. 14–96–LNG]

Alaska LNG Project LLC; Order Affirming and Amending DOE/FE Order No. 3643–A Following Partial Grant of Rehearing

AGENCY: Office of Fossil Energy and Carbon Management, Department of Energy.

ACTION: Amended record of decision.

SUMMARY: The Office of Fossil Energy and Carbon Management (FECM) of the Department of Energy (DOE) gives notice of an Amended Record of Decision (ROD) published under the National Environmental Policy Act of 1969 (NEPA) and implementing regulations. This Amended ROD is an Appendix to DOE/FECM Order No. 3643–C, an order that affirms and amends the previously-issued DOE/FE Order No. 3643–A, an order authorizing Alaska LNG Project LLC to export domestically-produced liquefied natural gas (LNG) to non-free trade agreement countries under section 3(a) of the Natural Gas Act (NGA).

FOR FURTHER INFORMATION CONTACT:

Brian Lavoie, U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Resource Sustainability, Office of Fossil Energy and Carbon Management, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–2459, *brian.lavoie@hq.doe.gov*

Cassandra Bernstein, U.S. Department of Energy (GC–76), Office of the Assistant General Counsel for Energy Delivery and Resilience, Forrestal Building, Room 6D–033, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–9793, *cassandra.bernstein@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: On April 13, 2023, DOE issued Order No. 3643–C to Alaska LNG Project LLC (Alaska LNG) under NGA section 3(a), 15 U.S.C.

717b(a). This Order affirms and amends Order No. 3643–A, previously issued to Alaska LNG on August 20, 2020, under NGA section 3(a). Order No. 3643–A authorized Alaska LNG to export LNG produced from Alaskan sources by vessel to any country with which the United States has not entered into a free trade agreement (FTA) requiring national treatment for trade in natural gas, and with which trade is not prohibited by U.S. law or policy (non-FTA countries). On April 15, 2021, DOE issued Order No. 3643–B, which granted rehearing of Order No. 3643–A for the purpose of conducting two Alaska-specific environmental studies. DOE issued Order No. 3643–C following its evaluation of the additional studies.

Under Order No. 3643–C, Alaska LNG is authorized to export LNG in a volume equivalent to 929 billion cubic feet (Bcf) per year of natural gas (2.55 Bcf/day) to non-FTA countries from the proposed Alaska LNG Project (Project) to be located in the Nikiski area of the Kenai Peninsula, Alaska. The Order reaffirms and maintains all obligations, rights, responsibilities, and deadlines established in Order No. 3643–A. In addition, it requires Alaska LNG to certify monthly to DOE that, except under strictly limited circumstances, the natural gas produced for export in the form of LNG in the prior month did not result in the venting of byproduct carbon dioxide into the atmosphere.

DOE conducted the additional environmental studies in the rehearing process through preparation of a Supplemental Environmental Impact Statement (SEIS). DOE had participated as a cooperating agency with the Federal Energy Regulatory Commission in preparing an environmental impact statement (EIS) analyzing the potential environmental impacts of the proposed Project (including an LNG export terminal, along with the associated facilities and pipeline) that would be used to support the export authorization Alaska LNG sought from DOE. DOE adopted the EIS and prepared a ROD, which is attached as an appendix to Order No. 3643–A. The Amended ROD is based on the SEIS and is attached as an appendix to Order No. 3643–C. The Amended ROD can be found here: *www.energy.gov/sites/default/files/2023–04/ord3643–C.pdf.*

Signed in Washington, DC, on April 26, 2023.

Amy Sweeney,

Director, Office of Regulation, Analysis, and Engagement, Office of Resource Sustainability.

[FR Doc. 2023–09159 Filed 4–28–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Paducah

AGENCY: Office of Environmental Management, Department of Energy.

ACTION: Notice of open meeting: correction.

SUMMARY: On April 24, 2023, the Department of Energy published a notice of open meeting announcing a meeting on May 18, 2023, of the Environmental Management Site-Specific Advisory Board, Paducah, in the April 24, 2023 **Federal Register**. This document makes a correction to that notice.

FOR FURTHER INFORMATION CONTACT: Eric Roberts, Board Support Manager, by Phone: (270) 554–3004 or Email: *eric@pgdpcab.org.*

Corrections

In the **Federal Register** of April 24, 2023, in FR Doc. 2023–08520, on page 24785, please make the following corrections:

In that notice under **DATES**, third column, second paragraph, the meeting date has been changed. The original date was May 18, 2023. The new date is May 25, 2023.

In that notice under **ADDRESSES**, third column, third paragraph, the meeting room has been changed. The original address and meeting room was West Kentucky Community and Technical College, Emerging Technology Center, Room 109, 5100 Alben Barkley Drive, Paducah, Kentucky 42001. The new meeting room is Room 216.

The reason for the corrections is a scheduling conflict with the original meeting date.

Signed in Washington, DC, on April 26, 2023.

LaTanya Butler,

Deputy Committee Management Officer.

[FR Doc. 2023–09122 Filed 4–28–23; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[Docket No. 13–132–LNG]

Magnolia LNG LLC; Order Amending Long-Term Authorization To Export Liquefied Natural Gas to Non-Free Trade Agreement Nations

AGENCY: Office of Fossil Energy and Carbon Management, Department of Energy.

ACTION: Amended record of decision.

SUMMARY: The Office of Fossil Energy and Carbon Management (FECM) of the Department of Energy (DOE) gives notice of an Amended Record of Decision (ROD) published under the National Environmental Policy Act of 1969 (NEPA) and implementing regulations. This Amended ROD is an Appendix to DOE/FECM Order No. 3909–C, an order that amends the previously-issued DOE/FE Order No. 3909, an opinion and order authorizing Magnolia LNG LLC to export domestically-produced liquefied natural gas (LNG) to non-free trade agreement countries under section 3(a) of the Natural Gas Act (NGA).

FOR FURTHER INFORMATION CONTACT:

Brian Lavoie, U.S. Department of Energy (FE–34), Office of Regulation, Analysis, and Engagement, Office of Resource Sustainability, Office of Fossil Energy and Carbon Management, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–2459, *brian.lavoie@hq.doe.gov*.

Cassandra Bernstein, U.S. Department of Energy (GC–76), Office of the Assistant General Counsel for Energy Delivery and Resilience, Forrestal Building, Room 6D–033, 1000 Independence Avenue SW, Washington, DC 20585, (202) 586–9793, *cassandra.bernstein@hq.doe.gov*.

SUPPLEMENTARY INFORMATION: On April 27, 2022, DOE issued Order No. 3909–C to Magnolia LNG LLC (Magnolia LNG) under NGA section 3(a), 15 U.S.C. 717b(a). This Order further amends Order No. 3909, previously issued to Magnolia LNG on November 30, 2016, under NGA section 3(a). Order No. 3909, as amended, authorized Magnolia LNG to export domestically-produced LNG by vessel to any country with which the United States has not entered into a free trade agreement (FTA) requiring national treatment for trade in natural gas, and with which trade is not prohibited by U.S. law or policy (non-FTA countries).

Order No. 3909–C authorizes an increase in the volume of exports previously authorized in the amended Order No. 3909. Under Order No. 3909–C, Magnolia LNG is authorized to export LNG in a volume equivalent to 449 billion cubic feet (Bcf) per year of natural gas (approximately 1.23 Bcf per day) to non-FTA countries from the proposed Magnolia LNG Terminal, to be located near Lake Charles, Calcasieu Parish, Louisiana.

DOE participated as a cooperating agency with the Federal Energy Regulatory Commission (FERC) in preparing a supplemental

environmental impact statement (SEIS) analyzing the potential environmental impacts of the proposed increase in authorized export capacity. DOE adopted the SEIS and reviewed FERC's order authorizing the volume increase, under NEPA. DOE also supplemented FERC's environmental review with its own additional environmental studies, as well as the Marine Transport Technical Support Document prepared by DOE to consider the potential effects associated with transporting natural gas, including LNG, on marine vessels. On the basis of this record, DOE issued an Amended ROD, which is attached as an appendix to the Order. The Amended ROD can be found here: *www.energy.gov/sites/default/files/2022-04/ord3909c.pdf.*

Signed in Washington, DC, on April 26, 2023.

Amy Sweeney,

Director, Office of Regulation, Analysis, and Engagement, Office of Resource Sustainability.

[FR Doc. 2023–09161 Filed 4–28–23; 8:45 am]

BILLING CODE 6450–01–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: ER10–1852–078; ER10–2641–045.

Applicants: Oleander Power Project, Limited Partnership, Florida Power & Light Company.

Description: Notice of Change in Status of Florida Power & Light Company, et al.

Filed Date: 4/20/23.

Accession Number: 20230420–5252.

Comment Date: 5 p.m. ET 5/11/23.

Docket Numbers: ER18–2418–008.

Applicants: Great River Hydro, LLC.

Description: Notice of Non-Material Change in Status of Great River Hydro, LLC.

Filed Date: 4/24/23.

Accession Number: 20230424–5282.

Comment Date: 5 p.m. ET 5/15/23.

Docket Numbers: ER23–1277–000.

Applicants: Aron Energy Prepay 23 LLC.

Description: Supplement to Aron Energy Prepay 23 LLC submits tariff filing per 35.12: Baseline new to be effective 5/9/2023.

Filed Date: 3/28/23.

Accession Number: 20230328–5303.

Comment Date: 5 p.m. ET 5/5/23.

Docket Numbers: ER23–1700–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Update Default Gross Cost of New Entry & Default Gross Avoidable Cost Rate to be effective 6/23/2023.

Filed Date: 4/24/23.

Accession Number: 20230424–5203.

Comment Date: 5 p.m. ET 5/15/23.

Docket Numbers: ER23–1701–000.

Applicants: PacifiCorp.

Description: § 205(d) Rate Filing: Tri-State Master Installation, O&M Agmt for Metering (Rev 5) to be effective 6/25/2023.

Filed Date: 4/25/23.

Accession Number: 20230425–5091.

Comment Date: 5 p.m. ET 5/16/23.

Docket Numbers: ER23–1702–000.

Applicants: Alabama Power Company, Georgia Power Company, Mississippi Power Company.

Description: Tariff Amendment: Alabama Power Company submits tariff filing per 35.15: Columbiana PV II LGIA Termination Filing to be effective 4/25/2023.

Filed Date: 4/25/23.

Accession Number: 20230425–5144.

Comment Date: 5 p.m. ET 5/16/23.

Docket Numbers: ER23–1703–000.

Applicants: Stanton Battery Energy Storage, LLC.

Description: Baseline eTariff Filing: Application for Market Based Rate Authority to be effective 6/5/2023.

Filed Date: 4/25/23.

Accession Number: 20230425–5174.

Comment Date: 5 p.m. ET 5/16/23.

Docket Numbers: ER23–1704–000.

Applicants: WGP Redwood Holdings, LLC.

Description: § 205(d) Rate Filing: Updated Market Based Rate Tariff to be effective 4/26/2023.

Filed Date: 4/25/23.

Accession Number: 20230425–5176.

Comment Date: 5 p.m. ET 5/16/23.

Docket Numbers: ER23–1705–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original NSA, Service Agreement No. 6884; Queue No. AC1–074/AC2–075 to be effective 6/26/2023.

Filed Date: 4/25/23.

Accession Number: 20230425–5191.

Comment Date: 5 p.m. ET 5/16/23.

Docket Numbers: ER23–1706–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Original NSA, SA No. 6869; Queue No. AE2–071/AF1–203 to be effective 4/26/2023.

Filed Date: 4/25/23.

Accession Number: 20230425–5192.

Comment Date: 5 p.m. ET 5/16/23.

Docket Numbers: ER23–1707–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Amendment to ISA, Service Agreement No. 6436; Queue No. AE2–224 to be effective 6/26/2023.

Filed Date: 4/25/23.

Accession Number: 20230425–5197.

Comment Date: 5 p.m. ET 5/16/23.

Docket Numbers: ER23–1708–000.

Applicants: Florida Power & Light Company.

Description: § 205(d) Rate Filing: FPL 2021 True-Up Revisions to Appendix B of Rate Schedule No. 317 to be effective 1/1/2021.

Filed Date: 4/25/23.

Accession Number: 20230425–5229.

Comment Date: 5 p.m. ET 5/16/23.

Docket Numbers: ER23–1709–000.

Applicants: Florida Power & Light Company.

Description: § 205(d) Rate Filing: FPL 2021 True-Up Revisions to Appendix B of Rate Schedule No. 322 to be effective 1/1/2021.

Filed Date: 4/25/23.

Accession Number: 20230425–5231.

Comment Date: 5 p.m. ET 5/16/23.

Docket Numbers: ER23–1710–000.

Applicants: El Paso Electric Company.

Description: § 205(d) Rate Filing: Concurrence of EPE to APS Service Agreement No. 387, Sonoran Solar Energy to be effective 5/7/2023.

Filed Date: 4/25/23.

Accession Number: 20230425–5265.

Comment Date: 5 p.m. ET 5/16/23.

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 or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: April 25, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–09132 Filed 4–28–23; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 2853–073]

Montana Department of Natural Resources and Conservation; Notice of Application Accepted for Filing and Soliciting Motions To Intervene and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* New Major License.

b. *Project No.:* 2853–073.

c. *Date Filed:* June 30, 2022.

d. *Applicant:* Montana Department of Natural Resources and Conservation (Montana DNRC).

e. *Name of Project:* Broadwater Hydroelectric Project (project).

f. *Location:* On the Missouri River near the town of Toston in Broadwater County, Montana. The project is adjacent to and includes federal lands administered by the Bureau of Land Management.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. 791(a)–825(r).

h. *Applicant Contact:* David Lofftus, Hydro Power Program Manager, Montana Department of Natural Resources and Conservation, 1424 9th Avenue, P.O. Box 201601, Helena, Montana 59620; Phone at (406) 444–6659; or email at *dlofftus@mt.gov.*

i. *FERC Contact:* Ingrid Brofman at (202) 502–8347, or *ingrid.brofman@ferc.gov.*

j. *Deadline for filing motions to intervene and protests:* June 24, 2023.

The Commission strongly encourages electronic filing. Please file motions to intervene and protests using the Commission's eFiling system at *https://ferconline.ferc.gov/FERCOnline.aspx.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, you may submit a paper copy. Submissions sent via the U.S. Postal Service must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE, Room 1A, Washington, DC 20426. Submissions sent via any other carrier must be addressed to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 12225 Wilkins Avenue, Rockville, Maryland 20852. All filings must clearly identify the project name and docket number on the first page: Broadwater Hydroelectric Project (P–2853–073).

The Commission's Rules of Practice and Procedure require all interveners filing documents with the Commission to serve a copy of that document on each person on the official service list for the project. Further, if an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. This application has been accepted for filing, but is not ready for environmental analysis at this time.

l. The existing Broadwater Hydroelectric Project consists of: (1) a 630-foot-long, 24-foot-high concrete gravity dam with a 360-foot-long spillway containing seven inflatable rubber gates capable of raising the dam's crest elevation by 11 feet; (2) a 275-acre, 9-mile-long reservoir; (3) a 160-foot long rock jetty that extends upstream into the reservoir that serves to separate inflow to the powerhouse from the headworks of the non-project irrigation canal adjacent to the dam; (4) an intake integral with the powerhouse and covered by two inclined trashracks, each 20 feet wide and 40 feet high, with a clear bar spacing of 3 inches; (5) a 160-foot-long, 46-foot-wide, 64-foot high powerhouse containing a single Kaplan turbine with a rated capacity of 9.66 megawatts; (6) a 100-kilovolt, 2.8-mile-long transmission line; and (7) appurtenant facilities.

The project is operated in a run-of-river mode and generates an estimated average of 40,669 megawatt-hours per year.

Montana DNRC proposes to remove the jetty that separates the hydropower intake and the irrigation canal intake and install two parallel 100-foot-long, 10-foot-wide by 10-foot-high box culverts within the irrigation intake canal and a bulkhead near the current irrigation headworks. Once these facilities are installed, any water diverted for irrigation first pass through a new angled screen with 6-inch spacing between the bars and then pass through the two new box culverts before entering the existing irrigation intake at the dam. The existing irrigation intake and facilities at the dam conveying water to the Broadwater-Missouri irrigation canal system would remain in place. Montana DNRC proposes to include the new tilted screen and box culverts as licensed project facilities.

Montana DNRC also proposes to modernize the project trash rake (*i.e.,* replace and recalibrate sensors on the rake) to minimize debris buildup on the dam intake and to upgrade its SCADA monitoring system (*i.e.,* improving connectivity to the substation, protective relaying, and automation upgrades).

Montana DNRC proposes to continue to operate the project in an automated run-of-river mode throughout the year where outflow from the project approximates inflow (minus flows diverted for irrigation). Montana DNRC proposes to modify its procedures for responding to an unplanned unit trip to reduce the potential for fish stranding downstream of the project.

m. A copy of the application is available for review 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. For assistance, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll free, (886) 208–3676 or TTY (202) 502–8659.

You may also register online at *https://ferconline.ferc.gov/FERCOnline.aspx* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

n. Anyone may submit a protest or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, 385.211, and 385.214. In determining the appropriate action to take, the Commission will consider all protests filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any protests or motions to intervene must be received on or before the specified deadline date for the particular application.

When the application is ready for environmental analysis, the Commission will issue a public notice requesting comments, recommendations, terms and conditions, or prescriptions.

All filings must (1) bear in all capital letters the title ''PROTEST'' or ''MOTION TO INTERVENE;'' (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. Agencies may obtain copies of the application directly from the applicant.

A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application.

o. *Procedural schedule:* The application will be processed according to the following schedule. Revisions to the schedule will be made as appropriate.

Issue Notice of Ready for Environmental Analysis: June 2023.

Deadline for Filing Comments, Recommendations, and Agency Terms and Conditions/Prescriptions: July 2023.

Deadline for Filing Reply Comments: September 2023.

Dated: April 25, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–09133 Filed 4–28–23; 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 & Oil Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP23–700–000.

Applicants: ANR Pipeline Company.

Description: Compliance filing: 2023 Operational Purchases and Sales Report to be effective N/A.

Filed Date: 4/24/23.

Accession Number: 20230424–5142.

Comment Date: 5 p.m. ET 5/8/23.

Docket Numbers: RP23–701–000.

Applicants: ANR Storage Company.

Description: Compliance filing: 2023 Operational Purchases and Sales Report to be effective N/A.

Filed Date: 4/24/23.

Accession Number: 20230424–5150.

Comment Date: 5 p.m. ET 5/8/23.

Docket Numbers: RP23–702–000.

Applicants: Transcontinental Gas Pipe Line Company, LLC.

Description: § 4(d) Rate Filing: Rate Schedule GSS/LSS Fuel Retention Percentage Tracker Filing to be effective 5/1/2023.

Filed Date: 4/24/23.

Accession Number: 20230424–5156.

Comment Date: 5 p.m. ET 5/8/23.

Docket Numbers: RP23–703–000.

Applicants: Bison Pipeline LLC.

Description: Compliance filing: 2023 Operational Purchases and Sales Report to be effective N/A.

Filed Date: 4/24/23.

Accession Number: 20230424–5159.

Comment Date: 5 p.m. ET 5/8/23.

Docket Numbers: RP23–704–000.

Applicants: Blue Lake Gas Storage Company.

Description: Compliance filing: 2023 Operational Purchases and Sales Report to be effective N/A.

Filed Date: 4/24/23.

Accession Number: 20230424–5168.

Comment Date: 5 p.m. ET 5/8/23.

Docket Numbers: RP23–705–000.

Applicants: Ruby Pipeline, L.L.C.

Description: § 4(d) Rate Filing: RP 2023–04–24 GT&C Revisions to be effective 5/22/2023.

Filed Date: 4/24/23.

Accession Number: 20230424–5169.

Comment Date: 5 p.m. ET 5/8/23.

Docket Numbers: RP23–706–000.

Applicants: Great Lakes Gas Transmission Limited Partnership.

Description: Compliance filing: 2023 Operational Purchases and Sales Report to be effective N/A.

Filed Date: 4/24/23.

Accession Number: 20230424–5179.

Comment Date: 5 p.m. ET 5/8/23.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

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.

Dated: April 25, 2023.

Debbie-Anne A. Reese,

Deputy Secretary.

[FR Doc. 2023–09134 Filed 4–28–23; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OLEM–2023–0244, FRL–10921–01–OLEM]

Agency Information Collection Activities; Proposed Collection; Comment Request; Disposal of Coal Combustion Residuals From Electric Utilities, EPA ICR No. 2609.03, OMB Control No. 2050–0223

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit the information collection request (ICR), Disposal of Coal Combustion Residuals from Electric Utilities, EPA ICR No. 2609.03, OMB Control No. 2050–0223 to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA). Before doing so, the EPA is soliciting public comments on specific aspects of the proposed information collection as described in **SUPPLEMENTARY INFORMATION**. This is a proposed extension of the ICR, which is currently approved through December 31, 2023. 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.

DATES: Comments must be submitted on or before June 30, 2023.

ADDRESSES: Submit your comments, referencing by Docket ID No. EPA–HQ–OLEM–2023–0244, at *https://www.regulations.gov* (our preferred method), or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460.

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 to EPA's docket at *https://www.regulations.gov* 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.*

FOR FURTHER INFORMATION CONTACT: Peggy Vyas, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: 202–566–0453; *vyas.peggy@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov.* Materials can also be viewed at the Reading Room located at the EPA Docket Center, WJC West Building, Room 3334, 1301 Constitution Avenue NW, Washington, DC 20004. The Docket Center's hours of operations are 8:30 a.m.–4:30 p.m., Monday–Friday (except Federal Holidays). The telephone number for the Docket Center is 202–566–1744.

Pursuant to section 3506(c)(2)(A) of the PRA, the EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, the EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: The EPA published a final rule to regulate the disposal of coal combustion residuals (CCR) from electric utilities as solid waste under RCRA Subtitle D (see 80 FR 21302, April 17, 2015). EPA established national minimum criteria for existing and new CCR landfills and CCR surface impoundments and all lateral expansions to include location restrictions, design and operating criteria, groundwater monitoring and corrective action, closure requirements and post-closure care, and recordkeeping, notification, and internet posting requirements. Since the final rule, several court decisions have required accelerated closure timelines for many units and forced closures for many units previously categorized as lined. In 2020, EPA published the ''Hazardous and Solid Waste Management System: Disposal of CCR; A Holistic Approach to Closure Part B: Alternate Demonstration for Unlined Surface Impoundments Rule'' which allows for units to receive variances for unlined surface impoundments (see 85 FR 72506, November 12, 2020). This ICR includes the voluntary action that states may take to obtain permit program approval. With this renewal, this ICR also incorporates the burden currently covered by OMB Control No. 2050–0053.

Form Numbers: None.

Respondents/affected entities: Business and other for-profit as well as States, Local and Tribal governments.

Respondent's obligation to respond: Required to obtain or retain a benefit (RCRA Sections 1008, 4004, 4005(a)).

Estimated number of respondents: 730.

Frequency of response: On occasion.

Total estimated burden: 177,498 hours. Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $18,347,854, which includes $10,024,078 annualized labor costs and $8,323,776 annualized capital or O&M costs.

Changes in estimates: The burden hours are likely to stay substantially the same.

Carolyn Hoskinson,

Director, Office of Resource Conservation and Recovery.

[FR Doc. 2023–09123 Filed 4–28–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9542–04–OAR]

Final Allocations of Cross-State Air Pollution Rule Allowances From New Unit Set-Asides for 2022 Control Periods

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of data availability.

SUMMARY: The Environmental Protection Agency (EPA) is providing notice of the availability of data on emission allowance allocations to certain units under the Cross-State Air Pollution Rule (CSAPR) trading programs. EPA has completed final calculations for the allocations of allowances from the CSAPR new unit set-asides (NUSAs) for the 2022 control periods and has posted spreadsheets containing the calculations on EPA's website. EPA has also completed calculations for allocations of the remaining 2022 NUSA allowances to existing units and has posted spreadsheets containing those calculations on EPA's website as well.

DATES: May 1, 2023.

FOR FURTHER INFORMATION CONTACT: Questions concerning this action should be addressed to Jason Kuhns at (202) 564–3236 or *kuhns.jason@epa.gov* or Andrew Reighart at (202) 564–0418 or *reighart.andrew@epa.gov.*

SUPPLEMENTARY INFORMATION: Under each CSAPR trading program where EPA is responsible for determining emission allowance allocations, a portion of each state's emissions budget for the program for each control period is reserved in a NUSA (and in an additional Indian country NUSA in the case of states with Indian country within their borders) for allocation to certain units that would not otherwise receive allowance allocations. The procedures for identifying the eligible units for each control period and for allocating allowances from the NUSAs and Indian country NUSAs to these units are set forth in the CSAPR trading program regulations at 40 CFR 97.411(b) and 97.412 (NO_X Annual), 97.511(b) and 97.512 (NO_X Ozone Season Group 1), 97.611(b) and 97.612 (SO_2 Group 1), 97.711(b) and 97.712 (SO_2 Group 2), 97.811(b) and 97.812 (NO_X Ozone Season Group 2), and 97.1011(b) and 97.1012 (NO_X Ozone Season Group 3). Each NUSA allowance allocation process involves allocations to eligible units, termed ''new'' units, followed by the allocation to ''existing'' units of any allowances not allocated to new units.

In a notice of data availability (NODA) published in the **Federal Register** on February 27, 2022 (88 FR 12356), EPA provided notice of the preliminary calculations of NUSA allowance allocations for the 2022 control periods and described the process for submitting any objections. EPA received no objections in response to the February 27, 2022 NODA. This NODA concerns the final NUSA allowance allocations, which are unchanged from the preliminary calculations.

The detailed unit-by-unit data and final allowance allocation calculations are set forth in Excel spreadsheets titled

''CSAPR_NUSA_2022_NOx_Annual_Final_Data_New_Units,'' ''CSAPR_NUSA_2022_NOx_OS_Final_Data_New_Units,'' ''CSAPR_NUSA_2022_SO2_Final_Data_New_Units,'' ''CSAPR_NUSA_2022_NOx_Annual_Final_Data_Existing_Units,'' ''CSAPR_NUSA_2022_NOx_OS_Final_Data_Existing_Units,'' and ''CSAPR_NUSA_2022_SO2_Final_Data_Existing_Units'', available on EPA's website at *https://www.epa.gov/csapr/csapr-compliance-year-2022-nusa-nodas.*

EPA notes that an allocation or lack of allocation of allowances to a given unit does not constitute a determination that CSAPR does or does not apply to the unit. EPA also notes that, under 40 CFR 97.411(c), 97.511(c), 97.611(c), 97.711(c), 97.811(c), and 97.1011(c), allocations are subject to potential correction if a unit to which allowances have been allocated for a given control period is not actually an affected unit as of the start of that control period.

(Authority: 40 CFR 97.411(b), 97.511(b), 97.611(b), 97.711(b), 97.811(b), and 97.1011(b).)

Rona Birnbaum,

Director, Clean Air Markets Division, Office of Atmospheric Protection, Office of Air and Radiation.

[FR Doc. 2023–08795 Filed 4–28–23; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2022–0706; FRL–10934–01–OMS]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Production, Import, Export, Recycling, Destruction, Transhipment, and Feedstock Use of Ozone-Depleting Substances (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) has submitted an information collection request (ICR), Production, Import, Export, Recycling, Destruction, Transhipment, and Feedstock Use of Ozone-Depleting Substances (EPA ICR Number 1432.38, OMB Control Number 2060–0170) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act. This is a proposed extension of the ICR, which is currently approved through April 30, 2023. Public comments were previously requested via the **Federal Register** on August 24, 2022 during a 60-day comment period. This notice allows for an additional 30 days for public comments.

DATES: Comments may be submitted on or before May 31, 2023.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2022–0706, to EPA online using *www.regulations.gov* (our preferred method), by email to *a-and-r-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW, Washington, DC 20460. EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

Submit written comments and recommendations to OMB for the proposed information collection 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: Robert Burchard, Stratospheric Protection Division, (6205A), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460; telephone number: (202) 343–9126; email address: *burchard.robert@epa.gov.*

SUPPLEMENTARY INFORMATION: This is a proposed extension of the ICR, which is currently approved through April 30, 2023. 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.

Public comments were previously requested via the **Federal Register** on August 24, 2022, during a 60-day comment period (87 FR 51976). This notice allows for an additional 30 days for public comments. Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW, Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: This ICR covers provisions under the Montreal Protocol on Substances that Deplete the Ozone Layer (Montreal Protocol) and Title VI of the CAA that establish limits on total U.S. production, import, and export of class I and class II ozone-depleting substances (or controlled substances). Production and import of class I controlled substances (chlorofluorocarbons and others) was phased out in the United States. The phaseout includes exceptions for essential uses, critical uses of methyl bromide, quarantine and pre-shipment uses of methyl bromide, previously used material, and material that will be transformed or destroyed. There are also regulations that restrict the use of class II controlled substances and require a gradual reduction in the production and consumption of these chemicals leading to their eventual phaseout. The class II controlled substance phaseout regulations include exceptions for previously used material and material that will be transformed or destroyed.

Form Numbers: 5900–137, 5900–136, 5900–149, 5900–150, 5900–153, 5900–151, 5900–199, 5900–202, 5900–200, 5900–201, 5900–205, 5900–155, 5900–140, 5900–144, 5900–142, 5900–141, 5900–148, 5900–147, 5900–473, 5900–138, 5900–139, 5900–152, 5900–472, 5900–154, 5900–146.

Respondents/affected entities: Producers, importers, exporters, and certain users of ozone-depleting substances; methyl bromide applicators, distributors, and end users including commodity storage and quarantine users.

Respondent's obligation to respond: Mandatory (CAA sections 114, 603(b), and 604(d)(6)).

Estimated number of respondents: 1,174 (total).

Frequency of response: Quarterly, annually, as needed.

Total estimated burden: 3,022 hours (per year). Burden is defined at 5 CFR 1320.03(b)

Total estimated cost: $375,086 (per year), includes $8,250 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is an increase of 83 hours in the total estimated respondent burden compared with the ICR currently approved by OMB. This increase is a result of updated assumptions associated with recordkeeping requirements that are more consistent with other ICRs that cover similar recordkeeping activities (*e.g.,* the HFC Allowance Allocation

Program ICR, OMB Control No. 2060–0734).

Courtney Kerwin,

Director, Regulatory Support Division.

[FR Doc. 2023–09060 Filed 4–28–23; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–1161; FR ID 138217]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before June 30, 2023. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–1161.

Title: Construction requirements; Interim reports—Sections 27.14(g)–(l).

Form Number: N/A.

Type of Review: Extension of currently approved information collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 168 respondents; 168 responses.

Estimated Time per Response: 15 hours.

Frequency of Response: One-time reporting requirement and on occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for, these collections are contained in 47 U.S.C. 154, 301, 302(a), 303, 309, 332, 336, and 337 unless otherwise noted.

Total Annual Burden: 2,265 hours.

Total Annual Cost: $214,950.

Needs and Uses: The information collection requirements contained in this collection are as follows: a. 700 MHz Construction Notification—47 CFR 27.14(k). 47 CFR 27.14(k) requires certain 700 MHz licensees to file a construction notification with the Commission within 15 days of the expiration of the relevant benchmark in accordance with the provisions set forth in 47 CFR 1.946(d), demonstrating compliance with performance requirements or, if they have not met the performance requirements, a description and certification of the areas for which they are providing service. In the construction notification, a licensee must certify whether it has met the applicable performance requirement as set forth below. The licensee must file a description and certification of the areas for which it is providing service, using electronic coverage maps, supporting technical documentation and other information as the Wireless Telecommunications Bureau may prescribe by Public Notice.

47 CFR 27.14(g). 47 CFR 27.14(g) requires 700 MHz licensees holding EA authorizations for Block A in the 698–704/728–734 MHz bands (''Block A''), CMA authorizations for Block B in the 704–710/734–740 MHz bands (''Block B''), and EA authorizations for Block E in the 722–728 MHz band (''Block E''), where the results of the first auction in which licenses for such authorizations were offered satisfy the reserve price for the applicable block, to file construction notifications with the Commission within 15 days after:

(1) June 12, 2013, or the fourth anniversary of initial license grant if the initial authorization in a market is granted after June 12, 2009. In the construction notification, licensees must certify and demonstrate that they are providing signal coverage and offering service over at least 35 percent of the geographic area of each of their license authorizations.

(2) The end of the applicable license term. In the construction notification, licensees must certify and demonstrate that they are providing such service over at least 70 percent of the geographic area of each of these authorizations.

47 CFR 27.14(h). 700 MHz licensees holding REAG authorizations for Block C in the 746–757/776–787 MHz bands (''Block C''), as well as 700 MHz licensees holding REAG authorizations for Block C2 in the 752–757/782–787 MHz bands (C2), must file construction notifications with the Commission within 15 days after:

(1) June 12, 2013, or the fourth anniversary of initial license grant if the initial authorization in a market is granted after June 12, 2009. In the construction notification, licensees must certify and demonstrate that they are providing signal coverage and offering service over at least 40 percent of the population in each EA comprising the REAG license area.

(2) The end of the applicable license term. In the construction notification, licensees must certify and demonstrate that they are providing such service over at least 75 percent of the population of each of these EAs.

47 CFR 27.14(i). 700 MHz licensees holding EA authorizations for Block A, CMA authorizations for Block B, and EA authorizations for Block E where the results of the first auction in which licenses for such authorizations in Blocks A, B, and E were offered did not satisfy the reserve price for the applicable block, as well as EA authorizations for Block C1 in the 746–752/776–782 MHz bands (''Block C1'') must file construction notifications with the Commission within 15 days after:

(1) June 12, 2013, or the fourth anniversary of initial license grant if the initial authorization in a market is granted after June 12, 2009. In the construction notification, licensees must certify and demonstrate that they are providing signal coverage and offering service over at least 40 percent of the population in each license area.

(2) The end of the applicable license term. In the construction notification, licensees must certify and demonstrate that they are providing such service over at least 75 percent of the population of the areas.

47 CFR 27.14(j). 47 CFR 27.14(j) provides that, in the event that a licensee's authority to operate in an area terminates automatically for failure to comply with the applicable construction requirements identified in 47 CFR 27.14(g), (h), or (i), the unserved area will become available for relicensing to third parties. A 700 MHz licensee holding an authorization granted pursuant to the unserved area licensing procedures set forth in 47 CFR 27.14(j) must file a construction notification with the Commission within 15 days after the one-year anniversary of initial license grant. In the construction notification, a licensee must certify and demonstrate that it is providing signal coverage and offering service over 100 percent of the geographic area of the new license area.

700 MHz Interoperability Order. Pursuant to the 700 MHz Interoperability Order, the interim construction deadline for Block A and Block B licensees was extended to December 13, 2016. The 700 MHz Interoperability Order waived the interim construction requirement for certain Block A licensees due to technical issues arising from their proximity to Television Channel 51 stations. Further, the interim construction deadline for Block E was extended to March 7, 2017, and the final Block E construction deadline was moved to March 7, 2021.

b. 700 MHz Interim Reporting Requirement—47 CFR 27.14(l). Pursuant to 47 CFR 27.14(l), 700 MHz licensees with authorizations in the spectrum blocks identified above (Blocks A, B, E, C, C1 and C2), excluding any licensee that obtained its license pursuant to the procedures set forth in 47 CFR 27.14(j), must file interim reports with the Commission that provide the Commission, at a minimum, with information concerning the status of their efforts to meet the performance requirements applicable to their authorizations in such spectrum blocks and the manner in which that spectrum is being utilized.

Required Information. Licensees must identify the date the license term commenced, and provide a description of the steps the licensee has taken toward meeting its construction obligations in a timely manner, including the technology or technologies and service(s) being provided, as well as the areas within their license areas in which those services are available.

Deadlines. Pursuant to 47 CFR 27.14(l), licensees were required to file their first interim report with the Commission no later than June 12, 2011 and no sooner than 30 days prior to this date. Licensees that meet their interim construction benchmarks must file a second interim report with the Commission no later than June 12, 2016, and no sooner than 30 days prior to this date. Licensees that do not meet their interim construction benchmarks must file their second interim report no later than on June 12, 2015, and no sooner than 30 days prior to this date.

However, the 700 MHz Interoperability Order waived the second interim report requirement for Lower 700 MHz band A and B Block licensees subject to the extended interim construction benchmark deadline. The 700 MHz Interoperability Order did not waive the reporting requirement for Lower 700 MHz band A Block licensees subject to a waiver of the interim construction benchmark deadline because of Channel 51 interference protection requirements. That order also extended the deadline until March 7, 2019, for Lower 700 MHz band E Block licensees to file a second status report regarding the licensees' efforts to meet their performance requirements.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–09083 Filed 4–28–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0346; FR ID 138253]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before June 30, 2023. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov*.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0346.

Title: Section 78.27, License Conditions.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business and other for-profit entities; not-for-profit institutions.

Frequency of Response: Annual reporting requirement; on occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 Section 154(i) of the Communications Act of 1934, as amended.

Number of Respondents and Responses: 4 respondents; 4 responses.

Estimated Time per Response: 10 mins. (0.166 hrs.).

Total Annual Burden: 1 hour.

Total Annual Cost: None.

Needs and Uses: The information collection requirements contained in 47 CFR 78.27(b)(1) require the licensee of a Cable Television Relay Service (CARS)

station to notify the Commission in writing when the station commences operation. Such notification shall be submitted on or before the last day of the authorized one year construction period; otherwise, the station license shall be automatically forfeited. The information collection requirements contained in 47 CFR 78.27(b)(2) require CARS licensees needing additional time to complete construction of the station and commence operation shall request an extension of time 30 days before the expiration of the one year construction period. Exceptions to the 30-day advance filing requirement may be granted where unanticipated delays occur.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–09084 Filed 4–28–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–XXXX, OMB 3060–XXXX; FR ID 137877]

Information Collections Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995, the Federal Communications Commission (FCC or the Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collection. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid Office of Management and Budget (OMB) control number.

DATES: Written PRA comments should be submitted on or before June 30, 2023. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *nicole.ongele@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Nicole Ongele, (202) 418–2991.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–XXXX.

Title: Section 90.175(g)(2), Amendment of Part 90 of the Commission's Rules.

Form Number: N/A.

Type of Review: New information collection.

Respondents: State, Local or Tribal Government.

Number of Respondents and Responses: 213 respondents, 213 responses.

Estimated Time per Response: 1 hour.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to retain or retain benefits. Statutory authority for this collection is contained in 47 U.S.C. 154(i), 161, 303(g), 303(r), 332(c)(7), and 1401–1473 of the Communications Act of 1934.

Total Annual Burden: 213 hours.

Total Annual Cost: $234,300.

Needs and Uses: This collection will be submitted as a new collection after this 60-day comment period to the Office of Management and Budget (OMB) in order to obtain the full three-year clearance.

Section 90.175(g)(2) adopted in the Commission's Report and Order FCC 23–3 requires public safety applicants seeking to license new or modify existing facilities in the 4.9 GHz band to obtain a frequency recommendation from the nationwide Band Manager before the application is filed with the Commission.

The purpose of requiring each public safety applicant to obtain a frequency recommendation from the nationwide Band Manager is to ensure that public safety entities seeking to license new or modify existing facilities in the 4.9 GHz band cause no interference to incumbent licensees or previously filed applicants.

OMB Control Number: 3060–XXXX.

Title: Sections 90.1207(e)–(f), Amendment of Part 90 of the Commission's Rules.

Form Number: N/A.

Type of Review: New information collection.

Respondents: State, Local or Tribal Government.

Number of Respondents and Responses: 3,871 respondents, 3,871 responses.

Estimated Time per Response: 16–160 hours.

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection is contained in 47 U.S.C. 154(i), 161, 303(g), 303(r), 332(c)(7), and 1401–1473 of the Communications Act of 1934.

Total Annual Burden: 592,288 hours.

Total Annual Cost: $14,882,400.

Needs and Uses: This collection will be submitted as a new collection after this 60-day comment period to the Office of Management and Budget (OMB) in order to obtain the full three-year clearance.

Section 90.1207(e) adopted in the Commission's Report and Order FCC 23–3 requires public safety applicants seeking to license new or modify existing facilities in the 4.9 GHz band to submit granular technical data on their proposed operations into ULS. Section 90.1207(f), also adopted in the Commission's Report and Order FCC 23–3, requires incumbent public safety licensees to perform a one-time submission into ULS of the granular data specified in paragraph (e) for their existing operations and gives incumbent licensees at least a one-year period to complete this one-time collection.

The purpose of requiring incumbent public safety licensees and public safety applicants in the 4.9 GHz band to submit granular technical data into ULS is to enable the Band Manager at 4.9 GHz to use the granular technical data on public safety deployments to perform its frequency coordination duties and facilitate non-public safety access to the band.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–09081 Filed 4–28–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0132; FR ID 137944]

Information Collection Being Reviewed by the Federal Communications Commission Under Delegated Authority

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act of 1995 (PRA), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before June 30, 2023. If you anticipate that you will be submitting comments but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email to *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0132.

Title: Supplemental Information—72–76 MHz Operational Fixed Stations, FCC Form 1068A.

Form No.: FCC Form 1068A.

Type of Review: Extension of a currently approved collection.

Respondents: Individuals or household; state, local or tribal government; business or other for-profit entities; not-for-profit institutions.

Number of Respondents and Responses: 300 respondents and 300 responses.

Estimated Time per Response: 0.5 hours (30 minutes).

Frequency of Response: On occasion reporting requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in 47 CFR 90.257 of the Commission's rules and the Communications Act of 1934, as amended.

Total Annual Burden: 150 hours.

Total Annual Cost: No costs.

Needs and Uses: FCC rules require that the applicant agrees to eliminate any harmful Interference caused by the operation to TV reception on either channel 4 or 5 that might develop. This form is required by the Communications Act of 1934, as amended; International Treaties and FCC Rules 47 CFR 90.257. FCC staff will use the data to determine if the information submitted will meet the FCC Rule requirements for the assignment of frequencies in the 72–76 MHz band.

Federal Communications Commission.

Marlene Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2023–09082 Filed 4–28–23; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meetings

TIME AND DATE: Thursday, May 4, 2023 at 12:45 p.m.

PLACE: Hybrid meeting: 1050 First Street NE, Washington, DC (12th floor) and virtual.

Note: For those attending the meeting in person, current Covid–19 safety protocols for visitors, which are based on the CDC Covid–19 community level in Washington, DC, will be updated on the commission's contact page by the Monday before the meeting. See the contact page at *https://www.fec.gov/contact/.* If you would like to virtually access the meeting, see the instructions below.

STATUS: This meeting will be open to the public, subject to the above-referenced guidance regarding the Covid–19 community level and corresponding health and safety procedures. To access the meeting virtually, go to the commission's website *www.fec.gov* and click on the banner to be taken to the meeting page.

MATTERS TO BE CONSIDERED:

Draft Advisory Opinion 2023–03: Colorado Republican State Central Committee.

Audit Division Recommendation Memorandum on Latinos for America First (A21–12).

Revised Audit Procedures.

Management and Administrative Matters.

CONTACT PERSON FOR MORE INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220

Individuals who plan to attend in person and who require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Laura E. Sinram, Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the meeting date.

(Authority: Government in the Sunshine Act, 5 U.S.C. 552b)

Laura E. Sinram,

Secretary and Clerk of the Commission.

[FR Doc. 2023–09271 Filed 4–27–23; 4:15 pm]

BILLING CODE 6715–01–P

GENERAL SERVICES ADMINISTRATION

[Notice–MA–2023–01; Docket No. 2023–0002; Sequence No. 1]

Revision to Foreign Gift Minimal Value—Correction

AGENCY: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Notice of GSA bulletin; correction.

SUMMARY: The General Services Administration (GSA) is issuing a correction to Notice–MA–2023–01: Revision to Foreign Gift Minimal Value. The document contained an incorrect bulletin number. This document contains the correct bulletin number.

DATES: The subject bulletin continues to be applicable as of January 1, 2023.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact Mr. William Garrett, Director, Personal Property Policy, Office of Government-wide Policy, Office of Asset and Transportation Management, at 202–368–8163, or by email at *william.garrett@gsa.gov.* Please cite Notice of GSA Bulletin FMR B–54.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of March 13, 2023, at 88 FR 15398, correct the following:

a. On page 15398, in the third column, correct the Action to read ''Notice of GSA Bulletin FMR B–54, Foreign Gift and Decoration Minimal Value.''.

b. On page 15399, in the first column, correct the last sentence of the Contact section to read ''Please cite Notice of GSA Bulletin FMR B–54.''.

c. On page 15399, in the second column, correct the last paragraph of the Background to read ''FMR Bulletin B–54 is available at *https://www.gsa.gov/policy-regulations/regulations/federal-management-regulation/federal-management-regulation-fmr-related-files#PersonalPropertyManagement.*''.

Krystal J. Brumfield,

Associate Administrator, Office of Government-wide Policy.

[FR Doc. 2023–09069 Filed 4–28–23; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Board on Radiation and Worker Health, Subcommittee for Procedure 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 a meeting of 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 an oral 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 June 21, 2023, from 11 a.m. to 4:30 p.m., EDT. Written comments must be received on or before June 14, 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, 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 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 (SEC). In December 2000, the President delegated responsibility for funding, staffing, and operating the Advisory Board to HHS, which subsequently delegated this authority to CDC. 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, advise 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. 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: (a) ORAUT–OTIB–0052, DCAS–PER–049, DCAS–PER–092, Peek Street; DCAS–PER–073 (Birdsboro), Battelle-TBD–5000, and example of a ''not suitable closeout for matrix'' presentation, (b) Newly issued Sandford Cohen & Associates reviews, (c) Preparation for August 2023 full ABRWH meeting, and (d) Newly issued Guidance Documents 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, Strategic Business Initiatives Unit, 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, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–09072 Filed 4–28–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC–2023–0031; NIOSH 232]

Board of Scientific Counselors, National Institute for Occupational Safety and Health, National Firefighter Registry Subcommittee

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of meeting and request for comment.

SUMMARY: In accordance with regulatory provisions, the Centers for Disease

Control and Prevention (CDC) announces the following meeting of the Board of Scientific Counselors, National Institute for Occupational Safety and Health (BSC, NIOSH), National Firefighter Registry Subcommittee. This is a virtual meeting. It is open to the public, limited only by the number of web conference lines (500 web conference lines are available). Time will be available for public comment.

DATES: The meeting will be held on June 13, 2023, from 9 a.m. to 4:15 p.m., EDT.

Written comments must be received on or before June 6, 2023.

ADDRESSES: If you wish to attend the meeting, please register at the NIOSH website at *https://www.cdc.gov/niosh/bsc/nfrs/registration.html* or by telephone at (404) 498–2581 no later than June 6, 2023.

You may submit comments, identified by Docket No. CDC–2023–0031; NIOSH–232, by either of the methods listed below. CDC does not accept comments by email.

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Ms. Sherri Diana, NIOSH Docket Office, National Institute for Occupational Safety and Health, 1090 Tusculum Avenue, Mailstop C–34, Cincinnati, Ohio 45226. Attn: Docket No. CDC–2023–0031; NIOSH–232.

Instructions: All submissions received must include the Agency name and docket number. Docket number CDC–2023–0031; NIOSH–232 will close June 6, 2023.

FOR FURTHER INFORMATION CONTACT: Emily J.K. Novicki, M.A., M.P.H., Designated Federal Officer, Board of Scientific Counselors, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop V24–4, Atlanta, Georgia 30329–4027. Telephone: (404) 498–2581; Email: *ENovicki@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Background: The Secretary of Health and Human Services, the Assistant Secretary for Health, and by delegation, the Director, Centers for Disease Control and Prevention (CDC), are authorized under Sections 301 and 308 of the Public Health Service Act to conduct directly, or by grants or contracts, research, experiments, and demonstrations relating to occupational safety and health and to mine health.

The Board of Scientific Counselors, National Institute for Occupational Safety and Health (BSC, NIOSH) provides advice to the NIOSH Director on NIOSH research and prevention programs. The Board also provides guidance on the Institute's research activities related to developing and evaluating hypotheses, systematically documenting findings, and disseminating results. In addition, the Board evaluates the degree to which the activities of NIOSH: (1) conform to those standards of scientific excellence appropriate for federal scientific institutions in accomplishing objectives in occupational safety and health; (2) address currently relevant needs in the fields of occupational safety and health either alone or in conjunction with other known activities inside and outside of NIOSH; and (3) produce their intended results in addressing important research questions in occupational safety and health, both in terms of applicability of the research findings and dissemination of the findings.

Purpose: The BSC, NIOSH National Firefighter Registry Subcommittee provides scientific expertise to the Board that assists the BSC, NIOSH in advising the NIOSH Director about the Institute's efforts to establish and operate the National Firefighter Registry. Specifically, the Subcommittee advises the Board on the following issues pertaining to the ''required strategy'' as mandated by the Firefighter Cancer Registry Act of 2018 (the Act): (1) increase awareness of the National Firefighter Registry and encourage participation among all groups of firefighters; (2) consider data collection needs; (3) consider data storage and electronic access of health information; and (4) in consultation with subject matter experts, develop a method for estimating the number and type of fire incidents attended by a firefighter. Additional responsibilities of the Subcommittee are to provide guidance to the Board regarding the inclusion and maintenance of data on firefighters as required by the Act.

Matters To Be Considered: The agenda for the meeting includes the National Firefighter Registry project overview, status, national launch and updates, communication strategies, targeted enrollment approach, follow-up questionnaire planning, and future planning applicable to stakeholders. Agenda items are subject to change as priorities dictate.

The agenda is also posted on the NIOSH website at *https://www.cdc.gov/niosh/bsc/nfrs/.*

Public Participation

Written Public Comment: Written comments will be accepted per the instructions provided in the addresses section above. Comments received in advance of the meeting are part of the public record and are subject to public disclosure. The comments will be included in the official record of the meeting. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure. If you include your name, contact information, or other information that identifies you in the body of your comments, that information will be on public display. CDC will review all submissions and may choose to redact, or withhold, submissions containing private or proprietary information such as Social Security numbers, medical information, inappropriate language, or duplicate/near-duplicate examples of a mass-mail campaign. CDC will carefully consider all comments submitted into the docket.

Written comments received by June 6, 2023, will be provided to the Subcommittee prior to the meeting.

Oral Public Comment: The public is welcome to participate during the public comment period, from 11:45 a.m. to 12 p.m., EDT, June 13, 2023. Each commenter will be provided up to five minutes for comment. A limited number of time slots are available and will be assigned on a first-come, first-served basis. Members of the public who wish to address the Subcommittee are requested to contact the Designated Federal Officer for scheduling purposes (see **FOR FURTHER INFORMATION CONTACT** above).

The Director, Strategic Business Initiatives Unit, 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, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–09065 Filed 4–28–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Board of Scientific Counselors, National Center for Injury Prevention and Control

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of closed meeting.

SUMMARY: In accordance with regulatory provisions, the Centers for Disease Control and Prevention (CDC) announces the following meeting for the Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC or Board). This meeting is closed to the public.

DATES: The meeting will be held on June 8, 2023, from 1 p.m. to 3:30 p.m., EDT (CLOSED).

ADDRESSES: Webinar, Atlanta, Georgia.

FOR FURTHER INFORMATION CONTACT: Christopher R. Harper, Ph.D., Designated Federal Officer, National Center for Injury Prevention and Control, Centers for Disease Control and Prevention, 4770 Buford Highway NE, Mailstop S–1069, Atlanta, Georgia 30341. Telephone: (404) 718–8330; Email: *ncipcbsc@cdc.gov.*

SUPPLEMENTARY INFORMATION: The meeting referenced above will be closed to the public in accordance with provisions set forth in Section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to 5 U.S.C. 1009 (Pub. L. 92–463, as amended).

Purpose: The Board of Scientific Counselors, National Center for Injury Prevention and Control (BSC, NCIPC or Board) will: (1) conduct, encourage, cooperate with, and assist other appropriate public health authorities, scientific institutions, and scientists in the conduct of research, investigations, experiments, demonstrations, and studies relating to the causes and strategies related to the prevention of injury and violence; (2) assist States and other entities in preventing intentional and unintentional injuries, and to promote health and well-being; and (3) make recommendations of grants and cooperative agreements for research and prevention activities related to injury and violence. The BSC, NCIPC makes recommendations regarding policies, strategies, objectives, and priorities and reviews progress toward injury and violence prevention. The Board also provides advice on the appropriate balance of intramural and extramural research and provides guidance on the needs, structure, progress, and performance of intramural programs. The Board also provides guidance on extramural scientific program matters. The Board provides second-level scientific and programmatic review for applications for research grants, cooperative agreements, and training grants related to injury and violence prevention, and recommends approval of projects that merit further consideration for funding support. The Board also recommends areas of research to be supported by contracts and cooperative agreements and provides concept reviews of program proposals and announcements.

Matters To Be Considered: The closed meeting will focus on the Secondary Peer Review of extramural research grant applications received in response to five (5) Notices of Funding Opportunity: RFA–CE–23–002—''Grants to Support New Investigators in Conducting Research Related to Understanding Polydrug Use Risk and Protective Factors''; RFA–CE–23–003—''Grants to Support New Investigators in Conducting Research Related to Preventing Interpersonal Violence Impacting Children and Youth''; RFA–CE–23–004—''Research Grants for Preventing Violence and Violence Related Injury (R01)''; RFA–CE–23–005—''Research Grants to Inform Firearm-Related Violence and Injury Prevention Strategies (R01)''; and RFA–CE–23–006—''Research Grants to Rigorously Evaluate Innovative and Promising Strategies to Prevent Firearm-Related Violence and Injuries (R01).'' Agenda items are subject to change as priorities dictate.

The Director, Strategic Business Initiatives Unit, 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, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–09066 Filed 4–28–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–23–23EH; Docket No. CDC–2023–0030]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Public Health Emergency Management Capacity Assessment Tool (PHEM Tool). The Center for Disease Control and Prevention's (CDC) Global Emergency Management Capacity Development (GEMCD) team will use the PHEM Tool to assess the public health emergency management (PHEM) program and Public Health Emergency Operations Center (PHEOC) capacity of Global Health Security Agenda (GHSA) countries.

DATES: CDC must receive written comments on or before June 30, 2023.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2023–0030 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger,

Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

Public Health Emergency Management Capacity Assessment Tool (PHEM Tool)—New—Office of Readiness and Response (ORR), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Center for Disease Control and Prevention's (CDC) Global Emergency Management Capacity Development (GEMCD) team strengthens emergency management capacity development globally. It helps countries to prepare for, anticipate, and respond to all forms of public health threats. GEMCD's mission is to build resilient Public Health Emergency Management (PHEM) programs throughout the world.

The GEMCD team's Emergency Management Technical Advisors (EMTAs) will use the PHEM Tool to guide an in-person interview with GHSA countries Ministry of Health, Public Health Emergency Operations Center (PHEOC) Manager, and optional additional staff, to characterize the country's PHEM program and capabilities. EMTAs will document responses in an excel based form that will be entered into and maintained in the CDCReady data base. Collected data will identify strengths and weaknesses, capabilities, and gaps in PHEM programs and PHEOCs in GHSA countries. Findings will guide GEMCD team program planning initiatives and determine appropriate technical assistance (TA) for GHSA countries. Data will be analyzed to identify the presence or absence of specific PHEM and PHEOC requirements, such as plans, policies, and procedures, etc. Additional analysis will focus upon the status of PHEM and PHEOC plans, policies, and procedures (*e.g.,* date of publication, relevance). The survey will be conducted annually to identify progress and document changes from one year to the next in terms of PHEM program and PHEOC capabilities.

OMB approval is requested for three years. The estimated annualized burden for this information collection is 72 hours. There is no cost to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Ministry of Health personnel responsible for Public Health Emergency Management (PHEM) Program in participating GHSA countries.	PHEM Tool	12	1	6	72
Total					72

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2023–09087 Filed 4–28–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Healthcare Infection Control Practices 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 for the Healthcare Infection Control Practices Advisory Committee (HICPAC). This virtual meeting is open to the public, limited only by room seating available (120). The public is also welcomed to listen to the meeting via Zoom; 500 teleconference lines are available. Time will be available for public comment. Registration is required.

DATES: The meeting will be held on June 8, 2023, 9 a.m. to 5 p.m., EDT, and June 9, 2023, 9 a.m. to 12 p.m., EDT.

ADDRESSES: Registration is required to attend in person or on the phone. Interested parties must be processed in accordance with established federal policies and procedures and may

register at *https://www.cdc.gov/hicpac.* All registered participants will receive instructions shortly before the meeting. Please click first link for day one and the second link for day two to join the webinar:

https://cdc.zoomgov.com/j/1616828862?pwd=N3hmSTEvQjQ3ZHFScVMyM1k2Mk8yUT09.

Meeting ID: 161 682 8862.

Passcode: 74249065.

https://cdc.zoomgov.com/j/1614944394?pwd=UWdBRDNNK2pDdS9PMjlMZzYvRVFzZz09.

Meeting ID: 161 494 4394.

Passcode: 26658671.

FOR FURTHER INFORMATION CONTACT: Sydnee Byrd, M.P.A., HICPAC, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention, l600 Clifton Road NE, Mailstop H16–3, Atlanta, Georgia 30329. Telephone (404) 718–8039; Email: *hicpac@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The Committee is charged with providing advice and guidance to the Director, Division of Healthcare Quality Promotion, the Director, NCEZID, the Director, CDC, and the Secretary, Health and Human Services, regarding (1) the practice of healthcare infection prevention and control; (2) strategies for surveillance, prevention, and control of infections, antimicrobial resistance, and related events in settings where healthcare is provided; and (3) periodic updating of CDC guidelines and other policy statements regarding prevention of healthcare-associated infections and healthcare-related conditions.

Matters To Be Considered: The agenda will include updates on CDC's activities for prevention of healthcare-associated infections. It will also include updates from the following HICPAC workgroups: the Isolation Precautions Guideline workgroup, the Dental Unit Waterline Guideline Workgroup, the Healthcare Personnel Guideline Workgroup, the Neonatal Intensive Care Unit Guideline Workgroup, and the National Healthcare Safety Network Workgroup. The agenda also includes updates on CDC and DHQP activities. Agenda items are subject to change as priorities dictate.

Public Participation

Oral Public Comment: Time will be available for public comment. Members of the public who wish to provide public comments should plan to attend the public comment session at the start time listed. Please note that the public comment period may end before the time indicated, following the last call for comments.

Written Public Comment: The public is welcomed to submit written comments in advance of the meeting. Comments should be submitted in writing by email to the contact person listed above. The deadline for receipt of written public comment is May 26, 2023. All requests must contain the name, address, and organizational affiliation of the speaker, as well as the topic being addressed. Written comments should not exceed one single-spaced typed page in length and delivered in 3 minutes or less. Written comments received in advance of the meeting will be included in the official record of the meeting.

The Director, Strategic Business Initiatives Unit, 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, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–09063 Filed 4–28–23; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Advisory Committee to the Director (ACD), Centers for Disease Control and Prevention (CDC); Notice of Charter Renewal

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice of charter renewal.

SUMMARY: The Centers for Disease Control and Prevention (CDC), within the Department of Health and Human Services (HHS), announces the renewal of the charter of the Advisory Committee to the Director (ACD).

FOR FURTHER INFORMATION CONTACT: Bridget Richards, MPH, Office of the Chief of Staff, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–10, Atlanta, Georgia 30329–4027; Telephone: (404) 718–5028; Email: *ACDirector@cdc.gov.*

SUPPLEMENTARY INFORMATION: CDC is providing notice under 5 U.S.C. 1001–1014. This charter has been renewed for a two-year period through April 15, 2025.

The Director, Strategic Business Initiatives Unit, 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, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–09071 Filed 4–28–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Mine Safety and Health Research 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 for the Mine Safety and Health Research Advisory Committee (MSHRAC). This is a hybrid meeting, accessible both in person and virtually. It is open to the public and limited only by the space available and the number of web conference lines available. Time will be available for public comment.

DATES: The meeting will be held on May 24, 2023, from 8:30 a.m. to 4:25 p.m., PDT.

ADDRESSES: Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, Spokane Campus, 315 East Montgomery Avenue, Spokane, Washington 99207–2291. The conference room space accommodates approximately 49 people.

Please note that the meeting location is a federal facility, and in-person access is limited to United States citizens unless prior authorizations, taking up to 30 days, have been made.

If you wish to attend the meeting, either in person or virtually, please contact Ms. Berni Metzger by email at *Metzger@cdc.gov* or by phone at (412) 386–4541 at least 5 business days in advance of the meeting. If you are

attending virtually, she will provide you with the Zoom web conference access information (500 web conference lines are available).

FOR FURTHER INFORMATION CONTACT: George W. Luxbacher, PE, Ph.D., Designated Federal Officer, Mine Safety and Health Research Advisory Committee, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop V24–4, Atlanta, Georgia 30329–4027. Telephone: (404) 498–2808; Email: *GLuxbacher@cdc.gov.*

SUPPLEMENTARY INFORMATION:

Purpose: The Mine Safety and Health Research Advisory Committee (MSHRAC) is charged with providing advice to the Secretary, Department of Health and Human Services; the Director, Centers for Disease Control and Prevention; and the Director, National Institute for Occupational Safety and Health (NIOSH), on priorities in mine safety and health research, including grants and contracts for such research, 30 U.S.C. 812(b)(2), Section 102(b)(2).

Matters To Be Considered: The agenda will include presentations of and discussions on current NIOSH mining safety and health research projects, focusing on the Spokane Mining Research Division. Agenda items are subject to change as priorities dictate.

Public Participation

Written Public Comment: The public may submit written comments or questions in advance of the meeting, to the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT** above). Written comments received in advance of the meeting will be included in the official record of the meeting, and questions will be answered during the oral comment period open to public participation.

Oral Public Comment: The meeting will include time for members of the public to make an oral comment. The public comment session will be held on May 24, 2023, at 3:15 p.m., PDT, or at the conclusion of the presentations and discussion, and will conclude at 3:45 p.m., PDT, or following the final call for public comment, whichever comes first.

The Director, Strategic Business Initiatives Unit, 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, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–09068 Filed 4–28–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to 5 U.S.C. 1009(d), 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, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. 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: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—PAR 18–812, NIOSH Member Conflict Review.

Date: June 8, 2023.

Time: 1 p.m.–3 p.m., EDT.

Place: Teleconference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Michael Goldcamp, Ph.D., Scientific Review Officer, Office of Extramural Programs, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, 1095 Willowdale Road, Morgantown, West Virginia 26506. Telephone: (304) 285–5951; Email: *MGoldcamp@cdc.gov.*

The Director, Strategic Business Initiatives Unit, 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, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–09064 Filed 4–28–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–23–0106; Docket No. CDC–2023–0029]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other federal agencies the opportunity to comment on a continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Preventive Health and Health Services Block Grant. CDC will use the Block Grant Information System to collect recipient data, monitor awardees' progress, identify activities and personnel supported with Block Grant funding, conduct compliance reviews of Block Grant recipients, and promote the use of evidence-based guidelines and interventions in accordance with legislative mandates.

DATES: CDC must receive written comments on or before June 30, 2023.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2023–0029 by either of the following methods:

- *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without change, all relevant comments to *www.regulations.gov.*

Please note: Submit all comments through the Federal eRulemaking portal (*www.regulations.gov*) or by U.S. mail to the address listed above.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the information collection plan and instruments, contact Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS H21–8, Atlanta, Georgia 30329; Telephone: 404–639–7570; Email: *omb@cdc.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (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. In addition, the PRA also requires federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each new proposed collection, each proposed extension of existing collection of information, and each reinstatement of previously approved information collection before submitting the collection to the OMB for approval. To comply with this requirement, we are publishing this notice of a proposed data collection as described below.

The OMB is particularly interested in comments that will help:

1. Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

2. Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

3. Enhance the quality, utility, and clarity of the information to be collected;

4. Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submissions of responses; and

5. Assess information collection costs.

Proposed Project

Preventive Health and Health Services Block Grant (OMB Control No. 0920–0106, Exp. 02/29/2024)—Extension—National Center for State, Tribal, Local and Territorial Public Health Infrastructure and Workforce (NCSTLTPHIW), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The CDC's National Center for State, Tribal, Local and Territorial Public Health Infrastructure and Workforce (NCSTLTPHIW) plays a vital role in helping health agencies work to enhance their capacity and improve their performance to strengthen the public health system on all levels. NCSTLTPHIW is CDC's primary connection to health officials and leaders of state, tribal, local, and territorial public health agencies, as well as other government leaders who work with health departments.

NCSTLTPHIW administers the Preventive Health and Health Services Block Grant (PHHSBG) funding for health promotion and disease prevention programs. Sixty-one awardees (50 states, the District of Columbia, two American Indian Tribes, five U.S. territories, and three freely associated states) receive Block Grant funds to address locally-defined public health needs in innovative ways. The PHHS Block Grant allows awardees to prioritize the use of funds to fill funding gaps in programs that deal with leading causes of death and disability, as well as the ability to respond rapidly to emerging health issues, including outbreaks of food-borne infections and water-borne diseases. NCSTLTPHIW ensures that the CDC PHHS Block Grant Program Managers and recipients account for funds in accordance with legislative mandates. Each awardee is required to submit a work plan with its selected health outcome objectives, as well as descriptions of the health problems, identified target populations (including portions of those populations disproportionately affected by the health problems), and activities to be addressed in the planned work. The CDC will use the Block Grant Information System to collect recipient data, monitor awardees' progress, identify activities and personnel supported with Block Grant funding, conduct compliance reviews of Block Grant recipients, and promote the use of evidence-based guidelines and interventions.

CDC requests OMB approval for this Extension to an existing information collection request. As specified in the authorizing legislation, CDC currently collects information from Block Grant awardees to monitor their objectives and activities. Awardees will submit information on the following:

- Recipient information: collects unique identifying information about each recipient.
- Work plan: collects information about objectives, activities, and the populations to be addressed each year.
- Annual Progress Report: collects information about success and progress toward meeting health objectives.

Since 2021, CDC has collected this information using a web-based electronic system, the Block Grant Information System (BGIS). The respondent universe will include PHHSBG program Block Grant Coordinators. All modules will be accessed electronically through the BGIS system. CDC requests OMB approval for an estimated 1,464 annual burden hours.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
PHHS Block Grant Coordinator	Workplan start and advisory committee questions worksheet.	61	1	2	122
PHHS Block Grant Coordinator	Workplan program questions worksheet.	61	1	11	671
PHHS Block Grant Coordinator	Combined Annual Progress Report template.	61	1	11	671
Total					1,464

Jeffrey M. Zirger,

Lead, Information Collection Review Office, Office of Scientific Integrity, Office of Science, Centers for Disease Control and Prevention.

[FR Doc. 2023–09088 Filed 4–28–23; 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 Healthcare Infection Control Practices 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 seeking nominations for membership on the Healthcare Infection Control Practices Advisory Committee (HICPAC). The HICPAC consists of 14 experts in fields including but not limited to, infectious diseases, infection prevention, healthcare epidemiology, nursing, clinical microbiology, surgery, hospitalist medicine, internal medicine, epidemiology, health policy, health services research, public health, and related medical fields.

DATES: Nominations for membership on the HICPAC must be received no later than September 29, 2023. Packages received after this time will not be considered for the current membership cycle.

ADDRESSES: All nominations should be emailed to HICPAC, Division of Healthcare Quality Promotion, National Center for Emerging and Zoonotic Infectious Diseases, CDC, l600 Clifton Road NE, Mailstop H16–3, Atlanta, Georgia 30329, emailed (recommended) to *hicpac@cdc.gov,* or faxed to (404) 639–4043.

FOR FURTHER INFORMATION CONTACT: Sydnee Byrd, MPA, Healthcare Infection Control Practices Advisory Committee, Division of Healthcare Quality Promotion, NCEZID, Centers for Disease Control and Prevention, l600 Clifton Road NE, Mailstop H16–3, Atlanta, Georgia 30329–4027. Telephone (404) 718–8039; Email: *hicpac@cdc.gov.*

SUPPLEMENTARY INFORMATION: The Healthcare Infection Control Practices Advisory Committee shall provide advice and guidance to the Secretary, Department of Health and Human Services (HHS); the Director, Centers for Disease Control and Prevention (CDC); the Director, National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), CDC; and the Director, Division of Healthcare Quality Promotion (DHQP), NCEZID, CDC; and the Director, Division of Healthcare Quality Promotion (DHQP), NCEZID, CDC, regarding the practice of infection control and strategies for surveillance, prevention, and control of healthcare-associated infections antimicrobial resistance and related events in settings where healthcare is provided, including hospitals, outpatient settings, long-term care facilities, and home health agencies.

Nominations are being sought for individuals who have expertise and qualifications necessary to contribute to the accomplishments of the committee's objectives. Nominees will be selected based on expertise in the fields of infectious diseases, infection prevention, healthcare epidemiology, nursing, environmental and clinical microbiology, surgery, internal medicine, and public health. Federal employees will not be considered for membership. Members may be invited to serve for four-year terms. Selection of members is based on candidates' qualifications to contribute to the accomplishment of HICPAC objectives.

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 of and annually during their terms. CDC reviews potential candidates for HICPAC 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 July 2023, 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:

- 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 the U.S. Department of Health and Human Services. (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, NIH, FDA, etc.).

Nominations may be submitted by the candidate him- or herself, or by the person/organization recommending the candidate.

The Director, Strategic Business Initiatives Unit, 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, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2023–09067 Filed 4–28–23; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier CMS–10717]

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 June 30, 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–10717 Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols

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:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Part C and Part D Program Audit and Industry-Wide Part C Timeliness Monitoring Project (TMP) Protocols; *Use:* Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 and implementing regulations at 42 CFR parts 422 and 423, Medicare Part D plan sponsors and Medicare Advantage organizations are required to comply with all Medicare Parts C and D program requirements. CMS' annual audit plan ensures that we evaluate sponsoring organizations' compliance with these requirements by conducting program audits that focus on high-risk areas that have the greatest potential for beneficiary harm. As such, CMS has developed the following audit protocols for use by sponsoring organizations to prepare for their audit:

- Compliance Program Effectiveness (CPE)
- Part D Formulary and Benefit Administration (FA)
- Part D Coverage Determinations, Appeals, and Grievances (CDAG)
- Part C Organization Determinations, Appeals, and Grievances (ODAG)
- Special Needs Plans Care Coordination (SNPCC)

CMS generally conducts program audits at the parent organization level in an effort to reduce burden and, for routine audits, subjects each sponsoring organization to all applicable program area protocols. For example, if a sponsoring organization does not offer a special needs plan, or an accrediting organization has deemed a special needs plan compliant with CMS regulations and standards, CMS would not apply the SNPCC protocol. Likewise, CMS would not apply the ODAG audit protocol to an organization that offers only a standalone prescription drug plan since that organization does not offer the MA benefit. Conversely, ad hoc audits resulting from referral may be limited in scope and, therefore, all program area protocols may not be applied.

The information gathered during this program audit will be used by the Medicare Parts C and D Oversight and Enforcement Group (MOEG) within the Center for Medicare (CM) and CMS Regional Offices to assess sponsoring organizations' compliance with Medicare program requirements. If outliers or other data anomalies are detected, Regional Offices will work in collaboration with MOEG and other divisions within CMS for follow-up and resolution. Additionally, MA and Part D organizations will receive the audit results and will be required to implement corrective action to correct any identified deficiencies. *Form Number:* CMS–10717 (OMB control number: 0938–1395); *Frequency:* Yearly; *Affected Public:* Private Sector, State, Local, or Tribal Governments, Federal Government, Business or other for-profits, Not-for-Profit Institutions; *Number of Respondents:* 182; *Total Annual Responses:* 182; *Total Annual Hours:* 36,444. (For policy questions regarding this collection contact Matthew Guerand at 303–844–7120.)

Dated: April 26, 2022.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

Editorial Note: This document arrived at the Office of the Federal Register on April 26, 2023.

[FR Doc. 2023–09142 Filed 4–28–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2022–N–0081]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Tradeoff Analysis of Prescription Drug Product Claims in Direct-to-Consumer and Healthcare Provider Promotion

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the

Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by May 31, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The title of this information collection is ''Tradeoff Analysis of Prescription Drug Product Claims in Direct-to-Consumer and Healthcare Provider Promotion.'' Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *PRAStaff@fda.hhs.gov.*

For copies of the questionnaire, contact: Office of Prescription Drug Promotion (OPDP) Research Team, *DTCresearch@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Tradeoff Analysis of Prescription Drug Product Claims in Direct-to-Consumer and Healthcare Provider Promotion

OMB Control Number 0910–NEW

I. Background

Section 1701(a)(4) of the Public Health Service Act (42 U.S.C. 300u(a)(4)) authorizes FDA to conduct research relating to health information. Section 1003(d)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 393(d)(2)(C)) authorizes FDA to conduct research relating to drugs and other FDA-regulated products in carrying out the provisions of the FD&C Act.

The OPDP's mission is to protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated. OPDP's research program provides scientific evidence to help ensure that our policies related to prescription drug promotion will have the greatest benefit to public health. Toward that end, we have consistently conducted research to evaluate the aspects of prescription drug promotion that are most central to our mission. Our research focuses in particular on three main topic areas: (1) advertising features, including content and format; (2) target populations; and (3) research quality. Through the evaluation of advertising features, we assess how elements such as graphics, format, and disease and product characteristics impact the communication and understanding of prescription drug risks and benefits. Focusing on target populations allows us to evaluate how understanding of prescription drug risks and benefits may vary as a function of audience, and our focus on research quality aims at maximizing the quality of research data through analytical methodology development and investigation of sampling and response issues. This study will inform the first and second topic areas, advertising features and target populations.

Because we recognize that the strength of data and the confidence in the robust nature of the findings are improved by using the results of multiple converging studies, we continue to develop evidence to inform our thinking. We evaluate the results from our studies within the broader context of research and findings from other sources, and this larger body of knowledge collectively informs our policies as well as our research program. Our research is documented on our home page, which can be found at: *https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/office-prescription-drug-promotion-opdp-research*. The website includes links to the latest **Federal Register** notices and peer-reviewed publications produced by our office.

The proposed research examines the relative importance of prescription drug product information such as prescription drug efficacy, risk, adherence, and patient preference claims in two medical conditions (type 2 diabetes and psoriasis) in consumer and physician samples. When confronted with an important decision, people tend to make choices that reflect a series of tradeoffs between certain desirable and undesirable attributes of a product, service, or experience. Pharmaceutical manufacturers provide information about prescription drug products, including side effects, contraindications, and effectiveness, through product labeling and promotional materials (21 CFR 202.1(e)). The treatment choices of diagnosed consumers and treating physicians have been shown to be influenced by certain characteristics, such as the drug's perceived impact on quality of life, complexity of dosage regimens, mode of administration, cost to family and self, and marketing claims unrelated to medicinal properties (Refs. 1 to 5). Although diagnosed consumers may weigh the risks, benefits, or other salient characteristics of prescription drug products differently than physicians, little research directly compares the treatment preferences of these two groups (Ref. 6). Understanding the tradeoffs among drug product characteristics diagnosed consumers make—and how the tradeoffs could potentially differ from the tradeoffs made by physicians—will provide valuable insight into the relevance and impact of various product attributes and promotional claims on informed choices and treatment decisions.

We intend to examine these tradeoffs using a choice-based conjoint analysis, also known as a discrete choice experiment. Conjoint analysis is a broad class of survey-based techniques used to estimate how attractive or influential different features of choice options or product attributes are in determining purchase behavior or treatment choices (Ref. 7). Conjoint analysis can be used to examine the joint effects and tradeoffs of multiple variables or product attributes on decisions. A choice-based conjoint analysis is based on the principle that products are composed of a set of attributes, and each attribute can be described using a finite number of levels. In the proposed research, participants will be shown a carefully designed sequence of choice tasks containing up to five hypothetical product attributes—in this case, profiles describing fictitious prescription drug products for either type 2 diabetes or psoriasis. Using data from the choices that participants make across these tasks, we can use statistical techniques to draw inferences about the relative value they place on different product attributes, estimate the relative importance of different attributes, explore the tradeoffs that consumers and physicians are willing to make to avoid or accept specific attribute levels, and compare the preferences of these two groups (Ref. 8).

We estimate that participation in the study will take approximately 20 minutes. Adult participants aged 18 years or older will be recruited by email through an internet panel, and participant eligibility will be determined with a screener at the beginning of the online survey. The consumer sample will consist of adults who self-report as having been diagnosed by a healthcare provider with either psoriasis or type 2 diabetes. For the consumer sample, we will exclude

individuals who work in healthcare settings because their knowledge and experiences may not reflect those of the average consumer. The physician sample will consist of primary care physicians and specialists who report treating patients with psoriasis or type 2 diabetes. For the physician sample, we will exclude individuals who spend less than 50 percent of their time on direct patient care. Department of Health and Human Services employees and individuals who work in the marketing, advertising, or pharmaceutical industries will be excluded from both respondent groups. Respondents will receive a survey invitation with a unique password-protected link. All panel members are recruited following a double opt-in process. Sample sizes were estimated by combining approaches for conjoint analysis suggested by Orme (Ref. 9) and Johnson et al. (Ref. 10).

The target sample size for the main study is 800 physicians and 800 consumers, with half of each cohort focusing on treatments for psoriasis and the other half focusing on treatments for type 2 diabetes. Prior to conducting the main study, we will conduct at least one pretest. If the first pretest reveals that changes to the measurement instruments, stimuli, or procedures are required, a second pretest will be conducted with revised materials. The target sample size for each wave of pretests is 60 physicians and 60 consumers.

In the **Federal Register** of April 25, 2022 (87 FR 24313), FDA published a 60-day notice requesting public comment on the proposed collection of information. Two submissions (*https://www.regulations.gov* tracking numbers l3s–66ri–uyh2 and l2z–6w2l–mpk1) were outside the scope of the research and are not addressed further.

FDA received eight comments that were PRA-related. Within those submissions, FDA received multiple comments that the Agency has addressed. For brevity, some public comments are paraphrased and therefore may not state the exact language used by the commenter. We assure the commenter that the entirety of their comments was considered even if not fully captured by our paraphrasing in this document. Comments and responses are numbered here for organizational purposes only.

(Comment 1) Five comments expressed support for the study.

(Response 1) We acknowledge and appreciate the support of this study.

(Comment 2) One comment stated the collection of information is not necessary for the proper performance of FDA functions and questioned the practical utility of the study. Another comment asked for clarification about how the results would be applied to OPDP decision making. The first of these comments suggests that an alternate approach would be to dedicate resources to enforcing heavier penalties for misleading, incomplete, or false information.

(Response 2) The OPDP's mission is to protect the public health by helping to ensure that prescription drug promotion is truthful, balanced, and accurately communicated. Understanding the tradeoffs among drug product characteristics diagnosed consumers make—and how the tradeoffs could potentially differ from the tradeoffs made by physicians—will provide OPDP valuable insight into the relevance and impact of various product attributes and promotional claims on informed choices and treatment decisions. Gaining a better understanding of what information has the most meaning and impact for audiences informs OPDP's approach to ensuring that promotional communications are truthful, balanced, and accurately communicated.

(Comment 3) One comment expressed concern that results of the study possibly could inform potential guidance on patient-focused drug development.

(Response 3) The purpose of this research is to examine the tradeoffs that consumers and physicians make when considering product claims that may appear in promotional communications. The fact that FDA is conducting research does not create any requirements.

(Comment 4) One comment asked how adherence and patient preference claims would be included in drug product information, as the commenter does not believe there is currently a patient preference claim or adherence data in FDA-approved prescription drug information for any product in either of the two conditions proposed in this study.

(Response 4) Prescription drug promotion often includes information beyond what is contained in the FDA-approved prescription information for the product. The attributes that make up the ''additional information about the drug'' are example marketing claims that have been used in product promotion. We will test reasonable scenarios based on realistic examples.

(Comment 5) One comment suggested clarification of the sentence, ''The treatment preferences of diagnosed consumers and treating physicians have been shown to be influenced by certain characteristics, such as the drug's perceived impact on quality of life, complexity of dosage regimens, mode of administration, cost to family and self, and marketing claims unrelated to medicinal properties (Refs. 1 to 5)'' (87 FR 24313 at 24315). The comment asserts that it is inaccurate to state that ''preferences'' are influenced by the characteristics of alternatives, when it is actually ''choice'' that is a reflection of the characteristics or attributes.

(Response 5) We have revised the sentence in question, as suggested, to make it clear that treatment choices are influenced by these example characteristics. The revised sentence reads, ''The treatment choices of diagnosed consumers and treating physicians have been shown to be influenced by certain characteristics, such as the drug's perceived impact on quality of life, complexity of dosage regimens, mode of administration, cost to family and self, and marketing claims unrelated to medicinal properties.''

(Comment 6) Two comments asked for clarification on the guidelines that will be used to determine the attributes and levels in the experiment.

(Response 6) We selected attributes and attribute levels based on information gathered through: (1) a systematic literature review of preference elicitation studies targeted toward prescription pharmacological treatments for psoriasis or type 2 diabetes among diagnosed consumers or healthcare providers (HCPs) reported in peer-reviewed journal articles or book chapters published in English through the end of September 2020 and (2) semistructured, one-on-one interviews with physicians and diagnosed consumers conducted as part of the formative work for this project.

The systematic literature review focused on research examining preferences for attributes and characteristics of prescription drug products indicated for psoriasis and type 2 diabetes. The review addressed two research questions with an emphasis on informing our choice of elicitation method for the main study and identifying characteristics of prescription drug products relating to risk, burden, adherence, and benefits that physicians and consumers who have been diagnosed with the target medical conditions consider when choosing among treatment options. After screening candidate articles against our eligibility criteria, we retained and extracted information from 30 articles related to psoriasis and 28 articles for type 2 diabetes that informed our choice of attributes and levels. Our aim with the one-on-one interviews was

to better understand how physicians and diagnosed consumers navigate decision making related to prescription drug products and to verify that attributes identified through the systematic literature review corresponded with the characteristics that physicians and consumers care about when making prescription drug choices. In all, we conducted 35 interviews with physicians who treat psoriasis or type 2 diabetes and 70 interviews with consumers who self-reported that they have been diagnosed with one of the two chronic conditions (n = 35 per condition). We asked specific questions about attributes and attribute levels found in the literature review. We also used the interviews to elicit additional characteristics that may not have been represented in the literature.

(Comment 7) One comment suggests use of an opt-out (*i.e.,* decline therapy) or status quo (*i.e.,* no change) option in the questionnaires.

(Response 7) There can be benefits to including an ''opt-out'' or ''status quo'' option in choice experiments, depending on the goals of the research. For example, if one is interested in estimating treatment uptake, the inclusion of an ''opt-out'' option may be helpful. However, estimating treatment uptake is not a goal of this study, and we believe the limitations of including an ''opt-out'' or ''status quo'' option outweigh the benefits in this instance. One limitation is the potential for satisficing—participants choosing the ''opt-out'' or ''status quo'' option because it requires less effort than reflecting on the option that best aligns with their preferences (Ref. 11). Additionally, in the context of this study, the status quo will differ among participants, raising the issue of how to interpret findings from diagnosed consumers who choose that option.

(Comment 8) Two comments question the decision to employ a discrete choice experiment (DCE) method and the number of attributes chosen, with one comment noting that there are other methods that may allow for a higher number of attributes to be tested. One of the comments noted the existence of other DCE studies conducted in similar treatment populations and requested clarification about how this study would differ from prior research.

(Response 8) One of the goals of the systematic literature review we conducted as part of the formative work for this study was to examine methods that have been used to elicit consumer or HCP preferences regarding treatment options for psoriasis and type 2 diabetes. An overarching observation from the systematic literature review is that there is a gap in the literature for studies that directly compare treatment preferences of diagnosed consumers and HCPs. There is also a lack of studies that examine the relative importance of marketing claims versus other types of promotional claims. This study will help fill these gaps. A DCE was the most common methodology used in prior research, and it has clear advantages over other methods for the purposes of the proposed study. Perhaps the most relevant benefits of the method are the flexibility to efficiently estimate the overall utility of different treatment profiles, the relative importance of attributes, and the preference weights for specific attribute levels all within the same design (see Ref. 12 for an analysis that covers all three of these aspects). Moreover, tradeoffs that diagnosed consumers and HCPs are willing to make between attributes can be estimated from DCE data by calculating the marginal rate of substitution or the ratio of relative importance scores for pairs of attributes (Refs. 12 to 15).

In designing the DCE for this project, we aim to conduct subgroup analyses comparing these research populations. Generally, this requires using the same attributes and levels for both research populations, though some degree of latitude is required to tailor the wording of background information, questions, and stimuli to match the target audience (*e.g.,* plain language for consumers, medical terminology when appropriate for HCPs).

For planning purposes and in order to establish target sample sizes, in the 60-day **Federal Register** notice for this study, we assumed a design with 5 attributes, 2 to 4 levels per attribute, 10 choice tasks per participant, and 2 options per task square. Our review revealed that these assumptions are well within the median design parameters used in prior studies.

We will include methodological details concerning the experimental design in the report of results. Finally, while the comment did not identify any specific ongoing research as overlapping, we note that in general, in any event, OPDP may conduct concurrent or overlapping studies on similar topics.

(Comment 9) One comment suggested use of an efficient design, including blocking, as a way to minimize the burden of collection on respondents.

(Response 9) We intend to use an efficient design to reduce the number of choice tasks and have noted it as a burden reduction strategy in the information collection submission to OMB.

(Comment 10) One comment asserted that internet panels are prone to selection bias and suggested the study address this potential limitation.

(Response 10) Participants in the proposed studies will be convenience samples rather than probability-based samples of diagnosed consumers and physicians. The strength of the experimental design used in this study lies in its internal validity, on which meaningful estimates of differences across manipulated attributes can be produced and generalized. This is a counterpoint to observational survey methodologies, where estimating population parameters is the primary focus of statistical analysis. The recruitment procedures in this study are not intended to meet criteria used in survey sampling, where each unit in the sampling frame has an equal probability of being selected to participate. In a representative, observational survey study, response rates are often used as a proxy measure for survey quality, with lower response rates indicating poorer quality. Nonresponse bias analysis is also commonly used to determine the potential for nonresponse sampling error in survey estimates. However, concerns about sampling error do not generally apply to experimental designs, where the parameters of interest are under the control of the researcher—rather than being pre-established characteristics of the participants. Participants will be recruited through online panels, which include a diverse range of participants in regard to age, race/ethnicity, income, education, and employment. We also have proposed the use of soft quotas to further ensure that we will recruit a diverse sample. See Response 12 for a more detailed description of the panels to be used in this research.

(Comment 11) Two comments questioned the Agency's methods for ensuring it is selecting patients as study participants.

(Response 11) Our eligibility criteria involve a self-reported diagnosis of plaque psoriasis or type 2 diabetes, which appropriately reflects the audience for DTC promotion where a verified diagnosis is not a criterion. The screener includes a question (screening question 5 (S5)) that asks whether a doctor, nurse, or other health professional has ever told the respondent they had at least one of seven health conditions. Participants who do not select plaque psoriasis or type 2 diabetes will be flagged as ineligible for the study. The other conditions are included as response

options to help disguise eligibility criteria from respondents as they complete the screener.

(Comment 12) One comment stated it is unclear how physicians will be recruited, and one comment asserted that how consumers will be identified is not mentioned.

(Response 12) For the pretests and main study, participants will be drawn from participant panels managed by Dynata. Dynata recruits panel members through a combination of email and online marketing and by invitation, with over 300 diverse online and offline affiliate partners and targeted website advertising. By using multiple recruitment methods, Dynata is able to recruit a diverse set of consumers and decision makers to participate in their panels and will ensure demographic diversity of participants' genders, ages, and education levels. Panel inclusion is by invitation only, and Dynata invites only pre-validated individuals with known characteristics to participate in the consumer panels. The physician sample for the pretest and main study will be drawn from Dynata's Healthcare Panel, which is a physician panel used exclusively for healthcare research. Dynata's Healthcare Panel uses a multimode approach that combines email, fax, and direct mail to recruit HCPs to participate in online surveys. Additionally, Dynata purchases professional association and governmental databases to verify an HCP's practicing status. These verification resources include the Drug Enforcement Agency number (DEA#) and the American Medical Association Medical Education Number (ME#).

(Comment 13) One comment suggested that the samples should be prepared for heterogeneity of preference.

(Response 13) We agree that our modeling approach is to account for potential preference heterogeneity. At the design phase, we are intentionally setting up the study to allow us to compare preference weights between diagnosed consumers and physicians within each health condition. Additionally, we intend to analyze the data using several modeling approaches with other sources of preference heterogeneity in mind.

(Comment 14) One comment suggested the study collect respondents' demographic information, including race/ethnicity, income, geographical region, educational attainment, and healthcare system experiences, particularly negative experiences with an HCP due to their race; two comments suggested the study collect additional data on participants' baseline HbA1c status.

(Response 14) We will measure several demographic variables about respondents, including race/ethnicity, educational attainment, gender, age, geographical location, health literacy, and numeracy. We will also collect information about time since diagnosis, perceived severity of their health condition, and experience/familiarity with prescription drugs to treat the condition. Based on prior experience, we expect these variables to have a direct or indirect effect on our measures. See also Response 13 regarding preference heterogeneity (*i.e.,* the extent to which tastes and preferences vary across participants and/or groups). We are avoiding requesting potentially sensitive personal information from respondents. Although we agree that information about consumers' A1C status could be useful for explaining preference heterogeneity that we may observe, collecting data at that level of personal detail is not warranted given the goals of the research. Instead, we have included a less intrusive perceived severity measure.

(Comment 15) One comment requested clarification of the rationale for determining the study's sample size (800 consumers and 800 physicians). Another comment questioned whether the sample size per demographic may be insufficient to understand how these conditions affect different populations.

(Response 15) The proposed sample size in the two main studies is $n = 400$ participants for each subgroup of interest (diagnosed consumers and physicians), for a total combined $N = 1600$. For our power estimates, we assumed an experimental design with no less than 5 conjoint questions per participant ($t = 5$), 2 alternatives per question ($a = 2$), and 4 levels per attribute ($c = 4$). This implies a sample of 400 participants per subgroup per study.

(Comment 16) One comment asked that a Spanish-language version of the survey be included to ensure that the experiences of this population are included.

(Response 16) We are limiting the survey to the English language, as the majority of advertising for these products is disseminated in English at this time.

(Comment 17) One comment encouraged FDA to broadly and systematically disseminate all final results of completed research related to this topic.

(Response 17) The Agency anticipates disseminating the results of the study after the final analyses of the data are completed, reviewed, and cleared. The exact timing and nature of any such dissemination has not been determined but may include presentations at trade and academic conferences, publications, articles, and posting on FDA's website.

(Comment 18) One comment asserted that access to the choice tasks and proposed questions, including content-specific language and terms, would allow a more substantive review of the proposed research.

(Response 18) Our questionnaires were made available during the public comment process. Our full stimuli are under development during the PRA process. We do not make draft stimuli public during this time because of concerns that this may contaminate our participant pool and compromise our research. In our research proposals, we describe the purpose of the study, the design, the population of interest, and the estimated burden.

(Comment 19) One comment suggested considering adding a ''don't know'' response option throughout the questionnaire, where appropriate.

(Response 19) We understand the value of providing such responses for items of a factual nature. The drawback to providing such response options to these questions, however, is that we may lose information by allowing respondents to choose an easy response instead of giving the item some thought. Research has demonstrated that providing ''no opinion'' options likely results in the loss of data without any corresponding increase in the quality of the data. Thus, we prefer not to add these options to the survey.

(Comment 20) One comment suggested revising S5 to read ''are you currently being treated for the following conditions . . .''

(Response 20) The current wording of S5 is consistent with the eligibility criterion that consumers self-identify as having been diagnosed with plaque psoriasis or type 2 diabetes. We will maintain this wording.

(Comment 21) One comment noted that it is unclear what method will be used to achieve the literacy goal of screening question 11.

(Response 21) The programming note for question S11 indicates that participants would count toward the low health literacy quota if the numeral value assigned to their response is greater than or equal to 3, where 3 = ''Sometimes,'' 4 = ''Often,'' and 5 = ''Always.''

(Comment 22) Two comments expressed confusion about whether question A2 is measuring severity from the patient's or physician's perspective

and recommended clarifying the question or replacing it.

(Response 22) We have revised question A2, as suggested, to clarify that we are asking about the perceived severity of the condition from the participant's perspective.

(Comment 23) One comment recommended rephrasing question A6 to specify ''forms'' rather than ''types'' and to clarify the difference between a prefilled pen and a syringe (diabetes questionnaire).

(Response 23) We have reworded question A6, replacing the term ''types'' with ''forms.'' In the one-on-one interviews, none of the participants expressed confusion about the two terms.

(Comment 24) One comment recommended revising the patient profile in the physician survey to reflect that most patients are diagnosed with type 2 diabetes in their 50s or 60s.

(Response 24) We appreciate your recommendations concerning the realism of the patient profile. In consultation with a medical advisor, we have maintained the patient profile age of 57 years but have changed the diabetes duration in the patient profile from 14 years to 4 years to reflect more standard disease state information.

(Comment 25) One comment suggested adding context to the diabetes questionnaire instructions to reduce ambiguity and facilitate comparisons between the physician and consumer surveys. Specifically, the comment suggests adding more information to the consumer survey about the baseline and changed A1C levels in the introduction (Section B).

(Response 25) Section B introduces each attribute that will be varied in the DCE. The language in the Section B introduction in the physician and consumer questionnaires is tailored to the audience but has the same information about the A1C goal and point reductions that will be examined in the study, which will facilitate comparisons between the two samples. Section C provides the patient profile that will be used as the basis for the DCE. For physicians, the profile is for a hypothetical patient. For consumers, the instructions ask the participant to imagine their doctor recommends they try a prescription drug to help lower their A1C. The change in A1C levels used in the choice tasks for both consumers and physicians includes examples that are anchored to an A1C of 8.5.

(Comment 26) One comment suggested adding itch (pruritis) as an attribute.

(Response 26) In choosing and defining product attributes to include in the study, we selected characteristics based on evidence that they will impact choice. Itch relief didn't feature prominently in the results of our literature review or in the one-on-one interviews with consumers or physicians. In comparison, effectiveness at achieving skin clearance was an attribute in every DCE study included in our literature review, had the greatest relative importance in many of those studies, and was mentioned as an important consideration in open-ended comments and ranked among the three most important characteristics by most participants in our one-on-one interviews.

(Comment 27) One comment recommended adding more description, using both simple text and simple graphics, to the ''serious side effects'' to depict the chance of experiencing a serious side effect, and it recommended adding definitions for the additional attributes.

(Response 27) Rare but serious adverse reactions/side effects will be presented to participants as a single attribute but may be treated as a set of dichotomous attributes for study design and analysis purposes (*e.g.,* each side effect will be either present or absent in a profile). Varying more than one factor at a time within an attribute makes it difficult to distinguish the effect of each factor separately.

The ''additional information'' attributes are essentially marketing claims; however, we have labeled the attribute ''additional information about the drug'' to avoid eliciting reactance from participants in response to the term ''marketing.'' Marketing claims are not typically presented with definitions, so we do not provide definitions for the levels of this attribute.

(Comment 28) One comment suggested replacing ''adherence'' with ''usage'' in the consumer questionnaires and standardizing preference description across the patient and physician questionnaires.

(Response 28) We will assess participant comprehension of the term ''adherence'' during cognitive interviews, and we can make changes, if indicated.

Descriptions of the preference attribute are the same in the physician and consumer questionnaires within each health condition. The attributes for each health condition are designed to be relevant to that particular health condition. We do not intend to make formal comparisons between health conditions.

(Comment 29) One comment suggested revising questions B1 to B5 from ''how important is it'' to instead obtain information about prior experience with each attribute.

(Response 29) The purpose of questions B1 to B5 is to collect self-report ratings of how important each attribute is to participants, which we may use to validate the relative importance scores derived from the DCE. We derived these questions from similar questions included in Janssen et al. (Ref. 17), a study that was conducted to illustrate how DCE could be conducted when following International Society for Pharmacoeconomics and Outcomes Research (ISPOR) recommendations for good research practices.

(Comment 30) One comment asserted that most current diabetes drugs are not associated with heart disease and suggested removing that attribute and adding questions related to weight loss and potential cardiovascular benefits.

(Response 30) We agree that cardiovascular mortality is not an adverse reaction associated with most diabetes drugs; however, there is evidence of increased risk of cardiovascular mortality for some oral antidiabetic agents (*e.g.,* sulfonylureas, thiazolidinediones, and dipeptidyl peptidase 4 inhibitors (Refs. 18 and 19); we are not examining use of insulin in this study). Our approach with the serious adverse reactions/side effects attribute is to present a range of category-appropriate adverse reactions that differ greatly in terms of severity. The reasoning is similar to that behind manipulating extremes in an experimental study in order to increase variance, even if the resulting attributes do not reflect what is typical for the category.

(Comment 31) One comment asserted that the planned data analysis and how data between consumers and physicians would be compared is unclear.

(Response 31) We will use a variety of statistical techniques to analyze the data, adapting our modeling approach to the specific research questions and observed characteristics of the data. A variety of modeling approaches can be used to estimate preference weights in choice-based conjoint studies (Ref. 14)—including conditional logit, mixed logit, Bayesian latent utility, and latent class conditional logistic regression models. The results of the statistical analysis will be used to: (1) identify which attributes of prescription drug products diagnosed consumers and physicians value most, (2) calculate the relative importance of attributes, (3) identify differences in preferences between the

two subgroups (*e.g.,* by including interaction terms in the model), and (4) determine how participants make tradeoffs among attributes to make treatment choices. We intend to examine responses within medical conditions. Where commonalities in survey questions exist, we may compare the consumer and physician responses. Details of our research questions are included as part of the information collection submission to OMB.

(Comment 32) One comment suggested that physicians review the patient survey during pretesting to ensure that the physician and patient surveys are aligned.

(Response 32) Although some wording may differ between the physician and consumer questionnaires to reflect the knowledge and expertise of each sample, we have endeavored to ensure that the concepts are equally represented in the questionnaires across samples. Additionally, we have solicited peer review feedback on the questionnaires from experts in the field. We will also conduct cognitive interviews and pretests to help identify areas where the materials are ambiguous or confusing for participants and make any necessary refinements.

(Comment 33) Three comments had questions about the purpose of the pretesting and the accuracy of the burden estimation for the pretesting, and one comment stated that the burden estimate seemed reasonable.

(Response 33) We will conduct both cognitive interviews and pretests. The burden chart reflects both the cognitive interviews and the pretesting. Qualitative, one-on-one cognitive testing will be used to help identify areas where the materials would benefit from refinements. Additionally, up to two rounds of quantitative pretesting per study will be employed to evaluate the procedures and measures used in the main study. We will balance various factors that affect study completion time and limit the questionnaire to a mean of 20 minutes or less.

The way attribute levels are combined to form hypothetical choice options in a choice-based conjoint analysis, or DCE, are determined by the study's experimental design. Although the number of possible combinations is often too large for each participant to evaluate them all, we will generate a statistically efficient design that reduces the number of choice tasks participants must complete while maintaining sufficient balance and orthogonality for reliable parameter estimation.

(Comment 34) One comment referred to an abstract describing a DCE examining patients' preferences for newer second-line antihyperglycemic agents.

(Response 34) We appreciate bringing the abstract to our attention.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response [1]	Total hours
Cognitive Interview Screener, Consumers	150	1	150	0.08 (5 min)	12
Cognitive Interviews, Consumers	9	1	9	1	9
Pretest 1 Screener, Physicians [2]	95	1	95	0.08 (5 min)	8
Pretest 1 Screener, Consumers [3]	95	1	95	0.08 (5 min)	8
Physician Pretest 1	66	1	66	0.33 (20 min)	22
Consumer Pretest 1	66	1	66	0.33 (20 min)	22
Pretest 2 Screener, Physicians [2 3]	95	1	95	0.08 (5 min)	8
Pretest 2 Screener, Consumers [2 3]	95	1	95	0.08 (5 min)	8
Physician Pretest 2 [2]	66	1	66	0.33 (20 min)	22
Consumer Pretest 2 [2]	66	1	66	0.33 (20 min)	22
Physician Main Study Screener [2]	1,258	1	1,258	0.08 (5 min)	101
Physician Main Study	880	1	880	0.33 (20 min)	290
Consumer Main Study Screener [2]	1,258	1	1,258	0.08 (5 min)	101
Consumer Main Study	880	1	880	0.33 (20 min)	290
Total			5,079		923

[1] Burden estimates of less than 1 hour are expressed as a fraction of an hour in decimal format.
[2] Number of screener respondents assumes a 70 percent eligibility rate with targeted recruitment.
[3] Pretest 2 will be conducted only if changes to study materials are made in response to the findings of Pretest 1.

As with most online and mail surveys, it is always possible that some participants will be in the process of completing the survey when the target number is reached and that those surveys will be completed and received before the survey is closed out. To account for this, we have estimated approximately 10 percent overage for both samples in the pretest and main study.

II. References

The following references marked with an asterisk (*) are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *https://www.regulations.gov.* References without asterisks are not on public display at *https://www.regulations.gov* because they have copyright restriction. Some may be available at the website address, if listed. References without asterisks are available for viewing only at the Dockets Management Staff. FDA has verified the website addresses, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

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Dated: April 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09183 Filed 4–28–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–0297]

Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products; Guidance for Industry.'' The document provides guidance to assist sponsors in the clinical development of nicotine replacement therapy (NRT) drug products, including but not limited to those intended for smoking cessation and related chronic indications. This guidance finalizes the draft guidance of the same title issued on February 22, 2019.

DATES: The announcement of the guidance is published in the **Federal Register** on May 1, 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–2019–D–0297 for ''Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products.'' 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. 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: Heather Dorsey, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Silver Spring, MD 20903–0002, 240–429–4192, *heather.dorsey@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products.'' This guidance reflects the FDA's current thinking regarding overall development programs to support the approval of NRT drug products for smoking cessation and related chronic indications. There are several FDA-approved prescription and nonprescription NRT drug products for cessation of smoking cigarettes, but the Agency encourages the development of additional NRT drug products, which could help more smokers quit.

The guidance focuses on drug development and trial design issues that are specific to the study of NRT drug products. NRT drug products are typically studied and labeled for use as adjuncts to behavioral self-help materials and to date have involved single treatment regimens that begin on the patient's quit day (first day without a cigarette). Alternate treatment regimens (*e.g.,* pretreatment before quit day, quitting by gradual reduction (reduce to quit), using multiple NRT drug products together) are discussed in the guidance.

As outlined in the guidance, NRT drug products can be developed for smoking cessation and/or reduction in risk of relapse. NRT drug products that first have demonstrated efficacy for at least one of these indications can also include additional information in labeling by demonstrating efficacy in certain secondary endpoints. Sponsors can evaluate reduction in the urge to smoke or relief of cue-induced craving in former smokers as secondary endpoints. Additionally, sponsors that can demonstrate, via a secondary endpoint, that the drug product provides relief of withdrawal symptoms in smokers *who are not trying to quit smoking* may be able to include labeling instructions to address situations when such individuals are required to abstain and therefore experience withdrawal symptoms (*e.g.,* while traveling on an airplane).

FDA is aware of the serious risks associated with smoking and is committed to facilitating the development of therapies to support smoking cessation efforts. Both the regulatory pathway for an NRT drug product and the amount of nonclinical or clinical data needed to support approval will depend on the characteristics of the proposed NRT drug product relative to an approved NRT drug product. This guidance outlines general considerations for NRT drug development and trial design, and FDA encourages sponsors to contact FDA for feedback on their proposed development plans. Sponsors developing nonprescription drug product should bear in mind that it is often not possible to answer all regulatory questions in a single trial, and additional sequential steps may be needed.

This guidance finalizes the draft guidance entitled ''Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products'' issued on February 22, 2019 (84 FR 5693). FDA considered comments received on the draft guidance as the guidance was finalized. Changes from the draft to the final guidance include clarification that the document does not address the development of NRT to aid in the cessation of non-combustible tobacco products (*e.g.,* e-cigarettes); information regarding the pathway described in section 505(b)(2) (21 U.S.C. 355(b)(2)) of the Federal Food, Drug, and Cosmetic Act and reliance on published literature; and clarification regarding mode of administration and route of administration. In addition, editorial changes were made to improve clarity. This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Smoking Cessation and Related Indications: Developing Nicotine Replacement Therapy Drug Products.'' 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.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 312 pertaining to the submissions of investigational new drug applications, including clinical trial design and study protocols, have been approved under OMB control number 0910–0014. The

collections of information in 21 CFR part 314 regarding the submission of new drug applications including formal meetings with sponsors and applicants for Prescription Drug User Fee Act products, abbreviated new drug applications and supplemental applications have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 pertaining to the submission of biologics license applications have been approved under OMB control number 0910–0338. The collections of information relating to expedited program for serious conditions for drug and biological product development programs have been approved under OMB control number 0910–0765. The collections of information pertaining to the submission of special protocol assessments have been approved under OMB control number 0910–0470. The collections of information in 21 CFR 201.56 and 201.57 for the submission of certain prescription drug product labeling have been approved under OMB control number 0910–0572. The collections of information in 21 CFR parts 50 and 56 (Protection of Human Subjects: Informed Consent; Institutional Review Boards) have been approved under OMB control number 0910–0130. The collections of information pertaining to good clinical practice have been approved under OMB control number 0910–0843. The collections of information pertaining to adverse events reporting have been approved under OMB control number 0910–0291.

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/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: April 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09170 Filed 4–28–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–0451]

Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is reopening the comment period for the draft guidance entitled ''Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements; Guidance for Industry,'' which was announced in the **Federal Register** of February 23, 2023. We are taking this action in response to requests for an extension to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period on the draft guidance published February 23, 2023 (88 FR 11449). Submit either electronic or written comments on the draft guidance by July 31, 2023, to ensure that we consider your comment on the draft guidance before we begin work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance 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–0451 for ''Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request.'' 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.'' We will review this copy, including the claimed confidential information, in our 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.

FOR FURTHER INFORMATION CONTACT: Jeanmaire Hryshko, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371; or Philip Chao, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS–024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION: In the **Federal Registe**r of February 23, 2023 (88 FR 11449), we published a notice of availability for a draft guidance entitled ''Labeling of Plant-Based Milk Alternatives and Voluntary Nutrient Statements; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request.'' This action opened a docket with a 60-day comment period.

We have received requests for a 90-day extension of the comment period for the draft guidance. We have concluded that it is reasonable to reopen the comment period for 90 days, until July 31, 2023. We are reopening the comment period because the request for an extension of the comment period arrived too late for us to extend the comment period. We believe that an additional 90 days allows adequate time for interested persons to submit comments.

Dated: April 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09176 Filed 4–28–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–D–0875]

S12 Nonclinical Biodistribution Considerations for Gene Therapy Products; International Council for Harmonisation; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''S12 Nonclinical Biodistribution Considerations for Gene Therapy Products.'' The guidance was prepared under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The final guidance provides harmonized recommendations for the conduct and overall design of nonclinical biodistribution (BD) studies for gene therapy (GT) products. The recommendations in the guidance endeavor to facilitate the development of investigational GT products, while avoiding unnecessary use of animals, in accordance with the 3Rs (reduce/refine/replace) principles. The final guidance replaces the draft guidance entitled ''S12 Nonclinical Biodistribution Considerations for Gene Therapy Products'' issued on September 9, 2021.

DATES: The announcement of the guidance is published in the **Federal Register** on May 1, 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–2021–D–0875 for ''S12 Nonclinical Biodistribution Considerations for Gene Therapy Products.'' 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 the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research (CBER), 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. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT:

Regarding the guidance: Alyssa Galaro, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 6260, Silver Spring, MD, 20993–0002, 301–796–6589.

Regarding the ICH: Jill Adleberg, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6364, Silver Spring, MD 20993–0002, 301–796–5259, *Jill.Adleberg@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''S12 Nonclinical Biodistribution Considerations for Gene Therapy Products.'' The guidance was prepared under the auspices of ICH. ICH has the mission of achieving greater regulatory harmonization worldwide to ensure that safe, effective, high-quality medicines are developed, registered, and maintained in the most resource-efficient manner.

By harmonizing the regulatory requirements in regions around the world, ICH guidelines enhance global drug development, improve manufacturing standards, and increase the availability of medications. For example, ICH guidelines have substantially reduced duplicative clinical studies, prevented unnecessary animal studies, standardized the reporting of important safety information, and standardized marketing application submissions.

The six Founding Members of the ICH are FDA; the Pharmaceutical Research and Manufacturers of America; the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; and the Japanese Pharmaceutical Manufacturers Association. The Standing Members of the ICH Association include Health Canada and Swissmedic. ICH membership continues to expand to include other regulatory authorities and industry associations from around the world (refer to *https://www.ich.org/*).

ICH works by engaging global regulatory and industry experts in a detailed, science-based, and consensus-driven process that results in the development of ICH guidelines. The regulators around the world are committed to consistently adopting these consensus-based guidelines, realizing the benefits for patients and for industry.

As a Founding Regulatory Member of ICH, FDA plays a major role in the development of each of the ICH guidelines, which FDA then adopts and issues as guidance for industry. FDA's guidance documents do not establish legally enforceable responsibilities. Instead, they describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited.

In the **Federal Register** of September 9, 2021 (86 FR 50536), FDA published a notice announcing the availability of a draft guidance entitled ''S12 Nonclinical Biodistribution Considerations for Gene Therapy Products.'' The notice gave interested persons an opportunity to submit comments by November 8, 2021.

After consideration of the comments received and revisions to the guideline, a final draft of the guideline was submitted to the ICH Assembly and endorsed by the regulatory agencies on March 14, 2023.

This guidance finalizes the draft guidance of the same title issued on September 9, 2021. The guidance is intended to promote harmonization of recommendations for the BD assessment for investigational GT products and facilitate a more efficient and timely nonclinical development program. The revisions to the draft guidance aimed to clarify key elements of the BD assessment by providing additional information on selecting dose levels and identifying a biologically relevant model. Additional details were provided on what product and study characteristics should be considered to determine if previous BD data can be leveraged.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''S12 Nonclinical Biodistribution Considerations for Gene Therapy Products.'' 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.

II. Paperwork Reduction Act of 1995

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

Dated: April 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09179 Filed 4–28–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1029]

Agency Information Collection Activities; Proposed Collection; Comment Request; Cosmetic Labeling Requirements and Facility Registration and Cosmetic Product Listing Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection provisions in FDA's cosmetic labeling regulations and new statutory provisions for cosmetic labeling, facility registration, and products listing.

DATES: Either electronic or written comments on the collection of information must be submitted by June 30, 2023.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 30, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–N–1029 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Cosmetic Labeling Requirements and Facility Registration and Cosmetic Product Listing Program.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the

information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Cosmetic Labeling Requirements and Facility Registration and Cosmetic Product Listing Program

OMB Control Number 0910–0599—Revision

This information collection supports FDA's cosmetic labeling regulations and new statutory provisions for cosmetic labeling, facility registration, and products listing. On December 29, 2022, the President signed into law the Consolidated Appropriations Act, 2023 (Pub. L. 117–328), which included the Modernization of Cosmetics Registration Act of 2022 (MoCRA). MoCRA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by requiring, among other requirements, manufacturers of cosmetic products to label products intended for use only by licensed professionals to bear a label that the product must be administered or used only by licensed professionals, in addition to providing the same information on the label that is required of cosmetic products intended for consumers. MoCRA also added the requirement for cosmetic product labels to include contact information through which the responsible person can receive adverse event reports. Other requirements introduced by MoCRA include facility registration and cosmetic product listing.

Cosmetic Labeling Requirements

The FD&C Act and the Fair Packaging and Labeling Act (the FPLA) require that cosmetic manufacturers, packers, and distributors disclose information about themselves or their products on the labels or labeling of their products. Sections 201, 301, 502, 601, 602, 603, 701, and 704 of the FD&C Act (21 U.S.C. 321, 331, 352, 361, 362, 363, 371, and 374) and sections 4 and 5 of the FPLA (15 U.S.C. 1453 and 1454) provide authority to FDA to regulate the labeling of cosmetic products. Failure to comply with the requirements for cosmetic labeling may render a cosmetic adulterated under section 601 of the FD&C Act or misbranded under section 602 of the FD&C Act.

FDA's cosmetic labeling regulations are codified in part 701 (21 CFR part 701). Section 701.3 (21 CFR 701.3) requires the label of a cosmetic product to bear a declaration of the ingredients in descending order of predominance. Section 701.11 (21 CFR 701.11) requires the principal display panel of a cosmetic product to bear a statement of the identity of the product. Section 701.12 (21 CFR 701.12) requires the label of a cosmetic product to specify the name and place of business of the manufacturer, packer, or distributor. Section 701.13 (21 CFR 701.13) requires the label of a cosmetic product to declare the net quantity of contents of the product.

MoCRA amended the FD&C Act by requiring, among other requirements, manufacturers of cosmetic products to label products intended for use only by licensed professionals to bear a label that the product must be administered or used only by licensed professionals, in addition to providing the same information on the label that is required of cosmetic products intended for consumers. MoCRA also added the requirement for cosmetic product labels to include contact information (domestic address, phone number, or electronic contact information that may include a website) through which the responsible person can receive adverse event reports.

Facility Registration and Cosmetic Product Listing Program

MoCRA amended the FD&C Act by requiring, among other requirements, operators and owners of facilities manufacturing or processing cosmetic products to register with FDA and renew such registrations biennially. Facilities will also need to notify FDA of any changes to information that was required as part of registration. FDA may suspend registration if we determine that a cosmetic product manufactured or processed by a registered facility has a reasonable probability of causing serious adverse health consequences or death. Upon notice that FDA intends to suspend registration, the responsible person for the facility may submit a corrective action plan for addressing the reasons for possible suspension of the facility registration. MoCRA also added the requirement for responsible persons to submit a product listing for each of their cosmetic products to FDA.

As we develop a process to accept submissions for registrations and product listings consistent with the provisions in MoCRA, we have discontinued use of Forms FDA 2511, 2512, and 2512a, previously used for voluntary registration activities and have stopped accepting new submissions to the Voluntary Cosmetic Registration Program (VCRP).

Description of Respondents: Respondents to this collection of information include cosmetic manufacturers and processors. Respondents are from the private sector (for-profit businesses).

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR or FD&C Act section; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours	Total capital costs [2]
§ 701.3; ingredients in order of predominance	1,518	21	31,878	1	31,878	.....
§ 701.11; statement of identity	1,518	24	36,432	1	36,432	.....
§ 701.12; name and place of business	1,518	24	36,432	1	36,432	.....
§ 701.13; net quantity of contents	1,518	24	36,432	1	36,432	.....
Sec. 609(a) of the FD&C Act (MoCRA); contact information to send adverse event reports	1,518	24	36,432	1	36,432	$91,080,000
Sec. 609(c) of the FD&C Act (MoCRA); professional use only	100	12	1,200	1	1,200	3,000,000
Total	.....	.....	.....	.....	178,806	$94,080,000

[1] There are no operating and maintenance costs associated with this collection of information.
[2] One-time burden for capital costs.

The estimated annual third-party disclosure burden for labeling is based on data available to the Agency, our knowledge of and experience with cosmetics, and informal communications with industry. The hour burden is the additional or incremental time that establishments need to design and print labeling that includes the following required elements: a declaration of ingredients in decreasing order of predominance, a statement of the identity of the product, a specification of the name and place of business of the establishment, and a declaration of the net quantity of contents. These requirements increase the time establishments needed to design labels because they increase the number of label elements that establishments must consider when designing labels. These requirements do not generate any recurring burden per label because establishments must already print and affix labels to cosmetic products as part of normal business practices. Regarding the new statutory labeling requirements for products intended for professional use only and contact information for manufacturers to receive reports of adverse events, we estimate that there will be a capital cost of $94,080,000 associated with relabeling. This is the cost of designing a revised label and incorporating it into the manufacturing process. We believe that this will be a one-time cost. We estimate that the total third-party disclosure burden is 178,806 hours.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN [1]

MoCRA citation; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Sec. 607(a)(1) of the FD&C Act; initial registrations	3,400	1	3,400	1	3,400
Sec. 607(a)(2) and (5) of the FD&C Act; biennial registration renewals.	1,700	1	1,700	0.25 (15 minutes)	425
Sec. 607(a)(4) of the FD&C Act; registration updates ..	100	1	100	0.25 (15 minutes)	25
Sec. 607(f) of the FD&C Act; post-hearing corrective action plan.	5	1	5	10	50
Sec. 607(c)(1) and (2) of the FD&C Act; cosmetic product listing.	3,400	5	17,000	0.50 (30 minutes)	8,500
Sec. 607(c)(3) of the FD&C Act; product listing renewals.	3,400	5	17,000	0.25 (15 minutes)	4,250
Sec. 607(c)(5) of the FD&C Act; product listing updates.	200	1	200	0.25 (15 minutes)	50
Total	.....	.....	.....	.....	16,700

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We base our estimate of reporting burden hours on information from the VCRP, because it provided the best available data to FDA in terms of the number of respondents and responses. We believe that the VCRP reflected less than half of cosmetic manufacturers and processors because it was a voluntary system. Accordingly, we doubled our estimate for the number of respondents registering and used this number to estimate other activities related to facility registration and cosmetic product listing. Based on a review of the information collection since our last request for OMB approval, we have increased our estimate to account for an anticipated increase in respondents resulting from new statutory requirements.

Dated: April 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09178 Filed 4–28–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1052]

Food and Drug Administration Data and Technology Strategic Plan; Request for Information and Comments; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for information and comments; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice announcing a request for information and comments that appeared in the **Federal Register** of April 13, 2023. In that notice, FDA requested information and comments on the FDA Data and Technology Strategic Plan. The Agency is taking this action to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice published April 13, 2023 (88 FR 22453). Either electronic or written comments must be submitted by June 12, 2023, to ensure that the Agency considers your comment on this request for information and comments before it begins work on the strategic plan.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 12, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

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–N–1052 for ''FDA Data and Technology Strategic Plan.'' Received comments, those filed in a timely manner (see **ADDRESSES**), 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.

FOR FURTHER INFORMATION CONTACT: Casi Alexander, Office of Digital Transformation, Food and Drug Administration, FDA Library, 5630 Fishers Lane, Rm. 1087, Rockville, MD 20857, 240–402–5171, *Casi.Alexander@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 13, 2023, FDA published a notice announcing a request for information and comments entitled ''FDA Data and Technology Strategic Plan; Request for Information and Comments.'' Interested persons were originally given until May 15, 2023, to comment on the document. The Agency has elected to extend the comment period so that all interested parties are able to more thoroughly consider the request for input. FDA is extending the comment period for 30 days, until June 12, 2023. The Agency believes that this 30-day extension allows adequate time for interested persons to submit comments.

Dated: April 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09169 Filed 4–28–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1443]

Draft Pharmaceutical Quality/Chemistry Manufacturing and Controls Data Elements and Terminologies; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is requesting comment on the draft Pharmaceutical Quality/Chemistry Manufacturing and Controls (PQ/CMC) Data Elements and Terminologies for the electronic submission of PQ/CMC data. Building on the Agency's previous **Federal Register** notices published on July 11, 2017, and March 18, 2022, requesting comments on PQ/CMC data elements and controlled terminology, the Agency is continuing to seek comment on the accuracy, suitability, and appropriateness of revised and/or new data elements and terminologies for submission of PQ/CMC data. In addition, the progress toward the establishment of standardized pharmaceutical data elements and terminologies will require further interactions between the Agency and interested parties and various stakeholders, including industry. Accordingly, FDA is planning to request comment on additional PQ/CMC data elements and terminologies over time. FDA is establishing an open docket to facilitate efficient receipt of comments and public posting of updated draft documents on PQ/CMC data elements and terminologies.

DATES: Comments may be submitted to this docket at any time.

ADDRESSES: You may submit comments 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–N–1443 for ''Draft Pharmaceutical Quality/Chemistry Manufacturing and Controls Data Elements and Terminologies; Request for Comments.'' Received comments filed in a timely manner 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.

FOR FURTHER INFORMATION CONTACT: Scott Gordon, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1192, Silver Spring, MD 20993–0002, *Gideon.Gordon@fda.hhs.gov,* 240–402–8560; Diane Maloney, Center for Biologics Evaluation and Research, Food and Drug Administration, Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911; or Norman Gregory, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., HFV–143, Rockville, MD 20855, *Norman.Gregory@fda.hhs.gov,* 240–402–0684.

SUPPLEMENTARY INFORMATION:

I. Background

PQ/CMC is a term used to describe manufacturing and testing data of pharmaceutical products. PQ/CMC encompasses topics such as drug stability, quality specification, batch formula, and batch analysis, which are important aspects of drug development and manufacturing. PQ/CMC plays an integral part in the regulatory review process and life-cycle management of pharmaceutical products. The development of a structured format for PQ/CMC data will enable consistency in the content and format of PQ/CMC data submitted, thus providing a harmonized language for submission content, allowing reviewers to query the data, and, in general, contributing to a more efficient and effective regulatory decision-making process by creating a standardized data dictionary.

The impetus for this standardization effort was the provisions from the 2012 Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), which authorized the Agency to require certain submissions to be submitted in a specified electronic format. PQ/CMC standardization supports FDA's regulatory needs in receiving structured and standardized pharmaceutical quality data and includes two objectives: (1) to standardize the pharmaceutical quality data that is currently received by FDA in electronic common technical document (eCTD) Module 3 (and relevant sections of Module 2) from the sponsoring organizations, and (2) to use these structured elements and develop a Health Level 7 Fast Health Interoperability Resources data exchange solution.

On July 11, 2017, FDA published a **Federal Register** notice requesting comment on a draft PQ/CMC Data Elements and Controlled Terminology document (82 FR 32003). That document proposed structured data standards for a set of eCTD Module 3 content. Based on a range of public feedback, FDA published a **Federal Register** notice on March 18, 2022 (87 FR 15435), requesting comment on a significantly revised and expanded set of data elements and terminologies, including additional subject areas of Module 3. The information released for public comment is not intended to be comprehensive in covering all eCTD product quality information, only those concepts that were considered amenable to structuring and would bring value to the quality review process. This information should not be viewed as guidance, technical specification, or an implementation guide, as it is meant solely for comment.

Through this notice, the Agency is continuing to seek comment on the accuracy, suitability, and appropriateness of revised and/or new data elements and terminologies for submission of PQ/CMC data. The Agency intends to issue guidance on the standardization of PQ/CMC data elements and terminologies for electronic submissions.

II. Establishment of a Docket

FDA is establishing an open docket on matters related to PQ/CMC Data Elements and Controlled Terminologies. Coinciding with publication of this notice, a document will be available at FDA's PQ/CMC web page designated as ''Chapters,'' each of which will cover information relevant to selected parts of eCTD Module 3 and/or Module 2.3. The first Chapter, Chapter 1, is provided solely for context as it is a reiteration of content previously released for

comment. FDA is not seeking comment on the content of Chapter 1. Chapter 2 in this document is the first new Chapter, which provides draft designs of data elements and terminologies, in some cases new and in other cases updated from Chapter 1, associated with PQ/CMC subject areas and concepts and scoped to some of what is currently submitted in Module 3 of the eCTD submission. Since the data elements and terminologies in Chapter 2 are new and/or updated, review of Chapter 1, solely as a reference, is highly recommended.

After publication of this notice with Chapter 2 of the PQ/CMC Data Elements and Terminologies document, subsequent Chapters will be posted on FDA's PQ/CMC web page (*https://www.fda.gov/industry/fda-data-standards-advisory-board/pharmaceutical-quality-chemistry-manufacturing-controls-pqcmc*). Public comments, specifying to which Chapter the comments are submitted, can be made to the open docket. Comments may be submitted to this docket at any time, but comments should be submitted on new Chapters within 60 days of being posted on FDA's PQ/CMC web page to ensure that the Agency considers your comment before it begins work on the final version of the Chapter. FDA will aim to provide a new Chapter of the PQ/CMC Data Elements and Terminologies periodically. FDA is targeting posting updates to this content to FDA's PQ/CMC web page by the end of the calendar months of March, June, September, and December of each year. This update may consist of a note that there is no new content for review in this period or, alternatively, that there is new content to be reviewed for comment, along with a link to the relevant documentation, background, and instructions on submitting comments.

III. Electronic Access

Persons with access to the internet may obtain the draft data elements and terminologies at either *https://www.fda.gov/industry/fda-data-standards-advisory-board/pharmaceutical-quality-chemistry-manufacturing-controls-pqcmc* or *https://www.regulations.gov.*

Dated: April 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09173 Filed 4–28–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–1358]

FDA Science Forum 2023; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled ''FDA Science Forum 2023.'' The purpose of the public workshop is to inform the public about the breadth of research underway at the Agency, and to show how cutting-edge science informs FDA's regulatory decision-making to protect and promote public health.

DATES: The public workshop will be held on June 13, 2023 (Day 1), from 9 a.m. to 3:30 p.m. Eastern Time, and June 14, 2023 (Day 2), from 9 a.m. to 2 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public workshop will be held via webcast.

FOR FURTHER INFORMATION CONTACT: Rokhsareh Shahidzadeh, Office of Scientific Professional Development, Office of the Chief Scientist, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 2383, Silver Spring, MD 20993, 301–796–8740, *FDASciProDev@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The FDA Science Forum is held biennially to inform the public about the groundbreaking science conducted at the Agency, and to show how scientific research is used in FDA's regulatory decisions to protect and promote public health. Open to the public, industry, academia, patient advocates, government agencies, and current and potential collaborators, the 2-day event offers an opportunity to hear FDA scientific experts and nationally renowned scientists speak on a range of topics associated with regulatory science.

II. Topics for Discussion at the Public Workshop

The theme for the 2023 FDA Science Forum, ''Advancing Regulatory Science Through Innovation,'' will highlight areas of FDA research, including: (1) improving clinical and postmarket evaluation, (2) tools to effectively use big data, (3) product development tools and manufacturing, and (4) medical countermeasures (MCMs), infectious disease and pathogen reduction technologies.

III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following website: *https://www.fda.gov/scienceforum.*

Registration is free. Persons interested in attending this public workshop must register by June 12, 2023, at 5 p.m. Eastern Time. Registrants will receive confirmation when they have been accepted.

If you need special accommodations due to a disability, please contact Rokhsareh Shahidzadeh (see **FOR FURTHER INFORMATION CONTACT**) no later than June 5, 2023, by 5 p.m. Eastern Time.

Streaming Webcast of the public workshop: This public workshop will be webcast. To register, please visit the following website: *https://www.fda.gov/scienceforum.* Participants interested in viewing via webcast must register by June 12, 2023, at 5 p.m. Eastern Time.

Dated: April 26, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–09175 Filed 4–28–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Tribal Self-Governance Negotiation Cooperative Agreement Program

Announcement Type: New.

Funding Announcement Number: HHS–2023–IHS–TSGN–0001.

Assistance Listing (Catalog of Federal Domestic Assistance or CFDA) Number: 93.444.

Key Dates

Application Deadline Date: May 1, 2023.

Earliest Anticipated Start Date: July 31, 2023.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) is accepting applications for cooperative agreements for the Tribal Self-Governance Negotiation Cooperative Agreement Program. This program is authorized under the Snyder Act, 25 U.S.C. 13; the Transfer Act, 42 U.S.C.

2001(a); and Title V of the Indian Self-Determination and Education Assistance Act (ISDEAA), 25 U.S.C. 5383(e). The Assistance Listings section of *SAM.gov* (*https://same.gov/content/home*) describes this program under 93.444.

Background

The Tribal Self-Governance Program (TSGP) is more than an IHS program; it is an expression of the government-to-government relationship between the United States (U.S.) and Indian Tribes. Through the TSGP, Tribes negotiate with the IHS to assume Programs, Services, Functions, and Activities (PSFAs), or portions thereof, which gives Tribes the authority to manage and tailor health care programs in a manner that best fits the needs of their communities.

Participation in the TSGP affords Tribes the most flexibility to tailor their health care needs by choosing one of three ways to obtain health care from the Federal government for their citizens. Specifically, Tribes can choose to: (1) receive health care services directly from the IHS; (2) contract with the IHS to administer individual programs and services the IHS would otherwise provide (referred to as Title I Self-Determination Contracting); and (3) compact with the IHS to assume control over health care programs the IHS would otherwise provide (referred to as Title V Self-Governance Compacting or the TSGP). These options are not exclusive and Tribes may choose to combine options based on their individual needs and circumstances.

The TSGP is a tribally-driven initiative and strong Federal-Tribal partnerships are essential to the program's success. The IHS established the Office of Tribal Self-Governance (OTSG) to implement the Tribal Self-Governance authorities under the ISDEAA. The primary OTSG functions are to: (1) serve as the primary liaison and advocate for Tribes participating in the TSGP; (2) develop, direct, and implement TSGP policies and procedures; (3) provide information and technical assistance to Self-Governance Tribes; and (4) advise the IHS Director on compliance with TSGP policies, regulations, and guidelines. Each IHS Area has an Agency Lead Negotiator (ALN), designated by the IHS Director to act on his or her behalf, who has authority to negotiate Self-Governance Compacts and Funding Agreements (FA). Tribes interested in participating in the TSGP should contact their respective ALN to begin the Self-Governance planning and negotiation process. Tribes currently participating in the TSGP that are interested in expanding existing or adding new PSFAs should also contact their respective ALN to discuss the best methods for expanding or adding new PSFAs.

Purpose

The purpose of this Negotiation Cooperative Agreement is to provide Tribes with resources to help defray the costs associated with preparing for and engaging in TSGP negotiations. TSGP negotiations are a dynamic, evolving, and tribally-driven process that requires careful planning, preparation, and sharing of precise, up-to-date information by both Tribal and Federal parties. Because each Tribal situation is unique, a Tribe's successful transition into the TSGP, or expansion of their current program, requires focused discussions between the Federal and Tribal negotiation teams about the Tribe's specific health care concerns and plans. One of the hallmarks of the TSGP is the collaborative nature of the negotiations process, which is designed to: (1) enable a Tribe to set its own priorities when assuming responsibility for IHS PSFAs; (2) observe and respect the government-to-government relationship between the U.S. and each Tribe; and (3) involve the active participation of both Tribal and IHS representatives, including the OTSG. Negotiations are a method of determining and agreeing upon the terms and provisions of a Tribe's Compact and FA, the implementation documents required for the Tribe to enter into the TSGP. The Compact sets forth the general terms of the government-to-government relationship between the Tribe and the Secretary of the U.S. Department of Health and Human Services (HHS). The FA: (1) describes the length of the agreement (whether it will be annual or multi-year); (2) identifies the PSFAs, or portions thereof, the Tribe will assume; (3) specifies the amount of funding associated with the Tribal assumption; and (4) includes terms required by Federal statutes and other terms agreed to by the parties. Both documents are required to participate in the TSGP and they are mutually negotiated agreements that become legally binding and mutually enforceable after both parties sign the documents. Either document can be renegotiated at the request of the Tribe.

The negotiation process has four major stages, including: (1) planning; (2) pre-negotiations; (3) negotiations; and (4) post-negotiations. Title V of the ISDEAA requires that a Tribe or Tribal Organization (T/TO) complete a planning phase to the satisfaction of the Tribe. The planning phase must include legal and budgetary research and internal Tribal government planning and organizational preparation relating to the administration of health care programs. See 25 U.S.C. 5383(d). The planning phase is critical to the negotiation process and assists Tribes with making informed decisions about which PSFAs to assume and what organizational changes or modifications are necessary to support those PSFAs. A thorough planning phase improves timeliness and efficient negotiations and ensures that the Tribe is fully prepared to assume the transfer of IHS PSFAs to the Tribal health program.

During pre-negotiations, the Tribal and Federal negotiation teams review and discuss issues identified during the planning phase. Pre-negotiations provide an opportunity for the Tribe and the IHS to identify and discuss issues directly related to the Tribe's Compact, FA, and Tribal shares.

In advance of final negotiations, the Tribe should work with the IHS to secure the following: (1) program titles and descriptions; (2) financial tables and information; (3) information related to the identification and justification of residuals; and (4) the basis for determining Tribal shares (distribution formula). The Tribe may also wish to discuss financial materials that show estimated funding for next year and the increases or decreases in funding it may receive in the current year, as well as the basis for those changes.

During the final negotiation, both the Federal and Tribal negotiation teams work together in good faith to determine and agree upon the terms and provisions of the Tribe's Compact and FA. Negotiations are not an allocation process; they provide an opportunity to mutually review and discuss budget and program issues to reach agreement and finalize documents.

There are various entities involved throughout the negotiation process. For example, a Tribal government selects its representative(s) for the Tribal negotiation team, which may include a Tribal leader from the governing body, a Tribal health director, technical and program staff, legal counsel, and other consultants. Regardless of the composition of the Tribal team, Tribal representatives must have decision-making authority from the Tribal governing body to successfully negotiate and agree to the provisions within the agreements. The Federal negotiation team is led by the ALN and may include area and headquarters subject matter experts, OTSG staff, the Office of Finance and Accounting, and the Office

of the General Counsel. The ALN is the only member of the Federal negotiation team with delegated authority to negotiate on behalf of the IHS Director. The ALN is the designated official that provides Tribes with Self-Governance information, assists Tribes in planning, organizes meetings between the Tribe and the IHS, and coordinates the agency's response to Tribal questions during the negotiation process. The ALN role requires detailed knowledge of the IHS, awareness of current policy and practice, and understanding of the rights and authorities available to a Tribe under Title V of the ISDEAA.

In post-negotiations, the mutually agreed to and negotiated Compact and FA are signed by the authorizing Tribal official and submitted to the OTSG in preparation for the IHS Director's signature. Once the Compact and FA have been signed by both parties, they become legally binding and enforceable agreements. A signed Compact and FA are necessary for the payment process to begin. The negotiating Tribe then becomes a ''Self-Governance Tribe'' and a participant in the TSGP.

Acquiring a Negotiation Cooperative Agreement is not a prerequisite to enter the TSGP. A Tribe may use other resources to develop and negotiate its Compact and FA. See 42 CFR 137.26. Tribes that receive a Negotiation Cooperative Agreement are not obligated to participate in Title V and may choose to delay or decline participation or expansion in the TSGP.

II. Award Information

Funding Instrument—Cooperative Agreement

Estimated Funds Available

The total funding identified for fiscal year (FY) 2023 is approximately $420,000. The IHS anticipates individual award amounts will be $84,000. The funding available for competing awards issued under this announcement is subject to the availability of appropriations and budgetary priorities of the Agency. The IHS is under no obligation to make awards to applicants selected for funding under this announcement.

Anticipated Number of Awards

The IHS anticipates issuing approximately five awards under this program announcement.

Period of Performance

The period of performance is for 1 year.

Cooperative Agreement

Cooperative agreements awarded by the Department of Health and Human Services (HHS) are administered under the same policies as grants. However, the funding agency, IHS, is anticipated to have substantial programmatic involvement in the project during the entire period of performance. Below is a detailed description of the level of involvement required of the IHS.

Substantial Agency Involvement Description for Cooperative Agreement

A. Provide descriptions of PSFAs and associated funding at all organizational levels (service unit, area, and headquarters) including funding formulas and methodologies related to determining Tribal shares.

B. Meet with Negotiation Cooperative Agreement recipients to provide program information and discuss methods currently used to manage and deliver health care.

C. Identify and provide statutes, regulations, and policies that provide authority for administering IHS programs.

D. Provide technical assistance on the IHS budget, Tribal shares, and other topics as needed.

III. Eligibility Information

1. Eligibility

To be eligible for this opportunity, an applicant must meet the following criteria:

- Applicant must be an ''Indian Tribe'' as defined in 25 U.S.C. 5304(e); a ''Tribal Organization'' as defined in 25 U.S.C. 5304(l); or an ''Inter-Tribal Consortium'' as defined at 42 CFR 137.10. Please note that Tribes prohibited from contracting pursuant to the ISDEAA are not eligible. See section 424(a) of the Consolidated Appropriations Act, 2014, Public Law 113–76, as amended by section 445 of the Consolidated Appropriations Act, 2023, Public Law 117–328.
- Pursuant to 25 U.S.C. 5383(c)(1)(B), applicant must request participation in self-governance by resolution or other official action by the governing body of each Indian Tribe to be served.
- Pursuant to 25 U.S.C. 5383(c)(1)(C), applicant must demonstrate financial stability and financial management capability for 3 fiscal years.

Meeting the eligibility criteria for a Negotiation Cooperative Agreement does not mean that a T/TO is eligible for participation in the IHS TSGP under Title V of the ISDEAA. See 25 U.S.C. 5383, 42 CFR 137.15–23. For additional information on the eligibility for the IHS TSGP, please visit the ''Eligibility and Funding'' page on the OTSG website located at *https://www.ihs.gov/SelfGovernance.* The Division of Grants Management (DGM) will notify any applicants deemed ineligible.

2. Additional Information on Eligibility

The IHS does not fund concurrent projects. If an applicant is successful under this announcement, any subsequent applications in response to other Tribal Self-Governance Negotiation Cooperative Agreement Program announcements from the same applicant will not be funded. Applications on behalf of individuals (including sole proprietorships) and foreign organizations are not eligible and will be disqualified from competitive review and funding under this funding opportunity.

Note: Please refer to Section IV.2 (Application and Submission Information/ Subsection 2, Content and Form of Application Submission) for additional proof of applicant status documents required, such as Tribal Resolutions, proof of nonprofit status, etc.

3. Cost Sharing or Matching

The IHS does not require matching funds or cost sharing for grants or cooperative agreements.

4. Other Requirements

Applications with budget requests that exceed the highest dollar amount outlined under Section II Award Information, Estimated Funds Available, or exceed the period of performance outlined under Section II Award Information, Period of Performance, are considered not responsive and will not be reviewed. The DGM will notify the applicant.

Additional Required Documentation

Tribal Resolution

The DGM must receive an official, signed Tribal Resolution prior to issuing a Notice of Award (NoA) to any T/TO selected for funding. An applicant that is proposing a project affecting another Indian Tribe must include resolutions from all affected Tribes to be served. However, if an official signed Tribal Resolution cannot be submitted with the application prior to the application deadline date, a draft Tribal Resolution must be submitted with the application by the deadline date in order for the application to be considered complete and eligible for review. The draft Tribal Resolution is not in lieu of the required signed resolution but is acceptable until a signed resolution is received. If an application without a signed Tribal Resolution is selected for funding, the applicant will be contacted by the

Grants Management Specialist (GMS) listed in this funding announcement and given 90 days to submit an official signed Tribal Resolution to the GMS. If the signed Tribal Resolution is not received within 90 days, the award will be forfeited.

Applicants organized with a governing structure other than a Tribal council may submit an equivalent document commensurate with their governing organization.

IV. Application and Submission Information

Grants.gov uses a Workspace model for accepting applications. The Workspace consists of several online forms and three forms in which to upload documents—Project Narrative, Budget Narrative, and Other Documents. Give your files brief descriptive names. The filenames are key in finding specific documents during the merit review and in processing awards. Upload all requested and optional documents individually, rather than combining them into a single file. Creating a single file creates confusion when trying to find specific documents. Such confusion can contribute to delays in processing awards, and could lead to lower scores during the merit review.

1. Obtaining Application Materials

The application package and detailed instructions for this announcement are available at *https://www.Grants.gov.*

Please direct questions regarding the application process to *DGM@ihs.gov.*

2. Content and Form Application Submission

Mandatory documents for all applicants include:

- Application forms:

1. SF–424, Application for Federal Assistance.

2. SF–424A, Budget Information—Non-Construction Programs.

3. SF–424B, Assurances—Non-Construction Programs.

4. Project Abstract Summary form.

- Project Narrative (not to exceed 10 pages). See Section IV.2.A, Project Narrative for instructions.

1. Background information on the organization.

2. Proposed scope of work, objectives, and activities that provide a description of what the applicant plans to accomplish.

- Budget Narrative (not to exceed 5 pages). See Section IV.2.B, Budget Narrative for instructions.
- One-page Timeframe of award activities.
- Tribal Resolution(s) as described in Section III, Eligibility.
- Biographical sketches for all Key Personnel.
- Contractor/Consultant resumes or qualifications and scope of work.
- Disclosure of Lobbying Activities (SF–LLL), if applicant conducts reportable lobbying.
- Certification Regarding Lobbying (GG-Lobbying Form).
- Copy of current Negotiated Indirect Cost (IDC) rate agreement (required in order to receive IDC).
- Organizational Chart (optional).
- Documentation sufficient to demonstrate financial stability and financial management capability for 3 fiscal years. The Indian Tribe must provide evidence that, for the 3 fiscal years prior to requesting participation in the TSGP, the Indian Tribe has had no uncorrected significant and material audit exceptions in the required annual audit of the Indian Tribe's Self-Determination Contracts or Self-Governance Funding Agreements with any Federal agency. See 25 U.S.C. 5383, 42 CFR 137.15–23. For T/TO that expended $500,000 or more in Federal awards, the OTSG shall retrieve the audits directly from the Federal Audit Clearinghouse. For T/TO that expended less than $500,000 in Federal awards, the T/TO must provide evidence of the program review correspondence from the IHS or Bureau of Indian Affairs officials. See 42 CFR 137.21–23.
- Documentation of current Office of Management and Budget (OMB) Financial Audit.

Acceptable forms of documentation include:

1. Email confirmation from Federal Audit Clearinghouse (FAC) that audits were submitted; or

2. Face sheets from audit reports. Applicants can find these on the FAC website at *https://facdissem.census.gov/.*

Public Policy Requirements

All Federal public policies apply to IHS grants and cooperative agreements. Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of their exclusion from benefits limited by Federal law to individuals eligible for benefits and services from the IHS. See *https://www.hhs.gov/grants/grants/grants-policies-regulations/index.html.*

Requirements for Project and Budget Narratives

A. *Project Narrative:* This narrative should be a separate document that is no more than 10 pages and must: (1) have consecutively numbered pages; (2) use black font 12 points or larger (applicants may use 10-point font for tables); (3) be single-spaced; and (4) be formatted to fit standard letter paper (8½ x 11 inches). Do not combine this document with any others.

Be sure to succinctly answer all questions listed under the evaluation criteria (refer to Section V.1, Evaluation Criteria), and place all responses and required information in the correct section noted below or they will not be considered or scored. If the narrative exceeds the overall page limit, the reviewers will be directed to ignore any content beyond the page limit. The 10-page limit for the project narrative does not include the work plan, standard forms, Tribal Resolutions, budget, budget narratives, and/or other items. Page limits for each section within the project narrative are guidelines, not hard limits.

There are three parts to the project narrative: Part 1—Program Information; Part 2—Program Planning and Evaluation; and Part 3—Program Report. See below for additional details about what must be included in the narrative.

The page limits below are for each narrative and budget submitted.

Part 1: Program Information (Limit—4 Pages)

Section 1: Needs

Demonstrate that the Tribe has conducted previous Self-Governance planning activities by clearly stating the results of what was learned during the planning process. Explain how the Tribe has determined it has the knowledge and expertise to assume or expand PSFAs and the administrative infrastructure to support the assumption of PSFAs. Identify the need for assistance and how the Negotiation Cooperative Agreement would benefit the health activities the Tribe is preparing to assume or expand.

Part 2: Program Planning and Evaluation (Limit—4 Pages)

Section 1: Program Plans

State in measurable terms the objectives and appropriate activities to achieve the following Negotiation Cooperative Agreement recipient award activities:

(A) Determine the PSFAs that will be negotiated into the Tribe's Compact and FA. Prepare and discuss each PSFA in comparison to the current level of services provided so that an informed decision can be made on new or expanded program assumption.

(B) Identify Tribal shares associated with the PSFAs that will be included in the FA.

(C) Develop the terms and conditions that will be set forth in both the

Compact and FA to submit to the ALN prior to negotiations.

Describe fully and clearly how the Tribe's proposal will result in an improved approach to managing the PSFAs to be assumed or expanded. Include how the Tribe plans to demonstrate improved health services to the community and incorporate the proposed timelines for negotiations.

Section 2: Program Evaluation

Describe fully and clearly how the goals and proposed activities will improve the health care system and identify the anticipated or expected benefits for the Tribe. Define the criteria to be used to evaluate objectives associated with the project using a model for tracking.

Part 3: Program Report (Limit—2 Pages)

Section 1

Describe your organization's significant program activities and accomplishments over the past several years associated with the goals of this announcement and leading up to the negotiation phase.

Please identify and describe significant program activities and achievements associated with the delivery of quality health services. Provide a comparison of the actual accomplishments to the goals established for the project period or, if applicable, provide justification for the lack of progress.

B. Budget Narrative (Limit—5 Pages)

Provide a budget narrative that explains the amounts requested for each line item of the budget from the SF–424A (Budget Information for Non-Construction Programs) for the project. The applicant can submit with the budget narrative a more detailed spreadsheet than is provided by the SF–424A (the spreadsheet will not be considered part of the budget narrative). The budget narrative should specifically describe how each item would support the achievement of proposed objectives. Be very careful about showing how each item in the ''Other'' category is justified. Do NOT use the budget narrative to expand the project narrative.

3. Submission Dates and Times

Applications must be submitted through *Grants.gov* by 11:59 p.m. Eastern Time on the Application Deadline Date. Any application received after the application deadline will not be accepted for review. *Grants.gov* will notify the applicant via email if the application is rejected.

If technical challenges arise and assistance is required with the application process, contact *Grants.gov* Customer Support (see contact information at *https://www.Grants.gov*). If problems persist, contact Mr. Paul Gettys, Deputy Director, DGM, by email at *DGM@ihs.gov.* Please be sure to contact Mr. Gettys at least 10 days prior to the application deadline. Please do not contact the DGM until you have received a *Grants.gov* tracking number. In the event you are not able to obtain a tracking number, call the DGM as soon as possible.

The IHS will not acknowledge receipt of applications.

4. Intergovernmental Review

Executive Order 12372 requiring intergovernmental review is not applicable to this program.

5. Funding Restrictions

- Pre-award costs are not allowable.
- The available funds are inclusive of direct and indirect costs.
- Only one cooperative agreement may be awarded per applicant.

6. Electronic Submission Requirements

All applications must be submitted via *Grants.gov*. Please use the *https://www.Grants.gov* website to submit an application. Find the application by selecting the ''Search Grants'' link on the homepage. Follow the instructions for submitting an application under the Package tab. No other method of application submission is acceptable.

If you cannot submit an application through *Grants.gov*, you must request a waiver prior to the application due date. You must submit your waiver request by email to *DGM@ihs.gov.* Your waiver request must include clear justification for the need to deviate from the required application submission process. The IHS will not accept any applications submitted through any means outside of *Grants.gov* without an approved waiver.

If the DGM approves your waiver request, you will receive a confirmation of approval email containing submission instructions. You must include a copy of the written approval with the application submitted to the DGM. Applications that do not include a copy of the waiver approval from the DGM will not be reviewed. The Grants Management Officer of the DGM will notify the applicant via email of this decision. Applications submitted under waiver must be received by the DGM no later than 5:00 p.m. Eastern Time on the Application Deadline Date. Late applications will not be accepted for processing. Applicants that do not register for both the System for Award Management (SAM) and *Grants.gov* and/or fail to request timely assistance with technical issues will not be considered for a waiver to submit an application via alternative method.

Please be aware of the following:

- Please search for the application package in *https://www.Grants.gov* by entering the Assistance Listing number or the Funding Opportunity Number. Both numbers are located in the header of this announcement.
- If you experience technical challenges while submitting your application, please contact *Grants.gov* Customer Support (see contact information at *https://www.Grants.gov*).
- Upon contacting *Grants.gov,* obtain a tracking number as proof of contact. The tracking number is helpful if there are technical issues that cannot be resolved and a waiver from the agency must be obtained.
- Applicants are strongly encouraged not to wait until the deadline date to begin the application process through *Grants.gov* as the registration process for SAM and *Grants.gov* could take up to 20 working days.
- Please follow the instructions on *Grants.gov* to include additional documentation that may be requested by this funding announcement.
- Applicants must comply with any page limits described in this funding announcement.
- After submitting the application, you will receive an automatic acknowledgment from *Grants.gov* that contains a *Grants.gov* tracking number. The IHS will not notify you that the application has been received.

System for Award Management

Organizations that are not registered with the System for Award Management (SAM) must access the SAM online registration through the SAM home page at *https://sam.gov.* Organizations based in the U.S. will also need to provide an Employer Identification Number from the Internal Revenue Service that may take an additional 2–5 weeks to become active. Please see *SAM.gov* for details on the registration process and timeline. Registration with the SAM is free of charge but can take several weeks to process. Applicants may register online at *https://sam.gov.*

Unique Entity Identifier

Your *SAM.gov* registration now includes a Unique Entity Identifier (UEI), generated by *SAM.gov,* which replaces the DUNS number obtained from Dun and Bradstreet. *SAM.gov* registration no longer requires a DUNS number.

Check your organization's *SAM.gov* registration as soon as you decide to apply for this program. If your *SAM.gov*

registration is expired, you will not be able to submit an application. It can take several weeks to renew it or resolve any issues with your registration, so do not wait.

Check your *Grants.gov* registration. Registration and role assignments in *Grants.gov* are self-serve functions. One user for your organization will have the authority to approve role assignments, and these must be approved for active users in order to ensure someone in your organization has the necessary access to submit an application.

The Federal Funding Accountability and Transparency Act of 2006, as amended (''Transparency Act''), requires all HHS recipients to report information on sub-awards. Accordingly, all IHS recipients must notify potential first-tier sub-recipients that no entity may receive a first-tier sub-award unless the entity has provided its UEI number to the prime recipient organization. This requirement ensures the use of a universal identifier to enhance the quality of information available to the public pursuant to the Transparency Act.

Additional information on implementing the Transparency Act, including the specific requirements for SAM, are available on the DGM Grants Management, Policy Topics web page at *https://www.ihs.gov/dgm/policytopics/.*

V. Application Review Information

Possible points assigned to each section are noted in parentheses. The project narrative and budget narrative should include only the first year of activities. The project narrative should be written in a manner that is clear to outside reviewers unfamiliar with prior related activities of the applicant. It should be well organized, succinct, and contain all information necessary for reviewers to fully understand the project. Attachments requested in the criteria do not count toward the page limit for the narratives. Points will be assigned to each evaluation criteria adding up to a total of 100 possible points. Points are assigned as follows:

1. Evaluation Criteria

A. Introduction and Need for Assistance (25 Points)

Demonstrate that the Tribe has conducted previous Self-Governance planning activities by clearly stating the results of what was learned during the planning process. Explain how the Tribe has determined it has the knowledge and expertise to assume or expand PSFAs and the administrative infrastructure to support the assumption of PSFAs. Identify the need for assistance and how the Negotiation Cooperative Agreement would benefit the health activities the Tribe is preparing to assume or expand.

B. Project Objective(s), Work Plan and Approach (25 Points)

State in measurable terms the objectives and appropriate activities to achieve the following Negotiation Cooperative Agreement recipient award activities:

1. Determine the PSFAs that will be negotiated into the Tribe's Compact and FA. Prepare and discuss each PSFA in comparison to the level of services provided so that an informed decision can be made on new or expanded program assumption.

2. Identify Tribal shares associated with the PSFAs that will be included in the FA.

3. Develop the terms and conditions that will be set forth in both the Compact and FA to submit to the ALN prior to negotiations. Clearly describe how the Tribe's proposal will result in an improved approach to managing the PSFAs to be assumed or expanded. Include how the Tribe plans to demonstrate improved health care services to the community and incorporate the proposed timelines for negotiations.

C. Program Evaluation (25 Points)

Describe fully the improvements that will be made by the Tribe to manage the health care system and identify the anticipated or expected benefits for the Tribe. Define the criteria to be used to evaluate objectives associated with the project and how they will be measured.

D. Organizational Capabilities, Key Personnel, and Qualifications (15 Points)

Describe the organizational structure of the Tribe and its ability to manage the proposed project. Include resumes or position descriptions of key staff showing requisite experience and expertise. If applicable, include resumes and scope of work for consultants that demonstrate experience and expertise relevant to the project.

E. Categorical Budget and Budget Justification (10 Points)

Submit a budget with a narrative describing the budget request and matching the scope of work described in the project narrative. Justify all expenditures identifying reasonable and allowable costs necessary to accomplish the goals and objectives as outlined in the project narrative.

Additional documents can be uploaded as Other Attachments in *Grants.gov.*

These can include:

- Work plan, logic model, and/or timeline for proposed objectives.
- Position descriptions for key staff.
- Resumes of key staff that reflect current duties.
- Consultant or contractor proposed scope of work and letter of commitment (if applicable).
- Current Indirect Cost Rate Agreement.
- Organizational chart.
- Map of area identifying project location(s).
- Additional documents to support narrative (*i.e.,* data tables, key news articles, etc.).

2. Review and Selection

Each application will be prescreened for eligibility and completeness as outlined in the funding announcement. Applications that meet the eligibility criteria shall be reviewed for merit by the Review Committee (RC) based on the evaluation criteria. Incomplete applications and applications that are not responsive to the administrative thresholds (budget limit, period of performance limit) will not be referred to the RC and will not be funded. The DGM will notify the applicant of this determination.

Applicants must address all program requirements and provide all required documentation.

3. Notifications of Disposition

All applicants will receive an Executive Summary Statement from the OTSG within 30 days of the conclusion of the RC outlining the strengths and weaknesses of their application. The summary statement will be sent to the Authorizing Official identified on the face page (SF–424) of the application.

A. Award Notices for Funded Applications

The NoA is the authorizing document for which funds are dispersed to the approved entities and reflects the amount of Federal funds awarded, the purpose of the award, the terms and conditions of the award, the effective date of the award, the budget period, and period of performance. Each entity approved for funding must have a user account in GrantSolutions in order to retrieve the NoA. Please see the Agency Contacts list in Section VII for the systems contact information.

B. Approved but Unfunded Applications

Approved applications not funded due to lack of available funds will be

held for 1 year. If funding becomes available during the course of the year, the application may be reconsidered.

Note: Any correspondence, other than the official NoA executed by an IHS grants management official announcing to the project director that an award has been made to their organization, is not an authorization to implement their program on behalf of the IHS.

VI. Award Administration Information

1. Administrative Requirements

Awards issued under this announcement are subject to, and are administered in accordance with, the following regulations and policies:

A. The criteria as outlined in this program announcement.

B. Administrative Regulations for Awards:

- Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Awards currently in effect or implemented during the period of award, other Department regulations and policies in effect at the time of award, and applicable statutory provisions. At the time of publication, this includes 45 CFR part 75, at *https://www.govinfo.gov/content/pkg/CFR-2021-title45-vol1/pdf/CFR-2021-title45-vol1-part75.pdf.*
- Please review all HHS regulatory provisions for Termination at 45 CFR 75.372, at the time of this publication located at *https://www.govinfo.gov/content/pkg/CFR-2021-title45-vol1/pdf/CFR-2021-title45-vol1-sec75-372.pdf.*

C. Grants Policy:

- HHS Grants Policy Statement, Revised January 2007, at *https://www.hhs.gov/sites/default/files/grants/grants/policies-regulations/hhsgps107.pdf.*

D. Cost Principles:

- Uniform Administrative Requirements for HHS Awards, ''Cost Principles,'' at 45 CFR part 75 subpart E, at the time of this publication located at *https://www.govinfo.gov/content/pkg/CFR-2021-title45-vol1/pdf/CFR-2021-title45-vol1-part75-subpartE.pdf.*

E. Audit Requirements:

- Uniform Administrative Requirements for HHS Awards, ''Audit Requirements,'' at 45 CFR part 75 subpart F, at the time of this publication located at *https://www.govinfo.gov/content/pkg/CFR-2021-title45-vol1/pdf/CFR-2021-title45-vol1-part75-subpartF.pdf.*

F. As of August 13, 2020, 2 CFR part 200 was updated to include a prohibition on certain telecommunications and video surveillance services or equipment. This prohibition is described in 2 CFR part 200.216. This will also be described in the terms and conditions of every IHS grant and cooperative agreement awarded on or after August 13, 2020.

2. Indirect Costs

This section applies to all recipients that request reimbursement of IDC in their application budget. In accordance with HHS Grants Policy Statement, Part II–27, the IHS requires applicants to obtain a current IDC rate agreement and submit it to the DGM prior to the DGM issuing an award. The rate agreement must be prepared in accordance with the applicable cost principles and guidance as provided by the cognizant agency or office. A current rate covers the applicable award activities under the current award's budget period. If the current rate agreement is not on file with the DGM at the time of award, the IDC portion of the budget will be restricted. The restrictions remain in place until the current rate agreement is provided to the DGM.

Per 2 CFR 200.414(f) Indirect (F&A) costs,

> any non-Federal entity (NFE) [*i.e.,* applicant] that does not have a current negotiated rate, . . . may elect to charge a de minimis rate of 10 percent of modified total direct costs which may be used indefinitely. As described in Section 200.403, costs must be consistently charged as either indirect or direct costs, but may not be double charged or inconsistently charged as both. If chosen, this methodology once elected must be used consistently for all Federal awards until such time as the NFE chooses to negotiate for a rate, which the NFE may apply to do at any time.

Electing to charge a de minimis rate of 10 percent can be used by applicants that have received an approved negotiated indirect cost rate from HHS or another cognizant Federal agency. Applicants awaiting approval of their indirect cost proposal may request the 10 percent de minimis rate. When the applicant chooses this method, costs included in the indirect cost pool must not be charged as direct costs to the award.

Available funds are inclusive of direct and appropriate indirect costs. Approved indirect funds are awarded as part of the award amount, and no additional funds will be provided.

Generally, IDC rates for IHS recipients are negotiated with the Division of Cost Allocation at *https://rates.psc.gov/* or the Department of the Interior (Interior Business Center) at *https://ibc.doi.gov/ICS/tribal.* For questions regarding the indirect cost policy, please write to *DGM@ihs.gov.*

3. Reporting Requirements

The recipient must submit required reports consistent with the applicable deadlines. Failure to submit required reports within the time allowed may result in suspension or termination of an active award, withholding of additional awards for the project, or other enforcement actions such as withholding of payments or converting to the reimbursement method of payment. Continued failure to submit required reports may result in the imposition of special award provisions and/or the non-funding or non-award of other eligible projects or activities. This requirement applies whether the delinquency is attributable to the failure of the recipient organization or the individual responsible for preparation of the reports. Per DGM policy, all reports must be submitted electronically by attaching them as a ''Grant Note'' in GrantSolutions. Personnel responsible for submitting reports will be required to obtain a login and password for GrantSolutions. Please use the form under the Recipient User section of *https://www.grantsolutions.gov/home/getting-started-request-a-user-account/.* Download the Recipient User Account Request Form, fill it out completely, and submit it as described on the web page and in the form.

The reporting requirements for this program are noted below.

A. Progress Reports

Program progress reports are required semi-annually. The progress reports are due within 30 days after the reporting period ends (specific dates will be listed in the NoA Terms and Conditions). These reports must include a brief comparison of actual accomplishments to the goals established for the period, a summary of progress to date or, if applicable, provide sound justification for the lack of progress, and other pertinent information as required. A final report must be submitted within 120 days of the period of performance end date.

B. Financial Reports

Federal Financial Reports are due 90 days after the end of each budget period, and a final report is due 120 days after the end of the period of performance.

Recipients are responsible and accountable for reporting accurate information on all required reports: the Progress Reports and the Federal Financial Report.

Failure to submit timely reports may result in adverse award actions blocking access to funds.

C. Federal Sub-Award Reporting System (FSRS)

This award may be subject to the Transparency Act sub-award and executive compensation reporting requirements of 2 CFR part 170.

The Transparency Act requires the OMB to establish a single searchable database, accessible to the public, with information on financial assistance awards made by Federal agencies. The Transparency Act also includes a requirement for recipients of Federal awards to report information about first-tier sub-awards and executive compensation under Federal assistance awards.

The IHS has implemented a Term of Award into all IHS Standard Terms and Conditions, NoAs, and funding announcements regarding the FSRS reporting requirement. This IHS Term of Award is applicable to all IHS grant and cooperative agreements issued on or after October 1, 2010, with a $25,000 sub-award obligation threshold met for any specific reporting period.

For the full IHS award term implementing this requirement and additional award applicability information, visit the DGM Grants Management website at *https://www.ihs.gov/dgm/policytopics/.*

D. Non-Discrimination Legal Requirements for Recipients of Federal Financial Assistance (FFA)

The recipient must administer the project in compliance with Federal civil rights laws, where applicable, that prohibit discrimination on the basis of race, color, national origin, disability, age, and comply with applicable conscience protections. The recipient must comply with applicable laws that prohibit discrimination on the basis of sex, which includes discrimination on the basis of gender identity, sexual orientation, and pregnancy. Compliance with these laws requires taking reasonable steps to provide meaningful access to persons with limited English proficiency and providing programs that are accessible to and usable by persons with disabilities. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. See *https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html* and *https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html.*

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting your legal obligation to take reasonable steps to ensure meaningful access to your programs or activities by limited English proficiency individuals, see *https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html* and *https://www.lep.gov.*
- For information on your specific legal obligations for serving qualified individuals with disabilities, including reasonable modifications and making services accessible to them, see *https://www.hhs.gov/civil-rights/for-individuals/disability/index.html.*
- HHS funded health and education programs must be administered in an environment free of sexual harassment. See *https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html.*
- For guidance on administering your program in compliance with applicable Federal religious nondiscrimination laws and applicable Federal conscience protection and associated anti-discrimination laws, see *https://www.hhs.gov/conscience/conscience-protections/index.html* and *https://www.hhs.gov/conscience/religious-freedom/index.html.*
- Pursuant to 45 CFR 80.3(d), an individual shall not be deemed subjected to discrimination by reason of their exclusion from benefits limited by Federal law to individuals eligible for benefits and services from the IHS.

E. Federal Awardee Performance and Integrity Information System (FAPIIS)

The IHS is required to review and consider any information about the applicant that is in the FAPIIS at *https://www.fapiis.gov/fapiis/#/home* before making any award in excess of the simplified acquisition threshold (currently $250,000) over the period of performance. An applicant may review and comment on any information about itself that a Federal awarding agency previously entered. The IHS will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants, as described in 45 CFR 75.205.

As required by 45 CFR part 75 Appendix XII of the Uniform Guidance, NFEs are required to disclose in FAPIIS any information about criminal, civil, and administrative proceedings, and/or affirm that there is no new information to provide. This applies to NFEs that receive Federal awards (currently active grants, cooperative agreements, and procurement contracts) greater than $10 million for any period of time during the period of performance of an award/project.

Mandatory Disclosure Requirements

As required by 2 CFR part 200 of the Uniform Guidance, and HHS implementing regulations at 45 CFR part 75, the IHS must require an NFE or an applicant for a Federal award to disclose, in a timely manner, in writing to the IHS or pass-through entity all violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award.

All applicants and recipients must disclose in writing, in a timely manner, to the IHS and to the HHS Office of Inspector General all information related to violations of Federal criminal law involving fraud, bribery, or gratuity violations potentially affecting the Federal award. 45 CFR 75.113.

Disclosures must be sent in writing to:

U.S. Department of Health and Human Services, Indian Health Service, Division of Grants Management, ATTN: Marsha Brookins, Director, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, (Include ''Mandatory Grant Disclosures'' in subject line), Office: (301) 443–5204, Fax: (301) 594–0899, Email: *DGM@ihs.gov*

AND

U.S. Department of Health and Human Services, Office of Inspector General, ATTN: Mandatory Grant Disclosures, Intake Coordinator, 330 Independence Avenue SW, Cohen Building, Room 5527, Washington, DC 20201, URL: *https://oig.hhs.gov/fraud/report-fraud/,* (Include ''Mandatory Grant Disclosures'' in subject line), Fax: (202) 205–0604 (Include ''Mandatory Grant Disclosures'' in subject line) or, Email: *MandatoryGranteeDisclosures@oig.hhs.gov*

Failure to make required disclosures can result in any of the remedies described in 45 CFR 75.371 Remedies for noncompliance, including suspension or debarment (see 2 CFR part 180 and 2 CFR part 376).

VII. Agency Contacts

1. *Questions on the program matters may be directed to:* Roxanne Houston, Program Officer, Indian Health Service, Office of Tribal Self-Governance, 5600 Fishers Lane, Mail Stop: 08E09B, Rockville, MD 20857, Phone: (301) 443–7821, Email: *Roxanne.Houston@ihs.gov,* Website: *https://www.ihs.gov/SelfGovernance/.*

2. *Questions on awards management and fiscal matters may be directed to:*

Indian Health Service, Division of Grants Management, 5600 Fishers Lane, Mail Stop: 09E70, Rockville, MD 20857, Email: *DGM@ihs.gov.*

3. For technical assistance with *Grants.gov,* please contact the *Grants.gov* help desk at 800–518–4726, or by email at *support@grants.gov.*

4. For technical assistance with GrantSolutions, please contact the GrantSolutions help desk at (866) 577–0771, or by email at *help@grantsolutions.gov.*

VIII. Other Information

The Public Health Service strongly encourages all grant, cooperative agreement, and contract recipients to provide a smoke-free workplace and promote the non-use of all tobacco products. In addition, Public Law 103–227, the Pro-Children Act of 1994, prohibits smoking in certain facilities (or in some cases, any portion of the facility) in which regular or routine education, library, day care, health care, or early childhood development services are provided to children. This is consistent with the HHS mission to protect and advance the physical and mental health of the American people.

P. Benjamin Smith,

Deputy Director, Indian Health Service.

[FR Doc. 2023–09097 Filed 4–28–23; 8:45 am]

BILLING CODE 4165–16–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; Basket Clinical Trial U44.

Date: May 5, 2023.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1080, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jing Chen, Ph.D., Scientific Review Officer, Office of Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Room 1080, Bethesda, MD 20892–4874, *chenjing@mail.nih.gov,* (301) 827–3268.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: April 26, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09149 Filed 4–28–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Council for Biomedical Imaging and Bioengineering.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend in person should register at (*https://www.nibib.nih.gov/about-nibib/advisory-council/registration*) in advance of the meeting so that the meeting organizers can plan accordingly.

The meeting will be videocast and can be accessed from the NIH Videocasting website at (*https://videocast.nih.gov/watch=49359*).

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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Council for Biomedical Imaging and Bioengineering NACBIB, May 2023.

Date: May 16, 2023.

Open: 09:00 a.m. to 12:30 p.m.

Agenda: Report from the Institute Director, Council Members and other Institute Staff.

Place: William F. Bolger Center, 9600 Newbridge Drive, Franklin Building, Classroom 1, Potomac, MD 20854.

Closed: 2:15 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: William F. Bolger Center, 9600 Newbridge Drive, Franklin Building, Classroom 1, Potomac, MD 20854.

Contact Person: David T. George, Ph.D., Associate Director for Research Administration, Office of Research Administration, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Boulevard, Room 920, Bethesda, MD 20892, *georged@mail.nih.gov*.

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *https://www.nibib.nih.gov/about-nibib/advisory-council* where an agenda and any additional information for the meeting will be posted when available.

Dated: April 25, 2023.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09131 Filed 4–28–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 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 Institute on Aging Special Emphasis Panel; Mechanisms-focused research for MCI and AD/ADRD.

Date: June 1, 2023.

Time: 10:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Rajasri Roy, Ph.D., Scientific Review Officer, Scientific Review Branch, National Institute on Aging, National Institutes of Health, Gateway Building 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 496–6477, *rajasri.roy@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: April 25, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09100 Filed 4–28–23; 8:45 am]

BILLING CODE 4140–01–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; Understudied Proteins associated with Rare Diseases (R03) Review.

Date: July 19–20, 2023.

Time: 10:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Suite 1001, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Carol (Chang-Sook) Kim, Ph.D., Scientific Review Administrator, Office of Grants Management and Scientific Review, National Center for Advancing Translational Sciences, National Institutes of Health, 6701 Democracy Boulevard, Suite 1001, Bethesda, MD 20892, *carolko@mail.nih.gov,* (301) 827–7940.

(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: April 25, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09150 Filed 4–28–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 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 Institute on Aging Special Emphasis Panel; GRN mediated cell-cell interactions in AD.

Date: June 27, 2023.

Time: 11:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sandhya Sanghi, Ph.D., Scientific Review Officer, National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue (2N230), NIA/SRB, Bethesda, MD 20892, (301) 496–2879, *sandhya.sanghi@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: April 25, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09098 Filed 4–28–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; 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, contract proposals, and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Mental Health Special Emphasis Panel; BRAIN Initiative Cell Atlas Network (BICAN) (R01, UM1, U24).

Date: May 25, 2023.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Jasenka Borzan, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institutes of Mental Health, Neuroscience Center, 6001 Executive Blvd., Bethesda, MD 20892, 301–435–1260, *jasenka.borzan@nih.gov.*

Name of Committee: National Institute of Mental Health Special Emphasis Panel; Psychoactive Drug Screening Program (PDSP).

Date: May 25, 2023.

Time: 1:30 p.m. to 3:00 p.m.

Agenda: To review and evaluate contract proposals.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Rebecca Steiner Garcia, Ph.D., Scientific Review Officer, Division of Extramural Activities, National Institute of Mental Health, National Institutes of Health, Neuroscience Center, 6001 Executive Blvd., Bethesda, MD 20892–9608, 301–443–4525, *steinerr@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program No. 93.242, Mental Health Research Grants, National Institutes of Health, HHS)

Dated: April 26, 2023.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09151 Filed 4–28–23; 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; Topics in Instrumentation and Systems Development.

Date: June 1, 2023.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Joseph D. Mosca, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5158, MSC 7808, Bethesda, MD 20892, (301) 408–9465, *moscajos@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; PAR–20–131: Mammalian Models for Translational Research.

Date: June 6, 2023.

Time: 11:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jennifer Ann Sanders, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 496–3553, *jennifer.sanders@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: April 25, 2023.

Tyeshia M. Roberson-Curtis,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09126 Filed 4–28–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Deafness and Other Communication Disorders; 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: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Review on NIDCD Cooperative Agreement for Clinical Trials in Communication Disorders.

Date: May 25, 2023.

Time: 11:00 a.m. to 12:30 p.m.

Agenda: To review and evaluate cooperative agreement applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Shiguang Yang, DVM, Ph.D., Scientific Review Officer, Division of Extramural Activities, NIDCD, NIH, 6001 Executive Blvd., Room 8349, Bethesda, MD 20892, 301–496–8683, *yangshi@nidcd.nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Review on NIDCD Research Grant Applications for Translating Basic Research into Clinical Tools.

Date: May 25, 2023.

Time: 1:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Shiguang Yang, DVM, Ph.D., Scientific Review Officer, Division of Extramural Activities, NIDCD, NIH, 6001 Executive Blvd., Room 8349, Bethesda, MD 20892, 301–496–8683, *yangshi@nidcd.nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Chemosensory Fellowship Review.

Date: June 13, 2023.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Shiguang Yang, DVM, Ph.D., Scientific Review Officer, Division of Extramural Activities, NIDCD, NIH, 6001 Executive Blvd., Room 8349, Bethesda, MD 20892, 301–496–8683, *yangshi@nidcd.nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; NIDCD Voice, Speech and Language Fellowship Review.

Date: June 14, 2023.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Katherine Shim, Ph.D., Scientific Review Officer, Division of Extramural Activities, NIH/NIDCD, 6001 Executive Blvd., Room 8351, Bethesda, MD 20892, 301–496–8683, *katherine.shim@nih.gov.*

Name of Committee: Communication Disorders Review Committee.

Date: June 15–16, 2023.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW, Washington, DC 20015 (Hybrid Meeting).

Contact Person: Kausik Ray, Ph.D., Scientific Review Officer, National Institute on Deafness and Other Communication Disorders, National Institute of Health, 6001 Executive Blvd., Rockville, MD 20850, 301–402–3587, *rayk@nidcd.nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; Hearing and Balance Fellowship Review.

Date: June 22, 2023.

Time: 11:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Sonia Elena Nanescu, Ph.D., Scientific Review Officer, Division of Extramural Activities, NIDCD, NIH, 6001 Executive Blvd., Suite 8300, Bethesda, MD 20892, (301) 496–8683, *sonia.nanescu@nih.gov.*

Name of Committee: National Institute on Deafness and Other Communication Disorders Special Emphasis Panel; NIDCD Clinical Research Center Grant Review.

Date: June 26, 2023.

Time: 3:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: Andrea B. Kelly, Ph.D., Scientific Review Officer, National Institute

on Deafness and Other Communication Disorders, National Institutes of Health, 6001 Executive Boulevard, Room 8351, Bethesda, MD 20892, (301) 451–6339, *kellya2@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.173, Biological Research Related to Deafness and Communicative Disorders, National Institutes of Health, HHS)

Dated: April 25, 2023.

Victoria E. Townsend,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09130 Filed 4–28–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 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 Heart, Lung, and Blood Institute Special Emphasis Panel; R25 Research Education Program to Enhance Diversity.

Date: May 25, 2023.

Time: 11 a.m. to 2 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Sun Saret, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208–S, Bethesda, MD 20892, (301) 435–0270, *sun.saret@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: April 25, 2023.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09092 Filed 4–28–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Library of Medicine Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Literature Selection Technical Review Committee.

The meeting is devoted to the review and evaluation of journals for potential indexing by the National Library of Medicine and will be closed to the public in accordance with the provisions set forth in section 552b(c)(9)(B), Title 5 U.S.C., as amended. Premature disclosure of the titles of the journals as potential titles to be indexed by the National Library of Medicine, the discussions, and the presence of individuals associated with these publications could significantly frustrate the review and evaluation of individual journals.

Name of Committee: Literature Selection Technical Review Committee.

Date: June 22–23, 2023.

Closed: 10:00 a.m. to 1:30 p.m.

Agenda: To review and evaluate journals as potential titles to be indexed by the National Library of Medicine.

Place: Virtual Meeting.

Open: June 22, 2023, 1:30 p.m. to 2:30 p.m.

Agenda: Administrative.

Place: Virtual Meeting.

Closed: June 22, 2023, 2:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate journals as potential titles to be indexed by the National Library of Medicine.

Place: Virtual Meeting.

Closed: June 23, 2023, 8:30 a.m. to 12:00 p.m.

Agenda: To review and evaluate journals as potential titles to be indexed by the National Library of Medicine.

Place: Virtual Meeting.

Contact Person: Dianne Babski, Associate Director, Division of Library Operations, National Library of Medicine, 8600 Rockville Pike, Bethesda, MD 20894, 301–827–4729, *babskid@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice at least 7 days prior to the meeting to be considered. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

(Catalogue of Federal Domestic Assistance Program No. 93.879, Medical Library Assistance, National Institutes of Health, HHS).

Dated: April 25, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09152 Filed 4–28–23; 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 Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a 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: Center for Scientific Review Special Emphasis Panel; Member Conflicts: Bioengineering, Biodata, and Biomodeling Technologies.

Date: May 31, 2023.

Time: 11:00 a.m. to 2:00 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: David R. Filpula, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6181, MSC 7892, Bethesda, MD 20892, 301–435–2902, *filpuladr@mail.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: April 25, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09127 Filed 4–28–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a 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: NIGMS Initial Review Group; Training and Workforce Development Study Section—A Review of Applications for Medical Scientist Training Program and Basic Biomedical Predoctoral T32 awards.

Date: June 22–23, 2023.

Time: 10:00 a.m. to 6:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute of General Medical Sciences, Natcher Building, 45 Center Drive, Bethesda, Maryland 20892 (Virtual Meeting).

Contact Person: Isaah S. Vincent, Ph.D., Scientific Review Officer, Office of Scientific Review, National Institute of General Medical Sciences, National Institutes of Health, 45 Center Drive, Room 3AN12L, Bethesda, Maryland 20892, 301–594–2948, *isaah.vincent@nih.gov*.

Information is also available on the Institute's/Center's home page: *www.nigms.nih.gov/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program No. 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: April 25, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09128 Filed 4–28–23; 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: Brain Disorders and Clinical Neuroscience Integrated Review Group; Pathophysiological Basis of Mental Disorders and Addictions Study Section.

Date: May 31–June 1, 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.

Contact Person: Boris P. Sokolov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5217A, MSC 7846, Bethesda, MD 20892, 301–408–9115, *bsokolov@csr.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Behavioral Neuroendocrinology, Neuroimmunology, Rhythms, and Sleep Study Section.

Date: June 1–2, 2023.

Time: 8:00 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: Michael Selmanoff, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5164, MSC 7844, Bethesda, MD 20892, 301–435–1119, *selmanom@csr.nih.gov.*

Name of Committee: Population Sciences and Epidemiology Integrated Review Group; Kidney Endocrine and Digestive Disorders Study Section.

Date: June 1, 2023.

Time: 8:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Steven M. Frenk, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3141, Bethesda, MD 20892, (301) 480–8665, *frenksm@mail.nih.gov.*

Name of Committee: Integrative, Functional and Cognitive Neuroscience Integrated Review Group; Auditory System Study Section.

Date: June 1–2, 2023.

Time: 8:30 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Watergate, 2650 Virginia Avenue NW, Washington, DC 20037.

Contact Person: Brian H. Scott, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Bethesda, MD 20892, 301–827–7490, *brianscott@mail.nih.gov.*

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Biodata Management and Analysis Study Section.

Date: June 1–2, 2023.

Time: 9:00 a.m. to 8:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: E. Bryan Crenshaw, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–7129, *bryan.crenshaw@nih.gov.*

Name of Committee: Healthcare Delivery and Methodologies Integrated Review Group; Interdisciplinary Clinical Care in Specialty Care Settings Study Section.

Date: June 1–2, 2023.

Time: 9:30 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: Abu Saleh Mohammad Abdullah, Ph.D,. Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 827–4043, *abuabdullah.abdullah@nih.gov.*

Name of Committee: Cell Biology Integrated Review Group; Development—2 Study Section.

Date: June 5–6, 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: Rass M. Shayiq, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 2182, MSC 7818, Bethesda, MD 20892, (301) 435–2359, *shayiqr@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group; Cell Structure and Function 1 Study Section.

Date: June 6–7, 2023.

Time: 10:00 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: Jessica Smith, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, 301.402.3717, *jessica.smith6@nih.gov.*

Name of Committee: Biology of Development and Aging Integrated Review

Group; Mechanisms of Cancer Therapeutics B Study Section.

Date: June 8–9, 2023.

Time: 8:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Canopy by Hilton, 940 Rose Avenue, North Bethesda, MD 20852.

Contact Person: Maria Dolores Arjona Mayor, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 806D, Bethesda, MD 20892, (301) 827–8578, *dolores.arjonamayor@nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Molecular and Cellular Neuropharmacology Study Section.

Date: June 8–9, 2023.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Washington Marriott Georgetown, 1221 22nd Street NW, Washington, DC 20037.

Contact Person: Vanessa S. Boyce, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Rm. 4185, MSC 7850, Bethesda, MD 20892, (301) 402–3726, *boycevs@csr.nih.gov.*

Name of Committee: Cell Biology Integrated Review Group; Biology and Development of the Eye Study Section.

Date: June 8–9, 2023.

Time: 9:00 a.m. to 7:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Alexandria Old Town, 1767 King Street, Alexandria, VA 22314.

Contact Person: Kevin Czaplinski, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 480–9139, *czaplinskik2@csr.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Imaging Probes and Contrast Agents Study Section.

Date: June 8–9, 2023.

Time: 9:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Donald Scott Wright, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5108, MSC 7854, Bethesda, MD 20892, (301) 435–8363, *wrightds@csr.nih.gov.*

Name of Committee: Bioengineering Sciences & Technologies Integrated Review Group; Innovations in Nanosystems and Nanotechnology Study Section (INN).

Date: June 8–9, 2023.

Time: 9:30 a.m. to 7:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Joseph Thomas Peterson, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4118, MSC 7814, Bethesda, MD 20892, 301–408–9694, *petersonjt@csr.nih.gov.*

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Cancer Cell Biology Study Section.

Date: June 8–9, 2023.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Charles Morrow, MD, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6202, MSC 7804, Bethesda, MD 20892, 301–408–9850, *morrowcs@csr.nih.gov.*

Name of Committee: Biological Chemistry and Macromolecular Biophysics Integrated Review Group; Macromolecular Structure and Function C Study Section.

Date: June 8–9, 2023.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: William A. Greenberg, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4168, MSC 7806, Bethesda, MD 20892, (301) 435–1726, *greenbergwa@csr.nih.gov.*

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Neurogenesis and Cell Fate Study Section.

Date: June 8, 2023.

Time: 10:00 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.

Contact Person: Adem Can, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4190, MSC 7850, Bethesda, MD 20892, (301) 435–1042, *cana2@csr.nih.gov.*

Name of Committee: Surgical Sciences, Biomedical Imaging and Bioengineering Integrated Review Group; Bioengineering, Technology and Surgical Sciences Study Section.

Date: June 12–13, 2023.

Time: 8:00 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: Khalid Masood, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5120, MSC 7854, Bethesda, MD 20892, 301–435–2392, *masoodk@csr.nih.gov.*

Name of Committee: Center for Scientific Review Special Emphasis Panel; Small Business: The Cancer Biotherapeutics Development (CBD).

Date: June 12–13, 2023.

Time: 9:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Laurie Ann Shuman Moss, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 867–5309, *laurie.shumanmoss@nih.gov.*

Name of Committee: Cell Biology Integrated Review Group; Maximizing Investigators' Research Award C Study Section.

Date: June 12–13, 2023.

Time: 10:00 a.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Jimok Kim, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402–8559, *jimok.kim@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: April 25, 2023.

David W. Freeman,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09094 Filed 4–28–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 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 Institute on Aging Special Emphasis Panel; Program Project: Cognitive.

Date: July 10, 2023.

Time: 1:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Dario Dieguez, Ph.D., Scientific Review Officer, National Institutes of Health, National Institute on Aging, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 827–3101, *dario.dieguez@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: April 25, 2023.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2023–09095 Filed 4–28–23; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine and Oral Fluid Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine or Oral Fluid (Mandatory Guidelines).

FOR FURTHER INFORMATION CONTACT: Anastasia Donovan, Division of Workplace Programs, SAMHSA/CSAP, 5600 Fishers Lane, Room 16N06B, Rockville, Maryland 20857; 240–276–2600 (voice); *Anastasia.Donovan@samhsa.hhs.gov* (email).

SUPPLEMENTARY INFORMATION: In accordance with Section 9.19 of the Mandatory Guidelines, a notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at *https://www.samhsa.gov/workplace/resources/drug-testing/certified-lab-list.*

The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITFs) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines) using Urine and of the laboratories currently certified to meet the standards of the Mandatory Guidelines using Oral Fluid.

The Mandatory Guidelines using Urine were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); April 30, 2010 (75 FR 22809); and on January 23, 2017 (82 FR 7920).

The Mandatory Guidelines using Oral Fluid were first published in the **Federal Register** on October 25, 2019 (84 FR 57554) with an effective date of January 1, 2020.

The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100–71 and allowed urine drug testing only. The Mandatory Guidelines using Urine have since been revised, and new Mandatory Guidelines allowing for oral fluid drug testing have been published. The Mandatory Guidelines require strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on specimens for federal agencies. HHS does not allow IITFs to conduct oral fluid testing.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines using Urine and/or Oral Fluid. An HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that the test facility has met minimum standards. HHS does not allow IITFs to conduct oral fluid testing.

HHS-Certified Laboratories Approved To Conduct Oral Fluid Drug Testing

In accordance with the Mandatory Guidelines using Oral Fluid dated October 25, 2019 (84 FR 57554), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on oral fluid specimens:

At this time, there are no laboratories certified to conduct drug and specimen validity tests on oral fluid specimens.

HHS-Certified Instrumented Initial Testing Facilities Approved To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine dated January 23, 2017 (82 FR 7920), the following HHS-certified IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Dynacare, 6628 50th Street NW, Edmonton, AB Canada T6B 2N7, 780–784–1190 (Formerly: Gamma-Dynacare Medical Laboratories)

HHS-Certified Laboratories Approved To Conduct Urine Drug Testing

In accordance with the Mandatory Guidelines using Urine dated January 23, 2017 (82 FR 7920), the following HHS-certified laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504–361–8989/800–433–3823 (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.)

Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA 23236, 804–378–9130 (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.)

Clinical Reference Laboratory, Inc., 8433 Quivira Road, Lenexa, KS 66215–2802, 800–445–6917

Desert Tox, LLC, 5425 E Bell Rd., Suite 125, Scottsdale, AZ 85254, 602–457–5411/623–748–5045

DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800–235–4890

Dynacare *, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519–679–1630 (Formerly: Gamma-Dynacare Medical Laboratories)

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662–236–2609

Laboratory Corporation of America Holdings, 7207 N Gessner Road, Houston, TX 77040, 713–856–8288/800–800–2387
Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908–526–2400/800–437–4986 (Formerly: Roche Biomedical Laboratories, Inc.)
Laboratory Corporation of America Holdings, 1904 TW Alexander Drive, Research Triangle Park, NC 27709, 919–572–6900/800–833–3984 (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group)
Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866–827–8042/800–233–6339 (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center)
LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913–888–3927/800–873–8845 (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)
Legacy Laboratory Services Toxicology, 1225 NE 2nd Ave., Portland, OR 97232, 503–413–5295/800–950–5295
MedTox Laboratories, Inc., 402 W County Road D, St. Paul, MN 55112, 651–636–7466/800–832–3244
Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612–725–2088. Testing for Veterans Affairs (VA) Employees Only
Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800–328–6942 (Formerly: Centinela Hospital Airport Toxicology Laboratory)
Phamatech, Inc., 15175 Innovation Drive, San Diego, CA 92128, 888–635–5840
Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610–631–4600/877–642–2216 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)
U.S. Army Forensic Toxicology Drug Testing Laboratory, 2490 Wilson St., Fort George G. Meade, MD 20755–5235, 301–677–7085, Testing for Department of Defense (DoD) Employees Only

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on January 23, 2017 (82 FR 7920). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

Alicia Broadus,

Public Health Advisor.

[FR Doc. 2023–09061 Filed 4–28–23; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2023 Notice of Supplemental Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, Department of Health and Human Services (HHS).

ACTION: Notice of intent to award supplemental funding.

SUMMARY: This notice is to inform the public that the Substance Abuse and Mental Health Services Administration (SAMHSA) is supporting an administrative supplement in scope of the parent award for the one grant recipient funded in fiscal year (FY) 2020 under the Suicide Prevention Resource Center (SPRC) Notice of Funding Opportunity (NOFO) SM–20–011. The grant recipient may receive up to $2,817,614. The recipient's project period will be extended by 12 months until August 30, 2025. The supplemental funding will be used to develop the new National Strategy for Suicide Prevention, which sets the direction of the field to prioritize suicide prevention activities. This is being requested by the White House Domestic Policy Council.

FOR FURTHER INFORMATION CONTACT: Brandon J. Johnson, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857, telephone (240) 276–1222; email: *brandon.johnson1@samhsa.hhs.gov*.

SUPPLEMENTARY INFORMATION:

Funding Opportunity Title: FY 2020 Suicide Prevention Resource Center SM–20–011.

Assistance Listing Number: 93.243.

Authority: Section 520A and 520C of the Public Health Service Act, as amended.

Justification: Eligibility for this supplemental funding is limited to the University of Oklahoma Health Sciences Center which was funded in FY 2020 under the Suicide Prevention Resource Center grant. The University of Oklahoma Health Sciences Center has special expertise completing activities and developing previous versions of the National Strategy for Suicide Prevention.

This is not a formal request for application. Assistance will only be provided to the sole SPRC grant recipient funded in FY 2020 under SM–20–011 based on the receipt of a satisfactory application and associated budget that is approved by a review group.

Dated: April 26, 2023.

Ann Ferrero,

Public Health Analyst.

[FR Doc. 2023–09138 Filed 4–28–23; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Fiscal Year (FY) 2023 Notice of Supplemental Funding Opportunity

AGENCY: Substance Abuse and Mental Health Services Administration, Department of Health and Human Services (HHS).

ACTION: Notice of intent to award supplemental funding.

SUMMARY: This notice is to inform the public the Substance Abuse and Mental Health Services Administration (SAMHSA) is supporting a supplement

in scope of the original award to the University of North Carolina funded in FY 2018 under the National Center of Excellence for Eating Disorders (NCEED), Notice of Funding Opportunity (NOFO) SM–18–021. The recipient may receive up to $747,646. The supplemental funding will extend the project period by 12-months until September 29, 2024 and will: continue to develop and disseminate high-quality training and technical assistance to healthcare practitioners on issues related to eating disorders; facilitate the identification of model eating disorder programs; provide the most up-to-date information on eating disorders; and promote public awareness of eating disorders.

FOR FURTHER INFORMATION CONTACT: Nancy Kelly, Chief, Mental Health Prevention Branch, Substance Abuse and Mental Health Services Administration, 5600 Fishers Lane, Rockville, MD 20857, telephone 240–276–1143; email: *nancy.kelly@samhsa.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Funding Opportunity Title: FY 2018 Center of Excellence for Eating Disorders (NCEED) Notice of Funding Opportunity SM–18–021.

Assistance Listing Number: 93.243.

Authority: The NCEED is authorized under section 520A (290bb–32) of the Public Health Service Act, as amended.

Justification: Eligibility for this supplemental funding is limited to the University of North Carolina, which was funded in FY 2018 under the NCEED NOFO SM–18–021. The University of North Carolina has special expertise to develop and disseminate training and technical assistance for healthcare practitioners on issues related to addressing eating disorders.

This is not a formal request for application. Assistance will only be provided to NCEED recipient (University of North Carolina) funded in FY 2018 based on the receipt of a satisfactory application and associated budget that is approved by a review group.

Dated: April 26, 2023.

Ann Ferrero,

Public Health Analyst.

[FR Doc. 2023–09139 Filed 4–28–23; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–2023–0245]

National Commercial Fishing Safety Advisory Committee; May 2023 Meetings

AGENCY: Coast Guard, Department of Homeland Security.

ACTION: Notice of federal advisory committee meeting.

SUMMARY: The National Commercial Fishing Safety Advisory Committee (Committee) will conduct a series of meetings over three days to review, discuss, and make recommendations to the Secretary on matters relating to Marine Casualty investigation cases related to Personal Flotation Devices (PFD), Cold Water, and Falls Overboard. The meetings will be open to the public.

DATES:

Meetings: The Committee will hold a meeting on Tuesday, May 23, 2023, from 8 a.m. until 5 p.m. Eastern Daylight Time (EDT), Wednesday, May 24, 2023, from 8 a.m. until 5 p.m. EDT, and Thursday, May 25, 2023, from 8 a.m. until 5 p.m. EDT. The Committee meeting on Tuesday, May 23, 2023, from 8 a.m. until 9 a.m. will be dedicated to an administrative meeting (Committee members only). Please note these meetings may close early if the Committee has completed its business.

Comments and supporting documentation: To ensure your comments are received before the meeting, please submit your written comments no later than May 18, 2023.

ADDRESSES: The meeting will be held at the Norfolk Waterside Marriott, 235 East Main Street, Norfolk, Virginia 23510, *Hotel in Downtown Norfolk, VA | Norfolk Waterside Marriott.*

The National Commercial Fishing Safety Advisory Committee is committed to ensuring all participants have equal access regardless of disability status. If you require reasonable accommodation due to a disability to fully participate, please email Mr., Jonathan Wendland at *Jonathan.G.Wendland@uscg.mil* or call at 202–372–1245 as soon as possible.

Instructions: You are free to submit comments at any time, including orally at the meeting as time permits, but if you want your comment reviewed before the meeting, please submit your comments no later than May 18, 2023. We are particularly interested in comments regarding the topics in the ''Agenda'' section below. We encourage you to submit comments through Federal eRulemaking Portal at *https://www.regulations.gov.* If your material cannot be submitted using *https://www.regulations.gov,* call or email the individual in the **FOR FURTHER INFORMATION CONTACT** section of this document for alternate instructions. You must include the docket number [USCG–2023–0245]. Comments received will be posted without alteration at *https://www.regulations.gov* including any personal information provided. You may wish to review the Privacy and Security notice available on the homepage of *https://www.regulations.gov,* and DHS's eRulemaking System of Records notice (85 FR 14226, March 11, 2020). If you encounter technical difficulties with comment submission, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Docket Search: Documents mentioned in this notice as being available in the docket, and all public comments, will be in our online docket at *https://www.regulations.gov,* and can be viewed by following that website's instructions. Additionally, if you go to the online docket and sign-up for email alerts, you will be notified when comments are posted.

FOR FURTHER INFORMATION CONTACT: Mr. Jonathan Wendland, Alternate Designated Federal Officer (ADFO) of the National Commercial Fishing Safety Advisory Committee, 2703 Martin Luther King Jr Ave. SE, Stop 7509, Washington, DC 20593–7509, telephone 202–372–1245 or *Jonathan.G.Wendland@uscg.mil.*

SUPPLEMENTARY INFORMATION: Notice of this meeting is in compliance with the *Federal Advisory Committee Act,* (Pub. L. 117–286, 5 U.S.C., ch. 10). The National Commercial Fishing Safety Advisory Committee is authorized by section 601 of the *Frank LoBiondo Coast Guard Authorization Act of 2018,* (Pub. L. 115–282, 132 Stat. 4190), and is codified in 46 U.S.C. 15102. The Committee operates under the provisions of the *Federal Advisory Committee Act* and 46 U.S.C. 15109. The National Commercial Fishing Safety Advisory Committee provides advice and recommendations to the Secretary of Homeland Security through the Commandant of the U. S. Coast Guard, on matters relating to the safe operation of vessels including the matters of:

(A) navigation safety;

(B) safety equipment and procedures;

(C) marine insurance;

(D) vessel design, construction, maintenance, and operation; and

(E) personnel qualifications and training;

Additionally, the Committee will review regulations proposed under chapter 45 of Title 46 of U.S Code (during preparation of the regulations) and review marine casualties and investigations of vessels covered by chapter 45 of Title 46 U.S. Code and make recommendations to the Secretary to improve safety and reduce vessel casualties.

Agenda

Day 1

The agenda for the National Commercial Fishing Safety Advisory Committee is as follows:

I. Opening
- a. Call to Order/Designated Federal Officer (DFO) Remarks.
- b. Roll Call/Determination of Quorum.
- c. Swear in New Members.
- d. U.S. Coast Guard Leadership Remarks.

II. Administration
- a. Review and Adoption of Meeting Agenda.
- b. Meeting Goals.
- c. Roberts Rules.

III. General Updates
- a. Regulatory Status.
- b. U.S. Coast Guard Authorization Act.

IV. Information Session
- a. USCG District Presentations.
- b. NIOSH Data Presentation.
- c. NIOSH Grant(s) Fishing Vessel Training & Research.
- d. NIOSH Grant(s) Project Presentation.
- e. Marine Casualty Initiatives.
- f. Marine Casualties Presentation (CG–INV).
- g. Marine Casualty Case Familiarization.

V. Public Comment period.
VI. Meeting Recess.

Day 2

VII. New Business
- a. Committee Elect Chair/Vice Chair.
- b. Assignment of Task #01–23: Review (11) Marine Casualty investigation cases related to Personal Flotation Devices (PFD) and make recommendations to the Secretary of Homeland Security.
- c. Assignment of Task #02–23: Review (9) Marine Casualty investigation cases related to Cold Water and make recommendations to the Secretary of Homeland Security.
- d. Assignment of Task #03–23: Review (2) Marine Casualty investigation cases related to Falls Overboard and make recommendations to the Secretary of Homeland Security.

VIII. Subcommittee Discussions
- a. Action Items.

IX. Public Comment Period.
X. Committee Discussion/Actions.
XI. Meeting Recess.

Day 3

XII. Discussion of Subcommittee recommendations and Committee Actions.
XIII. Full Committee Open Discussion.
XIV. Public comment period.
XV. Closing Remarks/Plans for Next Meeting.
XVI. Adjournment of Meeting.

A copy of pre-meeting documentation will be available at *https://www.dco.uscg.mil/NCFSAC2023/* no later than May 12, 2023. Alternatively, you may contact Mr. Jonathan Wendland as noted in the **FOR FURTHER INFORMATION CONTACT** section above.

There will be a public comment period scheduled each day of the meeting. Speakers are requested to limit their comments to 3 minutes. Please note that the public comment period may end before the period allotted, following the last call for comments. Please contact the individual listed in the **FOR FURTHER INFORMATION CONTACT SECTION** to register as a speaker.

Dated: April 19, 2023.

Andrew J. Meyers,

Captain, U.S. Coast Guard, Acting Director of Inspections and Compliance.

[FR Doc. 2023–09135 Filed 4–28–23; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2022–0038; OMB No. 1660–NW144]

Agency Information Collection Activities: Submission for OMB Review, Comment Request; FEMA Region II Community and Faith-Based Organizations Needs/Capabilities and Continuity Program Survey

AGENCY: Federal Emergency Management Agency, Department of Homeland Security.

ACTION: 30-Day notice of new collection and request for comments.

SUMMARY: The Federal Emergency Management Agency (FEMA) will submit the information collection abstracted below to the Office of Management and Budget for review and clearance in accordance with the requirements of the Paperwork Reduction Act of 1995. The submission seeks comments concerning a series of surveys on continuity planning and organizational needs and capabilities from various stakeholders.

DATES: Comments must be submitted on or before May 31, 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: Requests for additional information or copies of the information collection should be made to Director, Information Management Division, 500 C St. SW, Washington, DC 20472, email address: *FEMA-Information-Collections-Management@fema.dhs.gov* or Jeremy Brooks, Management and Program Analyst, at *jeremy.brooks@fema.dhs.gov* or 202–355–4981.

SUPPLEMENTARY INFORMATION: The legal basis for the collection off the following information includes Titles 6 and 42 of the United States Code. The sections in Title 6 include 313, 314, and 317, which provides legal authority and responsibilities to the Federal Emergency Management Agency (FEMA) and to its respective regional offices to work with state, local, territorial and Tribal (SLTT) governments and private non-profits (PNP) with disaster preparedness. The sections in Title 42 include 5131(a), 5131(b), 5195, 5196(e), and 5196(f). The identified sub sections of 5131 provides legal authority to FEMA Federal and state disaster preparedness programs via utilization of services of other agencies and technical assistance. Section 5195 stats that a purpose of 42 U.S.C. *et seq.* is to vest responsibility for emergency preparedness in the Federal Government. Section 5195a provides definitions for relevant terms. Sections 5196(e) and 5196(f) provide detailed functions of administration for emergency preparedness measures and training programs. All these legal authorities affirm the authority of FEMA Region II to collect this information and the critical need to do so.

Additionally, the Presidential Policy Directive (PPD–8)—National Preparedness, directed the development of the National Preparedness Goal that identifies core capabilities necessary for preparedness and a National Preparedness System to guide activities to reach the Goal. The proposed

collection works to improve tracking of core capabilities across FEMA Region II to most efficiently use resources to meet the National Preparedness Goal by utilizing elements of the 2018 FEMA text, *Engaging Community and Faith-based Organizations.*

The Federal Emergency Management Agency (FEMA) National Preparedness Division (NPD) is responsible for educating and securing the nation with the capabilities required across the whole community to prevent, protect against, mitigate, respond to, and recover from the threats and hazards that pose the greatest risk. One of the ways FEMA accomplishes this is through conducting exercises, trainings, and webinars where stakeholders like SLTT governments and PNP entities participate.

The delivery methodology of these programs to a variety of stakeholders are always evolving and continuously improving to meet stakeholder's needs. Likewise, as internal agency policy changes, so can delivery methods. Specifically for FEMA, this includes release of the 2022–2026 FEMA Strategic Plan. Strategic Goal #3 includes Promote and Sustain a Ready FEMA and Prepared Nation, and the objectives 3.1—Strengthen the Emergency Management Workforce and 3.2—Posture FEMA to Meet Current and Emergency Threats. This strategic goal and its associated objectives are well aligned to priorities of FEMA Region II's National Preparedness Division, with internal goals of data-driven capacity building and a more equitable approach to program delivery.

By better gauging stakeholder capacity and needs at an organizational level we can better provide programs and services to our stakeholders to ultimately improve preparedness in FEMA Region II.

Authorities for the collection of information include the following: Presidential Policy Directive (PPD–8), National Preparedness; 6 U.S.C. 313, 314, 317(c); 42 U.S.C. 5195, 5196(e) and (f); 42 U.S.C. 5131(a) and (b).

This proposed information collection previously published in the **Federal Register** on January 3, 2023, at 88 FR 87 with a 60 day public comment period. One comment suggesting multiple detailed edits was received. The purpose of this notice is to notify the public that FEMA will submit the information collection abstracted below to the Office of Management and Budget for review and clearance.

Collection of Information

Title: FEMA Region II Community and Faith-Based Organizations Needs/Capabilities and Continuity Program Survey.

Type of Information Collection: New information collection.

OMB Number: 1660–NW144.

FEMA Forms: FEMA Form FF–008–FY–22–128, Region II Community and Faith-Based Organizations Needs/Capabilities Feedback Survey.

Abstract: FEMA Region II (NJ, NY, PR, VI) is working to better assess the ability of stakeholders' emergency response capabilities to better target program design and delivery in the future. These voluntary survey questions are designed to collect actionable data at the organizational level and allows for a better understanding of potential future collaborations.

Affected Public: Not-for-profit institutions; State, Local, or Tribal Government.

Estimated Number of Respondents: 1,862.

Estimated Number of Responses: 1,862.

Estimated Total Annual Burden Hours: 466.

Estimated Total Annual Respondent Cost: $19,086.

Estimated Respondents' Operation and Maintenance Costs: $0.

Estimated Respondents' Capital and Start-Up Costs: $0.

Estimated Total Annual Cost to the Federal Government: $9,878.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Millicent Brown Wilson,

Records Management Branch Chief, Office of the Chief Administrative Officer, Mission Support, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. 2023–09189 Filed 4–28–23; 8:45 am]

BILLING CODE 9111–27–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–7065–N–01; OMB Control No. 2535–0102]

60-Day Notice of Proposed Information Collection: Electronic Line of Credit Control System (eLOCCS) System Access Authorization Form Collection

AGENCY: Office of the Chief Financial 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 60 days of public comment.

DATES: *Comments Due Date:* June 30, 2023.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Written comments and recommendations for the proposed information collection can be sent within 60 days of publication of this notice to *OIRA_submission@omb.eop.gov* or *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 60-day Review—Open for Public Comments'' or by using the search function. Interested persons are also invited to submit comments regarding this proposal by name and/or OMB Control Number and can be sent to: Colette Pollard, Reports Management Officer, REE, Department of Housing and Urban Development, 451 7th Street SW, Room 8210, Washington, DC 20410–5000; telephone 202–402–3400 for Colette (this is not a toll-free number) or email at *PaperworkReductionActOffice@hud.gov* for a copy of the proposed forms or other available information.

FOR FURTHER INFORMATION CONTACT: Anna P. Guido, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW, Washington, DC 20410; email Anna P. Guido at *Anna.P.Guido@hud.gov* or telephone 202–402–5535. 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.

A. Overview of Information Collection

Title of Information Collection: Electronic Line of Credit Control System (eLOCCS) System Access Authorization Form.

OMB Approval Number: 2535–0102.

Type of Request: Reinstatement with change.

Form Number: HUD–27054e.

Description of the need for the information and proposed use: Establish access to the eLOCCS payment system.

Respondents: State or Local Government; Public Housing Authorities (PHAs), Individuals or Households.

Information collection	Number of respondents	Frequency of response	Responses per annum	Burden hour per response	Annual burden hours	Hourly cost per response	Annual cost
HUD—27054e	2,420.00	1.00	2,420.00	0.17	411.00	$24.29	$9,992.91
Total	.....	.....	.....	.....	411.00	$24.29	$9,992.91

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.

HUD encourages interested parties to submit comment in response to these questions.

C. Authority

Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

George J. Tomchick,

Deputy Chief Financial Officer.

[FR Doc. 2023–09062 Filed 4–28–23; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[BLM_HQ_FRN_MO4500170190]

Notice of Intent To Prepare an Environmental Impact Statement To Analyze the Potential Environmental Effects From Maintaining Secretary Jewell's Coal Leasing Moratorium

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of intent.

SUMMARY: In compliance with the National Environmental Policy Act of 1969, as amended (NEPA), and consistent with direction from the U.S. District Court of Montana, the Bureau of Land Management (BLM) intends to prepare an environmental impact statement (EIS) to analyze the potential environmental effects from maintaining or revoking former Secretary of the Interior Sally Jewell's coal leasing moratorium. This notice begins the process of defining the scope of the EIS by providing background on the Federal coal program and the direction received from the United States District Court for the District of Montana in *Citizens for Clean Energy,* v. *U.S. Dep't of the Interior.* With this notice, the BLM also solicits public comments for consideration in establishing the scope and content of the EIS.

DATES: The BLM invites interested agencies, States, Tribes, local governments, industry, organizations, and members of the public to submit comments or suggestions to assist in identifying significant issues that should be included in the scope of BLM's review of the potential environmental impacts from maintaining or revoking former Secretary Jewell's coal leasing moratorium.

The BLM will consider all written comments received or postmarked during the public comment period, which will close on June 15, 2023.

ADDRESSES: You may submit written comments by the following methods:

- *Website: https://eplanning.blm.gov/eplanning-ui/project/2024545/510.* This is the preferred method of commenting.
- *Email: BLM_HQ_320_CoalProgramReview@blm.gov.*
- *Mail, personal, or messenger delivery:* National Coal Program Review, 1849 C Street NW, Room 5622, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Timothy Barnes, Acting Chief, Division of Solid Minerals, telephone: 541–416–6858, email: *tbarnes@blm.gov.*

Individuals in the United States who are deaf, blind, 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: The BLM will prepare an EIS to analyze the potential environmental effects from maintaining or revoking former Secretary Jewell's coal leasing moratorium, as ordered by the U.S. District Court for the District of Montana in *Citizens for Clean Energy,* v. *U.S. Dep't of the Interior,* 4:17–cv–00042–BMM (D. Mont. 2022).[1] The court's decision is related to the environmental analysis that the BLM previously prepared to assess lifting a Federal coal leasing moratorium established on January 15, 2016, by then Secretary of the Interior Sally Jewell. Secretary Jewell established the moratorium through Secretary's Order No. 3338

[1] The Intervenor-Appellants, the National Mining Association, State of Wyoming and State of Montana, appealed this decision on October 7, 2022, and October 11, 2022, respectively. *Citizens for Clean Energy* v. *Dep't of the Interior,* Civ. No. 22–35789 (9th Cir.).

(Jewell Order), which directed the BLM to conduct a programmatic review of the Federal coal program through preparation of an EIS under NEPA. On March 29, 2017, then former Secretary of the Interior Ryan Zinke issued Secretary's Order No. 3348 (Zinke Order), which revoked the Jewell Order, halted preparation of the EIS, and lifted the moratorium on Federal coal leasing.

Background

Under the Mineral Leasing Act of 1920 (MLA), as amended, 30 U.S.C. 181 *et seq.,* and the Mineral Leasing Act for Acquired Lands of 1947 (MLAAL), as amended, 30 U.S.C. 351 *et seq.,* the BLM is responsible for leasing Federal coal and regulation of the development of that coal on approximately 570 million acres of the 700 million acres of mineral estate that is owned by the Federal Government. This responsibility encompasses Federal mineral rights on Federal lands and Federal mineral rights located under surface lands with non-Federal ownership. Under the authority of the MLA and MLAAL, the BLM administers leasing and monitors coal production. Other Departmental bureaus, in particular the Office of Surface Mining Reclamation and Enforcement (OSMRE) and the Office of Natural Resources Revenue (ONRR), also take actions related to coal mining on Federal lands. The OSMRE, and those States that have regulatory primacy under the Surface Mining Control and Reclamation Act of 1977, permit coal mining and reclamation activities, and monitor reclamation and reclamation bonding actions. The ONRR collects and audits all payments required under the lease, including bonus bids, royalties, and rental payments, and distributes those funds between the Federal Treasury and the States where coal resources are located.

The Jewell Order imposed a moratorium on the issuance of new Federal coal leases for thermal coal, with limited exceptions, until completion of the EIS.

On March 29, 2017, the Zinke Order implemented Executive Order (E.O.) 13783, which was entitled, ''Promoting Energy Independence and Economic Security,'' by rescinding the Jewell Order. Immediately thereafter, Citizens for Clean Energy, Ecocheyenne, Montana Environmental Information Center, Center for Biological Diversity, Defenders of Wildlife, Sierra Club, WildEarth Guardians, and the Northern Cheyenne Tribe filed a lawsuit in the U.S. District Court for the District of Montana asserting that the issuance of the Zinke Order required an environmental analysis in compliance with NEPA. Additionally, the States of California, New York, New Mexico, and Washington also filed suit and the Court consolidated the cases. The National Mining Association and the States of Wyoming and Montana intervened.

On April 19, 2019, the Court held that the Zinke Order was a final agency action that triggered the need to comply with NEPA, requiring the Department to conduct an appropriate environmental review of that action. To comply with the Court's Order, the BLM released an environmental assessment (EA) for public comment on May 22, 2019, and published the final EA and a Finding of No Significant Impact (FONSI) on its website on February 26, 2020. Shortly thereafter, the Plaintiffs amended their complaints to challenge the scope and content of the EA.

On January 20, 2021, President Biden issued E.O. 13990, entitled, ''Executive Order on Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis,'' revoking E.O. 13783. On April 16, 2021, Secretary Haaland rescinded the Zinke Order through Secretary's Order 3398, but did not reinstate the Federal coal leasing moratorium.

On August 12, 2022, the Court vacated and remanded the EA and associated FONSI and reinstated ''[t]he coal leasing program moratorium established by the Jewell Order . . . until the completion of sufficient NEPA review analyzing revocation of the moratorium.'' Order at 19. The Court determined that the EA's analysis failed ''to consider all direct, indirect, and cumulative impacts of re-starting the Federal coal-leasing program.'' Order at 13. Further, the Court held that the BLM should have considered ''a potential alternative that provided a baseline of an indefinite moratorium'' rather than limiting the EA's analysis to those leases granted during the estimated Programmatic EIS timeline providing that the ''BLM's analysis should have considered the effect of restarting coal leasing from a forward-looking perspective, including connected actions.'' *Id.* The Court directed the ''BLM [to] perform NEPA analysis that considers the full scope of the Zinke Order's effect on all then-pending lease applications, and other connected, cumulative, or similar actions.'' Order at 17. In October 2022, Intervenor-Defendants appealed the decision to the U.S. Court of Appeals for the Ninth Circuit.

Public Scoping Process

All public scoping comments must be submitted by email or by mail to the addresses listed under **ADDRESSES**. Before including you 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 public at any time. While you may request in your comment to have your personal identifying information withheld from public review, the BLM cannot guarantee that this will occur. The BLM will review and consider all public scoping comments received and will prepare a Scoping Summary Report. The Scoping Summary Report will be used by the BLM to identify issues to be included in the environmental analysis in the EIS, resources and issues that can be dismissed from detailed analysis because they are not present or not affected, and potential alternatives to be analyzed.

Request for Identification of Potential Alternatives, Information, and Analyses Relevant to the Scope of the Analysis of the Potential Environmental Effects From Maintaining Secretary Jewell's Coal Leasing Moratorium on Pending Federal Coal Lease Applications

In addition to comments concerning the scope of the environmental analysis, commenters are encouraged to identify relevant information, studies, and analyses that would assist the BLM in taking further action on the moratorium instituted by the Jewell Order and identifying potential alternatives.

Lead and Cooperating Agencies

The BLM is the lead agency for this EIS. Other Federal agencies, State, Tribal, and local governments with special expertise that are interested in participating in the preparation of this EIS should contact the previously mentioned Acting Chief of the Division of Solid Minerals.

Decision Maker

Director, Bureau of Land Management.

Nature of Decision To Be Made

Informed by the environmental analysis, the BLM will consider whether and to what extent to continue the coal leasing moratorium imposed by the Jewell Order on January 15, 2016, lifted by the Zinke Order on March 29, 2017, and reinstated by the U.S. District Court of Montana on August 12, 2022.

(Authority: 43 U.S.C. 1701 *et seq.,* 30 U.S.C. 118 *et seq.,* 30 U.S.C. 351 *et seq.*)

Benjamin E. Gruber,

Acting Assistant Director, Energy, Minerals and Realty Management, Bureau of Land Management, Department of the Interior.

[FR Doc. 2023–08960 Filed 4–28–23; 8:45 am]

BILLING CODE 4331–29–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–SER–VIIS–35617; PS.SSELA386.00.1]

Land Exchange at Virgin Islands National Park; Correction

AGENCY: National Park Service, Interior.

ACTION: Notice of land exchange; correction.

SUMMARY: The National Park Service published a document in the **Federal Register** of April 25, 2023, concerning request for comments on a Notice of Land Exchange at the Virgin Islands National Park. The document contained a typographical error in the **DATES** section.

FOR FURTHER INFORMATION CONTACT: Russell Webb, Supervisory Realty Specialist, *russell_webb@nps.gov,* Land Resources Program Office—National Park Service, 2975 Horseshoe Dr. S, Suite 800, Naples, Florida 34104, telephone (239) 261–0865.

SUPPLEMENTARY INFORMATION:

Correction

In the **Federal Register** of April 25, 2023, in FR Doc. 2023–08623, on page 25014, in the third column, correct the **DATES** caption to read:

DATES: The effective date of this *Notice of land exchange* is April 25, 2023. Comments on the land exchange must be received by 11:59 p.m. ET on June 9, 2023.

Mark A. Foust,

Regional Director, Interior Region 2.

[FR Doc. 2023–09158 Filed 4–26–23; 4:15 pm]

BILLING CODE 4312–52–P

DEPARTMENT OF THE INTERIOR

Bureau of Reclamation

[RR04093000, XXXR4081G3, RX.05940913. FY19400]

Public Meeting of the Glen Canyon Dam Adaptive Management Work Group

AGENCY: Bureau of Reclamation, Interior.

ACTION: Notice of public meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act of 1972, the Bureau of Reclamation (Reclamation) is publishing this notice to announce that a Federal Advisory Committee meeting of the Glen Canyon Dam Adaptive Management Work Group (AMWG) will take place.

DATES: The meeting will be held virtually on Wednesday, May 17, 2023, beginning at 9 a.m. (MDT) and concluding four (4) hours later in the respective time zones.

ADDRESSES: The virtual meeting held on Wednesday, May 17, 2023, may be accessed at: *https://rec.webex.com/rec/j.php?MTID=m069d7dac9f042ce419b775a5d2b462ff*;

Meeting Number: 2763 284 1693, Password: May17;

Phone Number: (877) 932–7704; Passcode: 8410783.

FOR FURTHER INFORMATION CONTACT: Mr. William Stewart, Bureau of Reclamation, telephone (385) 622–2179, email at *wstewart@usbr.gov.* 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: The Glen Canyon Dam Adaptive Management Program (GCDAMP) was implemented as a result of the Record of Decision on the Operation of Glen Canyon Dam Final Environmental Impact Statement to comply with consultation requirements of the Grand Canyon Protection Act (Pub. L. 102–575) of 1992. The AMWG makes recommendations to the Secretary of the Interior concerning Glen Canyon Dam operations and other management actions to protect resources downstream of Glen Canyon Dam, consistent with the Grand Canyon Protection Act. The AMWG meets two to three times a year.

Agenda: The AMWG will meet to receive updates on: (1) current basin hydrology and water year 2023 operations; (2) experiments considered for implementation in 2023; and (3) long-term funding considerations. The AMWG will also discuss other administrative and resource issues pertaining to the GCDAMP. To view a final copy of the agenda and documents related to the May meeting, please visit Reclamation's website at *https://www.usbr.gov/uc/progact/amp/amwg.html.*

Meeting Accessibility/Special Accommodations: The meeting is open to the public. Please make requests in advance for sign language interpreter services, assistive listening devices, or other reasonable accommodations. We ask that you contact Mr. William Stewart (see **FOR FURTHER INFORMATION CONTACT**) section of this notice at least seven (7) business days prior to the meeting to give the Department of the Interior sufficient time to process your request. All reasonable accommodation requests are managed on a case-by-case basis.

Public Disclosure of Comments: Time will be allowed for any individual or organization wishing to make extemporaneous and/or formal oral comments. To allow for full consideration of information by the AMWG members, written notice should be provided to Mr. William Stewart (see **FOR FURTHER INFORMATION CONTACT**) prior to the meeting. Depending on the number of persons wishing to speak, and the time available, the time for individual comments may be limited. Any written comments received will be provided to the AMWG members.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Authority: 5 U.S.C. appendix 10.

William Stewart,

Adaptive Management Group Chief, Resources Management Division, Upper Colorado Basin—Interior Region 7.

[FR Doc. 2023–09157 Filed 4–28–23; 8:45 am]

BILLING CODE 4332–90–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Blood Flow Restriction Devices with Rotatable Windlasses and*

Components Thereof, DN 3676; 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 Composite Resources, Inc. and North American Rescue, LLC on April 24, 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 blood flow restriction devices and components thereof. The complaint names as respondents: Anping Longji Medical Equipment Factory of China; Chaozhou Jiduo Trading Co., Ltd. of China; Dongguan Hongsui Electronic Commerce Co., Ltd. of China; Dongguanwin Si Hai Precision Mold Co., Ltd. of China; Eiffel Medical Supplies Co., Ltd. of China; Empire State Distributors Inc. of Brooklyn, NY; EMRN Medical Equipment of Canada; Express Companies, Inc. of Oceanside, CA; Fuzhou Meirun Medical Equipment Technology Co., Ltd. of China; GD Tianwu New Material Tech Co., Ltd. of China; Henan Eyocean E-Commerce Co., Ltd. of China; Hengshui Runde Medical Instruments Co., Ltd. of China; Huang Xia of China; Jingcai Jiang of China; Putian Dima Trading Co., Ltd. of China; Rhino Inc. of Lewes, DE; Shanghai Sixu International Freight Agent Co., Ltd. of China; Shen YI of China; Shenzhen Anben E-Commerce Co., Ltd. of China; Shenzhen Janxle E E Commerce Co., Ltd. of China; Shenzhen Smart Medical Co. Ltd. of China; Shenzhen TMI Medical Supplies Co., Ltd. of China; Shenzhen Yujie Commercial and Trading Co., Ltd. of China; Sun Minghui of China; SZY Holdings LLC of Brooklyn, NY; Wuxi Emsrun Technology Co., Ltd. of China; Wuxi Golden Hour Medical Technology Co., Ltd. of China; Wuxi Puneda Technology Co., Ltd. of China; Xia Guo Long of China; and Yinping Yin of China. The complainant requests that the Commission issue a general exclusion order, cease and desist orders, and impose a bond upon respondent 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. 3676) 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: April 25, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–09115 Filed 4–28–23; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–1333]

Certain Automated Put Walls and Automated Storage and Retrieval Systems, Associated Vehicles, Associated Control Software, and Component Parts Thereof (II); Notice of Commission Determination Not To Review an Initial Determination Terminating the Investigation Based on Withdrawal of the Complaint; Termination of the Investigation

AGENCY: International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (''ID'') (Order No. 7) issued by the presiding Chief Administrative Law Judge (''CALJ'') in the above-captioned investigation and terminating the investigation in its entirety based on the complainant's withdrawal of the complaint. The investigation is terminated.

FOR FURTHER INFORMATION CONTACT: Robert Needham, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436, telephone (202) 708–5468. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.* For help accessing EDIS, please email *EDIS3Help@usitc.gov.* General information concerning the Commission may also be obtained by accessing its internet server at *https://www.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: On October 18, 2022, the Commission instituted this investigation based on a complaint, as amended, filed on behalf of OPEX Corporation of Moorestown, New Jersey (''OPEX''). 87 FR 63089 (Oct. 18, 2022). The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain automated put walls and automated storage and retrieval systems, associated vehicles, associated control software, and components parts thereof by reason of infringement of certain claims of U.S. Patent Nos. 11,192,144 and 11,358,175. *Id.* The Commission's notice of investigation names as respondents HC Robotics (a.k.a. Huicang Information Technology Co., Ltd.) of Hangzhou City, China; and Invata, LLC (d/b/a Invata Intralogistics) of Conshohocken, Pennsylvania. *Id.* The Office of Unfair Import Investigations is not participating in this investigation. *Id.*

On March 20, 2023, OPEX filed an unopposed motion to terminate the investigation based on its withdrawal of the complaint. On March 27, 2023, the CALJ denied the motion based on excessive redaction in the motion's attached agreement. *See* Order No. 6 (Mar. 27, 2023). On March 28, 2023, OPEX filed a renewed unopposed motion to terminate the investigation based on a withdrawal of the complaint and containing fewer redactions.

On March 29, 2023, the CALJ issued the subject ID (Order No. 7) pursuant to Commission Rule 210.21(a)(1) (19 CFR 210.21(a)(1)), granting the motion and terminating the investigation. The ID finds that the motion complies with Commission Rule 210.21(a)(1) and that there are no extraordinary circumstances that would prevent the requested relief. No party petitioned for review of the subject ID.

The Commission has determined not to review the subject ID. This investigation is hereby terminated in its entirety.

The Commission vote for this determination took place on April 26, 2023.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: April 26, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–09163 Filed 4–28–23; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–585–586 and 731–TA–1383–1384 (Review)]

Stainless Steel Flanges From China and India; Institution of Five-Year Reviews

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it has instituted reviews pursuant to the Tariff Act of 1930 (''the Act''), as amended, to determine whether revocation of the antidumping and countervailing duty orders on stainless steel flanges from China and India would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission.

DATES: Instituted May 1, 2023. To be assured of consideration, the deadline for responses is May 31, 2023. Comments on the adequacy of responses may be filed with the Commission by July 13, 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 June 5, 2018, the Department of Commerce (''Commerce'')

[2] All contract personnel will sign appropriate nondisclosure agreements.

[3] Electronic Document Information System (EDIS): *https://edis.usitc.gov.*

issued a countervailing duty order on imports of stainless steel flanges from China (83 FR 26006). On August 1, 2018, Commerce issued an antidumping duty order on imports of stainless steel flanges from China (83 FR 37468). On October 5, 2018, Commerce issued a countervailing duty order on imports of stainless steel flanges from India (83 FR 50336). On October 9, 2018, Commerce issued an antidumping duty order on imports of stainless steel flanges from India (83 FR 50639). The Commission is conducting reviews pursuant to section 751(c) of the Act, as amended (19 U.S.C. 1675(c)), to determine whether revocation of the orders would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. Provisions concerning the conduct of this proceeding may be found in the Commission's Rules of Practice and Procedure at 19 CFR part 201, subparts A and B, and 19 CFR part 207, subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct full or expedited reviews. The Commission's determinations in any expedited reviews will be based on the facts available, which may include information provided in response to this notice.

Definitions.—The following definitions apply to these reviews:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the scope of the five-year reviews, as defined by Commerce.

(2) The *Subject Countries* in these reviews are China and India.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise.* In its original determinations, the Commission defined a single *Domestic Like Product* consisting of finished and unfinished stainless steel flanges, coextensive with Commerce's scope.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original determinations, the Commission defined the *Domestic Industry* to be all U.S. producers of stainless steel flanges, including both integrated domestic producers and non-integrated domestic producers that engage in only finishing operations.

(5) The *Order Dates* are the dates that the orders became effective. In these reviews, the *Order Dates* are as follows: June 5, 2018 (countervailing duty order concerning China); August 1, 2018 (antidumping duty order concerning China); October 5, 2018 (countervailing duty order concerning India); and October 9, 2018 (antidumping duty order concerning India).

(6) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

Participation in the proceeding and public service list.—Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission's designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post-employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Charles Smith, Office of the General Counsel, at 202–205–3408.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that information submitted in response to this request for information and throughout this proceeding or other proceeding 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 personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Written submissions.—Pursuant to § 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is May 31, 2023. Pursuant to § 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct expedited or full reviews. The deadline for filing such comments is July 13, 2023. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also 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. Also,

in accordance with §§ 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

Please note the Secretary's Office will accept only electronic filings at 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.

No response to this request for information is required if a currently valid Office of Management and Budget (''OMB'') number is not displayed; the OMB number is 3117 0016/USITC No. 23–5–567, expiration date June 30, 2023. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436.

Inability to provide requested information.—Pursuant to § 207.61(c) of the Commission's rules, any interested party that cannot furnish the information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to § 776(b) of the Act (19 U.S.C. 1677e(b)) in making its determinations in the reviews.

Information To Be Provided in Response to This Notice of Institution: If you are a domestic producer, union/worker group, or trade/business association; import/export *Subject Merchandise* from more than one *Subject Country;* or produce *Subject Merchandise* in more than one *Subject Country,* you may file a single response. If you do so, please ensure that your response to each question includes the information requested for each pertinent *Subject Country.* As used below, the term ''firm'' includes any related firms.

Those responding to this notice of institution are encouraged, but not required, to visit the USITC's website at *https://usitc.gov/reports/response_noi_worksheet,* where one can download and complete the ''NOI worksheet'' Excel form for the subject proceeding, to be included as attachment/exhibit 1 of your overall response.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is an interested party under 19 U.S.C. 1677(9) and if so, how, including whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandise,* a foreign producer or exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association (a majority of whose members are interested parties under the statute), or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping and countervailing duty orders on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in § 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry.*

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in § 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in each *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries since the *Order Date.*

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2022, except as noted (report quantity data in pounds and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Domestic Like Product* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from any *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2022 (report quantity data in pounds and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping or countervailing duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from each *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. commercial shipments of *Subject Merchandise* imported from each *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping and/or countervailing duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from each *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in any *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2022 (report quantity data in pounds and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping or countervailing duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in each *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in each *Subject Country* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from each *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in each *Subject Country* since the *Order Date,* and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in each *Subject Country,* and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This proceeding is being conducted under authority of Title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.61 of the Commission's rules.

By order of the Commission.

Issued: April 25, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–09026 Filed 4–28–23; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–TA–472 (Fifth Review)]

Silicon Metal From China; Institution of a Five-Year Review

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice that it has instituted a review pursuant to the Tariff Act of 1930 (''the Act''), as amended, to determine whether revocation of the antidumping duty order on silicon metal from China would be likely to lead to continuation or recurrence of material injury. Pursuant to the Act, interested parties are requested to respond to this notice by submitting the information specified below to the Commission.

DATES: Instituted May 1, 2023. To be assured of consideration, the deadline for responses is May 31, 2023. Comments on the adequacy of responses may be filed with the Commission by July 13, 2023.

FOR FURTHER INFORMATION CONTACT: Charles Cummings (202–708–1666), 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 June 10, 1991, the Department of Commerce (''Commerce'') issued an antidumping duty order on imports of silicon metal from China (56 FR 26649). Commerce issued a continuation of the antidumping duty order on imports of silicon metal from China following Commerce's and the Commission's first five-year reviews, effective February 16, 2001 (66 FR 10669), second five-year reviews, effective December 21, 2006 (71 FR 76636), third five-year reviews, effective April 20, 2012 (77 FR 23660), and fourth five-year reviews, effective June 4, 2018 (83 FR 25644). The Commission is now conducting a fifth review pursuant to section 751(c) of the Act, as amended (19 U.S.C. 1675(c)), to determine whether revocation of the order would be likely to lead to continuation or recurrence of material injury to the domestic industry within a reasonably foreseeable time. Provisions concerning the conduct of this proceeding may be found in the Commission's Rules of Practice and Procedure at 19 CFR part 201, subparts A and B, and 19 CFR part 207, subparts A and F. The Commission will assess the adequacy of interested party responses to this notice of institution to determine whether to conduct a full review or an expedited review. The Commission's determination in any expedited review will be based on the facts available, which may include information provided in response to this notice.

Definitions.—The following definitions apply to this review:

(1) *Subject Merchandise* is the class or kind of merchandise that is within the

scope of the five-year review, as defined by Commerce.

(2) The *Subject Country* in this review is China.

(3) The *Domestic Like Product* is the domestically produced product or products which are like, or in the absence of like, most similar in characteristics and uses with, the *Subject Merchandise.* In its original determination, the Commission defined the *Domestic Like Product* as all silicon metal, regardless of grade, having a silicon content of at least 96.00 percent but less than 99.99 percent of silicon by weight, and excluding semiconductor grade silicon, corresponding to Commerce's scope. In its full first and second five-year review determinations, its expedited third five-year review determination, and its full fourth five-year review determination, the Commission defined the *Domestic Like Product* as all silicon metal, regardless of grade, corresponding to Commerce's scope of the order.

(4) The *Domestic Industry* is the U.S. producers as a whole of the *Domestic Like Product,* or those producers whose collective output of the *Domestic Like Product* constitutes a major proportion of the total domestic production of the product. In its original determination, its full first and second five-year review determinations, its expedited third five-year review determination, and its full fourth five-year review determination, the Commission defined the *Domestic Industry* as all domestic producers of silicon metal.

(5) An *Importer* is any person or firm engaged, either directly or through a parent company or subsidiary, in importing the *Subject Merchandise* into the United States from a foreign manufacturer or through its selling agent.

Participation in the proceeding and public service list.—Persons, including industrial users of the *Subject Merchandise* and, if the merchandise is sold at the retail level, representative consumer organizations, wishing to participate in the proceeding as parties must file an entry of appearance with the Secretary to the Commission, as provided in § 201.11(b)(4) of the Commission's rules, no later than 21 days after publication of this notice in the **Federal Register**. The Secretary will maintain a public service list containing the names and addresses of all persons, or their representatives, who are parties to the proceeding.

Former Commission employees who are seeking to appear in Commission five-year reviews are advised that they may appear in a review even if they participated personally and substantially in the corresponding underlying original investigation or an earlier review of the same underlying investigation. The Commission's designated agency ethics official has advised that a five-year review is not the same particular matter as the underlying original investigation, and a five-year review is not the same particular matter as an earlier review of the same underlying investigation for purposes of 18 U.S.C. 207, the post-employment statute for Federal employees, and Commission rule 201.15(b) (19 CFR 201.15(b)), 79 FR 3246 (Jan. 17, 2014), 73 FR 24609 (May 5, 2008). Consequently, former employees are not required to seek Commission approval to appear in a review under Commission rule 19 CFR 201.15, even if the corresponding underlying original investigation or an earlier review of the same underlying investigation was pending when they were Commission employees. For further ethics advice on this matter, contact Charles Smith, Office of the General Counsel, at 202–205–3408.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and APO service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI submitted in this proceeding available to authorized applicants under the APO issued in the proceeding, provided that the application is made no later than 21 days after publication of this notice in the **Federal Register**. Authorized applicants must represent interested parties, as defined in 19 U.S.C. 1677(9), who are parties to the proceeding. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Certification.—Pursuant to § 207.3 of the Commission's rules, any person submitting information to the Commission in connection with this proceeding must certify that the information is accurate and complete to the best of the submitter's knowledge. In making the certification, the submitter will acknowledge that information submitted in response to this request for information and throughout this proceeding or other proceeding 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 personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements.

Written submissions.—Pursuant to § 207.61 of the Commission's rules, each interested party response to this notice must provide the information specified below. The deadline for filing such responses is May 31, 2023. Pursuant to § 207.62(b) of the Commission's rules, eligible parties (as specified in Commission rule 207.62(b)(1)) may also file comments concerning the adequacy of responses to the notice of institution and whether the Commission should conduct an expedited or full review. The deadline for filing such comments is July 13, 2023. All written submissions must conform with the provisions of § 201.8 of the Commission's rules; any submissions that contain BPI must also 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. Also, in accordance with §§ 201.16(c) and 207.3 of the Commission's rules, each document filed by a party to the proceeding must be served on all other parties to the proceeding (as identified by either the public or APO service list as appropriate), and a certificate of service must accompany the document (if you are not a party to the proceeding you do not need to serve your response).

Please note the Secretary's Office will accept only electronic filings at 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.

No response to this request for information is required if a currently valid Office of Management and Budget (''OMB'') number is not displayed; the OMB number is 3117 0016/USITC No. 23–5–566, expiration date June 30, 2023. Public reporting burden for the request is estimated to average 15 hours per response. Please send comments regarding the accuracy of this burden estimate to the Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436.

Inability to provide requested information.—Pursuant to § 207.61(c) of the Commission's rules, any interested party that cannot furnish the

information requested by this notice in the requested form and manner shall notify the Commission at the earliest possible time, provide a full explanation of why it cannot provide the requested information, and indicate alternative forms in which it can provide equivalent information. If an interested party does not provide this notification (or the Commission finds the explanation provided in the notification inadequate) and fails to provide a complete response to this notice, the Commission may take an adverse inference against the party pursuant to § 776(b) of the Act (19 U.S.C. 1677e(b)) in making its determination in the review.

Information To Be Provided in Response to This Notice of Institution: As used below, the term ''firm'' includes any related firms.

Those responding to this notice of institution are encouraged, but not required, to visit the USITC's website at *https://usitc.gov/reports/response_noi_worksheet,* where one can download and complete the ''NOI worksheet'' Excel form for the subject proceeding, to be included as attachment/exhibit 1 of your overall response.

(1) The name and address of your firm or entity (including World Wide Web address) and name, telephone number, fax number, and Email address of the certifying official.

(2) A statement indicating whether your firm/entity is an interested party under 19 U.S.C. 1677(9) and if so, how, including whether your firm/entity is a U.S. producer of the *Domestic Like Product,* a U.S. union or worker group, a U.S. importer of the *Subject Merchandise,* a foreign producer or exporter of the *Subject Merchandise,* a U.S. or foreign trade or business association (a majority of whose members are interested parties under the statute), or another interested party (including an explanation). If you are a union/worker group or trade/business association, identify the firms in which your workers are employed or which are members of your association.

(3) A statement indicating whether your firm/entity is willing to participate in this proceeding by providing information requested by the Commission.

(4) A statement of the likely effects of the revocation of the antidumping duty order on the *Domestic Industry* in general and/or your firm/entity specifically. In your response, please discuss the various factors specified in section 752(a) of the Act (19 U.S.C. 1675a(a)) including the likely volume of subject imports, likely price effects of subject imports, and likely impact of imports of *Subject Merchandise* on the *Domestic Industry.*

(5) A list of all known and currently operating U.S. producers of the *Domestic Like Product.* Identify any known related parties and the nature of the relationship as defined in § 771(4)(B) of the Act (19 U.S.C. 1677(4)(B)).

(6) A list of all known and currently operating U.S. importers of the *Subject Merchandise* and producers of the *Subject Merchandise* in the *Subject Country* that currently export or have exported *Subject Merchandise* to the United States or other countries after 2016.

(7) A list of 3–5 leading purchasers in the U.S. market for the *Domestic Like Product* and the *Subject Merchandise* (including street address, World Wide Web address, and the name, telephone number, fax number, and Email address of a responsible official at each firm).

(8) A list of known sources of information on national or regional prices for the *Domestic Like Product* or the *Subject Merchandise* in the U.S. or other markets.

(9) If you are a U.S. producer of the *Domestic Like Product,* provide the following information on your firm's operations on that product during calendar year 2016, except as noted (report quantity data in short tons and value data in U.S. dollars, f.o.b. plant). If you are a union/worker group or trade/business association, provide the information, on an aggregate basis, for the firms in which your workers are employed/which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total U.S. production of the *Domestic Like Product* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm to produce the *Domestic Like Product* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for downtime, maintenance, repair, and cleanup, and a typical or representative product mix);

(c) the quantity and value of U.S. commercial shipments of the *Domestic Like Product* produced in your U.S. plant(s);

(d) the quantity and value of U.S. internal consumption/company transfers of the *Domestic Like Product* produced in your U.S. plant(s); and

(e) the value of (i) net sales, (ii) cost of goods sold (COGS), (iii) gross profit, (iv) selling, general and administrative (SG&A) expenses, and (v) operating income of the *Domestic Like Product* produced in your U.S. plant(s) (include both U.S. and export commercial sales, internal consumption, and company transfers) for your most recently completed fiscal year (identify the date on which your fiscal year ends).

(10) If you are a U.S. importer or a trade/business association of U.S. importers of the *Subject Merchandise* from the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2022 (report quantity data in short tons and value data in U.S. dollars). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) The quantity and value (landed, duty-paid but not including antidumping duties) of U.S. imports and, if known, an estimate of the percentage of total U.S. imports of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') imports;

(b) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. commercial shipments of *Subject Merchandise* imported from the *Subject Country;* and

(c) the quantity and value (f.o.b. U.S. port, including antidumping duties) of U.S. internal consumption/company transfers of *Subject Merchandise* imported from the *Subject Country.*

(11) If you are a producer, an exporter, or a trade/business association of producers or exporters of the *Subject Merchandise* in the *Subject Country,* provide the following information on your firm's(s') operations on that product during calendar year 2022 (report quantity data in short tons and value data in U.S. dollars, landed and duty-paid at the U.S. port but not including antidumping duties). If you are a trade/business association, provide the information, on an aggregate basis, for the firms which are members of your association.

(a) Production (quantity) and, if known, an estimate of the percentage of total production of *Subject Merchandise* in the *Subject Country* accounted for by your firm's(s') production;

(b) Capacity (quantity) of your firm(s) to produce the *Subject Merchandise* in the *Subject Country* (that is, the level of production that your establishment(s) could reasonably have expected to attain during the year, assuming normal operating conditions (using equipment and machinery in place and ready to operate), normal operating levels (hours per week/weeks per year), time for

downtime, maintenance, repair, and cleanup, and a typical or representative product mix); and

(c) the quantity and value of your firm's(s') exports to the United States of *Subject Merchandise* and, if known, an estimate of the percentage of total exports to the United States of *Subject Merchandise* from the *Subject Country* accounted for by your firm's(s') exports.

(12) Identify significant changes, if any, in the supply and demand conditions or business cycle for the *Domestic Like Product* that have occurred in the United States or in the market for the *Subject Merchandise* in the *Subject Country* after 2016, and significant changes, if any, that are likely to occur within a reasonably foreseeable time. Supply conditions to consider include technology; production methods; development efforts; ability to increase production (including the shift of production facilities used for other products and the use, cost, or availability of major inputs into production); and factors related to the ability to shift supply among different national markets (including barriers to importation in foreign markets or changes in market demand abroad). Demand conditions to consider include end uses and applications; the existence and availability of substitute products; and the level of competition among the *Domestic Like Product* produced in the United States, *Subject Merchandise* produced in the *Subject Country,* and such merchandise from other countries.

(13) (OPTIONAL) A statement of whether you agree with the above definitions of the *Domestic Like Product* and *Domestic Industry;* if you disagree with either or both of these definitions, please explain why and provide alternative definitions.

Authority: This proceeding is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to § 207.61 of the Commission's rules.

By order of the Commission.

Issued: April 25, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–09023 Filed 4–28–23; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 731–1330 (Review)]

Dioctyl Terephthalate From South Korea; Cancellation of Hearing for Full Five-Year Review

AGENCY: International Trade Commission.

ACTION: Notice.

DATES: April 25, 2023.

FOR FURTHER INFORMATION CONTACT: Christopher Robinson ((202) 205–2602), Office of Industry and Competitive Analysis, 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 (*http://www.usitc.gov*). The public record for this review may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION: On December 16, 2022, the Commission established a schedule for the conduct of the full five-year review (87 FR 78708, December 22, 2022). On April 18, 2023, counsel for Eastman Chemical Company filed a request that the Commission cancel the scheduled hearing for this review given the lack of respondent interested party participation. On April 21, 2023, counsel for Eastman Chemical Company filed a request to appear at the hearing, contingent on the Commission's response to the request to cancel the hearing. Counsel indicated a willingness to respond to any Commission questions. No other party submitted a request to appear at the hearing. Consequently, the public hearing in connection with this review, scheduled to begin at 9:30 a.m. on Thursday, April 27, 2023, is cancelled. Parties to this review should respond to any written questions posed by the Commission in their posthearing briefs, which are due to be filed on May 5, 2023.

For further information concerning this review see the Commission's notice cited above and 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).

Authority: This review is being conducted under authority of title VII of the Tariff Act of 1930; this notice is published pursuant to section 207.62 of the Commission's rules.

By order of the Commission.

Issued: April 26, 2023.

Lisa Barton,

Secretary to the Commission.

[FR Doc. 2023–09137 Filed 4–28–23; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

[OMB Number 1121–0064]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Revision of a Currently Approved Collection; Annual Surveys of Probation and Parole

AGENCY: Bureau of Justice Statistics, Department of Justice.

ACTION: 60-day notice.

SUMMARY: The Department of Justice (DOJ), Office of Justice Programs, Bureau of Justice Statistics, will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995.

DATES: Comments are encouraged and will be accepted for 60 days until June 30, 2023.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Danielle Kaeble, Bureau of Justice Statistics, 810 Seventh Street NW, Washington, DC 20531 (email: *Danielle.Kaeble@usdoj.gov;* telephone: 202–598–1024).

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Bureau of Justice Statistics, including whether the information will have practical utility;

—Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information,

including the validity of the methodology and assumptions used;
—Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
—Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Abstract: These establishment surveys provide BJS with the capacity to report annually on changes in the size and composition of the community corrections populations in the United States. The surveys also track key outcomes of offenders on probation or parole, such as completion of supervision terms and return to incarceration (or recidivism). Data are collected from the known universe of probation and parole supervising agencies, using central reporters wherever possible to minimize burden the public. The ASPP provides the only national level, regularly collected, data on the community corrections populations, and, as such, they inform this key stage of the criminal justice process. Revisions include an updated frame of probation agencies including additional misdemeanor only supervising agencies, as well changes to the probation survey forms (CJ–8 and CJ–8M) to collect information separately for felony and misdemeanant probation.

Overview of this information collection:

1. *Type of Information Collection:* Revision of a previously approved collection.

2. *The Title of the Form/Collection:* Annual Surveys of Probation and Parole.

3. *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The Annual Surveys of Probation and Parole (ASPP) contain three forms: CJ–7: Annual Parole Survey CJ–8: Annual Probation Survey and CJ–8M: Annual Probation Survey (Misdemeanant Supervision Only). The applicable component within the Department of Justice is the Bureau of Justice Statistics (BJS), in the Office of Justice Programs.

4. *Affected public who will be asked or required to respond as well as the obligation:* The affected public is Federal Government. The obligation to respond is voluntary.

5. *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The ASPP will collect data from approximately 860 supervising agencies. The ASPP will collect data from approximately 860 supervising agencies. For each data collection cycle, we estimate an average burden of 96 minutes for the survey form CJ–7, 150 minutes for the updated survey form CJ–8, and 20 minutes for the updated survey form CJ–M. If needed, respondents to the CJ–7 and CJ–8 will be contacted by email or telephone to verify data quality issues. We estimate that data quality follow-up is needed for 70% of the CJ–7 and CJ–8 respondents (213) in each cycle and will run an average of 15 minutes for each respondent. We estimate a 10-minute follow-up for half (304) of the CJ–8M respondents.

6. *An estimate of the total public burden (in hours) associated with the collection:* There are approximately 3,015 hours, annual burden, associated with this information collection (1,005 per three years).

TOTAL BURDEN HOURS

Activity	Number of respondents	Frequency	Total annual responses	Time per response	Total annual burden (hours)
Survey	860	1	860	3.506	3,015
Unduplicated Totals	860		860	3,015	3,015

If additional information is required contact: John R. Carlson, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE, 4W–218, Washington, DC 20530.

Dated: April 25, 2023.

John R. Carlson,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2023–09190 Filed 4–28–23; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Claim for Reimbursement of Benefit Payments and Claims Expense Under the War Hazards Compensation Act

ACTION: Notice of availability; request for comments.

SUMMARY: The Department of Labor (DOL) is submitting this Office of Workers' Compensation Programs (OWCP)-sponsored information collection request (ICR) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995 (PRA). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that the agency receives on or before May 31, 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.

Comments are invited on: (1) whether the collection of information is necessary for the proper performance of the functions of the Department, including whether the information will have practical utility; (2) the accuracy of the agency's estimates of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of

automated collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT: Nicole Bouchet by telephone at 202–693–0213, or by email at *DOL_PRA_PUBLIC@dol.gov.*

SUPPLEMENTARY INFORMATION: Information collected using OWCP Form CA–278, Claim for Reimbursement of Benefit Payments and Claims Expense Under the War Hazards Compensation Act, will allow OWCP to consider requests filed by insurance carriers and self-insured that have paid benefits to workers injured due to a war-risk hazard to be reimbursed for such benefits out of the Employees' Compensation Fund. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on January 30, 2023 (88 FR 5926).

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless the OMB approves it and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid OMB Control Number. See 5 CFR 1320.5(a) and 1320.6.

DOL seeks PRA authorization for this information collection for three (3) years. OMB authorization for an ICR cannot be for more than three (3) years without renewal. The DOL notes that information collection requirements submitted to the OMB for existing ICRs receive a month-to-month extension while they undergo review.

Agency: DOL–OWCP.

Title of Collection: Claim for Reimbursement of Benefit Payments and Claims Expense Under the War Hazards Compensation Act.

OMB Control Number: 1240–0006.

Affected Public: Private Sector—Businesses or other for-profits.

Total Estimated Number of Respondents: 7.

Total Estimated Number of Responses: 1,264.

Total Estimated Annual Time Burden: 632 hours.

Total Estimated Annual Other Costs Burden: $2,427.

(Authority: 44 U.S.C. 3507(a)(1)(D))

Nicole Bouchet,

Senior PRA Analyst.

[FR Doc. 2023–09119 Filed 4–28–23; 8:45 am]

BILLING CODE 4510–26–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA–2023–0004]

Traylor Bros., Inc.; Application for Modification of Permanent Variance and Interim Order; Grant of Interim Order

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Notice; request for comments.

SUMMARY: In this notice, OSHA announces an application for modification of a permanent variance and for an interim order submitted by Traylor Bros., Inc. (Traylor). The application seeks to modify a permanent variance relating to work in compressed-air environments previously granted to Traylor to add Traylor-Sundt Joint Venture (SUNDTJV) as an additional employer and to add the Integrated Pipeline Tunnel Project. Traylor also requests an interim order to be effective until OSHA issues a final decision on the application. This notice presents the agency's preliminary findings on Traylor's application and announces the granting of an interim order. OSHA invites the public to submit comments on the variance modification application to assist the agency in determining whether to grant the applicant a modified permanent variance based on the conditions specified in this application.

DATES: Submit comments, information, documents in response to this notice, and request for a hearing on or before May 31, 2023. The Interim Order described in this notice will become effective on May 1, 2023, and shall remain in effect until the completion of the Integrated Pipeline Tunnel Project, the interim order is modified or revoked, or OSHA makes a final decision on the application for a modified permanent variance.

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.

Facsimile: If your comments, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693–1648.

Instructions: All submissions must include the agency name and OSHA docket number (OSHA–2023–0004). All comments, including any personal information you provide, are placed in the public docket without change, and may be made available online at *http://www.regulations.gov.*

Docket: To read or download comments or other material in the docket, go to *http://www.regulations.gov* or the OSHA Docket Office. All documents in the docket (including this **Federal Register** notice) are listed in the *http://www.regulations.gov* index; however, some information (*e.g.,* copyrighted material) is not publicly available to read or download through the website. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Contact the OSHA Docket Office at (202) 693–2350 (TTY (877) 889–5627) for assistance in locating docket submissions.

FOR FURTHER INFORMATION CONTACT: Information regarding this notice is available from the following sources:

Press inquiries: Contact Mr. Frank Meilinger, Director, OSHA Office of Communications, U.S. Department of Labor; telephone: (202) 693–1999; email: *meilinger.francis2@dol.gov.*

General and technical information: Contact Mr. Kevin Robinson, Director, Office of Technical Programs and Coordination Activities, Directorate of Technical Support and Emergency Management, Occupational Safety and Health Administration, U.S. Department of Labor; telephone: (202) 693–2110; email: *robinson.kevin@dol.gov.*

Copies of this ***Federal Register*** *notice:* Electronic copies of this **Federal Register** notice are available at *http://www.regulations.gov.* This **Federal Register** notice, as well as news releases and other relevant information, also are available at OSHA's web page at *http://www.osha.gov.*

Hearing Requests: According to 29 CFR 1905.15, hearing requests must include: (1) a concise statement of facts detailing how the proposed variance modification would affect the requesting party; (2) a specification of any statement or representation in the variance application that the commenter denies, and a concise summary of the evidence offered in support of each denial; and (3) any views or arguments on any issue of fact or law presented in the variance application.

SUPPLEMENTARY INFORMATION:

I. Notice of Application

This notice addresses Traylor's application by letter dated April 20, 2022, to modify the permanent variance granted to Traylor on March 11, 2016 (2016 Variance) (81 FR 12954), to include an additional employer, the

Traylor-Sundt Joint Venture (SUNDTJV), which is a joint venture made up of two construction companies, Traylor and Sundt Construction, Inc. (Sundt). Traylor also requested an interim order while OSHA evaluates the application (OSHA–2023–0004–0002). Because the joint venture includes an additional employer not covered by the 2016 Variance, OSHA will evaluate SUNDTJV's modification request as an application for a new permanent variance.

SUNDTJV was awarded the tunneling contract for the Integrated Pipeline Tunnel Project in Dallas, Texas (OSHA–2023–0004–0001). The Integrated Pipeline Tunnel Project includes two tunnels, the Cedar Creek Tunnel, and the Hollywood Lake Tunnel, which require two separate tunnel drives. This notice covers the Integrated Pipeline Tunnel Project only and is not applicable to future tunneling projects by Traylor, Sundt, or SUNDTJV.

Specifically, this notice addresses the application by Traylor (the applicant) for a permanent variance and interim order from the provisions of the standard governing compressed air work that: (1) prohibit compressed-air worker exposure to pressures exceeding 50 pounds per square inch (p.s.i.) except in an emergency (29 CFR 1926.803(e)(5)); [1] (2) require the use of the decompression values specified in decompression tables in Appendix A of the compressed-air standard for construction (29 CFR 1926.803(f)(1)); and (3) require the use of automated operational controls and a special decompression chamber (29 CFR 1926.803(g)(1)(iii) and .803(g)(1)(xvii), respectively).

OSHA has previously approved nearly identical provisions when granting several other very similar variances, as discussed in more detail in section II. OSHA preliminarily concludes that the variance is appropriate, grants an interim order temporarily allowing the proposed activity, and seeks comment on the variance application.

A. Background

The variance application seeks a permanent variance for Traylor-Sundt Joint Venture (SUNDTJV)'s work on the Integrated Pipeline Tunnel Project. SUNDTJV is a contractor that works on complex tunnel projects using innovations in tunnel-excavation methods. SUNDTJV's workers engage in the construction of tunnels using advanced shielded mechanical excavation techniques in conjunction with an earth pressure balance tunnel boring machine (TBM). Using shielded mechanical excavation techniques, in conjunction with precast concrete tunnel liners and backfill grout, TBMs provide methods to achieve the face pressures required to maintain a stabilized tunnel face through various geologies and isolate that pressure to the forward section (the working chamber) of the TBM.

SUNDTJV asserts that it bores tunnels using TBM at levels below the water table through soft soils consisting of clay, silt, and sand. TBMs are capable of maintaining pressure at the tunnel face, and stabilizing existing geological conditions, through the controlled use of a mechanically driven cutter head, bulkheads within the shield, ground-treatment foam, and a screw conveyor that moves excavated material from the working chamber. The forward-most portion of the TBM is the working chamber, and this chamber is the only pressurized segment of the TBM. Within the shield, the working chamber consists of two sections: the forward working chamber and the staging chamber. The forward working chamber is immediately behind the cutter head and tunnel face. The staging chamber is behind the forward working chamber and between the man-lock door and the entry door to the forward working chamber.

The TBM has twin man-locks located between the pressurized working chamber and the non-pressurized portion of the machine. Each man-lock has two compartments. This configuration allows workers to access the man-locks for compression and decompression, and medical personnel to access the man-locks if required in an emergency.

SUNDTJV's Hyperbaric Operations Manual (HOM) for the Integrated Pipeline Tunnel Project (OSHA–2023–0004–0003) indicates that the maximum pressure to which it is likely to expose workers during project interventions for the two tunnel drives (Cedar Creek Tunnel and Hollywood Lake Tunnel) associated with the Integrated Pipeline Tunnel Project is 58 p.s.i. Therefore, to work effectively, SUNDTJV must perform hyperbaric interventions in compressed air at pressures nearly 15% higher than the maximum pressure specified by the existing OSHA standard, 29 CFR 1926.803(e)(5), which states: ''No employee shall be subjected to pressure exceeding 50 pounds per square inch except in emergency'' (see footnote 1).

SUNDTJV employs specially trained personnel for the construction of the tunnel. To keep the machinery working effectively, SUNDTJV asserts that these workers must periodically enter the excavation working chamber of the TBM to perform hyperbaric interventions during which workers would be exposed to air pressures up to 58 p.s.i., which exceeds the maximum pressure specified by the existing OSHA standard at 29 CFR 1926.803(e)(5). These interventions consist of conducting inspections or maintenance work on the cutter-head structure and cutting tools of the TBM, such as changing replaceable cutting tools and disposable wear bars, and, in rare cases, repairing structural damage to the cutter head. These interventions are the only time that workers are exposed to compressed air. Interventions in the working chamber (the pressurized portion of the TBM) take place only after halting tunnel excavation and preparing the machine and crew for an intervention.

During interventions, workers enter the working chamber through one of the twin man-locks that open into the staging chamber. To reach the forward part of the working chamber, workers pass through a door in a bulkhead that separates the staging chamber from the forward working chamber. The man-locks and the working chamber are designed to accommodate three people, which is the maximum crew size allowed under the proposed variance. When the required decompression times are greater than work times, the twin man-locks allow for crew rotation. During crew rotation, one crew can be compressing or decompressing while the second crew is working. Therefore, the working crew always has an unoccupied man-lock at its disposal.

SUNDTJV asserts that these innovations in tunnel excavation have greatly reduced worker exposure to hazards of pressurized air work because they have eliminated the need to pressurize the entire tunnel for the project and would thereby reduce the number of workers exposed, as well as the total duration of exposure, to hyperbaric pressure during tunnel construction. These advances in technology substantially modified the methods used by the construction industry to excavate subaqueous tunnels compared to caisson work.

In addition to the reduced exposures resulting from the innovations in tunnel-excavation methods, SUNDTJV asserts that innovations in hyperbaric medicine and technology improve the

[1] The decompression tables in Appendix A of subpart S express the maximum working pressures as pounds per square inch gauge (p.s.i.g.), with a maximum working pressure of 50 p.s.i.g. Therefore, throughout this notice, OSHA expresses the 50 p.s.i. value specified by 29 CFR 1926.803(e)(5) as 50 p.s.i.g., consistent with the terminology in Appendix A, Table 1 of subpart S.

safety of decompression from hyperbaric exposures. These procedures, however, would deviate from the decompression process that OSHA requires for construction in 29 CFR 1926.803(e)(5) and (f)(1) and the decompression tables in Appendix A of 29 CFR 1926, subpart S. Nevertheless, according to SUNDTJV, their use of decompression protocols incorporating oxygen is more efficient, effective, and safer for tunnel workers than compliance with the decompression tables specified by the existing OSHA standard.

SUNDTJV therefore believes its workers will be at least as safe under its proposed alternatives as they would be under OSHA's standard because of the reduction in number of workers and duration of hyperbaric exposures, better application of hyperbaric medicine, and the development of a project-specific HOM that requires specialized medical support and hyperbaric supervision to provide assistance to a team of specially trained man-lock attendants and hyperbaric or compressed-air workers (CAWs).

Based on an initial review of the application for a permanent variance and interim order for the construction of the Integrated Pipeline Tunnel Project in Dallas, Texas, OSHA has preliminarily determined that Traylor has proposed an alternative that would provide a workplace at least as safe and healthful as that provided by the standard.

II. The Variance Application

Pursuant to the requirements of OSHA's variance regulations (29 CFR part 1905), the applicant has certified that it notified its workers [2] of the variance modification application and request for interim order by posting, at prominent locations where it normally posts workplace notices, a summary of the application and information specifying where the workers can examine a copy of the application.

A. OSHA History of Approval of Nearly Identical Variance Requests

OSHA has previously approved several nearly identical variances involving the same types of tunneling equipment used for similar projects (tunnel construction variances). OSHA notes that it granted seven subaqueous tunnel construction permanent variances from the same provisions of OSHA's compressed-air standard (29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii)) that are the subject of the present application: (1) Impregilo, Healy, Parsons, Joint Venture (IHP JV) for the completion of the Anacostia River Tunnel in Washington, DC (80 FR 50652, August 20, 2015); (2) Traylor JV for the completion of the Blue Plains Tunnel in Washington, DC (80 FR 16440, March 27, 2015); (3) Tully/OHL USA Joint Venture for the completion of the New York Economic Development Corporation's New York Siphon Tunnel project (79 FR 29809, May 23, 2014); (4) Salini-Impregilo/Healy Joint Venture for the completion of the Northeast Boundary Tunnel in Washington, DC (85 FR 27767, May 11, 2020); (5) Traylor-Shea Joint Venture for the completion of the Alexandria RiverRenew Tunnel Project in Alexandria, Virginia and Washington, DC (88 FR 15090, March 10, 2023); and (6) McNally/Kiewit Joint Venture for the completion of the Shoreline Storage Tunnel Project in Cleveland, Ohio (88 FR 15080, September 25, 2022). OSHA also granted an interim order to Ballard Marine for the Suffolk County Outfall Tunnel project in West Babylon, New York (86 FR 5253, January 19, 2021). The proposed alternate conditions in this notice are nearly identical to the alternate conditions of the previous permanent variances. OSHA is not aware of any injuries or other safety issues that arose from work performed under these conditions in accordance with the previous variances.

B. Variance From Paragraph (e)(5) of 29 CFR 1926.803, Prohibition of Exposure to Pressure Greater Than 50 p.s.i.

The applicant states that it may perform hyperbaric interventions at pressures up to 58 p.s.i. in the working chamber of the TBM; this pressure exceeds the pressure limit of 50 p.s.i. specified for nonemergency purposes by 29 CFR 1926.803(e)(5). The TBM has twin man-locks, with each man-lock having two compartments. This configuration allows workers to access the man-locks for compression and decompression, and medical personnel to access the man-locks if required in an emergency.

TBMs are capable of maintaining pressure at the tunnel face, and stabilizing existing geological conditions, through the controlled use of a mechanically driven cutter head, bulkheads within the shield, ground-treatment foam, and a screw conveyor that moves excavated material from the working chamber. As noted earlier, the forward-most portion of the TBM is the working chamber, and this chamber is the only pressurized segment of the TBM. Within the shield, the working chamber consists of two sections: the staging chamber and the forward working chamber. The staging chamber is the section of the working chamber between the man-lock door and the entry door to the forward working chamber. The forward working chamber is immediately behind the cutter head and tunnel face.

SUNDTJV will pressurize the working chamber to the level required to maintain a stable tunnel face. Pressure in the staging chamber ranges from atmospheric (no increased pressure) to a maximum pressure equal to the pressure in the working chamber. The applicant asserts that they may have to perform interventions at pressures up to 58 p.s.i.

During interventions, workers enter the working chamber through one of the twin man-locks that open into the staging chamber. To reach the forward part of the working chamber, workers pass through a door in a bulkhead that separates the staging chamber from the forward working chamber. The maximum crew size allowed in the forward working chamber is three. At certain hyperbaric pressures (*i.e.,* when decompression times are greater than work times), the twin man-locks allow for crew rotation. During crew rotation, one crew can be compressing or decompressing while the second crew is working. Therefore, the working crew always has an unoccupied man-lock at its disposal.

Further, the applicant has developed a project-specific HOM (OSHA–2023–0004–0003) that describes in detail the hyperbaric procedures, the required medical examination used during the tunnel-construction project, the standard operating procedures and the emergency and contingency procedures. The procedures include using experienced and knowledgeable man-lock attendants who have the training and experience necessary to recognize and treat decompression illnesses and injuries. The attendants are under the direct supervision of the hyperbaric supervisor (competent person experienced and trained in hyperbaric operations, procedures and safety) and attending physician. In addition, procedures include medical screening and review of prospective CAWs. The purpose of this screening procedure is to vet prospective CAWs with medical conditions (*e.g.,* deep vein thrombosis, poor vascular circulation, and muscle cramping) that could be aggravated by sitting in a cramped space (*e.g.,* a man-lock) for extended periods or by exposure to elevated pressures and compressed gas mixtures. A transportable recompression chamber (shuttle) is available to extract workers from the hyperbaric working chamber

[2] See the definition of ''Affected employee or worker'' in section V.D of this notice.

for emergency evacuation and medical treatment; the shuttle attaches to the topside medical lock, which is a large recompression chamber. The applicant believes that the procedures included in the HOM provide safe work conditions when interventions are necessary, including interventions above 50 p.s.i. or 50 p.s.i.g.

OSHA comprehensively reviewed the project-specific HOM and determined that the safety and health instructions and measures it specifies are appropriate and adequately protect the safety and health of the CAWs.

C. Variance From Paragraph (f)(1) of 29 CFR 1926.803, Requirement To Use OSHA Decompression Tables

OSHA's compressed-air standard for construction requires decompression in accordance with the decompression tables in Appendix A of 29 CFR 1926, subpart S (see 29 CFR 1926.803(f)(1)). As an alternative to the OSHA decompression tables, the applicant proposes to use newer decompression schedules (the 1992 French Decompression Tables) that rely on staged decompression and supplement breathing air used during decompression with air or oxygen (as appropriate).[3] The applicant asserts decompression protocols using the 1992 French Decompression Tables for air or oxygen as specified by the Integrated Pipeline Tunnel Project-specific HOM are safer for tunnel workers than the decompression protocols specified in Appendix A of 29 CFR 1926, subpart S. Accordingly, the applicant would commit to following the decompression procedures described in that HOM, which would require it to follow the 1992 French Decompression Tables to decompress CAWs after they exit the hyperbaric conditions in the working chamber.

Depending on the maximum working pressure and exposure times, the 1992 French Decompression Tables provide for air decompression with or without oxygen. Traylor asserts that oxygen decompression has many benefits, including (1) keeping the partial pressure of nitrogen in the lungs as low as possible; (2) keeping external pressure as low as possible to reduce the formation of bubbles in the blood; (3) removing nitrogen from the lungs and arterial blood and increasing the rate of nitrogen elimination; (4) improving the quality of breathing during decompression stops so that workers are less tired and to prevent bone necrosis; (5) reducing decompression time by about 33 percent as compared to air decompression; and (6) reducing inflammation.

In addition, the project-specific HOM requires a physician certified in hyperbaric medicine, to manage the medical condition of CAWs during hyperbaric exposures and decompression. A trained and experienced man-lock attendant is also required to be present during hyperbaric exposures and decompression. This man-lock attendant is to operate the hyperbaric system to ensure compliance with the specified decompression table. A hyperbaric supervisor, who is trained in hyperbaric operations, procedures, and safety, directly oversees all hyperbaric interventions and ensures that staff follow the procedures delineated in the HOM or by the attending physician.

D. Variance From Paragraph (g)(1)(iii) of 29 CFR 1926.803, Automatically Regulated Continuous Decompression

The applicant is applying for a permanent variance from the OSHA standard at 29 CFR 1926.803(g)(1)(iii), which requires automatic controls to regulate decompression. As noted above, the applicant is committed to conducting the staged decompression according to the 1992 French Decompression Tables under the direct control of the trained man-lock attendant and under the oversight of the hyperbaric supervisor.

Breathing air under hyperbaric conditions increases the amount of nitrogen gas dissolved in a CAW's tissues. The greater the hyperbaric pressure under these conditions and the more time spent under the increased pressure, the greater the amount of nitrogen gas dissolved in the tissues. When the pressure decreases during decompression, tissues release the dissolved nitrogen gas into the blood system, which then carries the nitrogen gas to the lungs for elimination through exhalation. Releasing hyperbaric pressure too rapidly during decompression can increase the size of the bubbles formed by nitrogen gas in the blood system, resulting in decompression illness (DCI), commonly referred to as ''the bends.'' This description of the etiology of DCI is consistent with current scientific theory and research on the issue.

The 1992 French Decompression Tables proposed for use by the applicant provide for stops during worker decompression (*i.e.,* staged decompression) to control the release of nitrogen gas from tissues into the blood system. Studies show that staged decompression, in combination with other features of the 1992 French Decompression Tables such as the use of oxygen, result in a lower incidence of DCI than the use of automatically regulated continuous decompression.[4] In addition, the applicant asserts that staged decompression administered in accordance with its HOM is at least as effective as an automatic controller in regulating the decompression process because the HOM includes a hyperbaric supervisor who directly supervises all hyperbaric interventions and ensures that the man-lock attendant, who is a competent person in the manual control of hyperbaric systems, follows the schedule specified in the decompression tables, including stops.

E. Variance From Paragraph (g)(1)(xvii) of 29 CFR 1926.803, Requirement of Special Decompression Chamber

The OSHA compressed-air standard for construction requires employers to use a special decompression chamber of sufficient size to accommodate all CAWs being decompressed at the end of the shift when total decompression time exceeds 75 minutes (see 29 CFR 1926.803(g)(1)(xvii)). Use of the special decompression chamber enables CAWs to move about and flex their joints to prevent neuromuscular problems during decompression.

Space limitations in the TBM do not allow for the installation and use of an

[3] In 1992, the French Ministry of Labour replaced the 1974 French Decompression Tables with the 1992 French Decompression Tables, which differ from OSHA's decompression tables in Appendix A by using: (1) staged decompression as opposed to continuous (linear) decompression; (2) decompression tables based on air or both air and pure oxygen; and (3) emergency tables when unexpected exposure times occur (up to 30 minutes above the maximum allowed working time).

[4] See, *e.g.,* Dr. Eric Kindwall, EP (1997), Compressed air tunneling and caisson work decompression procedures: development, problems, and solutions. *Undersea and Hyperbaric Medicine,* 24(4), pp. 337–345. This article reported 60 treated cases of DCI among 4,168 exposures between 19 and 31 p.s.i.g. over a 51-week contract period, for a DCI incidence of 1.44% for the decompression tables specified by the OSHA standard. Dr. Kindwall notes that the use of automatically regulated continuous decompression in the Washington State safety standards for compressed-air work (from which OSHA derived its decompression tables) was at the insistence of contractors and the union, and against the advice of the expert who calculated the decompression table and recommended using staged decompression. Dr. Kindwall then states, ''Continuous decompression is inefficient and wasteful. For example, if the last stage from 4 p.s.i.g. . . . to the surface took 1h, at least half the time is spent at pressures less than 2 p.s.i.g. . . ., which provides less and less meaningful bubble suppression. . . .'' In addition, Dr. Kindwall addresses the continuous-decompression protocol in the OSHA compressed-air standard for construction, noting that ''[a]side from the tables for saturation diving to deep depths, no other widely used or officially approved diving decompression tables use straight line, continuous decompressions at varying rates. Stage decompression is usually the rule, since it is simpler to control.''

additional special decompression lock or chamber. The applicant proposes that it be permitted to rely on the man-locks and staging chamber in lieu of adding a separate, special decompression chamber. Because only a few workers out of the entire crew are exposed to hyperbaric pressure, the man-locks (which, as noted earlier, connect directly to the working chamber) and the staging chamber are of sufficient size to accommodate all of the exposed workers during decompression. The applicant uses the existing man-locks, each of which adequately accommodates a three-member crew for this purpose when decompression lasts up to 75 minutes. When decompression exceeds 75 minutes, crews can open the door connecting the two compartments in each man-lock (during decompression stops) or exit the man-lock and move into the staging chamber where additional space is available. The applicant asserts that this alternative arrangement is as effective as a special decompression chamber in that it has sufficient space for all the CAWs at the end of a shift and enables the CAWs to move about and flex their joints to prevent neuromuscular problems.

III. Agency Preliminary Determinations

After reviewing the proposed alternatives, OSHA has preliminarily determined that the applicant's proposed alternatives on the whole, subject to the conditions in the request and imposed by this interim order, provide measures that are as safe and healthful as those required by the cited OSHA standards addressed in section II of this notice.

In addition, OSHA has preliminarily determined that each of the following alternatives are at least as effective as the specified OSHA requirements:

A. 29 CFR 1926.803(e)(5)

SUNDTJV has developed, and proposed to implement, effective alternative measures to the prohibition of using compressed air under hyperbaric conditions exceeding 50 p.s.i. The proposed alternative measures include use of engineering and administrative controls of the hazards associated with work performed in compressed-air conditions exceeding 50 p.s.i. while engaged in the construction of a subaqueous tunnel using advance shielded mechanical-excavation techniques in conjunction with the TBM. Prior to conducting interventions in the TBM's pressurized working chamber, SUNDTJV halts tunnel excavation and prepares the machine and crew to conduct the interventions. Interventions involve inspection, maintenance, or repair of the mechanical-excavation components located in the working chamber.

B. 29 CFR 1926.803(f)(1)

SUNDJV has proposed to implement equally effective alternative measures to the requirement in 29 CFR 1926.803(f)(1) for compliance with OSHA's decompression tables. The project-specific HOM specifies the procedures and personnel qualifications for performing work safely during the compression and decompression phases of interventions. The HOM also specifies the decompression tables the applicant proposes to use (the 1992 French Decompression Tables). Depending on the maximum working pressure and exposure times during the interventions, the tables provide for decompression using air, pure oxygen, or a combination of air and oxygen. The decompression tables also include delays or stops for various time intervals at different pressure levels during the transition to atmospheric pressure (*i.e.,* staged decompression). In all cases, a physician certified in hyperbaric medicine will manage the medical condition of CAWs during decompression. In addition, a trained and experienced man-lock attendant, experienced in recognizing decompression sickness or illnesses and injuries, will be present. Of key importance, a hyperbaric supervisor, trained in hyperbaric operations, procedures, and safety, will directly supervise all hyperbaric operations to ensure compliance with the procedures delineated in the project-specific HOM or by the attending physician.

Prior to granting the seven previous permanent variances to IHP JV, Traylor JV, Tully JV, Salini-Impregilo Joint Venture, Traylor-Shea JV and McNally/Kiewit JV and Ballard, OSHA conducted a review of the scientific literature and concluded that the alternative decompression method (*i.e.,* the 1992 French Decompression Tables) SUNDTJV proposed would be at least as safe as the decompression tables specified by OSHA when applied by trained medical personnel under the conditions that would be imposed by the proposed variance.

Some of the literature indicates that the alternative decompression method may be safer, concluding that decompression performed in accordance with these tables resulted in a lower occurrence of DCI than decompression conducted in accordance with the decompression tables specified by the standard. For example, H. L. Anderson studied the occurrence of DCI at maximum hyperbaric pressures ranging from 4 p.s.i.g. to 43 p.s.i.g. during construction of the Great Belt Tunnel in Denmark (1992–1996).[5] This project used the 1992 French Decompression Tables to decompress the workers during part of the construction. Anderson observed 6 DCI cases out of 7,220 decompression events and reported that switching to the 1992 French Decompression tables reduced the DCI incidence to 0.08% compared to a previous incidence rate of 0.14%. The DCI incidence in the study by H. L. Andersen is substantially less than the DCI incidence reported for the decompression tables specified in Appendix A.

OSHA found no studies in which the DCI incidence reported for the 1992 French Decompression Tables were higher than the DCI incidence reported for the OSHA decompression tables.[6]

OSHA's experience with the previous seven variances, which all incorporated nearly identical decompression plans and did not result in safety issues, also provide evidence that the alternative procedure as a whole is at least as effective for this type of tunneling project as compliance with OSHA's decompression tables. The experience of State Plans[7] that either granted variances (Nevada, Oregon and Washington)[8] or promulgated a new standard (California)[9] for hyperbaric exposures occurring during similar subaqueous tunnel-construction work, provide additional evidence of the effectiveness of this alternative procedure.

C. 29 CFR 1926.803(g)(1)(iii)

SUNDTJV developed, and proposed to implement, an equally effective

[5] Anderson HL (2002). Decompression sickness during construction of the Great Belt tunnel, Denmark. *Undersea and Hyperbaric Medicine,* 29(3), pp. 172–188.

[6] Le Péchon JC, Barre P, Baud JP, Ollivier F (September 1996). Compressed air work—French Tables 1992—operational results. *JCLP Hyperbarie Paris, Centre Medical Subaquatique Interentreprise, Marseille: Communication a l'EUBS,* pp. 1–5 (see Ex. OSHA–2012–0036–0005).

[7] Under section 18 of the OSH Act, Congress expressly provides that States and U.S. territories may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards. OSHA refers to such States and territories as ''State Plan States'' Occupational safety and health standards developed by State Plan States must be at least as effective in providing safe and healthful employment and places of employment as the Federal standards (29 U.S.C. 667).

[8] These state variances are available in the docket for the 2015 Traylor JV variance: Exs. OSHA–2012–0035–0006 (Nevada), OSHA–2012–0035–0005 (Oregon), and OSHA–2012–0035–0004 (Washington).

[9] See California Code of Regulations, Title 8, Subchapter 7, Group 26, Article 154, available at *http://www.dir.ca.gov/title8/sb7g26a154.html.*

alternative to 29 CFR 1926.803(g)(1)(iii), which requires the use of automatic controllers that continuously decrease pressure to achieve decompression in accordance with the tables specified by the standard. The applicant's alternative includes using the 1992 French Decompression Tables for guiding staged decompression to achieve lower occurrences of DCI, using a trained and competent attendant for implementing appropriate hyperbaric entry and exit procedures, and providing a competent hyperbaric supervisor and attending physician certified in hyperbaric medicine to oversee all hyperbaric operations.

In reaching this preliminary conclusion, OSHA again notes the experience of previous nearly identical tunneling variances, the experiences of State Plan States, and a review of the literature and other information noted earlier.

D. 29 CFR 1926.803(g)(1)(xvii)

SUNDTJV developed, and proposed to implement, an effective alternative to the use of the special decompression chamber required by 29 CFR 1926.803(g)(1)(xvii). The TBM's man-lock and working chamber appear to satisfy all of the conditions of the special decompression chamber, including that they provide sufficient space for the maximum crew of three CAWs to stand up and move around, and safely accommodate decompression times up to 360 minutes. Therefore, again noting OSHA's previous experience with nearly identical variances including the same alternative, OSHA preliminarily determined that the TBM's man-lock and working chamber function as effectively as the special decompression chamber required by the standard.

Pursuant to section 6(d) of the Occupational Safety and Health Act of 1970 (29 U.S.C. 655), and based on the record discussed above, the agency preliminarily finds that when the employer complies with the conditions of the proposed modified variance, the working conditions of the employer's workers would be at least as safe and healthful as if the employer complied with the working conditions specified by paragraphs (e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii) of 29 CFR 1926.803.

IV. Grant of Interim Order, Proposal for Permanent Variance, and Request for Comment

OSHA hereby announces the preliminary decision to grant an interim order to SUNDTJV for the Integrated Pipeline Tunnel Project in Dallas, Texas. This interim order permits SUNDTJV's CAWs to perform interventions in hyperbaric conditions not exceeding 58 p.s.i.g. during the Integrated Pipeline Tunnel Project, subject to the conditions that follow in this document. This interim order will remain in effect until completion of the Integrated Pipeline Tunnel Project or until the agency modifies or revokes the interim order or makes a final decision on the application for a permanent variance. During the period starting with the publication of this notice until completion of the Integrated Pipeline Tunnel Project, or until the agency modifies or revokes the interim order or makes a final decision on the application for a permanent variance, SUNDTJV is required to comply fully with the conditions of the interim order as an alternative to complying with the following requirements of 29 CFR 1926.803 (hereafter, ''the standard'') that:

1. Prohibit exposure to pressure greater than 50 p.s.i. (29 CFR 1926.803(e)(5));
2. Require the use of decompression values specified by the decompression tables in Appendix A of the compressed-air standard (29 CFR 1926.803(f)(1));
3. Require the use of automated operational controls (29 CFR 1926.803(g)(1)(iii)); and
4. Require the use of a special decompression chamber (29 CFR 1926.803(g)(1)(xvii)).

In order to avail itself of the interim order, SUNDTJV must: (1) comply with the conditions listed in the interim order for the period starting with the grant of the interim order and ending with SUNDTJV's completion of the Integrated Pipeline Tunnel Project (or until the agency modifies or revokes the interim order or makes a decision on its application for a modified permanent variance); (2) comply fully with all other applicable provisions of 29 CFR part 1926; and (3) provide a copy of this **Federal Register** notice to all employees affected by the proposed conditions, including the affected employees of other employers, using the same means it used to inform these employees of its application for a modified permanent variance.

OSHA is also proposing that the same requirements (see above section III, parts A through D) would apply to a permanent variance if OSHA ultimately issues one for this project. OSHA requests comment on those conditions as well as OSHA's preliminary determination that the specified alternatives and conditions would provide a workplace as safe and healthful as those required by the standard from which a variance is sought. After reviewing comments, OSHA will publish in the **Federal Register** the agency's final decision granting or denying a permanent variance.

V. Description of the Specified Conditions of the Interim Order and the Application for a Permanent Variance

This section describes the alternative means of compliance with 29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii) and provides additional detail regarding the proposed conditions that form the basis of Traylor's application for an interim order and for a modified permanent variance. The conditions are listed in section VI of this notice. For brevity, the discussion that follows refers only to the permanent variance, but the same conditions apply to the interim order.

Proposed Condition A: Scope

The scope of the proposed permanent variance would limit coverage to the work situations specified. Clearly defining the scope of the proposed permanent variance provides Traylor, SUNDTJV's employees, potential future applicants, other stakeholders, the public, and OSHA with necessary information regarding the work situations in which the proposed permanent variance would apply. To the extent that Traylor or SUNDTJV exceeds the defined scope of this variance, it would be required to comply with OSHA's standards.

Pursuant to 29 CFR 1905.11, an employer (or class or group of employers) [10] may request a permanent variance for a specific workplace or workplaces. If OSHA approves a permanent variance, it would apply only to the specific employer(s) that submitted the application and only to the specific workplace or workplaces designated as part of the project. In this instance, if OSHA were to grant a modified permanent variance, it would apply to only the applicant, SUNDJV, and only the Integrated Pipeline Tunnel Project.

Proposed Condition B: Duration

The interim order is only intended as a temporary measure pending OSHA's decision on the permanent variance, so this condition specifies the duration of the Order. If OSHA approves a permanent variance, it would specify

[10] A class or group of employers (such as members of a trade alliance or association) may apply jointly for a variance provided an authorized representative for each employer signs the application and the application identifies each employer's affected facilities.

the duration of the modified permanent variance as the remainder of the Integrated Pipeline Tunnel Project.

Proposed Condition C: List of Abbreviations

The proposed condition defines a number of abbreviations used in the proposed modified permanent variance. OSHA believes that defining these abbreviations serve to clarify and standardize their usage, thereby enhancing the applicant's and its employees' understanding of the conditions specified by the proposed permanent variance.

Proposed Condition D: Definitions

The proposed condition defines a series of terms, mostly technical terms, used in the proposed modified permanent variance to standardize and clarify their meaning. OSHA believes that defining these terms serves to enhance the applicant's and its employees' understanding of the conditions specified by the proposed permanent variance.

Proposed Condition E: Safety and Health Practices

This proposed condition requires the applicant to develop and submit to OSHA a HOM specific to the Integrated Pipeline Tunnel Project at least six months before using the TBM for tunneling operations. The applicant must also submit, at least six months before using the TBM, proof that the TBM's hyperbaric chambers have been designed, fabricated, inspected, tested, marked, and stamped in accordance with the requirements of ASME PVHO–1.2019 (or the most recent edition of *Safety Standards for Pressure Vessels for Human Occupancy*). These requirements ensure that the applicant develops hyperbaric safety and health procedures suitable for the project.

The submission of the HOM to OSHA, which SUNDTJV has already completed, enables OSHA to determine whether the safety and health instructions and measures it specifies are appropriate to the field conditions of the tunnel (including expected geological conditions), conform to the conditions of the variance, and adequately protect the safety and health of the CAWs. It also facilitates OSHA's ability to ensure that the applicant is complying with these instructions and measures. The requirement for proof of compliance with ASME PVHO–1.2019 is intended to ensure that the equipment is structurally sound and capable of performing to protect the safety of the employees exposed to hyperbaric pressure.

Additionally, the proposed condition includes a series of related hazard prevention and control requirements and methods (*e.g.,* decompression tables, job hazard analyses (JHA), operations and inspections checklists, incident investigation, and recording and notification to OSHA of recordable hyperbaric injuries and illnesses) designed to ensure the continued effective functioning of the hyperbaric equipment and operating system.

Proposed Condition F: Communication

This proposed condition requires the applicant to develop and implement an effective system of information sharing and communication. Effective information sharing and communication are intended to ensure that affected workers receive updated information regarding any safety-related hazards and incidents, and corrective actions taken, prior to the start of each shift. The proposed condition also requires the applicant to ensure that reliable means of emergency communications are available and maintained for affected workers and support personnel during hyperbaric operations. Availability of such reliable means of communications would enable affected workers and support personnel to respond quickly and effectively to hazardous conditions or emergencies that may develop during TBM operations.

Proposed Condition G: Worker Qualification and Training

This proposed condition requires the applicant to develop and implement an effective qualification and training program for affected workers. The proposed condition specifies the factors that an affected worker must know to perform safely during hyperbaric operations, including how to enter, work in, and exit from hyperbaric conditions under both normal and emergency conditions. Having well-trained and qualified workers performing hyperbaric intervention work is intended to ensure that they recognize, and respond appropriately to, hyperbaric safety and health hazards. These qualification and training requirements enable affected workers to cope effectively with emergencies, as well as the discomfort and physiological effects of hyperbaric exposure, thereby preventing worker injury, illness, and fatalities.

Paragraph (2)(e) of this proposed condition requires the applicant to provide affected workers with information they can use to contact the appropriate healthcare professionals if the workers believe they are developing hyperbaric-related health effects. This requirement provides for early intervention and treatment of DCI and other health effects resulting from hyperbaric exposure, thereby reducing the potential severity of these effects.

Proposed Condition H: Inspections, Tests, and Accident Prevention

Proposed Condition H requires the applicant to develop, implement, and operate a program of frequent and regular inspections of the TBM's hyperbaric equipment and support systems, and associated work areas. This condition would help to ensure the safe operation and physical integrity of the equipment and work areas necessary to conduct hyperbaric operations. The condition would also enhance worker safety by reducing the risk of hyperbaric-related emergencies.

Paragraph (3) of this proposed condition requires the applicant to document tests, inspections, corrective actions, and repairs involving the TBM, and maintain these documents at the jobsite for the duration of the job. This requirement would provide the applicant with information needed to schedule tests and inspections to ensure the continued safe operation of the equipment and systems, and to determine that the actions taken to correct defects in hyperbaric equipment and systems were appropriate, prior to returning them to service.

Proposed Condition I: Compression and Decompression

This proposed condition would require the applicant to consult with the designated medical advisor regarding special compression or decompression procedures appropriate for any unacclimated CAW and then implement the procedures recommended by the medical consultant. This proposed provision would ensure that the applicant consults with the medical advisor, and involves the medical advisor in the evaluation, development, and implementation of compression or decompression protocols appropriate for any CAW requiring acclimation to the hyperbaric conditions encountered during TBM operations. Accordingly, CAWs requiring acclimation would have an opportunity to acclimate prior to exposure to these hyperbaric conditions. OSHA believes this condition would prevent or reduce adverse reactions among CAWs to the effects of compression or decompression associated with the intervention work they perform in the TBM.

Proposed Condition J: Recordkeeping

Under OSHA's existing recordkeeping requirements in 29 CFR part 1904

regarding Recording and Reporting Occupational Injuries and Illnesses, the employer must maintain a record of any recordable injury, illness, or fatality (as defined by 29 CFR part 1904) resulting from exposure of an employee to hyperbaric conditions by completing the OSHA Form 301 Incident Report and OSHA Form 300 Log of Work Related Injuries and Illnesses. The applicant did not seek a variance from this standard and therefore SUNDTJV must comply fully with those requirements.

Examples of important information to include on the OSHA Form 301 Injury and Illness Incident Report (along with the corresponding questions on the form) are:

Q14

- the task performed;
- the composition of the gas mixture (*e.g.,* air or oxygen);
- an estimate of the CAW's workload;
- the maximum working pressure;
- temperature in the work and decompression environments;
- unusual occurrences, if any, during the task or decompression

Q15

- time of symptom onset;
- duration between decompression and onset of symptoms

Q16

- type and duration of symptoms;
- a medical summary of the illness or injury

Q17

- duration of the hyperbaric intervention;
- possible contributing factors;
- the number of prior interventions completed by the injured or ill CAW; and the pressure to which the CAW was exposed during those interventions.[11]

Proposed Condition J would add additional reporting responsibilities, beyond those already required by the OSHA standard. The applicant would be required to maintain records of specific factors associated with each hyperbaric intervention. The information gathered and recorded under this provision, in concert with the information provided under proposed Condition K (using OSHA Form 301 Injury and Illness Incident Report to investigate and record hyperbaric recordable injuries as defined by 29 CFR 1904.4, 1904.7, 1904.8–1904.12), would enable the applicant and OSHA to assess the effectiveness of the permanent variance in preventing DCI and other hyperbaric-related effects.

Proposed Condition K: Notifications

Under the proposed condition, the applicant is required, within specified periods of time, to notify OSHA of: (1) any recordable injury, illness, in-patient hospitalization, amputation, loss of an eye, or fatality that occurs as a result of hyperbaric exposures during TBM operations within 8 hours; (2) provide OSHA a copy of the hyperbaric exposures incident investigation report (using OSHA Form 301 Injury and Illness Incident Report) of these events within 24 hours of the incident; (3) include on OSHA Form 301 Injury and Illness Incident Report information on the hyperbaric conditions associated with the recordable injury or illness, the root-cause determination, and preventive and corrective actions identified and implemented; (4) provide the certification along with the OSHA Form 310, that affected workers were informed of the incident and the results of the incident investigation; (5) notify OSHA's Office of Technical Programs and Coordination Activities (OTPCA) and the OSHA Area Office in Dallas, Texas within 15 working days should the applicant need to revise the HOM to accommodate changes in its compressed-air operations that affect SUNDTJV's ability to comply with the conditions of the proposed modified permanent variance; and (6) provide OTPCA and the OSHA Area Office in Dallas, Texas, at the end of the project, with a report evaluating the effectiveness of the decompression tables within 30 days of the completion of the Integrated Pipeline Tunnel Project.

It should be noted that the requirement for completing and submitting the hyperbaric exposure-related (recordable) incident investigation report (OSHA 301 Injury and Illness Incident Report) is more restrictive than the current recordkeeping requirement of completing OSHA Form 301 Injury and Illness Incident Report within 7 calendar days of the incident (1904.29(b)(3)). This modified, more stringent incident investigation and reporting requirement is restricted to intervention-related hyperbaric (recordable) incidents only. Providing rapid notification to OSHA is essential because time is a critical element in OSHA's ability to determine the continued effectiveness of the variance conditions in preventing hyperbaric incidents, and the applicant's identification and implementation of appropriate corrective and preventive actions.

Further, these notification requirements also enable the applicant, its employees, and OSHA to assess the effectiveness of the permanent variance in providing the requisite level of safety to the applicant's workers and, based on this assessment, whether to revise or revoke the conditions of the proposed permanent variance. Timely notification permits OSHA to take whatever action may be necessary and appropriate to prevent possible further injuries and illnesses. Providing notification to employees informs them of the precautions taken by the applicant to prevent similar incidents in the future.

Additionally, this proposed condition requires the applicant to notify OSHA no later than seven (7) days of having knowledge that it will cease to do business, have a new address or location for the main office, or transfer the operations covered by the proposed permanent variance to a successor company. In addition, the condition specifies that the transfer of the permanent variance to a successor company must be approved by OSHA. These requirements allow OSHA to communicate effectively with the applicant regarding the status of the proposed permanent variance, and expedite the agency's administration and enforcement of the permanent variance. Stipulating that an applicant is required to have OSHA's approval to transfer a variance to a successor company provides assurance that the successor company has knowledge of, and will comply with, the conditions specified by the proposed permanent variance, thereby ensuring the safety of workers involved in performing the operations covered by the proposed permanent variance.

VI. Specific Conditions of the Interim Order and the Proposed Permanent Variance

The following conditions apply to the interim order OSHA is granting to SUNDTJV for the Integrated Pipeline Tunnel Project. These conditions specify the alternative means of compliance with the requirements of paragraphs 29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii). In addition, these conditions are specific to the alternative means of compliance with these requirements that OSHA is proposing for SUNDTJV's permanent variance. To simplify the presentation of the conditions, OSHA generally refers only to the conditions of the proposed permanent variance, but the same

[11] See 29 CFR 1904 Recording and Reporting Occupational Injuries and Illnesses (*http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=9631*); recordkeeping forms and instructions (*http://www.osha.gov/recordkeeping/RKform300pkg-fillable-enabled.pdf*); and OSHA Recordkeeping Handbook (*http://www.osha.gov/recordkeeping/handbook/index.html*).

conditions apply to the interim order except where otherwise noted.[12]

The conditions would apply with respect to all employees of SUNDTJV exposed to hyperbaric conditions. These conditions are outlined in this section:

A. Scope

The interim order applies, and the permanent variance would apply, only when SUNDTJV stops the tunnel-boring work, pressurizes the working chamber, and the CAWs either enter the working chamber to perform an intervention (*i.e.,* inspect, maintain, or repair the mechanical-excavation components), or exit the working chamber after performing interventions.

The interim order and proposed permanent variance apply only to work:

1. That occurs in conjunction with construction of the Integrated Pipeline Tunnel Project, a tunnel constructed using advanced shielded mechanical-excavation techniques and involving operation of an TBM;

2. In the TBM's forward section (the working chamber) and associated hyperbaric chambers used to pressurize and decompress employees entering and exiting the working chamber; and

3. Performed in compliance with all applicable provisions of 29 CFR part 1926 except for the requirements specified by 29 CFR 1926.803(e)(5), (f)(1), (g)(1)(iii), and (g)(1)(xvii).

B. Duration

The interim order granted to Traylor will remain in effect until SUNDTJV completes the Integrated Pipeline Tunnel Project, OSHA modifies or revokes this interim order, or OSHA grants Traylor's request for a permanent variance. The proposed permanent variance, if granted, would remain in effect until the completion of SUNDTJV's Integrated Pipeline Tunnel Project or until modified or revoked by OSHA pursuant to 29 CFR 1905.13(a)(2).

C. List of Abbreviations

Abbreviations used throughout this proposed permanent variance would include the following:

1. CAW—Compressed-air worker
2. CFR—Code of Federal Regulations
3. DCI—Decompression Illness
4. DMT—Diver Medical Technician
5. TBM—Earth Pressure Balanced Tunnel Boring Machine
6. HOM—Hyperbaric Operations Manual
7. JHA—Job hazard analysis
8. OSHA—Occupational Safety and Health Administration
9. OTPCA—Office of Technical Programs and Coordination Activities

D. Definitions

The following definitions would apply to this proposed permanent variance. These definitions would supplement the definitions in SUNDTJV's project-specific HOM.

1. *Affected employee or worker*—an employee or worker who is affected by the conditions of this proposed modified permanent variance, or any one of his or her authorized representatives. The term ''employee'' has the meaning defined and used under the Occupational Safety and Health Act of 1970 (29 U.S.C. 651 *et seq.*).

2. *Atmospheric pressure*—the pressure of air at sea level, generally 14.7 pounds per square inch absolute (p.s.i.a)., 1 atmosphere absolute, or 0 p.s.i.g.

3. *Compressed-air worker*—an individual who is specially trained and medically qualified to perform work in a pressurized environment while breathing air at pressures not exceeding 58 p.s.i.g.

4. *Competent person*—an individual who is capable of identifying existing and predictable hazards in the surroundings or working conditions that are unsanitary, hazardous, or dangerous to employees, and who has authorization to take prompt corrective measures to eliminate them.[13]

5. *Decompression illness*—an illness (also called decompression sickness or ''the bends'') caused by gas bubbles appearing in body compartments due to a reduction in ambient pressure. Examples of symptoms of decompression illness include, but are not limited to: joint pain (also known as the ''bends'' for agonizing pain or the ''niggles'' for slight pain); areas of bone destruction (termed dysbaric osteonecrosis); skin disorders (such as cutis marmorata, which causes a pink marbling of the skin); spinal cord and brain disorders (such as stroke, paralysis, paresthesia, and bladder dysfunction); cardiopulmonary disorders, such as shortness of breath; and arterial gas embolism (gas bubbles in the arteries that block blood flow).[14]

Note: Health effects associated with hyperbaric intervention, but not considered symptoms of DCI, can include: barotrauma (direct damage to air-containing cavities in the body such as ears, sinuses, and lungs); nitrogen narcosis (reversible alteration in consciousness that may occur in hyperbaric environments and is caused by the anesthetic effect of certain gases at high pressure); and oxygen toxicity (a central nervous system condition resulting from the harmful effects of breathing molecular oxygen (O_2) at elevated partial pressures).

6. *Diver Medical Technician*—Member of the dive team who is experienced in first aid.

7. *Earth Pressure Balanced Tunnel Boring Machine*—the machinery used to excavate a tunnel.

8. *Hot work*—any activity performed in a hazardous location that may introduce an ignition source into a potentially flammable atmosphere.[15]

9. *Hyperbaric*—at a higher pressure than atmospheric pressure.

10. *Hyperbaric intervention*—a term that describes the process of stopping the TBM and preparing and executing work under hyperbaric pressure in the working chamber for the purpose of inspecting, replacing, or repairing cutting tools and/or the cutterhead structure.

11. *Hyperbaric Operations Manual*—a detailed, project-specific health and safety plan developed and implemented by SUNDTJV for working in compressed air during the Integrated Pipeline Tunnel Project.

12. *Job hazard analysis*—an evaluation of tasks or operations to identify potential hazards and to determine the necessary controls.

13. *Man-lock*—an enclosed space capable of pressurization, and used for compressing or decompressing any employee or material when either is passing into, or out of, a working chamber.

14. *Medical Advisor*—medical professional experienced in the physical requirements of compressed air work and the treatment of decompression illness.

15. *Pressure*—a force acting on a unit area. Usually expressed as pounds per square inch (p.s.i.).

16. *p.s.i.a.*—pounds per square inch absolute, or absolute pressure, is the sum of the atmospheric pressure and gauge pressure. At sea-level, atmospheric pressure is approximately 14.7 p.s.i.a. Adding 14.7 to a pressure expressed in units of p.s.i.g. will yield the absolute pressure, expressed as p.s.i.a.

17. *p.s.i.g.*—pounds per square inch gauge, a common unit of pressure;

[12] In these conditions, OSHA is using the future conditional form of the verb (*e.g.,* ''would''), which pertains to the application for a permanent variance (designated as ''Permanent Variance'') but the conditions are mandatory for purposes of the interim order.

[13] Adapted from 29 CFR 1926.32(f).

[14] See Appendix 10 of ''A Guide to the Work in Compressed-Air Regulations 1996,'' published by the United Kingdom Health and Safety Executive available from NIOSH at *http://www.cdc.gov/niosh/docket/archive/pdfs/NIOSH-254/compReg1996.pdf.*

[15] Also see 29 CFR 1926.1202 for examples of hot work.

pressure expressed as p.s.i.g. corresponds to pressure relative to atmospheric pressure. At sea-level, atmospheric pressure is approximately 14.7 p.s.i.a Subtracting 14.7 from a pressure expressed in units of p.s.i.a. yields the gauge pressure, expressed as p.s.i.g. At sea level the gauge pressure is 0 psig.

18. *Qualified person*—an individual who, by possession of a recognized degree, certificate, or professional standing, or who, by extensive knowledge, training, and experience, successfully demonstrates an ability to solve or resolve problems relating to the subject matter, the work, or the project.[16]

19. *Working chamber*—an enclosed space in the TBM in which CAWs perform interventions, and which is accessible only through a man-lock.

E. Safety and Health Practices

1. SUNDTJV would have to adhere to the project-specific HOM submitted to OSHA as part of the application (see OSHA–2023–0004–0003). The HOM provides the minimum requirements regarding expected safety and health hazards (including anticipated geological conditions) and hyperbaric exposures during the tunnel-construction project.

2. SUNDTJV would have to demonstrate that the TBM on the project is designed, fabricated, inspected, tested, marked, and stamped in accordance with the requirements of ASME PVHO–1.2019 (or most recent edition of *Safety Standards for Pressure Vessels for Human Occupancy*) for the TBM's hyperbaric chambers.

3. SUNDTJV would have to implement the safety and health instructions included in the manufacturer's operations manuals for the TBM, and the safety and health instructions provided by the manufacturer for the operation of decompression equipment.

4. SUNDTJV would have to ensure that there are no exposures to pressures greater than 58 p.s.i.g.

5. SUNDTJV would have to ensure that air or oxygen is the only breathing gas in the working chamber.

6. SUNDTJV would have to follow the 1992 French Decompression Tables for air or oxygen decompression as specified in the HOM; specifically, the extracted portions of the 1992 French Decompression tables titled, ''French Regulation Air Standard Tables.''

7. SUNDTJV would have to equip man-locks used by employees with an air or oxygen delivery system, as specified by the HOM for the project. SUNDTJV would be prohibited from storing in the tunnel any oxygen or other compressed gases used in conjunction with hyperbaric work.

8. Workers performing hot work under hyperbaric conditions would have to use flame-retardant personal protective equipment and clothing.

9. In hyperbaric work areas, SUNDTJV would have to maintain an adequate fire-suppression system approved for hyperbaric work areas.

10. SUNDTJV would have to develop and implement one or more Job Hazard Analysis (JHA) for work in the hyperbaric work areas, and review, periodically and as necessary (*e.g.,* after making changes to a planned intervention that affects its operation), the contents of the JHAs with affected employees. The JHAs would have to include all the job functions that the risk assessment [17] indicates are essential to prevent injury or illness.

11. SUNDTJV would have to develop a set of checklists to guide compressed-air work and ensure that employees follow the procedures required by the proposed modified permanent variance and this interim order (including all procedures required by the HOM approved by OSHA for the project, which this proposed variance would incorporate by reference). The checklists would have to include all steps and equipment functions that the risk assessment indicates are essential to prevent injury or illness during compressed-air work.

12. SUNDTJV would have to ensure that the safety and health provisions of this project-specific HOM adequately protect the workers of all contractors and subcontractors involved in hyperbaric operations for the project to which the HOM applies.

F. Communication

SUNDTJV would have to:

1. Prior to beginning a shift, implement a system that informs workers exposed to hyperbaric conditions of any hazardous occurrences or conditions that might affect their safety, including hyperbaric incidents, gas releases, equipment failures, earth or rock slides, cave-ins, flooding, fires, or explosions.

2. Provide a power-assisted means of communication among affected workers and support personnel in hyperbaric conditions where unassisted voice communication is inadequate.

(a) Use an independent power supply for powered communication systems, and these systems would have to operate such that use or disruption of any one phone or signal location will not disrupt the operation of the system from any other location.

(b) Test communication systems at the start of each shift and as necessary thereafter to ensure proper operation.

G. Worker Qualifications and Training

SUNDTJV would have to:

1. Ensure that each affected worker receives effective training on how to safely enter, work in, exit from, and undertake emergency evacuation or rescue from, hyperbaric conditions, and document this training.

2. Provide effective instruction on hyperbaric conditions, before beginning hyperbaric operations, to each worker who performs work, or controls the exposure of others, and document this instruction. The instruction would need to include:

(a) The physics and physiology of hyperbaric work;

(b) Recognition of pressure-related injuries;

(c) Information on the causes and recognition of the signs and symptoms associated with decompression illness, and other hyperbaric intervention-related health effects (*e.g.,* barotrauma, nitrogen narcosis, and oxygen toxicity);

(d) How to avoid discomfort during compression and decompression;

(e) Information the workers can use to contact the appropriate healthcare professionals should the workers have concerns that they may be experiencing adverse health effects from hyperbaric exposure; and

(f) Procedures and requirements applicable to the employee in the project-specific HOM.

3. Repeat the instruction specified in paragraph (G) of this proposed condition periodically and as necessary (*e.g.,* after making changes to its hyperbaric operations).

4. When conducting training for its hyperbaric workers, make this training available to OSHA personnel and notify the OTPCA at OSHA's national office and OSHA's Dallas Area Office before the training takes place.

H. Inspections, Tests, and Accident Prevention

1. SUNDTJV would have to initiate and maintain a program of frequent and regular inspections of the TBM's hyperbaric equipment and support systems (such as temperature control, illumination, ventilation, and fire-prevention and fire-suppression systems), and hyperbaric work areas, as required under 29 CFR 1926.20(b)(2), including:

[16] Adapted from 29 CFR 1926.32(m).

[17] See ANSI/AIHA Z10–2012, American National Standard for Occupational Health and Safety Management Systems, for reference.

(a) Developing a set of checklists to be used by a competent person in conducting weekly inspections of hyperbaric equipment and work areas; and

(b) Ensuring that a competent person conducts daily visual checks and weekly inspections of the TBM.

2. Remove from service any equipment that constitutes a safety hazard until it corrects the hazardous condition and has the correction approved by a qualified person.

3. SUNDTJV would have to maintain records of all tests and inspections of the TBM, as well as associated corrective actions and repairs, at the job site for the duration of the tunneling project and for 90 days after the final project report is submitted to OSHA.

I. Compression and Decompression

SUNDTJV would have to consult with its attending physician concerning the need for special compression or decompression exposures appropriate for CAWs not acclimated to hyperbaric exposure.

J. Recordkeeping

In addition to completing OSHA Form 301 Injury and Illness Incident Report and OSHA Form 300 Log of Work-Related Injuries and Illnesses, SUNDTJV would have to maintain records of:

1. The date, times (*e.g.,* time compression started, time spent compressing, time performing intervention, time spent decompressing), and pressure for each hyperbaric intervention.

2. The names of all supervisors and DMTs involved for each intervention.

3. The name of each individual worker exposed to hyperbaric pressure and the decompression protocols and results for each worker.

4. The total number of interventions and the amount of hyperbaric work time at each pressure.

5. The results of the post-intervention physical assessment of each CAW for signs and symptoms of decompression illness, barotrauma, nitrogen narcosis, oxygen toxicity or other health effects associated with work in compressed air for each hyperbaric intervention.

K. Notifications

1. To assist OSHA in administering the conditions specified herein, SUNDTJV would have to:

(a) Notify the OTPCA and the OSHA Area Office in Dallas, Texas at *www.osha.gov/contactus/byoffice* of any recordable injury, illness, or fatality (by submitting the completed OSHA Form 301 Injuries and Illness Incident Report) resulting from exposure of an employee to hyperbaric conditions, including those that do not require recompression treatment (*e.g.,* nitrogen narcosis, oxygen toxicity, barotrauma), but still meet the recordable injury or illness criteria of 29 CFR 1904. The notification would have to be made within 8 hours of the incident or 8 hours after becoming aware of a recordable injury, illness, or fatality; a copy of the incident investigation (OSHA Form 301 Injuries and Illness Incident Report) must be submitted to OSHA within 24 hours of the incident or 24 hours after becoming aware of a recordable injury, illness, or fatality. In addition to the information required by OSHA Form 301 Injuries and Illness Incident Report, the incident-investigation report would have to include a root-cause determination, and the preventive and corrective actions identified and implemented.

(b) Provide certification to the OSHA Area Office in Dallas, Texas within 15 working days of the incident that SUNDTJV informed affected workers of the incident and the results of the incident investigation (including the root-cause determination and preventive and corrective actions identified and implemented).

(c) Notify the OTPCA and the OSHA Area Office in Dallas, Texas within 15 working days and in writing, of any change in the compressed-air operations that affects SUNDTJV's ability to comply with the proposed conditions specified herein.

(d) Upon completion of the Integrated Pipeline Tunnel Project, evaluate the effectiveness of the decompression tables used throughout the project, and provide a written report of this evaluation to the OTPCA and the OSHA Area Office in Dallas, Texas within 30 days after the workers final day onsite.

Note: The evaluation report would have to contain summaries of: (1) The number, dates, durations, and pressures of the hyperbaric interventions completed; (2) decompression protocols implemented (including composition of gas mixtures (air and/or oxygen), and the results achieved; (3) the total number of interventions and the number of hyperbaric incidents (decompression illnesses and/or health effects associated with hyperbaric interventions as recorded on OSHA Form 301 Injuries and Illness Incident Report and OSHA Form 300 Log of Work-Related Injuries and Illnesses, and relevant medical diagnoses, and treating physicians' opinions); and (4) root causes of any hyperbaric incidents, and preventive and corrective actions identified and implemented.

(e) To assist OSHA in administering the proposed conditions specified herein, inform the OTPCA and the OSHA Area Office in Dallas, Texas as soon as possible, but no later than seven (7) days, after it has knowledge that it will:

(i) Cease doing business;

(ii) Change the location and address of the main office for managing the tunneling operations specified herein; or

(iii) Transfer the operations specified herein to a successor company.

(f) Notify all affected employees of this proposed modified permanent variance by the same means required to inform them of its application for a modified permanent variance.

2. OSHA would have to approve the transfer of the proposed modified permanent variance to a successor company through a new application for a modified variance.

VII. Authority and Signature

James S. Frederick, Deputy Assistant Secretary of Labor for Occupational Safety and Health, 200 Constitution Avenue NW, Washington, DC 20210, authorized the preparation of this notice. Accordingly, the agency is issuing this notice pursuant to 29 U.S.C. 655(6)(d), Secretary of Labor's Order No. 8–2020 (85 FR 58393, Sept. 18, 2020), and 29 CFR 1905.11.

Signed at Washington, DC, on April 24, 2023.

James S. Frederick,

Deputy Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2023–09118 Filed 4–28–23; 8:45 am]

BILLING CODE 4510–26–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–0320; NRC–2023–0042]

TMI–2 Solutions, LLC; Three Mile Island Nuclear Station, Unit No. 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Environmental assessment and finding of no significant impact; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is considering an exemption for license no. DPR–73, issued on February 8, 1978, and held by TMI–2 Solutions, LLC for the operation of Three Mile Island Nuclear Station, Unit No. 2, located in Dauphin County, Commonwealth of Pennsylvania. The NRC is issuing an environmental assessment (EA) and finding of no significant impact (FONSI) associated with the proposed action.

DATES: The EA and FONSI referenced in this document are available on April 24, 2023.

ADDRESSES: Please refer to Docket ID NRC–2023–0042 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document using any of the following methods:

- *Federal Rulemaking Website:* Go to *https://www.regulations.gov* and search for Docket ID NRC–2023–0042. Address questions about Docket IDs in *Regulations.gov* to Stacy Schumann; telephone: 301–415–0624; email: *Stacy.Schumann@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Documents collection at *https://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *PDR.Resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in this document.
- *NRC's PDR:* You may examine and purchase copies of public documents, by appointment, at the NRC's PDR, Room P1 B35, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852. To make an appointment to visit the PDR, please send an email to *PDR.Resource@nrc.gov* or call 1–800–397–4209 or 301–415–4737, between 8 a.m. and 4 p.m. eastern time (ET), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Amy M. Snyder, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–6822; email: *Amy.Snyder@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is considering issuance of an exemption for license no. DPR–73, issued to TMI–2 Solutions, LLC (TMI–2 Solutions, the licensee), from section 70.24 of title 10 of the *Code of Federal Regulations* (CFR), ''Criticality accident requirements.'' The proposed action would exempt TMI–2 Solutions from the requirement to maintain a radiation monitoring system in each area where licensed special nuclear material (SNM) is handled, used, or stored that will energize clearly audible alarm signals if accidental criticality occurs during decommissioning.

As required by 10 CFR part 51, ''Domestic Licensing of Production and Utilization Facilities,'' the NRC prepared an EA documenting its environmental review (ADAMS Accession No. ML23026A348). Based on the results of the EA and the summary that follows, the NRC has determined not to prepare an environmental impact statement (EIS) for the exemption and is issuing a FONSI in accordance with 10 CFR 51.32 ''Finding of no significant impact.''

TMI–2 Solutions requested an exemption from 10 CFR 70.24 requirements. In its exemption application, TMI–2 Solutions states that criticality is not credible at TMI–2, and therefore it considers an exemption to 10 CFR 70.24 for a criticality monitoring system to be appropriate under the decommissioning licensing basis. The licensee stated that this is because of its updated Spent Fuel Mass Limit (SFML). Specifically, TMI–2 Solutions asserts that it arrived at this updated SFML by taking credit for impurities and actual enrichment based on the results of physical samples taken during the defueling effort in 1993. In its application, TMI–2 Solutions also asserts that administrative controls for geometric spacing are not necessary to further preclude a criticality accident because there is not enough Uranium Oxide (UO2) at TMI–2 to assemble an optimal critical configuration. Regardless, TMI–2 Solutions states that, as part of its Fuel Bearing Material Management Program, it will be implementing local administrative controls for the purpose of defense in depth of the activities which will handle the highest quantities of fuel bearing material.

II. Summary of Environmental Assessment

Description of the Proposed Action

The proposed action that is being considered by the Commission is an exemption during decommissioning from the requirements of 10 CFR 70.24 for a monitoring system capable of detecting a criticality accident.

The proposed action is in accordance with the licensee's application dated September 29, 2022 (ADAMS Accession No. ML22276A024).

Need for the Proposed Action

The proposed action would exempt the licensee from the requirements of 10 CFR 70.24, which, in relevant part, requires that each licensee authorized to possess SNM in certain quantities maintain a monitoring system that will energize clear audible alarms if accidental criticality occurs in each area in which SNM is handled, used, or stored. The proposed action would also exempt the licensee from the requirements to maintain emergency procedures for each area in which this licensed SNM is handled, used, or stored to ensure that all personnel withdraw to an area of safety upon the sounding of the alarm, to familiarize personnel with the evacuation plan, and to designate responsible individuals for determining the cause of the alarm, and to place radiation survey instruments in accessible locations for use in such an emergency.

Environmental Impacts of the Proposed Action

The NRC staff assessed the impacts of the proposed action on land use; visual and scenic resources/aesthetics; climatology; meteorology; air quality; noise; geology and soil; water; ecological resources; historical and cultural resources; socioeconomics; transportation and traffic; waste generation; and public and occupational health and safety. Approval of the proposed action would not result in an increased radiological risk to public health or the environment.

Environmental Impacts of the Alternatives to the Proposed Action

As an alternative to the proposed action, the staff considered denial of the proposed action (*i.e.,* the ''no-action'' alternative). Under the No-Action Alternative, the NRC would deny the requested action. Denying the action would have a larger environmental impact because occupational radiation exposure would increase due to personnel using radiation sources to calibrate criticality monitors during decommissioning.

Alternative Use of Resources

This action does not involve the use of any resources not previously considered in Supplement 3 to the Programmatic Environmental Impact Statement for TMI–2, dated August 1989, NUREG–0683. Additionally, the proposed action does not involve any environmental resources beyond those previously considered in the exemption for the 1992 Criticality Monitoring (57 FR 26668).

Agencies and Persons Consulted

On April 4, 2023, the NRC staff consulted with Commonwealth of Pennsylvania regarding the environmental impact of the proposed

action. On April 14, 2023 (ADAMS Accession No. ML23107A223), the state official concurred with the draft environmental assessment and finding of no significant impact.

III. Finding of No Significant Impact

On the basis of the EA referenced in Section II of this notice and incorporated by reference in this finding, the NRC finds that the proposed action will not have a significant environmental impact and that preparation of EIS is not warranted. Accordingly, the NRC has determined that a FONSI (ADAMS Accession No. ML23026A348) is appropriate.

Dated: April 26, 2023.

For the Nuclear Regulatory Commission.

Shaun M. Anderson,

Chief, Reactor Decommissioning Branch, Division of Decommissioning, Uranium Recovery, and Waste Programs, Office of Nuclear Material Safety and Safeguards.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97375; File No. SR–NYSEARCA–2023–33]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To List and Trade Shares of the Veridien Climate Action ETF Under Rule 8.900–E (Managed Portfolio Shares)

April 25, 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 April 18, 2023, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to list and trade shares of the following under Rule 8.900–E (Managed Portfolio Shares): Veridien Climate Action ETF. 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

NYSE Arca Rule 8.900–E permits the listing and trading, or trading pursuant to unlisted trading privileges, of Managed Portfolio Shares, which are securities issued by an actively managed open-end investment management company.[4] Rule 8.900–E(b)(1) requires the Exchange to file separate proposals under Section 19(b) of the Act before listing and trading any series of Managed Portfolio Shares on the Exchange. Therefore, the Exchange is submitting this proposal in order to list and trade Managed Portfolio Shares of the Veridien Climate Action ETF (the ''Fund''), a series of the Tidal Trust II (the ''Trust''), under Rule 8.900–E.

The Commission has previously approved or noticed for immediate effectiveness the listing and trading on the Exchange of Managed Portfolio Shares under NYSE Arca Rule 8.900–E.[5]

Description of the Fund and the Trust

The shares of the Fund (the ''Shares'') will be issued by the Trust, a statutory trust organized under the laws of the state of Delaware and registered with the Commission as an open-end management investment company.[6] The investment adviser to the Fund will be Toroso Investments, LLC (the ''Adviser''). Veridien Global Investors LLC will be the sub-adviser (the ''Sub-Adviser'') for the Fund. Foreside Fund Services, LLC (the ''Distributor'') will serve as the distributor for the Fund's Shares. U.S. Bank Global Fund Services will serve as the transfer agent for the Fund (the ''Transfer Agent''). U.S. Bank National Association will be the Fund's custodian (the ''Custodian''). All statements and representations made in this filing regarding (a) the description

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] Rule 8.900–E(c)(1) provides that the term ''Managed Portfolio Share'' means a security that (a) represents an interest in an investment company registered under the Investment Company Act of 1940 (''Investment Company'') organized as an open-end management investment company that invests in a portfolio of securities selected by the Investment Company's investment adviser consistent with the Investment Company's investment objectives and policies; (b) is issued in a Creation Unit, or multiples thereof, in return for a designated portfolio of instruments (and/or an amount of cash) with a value equal to the next determined net asset value and delivered to the Authorized Participant (as defined in the Investment Company's Form N–1A filed with the Commission) through a Confidential Account; (c) when aggregated into a Redemption Unit, or multiples thereof, may be redeemed for a designated portfolio of instruments (and/or an amount of cash) with a value equal to the next determined net asset value delivered to the Confidential Account for the benefit of the Authorized Participant; and (d) the portfolio holdings for which are disclosed within at least 60 days following the end of every fiscal quarter.

[5] *See* Securities Exchange Act Release Nos. 89663 (August 25, 2020), 85 FR 53868 (August 31, 2020) (SR–NYSEArca–2020–48) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 1, To List and Trade Shares of Gabelli ETFs Under Rule 8.900–E, Managed Portfolio Shares); 90528 (November 30, 2020), 85 FR 78389 (December 4, 2020) (SR–NYSEArca–2020–80) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 2, To List and Trade Shares of Alger Mid Cap 40 ETF and Alger 25 ETF Under Rule 8.900–E); 90683 (December 16, 2020), 85 FR 83665 (December 22, 2020) (SR–NYSEArca–2020–94) (Order Approving a Proposed Rule Change, as Modified by Amendments No. 1 and No. 2, To List and Trade Shares of the AdvisorShares Q Portfolio Blended Allocation ETF and AdvisorShares Q Dynamic Growth ETF Under NYSE Arca Rule 8.900–E); 92349 (July 19, 2021), 86 FR 39084 (July 23, 2021) (SR–NYSEArca–2021–54) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to List and Trade Shares of the Cambiar Large Cap ETF, Cambiar Small Cap ETF and Cambiar SMID ETF) (the ''Cambiar Notice''); 94629 (April 7, 2022), 87 FR 21993 (April 13, 2022) (SR–NYSEArca–2022–17) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to List and Trade Shares of the FMC Excelsior Focus Equity ETF under Rule 8.900–E (Managed Portfolio Shares)) (the ''FMC Notice'').

[6] The Trust is registered under the Investment Company Act of 1940 (the ''1940 Act''). On October 14, 2022, the Trust filed a registration statement on Form N–1A under the Securities Act of 1933 (the ''1933 Act'') and the 1940 Act for the Fund (File Nos. 333–264478 and 811–23793) (''Registration Statement''). The Trust subsequently filed Post-Effective Amendment No. 74 to the Registration Statement. *See* Post-Effective Amendment No. 74 to Registration Statement on Form N–1A for the Trust, dated April 21, 2023 (File Nos. 333–264478 and 811–23793). The Commission issued an order granting exemptive relief to the Trust (''Exemptive Order'') under the 1940 Act on March 21, 2023 (Investment Company Act Release No. 34863). The Exemptive Order was granted in response to the Trust's application for exemptive relief (the ''Exemptive Application'') (File No. 812–15411). The description of the operation of the Trust and the Fund herein is based, in part, on the Registration Statement. The Exchange will not commence trading in Shares of the Fund until the Registration Statement is effective.

of the portfolio or reference assets, (b) limitations on portfolio holdings or reference assets, or (c) the applicability of Exchange rules shall constitute continued listing requirements for listing the Shares on the Exchange, as provided under Rule 8.900–E(b)(1).

Rule 8.900–E(b)(4) provides that, if the investment adviser to the Investment Company issuing Managed Portfolio Shares is registered as a broker-dealer or is affiliated with a broker-dealer, such investment adviser will erect and maintain a ''fire wall'' between the investment adviser and personnel of the broker-dealer or broker-dealer affiliate, as applicable, with respect to access to information concerning the composition of and/or changes to such Investment Company portfolio and/or the Creation Basket.[7] Any person related to the investment adviser or Investment Company who makes decisions pertaining to the Investment Company's portfolio composition or has access to information regarding the Investment Company's portfolio composition or changes thereto or the Creation Basket must be subject to procedures designed to prevent the use and dissemination of material non-public information regarding the applicable Investment Company portfolio or changes thereto or the Creation Basket.

Rule 8.900–E(b)(4) is similar to Commentary .03(a)(i) and (iii) to Rule 5.2–E(j)(3); however, Commentary .03(a) in connection with the establishment of a ''fire wall'' between the investment adviser and the broker-dealer reflects the applicable open-end fund's portfolio, not an underlying benchmark index, as is the case with index-based funds.[8] Rule 8.900–E(b)(4) is also similar to Commentary .06 to Rule 8.600–E related to Managed Fund Shares, except that Rule 8.900–E(b)(4) relates to establishment and maintenance of a ''fire wall'' between the investment adviser and personnel of the broker-dealer or broker-dealer affiliate, as applicable, with respect to an Investment Company's portfolio and Creation Basket, and not just to the underlying portfolio, as is the case with Managed Fund Shares. The Adviser is not registered as a broker-dealer but is affiliated with a broker-dealer. The Adviser has implemented and will maintain a ''fire wall'' with respect to such broker-dealer affiliate regarding access to information concerning the composition of and/or changes to the Fund's portfolio and/or Creation Basket. The Sub-Adviser is not registered as a broker-dealer or affiliated with a broker-dealer.

In the event (a) the Adviser or Sub-Adviser becomes registered as a broker-dealer or becomes newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer, or becomes affiliated with a broker-dealer, it will implement and maintain a fire wall with respect to personnel of the broker-dealer or broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio and/or Creation Basket. Any person related to the Adviser, Sub-Adviser, or the Trust who makes decisions pertaining to the Fund's portfolio composition or that has access to information regarding the Fund's portfolio composition or that has access to information regarding the Fund's portfolio or changes thereto or the Creation Basket will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio or changes thereto and the Creation Basket.

Further, Rule 8.900–E(b)(5) requires that any person or entity, including an AP Representative (as defined below), custodian, Reporting Authority, distributor, or administrator, who has access to non-public information regarding the Investment Company's portfolio composition or changes thereto or the Creation Basket, must be subject to procedures reasonably designed to prevent the use and dissemination of material non-public information regarding the applicable Investment Company portfolio or changes thereto or the Creation Basket. Moreover, if any such person or entity is registered as a broker-dealer or affiliated with a broker-dealer, such person or entity will erect and maintain a ''fire wall'' between the person or entity and the broker-dealer with respect to access to information concerning the composition and/or changes to such Investment Company portfolio or Creation Basket.

Description of the Fund [9]

The Fund's holdings will conform to the permissible investments as set forth in the Exemptive Application and Exemptive Order, and the holdings will be consistent with all requirements in the Exemptive Application and Exemptive Order.[10]

The Fund's primary objective is to seek long-term growth of capital by investing in public companies with technologies and business models that contribute to climate change mitigation. Under normal circumstances, the Fund will invest at least 80% of its net assets, plus borrowings for investment purposes, in equity securities of companies that the Adviser and/or Sub-Adviser believes are making a substantial contribution to mitigating climate change. The Fund's portfolio will generally hold the securities of between 35 and 50 companies.

[7] Rule 8.900–E(c)(5) provides that the term ''Creation Basket'' means, on any given business day, the names and quantities of the specified instruments (and/or an amount of cash) that are required for an AP Representative to deposit in-kind on behalf of an Authorized Participant in exchange for a Creation Unit and the names and quantities of the specified instruments (and/or an amount of cash) that will be transferred in-kind to an AP Representative on behalf of an Authorized Participant in exchange for a Redemption Unit, which will be identical and will be transmitted to each AP Representative before the commencement of trading.

[8] An investment adviser to an open-end fund is required to be registered under the Investment Advisers Act of 1940 (the ''Advisers Act''). As a result, the Adviser, Sub-Adviser, and their related personnel will be subject to the provisions of Rule 204A–1 under the Advisers Act relating to codes of ethics. This Rule requires investment advisers to adopt a code of ethics that reflects the fiduciary nature of the relationship to clients as well as compliance with other applicable securities laws. Accordingly, procedures designed to prevent the communication and misuse of non-public information by an investment adviser must be consistent with Rule 204A–1 under the Advisers Act. In addition, Rule 206(4)–7 under the Advisers Act makes it unlawful for an investment adviser to provide investment advice to clients unless such investment adviser has (i) adopted and implemented written policies and procedures reasonably designed to prevent violations, by the investment adviser and its supervised persons, of the Advisers Act and the Commission rules adopted thereunder; (ii) implemented, at a minimum, an annual review regarding the adequacy of the policies and procedures established pursuant to subparagraph (i) above and the effectiveness of their implementation; and (iii) designated an individual (who is a supervised person) responsible for administering the policies and procedures adopted under subparagraph (i) above. The Fund will also be required to comply with Exchange rules relating to disclosure, including Rule 5.3–E(i).

[9] The Exchange represents that, for initial and continued listing, the Fund will be in compliance with Rule 10A–3 under the Act. *See* 17 CFR 240.10A–3.

[10] Pursuant to the Exemptive Order, the only permissible investments for the Fund are the following that trade on a U.S. exchange contemporaneously with Shares of the Fund: exchange-traded funds (''ETFs''), exchange-traded notes, exchange-listed common stocks, exchange-traded preferred stocks, exchange-traded American Depositary Receipts, exchange-traded real estate investment trusts, exchange-traded commodity pools, exchange-traded metal trusts, exchange-traded currency trusts, and exchange-traded futures for which the reference asset is one in which the Fund may invest directly, in the case of an index future traded on a U.S. exchange, is based on an index, the components of which are a type of asset in which the Fund could invest directly, as well as cash and cash equivalents (which are short-term U.S. Treasury securities, government money market funds, and repurchase agreements). All of the equity instruments or futures held by the Fund will be traded on an exchange that is a member of the Intermarket Surveillance group (''ISG'') or affiliated with a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

Investment Restrictions

The Fund's holdings will be consistent with all requirements described in the Exemptive Application and Exemptive Order.[11]

The Fund's investments, including derivatives, will be consistent with its investment objective and will not be used to enhance leverage (although certain derivatives and other investments may result in leverage). That is, the Fund's investments will not be used to seek performance that is the multiple or inverse multiple (*e.g.,* 2X or –3X) of the Fund's primary broad-based securities benchmark index (as defined in Form N–1A).[12]

Creations and Redemptions of Shares

Creations and redemptions of Shares will take place as described in Rule 8.900–E. Specifically, in connection with the creation and redemption of Creation Units [13] the delivery or receipt of any portfolio securities in-kind will be required to be effected through a separate confidential brokerage account (a ''Confidential Account'').[14] An Authorized Participant (''AP''), as defined in the applicable Form N–1A filed with the Commission, will sign an agreement with an AP Representative [15] establishing the Confidential Account for the benefit of the AP. AP Representatives will be broker-dealers. An AP must be a participant in the Continuous Net Settlement System of the National Securities Clearing Corporation (''NSCC'') or a participant in the Depository Trust Company, and must have executed an authorized participant agreement (''Participant Agreement'') with the Distributor with respect to the creation and redemption of Creation Units and formed a Confidential Account for its benefit in accordance with the terms of the Participant Agreement. For purposes of creations or redemptions, all transactions will be effected through the respective AP's Confidential Account, for the benefit of the AP, without disclosing the identity of such securities to the AP.

Each business day, the Fund's Custodian will transmit the underlying securities of the Fund's Creation Basket (as described below) to each AP Representative. This information will permit an AP that has established a Confidential Account with an AP Representative to transact in the underlying securities of the Creation Basket through their AP Representatives, enabling them to engage in in-kind creation or redemption activity without knowing the identity or weighting of those securities. Fund Shares will be issued and redeemed in Creation Units of 25,000 Shares. The size of a Creation Unit is subject to change. The Fund will offer and redeem Creation Units on a continuous basis at the net asset value (''NAV'') per Share next determined after receipt of an order in proper form. The Fund's NAV will be determined as of the scheduled closing time of the regular trading session on the Exchange (ordinarily, 4:00 p.m. Eastern Time (''E.T.'')) on each day that it is open for business.

In order to keep costs low and permit the Fund to be as fully invested as possible, Shares will be purchased and redeemed in Creation Units and generally on an in-kind basis. The Fund will issue Creation Units in exchange for a ''Fund Deposit,'' which is either (i) the in-kind deposit of a designated portfolio of securities (the ''Deposit Securities'') and the amount of the ''Cash Component'' (as defined below) or (ii) the cash value of the Deposit Securities. The Fund may permit or require the substitution of a ''cash in lieu'' amount (the ''Deposit Cash'') to be added to the Cash Component to replace any Deposit Security. The Cash Component is an amount equal to the difference between the NAV of the Shares (per Creation Unit) and the value of the Deposit Securities or Deposit Cash, as applicable. The Cash Component serves the function of compensating for any differences between the NAV per Creation Unit and the value of the Deposit Securities or Deposit Cash, as applicable. The Fund will redeem Creation Units either in-kind or in cash, or combination thereof, as determined by the Trust. Redemption proceeds may consist of a designated portfolio of securities (the ''Fund Securities'') plus cash in an amount equal to the difference between the NAV of Shares being redeemed, as next determined after a receipt of a redemption request in proper form, or the cash value of the Fund Securities (the ''Cash Redemption Amount''). In addition, at the Trust's discretion, an AP may receive the corresponding cash value of the securities in lieu of the in-kind securities value representing one or more Fund Securities.

On each business day, prior to the opening of business on the Exchange (ordinarily, 9:30 a.m. E.T.), the Custodian will transmit to each AP Representative the list of names and quantities of each Deposit Security and the amount of the Cash Component (if any) to be included in the current Fund Deposit (based on information as of the ends of the previous business day). Such Fund Deposit is applicable to purchases of Creation Units until such time as the next-announced Fund Deposit is made available. On each business day, prior to the opening of business on the Exchange, the Custodian will also transmit to each AP Representative the list of the names and quantities of the Fund Securities that will be applicable to redemption requests received in proper form on that day. On any given business day, the names and quantities of the instruments that constitute the Deposit Securities and the names and quantities of the instruments that constitute the Fund Securities will correspond pro rata to the positions in the Fund's portfolio and, thus, will be identical. These instruments may be referred to, in the case of either a purchase or a redemption, as the ''Creation Basket.''

Placement of Purchase Orders

The Fund will issue Shares through the Transfer Agent on a continuous basis at NAV. The Exchange represents that the issuance of Shares will operate in a manner substantially similar to that of other ETFs, including transparent ETFs. The Fund will issue Shares only

[11] *See id.*

[12] The Fund's broad-based securities benchmark index will be identified in a future amendment to the Registration Statement following the Fund's first full calendar year of performance.

[13] Rule 8.900–E(c)(6) provides that the term ''Creation Unit'' means a specified minimum number of Managed Portfolio Shares issued by an Investment Company at the request of an Authorized Participant in return for a designated portfolio of instruments and/or cash. Rule 8.900–E(c)(7) provides that the term ''Redemption Unit'' means a specified minimum number of Managed Portfolio Shares that may be redeemed to an Investment Company at the request of an Authorized Participant in return for a portfolio of instruments and/or cash. For purposes of this filing, the terms ''Creation Unit'' means either a Creation Unit as defined in Rules 8.900–E(c)(6) or a Redemption Unit as defined in Rule 8.900–E(c)(7).

[14] Rule 8.900–E(c)(4) provides that the term ''Confidential Account'' means an account owned by an Authorized Participant and held with an AP Representative on behalf of the Authorized Participant. The account will be established and governed by contractual agreement between the AP Representative and the Authorized Participant solely for the purposes of creation and redemption, while keeping confidential the Creation Basket constituents of each series of Managed Portfolio Shares, including from the Authorized Participant. The books and records of the Confidential Account will be maintained by the AP Representative on behalf of the Authorized Participant.

[15] Rule 8.900–E(c)(3) provides that the term ''AP Representative'' means an unaffiliated broker-dealer, with which an Authorized Participant has signed an agreement to establish a Confidential Account for the benefit of such Authorized Participant, that will deliver or receive, on behalf of the Authorized Participant, all consideration to or from the Investment Company in a creation or redemption. An AP Representative will not be permitted to disclose the Creation Basket to any person, including the Authorized Participants.

at the NAV per Share next determined after an order in proper form is received.

The Transfer Agent will furnish acknowledgements to those placing such orders that the orders have been accepted, but the Transfer Agent may reject any order which is not submitted in proper form, as described in the Fund's prospectus or Statement of Additional Information (''SAI''). The NAV of the Fund is expected to be determined once each business day as of the close of the regular trading session on the Exchange (ordinarily, 4:00 p.m. E.T.). An AP generally must submit an irrevocable purchase order no later than 4:00 p.m. E.T. (the ''Cut-Off Time'') in order to receive that business day's NAV. The business day the order is deemed received by the Transfer Agent is referred to as the ''Order Placement Date.'' An order to create Creation Units is deemed received on a business day if (i) such order is received by the Cut-Off Time on such day and (ii) all other procedures set forth in the Participant Agreement are properly followed. In purchasing the necessary securities, the AP Representative will use methods, such as breaking the transaction into multiple transactions and transacting in multiple marketplaces, to avoid revealing the composition of the Creation Basket.

Purchases of Shares will be settled in-kind and/or in cash for an amount equal to the applicable NAV per Share purchased plus applicable transaction fees.[16]

Authorized Participant Redemption

The Shares may be redeemed to the Fund in Creation Unit size or multiples thereof as described below. Redemption orders of Creation Units must be placed by or through an AP. Creation Units of the Fund will be redeemable at their NAV per Share next determined after receipt of a redemption request by the Fund through the Transfer Agent. A fixed redemption transaction fee may be imposed to offset costs associated with redemption orders.

Orders to redeem Creation Units must be submitted in proper form to the Transfer Agent prior to the Order Cut-Off Time. A redemption request is deemed received on a business day if (i) such order is received by the Transfer Agent by the Cut-off Time on such day and (ii) all other procedures set forth in the Participant Agreement are properly followed. As with the purchase of securities, the AP Representative will use methods, such as breaking the transaction into multiple transactions and transacting in multiple marketplaces, to avoid revealing the composition of the Creation Basket.

Redemptions will occur primarily in-kind, although redemption payments may also be made partly or wholly in cash. In the case of full or partial cash redemptions, the AP will receive the cash equivalent of the Fund Securities it would otherwise receive through an in-kind redemption, plus the same Cash Redemption Amount to be paid to an in-kind redeemer. The Participant Agreement signed by each AP will require establishment of a Confidential Account to receive distributions of securities in-kind upon redemption. Each AP will be required to open a Confidential Account with an AP Representative in order to facilitate orderly processing of redemptions.

Net Asset Value

The NAV will be calculated for the Shares of the Fund on each business day. The Fund's NAV is determined as of the scheduled close of regular trading on the Exchange, normally 4:00 p.m. E.T., each day the Exchange is open for business. The NAV of the Fund's Shares is determined by dividing the total value of the Fund's assets, less any liabilities, by the total number of Shares outstanding of the Fund at the time the determination is made.

Generally, the Fund's portfolio securities are valued each day at the last quoted sales price on each security's primary exchange. Securities traded or dealt in upon one or more securities exchanges for which market quotations are readily available and not subject to restrictions against resale shall be valued at the last quoted sales price on the primary exchange or, in the absence of a sale on the primary exchange, at the mean between the current bid and ask prices on such exchange. Securities primarily traded in the NASDAQ National Market System for which market quotations are readily available shall be valued using the NASDAQ Official Closing Price. If market quotations are not readily available, securities will be valued at their fair market value as determined in good faith by the Fund's fair value committee in accordance with procedures approved by the Board. Securities that are not traded or dealt in any securities exchange (whether domestic or foreign) and for which over-the-counter market quotations are readily available generally shall be valued at the last sale price or, in the absence of a sale, at the mean between the current bid and ask price on such over-the- counter market.

More information about the valuation of the Fund's holdings can be found in the SAI.

Information regarding the Fund's NAV and how often Shares of the Fund traded at a price above (*i.e.,* at a premium) or below (*i.e.,* at a discount) the Fund's NAV will be available on the Fund's website (*www.veridienglobalinvestors.com*).

Availability of Information

The Fund's website, *www.veridienglobalinvestors.com,* will include the prospectus for the Fund that may be downloaded. The Fund's website will include additional quantitative information updated on a daily basis, including the prior business day's NAV, market closing price or mid-point of the bid/ask spread at the time of calculation of such NAV (the ''Bid/Ask Price''),[17] and a calculation of the premium and discount of the market closing price or Bid/Ask Price against the NAV. The website and information will be publicly available at no charge.

Form N–PORT requires reporting of a Fund's complete portfolio holdings on a position-by-position basis on a quarterly basis within 60 days after fiscal quarter end. Investors can obtain a Fund's SAI, its shareholder reports, its Form N–CSR, filed twice a year, and its Form N–CEN, filed annually. The Fund's SAI and shareholder reports are available free upon request from the Fund, and those documents and the Form N–PORT, Form N–CSR, and Form N–CEN may be viewed onscreen or downloaded from the Commission's website at *www.sec.gov.*

Information regarding market price and trading volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. Information regarding the previous day's closing price and trading volume information for the Shares will be published daily in the financial section of newspapers. Quotation and last sale information for the Shares will be available via the Consolidated Tape Association (''CTA'') high-speed line. In addition, the Verified Intraday Indicative Value (''VIIV''), as defined in Rule 8.900–E(c)(2),[18] will be widely

[16] To the extent that the Fund allows creations or redemptions to be conducted in cash, such transactions will be effected in the same manner for all APs transacting in cash.

[17] The Bid/Ask Price of the Fund's Shares is determined using the mid-point between the current national best bid and offer at the time of calculation of the Fund's NAV. The records relating to Bid/Ask Prices will be retained by the Fund or its service providers.

[18] Rule 8.900–E(c)(2) provides that the term ''Verified Intraday Indicative Value'' is the indicative value of a Managed Portfolio Share based on all of the holdings of a series of Managed Portfolio Shares as of the close of business on the

Continued

disseminated by the Reporting Authority [19] and/or one or more major market data vendors in one second intervals during the Exchange's Core Trading Session and will be available to all market participants at the same time.

Dissemination of the VIIV

With respect to trading of the Shares, the ability of market participants to buy and sell Shares at prices near the VIIV is dependent upon their assessment that the VIIV is a reliable, indicative real-time value for the Fund's underlying holdings. Market participants are expected to accept the VIIV as a reliable, indicative real-time value because (1) the VIIV will be calculated and disseminated based on the Fund's actual portfolio holdings, (2) the securities in which the Fund plans to invest are generally highly liquid and actively traded and trade at the same time as the Fund and therefore generally have accurate real time pricing available, and (3) market participants will have a daily opportunity to evaluate whether the VIIV at or near the close of trading is indeed predictive of the actual NAV.

The VIIV will be widely disseminated to all market participants at the same time by the Reporting Authority and/or by one or more major market data vendors in one second intervals during the Exchange's Core Trading Session. The VIIV is based on the current market value of the securities in the Fund's portfolio that day. The methodology for calculating the Fund's VIIV is available on the Fund's website. The VIIV is intended to provide investors and other market participants with a highly correlated per Share value of the Fund's portfolio that can be compared to the current market price. Therefore, under normal circumstances the VIIV would be effectively a near real time approximation of the Fund's NAV, which is computed only once a day and is available free of charge from one or more market data vendors.

Trading Halts

With respect to trading halts, the Exchange may consider all relevant factors in exercising its discretion to halt or suspend trading in the Shares of the Fund.[20] Trading in Shares of the Fund will be halted if the circuit breaker parameters in Rule 7.12–E have been reached. Trading also may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. Trading in the Shares will be subject to Rule 8.900–E(d)(2)(C), which sets forth circumstances under which trading in the Shares of the Fund will be halted.

Specifically, Rule 8.900–E(d)(2)(C)(i) provides that the Exchange may consider all relevant factors in exercising its discretion to halt trading in a series of Managed Portfolio Shares. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the series of Managed Portfolio Shares inadvisable. These may include: (a) the extent to which trading is not occurring in the securities and/or the financial instruments composing the portfolio; or (b) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present.[21]

Rule 8.900–E(d)(2)(C)(ii) provides that, if the Exchange becomes aware that: (i) the VIIV of a series of Managed Portfolio Shares is not being calculated or disseminated in one second intervals, as required; (ii) the NAV with respect to a series of Managed Portfolio Shares is not disseminated to all market participants at the same time; (iii) the holdings of a series of Managed Portfolio Shares are not made available on at least a quarterly basis as required under the 1940 Act; or (iv) such holdings are not made available to all market participants at the same time (except as otherwise permitted under the currently applicable exemptive order or no-action relief granted by the Commission or Commission staff to the Investment Company with respect to the series of Managed Portfolio Shares), it will halt trading in such series until such time as the Verified Intraday Indicative Value, the NAV, or the holdings are available, as required.

Trading Rules

The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities. Shares will trade on the Exchange in all trading sessions in accordance with Rule 7.34–E(a). As provided in Rule 7.6–E, the minimum price variation (''MPV'') for quoting and entry of orders in equity securities traded on the NYSE Arca Marketplace is $0.01, with the exception of securities that are priced less than $1.00, for which the MPV for order entry is $0.0001. A minimum of 100,000 Shares of the Fund will be outstanding at the commencement of trading on the Exchange.

The Shares will conform to the initial and continued listing criteria under Rule 8.900–E, as well as all terms in the Exemptive Order. The Exchange will obtain a representation from the issuer of the Shares of the Fund that the NAV per Share of the Fund will be calculated daily and will be made available to all market participants at the same time.

Surveillance

The Exchange believes that its surveillance procedures are adequate to properly monitor the trading of Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws. Trading of Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products. As part of these surveillance procedures and consistent with Rule 8.900–E(b)(3) and 8.900–E(d)(2)(B), the Adviser will upon request make available to the Exchange and/or the Financial Industry Regulatory Authority (''FINRA''), on behalf of the Exchange, the daily portfolio holdings of the Fund. The issuer of the Shares of the Fund will be required to represent to the Exchange that it will advise the Exchange of any failure by the Fund to comply with the continued listing requirements, and, pursuant to its obligations under Section 19(g)(1) of the Exchange Act, the Exchange will surveil for compliance with the continued listing requirements. If the Fund is not

prior business day and, for corporate actions, based on the applicable holdings as of the opening of business on the current business day, priced and disseminated in one second intervals during the Exchange's Core Trading Session by the Reporting Authority.

[19] Rule 8.900–E(c)(8) provides that the term ''Reporting Authority'' in respect of a particular series of Managed Portfolio Shares means the Exchange, an institution, or a reporting service designated by the Exchange or by the exchange that lists a particular series of Managed Portfolio Shares (if the Exchange is trading such series pursuant to unlisted trading privileges), as the official source for calculating and reporting information relating to such series, including, but not limited to, the NAV, the VIIV, or other information relating to the issuance, redemption, or trading of Managed Portfolio Shares. A series of Managed Portfolio Shares may have more than one Reporting Authority, each having different functions.

[20] *See* Rule 7.12–E.

[21] The Exemptive Application provides that the Investment Company or their agent will request that the Exchange halt trading in the applicable series of Managed Portfolio Shares where: (i) the intraday indicative values calculated by the calculation engines differ by more than 25 basis points for 60 seconds in connection with pricing of the VIIV; or (ii) holdings representing 10% or more of a series of Managed Portfolio Shares' portfolio have become subject to a trading halt or otherwise do not have readily available market quotations. Any such requests will be one of many factors considered in order to determine whether to halt trading in a series of Managed Portfolio Shares and the Exchange retains sole discretion in determining whether trading should be halted. As provided in the Exemptive Application, each series of Managed Portfolio Shares would employ a pricing verification agent to continuously compare two intraday indicative values during regular trading hours in order to ensure the accuracy of the VIIV.

in compliance with the applicable listing requirements, the Exchange will commence delisting procedures under Exchange Rule 5.5–E(m).

FINRA, on behalf of the Exchange, or the regulatory staff of the Exchange, or both, will communicate as needed regarding trading in the Shares and certain exchange-traded instruments with other markets and other entities that are members of the ISG, and FINRA, on behalf of the Exchange, or the regulatory staff of the Exchange, or both, may obtain trading information regarding trading such securities from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and certain exchange-traded instruments from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

In addition, the Exchange also has a general policy prohibiting the distribution of material, non-public information by its employees.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[22] in general, and furthers the objectives of Section 6(b)(5) of the Act,[23] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The Exchange believes that this proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Fund would meet each of the rules relating to listing and trading of Managed Portfolio Shares. To the extent that the Fund is not in compliance with such rules, the Exchange would either prevent the Fund from listing and trading on the Exchange or commence delisting procedures under Rule 8.900–E(d)(2)(B). Specifically, the Exchange would consider the suspension of trading, and commence delisting proceedings under Rule 8.900–E(d)(2)(B), of the Fund under any of the following circumstances: (a) if, following the initial twelve-month period after commencement of trading on the Exchange, there are fewer than 50 beneficial holders of the Fund; (b) if the Exchange has halted trading in the Fund because the VIIV is interrupted pursuant to Rule 8.900–E(d)(2)(C)(ii) and such interruption persists past the trading day in which it occurred or is no longer available; (c) if the Exchange has halted trading in the Fund because the NAV with respect to such Fund is not disseminated to all market participants at the same time, the holdings of such Fund are not made available on at least a quarterly basis as required under the 1940 Act, or such holdings are not made available to all market participants at the same time pursuant to Rule 8.900–E(d)(2)(C)(ii) and such issue persists past the trading day in which it occurred; (d) if the Exchange has halted trading in Shares of the Fund pursuant to Rule 8.900–E(d)(2)(C)(i) and such issue persists past the trading day in which it occurred; (e) if the Fund has failed to file any filings required by the Commission or if the Exchange is aware that the Fund is not in compliance with the conditions of any currently applicable exemptive order or no-action relief granted by the Commission or Commission staff with respect to the Fund; (f) if any of the continued listing requirements set forth in Rule 8.900–E are not continuously maintained; (g) if any of the statements of representations regarding (a) the description of the portfolio, (b) limitations on portfolio holdings, or (c) the applicability of Exchange listing rules as specified herein to permit the listing and trading of the Fund, are not continuously maintained; or (h) if such other event shall occur or condition exists which, in the opinion of the Exchange, makes further dealings on the Exchange inadvisable.

As discussed above, the Adviser is not registered as a broker-dealer but is affiliated with a broker-dealer and has implemented and will maintain a ''fire wall'' with respect to such affiliate broker-dealer regarding access to information concerning the composition and/or changes to the Fund's portfolio and Creation Basket. The Sub-Adviser is neither registered as a broker-dealer nor affiliated with a broker-dealer. In the event that (a) the Adviser or Sub-Adviser becomes registered as a broker-dealer or becomes newly affiliated with a broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, the Adviser or Sub-Adviser, as applicable, will implement and maintain a fire wall with respect to personnel of the broker-dealer or broker-dealer affiliate regarding access to information concerning the composition and/or changes to the portfolio and/or Creation Basket. Any person related to the Adviser, Sub-Adviser, or the Trust who makes decisions pertaining to the Fund's portfolio composition or that has access to information regarding the Fund's portfolio or changes thereto or the Creation Basket will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio or changes thereto and the Creation Basket.

In addition, Rule 8.900–E(b)(5) requires that any person or entity, including an AP Representative, custodian, Reporting Authority, distributor, or administrator, who has access to non-public information regarding the Investment Company's portfolio composition or changes thereto or the Creation Basket, must be subject to procedures designed to prevent the use and dissemination of material non-public information regarding the applicable Investment Company portfolio or changes thereto or the Creation Basket. Moreover, if any such person or entity is registered as a broker-dealer or affiliated with a broker-dealer, such person or entity will erect and maintain a ''fire wall'' between the person or entity and the broker-dealer with respect to access to information concerning the composition and/or changes to such Investment Company portfolio or Creation Basket. Any person or entity who has access to information regarding the Fund's portfolio composition or changes thereto or the Creation Basket will be subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the portfolio or changes thereto or the Creation Basket.

The Exchange further believes that Rule 8.900–E is designed to prevent fraudulent and manipulative acts and practices related to the listing and trading of Shares of the Fund because it provides meaningful requirements about both the data that will be made publicly available about the Shares, as well as the information that will only be available to certain parties and the controls on such information. Specifically, the Exchange believes that the requirements related to information protection set forth in Rule 8.900–E(b)(5) will act as a safeguard against misuse and improper dissemination of information related to the Fund's portfolio composition, the Creation Basket, or changes thereto. The requirement that any person or entity implement procedures to prevent the use and dissemination of material non-public information regarding the portfolio or Creation Basket will act to prevent any individual or entity from

[22] 15 U.S.C. 78f(b).

[23] 15 U.S.C. 78f(b)(5).

sharing such information externally and the internal ''fire wall'' requirements applicable where an entity is a registered broker-dealer or affiliated with a broker-dealer will act to make sure that no entity will be able to misuse the data for their own purposes. Accordingly, the Exchange believes that this proposal is designed to prevent fraudulent and manipulative acts and practices.

The Exchange further believes that the proposal is designed to prevent fraudulent and manipulative acts and practices related to the listing and trading of Shares of the Fund and to promote just and equitable principles of trade and to protect investors and the public interest because the Exchange would halt trading under certain circumstances under which trading in the Shares of the Fund may be inadvisable. Specifically, trading in the Shares will be subject to Rule 8.900–E(d)(2)(C)(i), which provides that the Exchange may consider all relevant factors in exercising its discretion to halt trading in the Fund. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the series of Managed Portfolio Shares inadvisable. These may include: (a) the extent to which trading is not occurring in the securities and/or the financial instruments composing the portfolio; or (b) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present.[24] Additionally, trading in the Shares will be subject to Rule 8.900–E(d)(2)(C)(ii), which provides that the Exchange would halt trading where the Exchange becomes aware that: (a) the VIIV of a series of Managed Portfolio Shares is not being calculated or disseminated in one second intervals, as required; (b) the NAV with respect to a series of Managed Portfolio Shares is not disseminated to all market participants at the same time; (c) the holdings of a series of Managed Portfolio Shares are not made available on at least a quarterly basis as required under the 1940 Act; or (d) such holdings are not made available to all market participants at the same time (except as otherwise permitted under the currently applicable exemptive order or no-action relief granted by the Commission or Commission staff to the Investment Company with respect to the series of Managed Portfolio Shares). The Exchange would halt trading in such Shares until such time as the VIIV, the NAV, or the holdings are available, as required.

With respect to the proposed listing and trading of Shares of the Fund, the Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices in that the Shares will be listed and traded on the Exchange pursuant to the initial and continued listing criteria in Rule 8.900–E.[25] The Fund's holdings will conform to the permissible investments as set forth in the Exemptive Application and Exemptive Order.[26] As noted above, FINRA, on behalf of the Exchange, or the regulatory staff of the Exchange, or both, will communicate as needed regarding trading in the Shares and the underlying exchange-traded instruments with other markets and other entities that are members of the ISG, and FINRA, on behalf of the Exchange, or the regulatory staff of the Exchange, or both, may obtain trading information regarding trading such securities from such markets and other entities. In addition, the Exchange may obtain information regarding trading in the Shares and the underlying exchange-traded instruments from markets and other entities that are members of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

With respect to trading of Shares of the Fund, the ability of market participants to buy and sell Shares at prices near the VIIV is dependent upon their assessment that the VIIV is a reliable, indicative real-time value for the Fund's underlying holdings. Market participants are expected to accept the VIIV as a reliable, indicative real-time value because (1) the VIIV will be calculated and disseminated based on the Fund's actual portfolio holdings, (2) the securities in which the Fund plans to invest are generally highly liquid and actively traded and trade at the same time as the Fund and therefore generally have accurate real time pricing available, and (3) market participants will have a daily opportunity to evaluate whether the VIIV at or near the close of trading is indeed predictive of the actual NAV.

The proposed rule change is designed to promote just and equitable principles of trade and to protect investors and the public interest in that the Exchange will obtain a representation that the NAV per Share of the Fund will be calculated daily and that the NAV will be made available to all market participants at the same time. Investors can also obtain the Fund's SAI, its shareholder reports, its Form N–CSR (filed twice a year), and its Form N–CEN (filed annually). The Fund's SAI and shareholder reports will be available free upon request from the Fund, and those documents and the Form N–PORT, Form N–CSR, and Form N–CEN may be viewed on-screen or downloaded from the Commission's website at *www.sec.gov.* In addition, a large amount of information will be publicly available regarding the Fund and the Shares, thereby promoting market transparency. Quotation and last sale information for the Shares will be available via the CTA high-speed line. Information regarding the VIIV will be widely disseminated in one second intervals throughout the Exchange's Core Trading Session by the Reporting Authority and/or one or more major market data vendors. The website for the Fund will include a prospectus for the Fund that may be downloaded, and additional data relating to NAV and other applicable quantitative information, updated on a daily basis. Moreover, prior to the commencement of trading, the Exchange will inform its members in an Information Bulletin of the special characteristics and risks associated with trading the Shares.

In addition, as noted above, investors will have ready access to the VIIV, and quotation and last sale information for the Shares. The Shares will conform to the initial and continued listing criteria under Rule 8.900–E. The Fund's investments, including derivatives, will be consistent with its investment objective and will not be used to enhance leverage (although certain derivatives and other investments may result in leverage). That is, the Fund's investments will not be used to seek performance that is the multiple or inverse multiple (*e.g.,* 2X or –3X) of the Fund's primary broad-based securities benchmark index (as defined in Form N–1A).

The Exchange also believes that the proposed rule change is designed to perfect the mechanism of a free and open market and, in general, to protect investors and the public interest in that it will facilitate the listing and trading of actively-managed exchange-traded products that will enhance competition among market participants, to the benefit of investors and the marketplace. As noted above, the Exchange has in place surveillance procedures relating to trading in the Shares and may obtain information via ISG from other exchanges that are members of ISG or with which the Exchange has entered

[24] *See* note 20, *supra.*

[25] The Exchange represents that, for initial and continued listing, the Fund will be in compliance with Rule 10A–3 under the Act. *See* 17 CFR 240.10A–3.

[26] *See* note 9, *supra.*

into a comprehensive surveillance sharing agreement. In addition, as noted above, investors will have ready access to information regarding the VIIV and quotation and last sale information for the Shares.

For the above reasons, the Exchange believes that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act.

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 believes the proposed rule change would permit the listing and trading of an additional actively-managed exchange-traded product, thereby promoting competition among exchange-traded products to the benefit of investors and the marketplace.

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) of the Act [27] and Rule 19b–4(f)(6) thereunder.[28]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [29] permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange requested that the Commission waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission notes it has approved, and noticed for immediate effectiveness, proposed rule changes to permit listing and trading on the Exchange of Managed Portfolio Shares similar to the Funds.[30] The proposed listing rule for the Fund raises no novel legal or regulatory issues. Therefore, the Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposed rule change operative upon filing.[31]

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–NYSEARCA–2023–33 on the subject line.

Paper Comments

- Send paper comments in triplicate to: Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2023–33. 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 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. 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–NYSEARCA–2023–33 and should be submitted on or before May 22, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[32]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–09077 Filed 4–28–23; 8:45 am]

BILLING CODE 8011–01–P

[27] 15 U.S.C. 78s(b)(3)(A).

[28] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file 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.

[29] 17 CFR 240.19b–4(f)(6)(iii).

[30] *See supra* note 5.

[31] For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[32] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97373; File No. SR–NYSEARCA–2023–32]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the NYSE ARCA Options Fee Schedule

April 25, 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 April 18, 2023, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the NYSE Arca Options Fee Schedule (''Fee Schedule'') regarding fees for equipment for the Trading Floor. The Exchange proposes to implement the fee change effective April 18, 2023.[4] 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 purpose of this filing is to modify the Fee Schedule regarding Market Maker podium fees to reflect the availability of new equipment for Market Makers' use on the Trading Floor. The Exchange proposes to implement the rule change on April 18, 2023.

Currently, the Exchange equips each Market Maker podium with four 23″ monitors. Market Makers may request up to two additional monitors per podium for a monthly surcharge of $100. In addition, Market Makers currently have the option to upgrade the 23″ monitors provided by the Exchange to 25″ or 27″ monitors for a one-time surcharge of $200 or $300 per monitor, respectively.[5]

The Exchange now proposes to offer Market Makers an additional podium monitor upgrade option. Specifically, the Exchange proposes to modify the Fee Schedule to provide that Market Makers may upgrade their podium monitors to a 32″ size for a one-time surcharge of $600 per monitor. This proposed change would offer Market Makers the option to upgrade their podium monitors to a newly available larger size, which the Exchange believes would afford Market Makers additional flexibility in the configuration of their podia space. The Exchange notes that it established the current fees relating to Market Maker monitors in connection with the relocation of the Trading Floor to a new facility.[6] The proposed change would support fair and efficient use of Trading Floor space, as the Exchange believes that the available space on the Trading Floor can accommodate an additional monitor upgrade option for Market Makers.

The Exchange also proposes to amend the Fee Schedule to eliminate the current descriptions of the monitor sizes as ''standard,'' ''large,'' or ''extra-large'' and instead state the sizes of the available monitors (*e.g.,* 23″, 25″, and so forth). The Exchange believes this proposed change would add specificity and transparency to the Fee Schedule with respect to the sizes of the monitors available to Market Makers.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act, in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act, in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes the proposed change is reasonable, equitable and not unfairly discriminatory for the following reasons. First, the proposed fee for the 32″ monitor upgrade is reasonable, as the Exchange believes it is relatively proportional to the current fees for upgrades to monitors of smaller sizes and would support the existing cost structure designed to provide Market Makers with flexibility in configuring their Floor space consistent with their own business needs (*i.e.,* the cost structure will continue to allow a Market Maker to utilize only one podium with additional and/or upgraded monitors to facilitate additional personnel operating in the podium, as opposed to paying for multiple podia). Second, the proposed change is equitable because it would provide for the same fee for all Market Makers that wish to exercise the option to upgrade their podium monitors to the newly available 32″ size. Market Makers are not required to upgrade their podium equipment, but all those that choose to do so will be subject to the same fees. The Exchange also notes that the proposed fee for the newly available 32″ monitor would not impact any of the existing podium fees. Finally, the Exchange believes the proposed change is not unfairly discriminatory because it would apply to all Market Makers on an equal and non-discriminatory basis. Any Market Maker can choose to upgrade its podium monitors as suits its business needs, and the same surcharge, based on the size of the upgraded monitor, would apply to any such Market Maker. The Exchange further believes that the proposed change to replace the monitor size descriptors with the monitors' dimensions is reasonable, equitable, and not unfairly discriminatory because the change would add specificity and transparency to the Fee Schedule and would apply equally to all similarly situated market participants.

The Exchange also believes the proposed Floor Fees are reasonable, equitable, and not unfairly discriminatory because OTP Holders can choose whether to participate on the Exchange solely through electronic means, or with a presence on the Trading Floor. The proposed change, which would offer Market Makers added flexibility with respect to the configuration of their podium monitors, is designed to continue to encourage market participants to conduct business on the Trading Floor. Orders brought to the Trading Floor could benefit all market participants by facilitating more trading opportunities.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed change does not raise any competitive issues, as it is designed to

[4] The Exchange originally filed to amend the Fee Schedule on April 6, 2023 (SR–NYSEARCA–2023–21) and withdrew such filing on April 18, 2023.

[5] *See* Fee Schedule, NYSE Arca OPTIONS: FLOOR and EQUIPMENT, MARKET MAKER PODIUM FEES. The Fee Schedule also provides that podia are only available to Market Makers with an active OTP (*i.e.,* Market Makers that have only a Reserve OTP are ineligible for podia). In addition, each Market Maker on the Trading Floor may have no more than four (4) total podia and, each Market Maker in a given Trading Crowd, may have not more than two (2) podia, or eight (8) monitors. *Id.* The Exchange does not propose any changes to these aspects of Market Maker podium fees.

[6] *See* Securities Exchange Act Release No. 84874 (December 19, 2018), 83 FR 66818 (December 27, 2018) (SR–NYSEArca–2018–90) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Modify the NYSE Arca Options Fee Schedule in Conjunction with Relocating the Trading Floor to a New Trading Facility).

reflect the availability of optional new equipment for Market Maker use on the Exchange Trading Floor. Market Makers already have the option to upgrade their podium monitors from those provided by the Exchange to a larger size, and the proposed change would simply offer Market Makers an additional upgrade option that would, like the current upgrade options, be subject to a one-time surcharge. The Exchange believes the proposed change would afford Market Makers greater flexibility with respect to the configuration of their podia and could allow them to make more efficient use of their Trading Floor space.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A)[7] of the Act and subparagraph (f)(2) of Rule 19b–4[8] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[9] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEARCA–2023–32 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2023–32. 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 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. 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–NYSEARCA–2023–32, and should be submitted on or before May 22, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–09085 Filed 4–28–23; 8:45 am]

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[7] 15 U.S.C. 78s(b)(3)(A).

[8] 17 CFR 240.19b–4(f)(2).

[9] 15 U.S.C. 78s(b)(2)(B).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97371; File No. SR–CBOE–2023–020]

Self-Regulatory Organizations; Cboe Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Make the Nonstandard Expirations Pilot Program Permanent

April 25, 2023.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 11, 2023, Cboe Exchange, Inc. (''Exchange'' or ''Cboe Options'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. 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

Cboe Exchange, Inc. (the ''Exchange'' or ''Cboe Options'') proposes to make permanent the operation of its program that allows the Exchange to list broad-based index options with nonstandard expirations (''Nonstandard Expirations Pilot Program''). The text of the proposed rule change is provided below.

(additions are *italicized*; deletions are [bracketed])

* * * * *

Rules of Cboe Exchange, Inc.

* * * * *

Rule 4.13. Series of Index Options

(a)–(d) No change.

(e) Nonstandard Expirations [Pilot] Program.

(1)–(2) No change.

(3) [Duration of Nonstandard Expirations Pilot Program. The Nonstandard Expirations Pilot Program shall be through May 8, 2023.

(4)] Weekly Expirations and EOM Trading Hours on the Last Trading Day. On the last trading day, Regular Trading Hours for expiring Weekly Expirations and EOMs are from 9:30 a.m. and 4:00 p.m.

(f) No change.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

Interpretations and Policies

.01 The procedures for adding and deleting strike prices for index options are provided in Rule 4.5 and Interpretations and Policies related thereto, as otherwise generally provided by Rule 4.13, and include the following:

(a) No change.

(b) Notwithstanding the above paragraph, the interval between strike prices may be no less than $0.50 for options based on one-one hundredth of the value of the DJIA, including for series listed under either the Short Term Options Series Program in Rule 4.13(a)(2)(A) or the Nonstandard Expirations [Pilot] Program in Rule 4.13(e).

(c)–(h) No change.

(i) Notwithstanding Interpretation and Policies .01(a), .01(d) and .04 to Rule 4.13, the exercise prices for new and additional series of Mini-RUT options shall be listed subject to the following:

(1)–(2) No change.

(3) The lowest strike price interval that may be listed for standard Mini-RUT options, including LEAPS, is $1, and the lowest strike price interval that may be listed for series of Mini-RUT listed under the Nonstandard Expirations [Pilot] Program in Rule 4.13(e) and for QIX Mini-RUT options is $0.50.

* * * * *

.10 Notwithstanding Interpretations and Policies .01(a), .01(d) and .04 to Rule 4.13, the exercise prices for new and additional series of Mini-SPX options shall be listed subject to the following:

(a)–(b) No change.

(c) The lowest strike price interval that may be listed for standard Mini-SPX options is $1, including for LEAPS, and the lowest strike price interval that may be listed for series of Mini-SPX listed under either the Short Term Option Series Program in Rule 4.13(a)(2)(A) or the Nonstandard Expirations [Pilot] Program in Rule 4.13(e) is $0.50.

* * * * *

Rule 5.4. Minimum Increments for Bids and Offers

(a) Simple Orders for Equity and Index Options. The minimum increments for bids and offers on simple orders for equity and index options are as follows:

* * * * *

Class	Increment	Series trading price
* * * * *	*	*
Series of VIX options (if the Exchange does not list VIX on a group basis pursuant to Rule 4.13) and series of VIX Options not listed under the Nonstandard Expirations [Pilot] Program (if the Exchange lists VIX on a group basis pursuant to Rule 4.13).	$0.01.	Lower than $3.00.
	0.05	$3.00 and higher.
Series of VIX Options listed under the Nonstandard Expirations [Pilot] Program (if the Exchange lists VIX on a group basis pursuant to Rule 4.13).	0.01	All prices.

* * * * *

The text of the proposed rule change is also available on the Exchange's website (*http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx*), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to make permanent its Nonstandard Expirations Pilot Program. Specifically, the Exchanges proposes to be permitted to list P.M.-settled options on broad-based indexes that expire (1) on any Monday, Wednesday, or Friday (other than the third Friday-of-the-month or days that coincide with an end-of-month (''EOM'') expiration) and, with respect to options on the S&P 500 Index (''SPX options'') and the Mini-S&P 500 Index (''XSP options''), on any Tuesday or Thursday (other than days that coincide with an EOM expiration) (''Weekly Expirations'') and (2) on the last day of the trading month (''EOM Expirations'').[3] The Securities and Exchange Commission (the ''Commission'') approved a rule change that established a pilot program under which the Exchange is permitted to list P.M.-settled options on broad-based indexes to expire on (a) any Friday of the month, other than the third Friday-of-the-month, and (b) the last trading day of the month.[4] On January 14, 2016, the Commission approved a Cboe Options proposal to expand the pilot program to allow P.M.-settled options on broad-based indexes to expire on any Wednesday of month, other than those that coincide with an EOM.[5] On August 10, 2016, the Commission approved a Cboe Options proposal to expand the pilot program to allow P.M.-settled options on broad-based indexes to expire on any Monday of month, other than those that coincide with an EOM.[6] On April 12, 2022, the Commission approved a Cboe Options proposal to expand the pilot program to allow P.M.-settled SPX options to also expire on Tuesday or Thursday.[7] On September 15, 2022, the Commission approved a Cboe Options proposal to expand the pilot program to allow P.M.-settled XSP options to similarly expire on Tuesday or Thursday.[8] Under the terms of the Nonstandard Expirations Pilot Program, Weekly Expirations and EOMs are permitted on any broad-based index that is eligible for regular options trading. Weekly Expirations and EOMs are cash-settled and have European-style

[3] In addition to proposing to delete the language in Rule 4.13(e)(3) regarding the expiration date of the pilot program (and renumbering subparagraph (4) to be subparagraph (3)), the Exchange proposes to delete the word ''pilot'' from the heading of Rule 4.13(e)(3) and make corresponding changes to Rules 4.13, Interpretations and Policies .01(b) and (i)(3), .10(c), and 5.4(a).

[4] *See* Securities Exchange Act Release 62911 (September 14, 2010), 75 FR 57539 (September 21, 2010) (order approving SR–CBOE–2009–075).

[5] *See* Securities Exchange Act Release 76909 (January 14, 2016), 81 FR 3512 (January 21, 2016) (order approving SR–CBOE–2015–106).

[6] *See* Securities Exchange Act Release 78531 (August 10, 2016), 81 FR 54643 (August 16, 2016) (order approving SR–CBOE–2016–046).

[7] *See* Securities Exchange Act Release 94682 (April 12, 2022) (order approving SR–CBOE–2022–005).

[8] *See* Securities Exchange Act Release 95795 (September 21, 2022) (order approving SR–CBOE–2022–039).

exercise. The proposal became effective on a pilot basis for a period of fourteen months that commenced on the next full month after approval was received to establish the Program [9] and was subsequently extended.[10] Pursuant to Rule 4.13(e)(3), the Program is scheduled to expire on May 8, 2023. The Exchange hereby requests that the Commission approve the Nonstandard Expirations Pilot Program on a permanent basis.

By way of background, when cash-settled [11] index options were first introduced in the 1980s, settlement was based on the closing value of the underlying index on the option's expiration date. The Commission later became concerned about the impact of P.M.-settled, cash-settled index options on the markets for the underlying stocks at the close on expiration Fridays. Specifically, certain episodes of price reversals around the close on quarterly expiration dates attracted the attention of regulators to the possibility that the simultaneous expiration of index futures, futures options, and options might be inducing abnormal volatility in the index value around the close.[12] Academic research at the time provided at least some evidence suggesting that futures and options expirations contributed to excess volatility and reversals around the close on those days.[13] In light of the concerns with P.M. settlement and to help ameliorate the price effects associated with expirations of P.M.-settled, cash-settled index products, in 1987, the Commodity Futures Trading Commission (''CFTC'') approved a rule change by the Chicago Mercantile Exchange (''CME'') to provide for A.M. settlement [14] for index futures, including futures on the S&P 500.[15] The Commission subsequently approved a rule change by Cboe Options to list and trade A.M.-settled SPX options.[16] In 1992, the Commission approved Cboe Options' proposal to transition all of its European-style cash-settled options on the S&P 500 Index to A.M. settlement; [17] however, in 1993, the Commission approved a rule allowing Cboe Options to list P.M.-settled options on certain broad-based indices, including the S&P 500, expiring at the end of each calendar quarter (''Quarterly Index Expirations'') (since adopted as permanent).[18] Starting in 2006, the Commission approved numerous rule changes, on a pilot basis, permitting the Cboe Options to introduce other index options, including SPX options, with P.M.-settlement. These include P.M.-settled index options expiring weekly (other than the third Friday) and at the end of each month (''EOM''),[19] SPXPM, as well as P.M.-settled Mini-SPX Index (''XSP'') options and Mini-Russell 2000 Index (''MRUT'') options expiring on the third Friday.[20]

As stated above, since its inception in 2010, the Exchange has continuously extended the Nonstandard Expirations Pilot Program period and, during the course of the Nonstandard Expirations Pilot Program and in support of the extensions of the Nonstandard Expirations Pilot Program, the Exchange has submitted reports to the Commission regarding the Pilot Program that detail the Exchange's experience with the Pilot Program, pursuant to the Nonstandard Expirations Pilot Program Approval Order.[21] Specifically, the Exchange has submitted annual Pilot Program reports to the Commission that contain an analysis of volume, open interest, and trading patterns. In addition, for series that exceed certain minimum open interest parameters, the annual report would provide analysis of index price volatility and, if needed, share trading activity. The Exchange has also submitted periodic interim reports that contain some, but not all, of the information contained in the annual reports (together with the periodic interim reports, the ''pilot reports'').[22]

The pilot reports contained the following volume and open interest data:

(1) monthly volume aggregated for all Weekly and EOM trades;

(2) volume in Weekly and EOM series aggregated by expiration date;

(3) month-end open interest aggregated for all Weekly and EOM series;

(4) month-end open interest for EOM series aggregated by expiration date and week-ending open interest for Weekly series aggregated by expiration date;

(5) ratio of monthly aggregate volume in Weekly and EOM series to total monthly class volume; and

[9] *See supra* note 4.

[10] *See* Securities Exchange Act Release 65741 (November 14, 2011), 76 FR 72016 (November 21, 2011) (immediately effective rule change extending the Program through February 14, 2013); *see also* Securities Exchange Act Release 68933 (February 14, 2013), 78 FR 12374 (February 22, 2013) (immediately effective rule change extending the Program through April 14, 2014); 71836 (April 1, 2014), 79 FR 19139 (April 7, 2014) (immediately effective rule change extending the Program through November 3, 2014); 73422 (October 24, 2014), 79 FR 64640 (October 30, 2014) (immediately effective rule change extending the Program through May 3, 2016); 76909 (January 14, 2016), 81 FR 3512 (January 21, 2016) (extending the Program through May 3, 2017); 80387 (April 6, 2017), 82 FR 17706 (April 12, 2017) (extending the Program through May 3, 2018); 83165 (May 3, 2018), 83 FR 21316 (May 9, 2018) (SR–CBOE–2018–038) (extending the Program through November 5, 2018); 84534 (November 5, 2019), 83 FR 56119 (November 9, 2018) (SR–CBOE–2018–070) (extending the Program through May 6, 2019); 85650 (April 15, 2019), 84 FR 16552 (April 19, 2019) (SR–CBOE–2019–022) (extending the Program through November 4, 2019); 87462 (November 5, 2019), 84 FR 61108 (November 12, 2019) (SR–CBOE–2019–104) (extending the Program through May 4, 2020); 88673 (April 16, 2020), 85 FR 22507 (April 22, 2020) (SR–CBOE–2020–035) (extending the Program through November 2, 2020); 90262 (October 23, 2020) 85 FR 68616 (October 29, 2020) (SR–CBOE–2020–101); 91697 (April 28, 2021), 86 FR 23775 (May 4, 2021) (SR–CBOE–2021–026) (extending the Program through November 1, 2021); 93459 (October 28, 2021), 86 FR 60663 (November 3, 2021) (SR–CBOE–2021–063) (extending the Program through May 2, 2022); *and* 94800 (April 27, 2022) 87 FR 26248 (May 3, 2022) (SR–CBOE–2022–021 (extending the Program through November 7, 2022).

[11] The seller of a ''cash-settled'' index option pays out the cash value of the applicable index on expiration or exercise. A ''physically settled'' option, like equity and ETF options, involves the transfer of the underlying asset rather than cash. *See* Characteristics and Risks of Standardized Options, available at: *https://www.theocc.com/Company-Information/Documents-and-Archives/Options-Disclosure-Document.*

[12] The close of trading on the quarterly expiration Friday (*i.e.,* the third Friday of March, June, September and December), when options, index futures, and options on index futures all expire simultaneously, became known as the ''triple witching hour.''

[13] *See* Securities and Exchange Commission, Division of Economic Risk and Analysis, Memorandum, Cornerstone Analysis of PM Cash-Settled Index Option Pilots (February 2, 2021) (''DERA Staff PM Pilot Memo'') at 5, available at: *https://www.sec.gov/files/Analysis_of_PM_Cash_Settled_Index_Option_Pilots.pdf.*

[14] The exercise settlement value for an A.M.-settled index option is determined by reference to the reported level of the index as derived from the opening prices of the component securities on the business day before expiration.

[15] *See* Securities Exchange Act Release No. 24367 (April 17, 1987), 52 FR 13890 (April 27, 1987) (SR–CBOE–87–11) (noting that CME moved S&P 500 futures contract's settlement value to opening prices on the delivery date).

[16] *See id.*

[17] *See* Securities Exchange Act Release No. 30944 (July 21, 1992), 57 FR 33376 (July 28, 1992) (SR–CBOE–92–09). Thereafter, the Commission approved proposals by the options markets to transfer most of their cash-settled index products to A.M. settlement.

[18] *See* Securities Exchange Act Release No. 31800 (February 1, 1993), 58 FR 7274 (February 5, 1993) (SR–CBOE–92–13); *and see* Rule 4.13(a)(2)(B); *see also* Securities Exchange Act Release Nos. 54123 (July 11, 2006), 71 FR 40558 (July 17, 2006) (SR–CBOE–2006–65); *and* 60164 (June 23, 2009), 74 FR 31333 (June 30, 2009) (SR–CBOE–2009–029).

[19] *See* Securities Exchange Act Release Nos. 62911 (September 14, 2010), 75 FR 57539 (September 21, 2010) (SR–CBOE–2009–075); 76529 (November 30, 2015), 80 FR 75695 (December 3, 2015) (SR–CBOE–2015–106); 78132 (June 22, 2016), 81 FR 42018 (June 28, 2016) (SR–CBOE–2016–046); *and* 78531 (August 10, 2016), 81 FR 54643 (August 16, 2016) (SR–CBOE–2016–046).

[20] *See* Securities Exchange Act Release Nos. 70087 (July 31, 2013), 78 FR 47809 (August 6, 2013) (SR–CBOE–2013–055); *and* 91067 (February 5, 2021) 86 FR 9108 (February 11, 2021) (SR–CBOE–2020–116).

[21] *See supra* note 4.

[22] In providing the pilot reports to the Commission, the Exchange previously requested confidential treatment of the pilot reports under the Freedom of Information Act (''FOIA''). *See* 5 U.S.C. 552.

(6) ratio of month-end open interest in EOM series to total month-end class open interest and ratio of week-ending open interest in EOW series to total week-ending open interest.

The annual reports also contained the information noted in Items (1) through (6) above for Expiration Friday, A.M.-settled series, if applicable, for the period covered in the pilot report as well as for the six-month period prior to the initiation of the pilot. Upon request by the Commission, the Exchange provided data files containing: (1) Weekly and EOM option volume data aggregated by series, and (2) Weekly week-ending open interest for expiring series and EOM month-end open interest for expiring series. In the annual reports, the Exchange also provided a monthly analysis of Weekly and EOM trading patterns by undertaking a time series analysis of open interest in Weekly and EOM series aggregated by expiration date compared to open interest in near-term standard Expiration Friday A.M.-settled series in order to determine whether users were shifting positions from standard series to Weekly and Monthly series.

Finally, for series that exceed certain minimum parameters,[23] the annual reports contained the following analysis related to index price changes and underlying share trading volume at the close on Expiration Fridays:

(1) a comparison of index price changes at the close of trading on a given expiration date with comparable price changes from a control sample. The data includes a calculation of percentage price changes for various time intervals and compare that information to the respective control sample. Raw percentage price change data as well as percentage price change data normalized for prevailing market volatility, as measured by the Cboe Volatility Index (VIX), is provided; and

(2) a calculation of share volume for a sample set of the component securities representing an upper limit on share trading that could be attributable to expiring in-the-money Weekly and EOM expirations. The data includes a comparison of the calculated share volume for securities in the sample set to the average daily trading volumes of those securities over a sample period.

Also, during the course of the Nonstandard Expirations Pilot Program, the Exchange provided the Commission with any additional data or analyses the Commission requested if it deemed such data or analyses necessary to determine whether the Nonstandard Expirations Pilot Program was consistent with the Exchange Act. The Exchange has made public on its website all data and analyses previously submitted to the Commission under the Nonstandard Expirations Pilot Program,[24] and will continue to make public any data and analyses it submits to the Commission while the Nonstandard Expirations Pilot Program is still in effect.

The Exchange has concluded that the Nonstandard Expirations Pilot Program does not negatively impact market quality or raise any unique or prohibitive regulatory concerns. The Exchange has not identified any evidence from the pilot data indicating that the trading of Weekly and EOM options has any adverse impact on fair and orderly markets on Expiration Fridays for the underlying indexes or the underlying securities comprising those indexes, nor have there been any observations of abnormal market movements attributable to Weekly and EOM options from any market participants that have come to the attention of the Exchange. Based on a study conducted by the Commission's Division of Economic and Risk Analysis (''DERA'') staff on the pilot data from 2006 through 2018,[25] and the Exchange's review of the pilot data from 2019 through 2021, the size of the market for P.M.-settled SPX options (including quarterly, weekly, EOM and third Friday expirations) since 2007 has grown from a trivial portion of the overall market to a substantial share (from around 0.1% of open interest in 2007 to 30% in 2021).[26] Notional value of open interest in P.M.-settled SPX options increased from approximately a median of $1.5 billion in 2007 to $1.9 trillion in 2021, approximately 1260 times its value in 2007. Notional open interest in A.M.-settled SPX options was already hovering around a median of $1.4 trillion in 2007, and it has since increased to approximately $4.4 trillion in 2021. It is also important to note that open interest on expiring P.M.-settled SPX options, as compared to A.M.-settled options, is spread out across a greater number of expiration dates, which results in a smaller percentage of open interest expiring on any one date, thus mitigating concerns that SPXPM option expiration may have a disruptive effect on the market.[27] Daily trading volume in P.M.-settled SPX options has increased from a median of about 700 contracts in 2007 to nearly 1.9 million contracts in 2021,[28] and now exceeds trading volume in A.M.-settled SPX options.

Moreover, the DERA staff study of the P.M.-settled SPX options pilot data (2006 through 2018) did not identify any significant economic impact on S&P 500 futures,[29] the S&P 500, or the underlying component securities of the S&P 500 surrounding the close. For purposes of the study, volatility was by and large measured by using the standard deviation [30] of one-minute returns of S&P 500 futures values and the index value during regular hours on each day reviewed (excluding the first and last 15 minutes of trading) and then compared with the standard deviation of one-minute returns (for S&P 500 futures, the S&P 500, and the underlying component securities of the S&P 500) over the last 15 minutes of a trading day.[31] Using this as a general measure,[32] the DERA staff study then reviewed

[23] The Exchange and the Commission determined the minimum open interest parameters, control sample, time intervals, method for randomly selecting the component securities, and sample periods.

[24] Available at *https://www.cboe.com/aboutcboe/legal-regulatory/national-market-system-plans/pm-settlement-spxpm-data*.

[25] *See* DERA Staff PM Pilot Memo, at 13 (''Option settlement quantity data for A.M.- and P.M.-settled options were obtained from the Cboe, including the number of contracts that settled in-the-money for each exchange-traded option series on the S&P 500 index. . .on expiration days from January 20, 2006 through December 31, 2018. Daily open interest and volume data for [SPX] option series were also obtained from Cboe, including open interest data from January 3, 2006 through December 31, 2018 and trading volume data from January 3, 2006 through December 31, 2018.'')

[26] The DERA staff study reviewed and provided statistics for market share, median notional value of open interest and median volume in 2007 and in 2018. The Exchange provides updated statistics for market share, median notional value of open interest and median volume in 2021, replacing the 2018 statistics provided in the Commission staff study.

[27] *See* DERA Staff PM Pilot Memo, at 2.

[28] The Exchange notes that the DERA staff study used two-sided volume data for the median volume in 2007 and in 2018; therefore, the Exchange provides two-sided volume data for the median volume in 2021.

[29] Futures on the S&P 500 experience high volume and liquidity both before and after the close of the underlying market. Therefore, futures are a useful measure of abnormal volatility surrounding the close and the open. *See* DERA Staff PM Pilot Memo, at 14. The Exchange agrees with this approach.

[30] Standard deviation applied to a rate of return (in this case, one-minute) of an instrument can indicate that instrument's historical volatility. The greater the standard deviation, the greater the variance between price and the mean, which indicates a larger price range, *i.e.,* higher volatility.

[31] For example, if on a particular day the standard deviation of one-minute returns between 3:45 p.m. ET and 4:00 p.m. ET is 0.004 and the standard deviation of returns from 9:45 a.m. ET to 3:45 p.m. ET is 0.002, this metric would take on a value of 2 for that day, indicating that volatility during the last 15 minutes of the trading day was twice as high as it was during the rest of the trading day. *See* DERA Staff PM Pilot Memo, at 15; *see also* DERA Staff PM Pilot Memo, at Section V, which discusses in detail the metrics used to measure, for the purposes of the study, the extent to which the market may experience abnormal volatility surrounding SPXPM option settlement.

[32] *See* DERA Staff PM Pilot Memo, at Section V, which discusses in detail the metrics used to measure, for the purposes of the study, the extent to which the market may experience abnormal volatility surrounding SPXPM option settlement.

whether, and to what extent, the settlement quantity of SPXPM options and the levels of open interest in SPXPM options on expiration days (as compared to non-expiration days) may be associated with general price volatility and price reversals for S&P 500 futures, the S&P 500, and the underlying component securities of the S&P 500 near the close. From its review of the study, the Exchange agrees that, although volatility before the market close is generally higher than during the rest of the trading day, there is no evidence of any significant adverse economic impact to the futures, index, or underlying index component securities markets as a result of the quantity of P.M.-settled SPX options that settle at the close or the amount of expiring open interest in P.M.-settled SPX options. For example, the largest settlement event that occurred during the time period of the study (a settlement of $100.4 billion of notional on December 29, 2017) had an estimated impact on the futures price of only approximately 0.02% (a predicted impact of $0.54 relative to a closing futures price of $2,677).

In particular, the DERA staff study found that an additional P.M.-settled SPX options settlement quantity equal to $10 billion in notional value is associated with a marginal impact on futures prices during the last 15 minutes of the trading day of only about $0.06 (where the hypothetical index level is 2,500), additional expiring open interest in P.M.-settled SPX options equal to $10 billion in notional value is associated with a marginal impact on futures prices during the last 15 minutes of the trading day of only about $0.05 (assumed index level is 2,500). Also, an additional increase in settlement quantity or in expiring open interest, each equal to $20 million in notional value, did not result in any meaningful futures price reversals near the close (neither was found to cause a price reversal of over one standard deviation [33]).

Likewise, the study identified that an additional total P.M.-settled SPX options settlement quantity equal to $10 billion in notional value corresponds to price movement in the S&P 500 of only about $0.08 (assuming an index level of 2,500) during the last 15 minutes of the trading day, and that additional expiring open interest equal to $10 billion in notional value corresponds to a price movement in the S&P 500 of only about $0.06 (assuming an index level of 2,500) during the last 15 minutes of the trading day. The study also identified that it would take an increase of $34 billion in notional value of total settlement quantity and of expiring open interest for one additional S&P 500 price reversal of greater than two standard deviations to occur in the last 15 minutes before the market close. Also, regarding potential impact to S&P 500 component securities, it would take an increase in total P.M.-settled SPX options settlement quantity equal to $20 billion to effect a price movement of only approximately $0.03 for a $200 stock, an increase in expiring open interest in P.M.-settled SPX options equal to $10 billion to effect a price movement less than half a standard deviation, and an increase in total P.M.-settled SPX settlement quantity equal to $7 billion to achieve a price reversal greater two standard deviations.

The study employed the same metrics to determine whether there is greater price volatility for S&P 500 futures, the S&P 500, and the component securities of the S&P 500 related to SPXPM option settlements during an environment of high market volatility (*i.e.,* on days in which the VIX Index was in the top 10% of closing index values) and did not identify indicators of any significant economic impact on these markets near the close as a result of the P.M.-settled SPX options settlement.[34] In addition to this, the DERA staff study, applying the same metrics and analysis as for P.M.-settled SPX options to A.M.-settled SPX options, did not identify any evidence of a statistically significant relationship between settlement quantity or expiring open interest of A.M.-settled options and volatility near the open.

Upon review of the results of the DERA staff study, the Exchange agrees that each of the above-described marginal price movements in S&P 500 futures, the S&P 500, and the S&P 500 component securities affected by increases in P.M.-settled SPX options settlement quantity and expiring open interest appear to be de minimis pricing changes from those that occur over regular trading hours (outside of the last 15 minutes of the trading day). Further, the Exchange has not observed any significant economic impact or other adverse effects on the market from similar reviews of its pilot reports and data submitted after 2018.[35] In its review of a sample of the pilot data from 2019 through 2021, the Exchange similarly measured volatility over the final fifteen minutes of each trading day by taking the standard deviation of rolling one-minute returns of the S&P 500 level (excluding the first and last fifteen minutes of trading) and comparing such with the standard deviation of one-minute returns [36] of the S&P 500 level, over the last 15 minutes of a trading day. The Exchange identified an average standard deviation ratio of 1.42 for the S&P 500 on non-expiration days and an average standard deviation ratio of 1.54 for the S&P 500 on expiration days (a ratio between expiration days and non-expiration days of 1.09). The Exchange also notes that, using the same methodology, it observed that, from 2015 through 2019,[37] the average standard deviation ratio for the S&P 500 on non-expiration days was 1.11 and the average standard deviation ratio for the S&P 500 on expiration days was 1.22 (a ratio between expiration days and non-expiration days of 1.10). While the average standard deviation ratio on both expiration and non-expiration days was higher in 2019 through 2021 due to overall market volatility, the ratios between the standard deviation ratios on expiration days and non-expirations days remained nearly identical between the 2015 through 2019 timeframe and the 2019 through 2021. This shows that, in cases where overall market volatility may increase, the normalized impact on expiration days to non-expiration days generally remains consistent.

In addition to this, the Exchange notes that the S&P 500 Index is rebalanced quarterly. The changes resulting from each rebalancing coincide with the third-Friday of the quarterly rebalancing month (*i.e.,* March, June, September, October and December) [38] and generally drive an increase in trading activity from investors that seek to track the S&P 500. As such, The Exchange measured volatility on quarterly rebalancing dates and found that the average standard deviation ratio was 1.62, which suggests more closing volatility on quarterly rebalance dates compared to non-quarterly expiration dates (for which the average standard deviation ratio was 1.22), thus indicating that the impact rebalancing may have on the S&P 500 is greater than any impact that P.M.-settled SPX options may have on the S&P 500.

The Exchange additionally focused its study of the post-2018 sample pilot data

[33] *See supra* note 26.

[34] The Exchange also notes that the study did not identify any evidence that less liquid S&P 500 constituent securities experienced any greater impact from the settlement of P.M.-settled SPX options.

[35] Total SPX open interest volumes were examined for expiration dates over a roughly two-year period between October 2019 and November 2021.

[36] Calculated at every tick for the prior minute.

[37] November 2015 through November 2021.

[38] *See* S&P Dow Jones Indices, Equity Indices Policies & Practices, Methodology (August 2021), at 15, available at *https://www.spglobal.com/spdji/en/documents/methodologies/methodology-sp-equity-indices-policies-practices.pdf.*

on reviewing for potential correlation between excess market volatility and price reversals and the hedging activity of liquidity providers. As explained in the DERA staff study, potential impact of P.M.-settled SPX options on the correlated equity markets is thought to stem from the hedging activity of liquidity providers in such options.[39] To determine any such potential correlation, the Exchange studied the expected action of liquidity providers that are the primary source of the hedging on settlement days. These liquidity providers generally delta-hedge their S&P 500 index exposure via S&P 500 futures and on settlement day unwind their futures positions that correspond with the delta of their in-the-money (ITM) expiring P.M.-settled SPX options. Assuming such behavior, the Exchange estimated the Market-On-Close (''MOC'')[40] volume for the shares of the S&P 500 component securities (*i.e.,* ''MOC share volume'') that could ultimately result from the unwinding of the liquidity providers' futures positions by equating the notional value of the futures positions that correspond to expiring ITM open interest to the number S&P 500 component security contracts (based on the weight of each S&P 500 component security). That is, the Exchange calculated (an estimate) of the amount of MOC volume in the S&P 500 component markets attributable hedging activity as a result of expiring ITM P.M.-settled SPX options (*i.e.,* ''hedging MOC''). The Exchange then: (1) compared the hedging MOC share volume to all MOC share volume on expiration days and non-expiration trading days; and (2) compared the notional value of the hedging futures positions (*i.e.,* that correspond to expiring ITM P.M.-settled SPX options open interest) to the notional value of expiring ITM P.M.-settled SPX options open interest, the notional value of all expiring P.M.-settled SPX options open interest and the notional value of all P.M.-settled SPX options open interest.

The Exchange observed that, on average, there were approximately 25% more MOC shares executed on expiration days (332 expiration days) than non-expiration days (209 non-expiration days). While, at first glance, the volume of MOC shares executed on expiration days seems much greater than the volume executed on non-expiration days, the Exchange notes that much of this difference is attributable to just eight expiration days—the quarterly index rebalancing dates captured within the scope of the post-2018 sample pilot data. The average MOC share volume on the eight quarterly rebalancing dates was approximately 4.8 times the average MOC share volume on the non-quarterly rebalancing expiration dates; again, indicating that the impact rebalancing may have on the S&P 500 Index is greater than any impact that P.M.-settled SPX options may have on the S&P 500 Index. That is, the Exchange observed that the majority of closing volume on quarterly rebalance dates is driven by rebalancing of shares in in the S&P 500, and not by P.M.-settled SPX options expiration-related hedging activity. Notwithstanding the MOC share volume on quarterly rebalancing dates, the volume of MOC shares executed on expiration days (324 expiration days) was only approximately 13% more than that on non-expiration days, substantially less than the increase in volume over non-expiration days wherein the eight index rebalancing dates are included in expiration day volume. In addition to this, the Exchange observed that the hedging MOC share volume (*i.e.,* the expected MOC share volume resulting from hedging activity in connection with expiring ITM P.M.-settled SPX options) was, on average, less than the MOC share volume on non-expiration days, and was only approximately 20% of the total MOC share volume on expiration days, indicating that other sources of MOC share volume generally exceed the volume resulting from hedging activity of expiring ITM P.M.-settled SPX options and would more likely be a source of any potential market volatility.

The Exchange also observed that, across all third-Friday expirations, the notional value of the hedging futures positions was approximately 25% of the notional value of expiring ITM P.M.-settled SPX options, approximately 3.8% of the notional value of all expiring P.M.-settled SPX options, and approximately only 0.5% of the notional value of all P.M.-settled SPX options. As such, the estimated hedging activity from liquidity providers on expiration days is a fraction of the expiring open interest in P.M.-settled SPX options, which, the Exchange notes, is only 14% of the total open interest in P.M.-settled SPX options; thus, indicating negligible capacity for hedging activity to increase volatility in the underlying markets.

While unrelated to the initial concerns of P.M.-settlement as described above, at the request of the Commission, the Exchange recently completed an analysis intended to evaluate whether the SPXPM Program impacted the quality of the SPX option market. Specifically, the Exchange compared values of key market quality indicators (specifically, the bid-ask spread[41] and effective spread[42]) in SPXW options both before and after the introduction of Tuesday expirations and Thursday expirations for SPXW options on April 18 and May 11, 2022, respectively.[43] Options on the Standard & Poor's Depositary Receipts S&P 500 ETF (''SPY'') were used as a control group to account for any market factors that might influence key market quality indicators. The Exchange used data from January 3, 2022 through March 4, 2022 (the two-month period prior to the introduction of SPXW options with Tuesday expirations) and data from May 11, 2022 to July 10, 2022 (the two-month period following the introduction of SPXW options with Thursday expirations).[44]

Given the time that as passed since the introduction of Weekly and EOM options, the Exchange is unable to analyze whether the introduction of Weekly and EOM options significantly impacted the market quality of corresponding A.M.-settled options. The Exchange believes analyzing whether the introduction of new SPXW P.M.-settled expirations (*i.e.,* SPXW options with Tuesday and Thursday expirations) impacted the market quality of then-existing SPXW P.M.-settled expirations (*i.e.,* SPXW options with Monday, Wednesday, and Friday expirations) provides a reasonable substitute to evaluate whether the introduction of Weekly and EOM options impacted the market quality of any corresponding A.M.-settled options when the pilot began.[45]

As a result of this analysis, the Exchange believes the introduction of

[39] *See* DERA Staff PM Pilot Memo, at 10–12.

[40] MOC orders allow a market participant to trade at the closing price. Market participants generally utilize MOC orders to ensure they exit positions at the end of the trading day.

[41] The Exchange calculated for each of SPXW options (with Monday, Wednesday, and Friday expirations) and SPY Weekly options (with Monday, Wednesday, and Friday expirations) the daily time-weighted bid-ask spread on the Exchange during its regular trading hours session, adjusted for the difference in size between SPXW options and SPY options (SPXW options are approximately ten times the value of SPY options).

[42] The Exchange calculated the volume-weighted average daily effective spread for simple trades for each of SPXW options (with Monday, Wednesday, and Friday expirations) and SPY Weekly options (with Monday, Wednesday, and Friday expirations) as twice the amount of the absolute value of the difference between an order execution price and the midpoint of the national best bid and offer at the time of execution, adjusted for the difference in size between SPXW options and SPY options.

[43] For purposes of comparison, the Exchange paired SPXW options and SPY options with the same moneyness and same days to expiration.

[44] The Exchange observed comparable market volatility levels during the pre-intervention and post-intervention time ranges.

[45] The full analysis is included in Exhibit 3 of this rule filing.

SPX options with Tuesday and Thursday options had no significant impact on the market quality of SPXW options with Monday, Wednesday, and Friday expirations. With respect to the majority of series analyzed, the Exchange observed no statistically significant difference in the bid-ask spread or the effective spread of the series in the period prior to introduction of the Tuesday and Thursday expirations and the period following the introduction of the Tuesday and Thursday expirations. While statistically insignificant, the Exchange notes that in many series, particularly as they were closer to expiration, the Exchange observed that the values of these spreads decreased during the period following the introduction of the Tuesday and Thursday expirations.[46]

To further note, given the significant changes in the closing procedures of the primary markets in recent decades, including considerable advances in trading systems and technology, the Exchange believes that the risks of any potential impact of Weekly and EOM options on the underlying cash markets are also de minimis.

The Exchange proposes to make the Nonstandard Expirations Pilot Program permanent as P.M.-settled index products, particularly Weekly and EOM options, have become an integral part of the Exchange's product offerings, providing investors with greater trading opportunities and flexibility. As indicated by the significant growth in the size of the market for P.M.-settled Weekly and EOM options, such options have been, and continue to be, well-received and widely used by market participants. Therefore, the Exchange wishes to be able to continue to provide investors with the ability to trade Weekly and EOM options on a permanent basis. The Exchange believes that the permanent continuation of the Nonstandard Expirations Pilot Program will serve to maintain the status quo by continuing to offer a product to which investors have become accustomed and have incorporated into their business models and day-to-day trading methodologies for approximately 13 years. As such, the Exchange also believes that ceasing to offer Weekly and EOM options may result in significant market disruption and investor confusion. The Exchange has not identified any significant impact on market quality nor any unique or prohibitive regulatory concerns as a result of the Nonstandard Expirations Pilot Program, and, as such, the Exchange believes that the continuation of the Nonstandard Expirations Pilot Program as a pilot, including the use of time and resources to compile and analyze quarterly and annual pilot reports and pilot data, is no longer necessary and that making the Nonstandard Expirations Pilot Program permanent will allow the Exchange to otherwise allocate time and resources to other industry initiatives.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the ''Act'') and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[47] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)[48] requirements that the rules of an exchange be 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.

In particular, the Exchange believes that the making the Nonstandard Expirations Pilot Program permanent will allow the Exchange to be able to continue to offer Weekly and EOM options—a product of which has become an integral part of the Exchange's offerings—on a continuous and permanent basis. Since their reintroduction beginning in 2006,[49] P.M.-settled options have been, and continue to be, well-received and widely used by market participants, providing investors with greater trading opportunities and flexibility. The Exchange believes that the permanent continuation of the Nonstandard Expirations Pilot Program will remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest by continuing to offer a product to which investors have become accustomed and have incorporated into their business models and day-to-day trading strategies for approximately 13 years. As indicated by the significant growth in the size of the market for P.M.-settled options, such options have been, and continue to be, well-received and widely used by market participants. Conversely, the Exchange believes ceasing to offer the Nonstandard Expirations Pilot Program may result in significant market disruption and investor confusion, as P.M.-settled index products, particularly Weekly and EOM options, have become an integral part of the Exchange's product offerings, providing investors with greater trading opportunities and flexibility.

The Exchange further believes that making the Nonstandard Expirations Pilot Program permanent will remove impediments to and perfect the mechanism of a free and open market and a national market system and protect investors, while maintaining a fair and orderly market, as the Exchange believes that previous concerns (arising in the 1980s) regarding options expirations potentially contributing to excess volatility and reversals around the close have been adequately diminished. As described in detail above, the Exchange has observed no significant adverse market impact or identified any meaningful regulatory concerns during the approximately 13-year operation of the Nonstandard Expirations Pilot Program as a pilot nor during the 15 years since P.M.-settled SPX options were reintroduced to the marketplace.[50] Notably, the Exchange did not identify any significant economic impact (including on pricing or volatility or in connection with reversals) on related futures, the underlying indexes, or the underlying component securities of the underlying indexes surrounding the close as a result of the quantity of Weekly and EOM options that settle at the close or the amount of expiring open interest in Weekly and EOM options, nor any demonstrated capacity for options hedging activity to impact volatility in the underlying markets. While the DERA staff study and corresponding Exchange study described above specifically evaluated SPX options, because Weekly and EOM options may only overly broad-based index options, the Exchange believes it is appropriate to extrapolate the data to apply to the Weekly and EOM options (which include SPX options). This is particularly true given that the reports submitted by the Exchange during the pilot period have similarly demonstrated no significant economic

[46] In any series in which the Exchange observed an increase in the market quality indicators, the Exchange notes any such increase was also statistically insignificant.

[47] 15 U.S.C. 78f(b).

[48] 15 U.S.C. 78f(b)(5).

[49] *See supra* notes 27–39. As described above, the Exchange's conclusion is consistent with the analysis in the DERA Staff PM Pilot Memo.

[50] *See supra* notes 26–39.

impact on the respective underlying indexes or other products.

The Exchange also believes the introduction of Weekly and EOM options had no significant impact on the market quality of corresponding A.M.-settled options or other options. The Exchange believes this as a result of its analysis conducted after the introduction of SPXW options with Tuesday and Thursday expirations, which demonstrated no statistically significant impact on the bid-ask or effective spreads of SPXW options with Monday, Wednesday, and Friday expirations after trading in the SPXW options with Tuesday and Thursday expirations began. While SPXW options are P.M.-settled and SPX options are A.M.-settled, they are otherwise nearly identical products. As noted above, Weekly and EOM options may only overly broad-based indexes, including the S&P 500. Therefore, the Exchange believes analyzing the impact of new SPXW options on then-existing SPXW options permit the Exchange to extrapolate from this data that it is unlikely the introduction of any other Weekly or EOM options significantly impacted the market quality of corresponding A.M.-settled SPX options when the pilot began. Additionally, the significant changes in the closing procedures of the primary markets in recent decades, including considerable advances in trading systems and technology, has significantly minimized risks of any potential impact of Weekly or EOM options on the underlying cash markets. As such, the Exchange believes that a permanent Nonstandard Expirations Pilot Program does not raise any unique or prohibitive regulatory concerns and that such trading has not, and will not, adversely impact fair and orderly markets on Expiration Fridays for the underlying indexes and their component securities. Further, as the Exchange has not identified any significant impact on market quality or any unique or prohibitive regulatory concerns as a result of offering Weekly and EOM options, the Exchange believes that the continuation of the Nonstandard Expirations Pilot Program as a pilot, including the gathering, submission and review of the pilot reports and data, is no longer necessary and that making the Nonstandard Expirations Pilot Program permanent will allow the Exchange to otherwise allocate time and resources to other industry initiatives.

B. Self-Regulatory Organization's Statement on Burden on Competition

Cboe Options 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 does not believe that making the Nonstandard Expirations Pilot Program permanent will impose any unnecessary or inappropriate burden on intramarket competition because Weekly and EOM options will continue to be available to all market participants who wish to participate in the Weekly and EOM options market. The Exchange believes that the significant and sustained growth the Weekly and EOM options market has experienced since their reintroduction through pilot programs indicates strong, continued investor interest and demand, warranting a permanent Nonstandard Expirations Pilot Program. The Exchange believes that, for the period that Weekly and EOM options have been in operation as pilot programs, they have provided investors with a desirable product with which to trade and wishes to permanently offer this product to investors. Furthermore, during the pilot period, the Exchange has not observed any significant adverse market effects nor identified any regulatory concerns as a result of the Weekly and EOM Program, and, as such, the continuation of the Nonstandard Expirations Pilot Program as a pilot, including the gathering, submission and review of the pilot reports and data, is no longer necessary—a permanent Nonstandard Expirations Pilot Program will allow the Exchange to otherwise allocate time and resources to other industry initiatives.

The Exchange further does not believe that making the Nonstandard Expirations Pilot Program permanent will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because it applies to a class of options listed only for trading on Cboe Options. The Exchange notes that other exchanges are free to and do offer competing products. To the extent that the permanent offering and continued trading of Weekly and EOM options may make Cboe Options a more attractive marketplace to market participants at other exchanges, such market participants may elect to become Cboe Options market participants.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

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 Exchange 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:

Electronic Comments

- Use the Commission's internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–CBOE–2023–020 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–CBOE–2023–020. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's internet website (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for

inspection and copying at the principal office of the Exchange. 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–CBOE–2023–020, and should be submitted on or before May 22, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[51]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–09079 Filed 4–28–23; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meetings

TIME AND DATE: 2 p.m. on Thursday, May 4, 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 his designee, has certified that, in his 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: April 27, 2023.

Vanessa A. Countryman,

Secretary.

[FR Doc. 2023–09266 Filed 4–27–23; 4:15 pm]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97372; File No. SR–NYSEAMER–2023–28]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Modify the NYSE American Options Fee Schedule

April 25, 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 April 18, 2023, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the NYSE American Options Fee Schedule (''Fee Schedule'') regarding routing fees and Floor Broker rebates and to delete text relating to discontinued programs. The Exchange proposes to implement the fee change effective April 18, 2023.[4] 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 purpose of this filing is to amend the Fee Schedule to (1) delete text relating to fees and credits for NYSE FANG+ Index (''FAANG'') transactions, (2) simplify the Routing Surcharge applied to orders routed to other markets, (3) eliminate the introductory pricing currently offered for Market Maker ATP fees and Premium Product fees, and (4) add a Floor Broker rebate program. The Exchange believes that the proposed changes would promote clarity and transparency in the Fee Schedule by eliminating fees and credits relating to programs that the Exchange proposes to discontinue and simplifying the fees charged for routed orders. The Exchange proposes to implement the rule change on April 18, 2023.

FAANG Transactions

Footnote 7 to Section I.A. of the Fee Schedule (Rates for Options transactions) currently provides for fees and credits relating to FAANG transactions. The Fee Schedule provides for a $0.35 per contract, per side fee for Non-Customer FAANG transactions, whether executed manually or electronically. FAANG transactions (i) on behalf of Customers or (ii) by NYSE American Options Market Makers, Specialists, e-Specialists or DOMMs do not incur a fee. Marketing Charges are not applied to FAANG transactions. Volume in FAANG transactions is included in the calculations to qualify

[51] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Exchange originally filed to amend the Fee Schedule on March 1, 2023 (SR–NYSEAMER–2023–18), withdrew such filing and amended the Fee Schedule on March 15, 2023 (SR–NYSEAMER–2023–21), withdrew such filing and amended the Fee Schedule on March 28, 2023 (SR–NYSEAMER–2023–24), and then withdrew such filing and amended the Fee Schedule on April 10, 2023 (SR–NYSEAMER–2023–26), which latter filing the Exchange withdrew on April 18, 2023.

for any volume-based incentives currently offered on the Exchange.

The Fee Schedule also provides for a credit to any firm that is an NYSE American Options Market Maker, Specialist, e-Specialist or DOMM that executes a specified minimum number of total monthly contract sides that open a position in FAANG on the Exchange (''eligible contract sides''), as set forth below (''MM FAANG Credit''):

- A credit of $5,000 for a minimum of 500 eligible contract sides; provided, however, that if more than five firms qualify for this MM FAANG Credit in a calendar month, the $5,000 MM FAANG Credit for each qualifying firm will be a pro rata share of $25,000; or
- A credit of $10,000 for a minimum of 2,000 eligible contract sides; provided, however, that if more than two firms qualify for this MM FAANG Credit in a calendar month, the $10,000 MM FAANG Credit for each qualifying firm will be a pro rata share of $25,000. A firm that qualifies for the $10,000 credit will not be eligible for the $5,000 credit.

Because FAANG options were delisted after monthly expiration in February 2023, the Exchange now proposes to delete the current text of Footnote 7 to Section I.A. to remove references to fees and credits relating to FAANG transactions, which would no longer be applicable for any market participants, and designate Footnote 7 as Reserved. The Exchange also proposes a conforming change to Section I.D. (Prepayment Program) of the Fee Schedule to delete the reference in that section to ''Section 1.A., note 7,'' to reflect the proposed deletion of the fees and credits relating to FAANG transactions. The Exchange believes this proposed change, which would remove text relating to a discontinued program, would promote clarity in the Fee Schedule.

Routing Surcharge

As set forth in Section I.L. of the Fee Schedule, the Exchange currently assesses a routing surcharge on all non-Customer orders routed to away markets and on Customer orders including Professional Customer orders that are charged transaction fees at another exchange. If the executing exchange does not charge a transaction fee for the execution of the Customer order, the Routing Surcharge will be waived. Currently, the Routing Surcharge is $0.11 per contract plus (i) any transaction fees assessed by the away exchange(s) (calculated on an order-by-order basis since different away exchanges charge different amounts) or (ii) if the actual transaction fees assessed by the away exchange(s) cannot be determined prior to the execution, the highest per contract charge assessed by the away exchange(s) for the relevant option class and type of market participant (*e.g.,* Customer, Firm, Broker/Dealer, Professional Customer or Market Maker). The Exchange applies the Routing Surcharge in addition to any customary execution fees applicable to the order.

The Exchange now proposes to modify the Routing Surcharge to be based on whether the routed order is in a Penny or non-Penny issue and to establish a single fee that would be applicable to all routed orders in Penny issues, and a single fee for all routed orders in non-Penny issues. Specifically, the Exchange proposes that the fee for routed orders would be set at a fixed amount intended to counterbalance the internal resources required to support the handling of orders routed away from the Exchange. The Exchange proposes to implement a flat fee structure for routing fees, which the Exchange believes would streamline the process of calculating fees applied to orders routed away from the Exchange because it would, among other things, reduce the administrative burden of recalibrating routing fees each time an away exchange modifies its relevant transaction fees. Accordingly, the Exchange proposes a Routing Surcharge of $0.61 in Penny issues, and $1.21 in non-Penny issues. The Exchange believes that having a single published rate for all routed orders in Penny issues and a single published rate for all routed orders in non-Penny issues would also reduce potential confusion relating to the amount of the surcharge for a given routed order (particularly in light of the variability in transaction fees across other options markets) and would permit market participants to determine execution costs at the time of order entry, thereby promoting clarity and transparency in the Fee Schedule. The Exchange believes the proposed routing fee structure is not novel, as at least one other options exchange similarly applies fixed routing fees based on whether the routed order is in a Penny or non-Penny issue, and that the proposed amounts of the fees are within the range of fees applied by other markets to routed orders.[5]

Introductory Pricing for Newly Enrolled Market Makers

Section III.A. of the Fee Schedule provides for monthly ATP fees. Footnote 2 of Section III.A. further provides that an ATP Holder that newly enrolls to operate as a Market Maker may be entitled to introductory pricing on ATP fees for up to six months.[6] The Exchange similarly offers newly enrolled Market Makers introductory pricing on Premium Product Fees for up to six months, as set forth in Section III.B, Footnote 1.[7]

The Exchange now proposes to delete Section III.A., Footnote 2 and Section III.B., Footnote 1 to eliminate the introductory pricing for newly enrolled Market Makers on ATP fees and Premium Product Fees, respectively, as no ATP Holders have qualified for this pricing in the last few years. The Exchange adopted this introductory pricing to encourage ATP Holders to enroll as Market Makers. However, because these pricing incentives have been underutilized (and therefore did not achieve their intended effect), the Exchange proposes to eliminate such pricing from the Fee Schedule and believes that ATP Holders would not be impacted by its removal.

Floor Broker Grow With Me Program

The Exchange proposes to add the Floor Broker Grow With Me program,

[5] *See, e.g.,* BOX Options Exchange Fee Schedule, *available at: https://boxexchange.com/assets/BOX-Fee-Schedule-as-of-March-6-2023.pdf* (providing for fixed routing fees of $0.60 per contract fee for customer orders in Penny classes and $0.85 per contract fee for customer orders in non-Penny class); Cboe Exchange, Inc. Options Fee Schedule, *available at: https://cdn.cboe.com/resources/membership/Cboe_FeeSchedule.pdf* (providing, for example, Customer routing fees of $0.75 for orders in Penny issues or $1.25 for orders in non-Penny issues routed to certain away markets and Non-Customer routing fees of $1.17 for all orders in Penny issues or $1.45 for all orders in non-Penny issues routed away).

[6] A newly enrolled Market Maker on the Exchange may be entitled to introductory pricing on its ATP Fees for up to six months, beginning the first month in which it registers. For the first three months (*i.e.,* months 1–3), the Exchange waives the ATP fees, and for the latter three months (*i.e.,* months 4–6), the Exchange discounts such ATP fees by 50%, unless the Market Maker achieves a monthly ADV equal to at least 0.05% of TCADV, at which time the Exchange would charge the Market Maker 100% of its ATP Fees for the remaining months, regardless of its monthly ADV in subsequent months. An ATP Holder may qualify for this introductory pricing only once in a 24-month period, which period begins in the first month the ATP Holder registers on the Exchange.

[7] A newly enrolled Market Maker on the Exchange may be entitled to introductory pricing on its Premium Product Fees for up to six months, beginning the first month in which it registers. For the first three months (*i.e.,* months 1–3), the Exchange waives Premium Product Fees, and for the latter three months (*i.e.,* months 4–6), the Exchange discounts such Premium Product Fees by 50%, unless the Market Maker achieves a monthly ADV equal to at least 0.05% of TCADV, at which time the Exchange would charge the Market Maker 100% of its Premium Product Fees for the remaining months, regardless of its monthly ADV in subsequent months. An ATP Holder may qualify for this introductory pricing only once in a 24-month period, which period begins in the first month the ATP Holder registers on the Exchange.

through which Floor Broker organizations (''Floor Brokers'') may earn a ($0.05) rebate on manual billable volume. The Exchange proposes to add this program in Section III.E.2. of the Fee Schedule, which is currently designated as Reserved. The Exchange proposes that the Floor Broker Grow With Me program would provide Floor Brokers with an opportunity to earn a rebate on manual billable volume based on demonstrated growth as compared to the Floor Brokers' manual billable volume ADV in January 2023 (the ''base period''). The Exchange proposes that Floor Brokers that achieve (1) manual billable contracts volume of 100% over their base period volume in a month or (2) an ADV of 25,000 manual billable contracts in a month, whichever is greater, would be eligible for a rebate of ($0.05) per billable side. The Exchange proposes that Floor Brokers new to the Exchange would be eligible to qualify for the program by achieving the second qualifying criteria, which is not tied to base period volume. The Exchange further proposes that the Floor Broker Grow With Me program would be in place with these qualifying criteria until July 31, 2023, which would allow the Exchange a period to evaluate such criteria and to submit a proposed rule change regarding qualifications for the program beyond that date.

Although the Exchange cannot predict with certainty whether the proposed change would encourage Floor Brokers to increase their manual billable volume on the Exchange, the proposed change is designed to continue to incentivize Floor Brokers to do so by offering a rebate on manual billable volume. All Floor Brokers, including new Floor Brokers, would be eligible to earn a rebate through the Floor Broker Grow With Me program, as proposed.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Sections 6(b)(4) and (5) of the Act,[9] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Proposed Rule Change Is Reasonable

The Exchange operates in a highly competitive market. The Commission has repeatedly expressed its preference for competition over regulatory intervention in determining prices, products, and services in the securities markets. In Regulation NMS, the Commission highlighted the importance of market forces in determining prices and SRO revenues and, also, recognized that current regulation of the market system ''has been remarkably successful in promoting market competition in its broader forms that are most important to investors and listed companies.'' [10]

There are currently 16 registered options exchanges competing for order flow. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[11] Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in January 2023, the Exchange had less than 8% market share of executed volume of multiply-listed equity and ETF options trades.[12]

The Exchange believes that the ever-shifting market share among the exchanges from month to month demonstrates that market participants can shift order flow, or discontinue or reduce use of certain categories of products, in response to fee changes. Accordingly, competitive forces constrain options exchange transaction fees. Stated otherwise, changes to exchange transaction fees can have a direct effect on the ability of an exchange to compete for order flow.

The Exchange believes the proposed change to the Routing Surcharge is reasonable because it would establish a single fee that would be applicable to all routed orders in Penny issues and a single fee that would be applicable to all routed orders in non-Penny issues, and such fees would be applicable to all market participants equally. In addition, the Exchange believes the proposed change is reasonable because it would provide for routing fees that would counterbalance the internal resources required to support the handling of orders routed away from the Exchange and would streamline the process of calculating routing fees by obviating the need to recalibrate fees based on individual away market fees (which are variable and subject to frequent change) and eliminating any potential confusion as to routing fees applicable to a given order. The Exchange also notes that a fixed fee structure for routing fees is not novel and that the amounts of the proposed Routing Surcharge amounts are within the range of routing fees currently charged by other options exchanges.[13]

The Exchange believes that the proposed change to delete FAANG transaction fees and credits is reasonable because FAANG options were delisted after monthly expiration in February 2023, and such fees and credits are no longer applicable to any market participants. The Exchange believes that the proposed change to eliminate certain introductory pricing for newly enrolled Market Makers is reasonable because these programs have not served to encourage ATP Holders to enroll as Market Makers on the Exchange. Accordingly, the Exchange believes that the proposed changes to eliminate text from the Fee Schedule relating to discontinued or underutilized programs would promote clarity in the Fee Schedule, to the benefit of all market participants.

The Exchange believes that the proposed Floor Broker Grow With Me Program is reasonable because it is designed to continue to incent Floor Brokers to increase their manual billable volume executed on the Exchange and provides Floor Brokers with two ways to earn the additional rebate offered by the program. The Exchange also believes that using a Floor Broker organization's January 2023 manual billable volume ADV as a basis for measuring growth is reasonable because it reflects each organization's recent volumes and that the 25,000 manual billable contracts alternative requirement is reasonable because it would permit new Floor Brokers without base period volume to qualify for the program by meeting a requirement that also applies to current Floor Brokers. The Exchange also believes that it is reasonable to implement the program with the proposed qualifying criteria through July 31, 2023, as the Exchange would be able to further evaluate such criteria in the interim period and prepare a proposed rule change regarding appropriate qualifying criteria for the program beyond such date.

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(4) and (5).

[10] *See* Securities Exchange Act Release No. 51808 (June 9, 2005), 70 FR 37496, 37499 (June 29, 2005) (S7–10–04) (''Reg NMS Adopting Release'').

[11] The OCC publishes options and futures volume in a variety of formats, including daily and monthly volume by exchange, *available here: https://www.theocc.com/Market-Data/Market-Data-Reports/Volume-and-Open-Interest/Monthly-Weekly-Volume-Statistics.*

[12] Based on a compilation of OCC data for monthly volume of equity-based options and monthly volume of ETF-based options, *see id.,* the Exchange's market share in equity-based options was 7.03% for the month of January 2022 and 7.96% for the month of January 2023.

[13] *See* note 5, *supra.*

To the extent that the proposed changes improve the clarity and transparency of the Fee Schedule, the Exchange believes they would continue to make the Exchange a more competitive venue for order execution, which, in turn, promotes just and equitable principles of trade and removes impediments to and perfects the mechanism of a free and open market and a national market system. The Exchange notes that all market participants stand to benefit from any increase in volume, which could promote market depth, facilitate tighter spreads and enhance price discovery, particularly to the extent the proposed change encourages market participants to utilize the Exchange as a primary trading venue, and may lead to a corresponding increase in order flow from other market participants.

Finally, to the extent the proposed change continues to attract greater volume and liquidity, the Exchange believes the proposed change would improve the Exchange's overall competitiveness and strengthen its market quality for all market participants. In the backdrop of the competitive environment in which the Exchange operates, the proposed rule change is a reasonable attempt by the Exchange to increase the depth of its market and improve its market share relative to its competitors. The Exchange's fees are constrained by intermarket competition, as market participants can choose to direct their order flow to any of the 16 options exchanges The Exchange believes that proposed rule change is designed to continue to incent market participants to direct liquidity to the Exchange, and, to the extent they continue to be incentivized to aggregate their trading activity at the Exchange, that increased liquidity could promote market depth, price discovery and improvement, and enhanced order execution opportunities for all market participants.

The Proposed Rule Change Is an Equitable Allocation of Fees and Credits

The Exchange believes the proposed rule change is an equitable allocation of its fees and credits. The proposed change to the Routing Surcharge is equitable because the proposed single fee for all routed orders in Penny issues and single fee for all routed orders in non-Penny issues would apply to all market participants equally and the proposed amounts are designed to offset internal resources necessary to support the handling of orders routed away from the Exchange. The proposed change would also streamline the process of calculating routing fees for all market participants and provide increased clarity regarding execution costs at the time of order entry. The proposed change to delete fees and credits relating to FAANG transactions is also equitable because their elimination would likewise apply to all market participants equally. The Exchange also believes that the proposed changes to eliminate introductory pricing for newly enrolled Market Makers in ATP fees and Premium Product Fees are equitable because the pricing programs would no longer be available to any ATP Holders, and, moreover, no ATP Holders have qualified for the introductory pricing in recent years. The Exchange believes that the proposed rebate for Floor Brokers through the Floor Broker Grow With Me Program is an equitable allocation of fees and credits because the rebate would be available to all qualifying Floor Brokers equally, and Floor Brokers may qualify for the rebate based on either growth over their own base period volume or an alternative that would permit new Floor Brokers that do not have base period volume to qualify for the program on a basis that is also applicable to current Floor Brokers. The Exchange also believes that the proposal to offer the Floor Broker Grow With Me program with the current qualifying criteria through July 31, 2023 is equitable because the intervening period would provide the Exchange an opportunity to evaluate the parameters of the program and to submit a proposed rule change regarding the criteria for the program going forward. The Exchange further believes that the proposed change is equitable because it is intended to encourage the role performed by Floor Brokers in facilitating the execution of orders via open outcry, a function which the Exchange wishes to support for the benefit of all market participants.

To the extent that the proposed changes continue to incent ATP Holders to utilize the Exchange as a primary execution venue and attract more volume on the Exchange, this increased order flow would continue to make the Exchange a more competitive venue for, among other things, order execution. Thus, the Exchange believes the proposed rule change would improve market quality for all market participants on the Exchange and, as a consequence, attract more order flow to the Exchange, thereby improving market-wide quality and price discovery.

The Proposed Rule Change Is Not Unfairly Discriminatory

The Exchange believes the proposed change is not unfairly discriminatory. The proposed change to the Routing Surcharge is not unfairly discriminatory because the proposed fees are intended to assess streamlined routing fees in amounts that would appropriately account for the internal resources necessary to support orders routed away from the Exchange and would apply equally to all market participants' routed orders, based on whether such order is in a Penny or non-Penny issue. The proposed change would simplify the calculation of routing fees for all market participants and add clarity and transparency to the Fee Schedule regarding the fees applicable to routed orders. The proposed change to delete fees and credits relating to FAANG transactions is not unfairly discriminatory because they are no longer applicable to any market participants following the delisting of FAANG options. The Exchange also believes that the proposed changes to eliminate introductory pricing for new Market Makers in ATP fees and Premium Product Fees are equitable because the pricing programs would be eliminated in their entirety and would no longer be available to any ATP Holders. Finally, the Exchange believes that the proposed Floor Broker Grow With Me Program is not unfairly discriminatory because current and new Floor Brokers alike are eligible to qualify for the rebate and is not unfairly discriminatory to non-Floor Brokers because Floor Brokers serve an important function in facilitating the execution of orders on the Exchange, which the Exchange wishes to encourage and support to promote price improvement opportunities for all market participants.

Thus, the Exchange believes that, to the extent the proposed rule change would continue to improve market quality for all market participants on the Exchange by promoting clarity and transparency in the Fee Schedule and attract more order flow to the Exchange, thereby improving market-wide quality and price discovery, the resulting increased volume and liquidity would provide more trading opportunities and tighter spreads to all market participants and thus would promote just and equitable principles of trade, remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, protect investors and the public interest.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act, the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, as discussed above, the Exchange believes that the proposed changes would encourage the submission of additional liquidity to a public exchange, thereby promoting market depth, price discovery and transparency and enhancing order execution opportunities for all market participants. As a result, the Exchange believes that the proposed change furthers the Commission's goal in adopting Regulation NMS of fostering integrated competition among orders, which promotes ''more efficient pricing of individual stocks for all types of orders, large and small.'' [14]

Intramarket Competition. The proposed change is designed to improve the clarity and transparency of the Fee Schedule and to continue to attract order flow to the Exchange. The proposed change to offer Floor Brokers a rebate on manual billable volume through the Floor Broker Grow With Me program is intended to attract additional order flow to the Exchange, which could increase the volumes of contracts traded on the Exchange. Greater liquidity benefits all market participants on the Exchange, and increased manual billable transactions could increase opportunities for execution of other trading interest. The Exchange believes that the proposed change to the Routing Surcharge would not impose any burden on competition that is not necessary or appropriate because it is intended to simplify the calculation of fees for routed orders and to continue to incent Firms to direct order flow to the Exchange, thereby promoting liquidity on the Exchange to the benefit of all market participants. The Exchange does not believe that the proposed changes relating to FAANG transactions or introductory pricing for newly enrolled Market Makers would impose any burden on competition that is not necessary or appropriate because the changes would apply equally to all ATP Holders and would add clarity to the Fee Schedule, to the benefit of all market participants.

Intermarket Competition. The Exchange operates in a highly competitive market in which market participants can readily favor one of the 16 competing option exchanges if they deem fee levels at a particular venue to be excessive. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow to the Exchange. Based on publicly-available information, and excluding index-based options, no single exchange has more than 16% of the market share of executed volume of multiply-listed equity and ETF options trades.[15] Therefore, no exchange possesses significant pricing power in the execution of multiply-listed equity and ETF options order flow. More specifically, in January 2023, the Exchange had less than 8% market share of executed volume of multiply-listed equity and ETF options trades.[16]

The Exchange believes that the proposed rule change reflects this competitive environment because it modifies the Exchange's fees and credits in a manner designed to continue to incent Floor Brokers to direct trading interest (particularly manual billable volume) to the Exchange, to provide liquidity, and to attract order flow. In addition, to the extent that the proposed change to simplify the Routing Surcharge incentivizes ATP Holders to utilize the Exchange as a primary trading venue for all transactions, all of the Exchange's market participants should benefit from the improved market quality and increased opportunities for price improvement. The Exchange also believes that the proposed rule change reflects this competitive environment because it removes underutilized programs from the Fee Schedule that did not achieve their intended purpose. The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues, including one that offers similarly structured routing fees.[17] In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges.

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.

[14] *See* Reg NMS Adopting Release, *supra* note 9, at 37499.

[15] *See* note 11, *supra.*

[16] *See* note 12, *supra.*

[17] *See* note 5, *supra.*

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [18] of the Act and subparagraph (f)(2) of Rule 19b–4 [19] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B) [20] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEAMER–2023–28 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–2023–28. 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

[18] 15 U.S.C. 78s(b)(3)(A).

[19] 17 CFR 240.19b–4(f)(2).

[20] 15 U.S.C. 78s(b)(2)(B).

proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for website viewing and printing in the Commission's Public Reference Room, 100 F Street NE, Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. 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–2023–28, and should be submitted on or before May 22, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[21]

Sherry R. Haywood,

Assistant Secretary.

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97374; File No. SR–NYSEAMER–2023–27]

Self-Regulatory Organizations; NYSE American LLC; Notice of Filing of Proposed Change To Amend Rule 915 (Criteria for Underlying Securities) To Accelerate the Listing of Options on Certain IPOs

April 25, 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 April 21, 2023, NYSE American LLC (''NYSE American'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by 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 amend Rule 915 (Criteria for Underlying Securities). 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 purpose of the proposed rule change is to amend Rule 915 (Criteria for Underlying Securities) (the ''Rule'') as set forth below. Following discussions with other exchanges and a cross-section of industry participants and in coordination with the Listed Options Market Structure Working Group (''LOMSWG'') (collectively, the ''Industry Working Group''), the Exchange proposes to modify the standard set forth in the Rule for the listing and trading of options on ''covered securities'' to reduce the time to market.

Commentary .01(4)(a) to Rule 915 sets forth the guidelines to be considered in evaluating for option transactions underlying securities that are ''covered securities,'' as defined in Section 18(b)(1)(A) of the Securities Act of 1933 (hereinafter ''covered security'' or ''covered securities'').[4] Currently, the Exchange permits the listing of an option on an underlying covered security that, amongst other things, has a market price of at least $3.00 per share for the previous three consecutive business days preceding the date on which the Exchange submits a certificate to The Options Clearing Corporation (''OCC'') to list and trade options on the underlying security (the ''three-day lookback period'').[5] Under the current rule, if an initial public offering (''IPO'') occurs on a Monday, the earliest date the Exchange could submit its listing certificate to OCC would be on Thursday, with the market price determined by the closing price over the three-day lookback period from Monday through Wednesday. The option on the IPO'd security would then be eligible for trading on the Exchange on Friday (*i.e.,* within four business days of the IPO inclusive of the day the listing certificate is submitted to OCC).[6]

The Exchange notes that the three-day look back period helps ensure that options on underlying securities may be listed and traded in a timely manner while also allowing time for OCC to accommodate the certification request. However, there are certain large IPOs that issue high-priced securities—well above the $3.00 per share threshold—that would obviate the need for the three-day lookback period. In this regard, the Industry Working Group has recently identified proposed changes to Commentary .01(4)(a) to Rule 915 that would help options on covered securities that have a market capitalization of at least $3 billion based upon the offering price of its IPO come to market earlier. The proposed change, which is intended to be harmonized across options exchanges, is designed to provide investors the opportunity to hedge their interest in IPO investments in a shorter amount of time than what is currently permitted.[7] The Exchange believes that options serve a valuable tool to the trading community and help markets function efficiently by mitigating risk. To that end, the Exchange believes that the absence of options in the early days after an IPO

[21] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] Rule 915(a) requires that, for underlying securities to be eligible for option transactions, such securities must be duly registered and be an ''NMS stock'' as defined in Rule 600 of Regulation NMS under the Act and will be characterized by a substantial number of outstanding shares which are widely held and actively traded. *See* Rule 915(a)(1) and (2).

[5] *See* Commentary .01(4)(a) to Rule 915. The Exchange is not proposing to make any changes to the guidelines for listing securities that are not a ''covered security.'' *See* Commentary .01(4)(b) to Rule 915.

[6] *See* proposed Commentary .01(4)(a)(ii) to Rule 915. The Exchange proposes a non-substantive change to number the existing and proposed criteria for covered securities as (i) and (ii) of paragraph (4)(a). *See* proposed Commentary .01(4)(a)(i) to Rule 915.

[7] While the Exchange acknowledges that market participants may utilize options for speculative purposes (in addition to as a hedging tool), the Exchange believes (as set forth below) that its existing surveillance technologies and procedures adequately address potential violations of exchange rules and federal securities laws applicable to trading on the Exchange.

may heighten volatility in the trading of IPO'd securities.

Accordingly, the Exchange proposes to modify Rule 915 to waive the three-day lookback period for covered securities that have a market capitalization of at least $3 billion based upon the offering price of the IPO of such securities and to allow options on such securities to be listed and traded starting on or after the second business day following the initial public offering day (*i.e.,* not inclusive of the day of the IPO).[8] The Exchange has reviewed trading data for IPO'd securities dating back to 2017 and is unaware of any such security that achieved a market capitalization of $3 billion based upon the offering price of its IPO that would not have also qualified for listing options based on the three-day lookback requirement. Specifically, the Exchange has determined that 202 of the 1,179 IPOs that took place between January 1, 2017, and October 21, 2022, met the $3 billion market capitalization/IPO offering price threshold. Options on all 202 of those IPO shares subsequently satisfied the three-day lookback requirement for listing and trading, *i.e.,* none of these large IPOs closed below the $3.00/share threshold during its first three days of its trading. As such, the Exchange believes the proposed capitalization threshold of $3 billion based upon the offering price of its IPO is appropriate.

Under the proposed rule, if an IPO for a company with a market capitalization of $3 billion based upon the offering price of its IPO occurs on a Monday, the Exchange could submit its listing certificate to OCC (to list and trade options on the IPO'd security) as soon as all the other requirements for listing are satisfied. If, on Tuesday, all requirements are deemed satisfied, the IPO'd security could then be eligible for trading on the Exchange on Wednesday (*i.e.,* starting on or after the second business day following the IPO day). Thus, the proposal could potentially accelerate the listing of options on IPO'd securities by two days.

The Exchange believes the proposed change would allow options on IPO'd securities to come to market sooner without sacrificing investor protection. The Exchange represents that trading in IPO'd securities—like all other securities traded on the Exchange—is subject to surveillances administered by the Exchange and to cross-market surveillances administered by FINRA on behalf of the Exchange. Those surveillances are designed to detect violations of Exchange rules and applicable federal securities laws.[9] The Exchange represents that those surveillances are adequate to reasonably monitor Exchange trading of IPO'd securities in all trading sessions and to reasonably deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange.[10] As such, the Exchange believes that its existing surveillance technologies and procedures, coupled with its findings related to the IPOs reviewed as described herein, adequately address potential concerns regarding possible manipulation or price stability.

Implementation Date

The proposed rule change will become operative within six months following the approval of the proposed Rule change to coincide with implementation on other options exchanges. The Exchange will announce the effective date of the proposed change by Trader Update distributed to all ATP Holders.[11]

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[12] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [13] requirements that the rules of an exchange be 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.

In particular, the Exchange believes the proposed change would facilitate options transactions and would remove impediments to and perfect the mechanism of a free and open market and a national market system, which would, in turn, protect investors and the public interest by providing an avenue for options on IPO'd securities to come to market earlier. The Exchange notes that the three-day look back period helps ensure that options on underlying securities may be listed and traded in a timely manner while also allowing time for OCC to accommodate the certification request. However, there are certain large IPOs that issue high-priced securities—well above the $3.00 per share threshold—that would obviate the need for the three-day lookback period. As noted above, the Exchange has reviewed trading data for IPO'd securities dating back to 2017 and is unaware of an IPO'd security with a market capitalization of $3 billion or more (based upon the offering price of its IPO) that subsequently would have failed to qualify for listing and trading as options under the three-day lookback requirement. The Exchange believes that the proposed amendment, which would be harmonized across options exchanges, would remove impediments to and perfect the mechanism of a free and open market and a national market system by providing an avenue for investors to hedge their interest in IPO investments in a shorter amount of time than what is currently permitted. The Exchange believes that options serve a valuable tool to the trading community and help markets function efficiently by mitigating risk. To that end, the Exchange believes that the absence of options in the early days after an IPO may heighten volatility to IPO'd securities.[14]

Further, as noted herein, the Exchange believes the proposed change would allow options on IPO'd securities to come to market sooner (*i.e.,* at least two business days post-IPO not inclusive of the day of the IPO) without sacrificing investor protection. The Exchange represents that trading in IPO'd securities—like all other securities traded on the Exchange—is subject to surveillances administered by the Exchange and to cross-market surveillances administered by FINRA on behalf of the Exchange. Those surveillances are designed to detect

[8] The Exchange acknowledges that the Options Listing Procedures Plan (or ''OLPP'') requires that the listing certificate be provided to OCC no earlier than 12:01 a.m. and no later than 11 a.m. (Chicago time) on the trading day prior to the day on which trading is to begin. *See* the OLPP, at p. 3, *available here: https://ncuoccblobdev.blob.core.windows.net/media/theocc/media/clearing-services/services/options_listing_procedures_plan.pdf.* The OLPP is a national market system plan that, among other things, sets forth procedures governing the listing of new options series.

[9] FINRA conducts cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

[10] *See supra* note 7.

[11] An ''ATP Holder'' refers to a natural person, sole proprietorship, partnership, corporation, limited liability company or other organization, in good standing that has been issued an ATP. *See* Rule 900.2NY. An ''ATP'' is an American Trading Permit issued by the Exchange for effecting approved securities transactions on the Exchange. *See id.*

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] *See supra* note 7.

violations of Exchange rules and applicable federal securities laws.[15] The Exchange represents that those surveillances are adequate to reasonably monitor Exchange trading of IPO'd securities in all trading sessions and to reasonably deter and detect violations of Exchange rules and federal securities laws applicable to trading on the Exchange, including wrongful efforts to manipulate the prices of those securities in order to bring them in compliance with the $3.00/share threshold for the listing of options. As such, the Exchange believes that its existing surveillance technologies and procedures, coupled with its findings related to the IPOs reviewed as described herein, would adequately address potential concerns regarding possible manipulation or price stability.

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 anticipates that the other options exchanges will adopt substantively similar proposals, such that there would be no burden on intermarket competition from the Exchange's proposal. Accordingly, the proposed change is not meant to affect competition among the options exchanges. For these reasons, the Exchange believes that the proposed rule change reflects this competitive environment and does not impose any undue burden on intermarket competition.

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

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 the 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:

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–2023–27 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–2023–27. 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 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. 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–2023–27 and should be submitted on or before May 22, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–09080 Filed 4–28–23; 8:45 am]

BILLING CODE 8011–01–P

[15] FINRA conducts cross-market surveillances on behalf of the Exchange pursuant to a regulatory services agreement. The Exchange is responsible for FINRA's performance under this regulatory services agreement.

[16] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–97378; File No. SR–NYSEARCA–2023–34]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend Certain Representations Relating to the Hennessy Stance ESG Large Cap ETF

April 25, 2023.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on April 21, 2023, NYSE Arca, Inc. (''NYSE Arca'' or the ''Exchange'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to make changes to certain representations made in the proposed rule change previously filed with the Securities and Exchange Commission (the ''Commission'' or ''SEC'') pursuant to Rule 19b–4 relating to the Hennessy Stance ESG Large Cap ETF, shares of which are currently listed and traded on the Exchange under NYSE Arca Rule 8.601–E. 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,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

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 Commission has approved the listing and trading on the Exchange of shares (''Shares'') of the Hennessy Stance ESG Large Cap ETF (the ''Fund''),[3] under NYSE Arca Rule 8.601–E, which governs the listing and trading of Active Proxy Portfolio Shares, which are securities issued by an actively managed open-end investment management company.[4] Shares of the Fund are currently listed and traded on the Exchange under NYSE Arca Rule 8.601–E.[5] The Shares of the Fund are issued by Hennessy Funds Trust (the ''Issuer''), a statutory trust organized under the laws of the State of Delaware and registered with the Commission as an open-end management investment company. The Fund's investment adviser is Hennessy Advisors, Inc. (the ''Adviser'').

The Releases stated that the Fund will invest primarily in exchange-traded equity securities of U.S. large capitalization issuers by investing mainly in companies that meet environmental, social and governance (''ESG'') standards, as determined by the Adviser. The Exchange proposes to update the investment strategy employed by the Fund to provide that the Fund may invest in exchange-traded equity securities of U.S. small- and medium-capitalization issuers that meet ESG standards, as determined by the Adviser, while continuing to invest primarily in exchange-traded equity securities of U.S. large-capitalization issuers that meet ESG standards, as determined by the Adviser.[6]

The Adviser believes the change to the Fund's investment strategy (as described herein) is appropriate and consistent with the best interest of the Fund and Fund shareholders. In connection with the change, the Fund's investment objective and principal investment strategies will remain substantially the same. While the Fund will have an increased ability to focus on investing in exchange-traded equity securities of U.S. small- and medium-capitalization issuers that meet ESG standards, the Fund will continue to invest primarily in exchange-traded equity securities of U.S. large-capitalization issuers that meet ESG standards, as determined by the Adviser. The Adviser further believes that this strategy change is not material because (1) the investment objective will remain the same and the principal investment strategies will remain substantially the same; (2) the Fund will continue to primarily invest in equity securities of large-capitalization companies; and (3) the principal investment risks are substantially the same.

As of the close of business on April 27, 2023, the Fund's non-material strategy change will be effected to allow the Fund an increased ability to focus on investing in exchange-traded equity securities of U.S. small- and medium-capitalization issuers that meet ESG standards, while continuing to invest primarily in exchange-traded equity securities of U.S. large-capitalization issuers that meet ESG standards, as determined by the Adviser. Accordingly, as of the close of business on April 27, 2023, the name of the Fund will change from Hennessy Stance ESG Large Cap ETF to Hennessy Stance ESG ETF.

The investment objective of the Fund, which is to seek long-term capital appreciation, will remain unchanged.

Except for the changes noted above, all other representations made in the Releases remain unchanged.[7] The Fund will comply with all continued listing requirements under Rule 8.601–E, including all other requirements and conditions set forth in the applicable exemptive order.

2. Statutory Basis

The basis under the Act for this proposed rule change is the requirement under Section 6(b)(5)[8] that an exchange have rules that are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to, and perfect the mechanism of a free and open market and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices, and is designed to promote just and equitable principles of trade and to protect investors and the

[3] *See* Securities Exchange Act Release No. 96559 (December 21, 2022), 87 FR 79919 (December 28, 2022) (SR–NYSEARCA–2022–84) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Amend Certain Representations) (Renaming the Fund from Stance Equity ESG Large Cap Core ETF to Hennessy Stance ESG Large Cap ETF).

[4] *See* Securities Exchange Act Release No. 89185 (June 29, 2020), 85 FR 40328 (July 6, 2020) (SR–NYSEArca–2019–95) (Approval of a Proposed Rule Change To Adopt NYSE Arca Rule 8.601–E To Permit the Listing and Trading of Active Proxy Portfolio Shares and To List and Trade Shares of the Natixis U.S. Equity Opportunities ETF Under Proposed NYSE Arca Rule 8.601–E). Rule 8.601–E(c)(1) provides that ''[t]he term ''Active Proxy Portfolio Share'' means a security that (a) is issued by a investment company registered under the Investment Company Act of 1940 (''Investment Company'') organized as an open-end management investment company that invests in a portfolio of securities selected by the Investment Company's investment adviser consistent with the Investment Company's investment objectives and policies; (b) is issued in a specified minimum number of shares, or multiples thereof, in return for a deposit by the purchaser of the Proxy Portfolio and/or cash with a value equal to the next determined net asset value (''NAV''); (c) when aggregated in the same specified minimum number of Active Proxy Portfolio Shares, or multiples thereof, may be redeemed at a holder's request in return for the Proxy Portfolio and/or cash to the holder by the issuer with a value equal to the next determined NAV; and (d) the portfolio holdings for which are disclosed within at least 60 days following the end of every fiscal quarter.'' Rule 8.601–E(c)(2) provides that ''[t]he term ''Actual Portfolio'' means the identities and quantities of the securities and other assets held by the Investment Company that shall form the basis for the Investment Company's calculation of NAV at the end of the business day.'' Rule 8.601–E(c)(3) provides that ''[t]he term ''Proxy Portfolio'' means a specified portfolio of securities, other financial instruments and/or cash designed to track closely the daily performance of the Actual Portfolio of a series of Active Proxy Portfolio Shares as provided in the exemptive relief pursuant to the Investment Company Act of 1940 applicable to such series.''

[5] The Commission previously approved the listing and trading of the shares of the Fund. *See* Securities Exchange Act Nos. 91266 (March 5, 2021) 86 FR 13930 (March 11, 2021) (SR–NYSEArca–2020–104) (Order Approving a Proposed Rule Change, as Modified by Amendment No. 2, To List and Trade Shares of the Stance Equity ESG Large Cap Core ETF Under NYSE Arca Rule 8.601–E) (''Approval Order''); and 90665 (December 15, 2020) 85 FR 83129 (December 21, 2020) (SR–NYSEArca–2020–104) (Notice of Filing of Proposed Rule Change To List and Trade Shares of the Stance Equity ESG Large Cap Core ETF Under NYSE Arca Rule 8.601–E) (''Notice''). (The Approval Order and the Notice are referred to collectively herein as the ''Releases'').

[6] The Fund filed a registration statement on Form N–1A under the Securities Act of 1933 (File No. 033–52154) and the Investment Company Act of 1940 (File No. 811–07168), which became effective on December 23, 2022 (the ''Registration Statement''). The Fund's final, definitive prospectus, dated as of December 23, 2022, was filed pursuant to Rule 497(c) of the Securities Act of 1933 on December 28, 2022, and contains the current name and investment strategy of the Fund (the ''Final Prospectus''). A supplement to the Final Prospectus containing the new name and revised strategy, as described herein, was filed on February 27, 2023 pursuant to Rule 497(e) of the Securities Act of 1933 (the ''Supplement''). The description of the Fund and the Shares contained herein are based on the Registration Statement, the Final Prospectus and the Supplement. The change to the Fund's investment strategy as described herein will be implemented effective as of the close of business on April 27, 2023.

[7] *See supra* note 5.

[8] 15 U.S.C. 78f(b)(5).

public interest. Consistent with the representations in the Releases, the Fund will continue to seek its investment objective by investing in exchange-traded securities of issuers that meet ESG standards. As a result of the change to the Fund's investment strategy, the Exchange is proposing to amend certain representations in the Releases regarding the universe of securities in which the Fund may invest and consistent with that change, to rename the Fund.

The Adviser believes the change to the Fund's investment strategy is appropriate and consistent with the best interest of the Fund and Fund shareholders. In connection with the change, the Fund's investment objective and principal investment strategies will remain substantially the same. While the Fund will have an increased ability to focus on investing in exchange-traded equity securities of U.S. small- and medium-capitalization issuers that meet ESG standards, the Fund will continue to invest primarily in exchange-traded equity securities of U.S. large-capitalization issuers that meet ESG standards, as determined by the Adviser. The Adviser further believes that this strategy change is not material because (1) the investment objective will remain the same and the principal investment strategies will remain the substantially the same; (2) the Fund will continue to primarily invest in equity securities of large-capitalization companies; and (3) the principal investment risks are substantially the same. The proposed changes to the investment strategy will remain consistent with applicable requirements under the 1940 Act.

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 purpose of the Act. The Exchange believes the proposed rule change will not impose a burden on competition and will benefit investors and the marketplace by permitting continued listing and trading of Shares of the Fund following implementation of the changes described above, which changes would not impact the investment objective of the Fund.

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[9] and Rule 19b–4(f)(6) thereunder.[10]

A proposed rule change filed under Rule 19b–4(f)(6)[11] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[12] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing. The Commission believes that waiver of the 30-day operative delay is consistent with the protection of investors and the public interest because the proposal does not raise any new or novel issues and doing so will allow the Shares to continue to be listed and traded on the Exchange without interruption in a manner that is consistent with the Commission's prior Approval Order and the applicable requirements under the Investment Company Act of 1940. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[13]

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[14] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's internet comment form (*https://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEARCA–2023–34 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE, Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2023–34. 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 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange.

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–NYSEARCA–2023–

[9] 15 U.S.C. 78s(b)(3)(A)(iii).

[10] 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.

[11] 17 CFR 240.19b–4(f)(6).

[12] 17 CFR 240.19b–4(f)(6)(iii).

[13] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[14] 15 U.S.C. 78s(b)(2)(B).

34 and should be submitted on or before May 22, 2023.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[15]

Sherry R. Haywood,

Assistant Secretary.

[FR Doc. 2023–09078 Filed 4–28–23; 8:45 am]

BILLING CODE 8011–01–P

SURFACE TRANSPORTATION BOARD

[Docket No. AB 55 (Sub-No. 811X)]

CSX Transportation, Inc.—Abandonment Exemption—in Bronx County, N.Y.

CSX Transportation, Inc. (CSXT), has filed a verified notice of exemption under 49 CFR part 1152 subpart F—*Exempt Abandonments* to abandon an approximately 0.77-mile rail line that runs between milepost Q## 3.79 and milepost Q## 4.5 on its Albany Division, New York Terminal, Putnam Branch, in Bronx County, N.Y. (the Line). The Line traverses U.S. Postal Service Zip Code 10463.

CSXT has certified that: (1) no local freight traffic has moved over the Line during the past two years; (2) any overhead traffic can be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government on behalf of such user) regarding cessation of service over the Line either is pending with the Surface Transportation Board (Board) or has been decided in favor of a complainant within the two-year period; and (4) the requirements at 49 CFR 1105.7(b) and 1105.8(c) (notice of environmental and historic reports), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to government agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received,[1] this exemption will be effective on May 31, 2023, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[2] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2), and interim trail use/rail banking requests under 49 CFR 1152.29 must be filed by May 11, 2023.[3] Petitions to reopen and requests for public use conditions under 49 CFR 1152.28 must be filed by May 22, 2023.

All pleadings, referring to Docket No. AB 55 (Sub-No. 811X), must be filed with the Surface Transportation Board either via e-filing on the Board's website or in writing addressed to 395 E Street SW, Washington, DC 20423–0001. In addition, a copy of each pleading must be served on CSXT's representative, Louis E. Gitomer, Law Offices of Louis E. Gitomer, LLC, 600 Baltimore Avenue, Suite 301, Towson, MD 21204.

If the verified notice contains false or misleading information, the exemption is void ab initio.

CSXT has filed a combined environmental and historic report that addresses the potential effects, if any, of the abandonment on the environment and historic resources. OEA will issue a Draft Environmental Assessment (Draft EA) by May 5, 2023. The Draft EA will be available to interested persons on the Board's website, by writing to OEA, or by calling OEA at (202) 245–0294. If you require an accommodation under the Americans with Disabilities Act, please call (202) 245–0245. Comments on environmental or historic preservation matters must be filed within 15 days after the Draft EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), CSXT shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the Line. If consummation has not been effected by CSXT's filing of a notice of consummation by May 1, 2024, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available at *www.stb.gov.*

Decided: April 24, 2023.

By the Board, Mai T. Dinh, Director, Office of Proceedings.

Eden Besera,

Clearance Clerk.

[FR Doc. 2023–09070 Filed 4–28–23; 8:45 am]

BILLING CODE 4915–01–P

SURFACE TRANSPORTATION BOARD

60-Day Notice of Intent To Seek Extension of Approval: Classification Index Survey Form

AGENCY: Surface Transportation Board.

ACTION: Notice and request for comments.

SUMMARY: As required by the Paperwork Reduction Act of 1995 (PRA), the Surface Transportation Board (STB or Board) gives notice of its intent to seek approval from the Office of Management and Budget (OMB) for an existing collection without an OMB Control Number of a Classification Index Survey Form, as described below.

DATES: Comments on this information collection should be submitted by June 30, 2023.

ADDRESSES: Direct all comments to Chris Oehrle, Surface Transportation Board, 395 E Street SW, Washington, DC 20423–0001, or to *PRA@stb.gov.* When submitting comments, please refer to ''Paperwork Reduction Act Comments, Classification Index Survey Form.'' For further information regarding this collection, contact Pedro Ramirez at (202) 245–0333 or *pedro.ramirez@stb.gov.* Assistance for the hearing impaired is available through the Federal Relay Service at (800) 877–8339.

SUPPLEMENTARY INFORMATION: Comments are requested concerning: (1) the accuracy of the Board's burden estimates; (2) ways to enhance the quality, utility, and clarity of the information collected; (3) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology, when appropriate; and (4) whether the collection of information is necessary for the proper performance of the functions of the Board, including whether the collection has practical utility. Submitted comments will be summarized and included in the Board's request for OMB approval.

[15] 17 CFR 200.30–3(a)(12).

[1] Persons interested in submitting an OFA must first file a formal expression of intent to file an offer, indicating the type of financial assistance they wish to provide (*i.e.,* subsidy or purchase) and demonstrating that they are preliminarily financially responsible. *See* 49 CFR 1152.27(c)(2)(i).

[2] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C.2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[3] Filing fees for OFAs and trail use requests can be found at 49 CFR 1002.2(f)(25) and (27), respectively.

Subjects: In this notice, the Board is requesting comments on the following information collection:

Description of Collection

Title: Classification Index Survey Form.

OMB Control Number: 2140–00XX.

Form Number: Classification Index Survey Form.

Type of Review: Existing Collection without an OMB Control Number.

Respondents: All railroad companies not required to file an Annual Report (Form R–1).

Number of Respondents: One per year.

Estimated Time per Response: Less than 24 hours. This estimate includes time spent reviewing instructions; searching existing data sources; gathering and maintaining the data needed; completing and reviewing the collection of information; and converting the data from the carrier's individual accounting system.

Frequency of Response: On occasion.

Total Annual Hour Burden: Less than 24 hours annually.

Total Annual ''Non-Hour Burden'' Cost: The Classification Index Survey Form may be submitted electronically without non-hourly costs.

Needs and Uses: Railroads are classified by size into groups of large, medium, and small carriers. The Board must determine the classification of each rail carrier as a Class I, Class II, or Class III railroad. Railroads with a Class I classification (large railroads) must file Annual Reports (Form R–1) under 49 U.S.C. 11145. See OMB Control Number 2140–0009 (Class I Railroad Annual Reports). These reports are used by the Board, other Federal agencies, and industry groups to monitor and assess railroad industry growth, financial stability, traffic, and operations, and to identify industry changes that may affect national transportation policy. All other railroads (those not required to file an (R–1) Annual Report) shall annually compute their adjusted revenues using the ''railroad revenue deflator formula,'' and, if the computation derived from that formula indicates a change in a carrier's classification, that carrier must submit a ''Classification Index Survey Form'' to the Board pursuant to 49 CFR 1201 General Instructions 1–1 and § 1241.15.

Under the PRA, a federal agency that conducts or sponsors a collection of information must display a currently valid OMB control number. A collection of information, which is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c), includes agency requirements that persons submit reports, keep records, or provide information to the agency, third parties, or the public. Under 44 U.S.C. 3506(c)(2)(A), federal agencies are required to provide, prior to an agency's submitting a collection to OMB for approval, a 60-day notice and comment period through publication in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information.

Dated: April 26, 2023.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2023–09153 Filed 4–28–23; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No. FAA–2023–0976]

Agency Information Collection Activities: Requests for Comments; Clearance of a Renewed Approval of Information Collection: National Air Tours Safety Standards

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, FAA invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. The collection involves requirements in FAA regulations that set safety and oversight rules for a broad variety of sightseeing and commercial air tour flights to improve the overall safety of commercial air tours by requiring all air tours to submit information.

DATES: Written comments should be submitted by June 30, 2023.

ADDRESSES: Please send written comments:

By Electronic Docket: www.regulations.gov (Enter docket number into search field).

By mail: Sandra Ray, Federal Aviation Administration, Voluntary Programs and Rulemaking Section AFS–260, 1187 Thorn Run Road, Suite 200, Coraopolis, PA 15108.

By fax: 412–239–3063.

FOR FURTHER INFORMATION CONTACT: *Sandra.ray@faa.gov;* phone: 412–329–3088.

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: 2120–0717.

Title: National Air Tours Safety Standards.

Form Numbers: None.

Type of Review: Renewal of an information collection.

Background: FAA regulations set safety and oversight rules for a broad variety of sightseeing and commercial air tour flights to improve the overall safety of commercial air tours by requiring all air tour operators to submit information. The FAA uses the information it collects and reviews to ensure compliance and adherence to regulations and, if necessary, take enforcement action on violators of the regulations.

Respondents: Commercial Air Tour Operators.

Frequency: Information is collected on occasion.

Estimated Average Burden per Response: Varies by Response.

Estimated Total Annual Burden: 1,400 Hours.

Issued in Washington, DC, on April 26, 2023.

Sandra L. Ray,

Aviation Safety Inspector, AFS–260.

[FR Doc. 2023–09117 Filed 4–28–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Public Notice of ADAP/FAAP Property Release; Hillsboro Airport, Hillsboro, Oregon

AGENCY: Federal Aviation Administration, (FAA), DOT.

ACTION: Notice.

SUMMARY: Notice is being given that the FAA is considering a request from the Port of Portland, Oregon to waive the ADAP/FAAP property requirements and dispose of approximately 5.6 acres of airport property located at Hillsboro Airport, in Hillsboro, Oregon.

DATES: Comments are due within 30 days of the date of the publication of this notice in the **Federal Register**.

Emailed comments can be provided to Mr. Tim House, Lead Planner, Seattle Airports District Office, *timothy.a.house@faa.gov.*

FOR FURTHER INFORMATION CONTACT: Tim House, Lead Planner, Seattle Airports District Office, 2200 S 216 St., Des Moines, WA 98198, *timothy.a.house@faa.gov,* (206) 231–4248. Documents reflecting this FAA action may be reviewed at the above locations.

SUPPLEMENTARY INFORMATION: Under the provisions of Title 49, U.S.C. 47153(c), and 47107(h)(2), the FAA is considering a proposal from the Port of Portland, to release a portion of the Hillsboro Municipal Airport from aeronautical use to non-aeronautical use and dispose of the property. The property is separated from the aeronautical area of the airport by NE 25th Ave and has been determined through study that the subject parcel will not be needed for aeronautical purposes. The property will be utilized by the City of Hillsboro to develop a Public Safety Facility. There will be proceeds generated from the proposed release of this property. The Port will receive not less than fair market value for the property and the revenue generated from the sale will be used for airport purposes.

The proposal consists of 5.6 acres, on the northwest side of the airport. The parcels do not have airfield access. The FAA concurs that the parcel is no longer needed for aeronautical purposes. The proposed use of this property is compatible with other airport operations in accordance with FAA's Policy and Procedures Concerning the Use of Airport Revenue, published in **Federal Register** on February 16, 1999.

Issued in Des Moines, Washington, on April 25, 2023.

Warren D. Ferrell,

Manager, Seattle Airports District Office.

[FR Doc. 2023–09109 Filed 4–28–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Docket No.: FAA–2023–0855]

Request for Comments on the Federal Aviation Administration's Review of the Civil Aviation Noise Policy, Notice of Public Meeting

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of public meeting; Request for comments.

SUMMARY: The FAA invites public comments from interested individuals, entities, and other parties to review four key considerations of its civil aviation noise policy, in the context of noise metrics and noise thresholds. The civil aviation noise policy sets forth how the FAA analyzes, explains, and publicly presents changes in noise exposure from aviation activity: recreational and commercial fixed wing airplanes, helicopters, commercial space transportation vehicles, unmanned aircraft systems, as well as emerging technology vehicles (newer types of vehicles that will operate in U.S. airspace). The FAA will consider how changes to the civil aviation noise policy may better inform agency decisionmaking, the types of impacts it considers in making decisions (*e.g.,* community annoyance, certain types of adverse health impacts highly correlated with aviation noise exposure), and potential improvements to how the FAA analyzes, explains, and presents changes in exposure to civil aviation noise.

DATES:

Comments: Send comments on or before July 31, 2023.

Public Meetings:

1. Tuesday, May 16, 2023, 1 to 3:00 p.m. Eastern Time (ET), virtual;
2. Thursday, May 18, 2023, 6 to 8:00 p.m. ET, virtual;
3. Tuesday, May 23, 2023, 9 to 11:00 p.m. ET, virtual; and
4. Thursday, May 25, 2023, 3 to 5:00 p.m. ET, virtual.

ADDRESSES: Send comments identified by docket number FAA–2023–0855 using any of the following methods:

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

Instructions: For detailed instructions on submitting comments and additional information on the public meeting, see the Public Participation heading of the **SUPPLEMENTARY INFORMATION** section of this document.

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 *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which you can review at *https://www.dot.gov/privacy.*

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

FOR FURTHER INFORMATION CONTACT:

For questions concerning this action, contact Mr. Donald S. Scata, Jr. or Ms. Krystyna Bednarczyk, Federal Aviation Administration, 800 Independence Ave. SW, Washington, DC 20591; telephone (202) 267–6999; email *NoisePolicyReview@faa.gov.*

SUPPLEMENTARY INFORMATION:

First, the FAA is reviewing research on the effects of exposure to aviation noise, including the correlation of exposure to aviation noise with adverse health impacts, economic impacts, and annoyance.

Second, the FAA is reviewing its standard noise metric that describes exposure to aircraft noise, and potential revisions to the choice of standard metric(s).

Third, the FAA is reviewing its definition of the threshold of significant noise exposure for actions analyzed under the National Environmental Policy Act of 1969 to determine if that threshold remains appropriate or requires revision.

Last, the FAA is examining the level of aircraft noise exposure below which land uses are considered ''normally compatible'' with airport operations, as that term is defined in the regulations implementing the Aviation Safety and Noise Abatement Act of 1979. This includes consideration of the criteria for application of noise mitigation measures to address adverse noise exposure in areas that the FAA currently considers to be ''normally compatible'' with airport operations under FAA's regulations.

The FAA will consider how changes to the civil aviation noise policy may better inform agency decisionmaking, the types of impacts it considers in making decisions (*e.g.,* community annoyance, certain types of adverse health impacts highly correlated with aviation noise exposure), and potential improvements to how the FAA

analyzes, explains, and presents changes in exposure to civil aviation noise. Because the review addresses the technical elements of the FAA's civil aviation noise policy, this review will not itself reduce noise associated with aviation. The FAA will hold virtual webinars to provide background information regarding the noise policy review and respond to technical matters.

I. Background

A. FAA Actions With Respect to Civil Aviation Noise

Aircraft and vehicles make noise. More than 2.3 million passengers fly daily in U.S. airspace. Demand continues to grow for aviation passenger and cargo services. At the same time, new users seek to operate in U.S. airspace using different aircraft and vehicles that will change where and how communities are affected by aircraft noise. Commercial space rocket launches, unmanned aircraft systems (UAS or drones), and urban air mobility/advanced air mobility (UAM/AAM) vehicles will operate in ways that differ fundamentally from traditional fixed wing aircraft and helicopters that take off and land at airports. As a result, these operations will change the way communities interact with aircraft and experience noise exposure.

The FAA, air carriers, airports, aircraft manufacturers, other stakeholders and industry members, local communities, and elected officials share responsibility for addressing aircraft noise concerns. For example, FAA does not make decisions about flight times, number of operations, and aircraft type departing from or landing at airports. These decisions rest with private industry. Airport location and land uses surrounding airports are a function of local community zoning and land use planning. Runway alignment is determined by the prevailing winds at that specific location. The FAA is charged with controlling aircraft noise by regulating source emissions, designing flight operational procedures, and managing the air traffic control system and navigable airspace in ways that minimize, where appropriate, noise impacts on the ground consistent with the highest standards of safety.[1]

The FAA has long recognized that aircraft noise is a primary and pivotal concern of many stakeholders. Accordingly, the FAA strives to reduce noise in ways within its purview, but its ability to control the change in airport noise exposure is limited. The FAA has acted continuously and effectively within the bounds of its authority to improve the environmental effects of the aviation sector by better understanding, managing, and, where possible, reducing the adverse environmental impacts of global aviation through research and technological innovation, policy,[2] and outreach to the public.[3]

Over the last six decades, aircraft have gotten much quieter due in part to action by the FAA. The FAA has phased out operations by older, noisier aircraft and set more stringent aircraft certification noise standards to reduce the amount of noise they emit.[4] The FAA also established research and development partnership programs with academia and industry to develop quieter aircraft technology.[5] As a result, the noise produced from one flight by a Boeing 707–200 jet, a typical commercial aircraft that began to fly in 1957 is roughly equivalent to the noise produced from 30 flights by a typical Boeing 737–800 jet.[6] At the same time, the number of enplanements has increased from approximately 200 million in 1975 to over 850 million today. Enplanements are predicted to grow over the next twenty years, on average, by 4.7 percent annually.[7]

As operations have increased substantially since the mid-1970's, the number of people adversely exposed to aviation noise (levels above the Day Night Average Sound Level of 65 decibels) in the U.S. has declined dramatically from roughly 7 million to just over 400,000 today. This is significant improvement in environmental outcomes because the U.S. Census Bureau indicates that between 1970 and 2010, the percentage of the population living in dense urban areas increased from 73.6 percent to 80.7 percent. FAA regulation of noise at the source has improved environmental outcomes. In the eyes of the public, however, aircraft noise and its impact on people continues to be a major source of concern.

This perception was reinforced by results of a nationally scoped survey that updated FAA's understanding of the dose-response relationship between exposure to aircraft noise and community annoyance (Neighborhood Environmental Survey or NES).[8] On January 13, 2021, the FAA published in the **Federal Register** a notice and request for input on the FAA's research activities that would inform the FAA's aircraft noise policy and would inform the future direction of the FAA noise research portfolio.[9] In addition to setting forth the FAA aircraft noise policy and research efforts, the notice described the results of the NES and research into the societal benefits and costs of noise mitigation measures. The FAA explained that the Neighborhood Environmental Survey updated the FAA's understanding of the dose-response relationship between exposure to aircraft noise and community annoyance. The NES showed that a

[1] *See* 49 U.S.C. 40103(b), 44502, and 44721, which provide extensive and plenary authority to the FAA concerning use and management of the navigable airspace, air traffic control, and air navigation facilities. The FAA has implemented this authority by promulgating regulations at 14 CFR parts 71, 73, 75, 91, 93, 95, and 97. *See also* 49 U.S.C. 44715, which requires the FAA Administrator to prescribe noise standards for aircraft noise and sonic boom and to prescribe regulations to control and abate aircraft noise and sonic boom by promulgating aircraft noise regulations. FAA has implemented this authority by promulgating regulations at 14 CFR part 36, on source noise reduction and limits on noise emissions of large aircraft of new or modified design. Essentially, part 36 establishes the quietest uniform standard then possible, after taking into account safety, economic reasonableness, and technological feasibility. In addition, the FAA has phased out older aircraft to achieve noise reductions consistent with Congressional mandates and international standards. As of January 2016, all civilian transport category aircraft, regardless of weight, are required to meet Stage 3 requirements in order to operate in the continental U.S. and any air carrier aircraft manufactured today must meet Stage 5 requirements.

[2] FAA established noise certification standards for new and modified designs of civil subsonic aircraft in 14 CFR part 36. The FAA does not intend to consider changes to these regulations in the NPR.

[3] FAA, 2020, *Report to Congress: FAA Reauthorization Act of 2018 (Pub. L. 115–254) Section 188 and Sec 173, https://www.faa.gov/about/plans_reports/congress/media/Day-Night_Average_Sound_Levels_COMPLETED_report_w_letters.pdf.*

[4] The FAA regulation of older, noisier aircraft technology is consistent with congressional direction and International Civil Aviation Organization standards. *See, e.g.,* 82 FR 46123 (Oct. 4, 2017).

[5] For more information, see the FAA's Continuous Lower Energy, Emissions, and Noise (CLEEN) Program, at *https://www.faa.gov/about/office_org/headquarters_offices/apl/research/aircraft_technology/cleen/.*

[6] Based on an average of approach and takeoff certificated noise levels as defined in 14 CFR part 36.

[7] This growth rate was developed by FAA as part of its 2022–2042 commercial aviation forecast, which incorporates assumptions from statistical (econometric) models to explain and account for emerging trends for different segments of the aviation industry. *See* FAA, *FAA Aerospace Forecast Fiscal Years 2022–2042* at 2, *https://www.faa.gov/sites/faa.gov/files/2022-06/FY2022_42_FAA_Aerospace_Forecast.pdf.*

[8] Miller, Nicholas P., et al. *Analysis of the neighborhood environmental survey.* DOT/FAA/TC–21/4. 2021, *https://www.airporttech.tc.faa.gov/Products/Airport-Safety-Papers-Publications/Airport-Safety-Detail/ArtMID/3682/ArticleID/2845/Analysis-of-NES. See also* FAA, *Overview of FAA Aircraft Noise Policy and Research Efforts: Request for Input on Research Activities to Inform Aircraft Noise Policy,* 86 FR 2722 (January 13, 2021).

[9] FAA, *Overview of FAA Aircraft Noise Policy and Research Efforts: Request for Input on Research Activities to Inform Aircraft Noise Policy,* 86 FR 2722 (January 13, 2021).

higher percentage of people were ''highly annoyed'' by aircraft noise across all levels of noise exposure that were studied.[10]

More than 4,100 comments were submitted in response to the FAA's January 13, 2021 **Federal Register** notice. Some commenters suggested additional topics for research, which the FAA has taken under consideration. Overwhelmingly, however, the public encouraged the FAA to revise its policy in light of its research findings rather than waiting for the results of the FAA's ongoing research.

In response to that feedback, the FAA initiated a review (noise policy review or NPR) of its civil aviation noise policy (policy). The FAA policy is set forth in various agency regulations, orders, guidance, and policy statements.[11] It identifies how the FAA analyzes, explains, and publicly presents changes in noise exposure from aviation activity: recreational and commercial fixed wing airplanes, helicopters, commercial space transportation vehicles, unmanned aircraft systems, as well as emerging technology vehicles (newer types of vehicles that will operate in U.S. airspace). It applies to actions the FAA regulates, conducts, authorizes, or funds.

As commenters on the January 13, 2021 notice pointed out, the current policy is based on research conducted many decades ago. Since the policy was first issued, additional research has been conducted into the effects of aircraft noise on individuals and communities. The research spans aviation noise topics such as the economic value of noise impacted property, community annoyance, children's learning, speech interference, sleep disturbance, and human health impacts such as cardiovascular health.[12] The NPR provides an opportunity to determine whether, and if so, how, to update the policy in response to these and other research findings described in the January 13, 2021 notice.

B. Effect of Changes in Aircraft and Vehicle Operations in U.S. Airspace.

As described in Section I.A., *infra,* the NPR will also consider how the noise environment is changing from newer users of the airspace using the airspace differently than operators of recreational or commercial fixed wing airplanes and helicopters. This includes newer users operating commercial space transportation vehicles (rocket launches and reentries), unmanned aircraft systems (also known as UAS or drones), and other emerging technology vehicles (newer types of vehicles that will operate in the U.S. airspace).

C. FAA Regulation of Noise Under the Aviation Safety and Noise Abatement Act of 1979 and Assessment of Changes in the Noise Environment Under the National Environmental Policy Act of 1969

In response to a law called the Aviation Safety and Noise Abatement Act of 1979,[13] the FAA took a series of actions related to aviation noise. First, the FAA established a system for measuring how aircraft noise is experienced on the ground. The experience of noise by people and other receptors on the ground is described in this notice as ''aircraft noise exposure.'' Currently, the FAA uses a single-metric system to analyze aircraft noise exposure. The noise metric [14] that is the heart of this single-metric system is called the Day-Night Average Sound Level (DNL).[15] Currently, DNL is the FAA's core metric for decisionmaking in situations involving aircraft noise exposure. This law requires the FAA to develop a single system for analyzing aircraft noise exposure; however, the system does not have to be composed of a single metric. Rather the system must have a high degree of correlation between the projected noise exposure levels and the surveyed reactions of people to those noise levels and must account for the intensity, duration, frequency, and tone of noise-producing activity, as well as the time of occurrence.[16]

Second, in response to that law, the FAA issued regulations (14 CFR part 150) to establish the requirements and the process and procedures for airport noise compatibility planning.[17]

Third, the regulations also identify land uses that are ''normally compatible'' with various noise exposure levels. These land use classifications were developed by the FAA based on its evaluation of the Federal land use compatibility guidelines established during the 1970s by a Federal interagency committee comprised of research agencies and agencies with expertise in aviation-related noise.[18] To the extent practicable, FAA's ''normally compatible'' and ''noncompatible'' land uses are comparable to and consistent with, although separate from, other Federal programs directed towards similar considerations of noise exposure.

As one of the four elements of the review, the FAA will consider how the agency's updated understanding of the effects of aircraft noise on individuals, communities, and noise-sensitive areas should be used to potentially revise the

[10] 86 FR 2724. *See also* FAA, *The Foundational Elements of the Federal Aviation Administration Civil Aircraft Noise Policy: The Noise Measurement System, its Component Noise Metrics, and Noise Thresholds* (April 2023), *https://www.faa.gov/noisepolicyreview/NPR-framing.*

[11] *See, e.g.,* 14 CFR part 36, *Noise Standards: Aircraft Type and Airworthiness Certification,* 34 FR 18364 (Nov. 18, 1969); 14 CFR part 150, *Airport Noise Compatibility Planning,* 49 FR 49269 (December 18, 1984); 14 CFR part 161, *Notice and Approval of Airport Noise and Access Restrictions,* 56 FR 48698 (Sept. 25, 1991); U.S. Department of Transportation and FAA, *The Aviation Noise Abatement Policy,* (Nov. 18, 1976) (ANAP) available at *https://www.faa.gov/regulations_policies/policy_guidance/envir_policy/;* FAA Order 1050.1F, *Environmental Policies and Procedures* (FAA Order 1050.1F), 80 FR 44209 (July 24, 2015); FAA Order 5050.4B, *National Environmental Policy Act (NEPA) Implementing Instructions for Airport Projects* (FAA Order 5050.4B); FAA Joint Order 7400.2N, *Procedures for Handling Airspace Matters* (Nov. 3, 2022) at Chapter 32. ''Environmental Matters and Appendix 9, Noise Policy for Management of Airspace Over Federally Managed Lands''; and FAA Order 1050.1F Desk Reference.

[12] Wolfe, Malina, Barrett & Waitz 2016, Cost and benefits of U.S. Aviation noise land-use policies, *Transportation Research Part D: Transport and Environment,* v. 44 (2016) 147–156, *https://dx.doi.org/10.1016/j.trd.2016.02.010* (assessed quantitatively the costs and health and public welfare benefits of noise mitigating land-use management practices at 16 U.S. airports, specifically housing insulation and property acquisition, as compared to control of noise at the source. This study estimated that reducing environmental noise exposure through local land-acquisition and soundproofing policies can provide health and welfare benefits from $10,000 per person when applied in low-income ($20,000 per capita) and low-noise-exposure (65 dB) communities and upwards of $25,000 per person in high-income ($60,000 per capita) and high-noise-exposure (75 dB) communities. However, the study concluded that the costs of these programs often exceed their benefits except for at the highest noise exposure levels.)

[13] Aviation Safety and Noise Abatement Act of 1979, codified at 49 U.S.C. 47501 *et seq.,* and implemented through 14 CFR part 150 (Part 150).

[14] A ''noise metric'' refers to the unit or quantity that quantitatively measures the exposure of individuals to noise.

[15] *See* 14 CFR 150.7. The Day-Night Average Sound Level (DNL) is the 24-hour average sound level, in decibels, for the period from midnight to midnight, obtained after the addition of ten decibels to sound levels for the periods between midnight and 7 a.m., and between 10 p.m., and midnight, local time. This is a cumulative noise metric.

[16] 49 U.S.C. 47502(2).

[17] This included procedures, standards, and methodology for airport development and submission, and FAA review of airport noise exposure maps and airport noise compatibility programs and the provision for using a single system to measure noise at airports and surrounding areas and determine exposure of individuals to noise that results from the operations of an airport when preparing these documents. *See* 14 CFR 150.1.

[18] The Federal agencies that are responsible for Federal programs in which noise exposure is a factor and which comprised the interagency committee that developed the Federal land use compatibility guidelines include, among others, the U.S. Department of Defense, U.S. Department of Housing and Urban Development, and the National Park Service.

definitions adopted by the FAA of land uses that are ''normally compatible'' with airport operations and associated with different levels of aviation noise exposure. This will include consideration of the criteria for application of noise mitigation measures to address adverse noise exposure in areas that the FAA currently considers to be ''normally compatible.'' In this notice, the FAA is focused on noise metrics and noise thresholds.[19] While the FAA will consider public comments regarding elements of the policy not related to noise metrics and noise thresholds, these comments will not be the agency's initial priority in the review.

The National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 *et seq.,* requires Federal agencies to analyze the potentially significant environmental impacts of actions the FAA takes directly and to actions taken by a non-Federal entity where the FAA has authority to condition the permit, license, or other approval of the non-Federal entity's action (''Federal action'').[20] The FAA established through an agency order (FAA Order 1050.1F) the policies and procedures that implement the requirements of NEPA and the Council on Environmental Quality (CEQ) regulations implementing NEPA. While the significance of an impact may vary with the context and setting of a proposed Federal action, FAA Order 1050.1F established a quantitative limit to describe the significance of changes in aviation noise exposure (NEPA significance threshold) based on community annoyance.[21] The NEPA significance threshold is triggered if a proposed Federal action ''would increase noise by DNL 1.5 dB or more for a noise sensitive area as defined in part 150 that is exposed to noise at or above the DNL 65 dB noise exposure level, or that will be exposed at or above the DNL 65 dB level due to a DNL 1.5 dB or greater increase, when compared to the no action alternative for the same timeframe.'' [22] For example, an increase from DNL 65.5 dB to 67 dB would be considered a significant impact, as would an increase from DNL 63.5 dB to 65 dB.[23]

The FAA considers the significance of project impacts when determining the appropriate level of environmental review and the level of public involvement that may be required before a decision on a proposed Federal action is made. Finally, while NEPA does not require any particular outcome, its requirements ensure that FAA officials make informed decisions after considering the environmental consequences of proposed Federal actions. The FAA's determination to establish a NEPA significance threshold, the type of impact (community annoyance) that informed the selection of the limit of the NEPA significance threshold, and the noise metric (DNL) that quantitatively describes the impact of noise exposure are three of the four elements of the policy that are under review as part of the NPR. Specifically, this review will consider whether the FAA should continue to use the cumulative DNL metric as the sole basis for decisions made in the context of analyses prepared pursuant to NEPA and the Part 150 regulations or adopt a suite of metrics to address different scenarios based on the noise environment, source of noise, and other considerations.

The result of this review may include modifying the FAA's system for considering aviation noise. Modifications could include replacing DNL as the sole decisionmaking noise metric; incorporating new decisionmaking noise metrics into the system; identifying when the metrics that may comprise the system should be used alone or in combination; and revising the FAA policy [24] on the use of supplemental metrics. In addition, the FAA will consider how these metrics should be calculated.

D. Immediate Effect of the Noise Policy Review

The FAA notes that none of the changes currently being considered through this noise policy review will immediately affect the level of noise to which an individual, community, or noise-sensitive area (*e.g.,* park, school, hospital, etc.) is exposed. A downward adjustment to the definition of existing significant noise exposure will not change the actual noise environment. Nor will real-world noise experienced by individuals and communities be changed if the FAA changes its criteria for identifying significant new noise exposure associated with proposed actions being examined in an environmental review conducted pursuant to NEPA.[25] No policy change on its own will cap or reduce the levels of aviation noise. The FAA normally takes actions that enhance the safety, efficiency, and capacity of U.S. airspace while considering associated noise impacts. As these actions are proposed, the FAA analyzes and discloses publicly the modeled change in the noise environment to help the public understand how their experience of aviation noise will change over time.

E. Next Steps

The FAA intends to give serious consideration to stakeholder [26] input on the policy. If the FAA decides to revise the policy, any revisions will also consider modern aviation noise research and how the evolving use of the U.S. airspace affects experiences of aviation noise. Any revisions to the policy will also promote more effective public disclosure of noise impacts under NEPA. In summary, this review should improve implementation of the major tenets of the 1976 Aviation Noise Abatement Policy, which sets forth the goals, policies, and strategies the FAA should employ to reduce the impact of aviation noise.

F. Purpose of This Notice

The FAA invites comments through this notice to inform its consideration of these foundational elements of the policy. The FAA recognizes that

[19] When FAA refers to ''noise thresholds'' collectively, it means both the definition of the level of significant noise exposure for actions subject to environmental review requirements set out in FAA Order 1050.1F as well as the definitions of the levels of noise exposure that are deemed to be ''normally compatible'' with airport operations, as set forth in Table 1 of Appendix A to Part 150.

[20] FAA Order 1050.1F at Paragraph 1–9.

[21] FAA Order 1050.1F at Exhibit 4–1.

[22] *Id.*

[23] *Id.*

[24] The FAA's NEPA procedures address the use of supplemental noise metrics. *See* FAA Order 1050.1F, *Environmental Impacts: Policies and Procedures,* Appendix B, paragraph B–1.6; *1050.1F Desk Reference,* Section 11.4.

[25] *See* 42 U.S.C. 4321 *et seq.,* 40 CFR parts 1500–1508, and FAA Order 1050.1F. NEPA directs the Federal government to ensure that the likely significant environmental effects of proposed policies, plans, programs, projects or other actions are identified and assessed before the Federal agency makes a decision on whether the proposal should proceed. It also identifies certain procedures that must be followed regarding the level of environmental analysis to be conducted as well as ensures certain types of public disclosure and public involvement before the FAA makes a decision or takes an action. This does not mean, however, that the FAA must choose the most environmental favorable or most environmentally acceptable option.

[26] The FAA will continue to coordinate on matters related to aviation noise research and policy through the Federal Interagency Committee on Aviation Noise (FICAN), which provides a forum for Federal agencies to coordinate on future research needs to understand, predict, and better control the effects of aviation noise. FICAN comprises Federal agencies that conduct research on aviation-related noise as well as agencies that do not conduct research but that have broad policy roles with respect to aviation noise issues. Current member agencies include: the U.S. Departments of Defense, Transportation, Interior, Health and Human Services, Housing and Urban Development as well as the Environmental Protection Agency and NASA. In addition, in accordance with 40 CFR parts 1500–1508, the FAA will coordinate with the Council on Environmental Quality if the FAA recommends changes to its NEPA implementing procedures (FAA Order 1050.1F).

exposure to aviation noise is a pivotal quality-of-life issue for the public and welcomes input on how the FAA's assessment and disclosure of noise impacts may improve community understanding and expectations regarding future noise exposure. The most helpful comments would reference a specific recommendation, explain the reason for any recommended change, and include supporting information.

At this time, the FAA cannot predict how many comments will be received, whether requests to extend the comment period will be submitted, or how long it will take to review and respond to public comments. While the FAA will work expeditiously to review the input when the public comment period closes, the FAA cannot provide information regarding the timing of follow-on actions. However, following the FAA's consideration of comments, the FAA will publish in the **Federal Register** a subsequent notice to announce the input it received and how the FAA considered it in developing its recommended revisions to the policy. That notice will identify the elements of the policy that will be modified and explain how the FAA recommends revising the policy. The FAA will identify the subsequent actions it will take to implement the recommendation and whether the future change to the policy will be implemented through proposed rulemaking or other administrative actions. That notice will identify the FAA office that will be primarily responsible for implementing the recommended revision and identify, with specificity, the agency regulations, orders, guidance, or policy statements that will be modified. Finally, that notice will set forth how the public can continue to provide input when the FAA proposes revisions to relevant documents.

II. Request for Comments

The FAA seeks written public comments on the ways it describes potential impacts of aircraft noise as well as how the FAA defines the threshold of significant noise exposure for noise sensitive receivers. In addition, the FAA seeks public comment on the noise exposure limit that normally would be considered compatible for noise-sensitive land uses. To provide background information and context for the questions set forth below, the FAA invites the public to review a framing paper entitled, *The Foundational Elements of the Federal Aviation Administration Civil Aircraft Noise Policy: The Noise Measurement System, its Component Noise Metrics, and Noise Thresholds,* available at: *https://www.faa.gov/noisepolicyreview/NPR-framing.* The FAA welcomes any comments from the public on any of these issues and is particularly interested in the public's responses to the questions and information requested below.

The FAA maintains a robust program of activities related to aviation noise. The FAA's approach is multi-pronged, including research and development, regulatory control, and public and stakeholder outreach programs relating to the public's experience of aviation noise. In the next section of this notice, the FAA presents a series of questions designed to solicit public input that will supplement and augment the FAA's technical consideration of these issues. The FAA intentionally designed the questions below to seek written comment from a range of aviation stakeholders with varying levels of familiarity with the FAA, its role in addressing aircraft noise exposure, and the noise metrics the FAA uses to analyze, explain, and publicly present adverse noise exposure. One of the FAA's key goals in issuing this notice is to obtain stakeholder input on the information FAA develops and uses to make decisions that affect aviation noise. Public comments addressing potential improvements in how, where, and with whom the FAA communicates regarding changes in aircraft noise exposure will be particularly helpful as the FAA continues to develop a policy that will respond to affected communities' core interests, concerns, and needs.

Comments that focus on the issues and questions identified below will be most helpful. These questions are meant as a guide and commenters may provide their views or submit general comments related to how the FAA describes and discloses aviation noise impacts. The more specific the comments, the more useful they will be in agency deliberations. If relevant, commenters are requested to provide technical information, data, or other evidence to support the comment submission. Finally, the FAA requests that commenters identify the number of each question to which a response is submitted.

1. *Vehicle Type.* When the FAA published the ANAP [27] in 1976, the impacts of aviation noise were related to commercial jet service at or in the immediate vicinity of airports. What types or elements of current or future air vehicle activity (*e.g.,* unmanned aircraft systems (also known as UAS or drones), advanced air mobility, rotorcraft, subsonic fixed wing, supersonic, or commercial space) should the policy describe and disclose? How should this information be described using noise metrics? Should the FAA use this information to make decisions or for public disclosure only? Please explain your reasoning.

2. *Operations of Air Vehicles.*

a. What elements of aircraft operations (*e.g.,* en-route, takeoff, landing) should the noise metric evaluate and disclose? Should the FAA use this information to make decisions or disclose to the public noise impacts? Please explain your reasoning.

b. What interests or concerns do communities in the vicinity of airports have? How can these concerns be addressed using noise metrics? What noise metrics would address these concerns? Please explain your reasoning.

c. What interests or concerns do overflight communities [28] have? How can these concerns be addressed using noise metrics? What noise metrics would address these concerns? Please explain your reasoning.

d. What interests or concerns do communities in the vicinity of commercial space transportation operations have? How can these concerns be addressed using noise metrics? What noise metrics would address these concerns? Please explain your reasoning.

e. What interests or concerns do communities in the vicinity of UAS (drone) package delivery or other newly emerging technology operations have? How can these concerns be addressed using noise metrics? What noise metrics would address these concerns? Please explain your reasoning.

3. *DNL.* What views or comments do you have about the FAA's core decisionmaking metric, DNL? How would these views regarding DNL be resolved if the FAA employed another noise metric (either in addition to, or to replace DNL) or if the FAA calculated DNL differently? Please explain your reasoning.

4. *Averaging.* DNL provides a cumulative description of the noise events expected to occur over the course of an entire year averaged into a representative day, described as an Average Annual Day (AAD).

[27] The ANAP was issued by the Secretary of Transportation and the FAA Administrator on November 18, 1976. This document is available on the FAA website at *https://www.faa.gov/regulations_policies/policy_guidance/envir_policy/.*

[28] The phrase ''overflight communities'' in this Notice refers to communities located under the flight paths of aircraft and vehicles that are distressed by aircraft noise and are located outside of the DNL 65 dB contour.

a. Do you believe an AAD is an appropriate way to describe noise impacts? Please explain why or why not.

b. If not, what alternative averaging schemes to AAD should be considered and why? What information would the use of an alternative averaging scheme capture that AAD does not?

5. *Decisionmaking Noise Metrics.* The FAA currently uses DNL as its primary decisionmaking metric for actions subject to NEPA and airport noise compatibility planning studies prepared pursuant to 14 CFR part 150.

a. Should different noise metrics be used in different circumstances for decisionmaking?

b. If the answer to Question 5.a. is ''yes,'' please identify: the metric, the information it provides that DNL does not, and explain when and how it should be employed by the FAA in its system (*e.g.,* should the FAA use a noise metric other than DNL to evaluate noise exposure in quiet settings, such as national parks, national wildlife and waterfowl refuges, etc.)? Should this metric be used when the FAA is making decisions that affect noise in these settings? Should this metric be used alone or in combination with another metric?

c. If the metric should be used in combination with another metric, please describe how they should be used together for decisionmaking.

d. If the answer to Question 5.a is ''no,'' should DNL remain the core decisionmaking metric or should another metric be substituted in all circumstances?

e. How would the use of the metrics that you recommend support better agency decisionmaking? Please explain and illustrate with specific examples how the use of the recommended metric(s) would benefit agency decisionmaking.

6. *Communication.*

a. Please identify whether and how the FAA can improve communication regarding changes in noise exposure (*e.g.,* what information FAA communicates, where and with whom FAA communicates, what information methods FAA uses to communicate and the venues at which FAA shares this information). Please explain your reasoning.

b. Should the FAA consider revisions to its policy on the use of supplemental noise metrics in the FAA's NEPA procedures? Please explain how this policy should be modified to improve FAA communication of noise changes when the FAA is making decisions that affect noise. Please explain your reasoning.

c. What information about the change in noise resulting from civil aviation operations (*e.g.,* UAS or drones, helicopters, fixed wing aircraft, rockets/commercial space transportation vehicles, and new entrant technologies) should the noise metric communicate to the public? Please explain your reasoning.

d. Please explain how the public will benefit if the FAA implements your proposal in response to Questions 6.a and 6.b.

7. *NEPA and Land Use Noise Thresholds Established Using DNL or for Another Cumulative Noise Metric.* The FAA has several noise thresholds that are informed by a dose-response curve (Schultz Curve [29]), which historically provided a useful method for representing the community response to aircraft noise. Two of the noise thresholds informed by the Schultz Curve are the FAA's significant noise impact threshold for actions being reviewed under the National Environmental Policy Act and the land use compatibility standards established in 14 CFR part 150, Appendix A. Both of these rely on the cumulative noise metric DNL and are referred to collectively in this question and questions 8–10 as ''the FAA noise thresholds.'' On January 11, 2021, the FAA published the results of the Neighborhood Environmental Survey,[30] a nationally representative dataset on community annoyance in response to aircraft noise. The Neighborhood Environmental Survey results show higher percentage of people who self-identify as ''highly annoyed'' by aircraft noise across all DNL levels studied in comparison to the Schultz Curve.

a. How should the FAA consider this information (*i.e.,* the Schultz Curve and Neighborhood Environmental Survey findings) when deciding whether to retain or modify the FAA noise thresholds [31] established using the DNL metric or to establish new FAA noise thresholds using other cumulative noise metrics? Please explain your reasoning.

b. Should the FAA consider other or additional information when deciding whether to retain or modify the FAA noise thresholds that were established using the DNL metric or to establish new FAA noise thresholds using other cumulative noise metrics? Please describe the reason for the recommendation and identify the data, information, or evidence that supports the recommendation.

c. How should research findings on auditory or non-auditory effects (*e.g.,* speech interference, sleep disturbance, cardiovascular health effects) of noise exposure caused by civil aircraft and vehicles be considered by the FAA when it decides whether to retain or modify the FAA noise thresholds [32] that were established using the DNL metric? How should the FAA consider this same research when deciding whether to establish new FAA noise thresholds using other cumulative noise metrics? Please explain your response.

d. In examining whether to change its metrics and thresholds for noise, the FAA needs reliable information to support any changes. One type of information that the FAA can rely on is epidemiological evidence. This means the study (scientific, systematic, and data-driven) of the distribution (frequency, pattern) and determinants (causes, risk factors) of health-related states and events (not just diseases) in specified populations (neighborhood, school, city, state, country, global). What amount of epidemiological evidence is sufficient to provide the FAA with a sound basis for establishing or modifying the FAA noise thresholds [33] either using the DNL metric or another cumulative noise metric? Please explain your response.

e. Should the FAA consider using factors other than annoyance to establish FAA noise thresholds [34] using the DNL metric or other cumulative noise metrics? What revisions to existing FAA noise thresholds or new noise thresholds do you recommend be

[29] *See* Schultz, T.J. 1978, ''Synthesis of Social Surveys on Noise Annoyance,'' *Journal of the Acoustical Society of America* 64(2): 377–405. The Schultz Curve in this document refers to the curve generated from a meta-analysis of social surveys which set forth a widely accepted relationship between DNL and the percentage of the population who are highly annoyed by noise. This meta-analysis was later validated by interagency government committees focused on aircraft noise issues. *See, e.g.,* Federal Agency Review of Selected Airport Noise Analysis Issues, 1992.

[30] Miller, Nicholas P., et al. *Analysis of the neighborhood environmental survey.* No. DOT/FAA/TC–21/4. 2021 available at: *https://www.airporttech.tc.faa.gov/Products/Airport-Safety-Papers-Publications/Airport-Safety-Detail/ArtMID/3682/ArticleID/2845/Analysis-of-NES. See also* FAA, *Overview of FAA Aircraft Noise Policy and Research Efforts: Request for Input on Research Activities to Inform Aircraft Noise Policy,* 86 FR 2722 (Jan. 13, 2021).

[31] As explained in this Notice in footnote 24, *infra,* when FAA refers to ''noise thresholds'' collectively, it means both the definition of the level of significant noise exposure for actions subject to environmental review requirements set out in FAA Order 1050.1F as well as the definitions of the levels of noise exposure that are deemed to be ''normally compatible'' with airport operations, as set forth in Table 1 of Appendix A to Part 150.

[32] *Id.*

[33] *Id.*

[34] *Id.*

established and why? Please explain your response.

8. *FAA Noise Thresholds Using Single-Event or Operational Metrics.* As the FAA learned from the results of the NES, people are bothered by individual aircraft noise events, but their sense of annoyance increases with the number of those noise events. Should the FAA consider employing new FAA noise thresholds [35] using single-event or operational metrics? If the answer is ''yes,'' which metrics should be used to establish the FAA noise thresholds? What should be the relevant noise exposure level for the new noise thresholds you propose? Please explain your reasoning. If the answer is ''no,'' please explain your reasoning.

9. *FAA Noise Thresholds for Low-Frequency Events.* Should FAA establish noise thresholds [36] for low-frequency events, such as those associated with the launch and reentry of commercial space transportation vehicles authorized by the FAA Office of Commercial Space Transportation? If the answer is ''yes,'' which metrics should be used to establish the noise thresholds? What should be the relevant noise exposure level for the new noise thresholds you propose? Please explain your reasoning. If the answer is ''no,'' please explain your reasoning.

10. *Miscellaneous.* What other issues or topics should the FAA consider in this review regarding noise metrics, the method of calculating them, the establishment of noise thresholds,[37] or FAA's method of communicating the change in noise exposure? Please explain your response.

11. *Literature Review.* In this review, the FAA will examine the body of scientific and economic literature to understand how aviation noise correlates with annoyance as well as environmental, economic, and health impacts. The FAA also will evaluate whether any of these impacts are statistically significant and the metrics that may be best suited to disclose these impacts. A bibliography of this body of research is available for review in the Background Materials tab in the Docket and as Appendix 1 to the FAA framing paper entitled, *The Foundational Elements of the Federal Aviation Administration Civil Aircraft Noise Policy: The Noise Measurement System, its Component Noise Metrics, and Noise Thresholds.* This framing paper is available at: *https://www.faa.gov/noisepolicyreview/NPR-framing.* Please identify any studies or data regarding civil aviation noise not already identified by the FAA in the bibliography that you believe the FAA should evaluate. Please explain the relevance and significance of the study or evidence and how it should inform FAA decisions regarding the policy.

[35] *Id.*

[36] *Id.*

[37] *Id.*

III. Public Participation

Virtual Webinars

The FAA recognizes that the noise policy is of interest to Federal agencies, project proponents, airport sponsors, airport and corridor communities, and the public generally. As a result, the FAA is taking steps to ensure stakeholders can request clarification, ask questions, and provide written feedback. The FAA will hold virtual webinars to provide background information regarding the review and respond to technical matters.

Participants may join the virtual webinars via telephone or virtually using Zoom. Access information and registration instructions will be made available on the FAA's Noise Policy Review website, located at *https://www.faa.gov/noisepolicyreview.*

If there is not sufficient time to respond to all questions asked, the FAA will make supplementary materials available on the FAA's website at a later date, located at *https://www.faa.gov/noisepolicyreview.* Further instructions on signing up and participating in the virtual webinars will be made available on the FAA's website at a later date, located at *https://www.faa.gov/noisepolicyreview.* Supporting materials and written feedback to questions to which the FAA was unable to respond during the virtual webinar will be submitted to the docket as described above and posted to the FAA's website at *https://www.faa.gov/noisepolicyreview.*

We request members of the press to RSVP to the person listed in the **FOR FURTHER INFORMATION CONTACT** section at least two weeks prior to the meeting that you plan to attend.

The U.S. Department of Transportation is committed to providing equal access to this meeting for all participants. If you need alternative formats or services because of a disability, such as sign language, interpretation, or other ancillary aids, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section at least two weeks prior to the meeting that you plan to attend.

How do I prepare and submit written comments?

To ensure that your comments are filed correctly in the docket, please include the docket number of this document in your comments. Please review information available at *https://www.faa.gov/noisepolicyreview* to assist you with submitting your comment to the docket using the instructions given above under **ADDRESSES**.

Please note, if you are submitting comments electronically as PDF (Adobe) file, the FAA asks that the documents submitted be scanned using an Optical Character Recognition (OCR) process, to allow the FAA to search and copy certain portions of your submissions.

The FAA will consider your comments and consider appropriate revisions to its policy. The FAA will publish in the **Federal Register** a notice announcing the revisions it expects to make to its policy and identify the relevant agency documents that will express the revised policy, which elements of the agency document it expects to modify, and the process the FAA will use to issue and implement the revised policy.

Will the FAA consider late comments?

The FAA will consider all comments received before the close of business on the comment closing date indicated above under **DATES**. To the extent possible, the FAA will also consider comments received after that date.

How can I read the comments submitted by others?

You may read the comments received on the internet, identified by the docket number at the heading of this notice, at *https://www.regulations.gov.* You may also read comments at the address given above under **ADDRESSES**.

Issued in Washington, DC.

Kevin Welsh,

Executive Director, Office of Environment and Energy.

[FR Doc. 2023–09113 Filed 4–28–23; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2018–0054; FMCSA–2018–0057; FMCSA–2020–0045]

Qualification of Drivers; Exemption Applications; Epilepsy and Seizure Disorders

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), Department of Transportation (DOT).

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew exemptions for three individuals from the requirement in the Federal Motor Carrier Safety Regulations (FMCSRs) that interstate commercial motor vehicle (CMV) drivers have ''no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause loss of consciousness or any loss of ability to control a CMV.'' The exemptions enable these individuals who have had one or more seizures and are taking anti-seizure medication to continue to operate CMVs in interstate commerce.

DATES: The exemptions are applicable on May 15, 2023. The exemptions expire on May 15, 2025. Comments must be received on or before May 31, 2023.

ADDRESSES: You may submit comments identified by the Federal Docket Management System Docket No. FMCSA–2018–0054, Docket No. FMCSA–2018–0057, or Docket No. FMCSA–2020–0045 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *www.regulations.gov/,* insert the docket number (FMCSA–2018–0054, FMCSA–2018–0057, or FMCSA–2020–0045) in the keyword box and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click on the ''Comment'' button. Follow the online instructions for submitting comments.
- *Mail:* Dockets Operations; U.S. Department of Transportation, 1200 New Jersey Avenue SE, West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE, Washington, DC 20590–0001 between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal Holidays.
- *Fax:* (202) 493–2251.

To avoid duplication, please use only one of these four methods. See the ''Public Participation'' portion of the **SUPPLEMENTARY INFORMATION** section for instructions on submitting comments.

FOR FURTHER INFORMATION CONTACT: Ms. Christine A. Hydock, Chief, Medical Programs Division, FMCSA, DOT, 1200 New Jersey Avenue SE, Room W64–224, Washington, DC 20590–0001, (202) 366–4001, *fmcsamedical@dot.gov.* Office hours are from 8:30 a.m. to 5 p.m. ET Monday through Friday, except Federal holidays. If you have questions regarding viewing or submitting material to the docket, contact Dockets Operations, (202) 366–9826.

SUPPLEMENTARY INFORMATION:

I. Public Participation

A. Submitting Comments

If you submit a comment, please include the docket number for this notice (Docket No. FMCSA–2018–0054, Docket No. FMCSA–2018–0057, or Docket No. FMCSA–2020–0045), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *www.regulations.gov/,* insert the docket number (FMCSA–2018–0054, FMCSA–2018–0057, or FMCSA–2020–0045) in the keyword box and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, click the ''Comment'' button, and type your comment into the text box on the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit.

If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. FMCSA will consider all comments and material received during the comment period.

B. Viewing Comments

To view comments go to *www.regulations.gov.* Insert the docket number (FMCSA–2018–0054, FMCSA–2018–0057, or FMCSA–2020–0045) in the keyword box and click ''Search.'' Next, sort the results by ''Posted (Newer-Older),'' choose the first notice listed, and click ''Browse Comments.'' If you do not have access to the internet, you may view the docket online by visiting Dockets Operations in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, between 9 a.m. and 5 p.m. ET Monday through Friday, except Federal holidays. To be sure someone is there to help you, please call (202) 366–9317 or (202) 366–9826 before visiting Dockets Operations.

C. Privacy Act

In accordance with 49 U.S.C. 31315(b)(6), DOT solicits comments from the public on the exemption request. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov.* As described in the system of records notice DOT/ALL 14 (Federal Docket Management System), which can be reviewed at *https://www.transportation.gov/individuals/privacy/privacy-act-system-records-notices,* the comments are searchable by the name of the submitter.

II. Background

Under 49 U.S.C. 31136(e) and 31315(b), FMCSA may grant an exemption from the FMCSRs for no longer than a 5-year period if it finds such exemption would likely achieve a level of safety that is equivalent to, or greater than, the level that would be achieved absent such exemption. The statutes also allow the Agency to renew exemptions at the end of the 5-year period. However, FMCSA grants medical exemptions from the FMCSRs for a 2-year period to align with the maximum duration of a driver's medical certification.

The physical qualification standard for drivers regarding epilepsy found in 49 CFR 391.41(b)(8) states that a person is physically qualified to drive a CMV if that person has no established medical history or clinical diagnosis of epilepsy or any other condition which is likely to cause the loss of consciousness or any loss of ability to control a CMV.

In addition to the regulations, FMCSA has published advisory criteria [1] to assist Medical Examiners in determining whether drivers with certain medical conditions are qualified to operate a CMV in interstate commerce.

The three individuals listed in this notice have requested renewal of their exemptions from the epilepsy and seizure disorders prohibition in § 391.41(b)(8), in accordance with FMCSA procedures. Accordingly, FMCSA has evaluated these applications for renewal on their merits and decided to extend each exemption for a renewable 2-year period.

III. Request for Comments

Interested parties or organizations possessing information that would otherwise show that any, or all, of these drivers are not currently achieving the statutory level of safety should immediately notify FMCSA. The

[1] These criteria may be found in APPENDIX A TO PART 391—MEDICAL ADVISORY CRITERIA, section H. *Epilepsy:* § 391.41(b)(8), paragraphs 3, 4, and 5, which is available on the internet at *https://www.gpo.gov/fdsys/pkg/CFR-2015-title49-vol5/pdf/CFR-2015-title49-vol5-part391-appA.pdf.*

Agency will evaluate any adverse evidence submitted and, if safety is being compromised or if continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b), FMCSA will take immediate steps to revoke the exemption of a driver.

IV. Basis for Renewing Exemptions

In accordance with 49 U.S.C. 31136(e) and 31315(b), each of the three applicants has satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition. The three drivers in this notice remain in good standing with the Agency, have maintained their medical monitoring and have not exhibited any medical issues that would compromise their ability to safely operate a CMV during the previous 2-year exemption period. In addition, for commercial driver's license (CDL) holders, the Commercial Driver's License Information System and the Motor Carrier Management Information System are searched for crash and violation data. For non-CDL holders, the Agency reviews the driving records from the State Driver's Licensing Agency. These factors provide an adequate basis for predicting each driver's ability to continue to safely operate a CMV in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of 2 years is likely to achieve a level of safety equal to that existing without the exemption.

As of May 15, 2023, and in accordance with 49 U.S.C. 31136(e) and 31315(b), the following three individuals have satisfied the renewal conditions for obtaining an exemption from the epilepsy and seizure disorders prohibition in the FMCSRs for interstate CMV drivers:

Kevin Addington (PA); Jose F.J. Maciel (CA); and John Shainline (PA).

The drivers were included in docket number FMCSA–2018–0054, FMCSA–2018–0057, or FMCSA–2020–0045. Their exemptions are applicable as of May 15, 2023 and will expire on May 15, 2025.

V. Conditions and Requirements

The exemptions are extended subject to the following conditions: (1) each driver must remain seizure-free and maintain a stable treatment during the 2-year exemption period; (2) each driver must submit annual reports from their treating physicians attesting to the stability of treatment and that the driver has remained seizure-free; (3) each driver must undergo an annual medical examination by a certified ME, as defined by § 390.5; and (4) each driver must provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy of his/her driver's qualification file if he/she is self-employed. The driver must also have a copy of the exemption when driving, for presentation to a duly authorized Federal, State, or local enforcement official. The exemption will be rescinded if: (1) the person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

VI. Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with this exemption with respect to a person operating under the exemption.

VII. Conclusion

Based on its evaluation of the three exemption applications, FMCSA renews the exemptions of the aforementioned drivers from the epilepsy and seizure disorders prohibition in § 391.41(b)(8). In accordance with 49 U.S.C. 31136(e) and 31315(b), each exemption will be valid for 2 years unless revoked earlier by FMCSA.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2023–09181 Filed 4–28–23; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: Claim for Relief on Account of Loss, Theft, or Destruction of U.S. Registered Securities

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Claim for Relief on Account of Loss, Theft, or Destruction of U.S. Registered Securities.

DATES: Written comments should be received on or before June 30, 2023 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006–A, P.O. Box 1328, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: Claim for Relief on Account of Loss, Theft, or Destruction of U.S. Registered Securities.

OMB Number: 1530–0029.

Form Number: FS Form 1025.

Abstract: The information is requested to establish ownership and support a request for relief due to the loss, theft, or destruction of United States Registered Securities.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 10.

Estimated Time per Respondent: 55 minutes.

Estimated Total Annual Burden Hours: 9.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: 1. Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: April 26, 2023.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2023–09166 Filed 4–28–23; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: Special Form of Request for Payment of US Savings and Retirement Securities Where Use of a Detached Request Is Authorized

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Special Form of Request for Payment of US Savings and Retirement Securities Where Use of a Detached Request is Authorized.

DATES: Written comments should be received on or before June 30, 2023 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006–A, P.O. Box 1328, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: Special Form of Request for Payment of US Savings and Retirement Securities Where Use of a Detached Request is Authorized.

OMB Number: 1530–0028.

Form Number: FS Form 1522.

Abstract: The information on the completed form is submitted by the owner, co-owner, surviving beneficiary, or legal representative of the estate of a deceased or incompetent owner, persons entitled to the estate of a deceased registrant, or such other persons to request payment of United States Savings Bonds, Savings Notes, Retirement Plan Bonds, and Individual Retirement Bonds.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 14,000.

Estimated Time per Respondent: 15 minutes.

Estimated Total Annual Burden Hours: 3,500.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: 1. Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: April 26, 2023.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2023–09165 Filed 4–28–23; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: Affidavit of Forgery for United States Bonds/Notes

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Affidavit of Forgery for United States Bonds/Notes.

DATES: Written comments should be received on or before June 30, 2023 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006–A, P.O. Box 1328, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: Affidavit of Forgery for United States Bonds/Notes.

OMB Number: 1530–0040.

Form Number: FS Form 0974.

Abstract: The information is requested to certify that the signatures to the requests for payment, form, or application related to United States Savings Securities were forged.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 10.

Estimated Time per Respondent: 15 minutes.

Estimated Total Annual Burden Hours: 3.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: 1. Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: April 26, 2023.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2023–09186 Filed 4–28–23; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: Report/Application for Relief on Account of Loss, Theft, or Destruction of U.S. Bearer Securities (Individuals)

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently the Bureau of the Fiscal

Service within the Department of the Treasury is soliciting comments concerning the Report/Application for Relief on Account of Loss, Theft, or Destruction of U.S. Bearer Securities (Individuals).

DATES: Written comments should be received on or before June 30, 2023 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006–A, P.O. Box 1328, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: Report/Application for Relief on Account of Loss, Theft, or Destruction of U.S. Bearer Securities (Individuals).

OMB Number: 1530–0033.

Form Number: FS Form 1022–1.

Abstract: The information is requested to establish ownership and support a request for relief due to the loss, theft, or destruction of United States Bearer Securities owned by individuals. Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 10.

Estimated Time per Respondent: 55 minutes.

Estimated Total Annual Burden Hours: 9.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: 1. Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: April 26, 2023.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2023–09167 Filed 4–28–23; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: Pools and Associations—Annual Letter

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning Annual Letters sent to Pools and Associations currently recognized by the U.S. Treasury as authorized reinsurers for non-Federal business.

DATES: Written comments should be received on or before June 30, 2023 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006–A, P.O. Box 1328, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: Pools and Associations—Annual Letter.

OMB Number: 1530–0007.

Abstract: The information is collected for the determinations of an acceptable percentage for each pool and association to allow Treasury certified companies credit on their Schedule F for authorized ceded reinsurance in determining the companies' underwriting limitations.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Business or other for-profit.

Estimated Number of Respondents: 84

Estimated Time per Respondent: 1 hour 30 minutes.

Estimated Total Annual Burden Hours: 126.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: 1. Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: April 26, 2023.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2023–09195 Filed 4–28–23; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: Certificate of Identity

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Certificate of Identity.

DATES: Written comments should be received on or before June 30, 2023 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006–A, P.O. Box 1328, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: Certificate of Identity.

OMB Number: 1530–0026.

Form Number: FS Form 0385.

Abstract: The information on the completed form is used to establish an individual's identity in a claim for payment of United States savings and retirement securities.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 1,400.

Estimated Time per Respondent: 10 minutes.

Estimated Total Annual Burden Hours: 234.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: 1. Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: April 26, 2023.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2023–09164 Filed 4–28–23; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: Report/Application for Relief on Account of Loss, Theft, or Destruction of U.S. Bearer Securities (Organizations)

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Report/Application for Relief on Account of Loss, Theft, or Destruction of U.S. Bearer Securities (Organizations).

DATES: Written comments should be received on or before June 30, 2023 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006–A, P.O. Box 1328, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: Report/Application for Relief on Account of Loss, Theft, or Destruction of U.S. Bearer Securities (Organizations).

OMB Number: 1530–0034.

Form Number: FS Form 1022.

Abstract: The information is requested to establish ownership and support a request for relief due to the loss, theft, or destruction of United States Bearer Securities owned by individuals.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Private Sector.

Estimated Number of Respondents: 10.

Estimated Time per Respondent: 55 minutes.

Estimated Total Annual Burden Hours: 9.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: 1. Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: April 26, 2023.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2023–09168 Filed 4–28–23; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: Affidavit by Individual Surety

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995. Currently the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the Affidavit by Individual Surety.

DATES: Written comments should be received on or before June 30, 2023 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for additional information to Bureau of the Fiscal Service, Bruce A. Sharp, Room #4006–A, P.O. Box 1328, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: Affidavit by Individual Surety.

OMB Number: 1530–0047.

Form Number: FS Form 4094.

Abstract: The information on the completed form is submitted to support a request to serve as surety for an indemnification agreement on a Bond of Indemnity.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 10.

Estimated Time per Respondent: 55 minutes.

Estimated Total Annual Burden Hours: 9.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: 1. Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; 2. the accuracy of the agency's estimate of the burden of the collection of information; 3. ways to enhance the quality, utility, and clarity of the information to be collected; 4. ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and 5. estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: April 26, 2023.

Bruce A. Sharp,

Bureau PRA Clearance Officer.

[FR Doc. 2023–09187 Filed 4–28–23; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Taxpayer Communications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Tuesday, May 16, 2023.

FOR FURTHER INFORMATION CONTACT: Conchata Holloway at 1–888–912–1227 or 214–413–6550.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. app. (1988) that a meeting of the Taxpayer Advocacy Panel Taxpayer Communications Project Committee will be held Tuesday, May 16, 2023, from 2:00 p.m. to 4:30 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Conchata Holloway. For more information, please contact Conchata Holloway at 1–888–912–1227 or 214–413–6550, or write TAP Office, 1114 Commerce St., MC 1005, Dallas, TX 75242 or contact us at the website: *http://www.improveirs.org.* The agenda includes a committee discussion involving subcommittee 1 Issue 54250; Increase E-filing of Forms/Tax Returns; and Issue 48294 Entities with multiple EIN's. Subcommittee 2 Issue 66193; and effectively measuring outreach.

Dated: April 25, 2023.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2023–09108 Filed 4–28–23; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Tuesday, May 16, 2023.

FOR FURTHER INFORMATION CONTACT: Robert Rosalia at 1–888–912–1227 or (718) 834–2203.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel's Tax Forms and Publications Project Committee will be held Tuesday, May 16, 2023, from 2:00 p.m. to 4:30 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Robert Rosalia. For more information, please contact Robert Rosalia at 1–888–912–1227 or (718) 834–2203, or write TAP Office, 2 Metrotech Center, 100 Myrtle Avenue, Brooklyn, NY 11201 or contact us at the website: *http://www.improveirs.org.* The agenda will include a committee discussion involving subcommittee 1: 62742—Form 8615 & Inst (Children Who Have Unearned Income). Subcommittee 2: 52664—Form 3520 & F3520A (Foreign Trust).

Dated: April 25, 2023.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2023–09107 Filed 4–28–23; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Notices and Correspondence Project Committee

AGENCY: Internal Revenue Service (IRS) Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Notices and Correspondence Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, May 18, 2023.

FOR FURTHER INFORMATION CONTACT: Ann Tabat at 1–888–912–1227 or (602) 636–9143.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel's Notices and Correspondence Project Committee will be held Thursday, May 18, 2023, from 2 p.m. to 4:30 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Ann Tabat. For more information, please contact Ann Tabat at 1–888–912–1227 or (602) 636–9143, or write TAP Office, 4041 N Central Ave, Phoenix, AZ 85012 or contact us at the website: *http://www.improveirs.org.* The agenda will include a committee discussion about the IRS response to Issue 53484–LTR 3030C (Bal-Due/Interest Due). There will be a discussion of the subcommittee's review on Issue 66192—Difficult/Challenging Letters/Notices, and Issue 52479 Review of Notice CP503.

Dated: April 25, 2023.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2023–09102 Filed 4–28–23; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Toll-Free Phone Lines Project Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Toll-Free Phone Lines Project Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving

customer service at the Internal Revenue Service.

DATES: The meeting will be held Tuesday, May 16, 2023.

FOR FURTHER INFORMATION CONTACT: Rosalind Matherne at 1–888–912–1227 or 202–317–4115.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel Toll-Free Phone Lines Project Committee will be held Tuesday, May 16, 2023, at 2:00 p.m. to 4:30 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Rosalind Matherne. For more information, please contact Rosalind Matherne at 1–888–912–1227 or 202–317–4115, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website: *http://www.improveirs.org.* The agenda includes a committee discussion that may involve Subcommittee 1 Issue #66342—Voicebot and Chatbot Project; Subcommittee 2 Issue #66029—Modify Certified Acceptance Agent Program to Resolve ID Theft Issues; and Issue #66342– Voicebot and Chatbot Project.

Dated: April 25, 2023.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2023–09101 Filed 4–28–23; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for the Advanced Manufacturing Production Credit

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Internal Revenue Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on continuing information collections, as required by the Paperwork Reduction Act of 1995. The IRS is soliciting comments concerning the advanced manufacturing production credit.

DATES: Written comments should be received on or before June 30, 2023 to be assured of consideration.

ADDRESSES: Direct all written comments to Andres Garcia, Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or by email to *pra.comments@irs.gov.* Please reference the information collection's ''OMB number 1545–2306 or Form number 7207'' in the subject line of the message.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Sara Covington (202) 317–5744, at Internal Revenue Service, Room 6526, 1111 Constitution Avenue NW, Washington, DC 20224, or through the internet, at *sara.l.covington@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Advanced Manufacturing Production Credit.

OMB Number: 1545–2306.

Form Number: Form 7207.

Abstract: This form is used to claim the advanced manufacturing production credit under section 45x for eligible components produced by the taxpayer and sold during the tax year in the taxpayer's trade or business to an unrelated person.

Current Actions: IRS is making revisions to the form and instructions to include Inflation Reduction Act of 2022 provisions for Tax Year 2024.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 1,000.

Estimated Time per Respondent: 3 hrs and 56 mins.

Estimated Total Annual Burden Hours: 3,930 hours.

The following paragraph applies to all the collections of information covered by this notice.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained if their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: April 25, 2023.

Andres Garcia Leon,

Supervisory Tax Analyst.

[FR Doc. 2023–09124 Filed 4–28–23; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Open Meeting of the Taxpayer Advocacy Panel's Special Projects Committee

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of meeting.

SUMMARY: An open meeting of the Taxpayer Advocacy Panel's Special Projects Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

DATES: The meeting will be held Thursday, May 18, 2023.

FOR FURTHER INFORMATION CONTACT: Antoinette Ross at 1–888–912–1227 or 202–317–4110.

SUPPLEMENTARY INFORMATION: Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that an open meeting of the Taxpayer Advocacy Panel's Special Projects Committee will be held Thursday, May 18, 2023, from 2 to 4:30 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited time and structure of meeting, notification of intent to participate must be made with Antoinette Ross. For more information please contact Antoinette Ross at 1–888–912–1227 or 202–317–4110, or write TAP Office, 1111 Constitution Ave. NW, Room 1509, Washington, DC 20224 or contact us at the website:

https://www.improveirs.org. The agenda includes a committee discussion involving subcommittee—1 Issue number 48336—Electronic Filing of Form 8621; Information Returns by a Shareholder of a Passive Foreign Investment Company; Issue 59522—International Phone Apps; subcommittee—2 Issue 58722—Misleading Wording on Website; and Issue 51824—Estate Gift Tax.

Dated: April 25, 2023.

Kevin Brown,

Acting Director, Taxpayer Advocacy Panel.

[FR Doc. 2023–09103 Filed 4–28–23; 8:45 am]

BILLING CODE 4830–01–P

FEDERAL REGISTER

Vol. 88 Monday,
No. 83 May 1, 2023

Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 411, 412, 419, et al.

Medicare Program; Proposed 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; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 411, 412, 419, 488, 489, and 495

[CMS–1785–P]

RIN 0938–AV08

Medicare Program; Proposed 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

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would: revise the Medicare 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.

DATES: To be assured consideration, comments must be received at one of the addresses provided in the **ADDRESSES** section, no later than 5 p.m. EDT on June 9, 2023.

ADDRESSES: In commenting, please refer to file code CMS–1785–P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. *Electronically.* You may (and we encourage you to) submit electronic comments on this regulation to *https://www.regulations.gov.* Follow the instructions under the ''submit a comment'' tab.

2. *By regular mail.* You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1785–P, P.O. Box 8013, Baltimore, MD 21244–8013.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments via express or overnight mail to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–1785–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

For information on viewing public comments, we refer readers to the beginning of the **SUPPLEMENTARY INFORMATION** section.

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:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: *https://www.regulations.gov/.* Follow the search instructions on that website to view public comments.

Tables Available on the CMS Website

The IPPS tables for this fiscal year (FY) 2024 proposed 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 Proposed rule Home Page'' or ''Acute Inpatient—Files for Download.'' The LTCH PPS tables for this FY 2024 proposed 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–P. For further details on the contents of the tables referenced in this proposed rule, we refer readers to section VI. of the Addendum to this FY 2024 IPPS/LTCH PPS proposed 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*.

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I. Executive Summary and Background

A. Executive Summary

1. Purpose and Legal Authority

This FY 2024 IPPS/LTCH PPS proposed rule would make 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 would make 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 proposed rule would also make policy changes to programs associated with Medicare IPPS hospitals, IPPS-excluded hospitals, and LTCHs. In this FY 2024 proposed rule, we are proposing to continue policies to address wage index disparities impacting low wage index hospitals. We are also proposing to make changes relating to Medicare graduate medical education (GME) for teaching hospitals and new technology add-on payments.

We are proposing 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 proposing 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, and change the scoring policy to include a health equity scoring adjustment and modify the Total Performance Score (TPS) maximum to be 110, resulting in 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 proposing to establish a validation reconsideration process for data validation and to add an additional targeting criterion for validation. We are not proposing any changes to the Hospital Readmissions Reduction Program.

In the Hospital IQR Program, we are proposing to add three new measures, to update three existing measures, and to remove three measures. We are proposing changes to the validation process. Additionally, we are seeking public comment on the potential future adoption of two measures.

In the PPS-Exempt Cancer Hospital Quality Reporting Program (PCHQR) we are proposing to add four new measures and to modify an existing measure.

In the LTCH QRP we are proposing new measures, modifying an existing measure, removing measures and proposing to increase the LTCH QRP data completion thresholds for LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS) items. Additionally, we are we are seeking information on principles for selecting and prioritizing LTCH QRP quality measures and concepts under consideration for future years and provide an update on CMS' continued efforts to close the health equity gap.

Under various statutory authorities, we either discuss continued program implementation or propose to 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)(3) of the Act offered incentive payments under Medicare for critical access hospitals (CAHs) for certain payment years, if they successfully adopted and demonstrated meaningful use of CEHRT during an electronic health record (EHR) reporting period.
- Section 1814(l)(4) of the Act authorized downward payment adjustments under Medicare, beginning with FY 2015, for CAHs that do not successfully demonstrate meaningful use of CEHRT for an 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(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 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 requires the Secretary to offered incentive payments under Medicare for eligible hospitals for certain payment years, if they successfully adopted and demonstrated meaningful use of CEHRT during an electronic health record (EHR) reporting period.
- 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 section 1886(d)(5)(F) of the Act for DSH (''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; (2) 1 minus the percent change in the percent of individuals who are uninsured; and (3) a 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 proposed rule. In general, these major provisions are being proposed 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 proposed rule is presented in section

I.D. of the preamble of this proposed rule.

a. Proposed Modification to the Rural Wage Index Calculation Methodology

As discussed in section III.G.1 of this proposed 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 are proposing 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 Medicare Geographic Classification Review Board (MGCRB) reclassifications) implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act.

b. Proposed 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 proposed 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 proposing 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 proposed rule, we are proposing to update our estimates of the three factors used to determine uncompensated care payments for FY 2024. We are also proposing 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 discontinuing use of the low-income insured days proxy in the uncompensated care payment methodology for these providers.

d. 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 proposed rule, we are proposing 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. We are also proposing to adopt the Severe Sepsis and Septic Shock: Management Bundle measure in the Safety Domain beginning with the FY 2026 program year. We are also proposing 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 proposing to adopt a health equity scoring change for rewarding excellent care in underserved populations beginning with the FY 2026 program year. We are also proposing 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 proposed health equity scoring change. We are also requesting feedback on potential additional future changes to the Hospital VBP Program scoring methodology that would address health equity.

e. Proposed Modification of the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure in the Hospital IQR Program, PCHQR Program, and LTCH QRP

In this FY 2024 IPPS/LTCH PPS proposed rule, we are proposing to modify the COVID–19 Vaccination Coverage among Health Care Personnel (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.

f. 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 this FY 2024 IPPS/LTCH PPS proposed rule, we are proposing several

changes to the Hospital IQR Program. We are proposing 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 Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Inpatient) eCQM beginning with the CY 2025 reporting period/FY 2027 payment determination. We are proposing 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 among Healthcare Personnel (HCP) measure beginning with the Quarter 4 CY 2023 reporting period/FY 2025 payment determination. We are proposing 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; (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 are proposing to codify our Measure Removal Factors. We are requesting comment on the potential future inclusion of geriatric measures and a potential future public-facing geriatric hospital designation in the Hospital IQR Program.

We are proposing two changes to current policies related to data submission, reporting, and validation: (1) Modification of the Hospital Consumer Assessment of Healthcare Providers and Systems (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.

g. 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 this FY 2024 IPPS/LTCH PPS proposed rule, we are proposing 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 proposing to adopt a modified version of the COVID–19 Vaccination Coverage among Health Care Personnel (HCP) measure beginning with the FY 2025 program year. We are also proposing to publicly report the Surgical Treatment Complications for Localized Prostate Cancer (PCH–37) measure beginning with data from the FY 2025 program year, and modified data submission and reporting requirements for the HCAHPS survey measure beginning with the FY 2027 program year.

h. Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

We are proposing several proposed changes to the LTCH QRP. Specifically, we are: (1) proposing to adopt a modified version of the COVID–19 Vaccination Coverage among Healthcare Personnel measure beginning with the FY 2025 LTCH QRP; (2) proposing to adopt the Discharge Function Score measure beginning with the FY 2025 LTCH QRP; (3) proposing to remove 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) proposing to remove 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) proposing to adopt the COVID–19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure beginning with the FY 2026 LTCH QRP; (6) proposing to increase the LTCH QRP data completion thresholds for the LTCH Continuity Assessment Record and Evaluation (CARE) Data Set (LCDS) beginning with the FY 2026 LTCH QRP; and (7) proposing to begin public reporting of the Transfer of Health (TOH) Information to the Patient-Post-Acute Care (PAC) and TOH Information to the Provider-PAC measures beginning with the FY 2025 LTCH QRP.

i. Medicare Promoting Interoperability Program

In this proposed rule, we are proposing several changes to the Medicare Promoting Interoperability Program. Specifically, we are proposing 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.

j. Hospital Readmissions Reduction Program

We are not proposing 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.

k. 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 proposed rule, we are proposing 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 proposing modification of the validation targeting criteria for extraordinary circumstances exceptions (ECEs) beginning with the FY 2027 program year, affecting calendar year 2024 discharges. We are also requesting feedback on potential future measures to adopt in the HAC Reduction Program that would address patient safety and health equity.

l. Safety Net Hospitals—Request for Information

As discussed in section X.D. of the preamble of this proposed rule, under the Biden-Harris Administration, CMS has made advancing health equity the first pillar in its Strategic Plan. Among the goals of CMS's health equity pillar is to evaluate policies to determine how CMS can support safety-net providers, including acute care hospitals. Safety-net 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 healthcare. Because they serve many low-income and uninsured patients, safety-net hospitals may experience greater financial challenges compared to other hospitals, and these challenges have been exacerbated by the impacts of the COVID–19 pandemic. As MedPAC noted in its June 2022 Report to Congress, the limited resources of many safety-net hospitals may make it difficult for them to compete with other hospitals for labor and technology, and in some cases may even lead to hospital closure.

We are interested in public feedback on the challenges faced by safety-net hospitals, and potential approaches to help safety-net hospitals meet those challenges. In section X.C. of the preamble of this proposed rule, we discuss the Safety-Net Index (SNI), which was developed by MedPAC as a potential measure of the degree to which a hospital functions as a safety-net hospital. In addition, we discuss a potential alternative to the SNI, in which safety-net hospitals would be identified using area-level indices. We seek public feedback and comment on whether either of these two approaches would serve as an appropriate basis for identifying safety-net hospitals for Medicare purposes.

m. Proposed Changes to the Severity Level Designation for Z Codes Describing Homelessness

As discussed in section II.C. of the preamble of this proposed rule, we are proposing to 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 provisions described in section I.A.3. of the preamble of this proposed rule.

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[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*).

Provision Description	Description of Costs, Transfers, Savings, and Benefits
Modification to the Rural Wage Index Calculation Methodology	Beginning with FY 2024, we are proposing 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.
Continuation of the Low Wage Index Hospital Policy	For FY 2024, we are proposing to continue 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 proposing to update our estimates of the three factors used to determine uncompensated care payments. We are proposing to continue 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)(*1*), 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. In addition, for FY 2024, we are proposing to follow the same overall methodological approach as was used to calculate Factor 3 for FY 2023. We project that the amount available to distribute as payments for uncompensated care for FY 2024 would decrease by approximately $161 million, as compared to our estimate of the uncompensated care payments that will be distributed in FY 2023. The uncompensated care payments have redistributive effects, based on a hospital's uncompensated care amount relative to the uncompensated care amount for all hospitals that are projected to be eligible to receive Medicare DSH payments, and the calculated payment amount is not directly tied to a hospital's number of discharges. The supplemental payment is not budget neutral and we estimate the impact for FY 2024 to be approximately $90.3 million, which would be an approximately $6 million decrease from our estimate of supplemental payments in FY 2023.
Update to the IPPS Payment Rates and Other Payment Policies	As discussed in Appendix A of this proposed rule, acute care hospitals are estimated to experience an increase of approximately $2.7 billion in FY 2024, primarily driven by: (1) a combined $3.2 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 $466 million resulting from estimated changes in new technology add-on payments, as modeled for this proposed rule.
Update to the LTCH PPS Payment Rates and Other Payment Policies	As discussed in Appendix A of this proposed rule, based on the best available data for the 333 LTCHs in our database, we estimate that the proposed changes to the payment rates and factors that we present in the preamble of and Addendum to this proposed rule, which reflect the proposed update to the LTCH PPS standard Federal payment rate for FY 2024, would result in an estimated decrease in payments in FY 2024 of approximately $24 million.
Proposed 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

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Provision Description	Description of Costs, Transfers, Savings, and Benefits
	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.
Proposal to Modify the COVID-19 Vaccination Coverage among Healthcare Personnel Measure in the Hospital IQR Program, PCHQR Program, and LTCH QRP	We estimate that the proposed modified version of this measure will have no financial impact on the LTCH QRP, PCHQR Program, or Hospital IQR Program
Proposed 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 proposed changes in this proposed rule would not result in a change in information collection burden for the FY 2025 program year and subsequent years.
Proposed Changes to the Hospital IQR Program	Across 3,150 IPPS hospitals, we estimate that our proposed changes for the Hospital IQR Program in this proposed rule would result in a total information collection burden decrease of 146,674 hours associated with our proposed policies, and updated burden estimates and a total cost decrease of approximately $6,748,067 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.
Proposed Changes to the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program	Across 11 PCHs, we estimate that our proposed changes for the PCHQR Program in this proposed rule would 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 proposal to adopt the Documentation of Goals of Care Discussions Among Cancer Patients measure beginning with the FY 2026 program year.
Proposed Changes to the LTCH QRP	Across 330 LTCHs, we estimate that our changes for the LTCH QRP in this proposed rule will result in a total information collection burden decrease of 1,292 hours associated with our proposed 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.
Proposed Changes to the Medicare Promoting Interoperability Program	Across 4,500 eligible hospitals and CAHs, we estimate that our proposed changes for the Medicare Promoting Interoperability Program in this proposed 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 proposed 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 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 Would Be Implemented in This Proposed 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. Summary of the Provisions of This Proposed Rule

In this proposed rule, 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 are proposing to make in this proposed rule.

1. Proposed Changes to MS–DRG Classifications and Recalibrations of Relative Weights

In section II. of the preamble of this proposed rule, we include 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 FDA marketing authorization deadline from July 1 to May 1, beginning with applications for FY 2025 (as discussed in section II.E.8. of the preamble of this proposed rule).

2. Proposed Changes to the Hospital Wage Index for Acute Care Hospitals

In section III. of the preamble of this proposed rule, we propose 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 2023 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.

3. Payment Adjustment for Medicare Disproportionate Share Hospitals (DSHs) for FY 2024

In section IV. of the preamble of this 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.

4. Other Decisions and Proposed Changes to the IPPS for Operating Costs

In section V. of the preamble of this 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 requirements for payment adjustments to hospitals under the HAC Reduction Program for FY 2024.
- 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.

4. Proposed FY 2024 Policy Governing the IPPS for Capital-Related Costs

In section VI. of the preamble to this 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.

5. Proposed Changes to the Payment Rates for Certain Excluded Hospitals: Rate-of-Increase Percentages

In section VII. of the preamble of this 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.

6. Proposed Changes to the LTCH PPS

In section VIII. of the preamble of this 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.

7. Proposed Changes Relating to Quality Data Reporting for Specific Providers and Suppliers

In section IX. of the preamble of this proposed rule, we address the following:

- Proposal to adopt a modified version of the COVID–19 Vaccination 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 quality reporting program for PPS exempt cancer hospitals (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.

8. Other Proposals and Comment Solicitations Included in the Proposed Rule

Section X. of the preamble to this proposed rule includes 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.

9. Other Provisions of the Proposed Rule

Section XI.A. of the preamble of this proposed rule includes our discussion of the MedPAC Recommendations.

Section XI.B. of the preamble to this proposed rule includes a descriptive listing of the public use files associated with this proposed rule.

Section XII. of the preamble to this proposed rule includes the collection of information requirements for entities based on our proposals.

Section XIII. of the preamble to this proposed rule includes information regarding our responses to public comments.

10. Determining Prospective Payment Operating and Capital Rates and Rate-of-Increase Limits for Acute Care Hospitals

In sections II. and III. of the Addendum to this 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 are proposing to establish the threshold amounts for outlier cases. In addition, in section IV. of the Addendum to this 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.

11. Determining Prospective Payment Rates for LTCHs

In section V. of the Addendum to this 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.

12. Impact Analysis

In Appendix A of this 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.

13. Recommendation of Update Factors for Operating Cost Rates of Payment for Hospital Inpatient Services

In Appendix B of this 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.

14. 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 this 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*.

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.

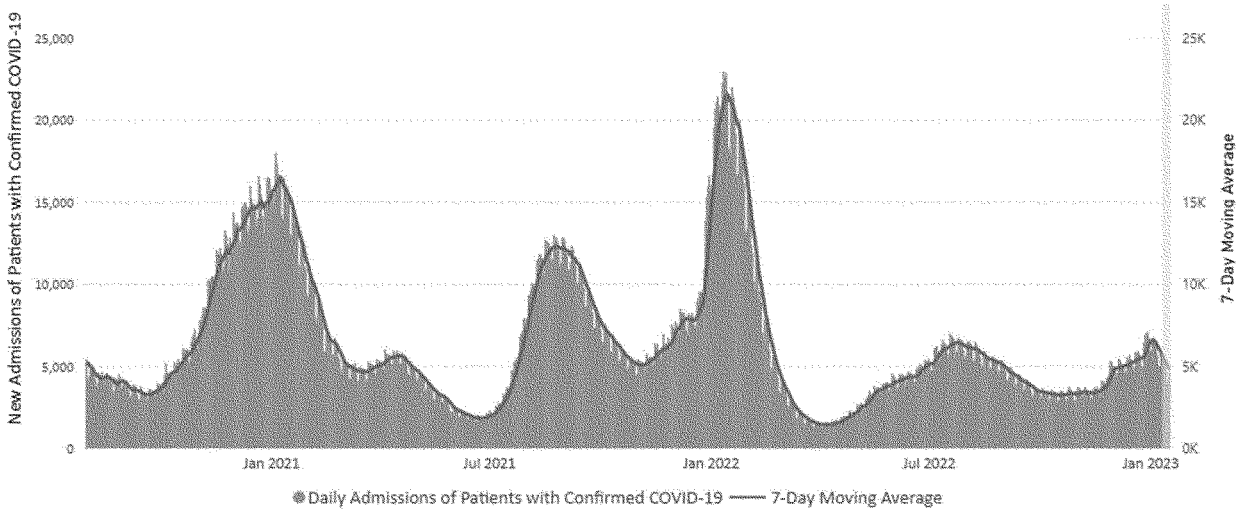
In the FY 2023 IPPS/LTCH PPS final rule (87 FR 48795 through 48798), we discussed that the FY 2021 MedPAR claims file and the FY 2020 HCRIS dataset (the most recently available data at the time of rulemaking) both contain data that was significantly impacted by the COVID–19 PHE, primarily in that the 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.

For this FY 2024 IPPS/LTCH PPS rulemaking, we have 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.

We have continued to monitor the latest COVID–19 related data and information released by the CDC. The CDC graph below 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)



As seen in the graph, in the United States, patients continue to be hospitalized with the virus that causes COVID–19. 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] Based on the information available at this 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. However, based on the information available at this 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, such that modifications to our usual ratesetting methodologies would be warranted.

As such, we believe 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 are proposing 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 are not proposing any modifications to our usual ratesetting methodologies to account for the impact of COVID–19 on the ratesetting data.

II. Proposed 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

[2] *https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html*, accessed January 20, 2023.

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 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).

C. Proposed Changes to Specific MS–DRG Classifications

1. Discussion of Changes to Coding System and Basis for Proposed 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 Proposed 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 this FY 2024 IPPS/LTCH PPS proposed rule we are providing 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 this proposed rule. We note that this test software reflects the proposed GROUPER logic for FY 2024. Therefore, it includes 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 this 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 this proposed rule. We note that at the time of the development of this proposed rule there were no procedure codes designated as invalid for FY 2024, and therefore, there is no Table 6D—Invalid Procedure Codes—FY 2024 associated with this proposed rule. These tables are not published in the Addendum to this 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 this proposed rule. Because the diagnosis codes no longer valid for FY 2024 are not reflected in the test software, we are making 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 will have access to the

test software allowing them to build case examples that reflect the proposals included in this proposed rule. In addition, users will be 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 are proposing to the MS–DRGs for FY 2024. We are inviting 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 this proposed rule. In some cases, we are proposing changes to the MS–DRG classifications based on our analysis of claims data and clinical appropriateness. In other cases, we are proposing to maintain the existing MS–DRG classifications based on our analysis of claims data and clinical appropriateness. For this 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 refer to these 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 refer to these claims data as the ''December 2022 update of the FY 2022 MedPAR file.'' Specifically, as discussed further 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.

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—Proposed 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.

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Criteria Number and Description	Three-Way Split 123 (MCC vs CC vs NonCC)	Two-Way Split 1_23 MCC vs (CC+NonCC)	Two-Way Split 12_3 (MCC+CC) vs 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 this 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 this 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 this 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. 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 refer 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 this 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 note that we also identified an additional 12 obstetric MS–DRGs (4 base MS–DRGs x 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 this 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 believe 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

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We also refer 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 note, 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 refer 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 this 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 note 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) do not reflect application of the 10-percent cap. We further note that changes in the status for transfer adjusted cases are reflected for the relative weights calculated using the proposed V41 GROUPER Software only and are not reflected for the alternate MS–DRG weights with application of the NonCC subgroup criteria. We note, 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). The findings are 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 are making 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 include 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 this proposed rule on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*.

For this FY 2024 IPPS/LTCH PPS proposed rule we are also providing 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 this proposed rule if the NonCC subgroup criteria were to be applied to existing MS–DRGs with a three-way severity level split. We note that this alternate test software reflects the proposed GROUPER logic for FY 2024 as modified by the application of the NonCC subgroup criteria. Therefore, it includes 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 this 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 this proposed rule. As previously noted, at the time of the development of this proposed rule there were no procedure codes designated as invalid for FY 2024, and therefore, there is no Table 6D– Invalid Procedure Codes—FY 2024 associated with this proposed rule. These tables are not published in the Addendum to this 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 this proposed rule. Because the diagnosis codes no longer valid for FY 2024 are not reflected in the alternate test software, we are making 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 will have access to the alternate test software allowing them to build case examples that reflect the proposals included in this 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 this 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 are making 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 are proposing 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 are 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.

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. 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 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 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.

For this FY 2024 IPPS/LTCH PPS proposed rule, 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. 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.

To begin our analysis, we identified the ICD–10–CM diagnosis codes that describe a diagnosis of epilepsy. We refer the reader to Table 6P.2a associated with this 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 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:

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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 note 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 have 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. While these neurostimulator cases have average costs that are $11,355 higher than the average costs of all cases in MS–DRG 023, there were only a total of 57 cases. We reviewed these data, and agreed with the requestor that the number of cases continues 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).

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, 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, 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

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 complication or comorbidity (CC) or a major complication or comorbidity (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 reviewed the clinical issues and the claims data, and continue 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. 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 continue 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). The differences in average length of stay and average costs based on the more recent data continue to support this recommendation.

We note, as discussed in section II.C.1.b of this 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 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 refer the reader to Table 6P.10b associated with this 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 then explored alternative options, as was requested. We do 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 is 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 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

We note 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 note 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. While these neurostimulator cases have average costs that are higher than the average costs of all cases in their respective MS–DRGs, it is difficult to detect patterns of complexity and resource intensity. Moreover, we are 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 note while our data findings demonstrate 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. While we appreciate the requestors' 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. 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, 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 this 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, 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 are not proposing 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 are also not proposing to create a new MS–DRG for cases involving a craniectomy/craniotomy with device implant at this time.

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 this proposed rule, at: *https://mearis.cms.gov/public/home*.

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.

For this FY 2024 IPPS/LTCH PPS proposed rule, 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. The requestor 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; and
- Suggested New MS–DRG XXX—Neurological Eye Disorders with Thrombolytic Agent without CC/MCC.

In reviewing this issue, it is 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.

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

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

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–DRGs 123.

To begin our analysis, 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.

The data analysis shows 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 reviewed these data, and do 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 warrants 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 are not proposing 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 recognize 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. 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 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 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.

Our analysis demonstrates 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 for the cases currently grouping to MS–DRG 124. We reviewed these data and support the addition of the eight 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 believe reassigning these diagnosis codes to MS–DRGs 124 and 125 will better account for the subset of patients who are treated with a thrombolytic agent, and will more appropriately reflect the resources involved in evaluating and treating these patients. We also support 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 are proposing 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 are also proposing to add the procedure codes describing the administration of a thrombolytic agent listed previously to MS–DRG 124. We note 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 are also proposing to designate these codes as non-O.R. procedures affecting the MS–DRG. Lastly, for consistency, we are also proposing 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.

4. MDC 04 (Diseases and Disorders of the Respiratory System)

a. Ultrasound Accelerated Thrombolysis for Pulmonary Embolism

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.

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 note 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 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 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 58579), available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*, for the detailed discussion.

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 note 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 note 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 4 (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 demonstrates 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 demonstrates 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 demonstrates 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.

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.

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).

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 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 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 previously, 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 t identifying USAT was performed, or a combination of both factors. Based on these findings related to the administration of thrombolytic(s), 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, 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]

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 note 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.

[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.

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).

In summary, 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.

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 this proposed 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 note 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 discussed in section II.C.1.b. of the preamble of this proposed 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 note 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 note 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 are proposing 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

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We believe 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 are proposing 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 this section of this proposed rule.

b. Respiratory Infections and Inflammations Logic

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.

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 are proposing 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.

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, 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.

For this FY 2024 IPPS/LTCH PPS proposed rule, 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. 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 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 refer readers to Tables 6P.3a and 6P.3b associated with this 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 this 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 this 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 this 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.

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. 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 note 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 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 catherization procedure reported to MS–DRGs that are defined by the performance of that procedure. We also note, as discussed in section II.C.1.b of this 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 note that the total number of cases in MS–DRG 218 is again below 500. We refer the reader to Table 6P.10b associated with this 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.

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 this 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.

The data analysis 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.

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, not solely the performance of open surgical ablation as suggested by the requestor, when compared to other cases in their respective MS–DRGs. We reviewed these data and note, 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. The data analysis clearly shows 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 are proposing 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.

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 believe the resulting proposed MS–DRG assignment is more clinically homogeneous, coherent and better reflects hospital resource use.

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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 this 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 are not proposing 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 are proposing 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 refer the reader to Table 6P.4a associated with this 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 are proposing to define in the logic for the proposed new MS–DRG. We note that discussion of the surgical hierarchy for the proposed modifications is discussed in section II.C.15. of this proposed rule.

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.

For this FY 2024 IPPS/LTCH PPS proposed rule, 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).

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. 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.

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, we note that we agree 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.

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, 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 note 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 note that the GROUPER logic for MS–DRG 003 is defined by a (1) 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 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.

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 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

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 suggest 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.

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. There is now a portfolio of short-term external heart assist devices available that each have different indications for use and techniques for implantation.

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 note 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 believe 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.

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
	All Cases	3,587	9	$86,774
215	without 02HA0RZ	3,534	9	$83,613
	All Cases	1,553	40.4	$235,135
001	with 02HA0RZ	1,606	39.4	$231,677
	All Cases	28	18.3	$108,476
002	with 02HA0RZ	35	15.3	$112,533

We believe 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 are proposing 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. Under this proposal, 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.

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. 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 this 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.

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.14. of the preamble of this proposed 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 are proposing 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. 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 the FY 2024 IPPS/LTCH PPS final rule that will be made publicly available in association with the final rule on the CMS website at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*.

c. Ultrasound Accelerated Thrombolysis for Deep Venous Thrombosis

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 this proposed 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.

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 note 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 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 58579), available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS*, for the detailed discussion.

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 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 this 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 demonstrates 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 demonstrates 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 demonstrates 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.

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).

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.

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 previously noted, 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, while the average costs are higher for cases reporting the administration of a thrombolytic, we question 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 this proposed 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, 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 this proposed rule and available on

[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.

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).

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. 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.

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.

In summary, 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 believe 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 believe a new MS–DRG would reflect more appropriate payment for USAT and standard CDT procedures of peripheral vascular structures.

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 this proposed 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 note 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 this proposed 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 note 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 believe a split (or CC subgroup) is warranted for the proposed new base MS–DRG. As a result, for FY 2024, we are proposing 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 are proposing 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 this proposed rule.

d. Coronary Intravascular Lithotripsy

We received a request 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

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 this proposed rule for a discussion regarding the proposed FY 2024 status of technologies approved for FY 2023 new technology add-on payments, including the Shockwave C2 Intravascular Lithotripsy System.

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. The requestor is also 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 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 246, 247, 248, and 249.

In analyzing this request, we noted 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 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). 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.

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.

We reviewed this data analysis and agree that the performance of percutaneous coronary IVL contributes to increased resource consumption for these PCI procedures. We also agree 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 are proposing 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 believe creating a separate MS–DRG for these cases as well would appropriately address the differential in resource consumption. Therefore, we are also proposing 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 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 applied the criteria to create subgroups in a base MS–DRG as discussed in section II.C.1.b. of this FY 2024 IPPS/LTCH PPS proposed 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

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 are not proposing 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 are proposing 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 are also proposing 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 this 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 are proposing to define in the logic for each of the proposed new MS–DRGs. We note that discussion of the surgical hierarchy for the proposed modifications is discussed in section II.C.15. of this proposed rule.

In reviewing this issue, we noted 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 code 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 earlier in this section of this proposed 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 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.

We again note 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 reviewed these findings and believe 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. The related data analysis clearly shows 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 are proposing the deletion of MS–DRGs 246, 247, 248, and 249, and the creation of new MS–DRGs.

We note 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

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). 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 is warranted.

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 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 this 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 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.

The proposed refinements for cases reporting percutaneous cardiovascular procedures with intraluminal devices represents 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 are making concerted efforts to continue refining the ICD–10 MS–DRGs and we believe 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 are proposing 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 are proposing to add the procedure codes from current MS–DRGs 246, 247, 248, and 249 to the proposed new MS–DRGs 321 and 322. We are also proposing 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 note that discussion of the surgical hierarchy for the proposed modifications is discussed in section II.C.15. of this proposed rule.

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 comment, 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, for this FY 2024 IPPS/LTCH PPS proposed rule, we received a related request 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.

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 reviewed the GROUPER logic. We note 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. The requestor is 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.

The requestor is 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 disagree, however, that this code can never be an appropriate principal diagnosis. We note 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 point 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/*.

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 reviewed these data and do 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 believe 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, it is 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 are not proposing 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.

During our review of this issue we noted that the data analysis shows 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.

The analysis of MS–DRGs 222, 223, 224, 225, 226, and 227 further demonstrates 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 believe that it may no longer be necessary to subdivide these MS–DRGs based on the diagnosis codes reported. We note 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.

Our analysis of claims data from the September 2022 update of the FY 2022 MedPAR 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 believe it is time to restructure these MS–DRGs accordingly.

We do 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 support 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 are proposing the deletion of MS–DRGs 222, 223, 224, 225, 226, and 227, and the creation of three new MS–DRGs. Our proposal includes 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.

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 propose 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 this FY 2024 IPPS/LTCH PPS proposed rule. We believe 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 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 this 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 are proposing 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 are also proposing 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).

We note 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 are also proposing to designate these codes as non-O.R. procedures affecting the MS–DRG. We refer the reader to Table 6P.7a and Table 6P.7b associated with this 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 are proposing to define in the logic for each of the proposed new MS–DRGs. We note that discussion of the surgical hierarchy for the proposed modifications is discussed in section II.C.15. of this proposed rule.

6. MDC 06 (Diseases and Disorders of the Digestive System): Appendicitis

In the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28163 through 28165) and final rule (87 FR 48849 through 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.

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.12. of the preamble of this 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 October 1, 2023. Included in this table are diagnosis codes K35.20 and K35.21. In addition, as shown in the following table and in Table 6A—New Diagnosis Codes associated with this proposed rule (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. 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, 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

As the acute appendicitis diagnosis code revisions have been finalized by the CDC/NCHS, we believe 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 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 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.

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 appear 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.

Based on our analysis for both the ''complicated'' and ''uncomplicated'' diagnoses combined with our review of all the cases in the MS–DRGs, we believe 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, 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 believe the findings support eliminating the logic for ''complicated'' and ''uncomplicated'' diagnoses and restructuring the six MS–DRGs. We also note 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 this 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 note 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 in the without CC/MCC subgroup; (2) at least 5 percent of the cases are in the MCC subgroup, the CC subgroup, and in 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 with 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 are proposing to delete MS–DRGs 338, 339, 340, 341, 342, and 343 and proposing to create new MS–DRGs 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 are also proposing to include the current list of appendectomy procedures in the logic for case assignment of appendix procedures for the proposed new MS–DRGs.

7. MDC 07 (Diseases and Disorders of the Hepatobiliary System and Pancreas): Alcoholic Hepatitis

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.

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 two 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

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 note 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.

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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
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
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

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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.

The data show that the 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 note 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 note 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.

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).

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 believe that these diagnoses are clinically coherent with the other diagnoses currently assigned to MS–DRGs 432, 433, and 434. 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 note 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 are proposing to maintain the structure of MS–DRGs 432, 433, and 434 for FY 2024.

We note, as discussed in section II.C.1.b. of this 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 indicate that MS–DRGs 432, 433, and 434, 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 this 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.

8. MDC 08 (Diseases and Disorders of the Musculoskeletal System and Connective Tissue): Spinal Fusion

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 note 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 note 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).

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.

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 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 previously discussed, the requestor expressed concerns that there may be unintentional miscoded claims from providers with whom they do not have an explicit relationship. We note 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.

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 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.

We note 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, 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.

Based on our review of this issue and our analysis of the claims data, we agree 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 believe further review is warranted. In addition, as previously discussed, 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. We also believe 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.

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. Because the procedure codes that we analyzed and presented findings for in this 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. However, we will continue to collaborate with the American Hospital Association (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 believe 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 are proposing to maintain the current structure of MS–DRGs 453, 454, 455, 456, 457, 458, 459, and 460 for FY 2024.

9. MDC 11 (Diseases and Disorders of the Kidney and Urinary Tract): Complications of Arteriovenous Fistulas and Shunts

We received a request 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

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.

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.

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 three 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, 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**

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. 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 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 ten 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 do 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). We note 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 believe 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 believe 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 are not proposing 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.

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 are proposing 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

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. 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

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 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 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 believe 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, 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 are proposing 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.

b. Open Excision of Muscle

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.

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 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 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

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 believe 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, 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 is clinically appropriate for the procedures to group to the same MS–DRGs as the principal diagnoses. Therefore, we are proposing 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.

c. Open Replacement of Skull With Synthetic Substitute

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

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 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 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.

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 believe that it is 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 are proposing 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.

d. Endoscopic Dilation of Ureters With Intraluminal Device

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

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 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 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

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 believe 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. 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), it is clinically appropriate for the procedures to group to the same MS–DRGs as the principal diagnoses.

Therefore, we are proposing 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.

e. Occlusion of Splenic Artery

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

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 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 this 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 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 this 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 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

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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. We also note 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. 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 it is 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 believe 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), 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 are proposing 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.

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 are also proposing 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.

In addition to the internal review of procedures producing assignment to MS–DRGs 981 through 983 or MS–DRGs 987 through 989, 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 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. 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 did not receive any requests suggesting reassignment. Therefore, for FY 2024 we are not proposing to 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 proposed 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 (84 FR 19158), 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.

For this 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 will provide more detail on this analysis and the methodology for conducting this review in future rulemaking.

We received the following requests regarding changing the designation of specific ICD–10–PCS procedure codes from non-O.R. to O.R. procedures. We summarize these requests in this section of this rule and address why we are not considering a change to the designation of these codes at this time.

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.

For this 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. 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 are not proposing 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 invite 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 this 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.

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.

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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

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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.

For this 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, we note 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 refer the reader to Table 6P.8a associated with this 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 note 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 this 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. 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 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 the listed MS–DRGs.

We reviewed these data and 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. 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 note 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 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 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 are not proposing 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.

12. Proposed 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/MedicareFee-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 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

[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.*

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 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 proposed rule for our proposed changes to the severity level designation for certain diagnosis codes that describe homelessness for FY 2024.

In this 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.

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 note 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 proposed rule for the discussion of the proposed changes to the ICD–10–CM and ICD–10–PCS coding systems for FY 2024.

c. Proposed 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

[8] *Available at: https://health.gov/healthypeople/objectives-and-data/social-determinants-health.*

available field on the claim when other diagnoses are reported instead.

For this 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	Description	Tota1 Count	Cnt1	C1	Cnt2	C2	Cnt3	C3
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

The table shows that the C1 finding 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. 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, the data again suggests 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, we note 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 homelessness and consideration of the nine guiding principles, we are proposing to change the severity level designation for diagnosis codes Z59.00

[9] ''Sheltered homelessness'' refers to people experiencing homelessness who were found in emergency shelters, safe havens, transitional housing, or other temporary settings. 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 (AHRQ), Karaca Z (AHRQ), Wong HS (AHRQ). Characteristics of Homeless Individuals Using Emergency Department Services in 2014. 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, 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. 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 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*.

Additionally, for this 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.

We note 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 do not yet reflect these new diagnosis codes. The proposed and finalized severity level designations for 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 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. 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 coded with 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 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 believe 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 believe it is 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.

d. Proposed Additions and Deletions to the Diagnosis Code Severity Levels for FY 2024

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

e. Proposed 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.

We are proposing 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 this FY 2024 IPPS/LTCH PPS proposed rule. Therefore, we have developed Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2024; Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2024; Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2024; and Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2024. For Table 6G.1, each secondary diagnosis code proposed for addition to the CC Exclusion List is shown with an asterisk and the principal diagnoses proposed 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 proposed 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 proposed 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 proposed 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 proposed rule are available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

We also note that in our review of the CC Exclusion List, 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 believe it is 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 this proposed rule, we are providing 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 this proposed rule is available on the CMS website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html*.

13. Proposed 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, and Table 6E.—Revised Diagnosis Code Titles for this proposed rule.

These tables are not published in the Addendum to this 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 this proposed rule. As discussed in section II.C.16. of the preamble of this proposed rule, the code titles are adopted as part of the ICD–10 (previously ICD–9–CM) 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.

We are proposing 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. In addition, 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 review 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 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 note 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.

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 proposed rule:

- Table 6A.—New Diagnosis Codes—FY 2024;
- Table 6B.—New Procedure Codes—FY 2024;
- Table 6C.—Invalid Diagnosis Codes—FY 2024;
- Table 6E.—Revised Diagnosis Code Titles—FY 2024;
- Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2024;
- Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2024;
- Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2024;
- Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2024;
- 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.

14. Proposed 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*.

For this FY 2024 IPPS/LTCH PPS proposed rule, we received one MCE request related to the Sex Conflict edit by the October 20, 2022 deadline, as discussed further in this section of the preamble of this proposed rule. Additionally, we discuss the proposals we are making based on our internal review and analysis.

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.12. of the preamble of this 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 are proposing to add the ICD–10–CM diagnosis codes shown in Table 6P.9a associated with this 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.

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).

(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.12. of the preamble of this 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 are proposing 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.

In addition, as discussed in section II.C.12. of the preamble of this proposed 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 are proposing to delete this code from the Perinatal/Newborn diagnoses edit code list.

(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.12. of the preamble of this 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 are proposing to add new ICD–10–CM diagnosis codes to the edit code list for the Maternity diagnoses category under the Age conflict edit.

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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

In addition, as discussed in section II.C.12. of the preamble of this proposed 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 are proposing to delete this code from the Maternity diagnoses edit code list.

(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.12. of the preamble of this 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 are proposing 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

c. Sex Conflict Edit

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.[16] We note that the requester 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 requester'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 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,[17] 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.

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.12. of the preamble of this proposed 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 are proposing 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

In addition, as discussed in section II.C.12. of the preamble of this proposed 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 are proposing to delete this code from the Manifestation code as principal diagnosis edit code list.

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 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.12. of the preamble of this proposed 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 are proposing to add the following new ICD–10–CM diagnosis codes to the Unacceptable Principal Diagnosis edit code list.

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[16] 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.

[17] *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.*

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

In addition, as discussed in section II.C.12. of the preamble of this proposed 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 are proposing 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

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.12. of the preamble of this proposed 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 are proposing 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

In addition, 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 are proposing 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

g. Future Enhancement

As we continue to evaluate the purpose and function of the MCE with respect to ICD–10, we encourage public input for future discussion. As we have discussed in prior rulemaking, we recognize a need to further examine the current list of edits and the definitions of those edits.

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 this proposed rule at: *https://mearis.cms.gov/public/home*, by October 20, 2023.

15. Proposed 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 proposed 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 are proposing to make for FY 2024, as discussed in section II.C. of the preamble of this proposed rule, we are proposing to modify the existing surgical hierarchy for FY 2024 as follows.

We are proposing 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 are proposing 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 this proposed rule, we are

proposing 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 are proposing 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 this proposed rule, we are proposing 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 are proposing to make for those MS–DRGs in MDC 05, we are proposing 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 are proposing 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 are proposing 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 this proposed rule, we are proposing 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 are also proposing 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 are proposing 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 are proposing to make for those MS–DRGs in MDC 05, we are proposing 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 are proposing 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 are proposing 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 are proposing to make as discussed in section II.C.8.a. of the preamble of this proposed rule, we are also proposing 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 this proposed rule, we are proposing 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 are proposing to make for those MS–DRGs in MDC 06 (Diseases and Disorders of the Digestive System), we are proposing to revise the surgical hierarchy for MDC 06 as follows: In MDC 06, we are proposing 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 this proposed rule, we are proposing 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.

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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
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

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: *http://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: *http://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 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.

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 proposed 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, and Table 6E.—Revised Diagnosis Code Titles for this proposed 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 rule, they are not subject to comment in the proposed rule. Because of the length of these tables, they are not published in the Addendum to the proposed rule. Rather, they are available via the internet as discussed in section VI. of the Addendum to the proposed 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*.

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) is implementing 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.

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 (which is 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 this proposed rule, we are soliciting 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.

In addition, 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 01, 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		
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

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The 34 procedure codes are also reflected in Table 6B—New Procedure Codes (which is 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 this proposed rule, we are soliciting 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 note 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 proposed 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.

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.

For FY 2023, there are currently 73,674 diagnosis codes and 78,530 procedure codes. As displayed in Table 6A.—New Diagnosis Codes and in Table 6B.—New Procedure Codes associated with this proposed rule (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 have been finalized for FY 2024 at the time of the development of this proposed rule. 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. We will continue to provide the October updates in this manner in the IPPS proposed and 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. Proposed Changes for FY 2024

As discussed in section II.C.5. of the preamble of this proposed rule, for FY 2024, we are proposing 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 is being proposed for assignment to proposed new MS–DRGs 275, 276, and 277. Therefore, we are proposing 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 are also proposing to continue to include the existing MS–DRGs currently subject to the policy as displayed in the following table.

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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
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	222	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock with MCC
05	223	Cardiac Defibrillator Implant with Cardiac Catheterization with AMI/Heart Failure/Shock without MCC
05	224	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock with MCC
05	225	Cardiac Defibrillator Implant with Cardiac Catheterization without AMI/Heart Failure/Shock without MCC
05	226	Cardiac Defibrillator Implant without Cardiac Catheterization with MCC

MDC	MS-DRG	MS-DRG Title
05	227	Cardiac Defibrillator Implant without Cardiac Catheterization without 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	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 included in the FY 2024 IPPS/LTCH PPS final rule and also will be issued to providers in the form of a Change Request (CR).

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 propose 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 proposed rule include discharges occurring on October 1, 2021, through September 30, 2022, based on bills received by CMS through December 31, 2022, 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 6,959,895 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 proposed 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 proposed 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 proposed 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 proposed rule, we used the December 2022 update of the FY 2021 HCRIS for calculating the FY 2024 cost-based relative weights. Consistent with our historical practice, for this FY 2024 proposed 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 proposed FY 2024 relative weights based on 19 CCRs. The methodology we are proposing 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 proposed FY 2024 MS–DRG classifications discussed in sections II.B. and II.C. of the preamble of this proposed 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 92.7 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 are also proposing 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 proposed 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 proposed19 national cost center CCRs. If we receive comments about the groupings in this supplemental data file, we may consider these comments as we finalize our policy.

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 this 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, we include statistics for the affected MS–DRGs both separately and with cases combined.

We are inviting public comments on our proposals related to recalibration of the proposed FY 2024 relative weights and the changes in relative weights from FY 2023.

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 would 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 [18] 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 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 would 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

[18] *https://www.cms.gov/files/document/r10571cp.pdf.*

guidance [19] 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.

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% of all cases that grouped to MS–DRG 018. In the FY 2022 MedPAR data used for this 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% 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 note 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, does not include the 10 cases in the FY 2022 MedPAR data 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 this FY 2024 IPPS/LTCH PPS proposed rule, we are proposing two changes to our methodology for identifying clinical trial claims and expanded access use claims in MS–DRG 018. First, we are proposing 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 are proposing 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 are proposing 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 ''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 are also proposing 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 this 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 non-clinical trial cases ($323,903). Accordingly, as we did for FY 2023, we are proposing 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 this 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 applying this same adjustor for the applicable cases that group to MS–DRG 018 for purposes of budget neutrality and outlier simulations. We are also proposing to update the value of the adjustor based on more recent data for the final rule.

d. 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

[19] *https://www.cms.gov/files/document/r11727cp.pdf.*

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 proposed rule, we present the proposed budget neutrality adjustment for reclassification and recalibration of the FY 2024 MS–DRG relative weights with application of this cap. We are also making available on the CMS website a supplemental file demonstrating the application of the permanent 10 percent cap for FY 2024. For a further discussion of the proposed budget neutrality adjustment for FY 2024, we refer readers to the Addendum of this proposed rule.

3. Development of Proposed National Average CCRs

We developed the proposed 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 proposed relative weight. 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 proposed FY 2024 relative weight equal to 90 percent of the FY 2023 relative weight. The proposed relative weights for FY 2024 as set forth in Table 5 associated with this proposed 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 proposed 19 national average CCRs for FY 2024 are as follows:

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Group	CCR
Routine Days	0.415
Intensive Days	0.352
Drugs	0.184
Supplies & Equipment	0.305
Implantable Devices	0.278
Inhalation Therapy	0.155
Therapy Services	0.272
Anesthesia	0.075
Labor & Delivery	0.42
Operating Room	0.162
Cardiology	0.087
Cardiac Catheterization	0.103
Laboratory	0.104
Radiology	0.129
MRIs	0.068
CT Scans	0.034
Emergency Room	0.153
Blood and Blood Products	0.251
Other Services	0.344

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 are proposing 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 are proposing 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)

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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% of the standardized amount (increased to reflect the difference between cost and charges) or 75% 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 are 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 note that, for the reasons discussed in section I.F. of the preamble of this proposed rule, we are proposing to use the FY 2022 MedPAR claims data for FY 2024 ratesetting. Consistent with this proposal, for the FY 2025 proposed threshold values, we are proposing to use the FY 2022 claims data to set the proposed thresholds for applications for new technology add-on payments for FY 2025.

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% of the costs of the new medical service or technology; or (2) 50% 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% of the costs of the new medical service or technology; or (2) 65% 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% of the costs of the new medical service or technology; or (2) 75% 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% of the costs of the new medical service or technology; or (2) 75% 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% (or 75% 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 approved or conditionally approved technologies 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.8. of the preamble of this proposed rule, beginning with the new technology add-on payment applications for FY 2025, we are proposing, 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 are also proposing 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.8. of the preamble of this proposed rule for a full discussion of these proposals.

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 received 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 this 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 are not summarizing any written comments in this proposed rule that are unrelated to the substantial clinical improvement criterion. In section II.E.6. of the preamble of this proposed rule, we are summarizing 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% of the operating outlier threshold for the claim or (2) 65% 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). If the PHE ends in May of 2023, as planned by the Department of Health and Human Services (HHS),[20] [21] discharges involving eligible products would 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 would 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*.

5. Proposed FY 2024 Status of Technologies Receiving New Technology Add-On Payments for FY 2023

In this section of the proposed rule, we discuss the proposed FY 2024 status of 24 technologies approved for FY 2023 new technology add-on payments, as set forth in the tables that follow. Specifically, we present our proposals to continue the new technology add-on payment 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 present 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 note 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, subject to the technology receiving FDA marketing authorization by July 1, 2023. As of the time of the development of this proposed rule, DefenCath™ has not yet received FDA approval. 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

[20] *https://www.hhs.gov/about/news/2023/02/09/letter-us-governors-hhs-secretary-xavier-becerra-renewing-covid-19-public-health-emergency.html.*

[21] *https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html.*

discharges beginning in the first quarter after FDA marketing authorization is granted. If 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. If DefenCath™ receives FDA marketing authorization prior to July 1, 2023, we are proposing to continue making new technology add-on payments for DefenCath™ for FY 2024. 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. 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, in the event that FDA market authorization is not received by July 1, 2023. We refer the reader to section II.E.7.b.(1). of the preamble of this proposed rule for discussion of the FY 2024 application 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).

Table II.P.–01 lists the technologies for which we are proposing 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 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, proposed maximum add-on payment amount, and coding assignments for each technology. We refer 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 are inviting public comments on our proposals to continue new technology add-on payments for FY 2024 for the technologies listed in the following table.

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TABLE II.P.-01: PROPOSED 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	Proposed Maximum NTAP Amount for FY 2023	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 proposing to discontinue new technology add-on payments for COVID-19 Hemolung RAS cases.

Table II.P.–02 lists the technologies for which we are proposing 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 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 refer 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.

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.

For this FY 2024 IPPS/LTCH PPS proposed rule, 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 are 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. As discussed in the FY 2023 IPPS/LTCH PPS final rule, we continue 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 note, as set forth in Table II.P.–01 of this section, that we are 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 consider 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 are proposing 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 are inviting public comments on our proposals to discontinue new technology add-on payments for FY 2024 for the technologies listed in the Table II.P.–02.

TABLE II.P.-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 are continuing to summarize each application in this proposed rule. However, 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 note that we are making 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 this 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 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 FY 2024 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 this proposed rule. We are addressing the remaining 19 applications.

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.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify CYTALUX®. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for CYTALUX® beginning in FY 2024. 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 believes 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/biologicals 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/biologicals 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/biologicals 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 are inviting public comments on whether CYTALUX® is substantially similar to existing technologies and whether CYTALUX® meets the newness criterion.

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% of cases map to these MS–DRGs. Please see Table 10.8.A.—CYTALUX® (ovarian) Codes—FY 2024 associated with this 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 this 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 this 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 this 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 are inviting public comments on whether 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 eleven 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.[22] 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.

[22] 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® SCI 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® SCI 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® SCI supportive ovarian cancer data: Targeted fluorescent imaging agents have potential to enable surgeons to identify malignant lesions intraoperatively	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.	
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.

After review of the information provided by the applicant, we have the following concerns regarding whether CYTALUX® meets the substantial clinical improvement criterion. We note that CYTALUX® showed a false

positive rate of 24.8% that led to resections in the Phase 3, randomized, multicenter, single dose, open-label study of this technology.[23] While the applicant submitted a separate comment stating there was no worsening in the safety profile for patients with false positive results, we continue 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, 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 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 are inviting public comments on whether CYTALUX® meets the substantial clinical improvement criterion.

In this section, we summarize and respond to written public comments received in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for CYTALUX®.

Comment: In response to a question regarding the impact of taking additional tissues that were false positive on patient outcomes, the applicant provided evidence based on results for the 27 patients in the full analysis set (FAS) from the central laboratory, for whom all NIR fluorescent lesions were false positive. The significant adverse event (SAE) rate (two of the 27 patients [7.4%]) and the severe AE rate (four of the 27 patients [14.8%]) demonstrated that there was no worsening in the safety profile for this false positive group, in comparison to the overall rates for this study (see the following table).

Additional Analysis - Serious Adverse Event and Severe Adverse Event Rates by Subgroup

N (%)	Safety Analysis Set (N=150)	Primary Endpoint Subset (N=36)	True Positive and False Positive Subset (N=57)	Secondary Endpoint FPRα (N=27)	Ovarian Cancer Surgery
SAEs	22/150 (14.7%)	4/36 (11.1%)	6/57 (10.5%)	2/27 (7.4%)	Intra-operative [a]: 8.5% - 18.9% Post-operative 10.9% - 38.7%
Severe AEs	29/150 (19.3%)	6/36 (16.7%)	9/57 (15.8%)	4/27 (14.8%)	22.3% [b]

Abbreviations: AE=adverse event; FPRp=False Positive Rate at the patient level; SAE=serious adverse event.
a The range was for standard to extended surgeries.
b Given for primary debulking.

Response: We thank the applicant for its comments and will take this information into consideration when deciding whether to approve new technology add-on payments for CYTALUX®.

Comment: In response to a question regarding how many patients in the study had a complete resection without CYTALUX®, the applicant stated that if subjects did not receive CYTALUX®, they were not in the clinical study, and no data was collected for these subjects. The applicant asserted that in a post-procedural questionnaire in the CYTALUX® Phase 3 study for ovarian cancer, investigators self-reported achieving complete R0 (no gross residual disease) resection in 62.4% (68 of 109) of patients. The applicant added that the post-procedural questionnaire was only completed for those procedures in which the patient was randomized to receive NIR imaging with CYTALUX®. The applicant presented that, in the literature, data for achieving R0 (no visible disease after surgery) is subjective given that surgeons self-report results. The literature suggests achievement of R1 (<1cm residual disease) is between 17–65%. The high recurrence rate of 70% of women diagnosed with ovarian cancer suggests the percentage of ovarian cancer surgeries where R0 is achieved is likely over-estimated. The applicant stated that in the Phase 3 study conducted for ovarian cancer, 36/109 (33%) of subjects with folate receptor positive ovarian cancer had one or more cancerous lesions found with CYTALUX® that were not identified by standard white light and palpation on tissue that was not planned for resection; therefore, this data indicates R0 would not have been achieved in any of these patients without the use of CYTALUX®.

Response: We thank the applicant for its comments. We would appreciate if the applicant could provide references for the cited literature regarding the achievement of R1 (<1cm residual disease) in the comment. We will take this information into consideration when deciding whether to approve new technology add-on payments for CYTALUX®.

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.

[23] 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.

CYTALUX® is to be used with a near-infrared imaging system (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® has 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 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 note that, as discussed previously, the applicant stated that CYTALUX® for ovarian cancer became commercially available on April 15, 2022. We are 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.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify CYTALUX®. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for CYTALUX® beginning in FY 2024. 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 believes 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.

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/biologicals 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/biologicals 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/biologicals 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 are inviting public comments on whether CYTALUX® is substantially similar to existing technologies and whether CYTALUX® meets the newness criterion.

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 (SAF) 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% of cases map to these MS–DRGs. Please see Table 10.9.A.—CYTALUX® (lung) Codes—FY 2024 associated with this 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 this 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 this 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 this 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 are inviting public comments on whether 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.[24] 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.

[24] 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® SCI 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 patients with the use of CYTALUX®.	Manuscript in preparation on the ELUCIDATE trial. Brief study description: 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.	One or more clinically significant events (CSE) occurred in 53% of evaluated participants compared to a prespecified 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® SCI 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	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	IMI with pafolacianine identified occult synchronous malignant lesions in nine patients (9%, 95% CI 4.2 – 16.4). Most (73%) IMI-identified synchronous

identified with conventional methods.	ELUCIDATE Trial. AATS 102nd Annual Meeting. Boston MA. May 2022. See prior study description	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.	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.

	See prior study description	
	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.

After review of the information provided by the applicant, we have the following concerns regarding whether CYTALUX® meets the substantial clinical improvement criterion. We note that CYTALUX® showed false positive rate of 25.8% that led to resections in the Phase 3, multicenter study of this technology.[25] While the applicant submitted a separate comment stating there was no worsening in the safety profile for patients with false positive results, we continue to question the impact on patient outcomes when taking additional tissues that were false positive. We note that the authors discussed in the results of the phase 3 trial that there was a decreased rate of subsequent diagnostic intervention. We question if they are referring to fewer resections in future surgical procedure, and/or if this also implies 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, 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, improved outcomes were inferred by relying on the assumption that increased or decreased scope of resection results in better outcomes. We are 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 are inviting public comments on whether CYTALUX® meets the substantial clinical improvement criterion.

In this section, we summarize and respond to written public comments received in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for CYTALUX®.

Comment: In response to a question regarding the impact of taking additional tissues that were false positive on patient outcomes, the applicant stated that in the CYTALUX® Phase 3 ELUCIDATE lung cancer trial, participants who had false positive synchronous lesions removed showed no associated increase in respiratory or pulmonary adverse events based on the tissue removed. A total of 134 specimens were excised from the 100 intraoperative molecular imaging (IMI) participants, with each participant contributing one or more specimens. All were sent for local histopathology, with 104 specimens found to be positive for cancer in 89 participants. Among all 134 specimens from participants with suspected or confirmed cancer, 108 (81%) had fluoresced under IMI in 78 participants. The estimated sensitivity for detecting a cancerous tissue was 80/104 or 76.9% (model estimate 76.5% (95% CI [66.7, 84.2])). There were 28/108 (25.9%) false positives (10 primary nodules, 18 synchronous lesions). Histology on the false positive tissues was mostly benign or normal lung parenchyma. Where pathology was identified, it was most often granulomatous disease, with one fibrous tumor, one meningothelial-like nodule, one anthracotic nodule and one lipoid pneumonia.

Response: We thank the applicant for its comments and will take this information into consideration when deciding whether to approve new technology add-on payments for CYTALUX®.

c. DuraGraft®

Marizyme, Inc. submitted an application for new technology add-on payment for DuraGraft® for FY 2024. According to the applicant, DuraGraft® is an intraoperative vein-graft preservation solution used during the harvesting and grafting interval during coronary artery bypass graft surgery (CABG). The applicant stated that use of DuraGraft® does not change clinical/surgical practice; it replaces solutions currently used for flushing and storage of the saphenous vein grafts (SVG) from harvesting through grafting, including tests for graft leakage. We note that Somahlution, Inc., acquired by Marizyme in 2020,[26] submitted and withdrew applications for new technology add-on payment for DuraGraft® for FY 2018 and FY 2019, as well as submitted an application again in FY 2020, as summarized in the FY

[25] 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.

[26] NASDAQ. Marizyme, Inc. Completes Acquisition of Somahlution, Inc. and Raises $7.0 Million in Private Placement | Nasdaq (accessed 1/23/2023).

2020 IPPS/LTCH PPS proposed rule (84 FR 19305 through 19312). The applicant withdrew its application again prior to the issuance of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42180).

Please refer to the online application posting for DuraGraft®, available at *https://mearis.cms.gov/public/publications/ntap/NTP221013TEMTR*, for additional detail describing the technology and intraoperative ischemic injury.

With respect to the newness criterion, the applicant stated that it is has submitted a De Novo classification request to FDA for DuraGraft.® Per the applicant, the proposed indication for DuraGraft® is for flushing and storage of vascular grafts during CABG surgery. The applicant stated that, effective October 1, 2017, the following ICD–10–PCS code may be used to uniquely describe procedures involving the use of DuraGraft®: XY0VX83 (Extracorporeal introduction of endothelial damage inhibitor to vein graft, new technology group 3).

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 payment.

With respect to the substantial similarity criteria, the applicant asserted that DuraGraft® is not substantially similar to other currently available technologies because DuraGraft® is a first-in-class product to address vein graft disease (post-CABG) and its complications. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for DuraGraft® for the applicant's complete statements in support of its assertion that DuraGraft® 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	DuraGraft® is a first-in-class product and there is no product that is similar. Common storage solutions are only salt solutions and have no ability to protect against oxidative damage and metabolic stress which are the primary mechanisms associated with ischemic injury. They are used to keep the graft wet. DuraGraft® has been formulated into a wetting solution. DuraGraft® treatment is associated with a reduction in both vein graft disease and clinical complications associated with vein graft failure post-CABG. There are currently no commercial products that prevent ischemic injury of vein grafts during CABG surgery or products that reduce vein graft disease or its complications following CABG surgery.
Is the technology assigned to the same MS-DRG as existing technologies?	Yes	MS-DRGs used during CABG surgery are aligned to the same DRGs for which DuraGraft® use is indicated.
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	DuraGraft® is used in the CABG patient population.

However, we note the following concern with regard to the newness criterion. As noted in the FY 2020 IPPS/LTCH PPS proposed rule, it seems that the mechanism of action of DuraGraft® may be the same or similar to other vein graft storage solutions. Specifically, we continue to question whether the current solutions used in vein graft surgical procedures may be the same or similar to DuraGraft® in composition and treatment indication and, therefore, have the same or similar mechanism of action.[27] We are inviting public comments on whether DuraGraft® is substantially similar to existing technologies and whether DuraGraft® meets the newness criterion.

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for DuraGraft®, the applicant searched the FY 2021 MedPAR file for cases reporting an ICD–10–PCS code describing common CABG procedures. Using the inclusion/exclusion criteria described in the following table, the applicant identified 54,636 cases mapping to 82 MS–DRGs. Please see Table 10.11.A.—DuraGraft® Codes—FY 2024 associated with this proposed rule for the complete list of MS–DRGs and ICD–10–CM PCS 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 $299,445, which exceeded the average case-weighted threshold amount of $218,294. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that DuraGraft® meets the cost criterion.

[27] 84 FR 19307.

DuraGraft® COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of ICD-10-PCS codes	Please see Table 10.11.A. - DuraGraft® Codes – FY 2024 associated with this proposed rule for the complete list of ICD-10-PCS codes included in the cost analysis.
List of MS-DRGs	Please see Table 10.11.A. – DuraGraft® Codes – FY 2024 associated with this proposed rule for the complete list of MS-DRGs included in the cost analysis.
Inclusion/exclusion criteria	The applicant identified cases by using the ICD-10-PCS procedure codes in Table 10.11.A. - DuraGraft® Codes – FY 2024 associated with this proposed rule. The applicant included only inpatient fee-for-service discharges. MS-DRGs with a total discharge count less than 11 were imputed with a count of 11. The applicant calculated the average unstandardized charge per case for each MS-DRG.
Charges removed for prior technology	Charges for related or prior technologies were not removed from the cost analysis. The applicant indicated that no technology is being replaced.
Standardized charges	The applicant stated that it 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 20.469% 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 DuraGraft® kit by the national average cost-to-charge ratio of 0.311 for supplies and equipment from the FY 2023 IPPS/LTCH PPS final rule. Per the applicant, one kit will be used per one patient, and the kit is comprised of two solutions that are mixed in the operating room during surgery.

We are inviting public comments on whether DuraGraft® meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that DuraGraft® represents a substantial clinical improvement over existing technologies because there is no other product or technology that reduces the incidence of peri-operative myocardial infarction. The applicant provided three studies to support its assertions and 44 background articles about reducing major adverse cardiac events (MACE).[28] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for DuraGraft® for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

[28] Sources that provide background information are not included in the table below but can be accessed via the online application.

Substantial Clinical Improvement Assertion #1: 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**
Reduced peri-operative myocardial infarction	Haime, M., R.R. McLean, and K.E. Kurgansky, et al. (2018). Relationship between intra-operative vein graft treatment with DuraGraft® or saline and clinical outcomes after coronary artery bypass grafting, *Expert Review of Cardiovascular Therapy*, 16:12, 963-970, Department of the Interior (DOI): 10.1080/14779072.2018.1532289 SVGs were consecutively treated with heparinized saline in 1,400 patients between 1996 and 1999, and with DuraGraft® in 1036 patients between 2001 and 2004.	At 3 and 12 months, total vessel diameter was significantly lower in the DuraGraft® group (3 month $p<0.01$, 12 month $p=0.02$).
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Reduced long term nonfatal MI	Haime et al. 2018. See prior study described.	Both crude and inverse probability treatment weight (IPTW)-adjusted models displayed a statistically significant risk reduction in patients who underwent treatment with DuraGraft®. In adjusted analyses, Treatment of SVGs with DuraGraft® resulted in a significantly lower risk for nonfatal MI, beginning at 1000 days, with a risk reduction of 45% (HR 0.55, 95% CI 0.41−0.74; $p < 0.0001$).
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Reduced long term MACE	Haime et al. 2018. See prior study described.	Treatment with DuraGraft® resulted in a significantly lower occurrence of MACE, with an adjusted risk reduction of 19% starting at 1,000 days after CABG (HR 0.81, 95% CI 0.70−0.94; P = 0.0051).
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Reduced Long Term Repeat Revascularization	Haime et al. 2018. See prior study described.	Treatment with DuraGraft® resulted in a significantly lower risk of repeat revascularization starting at 1,000 days with an adjusted 35% risk reduction (HR 0.65, 95% CI 0.44−0.97; P = 0.037).
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Reduced 12- month overall mean wall thickness (whole graft analysis)	Perrault, L.P., M. Carrier, and P. Voisine, et al. (2021). Sequential multidetector computed tomography assessments after venous graft treatment solution in coronary artery bypass grafting. *Journal of Thoracis and Cardiovascular Surgery*. Jan. 2021, Vol. 161, Number 1, 96-106. https://doi.org/10.1016/j.jtcvs.2019.10.115 This was a prospective, multi-center, randomized, double-blind, comparative within-patient study with 2 arms. 125 patients (mean	DuraGraft® treated SVGs had a significantly smaller mean wall thickness versus their saline-treated counterparts (P =.02).

Substantial Clinical Improvement Assertion #1: 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**
	age, 66.2 +- 6.8 years) were randomized and underwent CABG: with 125 grafts treated with DuraGraft versus 125 grafts treated with saline.	
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Reduced 12- month rate of development of wall thickness (proximal graft analysis)	Perrault et al. 2021. See prior study described.	Greater changes were found in wall thickness in the proximal segment of saline-treated grafts (0.09 + 0.29 vs 0.00 ± 0.03 mm; P =.04). The increase in wall thickness and maximum graft narrowing from 1 to 12 months was significantly smaller in the DuraGraft® group.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Reduced 12- month proximal segment wall thickness	Perrault et al. 2021, See prior study described.	Wall thicknesses in proximal segments of grafts were significantly lower for the DuraGraft® versus saline-treated grafts at 12 months (P = .01).
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Decreased maximum graft narrowing (proximal segment analysis)	Perrault et al. 2021, See prior study described.	The change in maximum narrowing was significantly smaller for the DuraGraft®-treated group between 1 and 12 months (P=01), Additionally, the increase in wall thickness and maximum graft narrowing from 1 to 12 months was significantly smaller in the DuraGraft® group.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Decreased Total Vessel Diameter (TVD)	Perrault et al. 2021, See prior study described.	At 3 and 12 months, TVD was significantly lower in the DuraGraft® group.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Decrease in Total Vessel Diameter (TVD) in the proximal segment	Perrault et al. 2021, See prior study described.	Vessel diameters in the proximal segments were smaller in the DuraGraft® group at 3 and 12 months.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Troponin-I values significantly decreased from 3-6 hours up to 4 days post- CABG in DuraGraft®group	Szalkiewicz, P., M.Y. Emmert, and P.P. Heinisch, et al. (2022). Graft Preservation confers myocardial protection during coronary artery bypass grafting. *Frontiers in Cardiovascular Medicine*, July 2022, pp 1-10. DOI 10.3389/fcvm.2022.922357 This was a single-center retrospective study in which 272 grafts were stored in either DuraGraft® or Saline/Biseko.	Post-surgery hs-TnI values were significantly lower from 3 to 6 hours (h) up to 4 days in the DuraGraft® group: 3–6 h: 4,034 ng/L [IQR 1,853–8,654] vs. 5,532 ng/L [IQR 3,633—8,862], p = 0.05; 12–24 h: 2,420 ng/L [IQR 1,408–5,782] vs. 4,166 [IQR 2,052–8,624], $p < 0.01$; 2 days: 1,095 ng/L [IQR 479–2,311] vs. 1,564 ng/L [IQR 659–5,057], p = 0.02 and at 4 days: 488 ng/L [IQR 232–1,061] vs. 745 ng/L [IQR 319–1,820], p = 0.03.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Significantly Reduced maximum (peak) values of troponin	Szalkiewicz et al. (2022). See prior study described.	The maximum value of troponin was significantly lower after graft treatment with DuraGraft® (maximum value: 4,151 ng/L [IQR 2056– 8621] vs. 6,349 ng/L [IQR 4061–12664], p < 0.01.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Significantly reduced median area under the curve (AUC) for Troponon-1	Szalkiewicz et al. (2022). See prior study described.	The median area under the curve (AUC): 6,146 ng/L/24 h [IQR 3,121–13,248] vs. 10,735 ng/L/24 h [IQR 4,859–21,484], p = 0.02 were lower in the DuraGraft® group.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
	Szalkiewicz et al. (2022). See prior study	Repeated graft flushing with DuraGraft® resulted in lower

Substantial Clinical Improvement Assertion #1: 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**
Improved myocardial protection	described.	Troponin values post-surgery suggesting enhanced myocardial protection compared to Saline/Biseko. The use of DuraGraft® for leak testing during distal anastomosis and its subsequent application to the downstream myocardium appeared to be associated with improved myocardial protection in patients undergoing on-pump coronary artery bypass grafting (ONCAB), identified by significantly lower hs-TnI levels including the maximum value and AUC during the early post-operative phase after CABG when compared to Saline/Biseko.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	

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After review of the information provided by the applicant, we have the following concerns regarding whether DuraGraft® meets the substantial clinical improvement criterion. First, we note that the Szalkiewicz and Perrault studies both used a relatively small sample size (166 and 125 patients respectively) as compared to the number of potentially eligible patients for this technology and relatively short follow-up periods (4 days and 12 months respectively).[29] [30] According to the applicant, about 400,000 CABG procedures were performed annually in the U.S. for which DuraGraft® can be used.[31] The applicant estimated that approximately 60% of these procedures (or 240,000 procedures annually or 20,000 procedures monthly) will be performed on Medicare beneficiaries. We are unsure if the sample was representative of the number of Medicare beneficiaries potentially eligible for DuraGraft®. Moreover, the sample size in the Perrault study was further reduced by SVG occlusion, from 125 grafts at the beginning of the study to 118 at 3-month follow up, a 6% decrease, and to 97 at 12-month follow up, a further reduction of 18%. We also note that Perrault et al. mentioned that a larger cohort and longer-term evaluation are needed to validate their findings. Similarly, Szalkiewicz et al. cautioned that the study was not powered for clinical outcome events. We are interested in whether similar results in reduced incidence of peri-operative myocardial infarction and associated clinical benefits would have been achieved with a larger patient sample and over a longer follow up period for clinical outcomes.

Second, we are concerned that there may be mixed evidence as to whether there is an association between exposure to DuraGraft® and clinical outcome improvement. For instance, the Haime study demonstrated that patients whose SVG was exposed to DuraGraft® and those whose SVG was exposed to saline had comparable risk for all-cause mortality.[32] We further note that in the Perrault study, patients whose SVGs were stored in DuraGraft® were just as likely to experience MACE, angina, and arrhythmias as those whose SVGs were stored in saline (MACE: 0 out of the 125 patients whose SVGs were stored in saline, 1 out of the 125 patients whose SVGs were stored in DuraGraft®, p = 0.32; angina: 0 out of the 125 patients whose SVGs were stored in saline, 1 out of the 125 patients whose SVGs were storied in DuraGraft®, p = 0.32; arrhythmia: 0 out of the 125 patients whose SVGs were stored in saline, 1 out of the 125 patients whose SVGs were storied in DuraGraft®, p = 0.32).[33] The study also found no significant differences between SVGs stored in DuraGraft® versus those in saline in maximum graft narrowing or mean lumen diameter at 1, 3, and 12 months. Similarly, the Szalkielwicz study did not identify any significant differences between patients whose SVG was exposed to DuraGraft® and those to saline in median length of hospital stay, all-cause mortality, and cardiac-related mortality.

Third, the Haime study was conducted among patients of the Veterans Administration (VA) medical system who were predominantly white (95%) and male (99%). We questioned whether the results from that study could be generalized to other patient groups, including nonveterans, women, or those from other racial or ethnic groups. We continue to question whether the demographic profiles in some of the studies that the applicant submitted for FY 2024 were comparable with those of the U.S. Medicare patients who underwent CABG surgery. For instance, in terms of patients' gender, the Perrault, Szalkiewica, and Haime studies were all conducted among CABG patients who were predominantly male (99% in the Haime study; 91% in the Perrault study; 83% in the Szalkiewicz study). However, among the

[29] Szalkiewicz, P., M.Y. Emmert, and P.P. Heinisch, et al. (2022). Graft Preservation confers myocardial protection during coronary artery bypass grafting. *Frontiers in Cardiovascular Medicine,* July 2022, pp 1–10. DOI 10.3389/fcvm.2022.922357.

[30] Perrault, L.P., M. Carrier, and P. Voisine, et al. (2021). Sequential multidetector computed tomography assessments after venous graft treatment solution in coronary artery bypass grafting. *Journal of Thoracis and Cardiovascular Surgery.* Jan. 2021, Vol. 161, Number 1, 96–106. *https://doi.org/10.1016/j.jtcvs.2019.10.115.*

[31] The applicant's estimates were based on Healthcare Cost and Utilization Project (HCUP) National Inpatient Sample (NIS) data.

[32] Haime, M., R.R. McLean, and K.E. Kurgansky, et al. (2018). Relationship between intra-operative vein graft treatment with DuraGraft® or saline and clinical outcomes after coronary artery bypass grafting, *Expert Review of Cardiovascular Therapy,* 16:12, 963–970, DOI: 10.1080/14779072.2018.1532289.

[33] Perrault et al. (2021), *op.cit.,* Table 6, p. 103.

Medicare fee-for-service beneficiaries who underwent CABG surgery, male patients accounted for only two-thirds (66%) of this population.[34] [35] We are interested in whether the results from the Haime, Perrault, and Szalkiewicz studies can be replicated among the Medicare population. The Haime study also noted that because they used VA data only, information about service utilization outside the VA system was not available to them. We question whether their findings would be replicable among the Medicare population.

In the FY 2020 IPPS/LTCH PPS proposed rule (84 FR 19311), we noted our concern that some of the studies provided by the applicant as supporting materials do not account for other variables that may have confounded the association between exposure to DuraGraft® and clinical outcomes. We continue to question whether potential confounding factors have been taken into account in assessing the association between exposure to DuraGraft® and clinical outcome improvement. Specifically, both the Szalkiewicz and Haime studies were single-center studies and we question whether site-specific characteristics could have contributed to differences in clinical outcomes between patients exposed to DuraGraft® versus those exposed to saline. Also, Szalkiewicz and his team conducted their study among patients for on-pump CABG surgery, which accounts for the majority of CABG surgeries conducted in the U.S.[36] We are interested to know whether the study results can be generalized for patients who undergo off-pump CABG surgery. In addition, Haime and his team conducted their study in two consecutive phases, during which they exposed patients' SVGs to heparinized saline from 1996 to 1999, and to DuraGraft® from 2001 to 2004. Haime and his team stated that surgical and post-operative protocols did not change substantially during these periods. However, their study did not mention whether the team has accounted for changes in generalized surgical techniques or operating room practices, either of which could have contributed to the observed outcomes. The Haime team also used propensity score weighting to minimize differences in age and several clinical characteristics between patients from the two periods. Theoretically, doing so would reduce the likelihood that these differences confound the association between exposure to DuraGraft® and clinical outcomes. However, propensity scoring can only control for confounding factors that are measured, that is, captured in the data. Unmeasured confounding factors could still impact the association between exposure to DuraGraft® (or heparinized saline) and clinical outcomes. This may be the reason the research team stated that they would not be able to rule out the possibility that other changes between these two periods, including patient selection criteria and intraoperative and post-operative protocols, might still have confounded the differences in clinical outcomes. Additionally, according to the VA, only 49% of veterans had used at least one VA benefit or service.[37] Veterans may use services outside of the VA for repeat revascularization to address further progress of coronary artery disease. Repeat vascularization may be a confounding factor that impacts the clinical outcomes for patients exposed to DuraGraft® or heparinized saline. As previously stated, the Haime study noted that because they used VA data only, information about service utilization outside the VA system was not available to them. As a result, it remains unclear whether we can reliably attribute any changes in clinical outcomes to exposure to DuraGraft®.

With regard to the Perrault study (2021), where two SVGs from each patient were randomly assigned to be stored in either DuraGraft® or saline, and the surgeons and operating room staff were blinded, we are interested in whether the SVGs in each arm were comparable in wall thickness or lumen diameter at the baseline. While the Perrault study (2021) was multi-center and drew patients from 7 sites, a sizable minority of patients (42%) came from one specific site. We wonder if the impact of DuraGraft® on clinical outcomes at 12-month follow-up is confounded by unique characteristics of that specific site. In addition, the Perrault team noted that the association between DuraGraft® and clinical outcome improvement may be confounded by precision of different modalities of MDCT angiography. We agree with Perrault and his team that further studies on the effects of confounding factors, like chronic conditions (for example, left main coronary artery disease,[38] diabetes control or hypercholesterolemia), medication use (for example, antiplatelet therapy or lipid-lowering drugs), graft and anastomosis characteristics (for example, quality, size, and diameter of target vessel), type of graft use, or surgical technique (for example, open vs endoscopic harvest) [39] may provide further insight.

We are inviting public comments on whether DuraGraft® meets the substantial clinical improvement criterion. In this section, we summarize and respond to written public comments received in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for DuraGraft®.

Comment: The applicant submitted a public comment in response to two questions posed at the Town Hall meeting and provided additional information. With regard to the first question asking for clarification with respect to any differences between GALA and DuraGraft® and whether any of the studies cited by the applicant used GALA rather than DuraGraft®, the applicant stated that GALA is a pharmacy-compounded product that has been used by hospitals for graft storage and is a precursor product to DuraGraft®. According to the applicant, DuraGraft® has the same intended composition and product characteristics (pH, isotonicity, osmolarity, and ionic balance) as GALA at the time of manufacture. The applicant stated that GALA was developed by scientists at Harvard University and the West Roxbury Veterans Administration (VA) Medical Center, and had been used at the latter as a pharmacy-compounded product. In 2012, the applicant acquired a license from the VA to exclusively commercialize GALA, but the product was never sold commercially. With a shelf-life of about a week, GALA 'as is' is rendered not suitable for distribution

[34] Angraal, S., K. Khera, and Y. Wang, et al. (2018) Sex and race differences in the utilization and outcome of coronary artery bypass grafting among Medicare beneficiaries, 2009–2014. *Journal of the American Heart Association.* 7:e009014. DOI: 10.1161/JAHA.118.009014.)

[35] McNeely, Markwell, Vassileva (2016). Trends in patient characteristics and outcomes of coronary artery bypass grafting in 2000–2012 Medicare population. *Annals of Thoracic Surgery.* 102:132–9 (*http://dx.doi.org/10.1016/j.athoracsur.2016.01.016*).

[36] E. Blackstone, and J.F. Sabik, III (August 2017). Changing the discussion on on-pump versus off-pump CABG. *New England Journal of Medicine.* 377: 692–693. DOI: 10.1056/NEJMe1706220.

[37] United States Department of Veterans Affairs (May 2020). VA Utilization Profile: FY 2017. National Center for Veterans Analysis and Statistics (VA_Utilization_Profile_2017.pdf, accessed 12/7/2022).

[38] Caliskan, E., M. Misfeld, and S. Sandner, et al. (August 2022) Clinical event rate in patients with and without left main disease undergoing isolated coronary artery bypass grafting: results from the European DuraGraft® Registry. *European Journal of Cardiao-Thoracic Surgery.* 62(4): ezac 403: *https://doi.org/10.1093/ejcts/ezac403.*

[39] Perrault et al. (2021), *See prior study described.*

and commercialization.[40] According to the applicant, GALA's shelf-life was primarily driven by chemical instability of L-glutathione and ascorbic acid, which were observed to be rapidly and substantially lost to oxidation within a few days of GALA compounding. L-glutathione and ascorbic acid are antioxidant components that play key roles in protecting vein grafts against ischemic injury and in particular oxidative damage, which is a primary driver of ischemic injury. The applicant noted that after obtaining the license for GALA, it addressed the product's instability issues without changing the composition of the product at its point of use by separating and configuring GALA's components into two (versus one) solutions. It observed that GALA's organic components, in particular L-glutathione and ascorbic acid, required a different environment for stability compared to the inorganic salts. The applicant formulated the organic components into Solution B, a pH 3 solution (optimal pH for chemical stability of the organic components including L-glutathione and ascorbic acid) concentrated 20-fold into 13.5 mls. Solution A is a pH 8 solution that includes all the inorganic salts (237.5 mls). At the point of use in the operating room, the two solutions are mixed to create a physiologic pH final solution to preserve vascular grafts. Per the applicant, this process enables DuraGraft® to achieve chemical stability while maintaining the same intended composition as GALA. As a result, while DuraGraft® is provided as a kit containing two separate solutions, Solution A and B, GALA was instead made as a single solution product. The applicant mentioned other changes in DuraGraft® (with respect to GALA), which are limited to manufacturing controls, most notably the incorporation of oxygen control processes during the manufacturing of Solution B to prevent loss of components to oxidation, aseptic processing controls used during the manufacture of both Solutions A and B, manufacturing of DuraGraft® according to Current Good Manufacturing Practice (CGMP) regulations[41] and inclusion of release specifications for DuraGraft®. The applicant remarked that combined changes in the manufacturing process and product configuration resulted in substantial differences in stability between GALA and DuraGraft®. In particular, L-ascorbic acid and L-glutathione have half-lives of several days in GALA versus over three years in DuraGraft®. The applicant confirmed that the GALA was used in the Haime study (2018).[42] The applicant did not conduct any studies that compared the impact of DuraGraft® and GALA on clinical outcomes.

With regard to the second question asking whether DuraGraft® was studied in Medicare patients, the applicant responded that DuraGraft® has not been studied in U.S. or U.S. Medicare patients. The applicant further stated that DuraGraft® has been studied in many European patients aged 65 or greater, which were the prospective randomized controlled trial published by Perrault et al. (2021)[43] and the retrospective study measuring postoperative Troponin levels published by Dr. Szalkiewicz et al. (2022).[44] The applicant stated that the ''European Multi-Center Registry To Assess Outcomes In Patients Undergoing CABG Surgery: Treatment Of Vascular Conduits With DuraGraft®, A Novel Endothelial Damage Inhibitor'' trial is an ongoing post-market study designed to support a European (International) CABG registry database used to assess the clinical outcomes of patients receiving DuraGraft® during CABG surgery and whose free vascular grafts (both venous and arterial) have been treated with DuraGraft®. According to the applicant, a total of 2,964 patients were enrolled in the trial, which completed enrollment on August 31, 2019. There were 45 enrolling centers in the trial in eight countries: Austria, Germany, Ireland, Italy, Spain, Switzerland, Turkey, and the United Kingdom. The applicant noted that follow-up data has been completed out to 30 days and one year, and that data will continue to be collected annually for up to five years. The applicant stated that as of August 2022, all patients have completed two full years of follow-up.

The applicant mentioned that the trial enrolled patients undergoing isolated CABG surgery or combined CABG plus mitral or aortic valve repair were aged 18 or older, with at least one SVG or radial artery graft used as a bypass conduit. Of the 2,532 isolated CABG patients, 1,617 patients were aged 65 or older. The applicant asserted that these patients were relevant to the Medicare population. The applicant also provided clinical outcomes at 1-year estimated by Kaplan-Meier method for the isolated CABG patients aged at least 65 and under age 65 according to Cox regression. The applicant stated that the trial is a single-arm registry, and therefore without a comparator arm. The applicant identified that adverse event rates in the aged 65 or older group were higher, as expected based on higher rates of comorbidities. The European System for Cardiac Operative Risk Evaluation (Version 2; EuroScore II) values for the aged 65 or older, compared to those under 65, were 2.7 ± 3.6 (1,617) vs. 1.5 ± 2.7 (915), $p < 0.001$. The applicant stated that this reflects the near double expected operative mortality in the Medicare aged patients.

The applicant stated that to compare outcomes with a U.S. population, it compared isolated CABG patients from the DuraGraft® Registry in Europe to a propensity-matched control group from the Society of Thoracic Surgeons (STS) Registry Adult Cardiac Surgery Database, a clinical outcomes registry with cardiac surgery procedure records submitted by cardiothoracic surgeons and anesthesiologists across the U.S. and Canada.[45] Altogether, 2,400 out of 2,532 patients were matched in the primary analysis cohort of isolated CABG patients. The two groups were matched on 35 prespecified variables reflecting mortality risk in the operative, peri-operative, and follow-up periods, out to one year. These variables included demographics, cardiac risk factors, pre-operative cardiac status, coronary anatomy, and surgical characteristics. According to the applicant, the propensity matched groups were well balanced on all important demographic, procedural and anatomic characteristics. The applicant stated that there were no significant differences in mortality rates between these two groups. The Hazard Ratio (HR) for DuraGraft® vs. standard of care was 0.88 (95% CI 0.67–1.15), $p = 0.347$; the estimated cumulative mortality at 1 year was 4.2% (95% CI 3.4–5.0) in the DuraGraft® cohort, compared to 4.8% (95% CI 3.9–5.7) in the STS Registry. The applicant also indicated that no difference was observed between mean survival times: DuraGraft® cohort: 353.25 days, SE = 1.29 (95% CI: 350.72–356.79) and STS cohort 353.30, SE = 1.25 (95% CI: 350.85–355.75). According to the applicant, no significant difference was found between the matched cohorts in the distribution of the selected outcome,

[40] The applicant observed that shelf-life did not pose an issue with use of compounded GALA within the West Roxbury VA Medical Center, as the product was cycled off the shelves weekly.

[41] Food and Drug Administration (November 16, 2022) Current Good Manufacturing Practice (CGMP) Regulations (Current Good Manufacturing Practice (CGMP) Regulations | FDA, accessed 1/4/2023).

[42] Haime et al. (2018) *op.cit.*

[43] Perrault et al. (2021) *op.cit.*

[44] Szakielwicz et al. (2022) *op.cit.*

[45] The Society of Thoracic Surgeons. What is the Adult Cardiac Surgery Database? (Frequently Asked Questions and Answers About the STS National Database and Public Reporting | STS, accessed 3/8/2023).

(that is, all-cause mortality rates through 1-year of follow up demonstrating the safety of the use of DuraGraft® in European and U.S. patients in propensity matched cohorts).

The applicant stated that it is currently in discussion with the STS Registry to perform a match of the DuraGraft® and STS cohorts to compare subsets of these cohorts matched with data from the Medicare database to compare rates of MI and repeat revascularization amongst the two-third of patients from the analysis cohorts that have data available in the Medicare Database. According to the applicant, this data will be available in mid-2023.

Response: We thank the applicant for its comment and will take this information into consideration when deciding whether to approve new technology add-on payment for the DuraGraft®.

d. Elranatamab

Pfizer, Inc. submitted an application for new technology add-on payments for elranatamab for FY 2024. Per the applicant, elranatamab is a heterodimeric humanized full-length bispecific antibody against B-cell maturation antigen (BCMA) and cluster of differentiation (CD)3 which, if FDA approved, will potentially be used for the treatment of adult patients with relapsed or refractory multiple myeloma (RRMM) who have received at least three prior therapies, including a proteasome inhibitor, an immunomodulatory agent, and an anti-CD38 monoclonal antibody. According to the applicant, elranatamab is proposed to act through direct bridging of the BCMA cell-surface antigen and the extracellular CD3 subunit expressed on T-cells.

Please refer to the online application posting for elranatamab, available at *https://mearis.cms.gov/public/publications/ntap/NTP221014RF1AA*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, the applicant stated it has not yet received FDA marketing authorization for elranatamab. According to the applicant, it is seeking biologics license application (BLA) approval from FDA for the treatment of adult patients with relapsed or refractory multiple myeloma who have received at least three prior therapies, including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and an anti-cluster of differentiation 38 (anti-CD38) monoclonal antibody before July 1, 2023. According to the applicant, elranatamab is provided as a solution in a histidine buffer at pH 5.8, in 40 mg/mL single-dose vials for subcutaneous injection. Elranatamab therapy begins with priming regimen for the first two injections with 12 mg given on day one and 32 mg on day four of the first cycle. Dosing thereafter is 76 mg once weekly. Dosing is reassessed after six cycles. The applicant anticipates that patients could be admitted to receive the first two step-up doses of elranatamab in the inpatient setting.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify elranatamab. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for elranatamab beginning in FY 2024. The applicant stated that diagnosis codes C90.00 (Multiple myeloma not having achieved remission), C90.01 (Multiple myeloma in remission), and C90.02 (Multiple myeloma in relapse) may be used to currently identify the indication for elranatamab 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 elranatamab is not substantially similar to currently available technologies (XPOVIO®, BLENREP, ABECMA®, CARVYKTI™, and traditional chemotherapy agents) because it does not use the same or similar mechanism of action when compared to these technologies to achieve a therapeutic outcome in patients with multiple myeloma (MM). Elranatamab will be a bispecific antibody therapy indicated for the treatment of RRMM in patients who have received at least three prior therapies. Other bispecific antibodies, excluding TECVAYLI™, that are currently approved by the FDA are not approved for the treatment of RRMM, and none of them target BCMA. The applicant further stated that those therapies that are currently indicated for treatment of RRMM, excluding TECVAYLI™, use entirely different mechanisms of action. The applicant also asserted that, for the purposes of the newness criterion, elranatamab is substantially similar to TECVAYLI™, which is also the subject of a new technology add-on payment application for FY 2024, as discussed separately later in this section, and which received BLA approval from FDA after submission of the application for new technology add-on payment. The applicant stated that because TECVAYLI™ and elranatamab are substantially similar for newness purposes, the applicant believes that a new technology add-on payment should apply to the BCMA-directed bispecific antibody class for the treatment of RRMM, which would be TECVAYLI™ and elranatamab (if approved). The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for elranatamab for the applicant's complete statements in support of its assertion that elranatamab is substantially similar to TECVAYLI™, but not to other currently available technologies. Please also see our discussion of TECVAYLI™'s application for new technology add on payments in section II.E.6.o of this proposed rule.

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?	Yes	Elranatamab uses the same or similar mechanism of action when compared to TECVAYLI™ to achieve a therapeutic outcome in patients with MM, but a different mechanism of action when compared to other existing technologies. While elranatamab and TECVAYLI™ are constructed from different antibody isotypes, they use a similar mechanism of action to achieve a therapeutic outcome in patients with MM. Elranatamab and TECVAYLI™ are both bispecific antibodies that engage CD3 on T-cells and BCMA on MM cells thereby bringing the cells in close proximity. The engagement of CD3 on the T-cell activates the T-cell, leading to the T-cells releasing cytokines that result in the killing of the MM cell. There are four other FDA-approved bispecific antibodies that are not approved for the treatment of RRMM, and none of them target BCMA: (1) BLINCYTO® (blinatumomab), (2) RYBREVANT® (amivantamab-vmjw), (3) HEMLIBRA® (emicizumab), and (4) VABYSMO™ (faricimab-svoa). With respect to other therapies indicated for the treatment of adult patients with RRMM who have received at least three (3) prior therapies, they use different mechanisms of action, as follows: (1) Selinexor is a nuclear export inhibitor that acts by selectively inhibiting XPO1, reactivating tumor suppressing proteins, and inducing tumor cell apoptosis; (2) belantamab mafodotin-blmf is a BCMA-directed antibody and microtubule inhibitor conjugate that binds to BCMA and releases monomethyl auristatin F (MMAF) inside the BCMA-expressing cell to kill the cell through disruption of the microtubule network; (3) idecabtagene vicleucel is a BCMA-directed CAR T-cell therapy; and (4) ciltacabtagene autoleucel is another BCMA-directed CAR T-cell therapy.
Is the technology assigned to the same MS-DRG as existing technologies?	Yes	We anticipate that patients receiving TECVAYLI™ and elranatamab (if approved) will be assigned to MS-DRGs that are currently applicable to MM patients admitted for the provision of anticancer treatments (not including stem cell or bone marrow transplant, or CAR T-cell therapy).
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	Elranatamab is anticipated to be indicated for the treatment of RRMM, for which there are other FDA approved therapies, as noted elsewhere in this application. For purposes of the newness criterion, elranatamab and TECVAYLI™ treat the same or similar type of disease and patient population.

With regard to the newness criterion, as stated by the applicant, elranatamab has a similar mechanism of action to that of TECVAYLI™, 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 four or more prior lines of therapy, including an immunomodulatory agent, a proteasome inhibitor, and an anti-CD38 monoclonal antibody. TECVAYLI™ was approved by FDA for this indication on October 25, 2022, and became commercially available on November 9, 2022. Per the new technology add on payment application for TECVAYLI™, the technology's mechanism of action is described as a bispecific antibody, with distinct binding domains that simultaneously bind the BCMA target on tumor cells and the CD3 T cell receptor. Because of the apparent similarity with the bispecific antibody for elranatamab that uses binding domains that simultaneously bind the BCMA target on tumor cells and the CD3 T cell receptor, we believe that the mechanism of action for elranatamab may be the same or similar to that of TECVAYLI™. We further believe that elranatamab and TECVAYLI™ may 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 elranatamab and TECVAYLI™ 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 believe 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 note that if this technology is substantially similar to TECVAYLI™, we believe the newness period for this technology would begin on November 9, 2022, the date TECVAYLI™ became commercially available. We are 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 elranatamab and TECVAYLI™ are substantially similar to each other

and therefore should be considered as a single application for purposes of new technology add-on payments.

We are inviting public comment on whether elranatamab meets the newness criterion, including whether elranatamab is substantially similar to TECVAYLI™ and whether these technologies should be evaluated as a single technology for purposes of new technology add-on payments.

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for treatment with elranatamab, the applicant searched the FY 2021 MedPAR file for cases reporting a diagnosis of Multiple Myeloma (in any position) and are assigned to MS–DRG 846, 847, or 848 (Chemotherapy without Acute Leukemia as Secondary Diagnosis family). The applicant noted that these case selection criteria were chosen as it is anticipated that patients could be admitted to receive the first two, step-up doses of elranatamab in the inpatient setting. Using the inclusion/exclusion criteria described in the following table, the applicant identified 674 claims mapping to two MS–DRGs, 846 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with Major Complication or Comorbidity) (MCC)) and 847 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with Complication or Comorbidity (CC)). 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 $60,579, which exceeded the average case-weighted threshold amount of $59,054. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that elranatamab meets the cost criterion.

Elranatamab COST ANALYSIS	
Data Source and Time Period	FY 2021MedPAR file
List of ICD-10-CM codes	C90.00 (Multiple myeloma not having achieved remission) C90.01 (Multiple myeloma in remission) C90.02 (Multiple myeloma in relapse)
List of MS-DRGs	846 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with MCC) 847 (Chemotherapy without Acute Leukemia as Secondary Diagnosis with CC)
Inclusion/exclusion criteria	The applicant included cases that had a diagnosis of Multiple Myeloma in any position (see list of ICD-10-CM codes noted previously) and are assigned to MS-DRG 846, 847, or 848. These case selection criteria were chosen as it is anticipated that patients could be admitted to receive the first two, step-up doses of elranatamab in the inpatient setting. 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.
Charges removed for prior technology	Per the applicant, the applicant removed 80% of drug charges from the analysis as elranatamab would replace currently used antineoplastics but some drug charges would remain the same whether elranatamab or an existing antineoplastic is used. For the purpose of this analysis, the applicant assumed that 20% of current drug charges would also be present in elranatamab cases.
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 20.47% 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.

We are inviting public comments on whether elranatamab meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that elranatamab represents a substantial clinical improvement over existing technologies because it is a new therapy for patients with RRMM who are unresponsive or unable to receive current therapies as demonstrated by low overall response rates (ORR) and access issues. The applicant stated that in clinical trials examining patients with RRMM, the ORR with elranatamab is higher than what is seen with available therapies based on empirical comparisons of individual trials. The applicant further stated that elranatamab also has a manageable safety profile. The applicant provided two studies to support these claims, as well as 13 background articles about RRMM.[46] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for elranatamab for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

[46] 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 finding(s) cited by the applicant from supporting evidence to support its statements**
MM is an incurable malignancy and with each relapse, the ability of a patient to respond to therapy and the amount of time spent in response shortens and patients run out of therapy options	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.	
CAR T-cell therapies are largely unavailable to Medicare beneficiaries with late-line RRMM and have limited data in the Medicare population	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.	
BCMA-directed bispecific antibodies will be a new treatment option for late-line patients with RRMM who are refractory to or otherwise ineligible or unable to access existing therapies	Nizar Bahlis, Michael H Tomasson, Mohamad Mohty, et al., Efficacy and safety of elranatamab in patients with relapsed/refractory multiple myeloma naïve to B-cell maturation antigen (BCMA)-directed therapies: Results from cohort A of the MagnetisMM-3 study; American Society of Hematology (ASH) 2022 submitted Brief study description: This abstract describes efficacy and safety results from Cohort A of MagnetisMM-3 (NCT04649359), an open-label, multicenter, non-randomized, phase 2 study to evaluate the safety and efficacy of elranatamab monotherapy in patients with RRMM. MagnetisMM-3 enrolled 123 patients refractory to at least 1 PI, 1 IMiD drug, and 1 anti-CD38 antibody in Cohort A.	The majority of patients enrolled in the MAGNETISMM-3 study were 65 years of age or older (65% of patients treated). 19.5% of patients enrolled were 75 years of age or older. Subset analyses were conducted to demonstrate that elderly patients had similar response rates to the overall population.
	Nizar Bahlis, Michael H Tomasson, Mohamad Mohty, et al., Efficacy and safety of elranatamab in patients with relapsed/refractory multiple myeloma naïve to B-cell maturation antigen (BCMA)-directed therapies: Results from cohort A of the MagnetisMM-3 study; ASH 2022 submitted See prior study description	Enrollment criterion for MagnetisMM-3 specifies that patients must be refractory to at least one PI, one IMiD drug, and one anti-CD38 mAb. Thus, elranatamab, as a bispecific antibody, is a new treatment option for late-line patients with RRMM who are refractory (and therefore ineligible) for treatment with existing therapies.
	Lesokhin AM, Arnulf B, Niesvizky R, Mohty M, Bahlis NJ, Tomasson MH, et al. Initial safety results for MagnetisMM-3: A phase 2 trial of elranatamab, a B-cell maturation antigen (BCMA)-CD3 bispecific antibody, in patients (pts) with relapsed/refractory (R/R) multiple myeloma (MM). Journal	Patients with moderate renal impairment were not excluded from the MagnetisMM-3 study. Enrollment was allowed if patients had an estimated creatinine clearance ≥30 mL/min (according to the Cockcroft Gault formula).

	of Clinical Oncology. 2022;40(16_suppl):8006. Brief study description: This abstract describes preliminary safety results from Cohort A of MagnetisMM-3 (NCT04649359), an open-label, multicenter, non-randomized, phase 2 study to evaluate the safety and efficacy of elranatamab monotherapy in patients with RRMM.	
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 applicants from supporting evidence to support its statements**
Elranatamab is expected to significantly improve outcomes compared to existing therapies approved for late-line MM.	Nizar Bahlis, Michael H Tomasson, Mohamad Mohty, et al., Efficacy and safety of elranatamab in patients with relapsed/refractory multiple myeloma naïve to B-cell maturation antigen (BCMA)-directed therapies: Results from cohort A of the MagnetisMM-3 study; ASH 2022 submitted. Brief study description: See prior study description	The primary endpoint of the study is ORR as judged by a blinded, independent, central review (BICR) committee. The ORR in this study was 61% after a median follow up of 6.8 months and 10.4 months. This was consistent in the subset of patients 65 years of age or greater and this ORR is numerically higher than the overall response rate reported with belantamab mafadotin (31%), selinexor in combination with dexamethasone (26%), and conventional chemotherapy (20.3%).
	Andrzej Jakubowiak, Nizar J Bahlis, Noopur S Raje, et al., Elranatamab, a BCMA-Targeted T-Cell Redirecting Immunotherapy, for Patients with Relapsed or Refractory Multiple Myeloma: Updated Results From MagnetisMM-1. American Society of Clinical Oncology (ASCO) 2022. Brief study description: This poster describes results fromMagnetisMM-1 (NCT03269136), an ongoing Phase 1 study in adult patients with RRMM (n=55).	The ORR in the study was 64% among 55 patients receiving elranatamab and 35% of patients achieved CR or better. A total of 77% of responders remained in response at month 9.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	

In addition to being efficacious, elranatamab has a manageable safety profile	Nizar Bahlis, Michael H Tomasson, Mohamad Mohty, et al., Efficacy and safety of elranatamab in patients with relapsed/refractory multiple myeloma naïve to B-cell maturation antigen (BCMA)-directed therapies: Results from cohort A of the MagnetisMM-3 study; ASH 2022 submitted. See prior study description	Any grade and grade 3/4 treatment-emergent adverse events (TEAEs) were reported in 100% and 74.8% of patients, respectively. Among patients who received the 2-step-up priming regimen (n=119), cytokine release syndrome (CRS) and immune effector cell-associated neurotoxicity syndrome (ICANS), respectively, were reported in 56.3% and 3.4%; of those patients, 44.8% (n=30/67) and 50.0% (n=2/4) received tocilizumab and/or steroids. All CRS and ICANS were grade 1 or 2. CRS events were confined to the first 2 priming doses (90.6%) and the first 3 doses (98.8%). No patients permanently discontinued treatment due to CRS or ICANS. Grade 3/4 Neutropenia was reported in 43.1% of patients, grade 3/4 thrombocytopenia was reported in 20.3% of patients, Grade 3/4 Anemia was reported in 33.3% of patients, Grade 3/4 lymphopenia was reported in 23.6% of patients. Infections were reported in 61.8% (grade 3/4, 31.7%) of patients; most frequently (≥10% of patients) reported were upper respiratory tract infections (14.6% [no grade 3/4]) and pneumonia (10.6% [grade 3/4, 5.7%]). No patients permanently discontinued treatment due to CRS or ICANS. A total of 7.3% of patients discontinued elranatamab due to adverse event. With longer term follow-up data with a median of 10.4 months, there continued to be no patients with Grade three or higher CRS or ICANS in patients who received the 12 mg & 32 mg step-up regimen and most cases of CRS (90.6%) occurred during the step-up regimen. There were no fatal neurotoxicity events observed.

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After review of the information provided by the applicant, we have the following concerns regarding whether elranatamab meets the substantial clinical improvement criterion. To support that the treatment offers an option for a patient population unresponsive to, or ineligible for, currently available treatment options, the applicant asserts that BCMA-directed bispecific antibodies will be a new treatment option for late-line patients with RRMM who are refractory to or otherwise ineligible or unable to access existing therapies. In particular, the applicant states the nature of the disease is such that patients often become refractory to all or some treatment options for late-line RRMM. The applicant further states that those patients who are not refractory to these treatment options may be ineligible for treatment due to renal insufficiency in the case of CAR T-cell therapy or unable to access therapy for other reasons. To support that elranatamab would offer a new treatment option for this patient population, the applicant references the eligibility criteria for MagnetisMM–3, a phase 2 study to evaluate the safety and efficacy of elranatamab monotherapy in patients with RRMM. The applicant states that 65% of patients were 65 years or older, patients with moderate renal impairment were not excluded, and patients must have been refractory to at least one PI, one IMiD drug, and one anti-CD38 mAb. The applicant states that these eligibility criteria indicate elranatamab was studied in a Medicare eligible population, may be appropriate for patients with renal impairment, and provides a new mechanism of action for patients with RRMM who have exhausted all other viable treatment options. However, to the extent late-line patients with RRMM who are refractory to or otherwise ineligible or unable to access CAR T-cell therapies may instead be eligible for XPOVIO®, which is also indicated for RRMM, it is unclear that this is a patient population unresponsive to, or ineligible for, all other currently available treatments. We note that this drug was studied in patients 65 years and older, is not contraindicated in renal impairment, and is also indicated for RRMM and, therefore, may also be a treatment option for patients with RRMM ineligible or unable to access CAR T-cell therapies.

The applicant also asserts CAR T-cell therapies are largely unavailable to Medicare beneficiaries with late-line RRMM due to long wait times with a median of 6 months.[47] However, as noted, to the extent these patients could also be eligible for XPOVIO®, which may be an option for patients unable to access CAR T-cell therapy, it is unclear that this supports the assertion that elranatamab offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, or that longer wait times would mean that a patient is ineligible for or unresponsive to CAR T-cell therapy. The applicant further asserts CAR T-cell therapies are not well-studied in the Medicare population with only 35% and 36% of patients being 65 years or older in the registrational studies for ABECMA® and

[47] Kourelis T, Bansal R, Patel KK, Berdeja JG, Raje NS, Alsina M, et al. Ethical challenges with CAR T slot allocation with idecabtagene vicleucel manufacturing access. Journal of Clinical Oncology. 2022;40(16_suppl):e20021–e.

CARVYKTI™, respectively.[48] [49] However, these percentages do indicate CAR T-cell therapies were studied in late-line RMMM patients 65 years and older and the studies included patients up to 78 years old. The applicant also asserts that ''renal impairment is one of the most common complications of MM,'' and that as a result, a large portion of RRMM patients may be ineligible for CAR T-cell therapy because they are ineligible for lymphodepleting chemotherapy, which is required for administration of CAR T-cell therapy.[50] However, Hunter et al. describe two patients with end stage renal disease who were successfully treated with CAR T-cell therapy; therefore, we question whether this is an accurate conclusion.[51]

To further support that elranatamab offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, the applicant asserts that MM is an incurable malignancy and with each relapse, the ability of a patient to respond to therapy and the amount of time spent in response shortens and patients run out of therapy options. The applicant states that almost all patients with MM eventually relapse and that the treatment of patients who have received two or more prior lines of therapy is becoming particularly challenging. The applicant also provides the ORRs of 26% for XPOVIO® with dexamethasone in patients with triple class refractory RRMM, 31% for BLENREP in patients with triple class refractory RRMM, and 29.8% with conventional chemotherapy.[52] [53] [54] However, the claim is based on the definition of the disease, RRMM, being relapsed or refractory disease. XPOVIO®, BLENREP, conventional chemotherapy, and elranatamab, if approved, would all be options for patients with RRMM. We question which patient population would benefit from elranatamab due to being ineligible for or unresponsive to all other options indicated for RRMM without data regarding the benefit of elranatamab in patients ineligible for or unresponsive to these other therapies.

The applicant also asserts that elranatamab significantly improves outcomes compared to existing therapies for RRMM. The supporting evidence is based on the ORRs for elranatamab, XPOVIO® with dexamethasone, BLENREP, and conventional chemotherapy, but does not consider the ORRs for CAR–T-cell therapies. Therefore, we question whether elranamatab provides improved outcomes compared to previously available therapy. Furthermore, the applicant asserts elranatamab has a manageable safety profile. However, having a manageable safety profile without a comparison to other therapies for RRMM does not provide evidence for an improved outcome compared to the other therapy options for RRMM.

We are inviting public comments on whether elranatamab meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for elranatamab.

e. epcoritamab

Genmab US, Inc. submitted an application for new technology add-on payments for epcoritamab for FY 2024. Per the applicant, epcoritamab is an investigational immunoglobulin G1 (IgG1) bispecific antibody which directly binds cluster of differentiation (CD)3 expressing T-cells and CD20 expressing B-cells to potently induce activation and cytotoxic activity of the T-cells against the malignant B-cells in a process that is strictly dependent on epcoritamab binding to both targets. According to the applicant, epcoritamab may be an effective treatment for patients with relapsed/refractory (R/R) Non-Hodgkin's Lymphoma (NHL), and more specifically R/R Large B-Cell Lymphoma (LBCL) by co-opting the patient's own immune system to target the disease.

Please refer to the online application posting for epcoritamab available at *https://mearis.cms.gov/public/publications/ntap/NTP221012JQM0G*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, the applicant stated it has not yet received FDA marketing authorization for epcoritamab. According to the applicant, it anticipates BLA approval from FDA for the indication of treatment of adult patients with R/R LBCL after two or more lines of systemic therapy before July 1, 2023. The applicant stated that epcoritamab 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 cycle 1–3, every 2 weeks in cycle 4–9, and every four weeks in cycle 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.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify administration of epcoritamab. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for epcoritamab beginning in FY 2024. The applicant provided a list of diagnosis codes that may be used to currently identify the indication for epcoritamab 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 asserted that epcoritamab is not substantially similar to other currently available technologies because epcoritamab is 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, 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 epcoritamab for the applicant's

[48] ABECMA (idecabtagene vicleucel), suspension for intravenous infusion (prescribing information); Celgene corporation and Bristol Myers Squibb company, Summit, New Jersey 2021.

[49] CARVYKTI™ (ciltacabtagene autoleucel) suspension for intravenous infusion (prescribing information); Janssen Biotech, Inc., Horsham, PA. 2022.

[50] Korbet SM, Schwartz MM. Disease of the Month: Multiple Myeloma. Journal of the American Society of Nephrology. 2006;17(9):2533–45.

[51] Hunter, B.D., Hoda, D., Nguyen, A. et al. Successful administration of chimeric antigen receptor (CAR) T-cell therapy in patients requiring hemodialysis. Exp Hematol Oncol 11, 10 (2022).

[52] A. Chari, D.T. Vogl, M. Gavriatopoulou, A.K. Nooka, et al., Oral Selinexor–Dexamethasone for Triple-Class Refractory Multiple Myeloma, N Engl J Med 2019;381:727–38.

[53] Sagar Lonial, Hans C Lee, Ashraf Badros, et al; Belantamab mafodotin for relapsed or refractory multiple myeloma (DREAMM–2): a two-arm, randomised, open-label, phase 2 study Lancet Oncol 2020: 21: 207–21.

[54] Maria-Victoria Mateos, Katja Weisel, Valerio De Stefano et al., LocoMMotion: a prospective, non-interventional, multinational study of real-life current standards of care in patients with relapsed and/or refractory multiple myeloma. Leukemia (2022) 36:1371–1376.

complete statements in support of its assertion that epcoritamab is not substantially similar to other currently available technologies.

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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	Epcoritamab 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, epcoritamab 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, epcoritamab. 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. Epcoritamab 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 MOA compared to epcoritamab. Within the immune 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. Epcoritamab 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

Substantial Similarity Criteria	Applicant Response	Applicant's assertions regarding this criterion
		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 epcoritamab 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	Epcoritamab 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 SCI section), the unmet need for this population is quite high as a significant number of patients are unresponsive to currently available treatments. Epcoritamab is posed to address this high unmet need by providing a safe and effective treatment option for a highly refractory patient population. See SCI 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 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

However, we note that epcoritamab may have a similar mechanism of action to that of glofitimab, for which we received an application for new technology add-on payments for FY 2024, for the treatment of adult patients with R/R LBCL/DLBCL after three or more prior lines of therapy. Glofitimab'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 glofitamab's application, the 2:1 structure of glofitimab 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 believe that the mechanism of action for epcoritamab may be the same or similar to that of glofitimab.

We further believe that epcoritamab and glofitimab 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, as it appears that epcoritamab and glofitimab 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 believe 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 are 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 epcoritamab and glofitimab are substantially similar to each other and therefore should be considered as a single application for purposes of new technology add-on payments.

We are inviting public comment on whether epcoritamab meets the newness criterion, including whether epcoritamab is substantially similar to glofitimab and whether these technologies should be evaluated as a single technology for purposes of new technology add-on payments.

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 epcoritamab. 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 epcoritamab 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 epcoritamab meets the cost criterion.

Epcoritamab 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 epcoritamab 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 a 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 epcoritamab 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 epcoritamab. The applicant will provide CMS with epcoritamab pricing information by June 30, 2023, subject to final FDA approval. Therefore, the applicant stated charges for epcoritamab were not incorporated because the price has not yet been finalized. However, once the price is finalized, this analysis will be updated to incorporate those charges.

We are inviting public comments on whether epcoritamab meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that epcoritamab 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®.[55] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for epcoritamab for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

[55] 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	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%

	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 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.	• 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%) • 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.	

After review of the information provided by the applicant, we have the following concerns regarding whether epcoritamab 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 epcoritamab as having stronger efficacy data in comparison to other 3L+ treatment options available. We note that the applicant provided many background studies regarding R/R DLBCL treatment options. However, they were unable to provide the complete study of epcoritamab (EPCORE NHL–1) in support of its claim of epcoritamab'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 are limited in our ability to fully evaluate and assess the supporting evidence for this claim. Furthermore, we note that there may be other available treatments for this specific population, including CAR T-cell therapies. We also note 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 epcoritamab as having better safety profiles and efficacy than existing treatments. However, the comparisons are not matched cases within a comparative study, and we question 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 would be interested in additional information to demonstrate that epcoritamab has significantly better efficacy and safety profiles than other available treatments.

We are inviting public comments on whether epcoritamab meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for epcoritamab.

f. Glofitamab

Genentech, Inc. submitted an application for new technology add-on payments for glofitamab for FY 2024. According to the applicant, glofitamab is a novel full-length, fully humanized, T-cell engaging bispecific antibody with a novel 2:1 structure (two CD20 binding domains, one CD3 binding domain [2:1 structure]) for the treatment of adults with relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) after two or more prior therapies. Per the applicant, glofitamab activates the patient's own immune system to eradicate malignant B-cells by simultaneously binding CD20 on malignant B-cells and CD3 on T-cells, bringing them into close proximity inducing proliferation and targeted killing of B-cells. The applicant stated that the novel 2:1 structure of glofitamab enables high-avidity, bivalent binding to CD20 that can result in activity against malignant B-cells even under low effector-to-target cells.

Please refer to the online application posting for glofitamab available at *https://mearis.cms.gov/public/publications/ntap/NTP221017RK2RD*, for additional detail describing the

technology and the disease treated by the technology.

With respect to the newness criterion, the applicant stated it has not yet received FDA marketing authorization for glofitamab but is seeking accelerated approval of a BLA from the FDA for the treatment of adults with R/R DLBCL after two or more prior therapies. According to the applicant, glofitamab 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 glofitamab 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% of the time it occurred after a 2.5 mg dose, 27% of the time it developed after a 10 mg dose, and 4% after a 30 mg dose. Therefore, according to the applicant, the expected average dose of glofitamab associated with an inpatient hospital stay is ((2.5 mg * 0.69) + (10 mg * 0.27) + (30mg * 0.04)) = 5.625 mg.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify administration of glofitamab. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for glofitamab beginning in FY 2024. The applicant provided a list of diagnosis codes that may be used to currently identify the indication for glofitamab 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 asserted that glofitamab is not substantially similar to other currently available technologies because the mechanism of action of glofitamab is distinct from other available DLBCL therapies and because glofitamab 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 glofitamab for the applicant's complete statements in support of its assertion that glofitamab 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	Glofitamab 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, glofitamab mechanism of action does not resemble that of any approved therapy in the treatment of DLBCL. Glofitamab 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 glofitamab 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 glofitamab 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. Glofitamab is distinct from the BiTE molecules (such as blinatumomab) because, unlike the BiTEs (which are protein fragments), glofitamab is a full-length antibody molecule, which contributes to the stability of the glofitamab 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, glofitamab does not entail a weeks-long manufacturing turn-around time, and physicians can readily access glofitamab for their patients "off-the-shelf," which is particularly beneficial for patients with aggressive disease who need treatment immediately. In addition, because glofitamab is not manufactured for an individual patient, product manufacture and supply can be consistent.
Is the technology assigned to the same MS-DRG as existing technologies?	Yes	Glofitamab 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	Glofitamab will fill an unmet need left by other 3L+ DLBCL approved therapies. Therefore, the use of glofitamab 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 glofitamab 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 glofitamab treatment were achieved across all patient subpopulations.

However, we note that glofitamab may have a similar mechanism of action to that of epcoritamab, for which we received an application for new technology add-on payments for FY 2024 for the treatment of adult patients with R/R LBCL after three or more prior lines of therapy. According to the new technology add-on payment application for glofitamab, the technology'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. The applicant stated that the 2:1 structure of glofitamab enables high-avidity, bivalent binding to CD20 that can result in activity against malignant B-cells even under low effector-to-target cells. The immunoglobulin G1 bispecific antibody of epcoritamab directly binds CD3 expressing T-cells and CD20 expressing B-cells to potently induce activation and cytotoxic activity of the T-cells against the malignant B-cells. Because of the potential similarity with the mechanism of binding and other actions, we believe that the mechanism of action for glofitamab may be the same or similar to that of epcoritamab.

While the applicant stated that the use of glofitamab 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 believe that glofitamab may treat the same or similar patient population as these existing FDA-approved treatments. We also believe that glofitamab and epcoritamab 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).

Accordingly, as it appears that glofitamab and epcoritamab 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 believe 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 are 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 glofitamab and epcoritamab are substantially similar to each other and therefore should be considered as a single application for purposes of new technology add-on payments.

We are inviting public comment on whether glofitamab meets the newness criterion, including whether glofitamab is substantially similar to epcoritamab and whether these technologies should be evaluated as a single technology for purposes of new technology add-on payments.

With respect to the cost criterion, the applicant searched the FY 2021 MedPAR file for potential cases representing patients who may be eligible for glofitamab, 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 glofitamab, 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 glofitamab 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 glofitamab meets the cost criterion.

GLOFITAMAB 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 glofitamab, 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 glofitamab 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 glofitamab 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 are inviting public comments on whether glofitamab meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that glofitamab 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.[56] The following table summarizes the applicant's assertions regarding the substantial clinical improvement. Please see the online posting for glofitamab for

[56] Background articles are not included in the following table but can be accessed via the online posting for the technology.

the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

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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**
Glofitamab 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 glofitamab.	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.	
Glofitamab 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.	
Glofitamab 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 glofitamab in R/R B-cell NHL with obinutuzumab pretreatment (Gpt).	7 days before the first dose of glofitamab, 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. Glofitamab was given as an initial 4 hour IV infusion, reduced to 2 hours once a prior infusion had occurred without complications. Glofitamab 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.	
Glofitamab is a therapy that can be made available across various geographics for patients with DLBCL	The applicant provided background information to support this claim, which can be accessed via the online posting for the technology.	
Glofitamab is expected to be an efficacious option for patients who are ineligible for ASCT or CAR T-cell therapies, expanding access to treatment for these patients	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)
	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 glofitamab 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**
Glofitamab 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.	
Glofitamab 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.	
Glofitamab 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.	
Glofitamab 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)

	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Glofitamab 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).
Glofitamab 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)

After review of the information provided by the applicant, we have the following concerns regarding whether glofitamab meets the substantial clinical improvement criterion. To support its assertion that glofitamab offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments, the applicant asserts that glofitamab expands treatment options for R/R DLBCL patients who have progressed after other 2L or 3L+ therapies. However, we note 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 glofitamab reduces mortality of patients who had progressed after ASCT or CAR T-cell therapy, we note that the applicant provided several background studies [57] [58] [59] [60] regarding other existing treatments for R/R DLBCL as well as the main glofitamab study, however, as this conclusion is based on the comparison of results across these independent studies, 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 glofitamab is an off-the-shelf therapy without any delay due to personalized manufacturing, such as CAR T-cell therapy, and that glofitamab can be made available across various geographies for patients with DLBCL, we question 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 glofitamab improves outcomes as compared to existing treatments, including safety and rate of treatment discontinuations, we note that only one single arm trial with no comparators was provided in support of this claim. We further note that the comparisons of the supporting evidence [61] [62] provided for other existing technologies to the main glofitamab study are not matched cases; for example, the studies do not adjust for type and severity of AEs. Therefore, we question whether these comparisons can be used to demonstrate a significant difference in safety or efficacy.

With respect to the applicant's claim that glofitamab is a fixed-treatment duration therapy, providing patients with time off treatment and the potential to improve patient quality of life, we note 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 glofitamab 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 would be interested in additional information regarding the association between treatment type and duration and quality of life, particularly how glofitamab's treatment type and duration results in higher quality of life as compared to the treatment type and duration of existing technologies.

We are inviting public comments on whether glofitamab meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for glofitamab.

g. 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 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

[57] Gisselbrecht C, et al. J Clin Oncol 2010; 28(27):4184–90.

[58] Schuster SJ, et al. Lancet Oncol 2021;21:1403–15.

[59] Abramson JS, et al. The Lancet. 2020;396(10254):839–52.

[60] Locke FL, et al. Lancet Oncol 2019;20:31–42.

[61] Salles G, et al. Lancet Oncol 2020;21(7):978–88.

[62] MONJUVI® (tafasitamab) [prescribing information]. Boston, MA: Morphosys US Inc; June 2021.

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 note that, 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 mosunetuzumab 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% of the time it occurred after a 60 mg dose, 20% of the time it developed after a 1 mg dose, and 5% after a 2 mg dose. Based on this information, it seems that the weighted average inpatient dose would be 45.3 mg.

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), and 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.

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 note 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 believe 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 are inviting public comments on whether Lunsumio™ is substantially similar to existing technologies and whether Lunsumio™ meets the newness criterion.

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 this 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 this 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 this 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 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 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 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 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 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 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™. The applicant stated it plans to update its analysis in the future to incorporate charges for Lunsumio™.

We are inviting public comments on whether 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 have a higher risk of TEAEs and neurological AEs.	Budde LE, et al. (2022). *op.cit.* See prior study description	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. 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, multicentre, phase II study was conducted at 49 centres 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 #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**
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 mosunetuzumab, 6 had second responses (4 CR and 2 Partial response (PR). Any grade AE related to mosunetuzumab: Initial treatment phase (N=15) 100%; Retreatment phase (N=15) 86.7% - Grade 3/4 AE related to mosunetuzumab: 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 mosunetuzumab monotherapy retreatment was efficacious in heavily pretreated patients with R/R NHL who initially achieved a CR with mosunetuzumab treatment, but subsequently developed progressive disease (PD), indicating treatment activity through multiple lines of therapy. mosunetuzumab 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.

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.	
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.	

After review of the information provided by the applicant, we have the following concerns regarding whether Lunsumio™ meets the substantial clinical improvement criterion. We note 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.[63] [64] [65] However, we note 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 are 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 are inviting public comments on whether Lunsumio™ meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for Lunsumio™.

h. 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 in Q2 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%, 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

[63] Cheah, Y.C. et al. (2022), *op.cit.*

[64] 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.

[65] Budde, L. et al. (2022), *op.cit.*

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.

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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.

However, we have the following concerns with regard to the newness criterion. 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 note 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 is unclear whether the proteolytic enzymes act similar to existing collagenase-based enzymatic debridement products since the applicant claimed that NexoBrid™ debrides denatured collagen in the wound. In addition, the applicant asserted that NexoBrid™ is not assigned to the same MS–DRGs as existing technologies used for burns, although it seems that NexoBrid™ would be assigned to the same burn MS–DRGs as other enzymatic and surgical debridement technologies.

We are inviting public comments on whether NexoBrid™ is substantially similar to existing technologies and whether NexoBrid™ meets the newness criterion.

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 combinations of ICD–10–CM codes and ICD–10–PCS codes to identify potential cases representing patients who may be eligible for NexoBrid™. The applicant explained that it used different codes to demonstrate two different cohorts that may be eligible for this technology

based on the presence of skin replacement. The applicant removed a different percentage of operating room charges for each cohort and followed the order of operations described in the following table.

For the first analysis, the applicant searched for claims using a combination of ICD–10–CM diagnosis codes for second- or third-degree burns as a primary diagnosis and ICD–10–PCS code(s) for excision or extraction of skin or subcutaneous tissue and fascia absent of a replacement procedure. Please see Table 10.15.A.—NexoBrid™ Codes—FY 2024 associated with this proposed rule for the complete list of codes that the applicant indicated were included in its cost analysis. Using the inclusion/exclusion criteria described in the following table, the applicant identified 274 claims mapping to three MS–DRGs: 935 (Non-Extensive Burns), 934 (Full Thickness Burn without Skin Graft or Inhalation Injury), and 928 (Full Thickness Burn with Skin Graft or Inhalation Injury with CC/MCC). The applicant calculated a final inflated average case-weighted standardized charge per case of $109,545, which exceeded the average case-weighted threshold amount of $59,487.

For the second analysis, the applicant searched for claims using a combination of ICD–10–CM diagnosis codes for second- or third-degree burns as a primary diagnosis and ICD–10–PCS code(s) for excision or extraction of skin or subcutaneous tissue and fascia including the presence of a replacement procedure. Please see Table 10.15.A.—NexoBrid™ Codes—FY 2024 associated with this proposed rule for the complete list of codes that the applicant indicated were included in its cost analysis. Using the inclusion/exclusion criteria described in the following table, the applicant identified 1,084 claims mapping to four MS–DRGs: 928 (Full Thickness Burn with Skin Graft or Inhalation Injury with CC/MCC), 929 (Full Thickness Burn with Skin Graft or Inhalation Injury without CC/MCC), 935 (Non-Extensive Burns), and 927 (Extensive Burns or Full Thickness Burns with MV >96 Hours with Skin Graft). The applicant calculated a final inflated average case-weighted standardized charge per case of $273,666, which exceeded the average case-weighted threshold amount of $154,855.

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 NexoBrid™ meets the cost criterion.

NEXOBRID™ COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR File
List of ICD-10-CM codes	Please see Table 10.15.A. - NexoBrid™ Codes – FY 2024 associated with this proposed rule for the complete list of ICD-10-CM codes provided by the applicant.
List of ICD-10-PCS codes	Please see Table 10.15.A. - NexoBrid™ Codes – FY 2024 associated with this proposed rule for the complete list of ICD-10-PCS codes provided by the applicant.
List of MS-DRGs	Scenario 1: Burn with Excision or Extraction without Grafting 935 (Non-Extensive Burns) 934 (Full Thickness Burns without Skin Graft or Inhalation Injury) 928 (Full Thickness Burns with Skin Graft or Inhalation Injury with CC/MCC) Scenario 2: Burn with Excision or Extraction and Grafting 927 (Extensive Burns or Full Thickness Burns with MV > 96 with Skin Graft) 928 (Non-Extensive Burns) 929 (Full Thickness Burns with Skin Graft or Inhalation Injury without CC/MCC) 935 (Non-Extensive Burns)
Inclusion/ exclusion criteria	The applicant selected claims with a principal diagnosis of second or third degree burn in combination with procedure codes for excision or extraction based on the codes listed in table 10.15.A- NexoBrid™ Codes - FY 2024 associated with this proposed rule. and created two subgroups from these cases based on the following: Scenario 1: Absence of a replacement procedure as listed in Table 10.15.A. - NexoBrid™ Codes - FY 2024 Scenario 2: Presence of a replacement procedure as listed in Table 10.15.A. - NexoBrid™ Codes - FY 2024 For both scenarios, the applicant excluded the following: • MS-DRGs with fewer than 11 cases. • Claims with ICD-10-PCS codes representing extracorporeal membrane oxygenation, respiratory ventilation, and bypass trachea (tracheotomy), as listed in Table 10.15.A. - NexoBrid™ Codes - FY 2024
Charges removed for prior technology	Scenario 1: The applicant removed 100% of charges associated with the operating room, as patients may be able to forgo surgery completely with the use of NexoBrid™, and 24.5% of charges associated with blood and blood products, as a conservative estimate of the impact of NexoBrid™ compared to the standard of care. Scenario 2: The applicant removed 20% of charges associated with the operating room, as an estimate of the percentage operating room time needed for autografting (the applicant removed a smaller amount of operating room charges for this scenario as patients would still need significant operating room time for autografting), and 24.5% of charges associated with blood and blood products, as a conservative estimate of the impact of NexoBrid™ compared to the standard of care.
Standardized charges	The applicant used the standardization formula provided in the 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 final rule.
Charges added for the new technology	The applicant determined the cost per patient based upon the average NexoBrid™-treated area from the applicant's Phase 3 clinical study (DETECT). The applicant found that the average U.S. patient in the study had approximately 7% TBSA treated with NexoBrid™, or about 14 grams of the product. The applicant stated that approximately 2.8 5-gram packs of NexoBrid™ would be required to treat 7% TBSA. The applicant added charges for the new technology by dividing the cost of the new technology by the national average cost-to-charge ratio for drugs (0.184) from the FY 2023 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

We are inviting public comments on whether NexoBrid™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that NexoBrid™ represents a substantial clinical improvement over existing technologies because it is associated with reduced time to complete eschar removal, prevented burn depth conversion, reduced overall surgical burden, reduced blood loss, and reduced incidence of autografting. The applicant asserted that for these reasons NexoBrid™ is a treatment option for a patient population unresponsive to, or ineligible for, currently available enzymatic and surgical eschar removal treatments; also, it offers the ability to diagnose burn wound depth earlier than allowed by currently available methods and significantly improves clinical outcomes relative to traditional surgical debridement. The applicant provided 10 studies to support these claims, as well as one background article about the

importance of donor site morbidity.[66]

[66] Background articles are not included in the following table but can be accessed via the online posting for the technology.

The following table summarizes the applicant's assertions regarding substantial clinical improvement. Please see the online posting for NexoBrid™ 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**
NexoBrid™ provides a non-surgical option for faster, effective eschar removal	Schulz, A., Fuchs, P.C., Rothermundt, I., Hoffmann, A., Rosenberg, L., Shoham, Y., Oberländer, H., & Schiefer, J. (2017). Enzymatic debridement of deeply burned faces: Healing and early scarring based on tissue preservation compared to traditional surgical debridement. *Burns*, 43(6), 1233-1243. https://doi.org/10.1016/j.burns.2017.02.016 Brief study description: Case control study of 13 patients with partial thickness and deep dermal facial burns treated with NexoBrid™ (compared to 13 excisional debridement patients from database).	NexoBrid enabled selective and efficient dissolution of burn eschar in a single use. Burn-induced compartmental pressures and time to complete debridement were also reduced. This current study indicates that NexoBrid use for severely burned hands offers a selective, rapid, and safe method of burn eschar removal that is superior to the accepted standard of traditional surgical debridement (TSD). By comparison, burn depth evaluation was more precise, vital tissue was effectively preserved, and healing was with satisfactory early scars.
	Krieger, Y., Bogdanov-Berezovsky, A., Gurfinkel, R., Silberstein, E., Sagi, A., & Rosenberg, L. (2012). Efficacy of enzymatic debridement of deeply burned hands. *Burns*, 38(1), 108-12. https://doi.org/10.1016/j.burns.2011.06.002 Brief study description: Retrospective data collection and analysis from prospective, open-label study in 275 hospitalized, deep thickness, treated burn patients.	69 hand burns diagnosed as 'deep' were analyzed; 36% of the wounds required surgical intervention after enzymatic debridement; 28.6% of the total burned area estimated initially as deep was covered by skin graft (statistically significant $p < 0.001$). Debridement of deep-hand burns with a selective enzymatic agent decreased the perceived full-thickness wound area and skin-graft use. Difference between the expected and actual number of hands requiring surgery (69 vs. 25) was found to be statistically significant using a chi-square test ($p = 0.04$). Skin grafting performed on 25 burn wounds. The total grafted area was significantly smaller than estimated prior to selective debridement, resulting in lesser need for skin grafting. Overall, 28.6% of the burn area that was initially assessed as deep was autografted.
	Schulz, A., Perbix, W., Shoham, Y., Daali, S., Charalampaki, C., Fuchs, P. C., & Schiefer, J. (2017). Our initial learning curve in the enzymatic debridement of severely burned hands - Management and pit falls of initial treatments and our development of a post debridement wound treatment algorithm. *Burns*, 43(2), 326–336. https://doi.org/10.1016/j.burns.2016.08.009 Brief study description: Presents fundamental procedure and pitfalls facing an inexperienced user during NexoBrid debridement. Number of patients: 20. Study arms: All 20 patients received treatment.	Particularly in hands, intricate anatomical structures including nerves, vessels, tendons, and muscles are densely packed in limited space without a subdermal tissue. This complex structure is therefore very vulnerable and might be easily harmed by surgical debridement. Page 327 Paragraph 1: Following our modified treatment algorithm, we found handling of NexoBrid in deeply burned hands to be easy, fast, cost efficient, and safe without special knowledge in burn wound depth evaluation prior to required treatment. Promising results were evaluated regarding efficiency and selectivity of debridement, healing potential and early rehabilitation.
	Hirche, C., Citterio, A., Hoeksema, H., Koller, J., Lehner, M., Martinez, J.R., Monstrey, S., Murray, A., Plock, J.A., Sander, F., Schulz, A., Ziegler, B., & Kneser, U. (2017). Eschar removal by bromelain based enzymatic debridement (Nexobrid ®) in burns: An European consensus. *Burns*, 43(8), 1640-1653. https://doi.org/10.1016/j.burns.2017.07.025	This article reinforces NexoBrid™'s clinical value in burn care from surgeons who have developed experience (from treating over 500 adult and pediatric patients) with the product.

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**
	Brief study description: European burn surgeon consensus statement supporting the use cases for NexoBrid. Article emphasizes early eschar removal and NexoBrid™ use in delicate areas, such as the hands, feet, and face.	
	Schulz, A., Shoham, Y., Rosenberg, L., Rothermund, I., Perbix, W., Christian Fuchs, P., Lipensky, A., & Schiefer, J. L. (2016). Enzymatic Versus Traditional Surgical Debridement of Severely Burned Hands: A Comparison of Selectivity, Efficacy, Healing Time, and Three-Month Scar Quality. *Journal of Burn Care & Research*, 38(4), e745–e755. https://doi.org/10.1097/BCR.0000000000000478 Brief study description: Study to compare NexoBrid with traditional surgical debridement (TSD) of deep dermal and full-thickness hand burns. Number of patients: 40; Study arms: 1st 20 patients debrided surgically; other 20 patients were using NexoBrid.	Time of initial debridement (days after admission); Time to complete debridement after first surgery (days); More superficial than initially assessed; Number of surgeries until complete debridement; Escharotomies performed; Autografting; Spontaneous healing; Number of surgeries until complete wound closure; Time to complete healing after first debridement (days); Time to complete healing after admission (days). Outcomes: Significantly reduced time to complete debridement after admission (0.95 vs 7.750 days/P<.001) and treatments needed for complete debridement (1.05 vs 1.45/P<.001), improving burn depth evaluation; Number of wounds requiring autografting was certainly reduced (15% vs 95%/P=.034), as was time to complete healing after first debridement (23.30 vs 32.00 days/P<.001); Early scar quality after 3 months was nearly equivalent, only heightened local redness in NexoBrid group (P<.001) NexoBrid enabled selective and efficient dissolution of burn eschar in a single use. Burn-induced compartmental pressures and time to complete debridement were also reduced. This current study indicates that NexoBrid use for severely burned hands offers a selective, rapid, and safe method of burn eschar removal that is superior to the accepted standard of TSD. By comparison, burn depth evaluation was more precise, vital tissue was effectively preserved, and healing was with satisfactory early scars.
	Cordts, T., Horter, J., Vogelpohl, J., Kremer, T., Kneser, U., & Hernekamp, J-F. (2016). Enzymatic debridement for the treatment of severely burned upper extremities - early single center experiences. *BMC Dermatology*, 16(1), 8. https://doi.org/10.1186/s12895-016-0045-2 Brief study description: Single arm prospective study (N =16) using NexoBrid™ to treat burns of the hands and arms.	Standard of care (SOC) for deep partial- and full-thickness burns is neurectomy and skin grafting but, especially when conducted on hands and forearms, it is often associated with poor aesthetic and functional outcome. In combined partial- and full-thickness wounds, conventional surgical intervention may cause unnecessary tissue loss, since vital tissue might be unnecessarily removed. This can be detrimental for functional outcomes, especially when distal extremities with a thin, soft tissue envelope are treated. Fingers and hands have a complex anatomy; sparse tissue coverage; and present vessels, nerves and tendons confined to a very small space. Results indicate that autografted area was considerably reduced relative to initial assessment. Additionally, no patient in the study required an escharotomy (relative to the cited rate of ~10% in SOC).

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**
Substantial Clinical Improvement Assertion #2: 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.		
NexoBrid™ allows for depth-of-burn diagnoses of indeterminant depth and/or mixed depth wounds	Rosenberg, L., Krieger, Y., Bogdanov-Berezovski, A., Silberstein, E., Shoham, Y., & Singer, A. J. (2014). A novel rapid and selective enzymatic debridement agent for burn wound management: a multi-center randomized controlled trial (RCT). *Burns,* 40(3), 466–474. https://doi.org/10.1016/j.burns.2013.08.013 Brief study description: A multi-center, open-label, randomized, controlled clinical trial including patients aged 4-55 years with deep partial and full thickness burns covering 5- 30% of their total body surface area (TBSA). Patients were randomly assigned to burn debridement with NexoBrid (applied for 4 h) or SOC, which included surgical excisional or non-surgical debridement.	There was a reduced rate of autografting in NexoBrid-treated arm. Autograft rate was 17.9% in NexoBrid-treated arm vs. 34.1% in SOC-treated arm (p=0.0099).
	Giudice, G., Filoni, A., Maggio, G., Bonamonte, D., & Vestita, M. (2017). Cost Analysis of a Novel Enzymatic Debriding Agent for Management of Burn Wounds. *BioMed Research International*, 2017, 9567498. https://doi.org/10.1155/2017/9567498 Brief study description: Cost analysis study retrospectively including 20 patients with intermediate or intermediate-deep thermal burns involving a total body surface area (TBSA) between 14% and 22%. All patients were aged >18 years. Ten patients were treated with SOC, while the remaining 10 patients were treated with NexoBrid.	Several studies have shown that NexoBrid is a safe, effective, and selective method for early eschar removal, reducing the need for surgery while achieving long-term outcomes that are comparable to those of SOC…in particular…lower percentage of wounds needing surgical debridement.
	Palao, R., Aguilera-Sáez, J., Serracanta, J., Collado, J.M., Santos, B.P., & Barret, J.P. (2017). Use of a selective enzymatic debridement agent (Nexobrid®) for wound management: Learning curve. *World Journal of Dermatology, 6*(2), 32-41. https://doi.org/10.5314/wjd.v6.i2.32 Brief study description: Evaluating the efficacy of Nexobrid® in the initial management of burns and lessons learned with the procedure. 25 patients aged between 18-94 years old with deep partial and full thickness burns were treated with Nexobrid® covering 1%-30% of their total body surface area (TBSA).	None of the 25 patients that we debrided with [NexoBrid] required surgical escharotomy.
Substantial Clinical Improvement Assertion #3: The technology significantly improves clinical outcomes relative to services or technologies previously available.		
NexoBrid™ eschar removal is	Schulz, A., Fuchs, P.C., Rothermundt, I., Hoffmann, A., Rosenberg, L., Shoham, Y.,	Scar quality after enzymatic debridement was superior compared to surgical debridement after

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**
associated with improved scar outcomes in comparison to the standard of care	Oberländer, H., & Schiefer, J. (2017). Enzymatic debridement of deeply burned faces: Healing and early scarring based on tissue preservation compared to traditional surgical debridement. *Burns*, 43(6), 1233-1243. https://doi.org/10.1016/j.burns.2017.02.016 See prior study description	12 months regarding pigmentation (p=.016), thickness (p=.16) and scar irregularity (p=.011)
	Schulz, A., Shoham, Y., Rosenberg, L., Rothermund, I., Perbix, W., Christian Fuchs, P., Lipensky, A., & Schiefer, J. L. (2016). Enzymatic Versus Traditional Surgical Debridement of Severely Burned Hands: A Comparison of Selectivity, Efficacy, Healing Time, and Three-Month Scar Quality. *Journal of Burn Care & Research,* 38(4), e745–e755. https://doi.org/10.1097/BCR.0000000000000478 See prior study description	Early scar quality after 3 months was nearly equivalent, with only heightened local redness in the NexoBrid™ treatment group (p<.001).
	Corrales-Benitez, C., Martinez-Mendez, J.R., Gonzalez-Miranda, A., Serrano-Alonso, M., & Casado-Perez, C. (2016). Reduced need for grafting and low incidence of hypertrophic scarring in burns after enzymatic debridement. *Journal of Plastic Surgery-Latin America,* 42(4), 339-346. http://dx.doi.org/10.4321/S0376-78922016000400005 Brief study description: Retrospective study evaluating the results of 36 patients treated with NexoBrid in one burn unit with the use of NexoBrid in mixed and deep dermal burns, assessing the ability to re-epithelialization after NexoBrid application, the graft rate in the treated patients, and the appearance of hypertrophic scarring.	In 32 of the 36 patients (88.9%), enzymatic debridement allowed complete removal of the eschar, while in 4 patients (11.1%), the number 12, 13, 15 and 28 of Table I, debridement was incomplete and required surgical debridement (Table II). In the 36 patients studied, the presence of deep burns suggested the need for surgery for debridement and coverage with grafts. After enzymatic debridement, only 13 patients (36.1%) required graft coverage (Table I). The reduction in the need for coverage with grafts compared to what was expected, it was shown to be significant: 36.1% versus 100% p<0.001 with 95% confidence interval (CI) (0.21-0.54). The reduction of the grafted surface was shown to be significant (p<0.001) (Graph 3). In the 13 patients who required grafting, the TBSA deep was 12.33% (SD 12.87%), but nevertheless the grafted deep TBSA was only 10.25% (DS 12.99%). The differences found in this group were also significant (p=0.027) (Graph 4). Only 4 of the 36 patients (11.1%), number 8, 12, 13 and 15 of Table I, developed hypertrophy in the area of the wound (Tables I and II). Keloid scarring appeared in none of them. All those who developed hypertrophic scarring had burns of at least the 13% TBSA. The use of NexoBrid® allows for complete enzymatic debridement of mixed and dermal burns deep in one setting. It is an effective alternative to standard debridement, reducing the percentage of patients requiring the use of autografts for definitive coverage. This approach

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**
		significantly reduces the grafted area, with a low rate of hypertrophic scarring.
NexoBrid™ reduces surgical burden associated with surgical excision, thereby reducing adverse events associated with surgery and general anesthesia	Rosenberg, L., Krieger, Y., Bogdanov-Berezovski, A., Silberstein, E., Shoham, Y., & Singer, A. J. (2014). A novel rapid and selective enzymatic debridement agent for burn wound management: a multi-center RCT. *Burns,* 40(3), 466–474. https://doi.org/10.1016/j.burns.2013.08.013 See prior study description	NexoBrid decreased the percentage of wounds requiring surgical excision compared to the SOC (24.5% vs 70%, p <.0001). NexoBrid also decreased the percentage burn area surgically excised (13.1% vs 56.7%; p<.0001) compared with SOC.
	Giudice, G., Filoni, A., Maggio, G., Bonamonte, D., & Vestita, M. (2017). Cost Analysis of a Novel Enzymatic Debriding Agent for Management of Burn Wounds. *BioMed Research International*, 2017, 9567498. https://doi.org/10.1155/2017/9567498 See prior study description	Several…studies have shown that NexoBrid is a safe, effective, and selective method for early eschar removal, reducing the need for surgery while achieving long-term outcomes that are comparable to those of SOC…in particular…lower percentage of wounds needing surgical debridement.
	Palao, R., Aguilera-Sáez, J., Serracanta, J., Collado, J.M., Santos, B.P., & Barret, J.P. (2017). Use of a selective enzymatic debridement agent (Nexobrid®) for wound management: Learning curve. World Journal of Dermatology, 6(2), 32-41. https://doi.org/10.5314/wjd.v6.i2.32 See prior study description	None of the 25 patients that we debrided with NexoBrid required surgical escharotomy.
NexoBrid™ reduces blood loss related to eschar removal	Rosenberg, L., Krieger, Y., Bogdanov-Berezovski, A., Silberstein, E., Shoham, Y., & Singer, A. J. (2014). A novel rapid and selective enzymatic debridement agent for burn wound management: a multi-center RCT. Burns, 40(3), 466–474. https://doi.org/10.1016/j.burns.2013.08.013 See prior study description	Blood loss, as measured by a reduction in hematocrit or hemoglobin concentrations before versus after initiating eschar removal, was also significantly reduced in NexoBrid-treated patients compared with those treated with the standard of care.
NexoBrid™ treatment reduces the need for autografting	Rosenberg, L., Krieger, Y., Bogdanov-Berezovski, A., Silberstein, E., Shoham, Y., & Singer, A. J. (2014). A novel rapid and selective enzymatic debridement agent for burn wound management: a multi-center RCT. Burns, 40(3), 466–474. https://doi.org/10.1016/j.burns.2013.08.013 See prior study description	"The need for autografting and total area grafted in deep partial thickness wounds were significantly lower in NexoBrid treated wounds" There was a lower rate of autografting in NexoBrid-treated arm: Autograft rate was 17.9% in NexoBrid-treated arm vs. 34.1% in SOC-treated arm (p=0.0099). Additionally, % of wound autografted lower in NexoBrid-treated arm: 8.4% vs. 21.5% (p=0.0054)
	Palao, R., Aguilera-Sáez, J., Serracanta, J., Collado, J.M., Santos, B.P., & Barret, J.P. (2017). Use of a selective enzymatic debridement agent (Nexobrid®) for wound management: Learning curve. World Journal of Dermatology, 6(2), 32-41. https://doi.org/10.5314/wjd.v6.i2.32 See prior study description	Fifteen of the twenty-five NexoBrid-treated patients required autografting, whereas if SOC treatment was used authors would have anticipated all patients receiving autograft.
	Schulz, A., Shoham, Y., Rosenberg, L., Rothermund, I., Perbix, W., Christian Fuchs, P.,	Results indicate a reduced need for autografting with NexoBrid, with 15% of NexoBrid-treated

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**
	Lipensky, A., & Schiefer, J. L. (2016). Enzymatic Versus Traditional Surgical Debridement of Severely Burned Hands: A Comparison of Selectivity, Efficacy, Healing Time, and Three-Month Scar Quality. Journal of Burn Care & Research, 38(4), e745–e755. https://doi.org/10.1097/BCR.0000000000000478 See prior study description	and 95% of SOC-treated patients required autografting (p=0.034).
	Schulz, A., Fuchs, P.C., Rothermundt, I., Hoffmann, A., Rosenberg, L., Shoham, Y., Oberländer, H., & Schiefer, J. (2017). Enzymatic debridement of deeply burned faces: Healing and early scarring based on tissue preservation compared to traditional surgical debridement. Burns, 43(6), 1233-1243. https://doi.org/10.1016/j.burns.2017.02.016 See prior study description	In a study of facial burns, debridement and healing results following NexoBrid and surgical debridement, NexoBrid enzymatic debridement led to an autografting rate of 15% (.376 standard deviation) compared to traditional surgical debridement which had a 77% rate of autografting (.439 SD). Reduced need for autografting with NexoBrid, 15% of NexoBrid-treated and 77% of SOC-treated patients required autografting (p=-0.002).

After review of the information provided by the applicant, we have the following concerns regarding whether NexoBrid™ meets the substantial clinical improvement criterion. As discussed in the FY 2022 IPPS/LTCH PPS proposed rule, we note the applicant's claims of superiority of NexoBrid™ to standard of care debridement methods are non-specific because the studies cited were not designed to compare NexoBrid™ to a specific non-surgical method or an enzymatic debridement product. In addition, we are unclear whether comparing NexoBrid™ to a surgical treatment modality is the most appropriate comparator since mechanical means of debridement have different clinical indications, risks, and benefits compared to enzymatic debridement. As discussed in the FY 2022 IPPS/LTCH PPS proposed rule, we also note studies did not demonstrate that NexoBrid™ selectively debrides eschar and does not injure viable skin. In addition, it may be difficult to generalize across studies of NexoBrid™ because the wound care and timing of the debridement and subsequent autografting varies across different burn centers and studies. Finally, we note that a review of the provided NexoBrid™ studies observed that when compared to the standard of care, there were variable reports of the cosmetic outcome of NexoBrid™,[67] [68] prolonged wound closure, longer lengths of stay,[69] and significant pain associated with NexoBrid™ eschar debridement.[70]

We are inviting public comments on whether NexoBrid™ meets the substantial clinical improvement criterion. In this section, we summarize and respond to written public comments received in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for NexoBrid™.

Comment: The applicant submitted a comment responding to questions raised at the Town Hall meeting. In response to a question regarding that availability of studies comparing NexoBrid™ to collagenase ointment (Santyl®), the applicant stated that no study currently exists comparing the two. The DETECT NexoBrid™ clinical trial included collagenase ointment in its standard of care treatment arm, but the data were not stratified in publications since the study was not powered to conduct this analysis. The applicant further stated that NexoBrid™ and collagenase ointment have different usage cases. Specifically, collagenase ointment is used primarily for wound care and is typically applied once or more daily for several days and requires days to weeks to effectively treat thermal burns. The applicant stated, in contrast, that NexoBrid™ is intended to be used only once to completely remove eschar from deep partial and/or full thickness thermal burn wounds. According to the applicant, in burn patient treatment, it is not advisable to compare NexoBrid™ and collagenase ointment. The applicant also asserted that NexoBrid™ has a novel mechanism of action and is the first enzymatic agent to have demonstrated rapid, consistent eschar removal. Currently, there is no technology or product similar to NexoBrid™ for eschar removal.

The applicant provided an additional study that leveraged a porcine burn wound model to compare NexoBrid™ and collagenase ointment. In the study, all FT burns that randomly received NexoBrid™ experienced complete eschar removal after a single application, while none of the collagenase-treated FT wounds experienced complete eschar removal after 14 days with one daily treatment. During the study, all NexoBrid™-treated DPT wounds also experienced complete eschar removal after a single

[67] Schulz, A., Shoham, Y., Rosenberg, L., Rothermund, I., Perbix, W., Christian Fuchs, P., Lipensky, A., & Schiefer, J. L. (2016). Enzymatic Versus Traditional Surgical Debridement of Severely Burned Hands: A Comparison of Selectivity, Efficacy, Healing Time, and Three-Month Scar Quality. Journal of Burn Care & Research, 38(4), e745–e755.

[68] Schulz, A., Fuchs, P.C., Rothermundt, I., Hoffmann, A., Rosenberg, L., Shoham, Y., Oberländer, H., & Schiefer, J. (2017). Enzymatic debridement of deeply burned faces: Healing and early scarring based on tissue preservation compared to traditional surgical debridement. Burns, 43(6), 1233–1243.

[69] Rosenberg, L., Krieger, Y., Bogdanov-Berezovski, A., Silberstein, E., Shoham, Y., & Singer, A. J. (2014). A novel rapid and selective enzymatic debridement agent for burn wound management: a multi-center RCT. Burns, 40(3), 466–474. *https://doi.org/10.1016/j.burns.2013.08.013.*

[70] Palao, R., Aguilera-Sáez, J., Serracanta, J., Collado, J.M., Santos, B.P., & Barret, J.P. (2017). Use of a selective enzymatic debridement agent (Nexobrid®) for wound management: Learning curve. World Journal of Dermatology, 6(2), 32–41.

application. None of the collagenase-treated DPT wounds experienced complete removal of eschar after 10 days of treatment; on day 14, 35% had complete eschar removal, 30% had >50% eschar removed, and 35% had <50% eschar removed.

Response: We thank the applicant for its comments and will take this information into consideration when deciding whether to approve new technology add-on payments for NexoBrid™.

i. Omidubicel

Gamida Cell, Inc. submitted an application for new technology add-on payments for omidubicel for FY 2024. Per the applicant, omidubicel is a one-time, patient-specific, cryopreserved allogeneic advanced cellular therapy consisting of two cell fractions: a cultured fraction (CF) and a non-cultured fraction (NF) which are both derived from the same patient-specific cord blood unit. According to the applicant, the CF consists of allogeneic, hematopoietic CD34+ progenitor cells that are expanded and enhanced through a proprietary process in the presence of cytokines and nicotinamide (NAM) technology used to inhibit differentiation of the hematopoietic progenitor cells, CD34+ cells and to increase the migration, bone marrow homing and engraftment efficiency of the hematopoietic progenitor cells (HPCs). The NF consists of allogeneic, hematopoietic mature myeloid and lymphoid cells that are washed, formulated into a suspension, and cryopreserved in a patient specific infusion bag. The resulting number of CD34+ HPCs in omidubicel and their functional fitness may lead to the long-term engraftment efficacy and rapid and broad immune reconstitution post-transplant. According to the applicant, NAM preserves the function and long-term engraftment ability of cord blood-derived stem cells and may lead to favorable engraftment and patient outcomes.

Please refer to the online application posting for omidubicel available at *https://mearis.cms.gov/public/publications/ntap/NTP2210100TN9R*, for additional detail describing the technology and its proposed uses.

With respect to the newness criterion, the applicant stated it has not yet received FDA marketing authorization for omidubicel. According to the applicant, it anticipates BLA approval from FDA for the treatment of patients with hematologic malignancies in need of a hematopoietic stem cell transplant before July 1, 2023. The applicant noted that a single dose of omidubicel consists of two separate components: the CF and the NF suspended in Dimethyl sulfoxide (DMSO) and supplied separately in two cryopreserved bags. CF must be administered first and contains a minimum of $8.0x10^8$ total viable cells with a minimum of 8.7% CD34+ cells and a minimum of $9.2x10^7$ CD34+ cells. NF contains a minimum of $4.0x10^8$ total viable cells with a minimum of $2.4x10^7$ CD3+ cells.

The applicant stated that effective October 1, 2022, the following ICD–10–PCS codes may be used to uniquely describe the transfusion of omidubicel: XW143C8 (Transfuse omidubicel in central vein, perc, new tech 8) and XW133C8 (Transfuse omidubicel in periph vein, perc, new tech 8). The applicant provided a list of diagnosis codes that may be used to currently identify the indication for omidubicel 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 asserted that omidubicel is not substantially similar to other currently available technologies because it does not use the same or similar mechanism of action as existing technology and when approved, it will be the first and only patient-specific advanced cell therapy for use as an allogeneic stem cell donor source, 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 omidubicel for the applicant's complete statements in support of its assertion that omidubicel 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	Omidubicel is not the same or similar mechanism of action as any currently available unrelated donor source and included in the 2021 100% Medicare Provider Analysis and Review (MedPAR) Limited Data Set. Upon FDA approval, omidubicel will be the first and only FDA-approved patient-specific advanced cellular therapy donor source used for allogeneic hematopoietic cell transplantation (HCT) in the treatment of patients with hematologic malignancies. Gamida Cell's pioneering, proprietary NAM technology platform has produced a cellular therapy based on ex vivo manipulation of hematopoietic progenitor cells with NAM in combination with cytokines: 1) NAM causes metabolic reprogramming, allowing for cell proliferation while preserving stemness and improved in vivo engraftment; 2) NAM downregulates gene expression pathways involved in the proliferation and differentiation of stem cells and upregulates gene expression pathways that preserve stemness; 3) The modulation of certain gene expression pathways, collectively, result in an environment that uniquely mimics the bone marrow niche during ex vivo manipulation of hematopoietic stem cells. Omidubicel contains stem cells capable of repopulating the bone marrow and effecting hematopoiesis and immune recovery after conditioning therapy. Importantly, omidubicel was designed and its mechanism of action has been demonstrated to enable the administration of stem cells. Omidubicel, using the proprietary NAM technology, is highly differentiated from allogeneic HCT using an unmanipulated cord blood donor source. The NAM technology allows for the improved quality of stem cells, that is, ability to home to the bone marrow niche and enhance repopulation potential, and the expansion of the numbers of stem cells available for transplantation from a single umbilical cord blood unit. As reported by Horwitz et al. 2014, the NAM technology increases the CD34 content of the starting materials by 33-fold compared to the cell content reported by the cord blood bank before cryopreservation and expansion. As will be shown in the Clinical Criterion section of this application, omidubicel improves time to hematopoietic recovery and immunologic recovery, reduces the rate of infections and toxicities, and decreases the length of hospitalization when compared to an unmanipulated cord blood HCT cohort. Omidubicel, using the proprietary NAM technology, will allow for the transplantation of partially HLA-matched NAM-manipulated stem cells for a broader population, including underserved minorities, and there is scientific rationale that patient outcomes will be improved. As noted earlier in this section, it is expected that, upon FDA approval, omidubicel will be the first and only patient-specific advanced cellular therapy for use as an allogeneic stem cell donor source for the treatment of patients with hematologic malignancies who are in need of an allogeneic HCT.
Is the technology assigned to the same MS-DRG as existing technologies?	No	Omidubicel will not be replacing any existing technology as there are no other FDA-approved cellular therapies for use as allogeneic HCT donor sources. Omidubicel is mapped to MS-DRG 014 (Allogeneic Bone Marrow Transplant), as are all allogeneic HCT procedure codes, along with their corresponding donor sources.
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	Omidubicel will be indicated for the treatment of patients with hematologic malignancies who are in need of allogeneic HCT. Omidubicel, once FDA approved, will provide reliable access to potentially curative, allogeneic HCT for patients with serious life-threatening hematologic malignancies, especially currently underserved racial and ethnic minorities.

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However, we have the following concerns with regard to the newness criterion. While the applicant has discussed how omidubicel is produced, we are unclear how the mechanism of action for omidubicel is different than standard HSCT. Although the applicant noted that omidubicel increases the CD34+ content compared to what is reported by the cord blood bank before cryopreservation and expansion, we question whether this relates to mechanism of action and not just development of the technology. We would appreciate additional information regarding how the mechanism of action for omidubicel differs from that of standard of care HSCT. In addition, we note that the applicant asserted that omidubicel is not assigned to the same MS–DRG as existing technologies, but also stated that it is assigned to the same MS–DRG as all allogeneic HCT procedures. We are inviting public comments on whether omidubicel is substantially

similar to existing technologies and whether omidubicel meets the newness criterion.

With respect to the cost criterion, the applicant provided a primary analysis and two sensitivity analyses to demonstrate that it meets the cost criterion. For each analysis, the applicant searched the FY 2021 MedPAR file using the same ICD–10–CM codes, with or without the addition of ICD–10–PCS codes, to identify potential cases representing patients who may be eligible for omidubicel. The applicant noted that it used the pharmacy cost center cost-to-charge ratio (CCR) to determine the potential charges for the technology in all three analyses and duplicated each analysis using a CAR T-cell CCR to determine the potential charges for the technology. See the following table for an explanation of how the CAR T-cell CCR was calculated.

We note that the applicant used the MS–DRG 018 [Chimeric Antigen Receptor (CAR) T-cell and other Immunotherapies] threshold for the cost criterion analyses rather than the threshold for MS–DRG 014 in its analyses. However, we note that the technology maps to MS–DRG 014 and the applicant has not made a formal request to map to a different MS–DRG. Therefore, we are substituting the threshold of MS–DRG 014 for all the analyses that follow rather than using the threshold of MS–DRG 018. Each analysis followed the order of operations described in the following table.

For the first analysis, in identifying the primary cohort, the applicant identified cases reporting a principal or secondary ICD–10–CM diagnosis code for blood cancer in MS–DRG 014. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 587 claims mapping to MS–DRG 014. The applicant used the pharmacy cost center CCR of 0.184 to determine the charges for the technology. The applicant calculated a final inflated average case-weighted standardized charge per case of $2,133,899 which exceeded the MS–DRG 014 threshold of $296,086. The applicant duplicated this analysis using the same steps noted previously but instead used a CAR T-cell CCR of 0.2788. The applicant calculated a final inflated average case-weighted standardized charge per case of $1,533,304 which exceeded the MS–DRG 014 threshold of $296,086.

For the second analysis, the applicant identified cases reporting a principal or secondary ICD–10–CM diagnosis code for blood cancer in MS–DRG 014 in combination with ICD–10–PCS codes for patients treated using an unrelated blood donor source. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 314 claims mapping to MS–DRG 014. The applicant calculated a final inflated average case-weighted standardized charge per case of $2,111,904 which exceeded the MS–DRG 014 threshold of $296,086. The applicant duplicated this analysis using the same steps noted previously but instead used a CAR T-cell CCR of 0.2788. The applicant calculated a final inflated average case-weighted standardized charge per case of $1,511,309 which exceeded the MS–DRG 014 threshold of $296,086.

For the third analysis, the applicant identified cases reporting a principal or secondary ICD–10–CM diagnosis code for blood cancer in MS–DRG 014 in combination with ICD–10–PCS codes for patients using a cord blood donor source. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 17 claims mapping to MS–DRG 014. The applicant calculated a final inflated average case-weighted standardized charge per case of $2,384,695 which exceeded the MS–DRG 014 threshold of $296,086. The applicant duplicated this analysis using the same steps noted previously but instead used a CAR T-cell CCR of 0.2788. The applicant calculated a final inflated average case-weighted standardized charge per case of $1,784,100 which exceeded the MS–DRG 014 threshold of $296,086.

Because the final inflated average case-weighted standardized charge per case exceeded the MS–DRG 014 threshold in all scenarios, the applicant asserted that omidubicel meets the cost criterion.

OMIDUBICEL COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of ICD-10-CM codes	C81.xx Hodgkin lymphoma C82.xx Follicular lymphoma C83.xx Non-follicular lymphoma C84.xx Mature T/NK-cell lymphomas C85.xx Other specified and unspecified types of non-Hodgkin lymphoma C86.xx Other specified types of T/NK-cell lymphoma C88.xx Malignant immunoproliferative diseases and certain other B-cell lymphomas C90.xx Multiple myeloma and malignant plasma cell neoplasms C91.xx Lymphoid leukemia C92.xx Myeloid leukemia C93.xx Monocytic leukemia C94.xx Other leukemias of specified cell type C95.xx Leukemia of unspecified cell type C96.xx Other and unspecified malignant neoplasms of lymphoid, hematopoietic and related tissue
List of ICD-10-PCS codes	Scenario 2: 30230G3 Transfusion of Allogeneic Unrelated Bone Marrow into Peripheral Vein, Open Approach 30230U3 Transfusion of Allogeneic Unrelated T-cell Depleted Hematopoietic Stem Cells into Peripheral Vein, Open Approach 30230X3 Transfusion of Allogeneic Unrelated Cord Blood Stem Cells into Peripheral Vein, Open Approach 30230Y3 Transfusion of Allogeneic Unrelated Hematopoietic Stem Cells into Peripheral Vein, Open Approach 30233G3 Transfusion of Allogeneic Unrelated Bone Marrow into Peripheral Vein, Percutaneous Approach 30233U3 Transfusion of Allogeneic Unrelated T-cell Depleted Hematopoietic Stem Cells into Peripheral Vein, Percutaneous Approach 30233X3 Transfusion of Allogeneic Unrelated Cord Blood Stem Cells into Peripheral Vein, Percutaneous Approach 30233Y3 Transfusion of Allogeneic Unrelated Hematopoietic Stem Cells into Peripheral Vein, Percutaneous Approach 30240G3 Transfusion of Allogeneic Unrelated Bone Marrow into Central Vein, Open Approach 30240U3 Transfusion of Allogeneic Unrelated T-cell Depleted Hematopoietic Stem Cells into Central Vein, Open Approach 30240X3 Transfusion of Allogeneic Unrelated Cord Blood Stem Cells into Central Vein, Open Approach 30240Y3 Transfusion of Allogeneic Unrelated Hematopoietic Stem Cells into Central Vein, Open Approach 30243G3 Transfusion of Allogeneic Unrelated Bone Marrow into Central Vein, Percutaneous Approach 30243U3 Transfusion of Allogeneic Unrelated T-cell Depleted Hematopoietic Stem Cells into Central Vein, Percutaneous Approach 30243X3 Transfusion of Allogeneic Unrelated Cord Blood Stem Cells into Central Vein, Percutaneous Approach 30243Y3 Transfusion of Allogeneic Unrelated Hematopoietic Stem Cells into Central Vein, Percutaneous Approach Scenario 3: 30230X2 Transfusion of Allogeneic Related Cord Blood Stem Cells into Peripheral Vein, Open Approach 30230X3 Transfusion of Allogeneic Unrelated Cord Blood Stem Cells into Peripheral Vein, Open Approach 30230X4 Transfusion of Allogeneic Unspecified Cord Blood Stem Cells into Peripheral Vein, Open Approach 30233X2 Transfusion of Allogeneic Related Cord Blood Stem Cells into Peripheral Vein, Percutaneous Approach 30233X3 Transfusion of Allogeneic Unrelated Cord Blood Stem Cells into Peripheral Vein, Percutaneous Approach 30233X4 Transfusion of Allogeneic Unspecified Cord Blood Stem Cells into Peripheral Vein, Percutaneous Approach 30240X2 Transfusion of Allogeneic Related Cord Blood Stem Cells into Central Vein, Open Approach 30240X3 Transfusion of Allogeneic Unrelated Cord Blood Stem Cells into Central Vein, Open Approach 30240X4 Transfusion of Allogeneic Unspecified Cord Blood Stem Cells into Central Vein, Open Approach 30243X2 Transfusion of Allogeneic Related Cord Blood Stem Cells into Central Vein, Percutaneous Approach 30243X3 Transfusion of Allogeneic Unrelated Cord Blood Stem Cells into Central Vein, Percutaneous Approach 30243X4 Transfusion of Allogeneic Unspecified Cord Blood Stem Cells into Central Vein, Percutaneous Approach
List of MS-DRGs	MS-DRG 014 (Allogeneic Bone Marrow Transplant)

OMIDUBICEL COST ANALYSIS	
Inclusion/exclusion criteria	Scenario 1 (primary cohort): The applicant identified cases of blood cancer in MS-DRG 014 with a principal or secondary ICD-10-CM diagnosis code listed in this table. Scenario 2: The applicant identified cases with a principal or secondary ICD-10-CM diagnosis code of blood cancer in MS-DRG 014 in combination with ICD-10-PCS codes listed in this table associated with this proposed rule for cases that were treated using an unrelated blood donor source. Scenario 3: The applicant identified cases with a principal or secondary ICD-10-CM diagnosis code of blood cancer in MS-DRG 014 in combination with ICD-10-PCS codes listed in this table associated with this proposed rule for cases that were treated using a cord blood donor source. The applicant excluded claims with the following: • Missing MS-DRG • Missing or zero covered days or charges • Patients under 25 years old • Claims where Medicare is not the primary payer • Claims from non-IPPS hospitals • Claims for Medicare Advantage enrollees • Claims that were part of clinical trials
Charges removed for prior technology	The applicant removed donor search and hematopoietic stem cell acquisition charges under revenue code 0815 (Allogeneic Stem Cell Acquisition/Donor Services) because the applicant stated that omidubicel cellular therapy donor source will be used for allogeneic stem cell transplant in the treatment of cancer patients. 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 final rule.
Inflation factor	The applicant applied an inflation factor of 13.22% 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 used the pharmacy cost center CCR of 0.184 to determine the potential estimated charges for the technology in all three analyses. The applicant duplicated the analysis for all three of the analyses by using a CAR T-cell CCR to determine the potential charges for the technology. The applicant calculated this CAR T-cell CCR based on the following three steps: Step 1) Obtained total drug charges for cases in MS-DRG 018 from the FY 2023 IPPS Final Rule After Outliers Removed/Before Outliers Removed (AOR/BOR) file from worksheet "AORv40"; Step 2) Divided total drug charges by the number of cases (398) reported in the AOR/BOR file to get an average drug charge per case $1,381,951 ($550,016,463 / 398); Step 3) Calculated a CAR T-cell CCR by dividing the estimate average WAC for CAR T-cell therapies by the average charge per case (0.2788 = $385,276 / $1,381,951). The applicant noted it would update the costs for the technology above upon FDA approval.

We are inviting public comments on whether omidubicel meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that omidubicel represents a substantial clinical improvement over existing technologies because the totality of the data (up to 10-year follow-up) powers the evidence that omidubicel, which would be the first patient-specific advanced cellular therapy donor source, meets a high unmet treatment need for a diverse group of patients with serious, life-threatening hematologic malignancies and provides high quality stem cells, clinically meaningful and highly statistically significant clinical improvement, lower healthcare resource utilization, with an overall favorable benefit/risk profile. The applicant provided 13 data submissions to support these claims, as well as 16 background articles about omidubicel.[71] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for omidubicel for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

[71] 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**
Omidubicel as an allogeneic donor source addresses key barriers to the widespread use of UCB as a donor source, including limited or inadequate cell dose for adults and adolescents	Horwitz ME, et al. Umbilical cord blood expansion with nicotinamide provides long-term multilineage engraftment. J Clin Invest 2014; 124:3121-8, Brief study description: Published, results of a phase 1 omidubicel trial of 11 patients.	The authors reviewed the literature to characterize the outcomes in adult recipients of umbilical cord blood (UCB) transplantation. Delayed hematopoietic and immunologic recovery, graft failure, and graft versus host disease (GvHD) all contribute to transplant-related mortality in adult recipients of UCB transplantation. Cell dose and human leukocyte antigen (HLA) matching are critical determinants of a successful outcome. For patients without a single UCB unit with adequate cell dose, dual UCB transplantation is an acceptable alternative. Yet, the problem of delayed hematopoietic recovery persists, leading to longer hospitalization and increased resource utilization.
	Szabolcs P, et al. Hematopoietic stem cell transplantation (HSCT) with omidubicel is associated with enhanced circulatory plasmacytoid dendritic cells (pDC), NK cells and CD4+ cells with lower rates of severe infections compared to standard umbilical cord blood transplantation. Slides presented at Transplantation & Cellular Therapy (TCT) Meetings of the American Society for Transplantation and Cellular Therapy (ASTCT) and Center for International Blood and Marrow Transplant Research (CIBMTR), April 2022. Abstract published Transplantation & Cellular Therapy. 2022;28(3, Supplement):S4-5 Brief study description: Slides for oral presentation of an immune reconstitution substudy of 37 patients from a phase 3 omidubicel trial.	The authors presented an immune reconstitution substudy where it was found that omidubicel using nicotinamide (NAM) technology delivers a full completement of $CD34^+$ progenitor cells and immune cells: 1) preserves the multipotency of progenitor cells for long-term repopulation, while increasing cell quantity for transplantation and 2) preserves stem cell function to optimize homing, engraftment, and differentiation. Finally, these results demonstrate rapid and functional reconstitution of T and B cell subsets following transplant and functional reconstitution following transplant with omidubicel, which provides mechanistic support for the lower rates of severe infection observed in omidubicel-treated patients as compared with UCB transplantation - Grade 2/3 infections over 65 days, n (%): bacterial infections – omidubicel 7 (41); UCB 14 (70), p 0.037; viral infections – omidubicel 1 (6); UCB 9 (45), p=0.010.
	Yackoubov D, et al. Nicotinamide (NAM) modulates transcriptional signature of ex vivo cultured UCB CD34+ cells (omidubicel) and preserves their stemness and engraftment potential. Abstract 3718/Poster.	The authors characterized the proprietary NAM-based mechanism of action of omidubicel and concluded that NAM is unique in mimicking the bone marrow niche during *ex vivo* expansion of hematopoietic stem cells (HSCs) and causes metabolic reprogramming, allowing for cell proliferation while preserving stemness and improved *in vivo* engraftment. Uniquely, NAM up-

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**
	Brief study description: American Society of Hematology (ASH) 2019, poster of results from a phase 1/2 omidubicel trial.	regulates key transcription factors (TFs) response for stem cell renewal and DNA repair while TFs that activate cell differentiation, inflammation and apoptosis are down-regulated. The authors concluded that the gene expression data reinforce the mechanism of action underlying the NAM-based technology of omidubicel and provides additional insights into the pathways leading to clinically significant engraftment of omidubicel in patients.
	Horwitz ME, et al. Phase I/II study of stem-cell transplantation using a single cord blood unit expanded ex vivo with nicotinamide. J Clin Oncol 2019; 37:367-74 Brief study description: Published results of a phase 1/2 omidubicel trial of 36 patients.	Positive results established the feasibility, safety and efficacy of omidubicel as a standalone allogeneic transplant with clinically meaningful benefits over UCB as a standalone transplant. After utilization of the proprietary NAM technology, the CD34 content increased by 33-fold to a median 4.5 x 108 (range, 1.6 to 13.1 x 108) CD34+ cells. Many adult recipients require 2 UCB units to ensure reliable engraftment; however, this is associated with delayed platelet recovery and a higher incidence of chronic graft versus host disease (GvHD). This Phase 1/2 study suggests that omidubicel obviates the need for a second UCB unit and paves the way for use of smaller, better-matched units for adult patients that otherwise could not be used because of excessive risk of graft failure.
	Horwitz ME, et al. Omidubicel vs standard myeloablative umbilical cord blood transplantation: results of a phase 3 randomized study. Blood. 21 October, 2021;138(16):1429-1440 Brief study description: Published results of a phase 3 omidubicel trial.	Transplantation with omidubicel results in faster hematopoietic recovery and reduces early transplant related complications compared with unmanipulated UCB transplantation. Of note, 67% of the unmanipulated UCB transplants were double versus a single UCB unit. The results suggest that omidubicel may be considered as a new standard of care for adult patients eligible for UCB transplantation.
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
Omidubicel provides access to a rapid and reliable donor source that allows for a higher degree of mismatch, addressing health disparities in the racial and ethnic minority population	Horwitz ME, et al. Omidubicel vs standard myeloablative umbilical cord blood transplantation: results of a phase 3 randomized study. Blood. 21 October, 2021;138(16):1429-1440 See prior study description	Currently, the under-representation of UCB grafts from Black donors has necessitated the use of smaller units compared with those for White recipients, which results in inferior outcome. There are encouraging results of transplantation with omidubicel for minority populations in need of allogeneic HCT.
	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.		
Omidubicel improves the time alive and out of hospital by a median of 13 days, reflective of rapid neutrophil engraftment and hematopoietic recovery and consistent with decreased infections	Horwitz ME, et al. Omidubicel vs standard myeloablative umbilical cord blood transplantation: results of a phase 3 randomized study. Blood. 21 October, 2021;138(16):1429-1440 See prior study description	Results from the Phase 3 study showed that patients transplanted with omidubicel spent more time out of hospital during the first 100 days after transplant (median, 61 vs 48 days; p=0.005) than those in the UCB transplantation arm. The median time from transplant to discharge from the hospital was 27 days for the omidubicel and 35 days for the UCB control arm (p=0.005). The authors noted that the reduction in time to engraftment, hospitalization duration, and infectious complications are expected to reduce the need to use resources over an unmanipulated UCB transplant. Finally, the authors concluded that the results of this trial demonstrate that omidubicel represents a major therapeutic advance and should be considered as a new standard of care for adult patients eligible for UCB transplantation.

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**
	Majhail NS, et al. Hospitalization and healthcare resource use of omidubicel vs umbilical cord blood (UCB) for hematologic malignancies in a global randomized Phase III clinical trial. Poster presented at TCT Meetings of the ASTCT and CIBMTR, April 2022 Brief study description: Poster of phase 3 omidubicel trial summarizing hospitalization and healthcare resource use.	The authors analyzed resource utilization data for patients treated with omidubicel (n=52) or UCB (n=56) (as treated [AT] population) in the Phase 3 clinical study, focusing on resource utilization within the first 100 days of transplantation. Key findings were: 1) within the first 100 days after transplant, patients receiving omidubicel experienced shorter average total length of hospital stay than UCB recipients (mean, 41.2 vs 50.8 days; p=0.027) and more days alive and out of the hospital (mean, 55.8 vs 43.7 days; p=0.023); 2) during the primary hospitalization (transplant to discharge), fewer patients receiving omidubicel required intensive care unit (ICU) stay (9.6% vs 23.2%) compared with UCB recipients; and 3) patients receiving omidubicel required fewer platelet or other transfusions (red blood cell, albumin, plasma, and factor product) within 100 days from transplant: average number of transfusions per patient – omidubicel 24.8; UCB 35.4, p=0.005 (significant at 99% confidence). The authors concluded that this analysis shows that significantly faster hematopoietic recovery and lower rates of infections in patients transplanted with omidubicel was associated with significantly shorter hospital length of stay, reduced stays in ICU settings, and reduced healthcare resource use compared with UCB.
	Horwitz ME, et al. ... final results of a phase III randomized, multicenter study Improved Clinical Outcomes with omidubicel versus standard myeloablative umbilical cord blood transplantation: results of a Phase III randomized, multicenter study. TCT 2022. Abstract published Transplantation & Cellular Therapy. 2022;28(3, Supplement):S73-74 Brief study description: Oral presentation of a phase 3 omidubicel trial, describing one-year follow-up data of 125 patients.	In a 1-year update analysis from the omidubicel Phase 3 study, the authors reported there were no unexpected severe adverse events, secondary graft failure was low, and no cases of new malignancies were reported during the 1-year follow-up. Patients transplanted with omidubicel spent more time out of hospital during the first 100 days after transplant (median, 61 vs 48 days; p=0.005) than the UCB arm. The authors concluded: 1) omidubicel is associated with rapid hematopoietic recovery, reduced rates of infections, and no increase in acute or chronic GvHD rates compared with standard UCB; 2) no unexpected adverse events attributable *to ex vivo* expansion were observed; 3) infectious complications remain significantly lower in omidubicel arm in the first year post transplant; and 4) reduction in non-relapse mortality (NRM) by almost 50% in the omidubicel arm as compared to standard UCB (p=0.07).
One-year follow-up data confirm that transplantation with omidubicel results in statistically significant lower incidence of infections, indicating a robust recovery of immune function	Horwitz ME, et al. Omidubicel vs standard myeloablative umbilical cord blood transplantation: results of a phase 3 randomized study. Blood. 21 October, 2021;138(16):1429-1440 See prior study description	From randomization and up to 100 days following transplantation in the Phase 3 study, the cumulative incidence of first grade 2/3 bacterial or invasive fungal infections was 37% for omidubicel and 57% for the unmanipulated UCB arm (p=0.03). The cumulative incidence of first grade 3 viral infection during the first year following transplant was also lower for those randomized to omidubicel (10% vs 26%, p=0.02). The authors reported that the risk ratio for all infections, irrespective of severity, was significantly lower among recipients of omidubicel compared to UCB. The same observation was made when bacterial and viral infections were analyzed individually. The authors note that the reduced risk of viral infections could perhaps be attributable to more robust NK cell reconstitution. The authors concluded that hematopoietic recovery after transplantation with omidubicel was faster, reduced early transplant-related complications, and reduced the number of days patients were hospitalized compared with unmanipulated UCB. The results of this trial

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		demonstrate that omidubicel represents a major therapeutic advance and should be considered as a new standard of care for adult patients eligible for UCB transplantation.
	Szabolcs P, et al. Hematopoietic stem cell transplantation (HSCT) with omidubicel is associated with enhanced circulatory plasmacytoid dendritic cells (pDC), NK cells and CD4+ cells with lower rates of severe infections compared to standard umbilical cord blood transplantation. Slides presented at TCT Meetings of the ASTCT and CIBMTR, April 2022. Abstract published Transplantation & Cellular Therapy. 2022;28(3, Supplement):S4-5 See prior study description	The authors presented an immune reconstitution substudy where it was found that omidubicel using nicotinamide (NAM) technology delivers a full completement of $CD34^+$ progenitor cells and immune cells: 1) preserves the multipotency of progenitor cells for long-term repopulation, while increasing cell quantity for transplantation and 2) preserves stem cell function to optimize homing, engraftment, and differentiation. Finally, these results demonstrate rapid and functional reconstitution of T and B cell subsets following transplant and functional reconstitution following transplant with omidubicel, which provides mechanistic support for the lower rates of severe infection observed in omidubicel-treated patients as compared with UCB transplantation - Grade 2/3 infections over 65 days, n (%): bacterial infections – omidubicel 7 (41); UCB 14 (70), p 0.037; viral infections – omidubicel 1 (6); UCB 9 (45), p=0.010.
	Horwitz ME, et al. ... final results of a phase III randomized, multicenter study Improved Clinical Outcomes with omidubicel versus standard myeloablative umbilical cord blood transplantation: results of a Phase III randomized, multicenter study. TCT 2022. Abstract published Transplantation & Cellular Therapy. 2022;28(3, Supplement) See prior study description	At the 1-year post-transplant follow-up, all patients from the Phase 3 study had completed 15 months of follow-up from randomization; median follow-up (intent-to-treat [ITT] population): 13.9 months (omidubicel arm) and 14.1 months (UCB arm). No unexpected severe adverse events were identified, low secondary graft failure (one patient in omidubicel arm at ~6 months following transplantation, concurrent with a diagnosis of acute lymphoblastic leukemia [ALL] relapse) and no cases of new malignancies. Notably, there was a reduction in NRM of 50% in the omidubicel arm compared to unmanipulated UCB (p=0.07).
The favorable benefit/risk profile of omidubicel is further supported by assessments of safety, health-related quality of life and, importantly, long-term durable substantial clinical improvements	Lin C, et al. Health-related quality of life following allogeneic hematopoietic stem cell transplantation with omidubicel versus standard umbilical cord blood. Transplantation and Cellular Therapy 2022. Doi: https://doi:org/10.101/j.jtct.2022.09.018 Sep 2022 Brief study description: Abstract of 108 patients from the phase 3 omidubicel trial who received health-related quality of life questionnaires.	Among 108 patients undergoing allogeneic hematopoietic cell transplant (allo-HCT) at 28 international academic centers, 75 (69%) completed health-related quality of life (HRQL) surveys at screening and on at least one follow-up visit were included. Validated HRQL surveys (FACT-BMT, EQ-5D-3L) were administered on screening and days 42, 100, 180, and 365 post-transplant. Baseline characteristics were similar between the omidubicel and unmanipulated UCB arms, including baseline HRQoL scores. In the secondary exploratory analysis, omidubicel showed clinically meaningful and sustained improvements in physical, functional and overall well-being compared to UCB transplantation. Over the first year, area under the curve (AUC) of physical well-being scores was better with omidubicel (p=0.02, mean difference 1.5-3.1), exceeding the minimal clinically important difference (MCID) of 2 points on days 180 and 365. Similarly, AUCs of HCT-specific and functional well-being scores favored omidubicel (p=0.04) AUCs of total FACT-BMT scores were better with omidubicel (p=0.01), mean difference 7.2-11), exceeding the MCID of 7 points at all time points. There were numerical but non-significant improvements in AUCs of FACT-BMT social/family, emotional and EQ-5D-3L general well-being scores with omidubicel.
	Lin C, et al. Allogeneic stem cell transplantation with omidubicel: long-term following from a single center.	A single institution retrospective study examining patients who had received transplant with omidubicel between November 2010 and January 2020 provides a

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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**
	Poster #1827 presented at American Society of Hematology (ASH) Annual Meeting 2021. [Encore poster: Lin C, et al. Allogeneic stem cell transplantation with omidubicel: long-term following from a single center. Encore poster presented at TCT Meetings of the ASTCT and CIBMTR, April 2022] Brief study description: Retrospective study of 26 patients transplanted with omidubicel therapy.	10-year follow-up post-transplant. Median follow-up was 2.3 years (range, 0.1-10 years). Eleven patients had died due to disease relapse (64%), aGvHD (27%) and infections (9%). The Kaplan-Meier survival analysis estimated a 10-year overall survival (OS) of 48.5% (95% CI: 31.0%-75.7%) and disease free survival (DFS) of 43.6% (95% CI: 26.8%-70.9%) demonstrating a plateau of the survival curves after 4 years, suggesting good graft durability and prolonged survival for a subset of patients. The authors concluded that omidubicel is a safe and reliable stem cell source that can provide long-term sustainable hematopoiesis and immune competence at follow-up periods of 10 years. Despite historical concerns that *ex vivo* expansion may compromise the integrity of long-term repopulating HSCs, there was only one case of secondary graft failure in this cohort and no secondary malignancies were observed. All but one case of chronic GvHD was mild or moderate disease and no deaths were attributed to GvHD.
	Horwitz ME, et al. ...final results of a phase III randomized, multicenter study Improved Clinical Outcomes with omidubicel versus standard myeloablative umbilical cord blood transplantation: results of a Phase III randomized, multicenter study. TCT 2022. Abstract published Transplantation & Cellular Therapy. 2022;28(3, Supplement):S73-74. See prior study description.	In a 1-year update analysis from the omidubicel Phase 3 study, the authors concluded: 1) omidubicel is associated with rapid hematopoietic recovery, reduced rates of infections, and no increase in acute or chronic GvHD rates compared with standard UCB; 2) no unexpected adverse events attributable *to ex vivo* expansion were observed; 3) infectious complications remain significantly lower in omidubicel arm in the first year post transplant; and 4) reduction in NRM by almost 50% in the omidubicel arm as compared to standard UCB (p=0.07).
	Lin C, et al. Multicenter long-term follow up of allogeneic hematopoietic stem cell transplantation (allo-HCT) with omidubicel: a pooled analysis of five prospective clinical trials. Abstract presented at Society for Hematologic Oncology (SOHO), Fall 2022 Brief study description: Poster of a pooled secondary analysis of omidubicel trials.	A pre-specified pooled secondary analysis of long-term outcomes of allogeneic HCT using omidubicel from 5 multicenter prospective trials (between 2006-2020) provides 10-year follow-up post-transplant. Among 116 patients transplanted with either standalone omidubicel (n=92) or omidubicel with supplementary UCB (n=24), 97 (83.6%) engrafted with omidubicel, 11 (9.5%) with UCB, 2 mixed chimerism, 1 unevaluable, and 5 (4.3%) primary graft failure. All patients aside from those engrafted with UCB were included in this study (n=105). Median follow-up was 22.0 months (range, 0.3-122.5). The 3-year OS and DFS were 62.5% (95% CI, 53.4-73.2) and 56.2% (95% CI, 47.0-67.1), respectively. Common causes of death included disease relapse (n=16) and infection (n=11). Three-year cumulative incidences of chronic GvHD and relapse were 37.8% (95% CI, 27.9-47.6) and 24.3% (95% CI, 16.1-33.3), respectively. Durable trilineage hematopoiesis was observed for up to 10 years. Similarly, median numbers of lymphoid subsets, including CD3+, CD4+, CD8+ T cells, CD19+ B cells, and CD16+/CD56+ NK cells, maintained within normal range for up to 8 years. Secondary graft failure was noted in 5 patients, 3 of whom underwent a second allo-HCT. Secondary hematologic malignancies included donor-derived myeloid neoplasm (dd-MN) (n=1; 40 months post-transplant) and post-transplant lymphoproliferative disorders (PTLD) (n=2; 17 and 20 months), with one death attributed to PTLD. The authors concluded that, in addition to the known early benefits, omidubicel demonstrated long-term graft

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		durability, with preserved trilineage hematopoiesis and immune competence at up to 10-years of follow-up. No late cases of secondary graft failure were observed beyond the 5 patients reported in the primary analysis.
	Horwitz ME, et al. Omidubicel vs standard myeloablative umbilical cord blood transplantation: results of a phase 3 randomized study. Blood. 21 October, 2021;138(16):1429-1440 See prior study description.	The authors noted that the Phase 3 study results confirm that omidubicel safely addresses the most vexing limitation of UCB transplantation, which is the delay in hematopoietic recovery. Additionally, omidubicel reduced by 10 days the median time to neutrophil recovery, and by 13 days median time to platelet recovery. Omidubicel also reduced the incidence of infectious complications and time spent in the hospital during the early post-transplant period. The incidence of treatment-emergent serious adverse events (TEAEs) was similar in the two study arms (40% vs 41% for omidubicel and UCB, respectively). The authors concluded that the Phase 3 study demonstrated the feasibility and safety of delivering a personalized, manufactured hematopoietic stem cell product to transplant centers around the world.
Patients with high-risk hematologic malignancies have highly statistically significant and clinically meaningful faster recovery of neutrophils with omidubicel vs unmanipulated UCB transplant	Horwitz ME, et al. Omidubicel vs standard myeloablative umbilical cord blood transplantation: results of a phase 3 randomized study. Blood. 21 October, 2021;138(16):1429-1440 See prior study description.	In this report on the Phase 3 study results, the authors begin by noting that, compared with transplants from adult donors, adult UCB transplantation has been associated with increased early treatment-related morbidity and mortality stemming from delayed hematopoietic recovery and immunologic reconstitution. It was noted that delayed hematopoietic recovery remains a problem after the advent of dual UCB transplantation. The primary endpoint in the Phase 3 study was time to neutrophil engraftment. Median time to neutrophil engraftment was 12 days (95% CI 10-14 days) and 22 days (CI 19-25 days) ($p<0.001$) for the omidubicel and UCB control arms, respectively. The cumulative incidence of neutrophil engraftment was 96% and 89%, respectively. The omidubicel arm had faster platelet recovery (55% vs 35% recovery by 42 days, $p=0.028$), a lower incidence of first grade 2/3 bacterial or invasive infections (37% vs 57%, $p=0.027$), and spent more time out of hospital during the first 100 days following transplant (median 61 vs 48 days, $p=0.005$) than controls. Differences in GvHD and survival between the two arms were not statistically significant. Transplantation with omidubicel results in faster hematopoietic recovery and reduced early transplant-related complications as compared to unmanipulated UCB. The authors note that the Phase 3 results suggest that omidubicel may be considered as a new standard of care for adult patients eligible for UCB transplantation.
	Horwitz ME, et al. ...Final results of a phase III randomized, multicenter study Improved Clinical Outcomes with omidubicel versus standard myeloablative umbilical cord blood transplantation: results of a Phase III randomized, multicenter study. TCT 2022. April 2022. Abstract published Transplantation & Cellular Therapy. 2022;28(3, Supplement):S73-74 See prior study description.	In a 1-year update analysis from the omidubicel Phase 3 study, the authors concluded: 1) omidubicel is associated with rapid hematopoietic recovery, reduced rates of infections, and no increase in acute or chronic GvHD rates compared with standard UCB; 2) no unexpected adverse events attributable *to ex vivo* expansion were observed; 3) infectious complications remain significantly lower in omidubicel arm in the first year post transplant; and 4) reduction in NRM by almost 50% in the omidubicel arm as compared to standard UCB ($p=0.07$).
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	

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After review of the information provided by the applicant, we have the following concerns regarding whether omidubicel meets the substantial clinical improvement criterion.

With respect to the applicant's claim that Omidubicel as an allogeneic donor source addresses key barriers to the widespread use of UCB as a donor source, including limited or inadequate cell dose for adults and adolescents, we note that the Horwitz et al., 2019[72] phase ½ trial of 36 patients compared results to historical controls. Despite best efforts at matching, this type of comparison does not account for unobserved differences between participants and historical controls. The trial authors noted that some study participants became ineligible during the pre-transplantation work-up and five withdrew because of logistical issues, but it is unclear if the historical controls would have been excluded for the same reasons. Furthermore, the study compared health and socioeconomic status but did not report social support received by omidubicel recipients compared to historical controls. These differences could affect non-relapse mortality. Additionally, the time frames of patient involvement are different and there may have been advances in supportive care or other therapies since the timeframe for historical controls (2010–2013). Finally, we note that in Table 2 of the study, overall survival and disease-free survival were not statistically significantly different for omidubicel recipients versus The Center for International Blood and Marrow Transplant Research (CIBMTR) control at 2 years.

Finally, with respect to the applicant's claim that by allowing a higher degree of donor-recipient mismatch, omidubicel addresses health disparities in the racial and ethnic minority population, we note that no substantiating data was presented. The applicant submitted background articles outlining disparities in utilization as well as some biologic differences.[73] [74] [75] However, we did not receive data on improvements in access or outcomes for this patient population with the use of this technology.

The Horwitz et al., 2021[76] phase 3 study serves as the applicant's primary reference in support of the assertion that omidubicel significantly improves clinical outcomes relative to current available treatments. We note that the baseline characteristics of the patients were not entirely matched as more patients receiving omidubicel had myelodysplastic syndrome (MDS) and chronic myeloid leukemia (CML) rather than other leukemias, such as acute myeloid leukemia (AML) and acute lymphoblastic leukemia (ALL). This may affect prognosis and response to therapy. We also note that the trial seems to be unblinded, which could introduce bias. We also question the utility of the primary endpoints. While the study demonstrated faster rates of neutrophil engraftment and platelet recovery, it is unclear whether this translates to clinical outcomes. The study was not powered to detect significance in progression-free survival (PFS) and overall survival (OS). The researchers compared the primary end point of infectious complications using intent-to-treat (ITT) analysis, but used cumulative incidence rates for secondary endpoints. It is unclear why cumulative incidence rates were used for secondary endpoints and not ITT analysis, and we question if this is because they were statistically significant. We are unclear of the reason that bacterial and fungal infections were combined while only grade three viral infections were reported. We note that the cumulative incidence of all GvHD trended higher for omidubicel at one year, but was not statistically significant. The supplementary tables 3 and 4 detailed emergent adverse events in the two treatment groups and it would be helpful to know if any of the incidence differences were statistically significant. We also note that patients in the prospective phase ½ and 3 omidubicel trials[77] [78] [79] [80] were under 65 and that there is currently no data available for the ages above 65, and we therefore question the generalizability of the therapy for the Medicare population.

Noting these potential limitations, while the primary endpoint data in the phase 3 study demonstrates that patients with high-risk hematologic malignancies have statistically significant faster recovery of neutrophils with omidubicel versus unmanipulated UCB transplants, it is not known whether this will translate to significantly improved clinical outcomes.

With regard to the applicant's other data sources, we note that the applicant provided materials demonstrating a steady increase in the number of haplo-identical donor (haplo) transplants, with a slight decline in cord blood (CB) transplants[81] and note that the comparison of haplo-HCT versus UCB transplant is an area of study[82] with planned evaluation of progression-free survival, non-relapse mortality, and overall survival. As such, we are interested in evidence that demonstrates more clinical data on substantial clinical improvement over current therapies. We note that the Lin et al., 2022 HRQL study[83] was a secondary exploratory analysis and that primary or secondary endpoints were not reported. We further note that differences in social, family, and emotional scores were not statistically significant. In addition, the mean age of participants was 36, and we question the generalizability of these results to the Medicare population.

We note that the Lin et al., SOHO 2022 study[84] is a multi-institutional pooled analysis of long-term outcomes of omidubicel transplantation from five prospective clinical trials. Although the individual clinical trials had controls, the pooled analysis had no control group and therefore no comparisons against standard UCB are made. Finally, the Majhail et al. 2022 study on resource

[72] Horwitz ME, et al. Phase I/II study of stem-cell transplantation using a single cord blood unit expanded ex vivo with nicotinamide. J Clin Oncol 2019;37:367–74.

[73] Dahlberg A and Milano F. Cord blood transplantation: rewind to fast forward. Bone Marrow Transplantation (2016), 1–4.

[74] Be The Match: Five Year Strategic Plan. 2019–2023; adopted May 2018.

[75] Joshua TV, et al. Access to hematopoietic stem cell transplantation: effect of race and sex. Cancer. 2010;116 (14): 3469–3476.

[76] Horwitz ME, et al. Omidubicel vs standard myeloablative umbilical cord blood transplantation: results of a phase 3 randomized study. Blood. 21 October, 2021;138(16):1429–1440.

[77] Horwitz ME, et al. Umbilical cord blood expansion with nicotinamide provides long-term multilineage engraftment. J Clin Invest 2014;124:3121–8.

[78] Horwitz ME, et al. Phase I/II study of stem-cell transplantation using a single cord blood unit expanded ex vivo with nicotinamide. J Clin Oncol 2019;37:367–74.

[79] Horwitz ME, et al. Omidubicel vs standard myeloablative umbilical cord blood transplantation: results of a phase 3 randomized study. Blood. 21 October, 2021;138(16):1429–1440.

[80] Lin C, et al. Multicenter long-term follow up of allogeneic hematopoietic stem cell transplantation (allo-HCT) with omidubicel: a pooled analysis of five prospective clinical trials. Abstract presented at Society for Hematologic Oncology (SOHO), Fall 2022.

[81] CIBMTR. Current uses and outcomes of hematopoietic cell transplantation (HCT) in US, 2021 summary slides, *https://www.cibmtr.org/ReferenceCenter/SlidesReports/SummarySlides/Pages/index.aspx*.

[82] *Clinicaltrials.gov:* NCT 01597778.

[83] Lin C, et al. Health-related quality of life following allogeneic hematopoietic stem cell transplantation with omidubicel versus standard umbilical cord blood. Transplantation and Cellular Therapy 2022. Doi: *https://doi:org/10.101/j.jtct.2022.09.018* Sep 2022.

[84] Lin C, et al. Multicenter long-term follow up of allogeneic hematopoietic stem cell transplantation (allo-HCT) with omidubicel: a pooled analysis of five prospective clinical trials. Abstract presented at Society for Hematologic Oncology (SOHO), Fall 2022.

use [85] for the Horwitz et al. phase 3 trial [86] stated that the patients transplanted with omidubicel had significantly shorter hospital length of stay, reduced stays in the ICU, and reduced healthcare resource use compared with standard UCB. We are interested in additional information regarding how the data on resource use was collected across the various sites.

We are inviting public comments on whether omidubicel meets the substantial clinical improvement criterion.

In this section, we summarize and respond to written public comments received in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for omidubicel.

Comment: We received two written comments in response to the New Technology Town Hall meeting, both related to reimbursement of omidubicel. Since we only summarize Town Hall comments related to substantial clinical improvement, these comments are therefore not summarized.

j. REBYOTA™ (Fecal Microbiota, Live-jslm)

Ferring Pharmaceuticals, Inc., an affiliate of the manufacturer, Rebiotix Inc., submitted an application for new technology add-on payments for REBYOTA™ for FY 2024. Per the applicant, REBYOTA™ is a broad consortium microbiota-based live biotherapeutic suspension indicated for the prevention of recurrence of Clostridioides difficile infection (CDI) in individuals 18 years of age and older, following antibiotic treatment for recurrent CDI.

Please refer to the online application posting for REBYOTA™, available at *https://mearis.cms.gov/public/publications/ntap/NTP221017WUDXM*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, the applicant stated that 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™ 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. 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.

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 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 stated that ICD–10–CM diagnosis codes A04.71 (Enterocolitis due to Clostridium difficile, recurrent) and A04.72 (Enterocolitis due to Clostridium difficile, not specified as recurrent) may be used to currently identify the indication for REBYOTA™ 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 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.

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[85] Majhail NS, et al. Hospitalization and healthcare resource use of omidubicel vs umbilical cord blood (UCB) for hematologic malignancies in a global randomized Phase III clinical trial. Poster presented at TCT Meetings of the ASTCT and CIBMTR, April 2022.

[86] Majhail NS, et al. Hospitalization and healthcare resource use of omidubicel vs umbilical cord blood (UCB) for hematologic malignancies in a global randomized Phase III clinical trial. Poster presented at TCT Meetings of the ASTCT and CIBMTR, April 2022.

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 nonstandardized 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 nonstandardized 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.

We note the following concerns with regard to the newness criterion. We note that the applicant stated that ZINPLAVA™ is restricted to high-risk patients, and we question whether these high-risk patients are 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 note that the indication for ZINPLAVA™ does not exclude patients with a history of CHF and the labeling has no listed contraindications. Therefore, we seek clarification from the applicant regarding the differences in patient populations for ZINPLAVA™ and REBYOTA™.

In addition, we note that REBYOTA™ may have a similar mechanism of action to SER–109, another microbiome therapeutic agent 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, as discussed later in this section. Notably, the exact mechanism of action for each biologic is not known; however, both appear to act on the gut microbiome to suppress *C. difficile* (C.diff.) and thereby prevent rCDI. Both REBYOTA™ and SER–109 appear to lead to compositional changes in the gastrointestinal microbiome that restore the diversity of gut flora which enable it to suppress outgrowth of C.diff. and rCDI, following standard-of-care treatment with antibiotics for rCDI. Further, both technologies appear 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 appears that REBYOTA™ and SER–109 are purposed to achieve the same therapeutic outcome using a similar mechanism of action and would be assigned to the same MS–DRG, we believe 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 SER–109 receives FDA approval by July 1, 2023. We are interested in information on how these two technologies may differ from each other with respect to the newness criterion to inform our analysis of whether REBYOTA™ and SER–109 are substantially similar to each other.

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, 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 REBYOTA™ became commercially available, January 23, 2023. We note that though, generally, our policy is 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 are inviting public comment on whether REBYOTA™ is substantially similar to existing technologies and meets the newness criterion, including whether REBYOTA™ is substantially similar to SER–109, and whether these technologies should be evaluated as a single technology for purposes of new technology add-on payments.

With respect to the cost criterion, the applicant searched the FY 2021 MedPAR file for potential cases representing patients who may be eligible for REBYOTA™ 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 this 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 this 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.

We are inviting public comments on whether REBYOTA™ meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant 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.[87] 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

[87] Background articles are not included in the table in this section but can be accessed via the online posting for the technology.

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**
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 nonresponders (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:	Across 5 trials with consistent investigational product and clinical endpoints, REBYOTA™ consistently reduced rCDI within 8 weeks after treatment.

	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).	
	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 gastrointestinal (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	Braun T, Guthmueller B, Harvey A. Safety of investigational microbiota-based live	Among 832 clinical trial participants who received ≥1 treatment with REBYOTA™ or

REBYOTA™ than with ZINPLAVA™	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.	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.	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.

	See prior study description.	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; September29, 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.	

After review of the information provided by the applicant, we have 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.[88] 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%, with no observable difference between participants who received one dose (83.3%) vs. two doses (82.5%). We note 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 believe additional information regarding whether REBYOTA™ was tested in patients with CHF to determine clinical outcomes would be helpful in our evaluation of the applicant's assertion. The applicant also referenced a poster presentation by Braun et al.[89] 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. Additional information demonstrating whether REBYOTA™ is safe for the patient population with CHF would help to inform an 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™ [90] and the PUNCH CD3 phase 3 trial [91] to demonstrate the superiority of REBYOTA™ over placebo, we question whether other treatment options indicated to prevent rCDI, such as ZINPLAVA™, would be a more appropriate comparator. Additional information regarding clinical outcomes as a result of treatment with REBYOTA™ compared to ZINPLAVA™, instead of placebo, would be helpful in our assessment of the substantial clinical improvement criterion. In summary, while we understand that there are no head-to-head trials comparing REBYOTA™ to ZINPLAVA™, additional information would help inform our assessment of whether REBYOTA™ demonstrates a substantial clinical improvement over existing technologies.

We are inviting public comments on whether REBYOTA™ meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for REBYOTA™.

k. Sabizabulin

Veru, Inc. submitted an application for new technology add-on payments for sabizabulin for FY 2024. Per the applicant, sabizabulin is a novel oral microtubule disruptor that will be indicated, upon FDA approval, for treatment of severe SARS–CoV–2 infection in hospitalized patients with moderate to severe COVID–19 at high risk for Acute Respiratory Distress Syndrome (ARDS) and death. According to the applicant, preclinical studies demonstrate that sabizabulin has both significant antiviral and anti-inflammatory activities by disrupting microtubule dynamics.

Please refer to the online application posting for sabizabulin, available at *https://mearis.cms.gov/public/publications/ntap/NTP221017FTANY*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, the applicant stated it anticipates Emergency Use Authorization (EUA) and/or NDA approval for treatment of SARS–CoV–2 infection in hospitalized patients with moderate to severe COVID–19 infection who are at high risk for ARDS before July 1, 2023. We note that, as discussed in prior rulemaking, a product available only through an EUA would not be eligible for new technology add-on payments. While an EUA is not marketing authorization within the meaning of § 412.87(e)(2) for purposes of eligibility for new technology add-on payments, data reflecting the costs of products that have received an EUA could become available as soon as the date of the EUA issuance and prior to receiving FDA approval or clearance (86 FR 45159 through 45160). The applicant stated that the recommended dosing of sabizabulin will be a 9 mg capsule administered orally daily for a maximum of 21 days or until the patient is discharged from the hospital. The applicant estimated the average number of treatment days for sabizabulin to be 11.4 days, based on the results of the phase 3 trial (Barnette et al., 2022). From this estimation, the applicant anticipates an average dose per inpatient stay of one 9 mg capsule (per day) $\times$ 11 days.

According to the applicant, there were no ICD–10–PCS procedure codes to distinctly identify sabizabulin at the time of application. We note that, effective April 1, 2023, the following ICD–10–PCS codes can be used to uniquely describe procedures involving the use of sabizabulin: XW0DXK8 (Introduction of sabizabulin into mouth and pharynx, external approach, new technology group 8), XW0G7K8 (Introduction of sabizabulin into upper GI, via natural or artificial opening, new technology group 8), and XW0H7K8 (Introduction of sabizabulin into lower GI, via natural or artificial opening, new technology group 8). The applicant stated that diagnosis code U07.1 (COVID–19) may be used to currently identify the indication for sabizabulin under the ICD–10–CM coding system.

[88] Feuerstadt P, Harvey A, Bancke L. RBX2660, 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.

[89] Braun T, Guthmueller B, Harvey A. Safety of investigational microbiota-based live biotherapeutic RBX2660 in individuals with recurrent Clostridioides difficile infection: data from five prospective clinical studies. Abstract presented at: 10th Annual IDWeek; September 29, 2021.

[90] 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.

[91] 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; September29, 2021.

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 sabizabulin is not substantially similar to other currently available technologies because sabizabulin has a unique mechanism of action, 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 sabizabulin for the applicant's complete statements in support of its assertion that sabizabulin 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	Sabizabulin is an orally available microtubule depolymerization agent which acts to disrupt and suppress the SARS-CoV-2 viral life cycle (for example, cell surface interaction, intracellular transport, and infectious viral particle release) and also to suppress inflammation (cytokine storm) triggered by COVID-19. Microtubule trafficking networks play a critical role in viral infection, replication, and spreading of new infectious viruses. Through inhibition of polymerization and depolymerization of microtubules, sabizabulin disrupts the microtubule trafficking networks making them unusable by the virus. Inhibition of microtubule polymerization and depolymerization of microtubules has been shown to suppress inflammasome activation and leucocyte mediated inflammatory activities including inhibition of leucocyte production of superoxides and release of various cytokines and pyrogens. This mechanism of action is distinct from Olumiant which acts solely to block extracellular inflammatory signals and from Veklury which acts solely to inhibit viral replication.
Is the technology assigned to the same MS-DRG as existing technologies?	Yes	The cases that use Veklury and/or Olumiant may map to the same MS-DRGs where the primary diagnosis is COVID-19.
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	At this time, there is not sufficient data to demonstrate a significant difference between patient populations who may receive sabizabulin and patients who may receive other COVID-19 treatments.

We are inviting public comments on whether sabizabulin is substantially similar to existing technologies and whether sabizabulin meets the newness criterion.

With respect to the cost criterion, the applicant provided three analyses to demonstrate that it meets the cost criterion. The applicant searched the FY 2021 MedPAR file using the ICD–10–PCS codes described in the following table, to identify potential cases representing patients who may be eligible for sabizabulin and then further divided the potential cases based on existence or absence of intensive care days. The applicant based the three cost analyses on three cohorts from a randomized, multicenter placebo-controlled phase 3 clinical trial demonstrating the efficacy of sabizabulin (Barnette et al., 2022), including: (1) Cases without mechanical ventilation or intensive care days; (2) Cases with intensive care days and without mechanical ventilation; and (3) Cases with mechanical ventilation. Each analysis followed the order of operations described in the following table.

For the first analysis, the applicant searched for cases reporting the ICD–10–CM diagnosis of COVID–19 (U07.1) in any position and a high/low flow oxygen ICD–10–PCS code, without the presence of mechanical ventilation ICD–10–PCS codes, and without intensive care days. Please see Table 10.19.A.—Sabizabulin Codes—FY 2024 associated with this proposed rule for the complete list of ICD–10–PCS codes and MS–DRGs that the applicant indicated were included in its cost analysis. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 16,664 claims mapping to 29 MS–DRGs. The applicant calculated a final inflated average case-weighted standardized charge per case of $115,916, which exceeded the average case-weighted threshold amount of $64,866.

For the second analysis, the applicant searched for the same criteria used for the first analysis, but instead with the presence of intensive care days. Please see Table 10.19.A.—Sabizabulin Codes—FY 2024 associated with this proposed rule for the complete list of ICD–10–PCS codes and MS–DRGs that the applicant indicated were included in its cost analysis. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 36,438 claims mapping to 46 MS–DRGs. The applicant calculated a final inflated average case-weighted standardized charge per case of $163,327, which exceeded the average case-weighted threshold amount of $66,501.

For the third analysis, the applicant searched for cases reporting the ICD–10–CM diagnosis of COVID–19 (U07.1) in any position, with a mechanical ventilation ICD–10–PCS code and/or

intensive care day(s). Please see Table 10.19.A.—Sabizabulin Codes—FY 2024 associated with this proposed rule for the complete list of ICD–10–PCS codes and MS–DRGs that the applicant indicated were included in its cost analysis. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 79,237 claims mapping to 100 MS–DRGs. The applicant calculated a final inflated average case-weighted standardized charge per case of $259,462, which exceeded the average case-weighted threshold amount of $171,026. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount in all analyses, the applicant asserted that sabizabulin meets the cost criterion.

Sabizabulin COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR File
List of ICD-10-CM codes	U07.1 (COVID-19)
List of ICD-10-PCS codes	Please see Table 10.19.A. – Sabizabulin Codes – FY 2024 associated with this proposed rule for the complete lists of ICD-10-PCS codes for mechanical ventilation and high/low flow oxygen that the applicant indicated were included in its cost analyses.
List of MS-DRGs	Please see Table 10.19.A. - Sabizabulin Codes – FY 2024 associated with this proposed rule for the complete lists of MS-DRGs provided by the applicant for all three analyses.
Inclusion/ exclusion criteria	The applicant excluded MS-DRGs with case volume less than 11 total cases. Cases meeting the imposed inclusion criteria were assigned to one of the three cohorts: Analysis 1: The applicant selected cohort 1 claims based on the ICD-10-CM diagnosis code U07.1 (Covid-19) in any position and a high/low flow oxygen ICD-10-PCS code, without any of the mechanical ventilation ICD-10-PCS codes and without intensive care days. See Table 10.19.A. - Sabizabulin Codes - FY 2024 for a complete list of ICD-10-PCS codes. Analysis 2: The applicant selected cohort 2 claims based on the ICD-10-CM diagnosis code U07.1 (Covid-19) in any position and a high/low flow oxygen ICD-10-PCS code, plus intensive care days, without any of the mechanical ventilation ICD-10-PCS codes. See Table 10.19.A. - Sabizabulin Codes - FY 2024 for a complete list of ICD-10-PCS codes. Analysis 3: The applicant selected cohort 3 claims based on the ICD-10-CM diagnosis code U07.1 (Covid-19) in any position, plus a mechanical ventilation ICD-10-PCS code and/or intensive care days. See Table 10.19.A. - Sabizabulin Codes - FY 2024 for a complete list of ICD-10-PCS codes. The applicant then calculated the average unstandardized charge per case for each MS-DRG.
Charges removed for prior technology	The applicant removed 100% of drug charges from cases to estimate the reduction in drug use and charges due to the use of sabizabulin across all three cohorts. The applicant then deducted charges, based on the corresponding reductions in charges recognized from the randomized, multicenter placebo-controlled phase 3 clinical trial demonstrating the efficacy of sabizabulin (Barnette et al., 2022): For cohort 1, the applicant applied a 26% reduction in routine care charges; for cohort 2, the applicant applied a 43% reduction in intensive care charges; for cohort 3, the applicant applied a 43% reduction in intensive care charges and a 49% reduction in inhalation charges for patients with intensive care days; and for patients without intensive care days, the applicant applied a 26% reduction in routine care charges and a 49% reduction in inhalation charges.
Standardized charges	Per the applicant, after removing the drug charges and additional related offsets from unstandardized average charge amounts, the applicant calculated the average standardized charge per case for each MS-DRG, using the standardization formula provided in the application. The applicant used all the relevant values reported in the standardizing file posted with the FY 2021 IPPS/LTCH PPS final rule.
Inflation factor	The applicant applied a 3-year inflation factor of 20.5% to the FY 2021 average standardized charge amount to inflate to FY 2024 values, 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 anticipated that sabizabulin would be given daily for up to 21 days of a patient stay. The applicant determined an average cost based on an 11 day stay, in alignment with the average length of stay in the aforementioned study. The applicant added charges for the new technology by dividing the cost by the national average cost-to-charge ratio of 0.184 (as listed in the FY 2023 IPPS/LTCH PPS final rule).

We note that the applicant's inclusion/exclusion criteria and reasoning for the third analysis are unclear. For the third analysis, the applicant searched for cases reporting the ICD–10–CM diagnosis of COVID–19 (U07.1) in any position, with a mechanical ventilation ICD–10–PCS code and/or intensive care day(s). The inclusion of a mechanical ventilation ICD–10–PCS code or intensive care days would allow inclusion of cases without

mechanical ventilation (but with intensive care days) in the cohort. However, the study (Barnette et al., 2022) which the analysis is intended to mirror appears to require mechanical ventilation for all cases in the third cohort. We would be interested in confirmation or clarification of the inclusion criteria for the third analysis, including which cases it is intended to capture. Additionally, we would be interested in information explaining what ''inhalation charges'' were removed in the third analysis. It is unclear if ''inhalation charges'' were intended to mean ventilation charges (during the associated 49% reduction in ventilation days), or otherwise. We are inviting public comments on whether sabizabulin meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that sabizabulin represents a substantial clinical improvement over existing technologies because sabizabulin has been shown to significantly improve clinical outcomes relative to other COVID–19 treatments because in a randomized, multicenter placebo-controlled phase 3 clinical trial, sabizabulin was associated with: reduction of least one clinically significant adverse event (SAE); fewer days in intensive care unit (ICU) on mechanical ventilation and in hospital; fewer adverse events (AEs); decreased rate of at least one subsequent diagnostic or therapeutic intervention; a reduced length of stay; and reduced recovery time. The following table summarizes the applicant's assertions regarding substantial clinical improvement. Please see the online posting for sabizabulin for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Substantial Clinical Improvement Assertion #1: 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**
Sabizabulin utilization demonstrates greater medication adherence and compliance.	Barnette, K. G., Gordon, M. S., Rodriguez, D., Bird, T. G., Skolnick, A., Schnaus, M., Skarda, P. K., Lobo, S., Sprinz, E., Arabadzhiev, G., Kalaydzhiev, P., & Steiner, M. (2022). Oral Sabizabulin for High-Risk, Hospitalized Adults with Covid-19: Interim Analysis. New England Journal of Medicine (NEJM) Evidence, 1(9), 1–11. https://doi.org/10.1056/EVIDoa2200145 Brief study description: A randomized, multicenter placebo-controlled phase 3 clinical trial to demonstrate the efficacy of sabizabulin treatment in patients with moderate to severe Covid-19 at high-risk of ARDS and death.	• In the sabizabulin treated group, 31.6% of the group received WHO 4 (oxygen by mask or nasal prongs) compared to 34.6% of the placebo cohort. • In the sabizabulin group, 5.1% of the group received WHO 6 (intubation and mechanical ventilation), compared to 11.5% in the placebo group. • There was a 34.4% absolute reduction in mortality at day 60 in the sabizabulin group compared to the placebo. There was 20.2% mortality at day 60 in the sabizabulin group compared to a 45.1% mortality in the placebo group. • The sabizabulin group spent an average of 17.4 days in the ICU compared to 30.8 days in the placebo group (p-value .0013). • The sabizabulin group spent an average of 14.4 days on mechanical ventilation compared to the placebo group of 28.5 days (p-value .0013). • Sabizabulin treated patients spent an average of 25.6 days in the hospital compared to 34.6 days in the placebo treated patient group (p-value .0277).
Sabizatulin results in a decreased rate of at least one subsequent diagnostic or therapeutic intervention.	Barnette, K. G., Gordon, M. S., Rodriguez, D., Bird, T. G., Skolnick, A., Schnaus, M., Skarda, P. K., Lobo, S., Sprinz, E., Arabadzhiev, G., Kalaydzhiev, P., & Steiner, M. (2022). Oral Sabizabulin for High-Risk, Hospitalized Adults with Covid-19: Interim Analysis. NEJM Evidence, 1(9), 1–11. https://doi.org/10.1056/EVIDoa2200145 See prior study description	• In the sabizabulin treated group, 6.2% of patients reported the adverse event of constipation compared to the placebo treated group reporting 8.7%. • Sabizabulin demonstrated reduced rates of infections with 5.4% of patients diagnosed with Pneumonia compared to 11.6% in the placebo group. The sabizabulin group reported .8% infection rate of Bacterial Pneumonia compared to 7.2% in the placebo group. Only 1.5% of sabizabulin patients reported septic shock compared to 5.8% of the placebo group. Sabizabulin demonstrated lower rates of development of chronic Bronchitis with 1.5% of the group reporting this adverse event compared to 5.8% of the placebo group. • Only .8% of the sabizabulin group reported Pneumothorax (collapsed lung) compared to 10.1% of the placebo group. • Sabizabulin demonstrates decreases in certain adverse events, which require further treatment, such as laxatives, further antiviral treatment (if available), antibiotic treatment, and treatment or surgery to alleviate symptoms of Pneumothorax.
Sabizabulin treatment resulted in a more rapid beneficial resolution of the disease process treatment including, but not limited to, a reduced length of stay or recovery time.	Barnette, K. G., Gordon, M. S., Rodriguez, D., Bird, T. G., Skolnick, A., Schnaus, M., Skarda, P. K., Lobo, S., Sprinz, E., Arabadzhiev, G., Kalaydzhiev, P., & Steiner, M. (2022). Oral Sabizabulin for High-Risk, Hospitalized Adults with Covid-19: Interim Analysis. NEJM Evidence, 1(9), 1–11. https://doi.org/10.1056/EVIDoa2200145 See prior study description	• Sabizabulin treatment resulted in statistically significant reductions in secondary endpoints compared to the placebo. In the following analyses, the values of the days were set to 60 days for all patients who died during the study. • There was a 43% relative reduction in days in the ICU (least-squares [LS] mean of -13.4 days; 95% CI, -21.5 to -5.3; P=0.0013) • 26% relative reduction in days in the hospital (LS mean of -8.4 days; 95% CI, -15.8 to-0.9; P=0.0277).
Sabizabulin leads to a reduction in at least one	Barnette, K. G., Gordon, M. S., Rodriguez, D., Bird, T. G., Skolnick, A., Schnaus, M., Skarda, P. K., Lobo, S.,	• In the primary efficacy end point of mortality up to day 60, a statistically significant 24.9 percentage point absolute reduction and a 55.2% relative reduction in mortality was

clinically significant adverse event, including a reduction in mortality or a clinically significant complication.	Sprinz, E., Arabadzhiev, G., Kalaydzhiev, P., & Steiner, M. (2022). Oral Sabizabulin for High-Risk, Hospitalized Adults with Covid-19: Interim Analysis. NEJM Evidence, 1(9), 1–11. https://doi.org/10.1056/EVIDoa2200145 See prior study description	observed in the sabizabulin-treated group compared with placebo (odds ratio, 3.23; 95% confidence interval [CI], 1.45 to 7.22; P=0.0042). • The beneficial effects of sabizabulin were observed starting as early as day 3 after dosing; by day 15, statistically significant reductions in mortality were observed. • The beneficial effects of sabizabulin treatment on mortality were maintained through day 29, the standard time point other studies have used as the efficacy end point, with mortality rate of 35.3% for placebo compared with 17% for sabizabulin • From days 29 to 60, the death rate increased by 9.8 percentage points in the placebo group and by 3.2 percentage points in the sabizabulin-treated group. Results of subgroup analyses evaluating the relative risk of death were consistent with the overall study results favoring sabizabulin treatment regardless of standard-of-care treatment received, baseline WHO ordinal clinical score, sex, age, baseline comorbidities, BMI, or geographic location. • In the United States, a 34.4 percentage point absolute reduction in mortality at day 60 (55.5% relative reduction) was observed in the sabizabulin group compared with placebo • Sabizabulin treatment resulting in a 51.6 percentage point relative reduction in deaths compared with placebo.
Patients in the sabizabulin-treated group experienced a relative reduction in ICU days, days on mechanical ventilation, and days in the hospital compared to patients in the placebo group.	Barnette, K. G., Gordon, M. S., Rodriguez, D., Bird, T. G., Skolnick, A., Schnaus, M., Skarda, P. K., Lobo, S., Sprinz, E., Arabadzhiev, G., Kalaydzhiev, P., & Steiner, M. (2022). Oral Sabizabulin for High-Risk, Hospitalized Adults with Covid-19: Interim Analysis. NEJM Evidence, 1(9), 1–11. https://doi.org/10.1056/EVIDoa2200145 See prior study description	• Sabizabulin treatment resulted in statistically significant reductions in secondary endpoints compared to the placebo. In the following analyses, the values of the days were set to 60 days for all patients who died during the study. • 43% relative reduction in days in the ICU (least-squares [LS] mean of -13.4 days; 95% CI, -21.5 to -5.3; P=0.0013) • 49% relative reduction in days on mechanical ventilation (LS mean of -14.1 days; 95% CI, -22.4to -5.6; P=0.0013) • 26% relative reduction in days in the hospital (LS mean of -8.4 days; 95% CI, -15.8 to-0.9; P=0.0277).
Patients in the sabizabulin treatment group experienced adverse events less frequently compared with the placebo group.	Barnette, K. G., Gordon, M. S., Rodriguez, D., Bird, T. G., Skolnick, A., Schnaus, M., Skarda, P. K., Lobo, S., Sprinz, E., Arabadzhiev, G., Kalaydzhiev, P., & Steiner, M. (2022). Oral Sabizabulin for High-Risk, Hospitalized Adults with Covid-19: Interim Analysis. NEJM Evidence, 1(9), 1–11. https://doi.org/10.1056/EVIDoa2200145 See prior study description	• The adverse events and serious adverse events observed in this study were consistent with patients with serious Covid-19 illness. • The proportion of patients who experienced any adverse event was lower in the sabizabulin-treated group (61.5%) compared with the placebo group (78.3%). • The proportion of patients with a serious adverse event observed during the study was also lower for the sabizabulin-treated group (29.2%) compared with placebo (46.4%). • The most frequently reported adverse events in either group were respiratory failure, acute kidney injury, pneumothorax, bacterial pneumonia, and hypotension. • The most frequently reported serious adverse events in either group were respiratory failure, acute kidney injury, pneumothorax, septic shock, and acute respiratory failure. • Adverse events leading to discontinuation were 4.7% for sabizabulin versus 5.9% for placebo.

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After review of the information provided by the applicant, we have the following concerns regarding whether sabizabulin meets the substantial

clinical improvement criterion. We note the applicant cites one study for all six claims, a randomized clinical trial that has a sample size of 130 patients treated, across five countries (United States, Brazil, Bulgaria, Argentina, and Mexico), with 204 patients randomly assigned to either treatment or placebo group. It is unclear whether the same results can be repeated since other studies were not provided. We question whether the findings from this study are directly applicable to the Medicare population, particularly if there were significant differences between the standards of care in the countries included in the study and standards of care in the U.S. The study's description of concurrent COVID–19 therapies does not appear to be consistent with guidelines in effect in the US [92] throughout the enrollment period. For example, only 83.7% of patients in the placebo group received dexamethasone, the volume of patients who received immunomodulators appears to be much less than recommended by National Institutes of Health guidelines, and antiviral therapy was uncommon (as noted by Peltan and Brown in a NEJM editorial).[93] A break-out in mortality rate was provided for the U.S. subgroup within the study, and while the U.S. subgroup would be expected to have greater consistency with standards of care for Medicare patients, we question whether the U.S. subgroup of the original sample was powered to show a statistically significant difference in outcome. No confidence interval or power calculations were provided for the U.S. subgroup results, which stated a 34.4% absolute reduction in mortality at day 60. Further, secondary outcomes were not provided for the U.S. subgroup. We question whether the different standards of care contributed to the high rate of mortality (35% at day 29; 45% at day 60) in the placebo group, and whether it is appropriate to compare against the results of the placebo group. The patients in the study underwent random assignment between May 18, 2021 and January 31, 2022. CDC's reporting for in-hospital mortality among patients hospitalized primarily for COVID–19 was 15.1% during the Delta period (July–October 2021), and 13.1% during the early Omicron period (January–March 2022).[94] While these may not be direct comparison groups, it is unclear why there would be a remarkable difference in the CDC published mortality rates among patients hospitalized primarily for COVID–19 and the mortality rates of the placebo group in this study. Rajesh T. Gandhi, MD also noted the mortality rate to be higher in the study referenced by the applicant (Barnette KG et al. NEJM Evid 2022 Jul 6) than in other recent trials [95] and he asserted that this high rate of mortality may have affected the results of the study. Dr. Gandhi goes on to say that while the high rate of mortality may be related to the severity of illness and underlying risk, it may also be due to chance because of the small number of participants, and that a larger, more definitive study of this drug may be warranted.[96] We further note that the study provided by the applicant shows a difference in outcomes with remdesivir usage at 34.7% among the sabizabulin group and 28.8% among the placebo group, and we question whether higher remdesivir usage rates in the sabizabulin group may have contributed to greater anti-viral effects.

Finally, with regard to the claim about medication adherence, we note that the study provided was not designed to measure medication compliance/adherence results, and no data was provided to directly support greater medication compliance/adherence for sabizabulin, or a comparison with self-administered medications. We therefore question how the results in this study support the assertion that sabizabulin utilization demonstrates greater medication adherence and compliance. We also note that patients who withdrew consent or refused the protocol were removed from the study, and we question the impact that may have had on analyses of medication compliance/adherence.

We are inviting public comments on whether sabizabulin meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for sabizabulin.

l. 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 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-

[92] DOI: *https://files.covid19treatmentguidelines.nih.gov/guidelines/archive/covid19treatmentguidelines-04-08-2022.pdf*.

[93] Ithan D. Peltan, M.D., M.Sc. and Samuel M. Brown, M.D., M.S. ''What Next? New Drugs, Old Drugs, and New Challenges in Choosing Treatments for Covid–19,'' August 23, 2022 DOI: *https://evidence.nejm.org/doi/full/10.1056/EVIDe2200189*.

[94] Adjei S, Hong K, Molinari NM, et al. Mortality Risk Among Patients Hospitalized Primarily for COVID–19 During the Omicron and Delta Variant Pandemic Periods—United States, April 2020–June 2022. MMWR Morb Mortal Wkly Rep 2022;71:1182–1189. DOI: *http://dx.doi.org/10.15585/mmwr.mm7137a4*.

[95] Dr. Gandhi referenced other recent studies with lower mortality rates. One reference was a review that he wrote on the of the National Institutes of Health–sponsored Adaptive COVID–19 Treatment Trial (ACTT–1); doi: *https://www.jwatch.org/na52072*; another reference was to a study on Remdesivir for the Treatment of Covid-19; doi: *https://www.nejm.org/doi/full/10.1056/nejmoa2007764*.

[96] Rajesh T. Gandhi, MD, NEJM Journal Watch, ''A Possible New Drug for Treatment of Hospitalized Patients with COVID–19,'' July 21, 2022 DOI: *https://www.jwatch.org/na55130/2022/07/21/possible-new-drug-treatment-hospitalized-patients-with*.

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 [97] 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).

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.

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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.

We have the following concerns with regard to the newness criterion. We note 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, it does not appear that these differences materially affect the mechanism of action of the technology. We note that both devices utilize a gene expression assay using reverse transcription polymerase chain reaction to quantify the relative expression levels of host response genes.[98] We further note that the applicant also appears to

[97] *https://www.accessdata.fda.gov/cdrh_docs/reviews/K163260.pdf.*

[98] *https://www.accessdata.fda.gov/cdrh_docs/reviews/K163260.pdf.*

consider the devices as similar, as they rely on studies conducted using the SeptiCyte® LAB to demonstrate substantial clinical improvement.

We also note 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 does not appear to be related to newness and we are 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 states 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 believe these technologies may be substantially similar to each other. We note 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) approval 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.

We are inviting public comments on whether SeptiCyte® RAPID is substantially similar to existing technologies and whether SeptiCyte® RAPID meets the newness criterion.

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 this 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 this 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 this 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 are inviting public comments on whether 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.[99] 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.

[99] 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 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,	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:

	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.	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 lll, 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 lll, 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 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

After review of the information provided by the applicant, we have the following concerns regarding whether SeptiCyte® RAPID meets the substantial clinical improvement criterion. First, we note that the applicant submitted two studies [100] [101] 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 note 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 question whether SeptiCyte® RAPID can provide an earlier diagnosis and affects the management of the patient. In addition, the applicant did not provide evidence for this claim other than the one-hour turnaround time for SeptiCyte® RAPID to provide test results. Additionally, we note 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 are inviting public comments on whether SeptiCyte® RAPID meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for SeptiCyte® RAPID.

[100] 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.*

[101] 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.

m. SER–109

Seres Therapeutics, Inc. submitted an application for new technology add-on payments for SER–109 for FY 2024. Per the applicant, SER–109 is an investigational oral microbiome therapeutic administered to reduce Clostridioides difficile (C. diff) infection (CDI) recurrence as part of a two-pronged treatment approach of (1) antibiotics to kill vegetative C. diff bacteria, followed by (2) SER–109 to repair the microbiome to manage CDI and prevent its recurrence. According to the applicant, SER–109 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.

Please refer to the online application posting for SER–109, available at *https://mearis.cms.gov/public/publications/ntap/NTP221016VHL8B*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, the applicant stated it has not yet received FDA marketing authorization for SER–109 but that it anticipates BLA approval before July 1, 2023 for the proposed indication to prevent the recurrence of CDI in adults with rCDI. According to the applicant, SER–109 will be commercially available after it receives FDA approval. The applicant stated that the proposed dose is four capsules taken orally once daily on an empty stomach before the first meal of the day for 3 consecutive days; recommended dosage and administration are subject to final FDA approval.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify SER–109. We note that the applicant submitted a request for approval for a unique ICD–10–PCS procedure code for SER–109 beginning in FY 2024. The applicant 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 SER–109 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 stated that SER–109 is not substantially similar to other currently available technologies because SER–109 does not have the same or 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 SER–109 meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criteria. Please see the online application posting for SER–109 for the applicant's complete statements in support of its assertion that SER–109 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	SER-109 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™, SER-109 prevents rCDI by repairing the microbiome. While the specific mechanism of action of SER-109 is still under investigation, findings from the ECOSPOR III clinical trial indicate that SER-109 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 SER-109 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. SER-109 treats rCDI using a two-pronged approach: when followed by antibiotics, which kill the active C. diff infection, SER-109 prevents the infection from recurring by repairing the microbiome. Thus, unlike antibiotics and ZINPLAVA™, SER-109 is intended to treat rCDI specifically by reestablishing the microbiome necessary to prevent reinfection. SER-109 also provides treatment options for patients who cannot currently access other therapies that might be used to treat CDI. In particular, SER-109 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.

We note the following concerns with regard to the newness criterion. The applicant asserted that SER–109 can be administered to patients with CHF and stated that the use of ZINPLAVA™ (bezlotoxumab) should be reserved in this patient population. We note that the indication for ZINPLAVA™ does not exclude patients with a history of CHF and the labeling has no listed contraindications. Therefore, we seek clarification from the applicant regarding the differences in patient populations for ZINPLAVA™ and SER–109.

In addition, we note that SER–109 may have a substantially similar mechanism of action as REBYOTA™, another microbiome therapeutic 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. Notably, the exact mechanism of action for each therapeutic is not known; however, both appear to act on the gut microbiome to prevent the increased germination of *C. difficile* (C. diff) and thereby prevent rCDI. Both SER–109 and REBYOTA™ appear to lead to compositional changes in the gastrointestinal microbiome that restore the diversity of gut flora which enable it to suppress outgrowth of C. diff. and rCDI, following standard-of-care treatment with antibiotics for rCDI. Further, both technologies appear 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 appears that SER–109 and REBYOTA™ are

purposed to achieve the same therapeutic outcome using a similar mechanism of action and would be assigned to the same MS–DRG, we believe 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 note that if this technology is substantially similar to REBYOTA™, 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, we believe the newness period for this technology would begin on January 23, 2023, the date REBYOTA™ became commercially available. We are 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 SER–109 and REBYOTA™ are substantially similar to each other and therefore should be considered as a single application for purposes of new technology add-on payments.

We are inviting public comment on whether SER–109 is substantially similar to existing technologies and meets the newness criterion, including whether SER–109 is substantially similar to REBYOTA™, and whether these technologies should be evaluated as a single technology for purposes of new technology add-on payments.

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for SER–109, 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 this 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 $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 SER–109 meets the cost criterion.

SER-109 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 this 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 SER-109 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 SER-109 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 are inviting public comments on whether SER–109 meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that SER–109 represents a substantial clinical improvement over existing technologies because SER–109 treats patients unresponsive to antibiotic treatment for rCDI and can be used in patients ineligible for ZINPLAVA™ due to CHF. The applicant also asserts that it improves clinical outcomes by reducing CDI recurrence, increasing resolution of the disease process by expediting microbiome repair, and reducing carriage of antimicrobial resistance genes. The applicant provided 5 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.[102] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for SER–109 for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

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[102] 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**
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 SER-109 versus placebo to reduce rCDI.	SER-109 was generally well tolerated among subjects. Adverse events (AEs) occurred in 76.7% (46/60) subjects given 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 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% 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 SER-109 and 13.8% on placebo. 13.5% (12/89) subjects experienced a serious AE: 15.0% (9/60) subjects who received 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.	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 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 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: ECOSPOR III was a double-blind, randomized, multicenter trial with patients randomized to receive SER-109 or matching placebo administered as 4 capsules daily for 3 days	This study provides 24-week follow-up data for the Phase III study (SER-109, an Oral Microbiome Therapy for Recurrent Clostridioides difficile Infection ("ECOSPOR III")) and supplement. Benefit from SER-109 was evident at week 2 and durable through 24 weeks. ECOSPOR III included 182 participants (89 given SER-109 and 93 given placebo); this October 2022 study assessed prespecified secondary 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 SER-109 group, compared to 44 in placebo). At 4, 8, 12, and 24 weeks, a significantly lower proportion of patients given SER-109 experienced recurrence, compared to placebo. Serious AEs occurred in 15 patients given SER-109 and 19 in placebo; none were

		considered drug-related. Overall, 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.	
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 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 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 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	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 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 SER-109 recipients were found to have a sustained clinical response, as compared with 60% of the placebo recipients. 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 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 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 SER-109 group, compared to 44 in placebo). At 4, 8, 12, and 24 weeks, a significantly lower proportion of patients given SER-109 experienced recurrence, compared to placebo. Serious AEs occurred in 15 patients given SER-109 and 19 in placebo; none were considered drug-related. Overall, 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 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	Study assessed engraftment by comparing the number of dose-species in stool samples at 3 time points. Minimal 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 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) Study evaluated whether the degree of engraftment differed by clinical outcome. Since 50% of recurrences were observed by day 11, study compared dose-species diversity at baseline and week 1 by clinical outcome. Before SER-109 treatment, dose-species diversity was not associated with outcome in either treatment group (Mann-Whitney U test). At week 1, 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 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 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 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 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 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 SER-109 after a first recurrence. Such earlier intervention (that is., after the first recurrence) with 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 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 SER-109 group, compared to 44 in placebo). At 4, 8, 12, and 24 weeks, a significantly lower proportion of patients given SER-109 experienced recurrence, compared to placebo. Serious AEs occurred in 15 patients given SER-109 and 19 in placebo; none were considered drug-related. Overall, SER-109 durably reduced rates of recurring CDI, and was well-tolerated through 24 weeks in patients with prevalent comorbidities.
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 outpatient medical claim for CDI plus a CDI treatment. Index CDI episodes occurred between Jan. 1, 2010–June 30, 2017.	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 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 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, 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 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 SER-109 group, compared to 44 in placebo). At 4, 8, 12, and 24 weeks, a significantly lower proportion of patients given SER-109 experienced recurrence, compared to placebo. Serious AEs occurred in 15 patients given SER-109 and 19 in placebo; none were considered drug-related. Overall, 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.	
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 SER-109 were observed through week 8. Adverse events that were related or possibly related to 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 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 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	See study outcomes previously described
	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 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 SER-109 group, compared to 44 in placebo). At 4, 8, 12, and 24 weeks, a significantly lower proportion of patients given SER-109 experienced recurrence, compared to placebo. Serious AEs occurred in 15 patients given SER-109 and 19 in placebo; none were considered drug-related. Overall, 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, 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), 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 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), 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 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 SER-109 on antimicrobial resistance genes (ARGs) abundance in the intestinal microbiota compared to placebo at weeks 1, 2, and 8.

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After review of the information provided by the applicant, we have the following concerns regarding whether SER–109 meets the substantial clinical improvement criterion. To demonstrate that SER–109 reduces rates of CDI recurrence compared to standard of care therapies, the application primarily cites to the ECOSPOR phase II trial and ECOSPOR III phase III trial. The application also cites a recently-presented abstract of the open-label single-arm ECOSPOR IV trial which does not appear to provide a comparison against currently available therapies. The major limitation of these data is that patients who received ZINPLAVA™ in the prior 3 months were excluded. While the study provides data comparing the

effectiveness of SER–109 to antibiotics alone, no data comparing the treatment of rCDI utilizing antibiotics plus ZINPLAVA™, as is currently recommended for rCDI, against antibiotics plus SER–109 (with or without ZINPLAVA™) was provided. Without a comparison against such currently available therapies, we question whether the information provided by the applicant is sufficient to support the applicant's statements that SER–109 is well-tolerated and mitigates the safety concerns of other alternative therapies, and that SER–109 can be used in patients ineligible for ZINPLAVA™ due to diagnosis of CHF.

With regard to the claim that SER–109 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. It is not clear whether this criterion necessarily excluded individuals with known pre-existing CHF from the study group; however, it is also not clear how many individuals diagnosed with CHF prior to or during the study were identified in the study populations. A lack of participants with CHF could potentially account for the low incidence of adverse effects, rather than being attributable to the safety of SER–109 relative to ZINPLAVA™ for patients with CHF. Absent additional information, it is therefore difficult to confirm that SER–109 offers a treatment option for patients ineligible for ZINPLAVA™ due to CHF.

According to the applicant, there is an increased resolution of the disease process because SER–109 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 cites three articles: two randomized controlled trials and one unpublished abstract. While the results of the Phase III randomized controlled trial [103] demonstrates the superiority of SER–109 over placebo, we question whether other treatment options indicated to prevent rCDI, such as ZINPLAVA™, would be a more appropriate comparator. Additional information regarding clinical outcomes as a result of treatment with SER–109 compared to such treatment options, instead of placebo, would be helpful in our assessment of the substantial clinical improvement criterion.

With respect to the applicant's claim that SER–109 may reduce the number of future hospitalizations or physician visits for patients diagnosed with rCDI, the applicant cites the Feurstadt study to suggest that reduced rates of rCDI shown in Phase III clinical trials would likely lead to fewer days in hospital. However, the study does not address this measure directly; rather, this is an inference by the applicant. We welcome additional data to support the claim SER–109 may reduce the number of future hospitalizations or physician visits for patients with rCDI.

With respect to the claim that SER–109 reduces the abundance of antimicrobial resistance genes (ARGs) and associated taxa compared to placebo, which accelerates microbiome recovery from antibiotics, the applicant cited one unpublished study showing treatment with SER–109 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 are inviting public comments on whether SER–109 meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for SER–109.

n. 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 currently under investigation for the treatment of flares in adult patients with generalized pustular psoriasis (GPP). We note 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 generalized pustular psoriasis (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 biologics, 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

[103] 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.

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.

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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.

We have 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 note that, when describing current treatments for the disease, the applicant stated that there are no FDA-approved therapies specifically indicated for GPP. However, we question 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 request additional information on any such treatments and how they compare to SPEVIGO® with regard to substantial similarity. We also note 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 believe these are the same MS–DRGs to which other treatments for GPP would map.

We are inviting public comments on whether SPEVIGO® is substantially similar to existing technologies and whether SPEVIGO® meets the newness criterion.

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 $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.

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.

We note 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 question whether it may be appropriate to remove some portion of these charges to avoid inappropriately inflating the average charge per case. We are inviting public comments on whether it may be appropriate to remove charges for the prior technology and whether 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.

After review of the information provided by the applicant, we have the following concerns regarding whether SPEVIGO® meets the substantial clinical improvement criterion. With regard to the Effisayil-1 study, we note that it is not designed to compare SPEVIGO® to current treatment options. While the applicant states that SPEVIGO® will be the first GPP treatment targeting the IL–36 pathway, we note that per the applicant, other treatments are available and we therefore question whether placebo is the most appropriate comparator. In particular, we note that the Effisayil-1 trial primarily assessed clearance of skin manifestations, not systemic symptoms which the applicant notes differentiates GPP from other forms of psoriasis. We note 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 note that there are treatments that are indicated for psoriasis generally, such as methotrexate[104] or retinoids,[105] which may be considered an on-label use for subtypes of psoriasis such as GPP.

[104] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/008085Orig1s071lbl.pdf.*

[105] *https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/019821s028lbl.pdf.*

Therefore, it is 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 seems 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 note that GPP occurs most frequently between the ages of 15–20 years with a smaller peak occurring at 55–60 years.[106] 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 question 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 question whether the information we have supports a finding of substantial clinical improvement. Additional information to support the applicant's assertion of superiority over existing technologies would be helpful in better informing our assessment of this criterion.[107] [108]

We are inviting public comments on whether SPEVIGO® meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for SPEVIGO®.

o. 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% 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.

[106] [20] Samotij et al. Generalized pustular psoriasis: divergence of innate and adaptive immunity. Int J Mol Sci 2021;22(16):9048.

[107] Krueger et al. Treatment options and goals for patients with generalized pustular psoriasis. Am J Clin Dermatol 2022:23(suppl 1):51–64.

[108] Choon et al. Clinical course and characteristics of generalized pustular psoriasis. Am J Clin Dermatol 2022;23(suppl 1):21–9.

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 MoA, 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 MoA, 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.

We note 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 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 believe that the mechanism of action for TECVAYLI™ may be the same or similar to that of elranatamab.

We believe 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 believe 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 are 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 are inviting 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.

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 are inviting public comments on whether 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.[109] The following table

[109] Background articles are not included in the following table but can be accessed via the online posting for the technology.

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.	

After review of the information provided by the applicant, we have the following concerns regarding whether TECVALI™ meets the substantial clinical improvement criterion. The applicant claims 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 discusses 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 question 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 United States indicating only 25% of potential patients were reported to receive CD19 CAR T-cell therapy, with a median wait time of 6 months.[110] 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 question whether the evidence related to B-cell

[110] 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.

lymphoma is applicable to T-cell therapies used to treat MM.

The applicant claims that CRS is less serious and less frequent for patients treated with TECVAYLI™ than with BCMA CAR T-cell therapies. Notably, the applicant compares data from separate, single-arm, open-label studies of these technologies.[111] [112] [113] In review, CRS occurrence rates were 72.1%, 95% and 84% for TECVAYLI™, ciltacabtagene autoleucel, and idecabtagene vicleucel, respectively. In addition, only 0.6% of the CRS events for TECVAYLI™ were of grade 3 or higher, compared to 4% for ciltacabtagene autoleucel and 5% for idecabtagene vicleucel. This improved safety claim, however, focuses 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%, 97% and 73% for TECVAYLI™, ciltacabtagene autoleucel, and idecabtagene vicleucel respectively. When comparing across studies, other metrics of efficacy noted in these studies also appear to support a superiority of the CAR T-cell therapies compared to TECVAYLI™ in the treatment of patients with RRMM. However, we also note these comparisons are not matched cases within a comparative study. Therefore, we question the conclusions drawn by the applicant regarding the relative efficacy and safety profiles across these studies.

The applicant claims that TECVAYLI™ improves clinical outcomes relative to other off-the-shelf therapies. The applicant states the overall response rate (ORR) for XPOVIO® and BLENREP were 25% and 31%, while the ORR for TECVAYLI™ was 63%. However, this claim does not consider the higher ORR for CAR T-cell therapies compared to TECVAYLI™ when comparing across studies, as previously mentioned. While this claim compares TECVAYLI™ only to other off-the-shelf therapies, which would not include CAR T-cell therapies, we question whether there is significant clinical improvement compared to existing therapies, which include CAR T-cell therapies.

We are inviting public comments on whether TECVAYLI™ meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for TECVAYLI™.

p. 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).

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® was granted NDA 505(b) approval from 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% 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% 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), and 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

[111] Moreau P, Garfall AL, van de Donk NWCJ, et al. Teclistamab in relapsed or refractory multiple myeloma. NEJM. 2022; 387(6): 495–505.

[112] 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.

[113] 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.

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 with efficacy and safety established by the FDA. 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), we note 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, does not necessarily speak to the treatment of a new patient population for HRS.

We are inviting public comments on whether TERLIVAZ® is substantially similar to existing technologies and whether TERLIVAZ® meets the newness criterion.

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 this 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.

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 this 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 inviting public comments on whether 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 in renal function with TERLIVAZ® treatment compared to placebo.	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. 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.	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 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	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

therapy with available options, yet this subgroup achieved a statistically significant improvement in renal function with TERLIVAZ®.		≤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 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 midodrine and octreotide for HRS, TERLIVAZ® treatment resulted in significantly greater rates of response.	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. 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.	The primary endpoint of the study was complete response at completion of treatment. A significantly higher rate of 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®	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%;

	as a treatment for HRS in patients aged ≥65 years using data from the CONFIRM trial.	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).
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	Wong F, Pappas SC, Curry MP, et al. Terlipressin plus albumin for the treatment of type 1	Results show the rates of RRT in TERLIVAZ® vs placebo groups,

associated with reductions in RRT requirements.	hepatorenal syndrome. N Engl J Med. 2021;384(9):818-828. See prior study description	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: This update from the AGA pertains to management of patients with cirrhosis and AKI and was based on best available published evidence.	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 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 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.	These guidelines recommend that patients who meet diagnostic criteria for 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 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.	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

	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.	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 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).

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After review of the information provided by the applicant, we have 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 note that the applicant provided evidence from data on file for the clinical study report of the CONFIRM trial. We note that this data on file appears to be a post-hoc analysis of the trial. As this was a post-hoc analysis, we are cautious about drawing conclusions from this analysis alone without additional outcome data.

We also note 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).[114] We also noted that the potential for HRS recurrence among patients treated with TERLIVAZ® after 30 days is unclear. We question whether a statistically significant difference in verified HRS reversal in the TERLIVAZ® group at 14 days is 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 note 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 RTT requirements in patients who received a liver transplant. Similar to our earlier concern, we question if we are able to draw conclusions from these post-hoc analyses alone without additional outcome data.

We also note 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 note 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 note that the difference in RRT requirements through 90 days in the CONFIRM study among surviving patients aged ≥65 years

[114] 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.

was not statistically significant. Although the results numerically favored the TERLIVAZ ® group, for those reasons, we question whether this analysis provides 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.[115]

We are inviting public comments on whether TERLIVAZ ® meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for TERLIVAZ ®.

q. VANFLYTA ® (Quizartinib)

Daiichi Sankyo, Inc. submitted an application for new technology add-on payments for VANFLYTA ® for FY 2024. Per the applicant, VANFLYTA ® is a kinase inhibitor intended to be indicated for use in combination with standard cytarabine and anthracycline induction chemotherapy and standard cytarabine consolidation chemotherapy, and as continuation monotherapy following consolidation, for the treatment of adult patients with newly diagnosed acute myeloid leukemia (AML) that is Feline McDonough Sarcoma (FMS)-like tyrosine kinase 3 internal tandem duplication (FLT3–ITD) positive as detected by an FDA-authorized test. The applicant asserted that, while other treatments for FLT3 AML are available, VANFLYTA ® is the only treatment to exclusively target the FLT3–ITD mutation, thereby inhibiting further downstream FLT3 receptor signaling and blocking FLT3–ITD-dependent cell proliferation. According to the applicant, VANFLYTA ® also does not target other kinases; this may mean that patients experience fewer off-target effects when undergoing therapy with VANFLYTA ®.

Please refer to the online application posting for VANFLYTA ®, available at *https://mearis.cms.gov/public/publications/ntap/NTP221017FK1AQ*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, the applicant stated it has not yet received FDA marketing authorization for VANFLYTA ®. According to the applicant, it anticipates NDA approval from FDA before July 1, 2023 for the following proposed indication: a kinase inhibitor indicated in combination with standard cytarabine and anthracycline induction and standard cytarabine consolidation chemotherapy, and as continuation monotherapy following consolidation, for the treatment of adult patients with newly diagnosed AML that is FLT3–ITD positive as detected by an FDA-authorized test. According to the applicant, VANFLYTA ® will be available on the market immediately after FDA approval. The applicant stated that VANFLYTA ® should be administered in combination with standard chemotherapy at a dose of 35.4 mg once daily for two weeks in each cycle of induction. For patients who achieved complete remission (CR) or complete remission with incomplete hematologic recovery (CRi), VANFLYTA ® should be administered at 35.4 mg once daily for two weeks in each cycle of consolidation chemotherapy followed by VANFLYTA ® continuation monotherapy initiated at 26.5 mg once daily. After two weeks, the continuation dose should be increased to 53 mg once daily if the QT interval[116] corrected by Fridericia's formula (QTcF) is less than or equal to 450 ms. Continuation monotherapy may be continued for up to 36 cycles.

The applicant provided an estimated average inpatient cost per stay for VANFLYTA ®. The applicant did not have data to provide relative frequencies for induction versus consolidation inpatient treatments so provided the following cost calculation. The daily VANFLYTA ® dose used was based on 80% of patients receiving the full daily dose and 20% of patients receiving the reduced dose. An average weighted induction cycle cost was calculated based on trial data that indicated 75% of patients would receive one cycle of induction inpatient and 25% of patients would receive two cycles of induction inpatient. The average consolidation cycle cost was calculated separately from induction and assumed a 9-day inpatient stay. The cost was adjusted based on 65% of consolidation cycles being administered inpatient and 35% of consolidation cycles being administered outpatient (the inpatient cost for outpatient therapy was $0). The adjusted number was multiplied by two since the average patient receives 2 cycles of consolidation. This was multiplied by 0.75 due to 75% of patients continuing with treatment to receive consolidation therapy after induction. This final consolidation therapy cost was added to the induction cycle cost to come up with the applicant's weighted average inpatient cost per stay.

Since the estimated average inpatient cost per stay would be used to determine the new technology add-on payment amount for VANFLYTA ®, if approved, we note the following concerns with regards to the applicant's average cost calculation. We believe the final costs for induction and consolidation should be averaged rather than summed since induction and consolidation cycles would likely be separate hospitalizations. We are inviting public comments on whether the applicant's average cost calculation is appropriate for calculating the new technology add-on payment amount if VANFLYTA ® is approved.

According to the applicant, there are currently no ICD–10–PCS codes to distinctly identify VANFLYTA ®. We note that the applicant submitted a request for approval for a unique ICD–10–PCS procedure code for VANFLYTA ® beginning in FY 2024. The applicant stated that ICD–10–CM diagnosis codes C92.00 (Acute myeloblastic leukemia not having achieved remission), C92.50 (Acute myelomonocytic leukemia not having achieved remission), C92.60 (Acute myeloid leukemia with 11q23-abnormality not having achieved remission), C92.A0 (Acute myeloid leukemia with multilineage dysplasia not having achieved remission), and C93.00 (Acute monoblastic-monocytic leukemia not having achieved remission) may be used to currently identify the indication for VANFLYTA ® 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 VANFLYTA ® is not substantially similar to other currently available technologies because VANFLYTA ® is the first drug to be expressly developed

[115] 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.

[116] The QT interval is the time between specific points in a heartbeat, as seen on an electrocardiogram (EKG).

as a FLT3 inhibitor, not a multi-kinase inhibitor, and specifically optimized to inhibit the FLT3–ITD AML, thereby targeting the subpopulation of newly diagnosed patients with the worst prognosis (higher risk of relapse and worse overall survival). Additionally, the applicant stated that VANFLYTA®, if approved, would be the only AML drug indicated for continuation monotherapy following consolidation chemotherapy (for up to 3 years), based on showing activity as a single agent for that use, 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 VANFLYTA® for the applicant's complete statements in support of its assertion that VANFLYTA® is not substantially similar to other currently available technologies.

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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	VANFLYTA® (quizartinib) is the first drug to be developed expressly as a FLT3 inhibitor and specifically optimized pharmacodynamically and pharmacokinetically to inhibit the FLT3-ITD mutation in AML, and not the FLT3-tyrosine kinase domain (TKD) mutation. Therefore, VANFLYTA®'s mechanism of action (MOA) is unique and should be considered new under this criterion. There are two types of FLT3 mutations, ITD and TKD, accounting for approximately 27% and 7% of AML patients respectively. ITD is the primary driver mutation associated with aggressive disease, resulting in an increased relapse rate and reduced overall survival. By contrast, TKD has not consistently been shown to influence AML prognosis. This is part of the scientific rationale behind VANFLYTA®'s MOA which targets ITD.
Is the technology assigned to the same MS-DRG as existing technologies?	No	VANFLYTA® is not assigned to the same DRG as existing technology. However, cases involving patients being medically treated for the type of AML indicated for VANFLYTA® would likely be mapped to the following MS-DRGs: 834 (Acute Leukemia without Major O.R. Procedure with MCC), 835 (Acute Leukemia without Major O.R. Procedure with CC), and 836 (Acute Leukemia without Major O.R. Procedure without CC/MCC).
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	Although VANFLYTA®, if FDA approved, and RYDAPT® would both be indicated for use in combination with standard induction and consolidation chemotherapy for the treatment of adult patients with newly diagnosed AML, VANFLYTA® is a much more selective FLT3 inhibitor. VANFLYTA® exclusively targets the FLT3-ITD mutation, rather than both FLT3-TKD and FLT3-ITD mutations. In this way, VANFLYTA® isolates the newly diagnosed patient population with the worst prognosis who may benefit the most from this targeted therapy. Additionally, VANFLYTA®, if approved, would be indicated as continuation monotherapy following consolidation chemotherapy, whereas RYDAPT® is not indicated in the United States for this use. The aim of continuation monotherapy (maintenance therapy) is to reduce the risk of relapse or to prolong survival. VANFLYTA® targets patients who may benefit from continuation monotherapy, those with FLT-ITD AML, as they are most at risk for relapse. VANFLYTA® is also different from XOSPATA® (gilteritinib), a multi-kinase inhibitor indicated for the treatment of adult patients who have relapsed or refractory AML with a FLT3 mutation as detected by an FDA-authorized test and targets patients with FLT3-TKD and FLT-ITD mutations. Finally, preclinical studies suggests that quizartinib might be a treatment option for patients who have failed on other available therapies and might otherwise be considered to have no other current treatment options.

We have the following concerns regarding the newness criterion. While the applicant stated that VANFLYTA® is more selective than existing technology since it targets only FLT3–ITD, we note that, as stated by the applicant, RYDAPT® also targets this same mutation and we therefore question whether the mechanisms of action for VANFLYTA® and RYDAPT® are the same or similar. We also note that while the applicant stated that VANFLYTA® is not assigned to the same MS–DRG as existing technology, per the applicant, VANFLYTA® would likely be mapped to three existing MS–DRGs for AML and therefore it appears that use of VANFLYTA® is not

expected to change the MS–DRG assignment from that of existing technologies.

The applicant asserted that the technology would not involve the treatment of the same or similar type of disease and patient population when compared to existing technology. However, VANFLYTA®, if approved, would appear to be indicated for a patient population included within the patient population indicated for RYDAPT®. RYDAPT® is indicated for adult patients with newly diagnosed AML who are FLT3 mutation-positive, which would be similar to VANFLYTA®'s proposed patient population of adult patients with newly diagnosed AML that is FLT3–ITD positive. In addition, the patient population for XOSPATA®, adult patients with relapsed or refractory AML with the FLT3 mutation, may be considered similar to that for VANFLYTA® since both patient populations are adults with AML that have a FLT3 mutation. While the applicant notes a potential unique patient population with regard to the proposed continuation monotherapy indication, this would not relate to the new technology add-on payment given this treatment would occur on an outpatient basis.

We are inviting public comments on whether VANFLYTA® is substantially similar to existing technologies and whether VANFLYTA® meets the newness criterion.

With respect to the cost criterion, the applicant submitted analyses based on two cohorts, a consolidation dosing scenario and an induction dosing scenario, to demonstrate that VANFLYTA® meets the cost criterion. To identify potential cases representing patients who may be eligible for VANFLYTA®, the applicant searched the CY 2021 Limited Data Set (LDS) Standard Analytic File (SAF) for cases reporting one of the ICD–10–CM diagnosis codes listed in the table that follows in the primary or secondary location of the discharge claim. Using the inclusion/exclusion criteria described in the following table, the applicant identified 6,084 claims mapping to six 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 $168,129 using consolidation dosing and $171,567 using induction dosing, both of which exceeded the average case-weighted threshold amount of $105,003. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that VANFLYTA® meets the cost criterion.

VANFLYTA® COST ANALYSIS	
Data Source and Time Period	CY 2021 LDS SAF 100% sample
List of ICD-10-CM codes	C92.00 (Acute myeloblastic leukemia not having achieved remission), C92.50 (Acute myelomonocytic leukemia not having achieved remission), C92.60 (Acute myeloid leukemia with 11q23-abnormality not having achieved remission), C92.A0 (Acute myeloid leukemia with multilineage dysplasia not having achieved remission), and C93.00 (Acute monoblastic/monocytic leukemia not having achieved remission).
List of MS-DRGs	834 (Acute Leukemia without Major O.R. Procedure with MCC), 835 (Acute Leukemia without Major O.R. Procedure with CC), 836 (Acute Leukemia without Major O.R. Procedure without CC/MCC), 837 (Chemotherapy with Acute Leukemia as SDX or with High Dose Chemotherapy Agent with MCC), 838 (Chemotherapy with Acute Leukemia as SDX with CC or High Dose Chemotherapy Agent), 839 (Chemotherapy with Acute Leukemia as SDX without CC/MCC)
Inclusion/ exclusion criteria	Cohort 1 and 2 The applicant identified cases by using the ICD-10-CM diagnosis codes in this table. The applicant calculated the average unstandardized charge per case for each MS-DRG.
Charges removed for prior technology	The applicant obtained the current wholesale acquisition cost (WAC) for RYDAPT® (midostaurin) from publicly available pricing compendia. According to the Package Insert (PI), patients take four tablets per day. Cohort 1 For the consolidation dosing scenario, the dosing was based on a 9-day inpatient stay for consolidation. The applicant removed charges for the consolidation dosing based on 4 pills a day for 4 days of therapy during a 9-day inpatient stay given the drug's dosing regimen. Cohort 2 For the induction dosing scenario, the applicant used 17.5 days of therapy as a weighted average days of inpatient therapy since approximately 75% of patients receive one cycle of induction and approximately 25% of patients receive two cycles of induction. The applicant removed charges for the induction dosing based on 4 pills a day over 17.5 days. The applicant did not remove any indirect 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 standardizing file posted with the FY 2021 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 used similar calculations as those used for charges removed for RYDAPT®, as previously discussed in this table. Cohort 1 For the consolidation dosing, a 9-day inpatient stay was used with 4 days of therapy based on the drug's dosing regimen. The applicant submitted the cost and did not use the cost-to-charge ratio to convert to the charge. As noted by the applicant, if the pharmacy CCR factor was used, the cost threshold would be exceeded by an even greater degree. Cohort 2 For the induction dosing scenario, 17.5 days of inpatient therapy was used. The applicant submitted the cost and did not use the cost-to-charge ratio to convert to charge. As noted by the applicant, if the pharmacy CCR factor was used, the cost threshold would be exceeded by an even greater degree. The applicant did not add indirect charges related to the new technology.

We are inviting public comments on whether VANFLYTA® meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that VANFLYTA® represents a substantial clinical improvement for Medicare beneficiaries and offers a treatment option for newly diagnosed patients with FLT3–ITD+ AML, the most treatment-resistant AML subtype, and patients receiving VANFLYTA® plus standard induction and consolidation therapy, and then continuation monotherapy for up to three years, had significantly reduced rates of relapse and overall improved survival, regardless of whether they received a hematopoietic stem cell transplantation (HSCT) when compared to the placebo group. The applicant referenced multiple sources regarding one study to support these claims, as well as five background articles about AML and RYDAPT®, a drug indicated for adult patients with newly diagnosed AML who are FLT3 mutation-positive.[117] The following table summarizes the applicant's assertions regarding the substantial clinical improvement criterion. Please see the online posting for VANFLYTA® for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

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[117] 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 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**
Clinical trial participants are more representative of the Medicare population, which has high prevalence of AML, compared to the competitor drug, RYDAPT®.	ClinicalTrials.gov identifier: NCT02668653. Last updated October 5, 2022. https://clinicaltrials.gov/ct2/show/NCT02668653. Pages 1 - 11. Brief study description: QUANTUM First study - Phase 3, randomized, double-blind, placebo-control study comparing the effect of quizartinib vs. placebo on overall survival (OS) in 539 enrolled patients with FLT3-ITD+ AML.	Ages eligible for the QUANTUM First study, 18 years to 75 years old (Adult, Older Adult).
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
VANFLYTA® reduced rate of relapse.	Erba H, et al. Abstract S100. EHA 2022; June 9-17, 2022; Vienna, AT NCT02668653 (Visual Abstract https://aml-hub.com/medical-information/va). Brief study description: Visual abstract of QUANTUM First study design and outcomes.	Quizartinib reduced rates of relapse in patients who achieved Complete Remission (CR) by the end of induction phase, with a cumulative incidence rate of relapse (CIR) at two (2) years of 31.2% vs. 43.3% with placebo. In a prespecified exploratory analysis, median Relapse Free Survival (RFS) was longer in patients treated with quizartinib who achieved CR at the end of induction (39.3 months vs. 13.6 months for placebo). The hazard ratio strongly favored quizartinib (HR, 0.613 (95% CI, 0.444–0.845). Further, the duration of CR with quizartinib was three (3) times longer compared with placebo (38.6 months vs. 12.4 months).
	Erba H. QUANTUM First Oral Presentation Slides at EHA. Vienna, AT. June 11, 2022. Abstract S100. Brief study description: EHA presentation slides on QUANTUM First study design and outcomes, including exploratory and post-hoc analyses.	Quizartinib reduced rates of relapse in patients who achieved complete remission (CR) by the end of induction, indicating that quizartinib plus chemotherapy may be able to prevent relapse compared with standard chemotherapy and surveillance alone, with a cumulative incidence rate of relapse (CIR) at two (2) years of 31.2% versus 43.3%, respectively. Further, slide 13 indicates that Relapse Free Survival (RFS) was longer in patients treated with quizartinib who achieved CR at the end of induction, at 39.3 months vs. 13.6 months for placebo (HR, 0.613 (95% CI, 0.444-0.845).
	The applicant also provided background information to support this claim, which can be accessed via the online posting for the technology.	
VANFLYTA® reduced mortality rate regardless of receiving an allogeneic hematopoietic stem cell transplantation (allo-HSCT) or not.	Erba H, et al. Abstract S100. EHA 2022; June 9-17, 2022; Vienna, AT NCT02668653 (Visual Abstract https://aml-hub.com/medical-information/va) See prior study description	Quizartinib plus chemotherapy reduced the risk of death by 22% and more than doubled the median overall survival compared with placebo plus chemotherapy with a median overall survival of 31.9 months vs. 15.1 months for placebo (HR, 0.776 (95% CI, 0.615–0.979) P=0.0324 (2-sided). P-value was calculated using a stratified log-rank test. When censored for allo-HSCT, overall survival trended longer with quizartinib plus chemotherapy compared to placebo plus chemotherapy [HR, 0.752 (95% CI, 0.562–1.008; 2-sided P=0.055)]. Results support the overall survival benefit of quizartinib, including in patients who do not undergo an allo-HSCT.
	Erba H. QUANTUM First Oral Presentation Slides at EHA. Vienna, AT. June 11, 2022. Abstract S100. See prior study description	When censored for allo-HSCT, quizartinib plus chemotherapy reduced the risk of death by 25% compared with placebo plus chemotherapy (HR, 0.752 (95% CI, 0.562–1.008). These results support the Overall Survival (OS) benefit of quizartinib, including in patients who do not undergo allo-HSCT. Additionally, the post hoc analysis on slide 10 shows that OS trended longer with quizartinib versus placebo in patients who achieved Complete Remission (CR) regardless of receiving transplant in CR1. See the OS in patients with CR who received allo-HSCT in CR1 (HR, 0.591 (95% CI, 0.330–1.059) as well as the OS in patients with CR not receiving allo-HSCT in CR1 (HR, 0.607 (95% CI, 0.387–0.954).

After review of the information provided by the applicant, we have the following concerns regarding whether VANFLYTA® meets the substantial clinical improvement criterion. We note the applicant provided only the results

of a single phase 3 trial testing VANFLYTA® in the form of presentation slides and an abstract. We further note that the visual abstract reference[118] provided by the applicant does not appear to include all data that the applicant cited as outcomes to support the claims for a reduced rate of relapse and reduced mortality rate with VANFLYTA® and we are therefore unable to fully evaluate the supporting evidence for these assertions. While TEAEs, grade 3 or higher TEAEs, TEAEs associated with fatal outcome, and serious adverse events (SAEs) appeared similar to placebo, there was a higher rate of drug discontinuation (20.4% versus 8.6%), dose interruption (34.0% versus 20.1%), and dose reduction (18.9% versus 6.3%) due to TEAEs for VANFLYTA® compared to placebo and we would appreciate additional information regarding these differences.

With regard to the claim that clinical trial participants are more representative of the Medicare population compared to the competitor drug (RYDAPT®), we note the QUANTUM First trial allowed inclusion of patients age 18 years to 75 years, while the Cancer and Leukemia Group B (CALGB) 10603 (RATIFY) trial, which compared RYDAPT® to placebo, included patients aged 18 years to 59 years. The applicant stated that in the QUANTUM First trial, 39.9% of the subjects were 60 years of age or older. This claim was provided in support of the assertion that the use of the new technology significantly improves clinical outcomes relative to technologies previously available. However, we question this assertion because age eligibility in a trial is not a clinical outcome, and eligibility may not correlate with improved outcomes.

With regard to the claim of a reduced rate of relapse compared to RYDAPT®, the applicant stated that a phase 3 trial demonstrated that the cumulative incidence of relapse (CIR) at 2 years was 40% for RYDAPT® [119] and in the QUANTUM First trial, the CIR at 2 years was 31.2% for VANFLYTA® and 43.3% with placebo. However, we note that this was based on comparing two separate phase 3 trials, which can involve numerous confounding variables, and the applicant did not provide support related to clinical trial design or statistical analysis to explain why the potential effect of confounding variables should not be a concern for purposes of this comparison. Additional data was also provided to indicate reduced rate of relapse of patients receiving VANFLYTA® compared to placebo in the QUANTUM First trial. However, the applicant did not provide these outcomes for the comparator drug, RYDAPT®. Therefore, we question whether the evidence presented is sufficient to show a reduced rate of relapse with VANFLYTA® compared to RYDAPT®.

With regard to the claim that VANFLYTA® reduced mortality rate regardless of receiving an allo-HSCT or not, we note that the evidence provided in support was based on data from the QUANTUM First trial, which compared VANFLYTA® to placebo rather than to RYDAPT® and we question whether this type of comparison can provide evidence to support a finding of improved outcomes compared to previously available therapy. Additionally, the overall survival data analyzed separately based on allo-HSCT status, as well as relapse rate data from QUANTUM First were both based on post-hoc analyses. We are cautious about drawing conclusions from these post-hoc analyses alone without additional outcome data.

We are inviting public comments on whether VANFLYTA® meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for VANFLYTA®.

r. VEST

Vascular Graft Solutions, Ltd. (VGS) submitted an application for new technology add-on payment for VEST for FY 2024. Per the applicant, VEST is an external support device which can be fitted over the saphenous vein when used as a bypass conduit in coronary artery bypass grafting (CABG) surgery. The applicant stated that VEST is the only technology that has been proven to prevent common vein graft failures as a result of graft kinking and vein graft disease (intimal hyperplasia). According to the applicant, VEST is designed to improve the long-term clinical outcome of CABG by reducing clinical events that are associated with graft failure.

Please refer to the online application posting for VEST, available at *https://mearis.cms.gov/public/publications/ntap/NTP221017VRFLQ*, for additional detail describing the technology and the disease treated by the technology.

With respect to the newness criterion, the applicant stated that it is seeking premarket approval from FDA for the indication to prevent vein graft intimal hyperplasia (IH) by providing permanent support to saphenous vein grafts which are being used as conduits in patients who undergo coronary artery bypass graft procedures, and anticipates receiving FDA marketing authorization before July 1, 2023. According to the applicant, VEST is expected to be commercially available once approved.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify VEST. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for VEST beginning in FY 2024.

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 payment.

With respect to the substantial similarity criteria, the applicant asserted that VEST is not substantially similar to other currently available technologies because there is no other technology with a similar mechanism of action with which VEST can be compared, and that therefore, the technology meets the newness criterion. The following table summarizes the applicant's assertions regarding the substantial similarity criterion. Please see the online application posting for VEST for the applicant's complete statements in support of its assertion that VEST is not substantially similar to other currently available technologies.

[118] Erba H, et al. Abstract S100. EHA 2022; June 9–17, 2022; Vienna, AT NCT02668653 (Visual Abstract, *https://aml-hub.com/medical-information/va*).

[119] Leukemia. 2021 September. 35(9)2539–2551.

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 is no product or technology in the market that addresses the problem of vein graft disease and failure by utilizing an external support device that provides permanent mechanical protection to the vein graft from the continuous arterial hemodynamic system, prevents abrupt conduit dilation, attenuates the higher arterial pressure to which the graft is exposed, mitigates against any associated increase in wall tension and enhances lumen uniformity. The VEST external support is pre-designed to maintain optimal diameter to limit the venous dilatation and the associated wall stretch and to minimize the diameter mismatch between the target artery and the vein graft. When applied over the vein graft, it reinforces the venous wall and thus absorbs the arterial pressure, and subsequently mitigates and suppresses the proliferative reaction induced by high wall stress.
Is the technology assigned to the same MS-DRG as existing technologies?	Yes	The utilization of VEST device will not impact MS-DRG assignment given it is an adjunct procedure to CABG.
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	VEST is indicated for the same patient population undergoing CABG procedure.

We are inviting public comments on whether VEST is substantially similar to existing technologies and whether VEST meets the newness criterion.

With respect to the cost criterion, the applicant provided two analyses to demonstrate that VEST meets the cost criterion, the first using 100 percent of all identified cases, and the second using 78 percent of all identified cases, based on the four MS–DRGs with the highest number of claims. The applicant searched the FY 2021 MedPAR file for potential cases representing patients who may be eligible for VEST using a list of ICD–10–PCS codes (cases representing any CABG procedure that involves a saphenous vein graft (SVG)). Please see Table 10.27.A.—VEST Codes—FY 2024 associated with this proposed rule for the complete list of codes that the applicant included in its cost analysis. The applicant used the inclusion/exclusion criteria described in the following table.

For the first analysis, the applicant used 100% of all cases identified. The applicant followed the order of operations described in the following table. The applicant identified 54,217 claims mapping to 82 MS–DRGs listed in Table 10.27.A.—VEST Codes—FY 2024 associated with this proposed rule. The applicant calculated a final inflated average case-weighted standardized charge per case of $293,241, which exceeded the average case-weighted threshold amount of $218,560.

For the second analysis, the applicant used 78% of all cases identified, limited to the four MS–DRGs with the highest number of claims. The applicant followed the order of operations described in the following table. The applicant identified 42,550 claims mapping to the four MS–DRGs listed in the following table. The applicant calculated a final inflated average case-weighted standardized charge per case of $256,817, which exceeded the average case-weighted threshold amount of $202,357.

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 VEST meets the cost criterion.

VEST COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR File
List of ICD-10-PCS codes	See Table 10.27.A. – VEST Codes – FY 2024 associated with this proposed rule for a complete list of ICD-10-PCS codes included in the cost analysis.
List of MS-DRGs	Scenario 1: See Table 10.27.A. – VEST Codes – FY 2024 associated with this proposed rule for a complete list of MS-DRGs included in the cost analysis. The applicant also identified the five MS-DRGs with the highest volume of cases: Scenario 2: 233 (Coronary Bypass with Cardiac Catheterization or Open Ablation with MCC) 234 (Coronary Bypass with Cardiac Catheterization or Open Ablation without MCC 235 (Coronary Bypass without Cardiac Catheterization with MCC) 236 (Coronary Bypass without Cardiac Catheterization without MCC)
Inclusion/ exclusion criteria	The applicant selected claims based on the ICD-10-PCS codes listed in table 10.27.A. – VEST Codes – FY 2024 as it believes this list represents any CABG procedure that involves a saphenous vein graft (SVG). The applicant included only inpatient discharges paid as fee-for-service. MS-DRGs with a total discharge count less than 11 were imputed with a count of 11. For the first scenario, the applicant included 100% of the cases identified. For the second scenario, the applicant included 78% of the cases identified, based on the top four DRGs. The applicant calculated the average unstandardized charge per case for each MS-DRG.
Charges removed for prior technology	The applicant stated the use of the VEST device is not expected to replace any other medical devices utilized in the CABG procedure; however, to provide a conservative estimate, 50% of the device charges in revenue centers 027X and 0624 were removed. The applicant did not remove any indirect charges.
Standardized charges	The applicant used the standardization formula provided in Technical Appendix B 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 20.47% 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	Based on an average of 2.3 VEST devices used per CABG procedure, 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 0.187 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 inviting public comments on whether VEST meets the cost criterion.

With regard to the substantial clinical improvement criterion, the applicant asserted that VEST represents a substantial clinical improvement over existing technologies because the strong clinical evidence showing the effect of VEST on the clinical outcome of CABG (multiple studies of different types with different, follow-up durations and with substantial endpoints) confirms the effect of VEST on (1) reducing incidence of cardiac events and the need for further interventions as a result of vein graft disease; (2) reducing graft failure rates as a result of kinking; and (3) mitigating vein graft disease. The applicant provided five 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 VEST for the applicant's complete statements regarding the substantial clinical improvement criterion and the supporting evidence provided.

Substantial Clinical Improvement Assertion # 1: 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 by the applicant from supporting evidence in support of its statements**
VEST improves the clinical outcome of CABG by reducing the incidence of cardiac events and the need for further interventions as a result of vein graft disease	Goldstein, D.J., Chang, H.L., Mack, M. J (2022). Intimal Hyperplasia, Saphenous Vein Graft Disease and Clinical Outcomes: Insights from the CTSN VEST Randomized Trial, *The Journal of Thoracic and Cardiovascular Surgery*. https://doi.org/10.1016/j.jtcvs.2022.10.034 Brief study description: A multicenter, two-arm, randomized, within-subject-control study with 224 patients undergoing on-pump CABG surgery enrolled from 17 centers across North America. Each patient with at least 2 SVGs had 1 randomized assigned to be stented with VEST and the other unstented. The primary endpoint was IH, lumen uniformity, graft stenosis, and graft profusion at 1-year follow-up. The secondary endpoint was major adverse cardiac and cerebrovascular event (MACCE).	This study highlights the relationship between vain graft disease (including lumen uniformity, graft stenosis, graft perfusion) and area of IH. Decrease in lumen uniformity was significantly associated with an increase in the number of MACCE and need for re-vascularization.
	Taggart, D., Gavilov, Y., Krasopoulos, G. et al. (Nov 2022). External stenting and disease progression in SVGs two years after coronary artery bypass grafting: A multicenter randomized trial. *The Journal of Thoracic and Cardiovascular Surgery*. https://doi.org/10.1016/j.jtcvs.2021.03.120 Brief study description: A prospective, within-patient, controlled, randomized, multicenter international trial with 184 patients undergoing isolated CABG surgery from across 14 European sites. It was a 2-arm study using 2 SVGs from each patient, 1 randomly assigned to be externally stented with VEST, the other unstented. The primary and secondary endpoints are graft patency and IH respectively, both at 2-year follow-up.	The treatment arm showed improvement in repeat revascularization rates 2-year post-CABG with a reduction of 42.1% when compared with the control arm, 2.09%, and 3.73% respectively. This is in correlation with a statistically significant reduction in IH and lumen irregularities between the VEST and the control, 22.5% and 17.7% respectively.
	Sandner, S., Angleitner, P., Netuschill, C., et al. (2022). External stenting of SVGs for coronary artery bypass: a single-center analysis of clinical outcomes. *The Journal of Cardiovascular Surgery*. DOI: 10.23736/s0021-9509.22.12008-2 Brief study description: A retrospective observational analysis of 74 patients undergoing isolated or combined CABG procedures in Austria. The primary and secondary endpoints were revascularization and MACCE respectively, both at 1-year post-CABG.	MI and repeat revascularization occurred in 0% at 1-year follow-up. Death, stroke, and MACE at 1-year follow-up occurred in 2.7%, 1.4%, and 4.1% respectively. At 3-year follow-up, the rates of freedom from revascularization, freedom from MACE, and survival were 94.8%, 88.3%, and 89.7% respectively.
	Weltert, L. P., Audisio, K., Bellisaro, A., et al. (2021) External stenting of vein grafts in coronary artery bypass grafting: interim results from two centers prospective study. *Journal of Cardiothoracis Surgery*, 16 (74). https://doi.org/10.1186/s13019-021-01406-0 Brief study description: A single-arm, prospective, multi-center study of 102 patients from 2 European sites undergoing CABG surgery. Each patient had at least 1 SVG stented with VEST. Each patient was followed up for graft patency, lumen uniformity, and MACCE every 6 months.	At 6-12 month follow-ups, 98.2% of the VEST grafts were patent, a much higher patency rate compared to the literature-based value of 78% at 1-year follow-up. Clinical follow-up at a mean time of 20 months showed 0% MACE (0/102).
	Du-Toit, H., B. Bernard, K. Sohan, et al. (2021) VEST Registry South Africa (VERSA), Presented at Baroque Medical Crossroads Specialists Training Forum, South Africa. Unpublished manuscript.	The revascularization rates for VERSA patients had been lower than those of CABG

	Brief study description: A retrospective, multi-center, observational study in South Africa and Namibia. 341 CABG patients were stented with VEST and followed up for 5 years post-surgery. The primary end-point is ischemic-driven target vessel revascularization. The study is on-going.	patients in a historical control study at 12, 24, 36, and 48 month follow-ups.[120,121]
VEST reduces graft failure rates as a result of kinking	Dushaj S, Odavic D, Haussler A, et al. Effect of external stenting for vein grafts on early perioperative patency – a study of 358 consecutive patients undergoing isolated CABG. Zurich Triemli City Hospital, Switzerland. Unpublished. Data on file. Brief study description: A retrospective analysis of 358 patients in a single center in Switzerland undergoing isolated off-pump CABG surgery. Patients either have at least 1 SVG stented or none of their SVGs stented. Among the 223 stented SVGs, 92% were so with VEST. All grafts were evaluated for patency.	At the graft level, the rate of SVG occlusion was lower in the stented SVGs compared with the non-stented SVGs (5.5 vs. 10.8%; P=.05). At the patient level, the rate of patients with at least 1 occluded SVG at discharge was significantly lower in the stented group compared to the non-stented group (6.7% vs 14.8%; P=.01).
VEST mitigates vein graft disease	Taggart et al. (2022). See prior study described.	At 1-year post-CABG, VEST significantly reduced IH with an increasing effect over time and improved lumen uniformity. At 2-year follow-up VEST had a significant effect on lumen uniformity, with a significantly higher rate of perfectly-patent grafts compared to the control group.

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After review of the information provided by the applicant, we have the following concerns regarding whether VEST meets the substantial clinical improvement criterion. Firstly, we question whether the evidence provided demonstrates that use of VEST results in clinical improvement or if any outcomes are only inferred. For example, the Taggart study (2022) [122] examined the differences in Fitzgibbon patency scale and IH between patients randomized to have their SVG stented with VEST (treatment group) and those with their SVG unstented (control group). The team found statistically significant differences between the two groups in IH, but not in patency, pulsatility, interoperative pulse rates, or occlusion rates. While the team found a difference in need for re-vascularization in the hypothesized direction, that is, a higher need for the non-stented (control) group, it is unclear whether the difference reached statistical significance. The Goldstein study (2022) [123] measured the association between indicators of graft health, like IH, lumen uniformity, graft stenosis, and graft perfusion, on MACCE at three-year follow up. Although the team demonstrated significant association between graft health and MACCE, they did not examine the impact of VEST on MACCE. As a result, we are unclear about the strength of direct association between VEST and clinical outcome improvement, or whether any outcomes are inferred from surrogate endpoints.

Secondly, we question whether the impact of VEST on clinical outcomes shown in the cited studies may have been confounded by demographic, clinical, or surgical factors (such as endoscopic harvesting methods,[124] graft harvesting techniques, on- versus off-pump,[125] [126] or use of no-touch procedures,[127] etc.). For example, in the Dushaj study [128] we note that differences remained between the treatment (stented with VEST) and control (non-stented) groups in terms of demographic and clinical baseline characteristics post-randomization. In particular, compared to patients in the control group, those stented with VEST tended to be younger, were more likely to be male, current smokers, to have diabetes, chronic obstructive pulmonary disease (COPD), diffuse peripheral vascular disease (PVD), have a history of MI, lower left ventricular systolic dysfunction (LVEF), and have undergone PCI previously. There also remained significant differences between the two groups in terms of SVG patency and number of arterial grafts undergoing stenting at baseline. We question whether these differences in baseline characteristics may have confounded the association between exposure to VEST and clinical improvement. The Dushaj study may also be limited by potential bias due to single site design, making it difficult to account for confounding variables that

[120] Mohr, F.W.M. Morice, A.P. Kappetein, et al. (2013), Coronary artery bypass graft surgery versus percutaneous coronary intervention in patients with three-vessel disease and left main coronary disease: 5-year follow-up of the randomized, clinical SYNTAX trial. *The Lancet.*

[121] Head, S.J. P.M. Davierwala, P.W. Serruys, et al. (2014) Coronary artery by pass grafting vs. percutaneous coronary intervention for patients with three-vessel disease: final five-year follow-up of the SYNTAX trial. *European Heart Journal.* 35:2821–2830.

[122] Taggart et al. (2022), *op.cit.*

[123] Goldstein, D.J., Chang, H.L., Mack, M. J (2022). Intimal Hyperplasia, Saphenous Vein Graft Disease and Clinical Outcomes: Insights from the CTSN VEST Randomized Trial, *The Journal of Thoracic and Cardiovascular Surgery. https://doi.org/10.1016/j.jtcvs.2022.10.034.*

[124] Goldstein et al., 2022, *op.cit.*

[125] Hattler B, Messenger JC, and Shroyer AL, et al. (Jun 2012). *Off-Pump coronary artery bypass surgery is associated with worse arterial and saphenous vein graft patency and less effective revascularization: Results from the Veterans Affairs Randomized On/Off Bypass (ROOBY) trial. Circulation.* 12;125(23):2827–35.

[126] Shroyer AL, Hattler B, Wagner TH, et al. (Aug 2017). *Five-Year Outcomes after On-Pump and Off-Pump Coronary-Artery Bypass. N Engl J Med.* 17;377(7):623–632.

[127] Samano N, Dashwood M, Souza D. (Sep 2018) *No-touch vein grafts and the destiny of venous revascularization in coronary artery bypass grafting-a 25th anniversary perspective. Ann Cardiothorac Surg.*;7(5):681–685.

[128] Dushaj et al., unpublished, *op.cit.*

may impact post-surgery outcomes such as cardiac rehabilitation referral rates [129] or clinical staff expertise.[130] The Goldstein study (2022) [131] was a two-arm, within-subject trial in which CABG patients with at least two SVGs were randomized to have one externally-stented with VEST and the other not stented. It is unclear whether the randomization technique has achieved balance of SVG attributes (for example, lumen diameter uniformity, graft stenosis, thrombolysis in myocardial infarction flow) between SVGs assigned to the stented group versus those to the non-stented group at the baseline. We are therefore uncertain whether the randomization technique minimized imbalance between the stented and non-stented groups, which could confound any association between VEST and clinical outcomes. We further note that the De-Toit study (2021) [132] used a historical control to compare the impact of VEST on need for revascularization. The study used SYNTAX, a clinical trial conducted by a different research team and completed before 2014,[133] as the historical control to which the effects of VEST were compared. The study reported that their CABG patients were less likely than those in the SYNTAX trial to need revascularization at 12, 24, 36, and 48 months. However, we note the following differences between the study and the historical control which may confound any comparisons. For example, 28 percent of the CABG patients in the Du-Toit study had undergone prior cardiac surgeries, while patients with prior CABG or PCI were excluded from the SYNTAX trial [134] and the SYNTAX trial included patients with de novo 3-vessel disease, left main (LM), or both, unlike the Du-Toit study. Also, since the Du-Toit study was conducted in South Africa and Namibia, while the SYNTAX trial was conducted in North America and Europe, the patient populations in the two studies were likely to have different racial demographics. The baseline clinical characteristics of patients in the Du-Toit study also differed from those in the SYNTAX trial with respect to diabetes (Du-Toit study: 27.9%; SYNTAX trial: 30.4%), any history of stroke (Du-Toit study: 1.8%; SYNTAX trial: 5.3%), MI (Du-Toit study: 36.5%; SYNTAX trial: 39%), and hypertension (Du-Toit study: 80%; SYNTAX trial: 65%). We question whether these differences between the two studies could confound any association between VEST and clinical outcomes, reducing the external validity of study findings.[135] For studies that did not conduct randomization on either patients or SVGs, confounders could further undermine external validity of the findings. For example, in the Weltert study (2021),[136] all patients underwent CABG with the internal mammary artery to the left anterior descending artery and additional artery and/or venous grafts. Half of the patients underwent off-pump CABG surgery. In addition to CABG, 13 percent also underwent concomitant valve or aortic surgery. Also, in addition to having at least one SVG supported by VEST, 23 percent also had their bilateral internal mammary artery grafted. Patients varied in terms of cross clamp, pump, and overall surgery time. Re-vascularization strategy was determined by the surgeon. While each of these surgical decisions could confound the impact of VEST on clinical outcomes, they were not accounted for in the result analysis.

Thirdly, we question to what extent the findings from the cited studies can be replicated among Medicare beneficiaries who undergo CABG surgery. Specifically, the studies cited in the application were conducted among patient populations that were predominantly male.[137] Among Medicare fee-for-service beneficiaries who underwent CABG surgery, only two-thirds (66%) were male.[138] [139] Because female CABG patients tended to have poorer outcomes than their male counterparts,[140] [141] we are interested in whether the impact of VEST on clinical outcomes is comparable between male and female CABG patients.

We are inviting public comments on whether VEST meets the substantial clinical improvement criterion.

In this section, we summarize and respond to written public comments received in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for VEST.

Comment: In response to a question regarding whether other aspects of the CABG procedure were tested, such as ''no touch'' procedures, the applicant stated that the surgical technique in Goldstein et al. (2022), the VEST US pivotal study, did not include patients with ''no touch'' vein harvesting technique. The VEST external support device cannot be applied over veins with excessive surrounding tissue included, due to the limitation of the external stent diameter. The applicant also stated the ''no touch'' technique is rarely used in clinical practice due to the increased risk of postoperative leg wound complications and the trend toward minimal surgical incisions; however, similarly to VEST, this technique supports the assertion that having an external support to vein grafts results in improved clinical outcome and vein graft longevity.

The applicant also stated, in response to a question on whether any adjustments to the p-value were made for multiple comparisons, that no adjustments were made to the p-values for multiple comparisons. The applicant noted that the Goldstein study (2022) was a prospective, multi-center, randomized, within-subject-controlled, pivotal clinical trial that enrolled 224 patients with multi vessel atherosclerotic coronary artery disease who were scheduled to undergo CABG procedure. The study design included a within-patient randomization in which one SVG was randomized to be supported by VEST and another SVG served as a control. Seventeen sites in the United States and Canada participated in the study, and the study was managed by the Cardiothoracic Surgery Clinical Trials Network (CTSN).

The applicant explained that the primary endpoint evaluated the degree

[129] Aragam, K.G., D. Dai, M. L. Neely (2015). Gaps in referral to cardiac rehabilitation of patients undergoing percutaneous coronary intervention in the United States. *Journal of the American College of Cardiology.* 65(19), 2079–2088.

[130] Elbardissi, A.W., A. Duclos, J.D. Rawn, et al. (2013). Cumulative team experience matters more than individual surgeon experience in cardiac surgery. *Journal of Thoracic and Cardiovascular Surgery.* 145(2): 328–33.

[131] Goldstein et al. (2022), *op. cit.*

[132] Du-Toit et al. (2021), *op.cit.*

[133] Mohr et al. (2013), *op.cit.,* Head et al. (2014), *op.cit.*

[134] Mohr et al. (2013), *op.cit.*

[135] Ghadessi, M., R. Tang, J. Zhou, et al. (2020) A roadmap to using historical controls in clinical trials—by Drug Information Association Adaptive Design Scientific Working Group (DIA–ADSWG). *Orphanet Journal of Rare Diseases.* 15:69.

[136] Weltert et al. (2021), *op.cit.*

[137] For example, 81% in Sandner et al. (2022), 82% in Goldstein et al. (2022), 84% in Taggart et al. (2022), 85% in Du-Toit (2021), 87% in Weltert et al. (2021), 86–92% in Dishaj et al. (unpublished manuscript).

[138] Angraal, S., K. Khera, and Y. Wang, et al. (2018) Sex and race differences in the utilization and outcome of coronary artery bypass grafting among Medicare beneficiaries, 2009–2014. *Journal of American Heart Association.*

[139] McNeely, Markwell, Vassileva (2016). Trends in patient characteristics and outcomes of coronary artery bypass grafting in 2000–2012 Medicare population. *Annals of Thoracic Surgery.* 102:132–9.

[140] Gaudino, M., D. Chadow, M. Rahouma, et al. (2023). Operative outcomes of women undergoing coronary artery bypass surgery in the US, 2011 to 2020. *JAMA Surgery.* doi:10.1001/jamasurg.2022.8156.

[141] Sandner, S., A. Kastrati, A. Niessner, et al. (2023). Sex diffeences among patients receiving tricagrelor monotherapy onr aspirin after coronary bypass surgery: A prespecified subgroup analysis of the TiCAB trial. *International Journal of Cardiology.* Vol. 370: 129–135. *https://doi.org/10.1016/j.ijcard.2022.10.166.*

of graft disease (that is, IH) known to be associated with worse clinical outcomes and increased rates of revascularization procedures. Graft disease was assessed at 1 year post-CABG using angiogram and intravenous ultrasound (IVUS). Thereafter, additional clinical follow-ups were conducted on a yearly basis for up to 5 years post-CABG. The applicant stated that to date, clinical follow-up on repeat revascularization procedures at 4 years post-CABG is available. The statistical analysis plan pre-specified multiple analysis-sets for the primary endpoint, which included both the actual observed data and data sets of all study subjects (including missing data using different pre-specified imputation methods). Per the applicant, pre-specified subgroup analysis, based on evidence from the literature regarding risk factors for accelerated vein graft disease and clinical outcomes (Goldstein et al. 2022), has shown that VEST was effective in mitigating vein graft disease proliferation 12 months post-CABG in all subgroups, with more pronounced effects in diabetic patients, who had higher risk for vein graft disease and MACCE. All analysis sets yielded consistent favorable effect for the VEST grafts results (with different p-values ranging between 0.006–0.072).

The applicant further stated that the results of the Goldstein study (2022) confirmed the following: VEST reduced vein graft disease at 1-year post-CABG. There was a direct correlation between degree of vein graft disease and clinical outcomes. Less vein graft disease was associated with less MACCE, which, in turn, was associated with fewer revascularization procedures. The clinical outcomes in the study, in which each CABG patient had one vein graft randomized to be supported by VEST and another not supported, were markedly better in performance at 1 year (7.1%) compared with the literature-based safety performance goal approved by FDA, which was total MACCE rate of up to 19 percent. Territories with vein grafts supported with VEST had much fewer repeated ischemic-driven revascularization procedures compared to standard-of-care grafts, and the difference between the two groups increased as follow up duration became longer; and the effectiveness of VEST in preventing vein graft disease 12 months post-CABG was better in all subgroups, compared to the control group. In certain groups, the effect of VEST was profoundly better than the control, especially in diabetic patients (50% of the patient population in the Goldstein study of 2022).

Response: We thank the applicant for its comments and will take this information into consideration when deciding whether to approve new technology add-on payment for VEST.

s. 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 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 and 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.

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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 note that although the applicant states that XENOVIEW™ has not been assigned to an MS–DRG and cannot be compared to an existing technology, we believe that based on its FDA 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 are inviting public comments on whether XENOVIEW™ is substantially similar to existing technologies and whether XENOVIEW™ meets the newness criterion.

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.

We note that the applicant limited its analysis to eight MS–DRGs. We are 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 are inviting public comments on whether 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 discreet 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[142] to provide information to aid	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

	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.	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 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. Brief study description:	The editorial described study results of significantly lower HP ^{129}Xe MRI RBC-to-barrier ratio in never-hospitalized and previously hospitalized subgroups compared to the healthy group and no

	This editorial reviewed a study (Grist et al., 2022)[143] 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	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, Drichuys 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 ($ven_{def+low}$) ($57.8 \pm 8.4\%$ to $52.5 \pm 10.6\%$; $p < 0.05$) and ventilation defect percent ($33.7 \pm 8.9\%$ vs. $29.5 \pm 11.4\%$, $p < 0.05$) 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 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	Thomen RP, Walkup LL, Roach DJ, Cleveland ZI, Clancy JP, Woods JC. Hyperpolarized ^{129}Xe for investigation of mild cystic fibrosis lung	FEV1 was not significantly different between healthy patients ($100.3 \pm 8.5\%$) and cystic fibrosis patients ($97.9 \pm 16.0\%$, $p = 0.672$; pg. 279). VDP was significantly

to identify patients with mild/early disease.	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%]).	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 129Xe 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 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	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

	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.	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 $p < 0.05$).

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After review of the information the applicant provided, we have the following concerns regarding whether XENOVIEW™ meets the substantial clinical improvement criterion. We note 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 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 do not appear to demonstrate that subsequently, treatment planning or disease management was affected.

For example, we note 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,[144] 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 is 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)[145] noted that clinically relevant VDP improvements were observed 14-days post-benralizumab in patients with minimal response detected using spirometry, it is 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 question the clinical significance of the findings in the Hahn et al. (2022) study[146] to support the applicant's statement that in patients with IPF, HP ^{129}Xe MRI can predict disease progression in patient 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 states that HP ^{129}Xe MRI can 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 question whether the detection of such abnormalities allows for a specific diagnosis of disease. For example, in the Grist et al. (2022) study,[147] a follow-up to the Grist et al. (2021) study,[148] 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)[149] study also indicated that HP

[142] 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.

[143] 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; inpress:1–26.

[144] 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.

[145] 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.

[146] 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.

[147] 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.

[148] 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.

[149] 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.

^{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 note that the Thomen et al. (2016) [150] study provided by the applicant consists of a pediatric population, and we question whether such detection of ventilation abnormalities by XENOVIEW™ would be generalizable to a Medicare population.

In summary, we question 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 would be 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 are inviting public comments on whether XENOVIEW™ meets the substantial clinical improvement criterion.

We did not receive any written comments in response to the New Technology Town Hall meeting notice published in the **Federal Register** regarding the substantial clinical improvement criterion for XENOVIEW™.

7. Proposed 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 are continuing to summarize each application in this proposed rule. However, 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 note that we are making 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 this 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 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 this proposed rule. Of the remaining 20 applications, 16 of the technologies received a Breakthrough Device designation from FDA and 1 has a pending Breakthrough Device designation from FDA. The remaining three applications were designated as a QIDP by FDA. We did not receive any applications for technologies approved through the LPAD pathway.

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 this proposed rule we are making a proposal to approve or disapprove each of these 20 applications for FY 2024 new technology add-on payments. Therefore, in this section of the preamble of this proposed rule, we provide background information on each alternative pathway application and propose whether or not each technology would be eligible for the new technology add-on payment for FY 2024. We refer readers to section II.H.8. of the preamble of the FY 2020 IPPS/LTCH PPS final rule (84 FR 42292 through 42297) and FY 2021 IPPS/LTCH PPS final rule (85 FR 58715 through 58733) for further discussion of the alternative new technology add-on payment pathways for these technologies.

a. Alternative Pathway for Breakthrough Devices

(1) 4WEB Medical Ankle Truss System

4WEB Medical Inc., submitted an application for new technology add-on

[150] 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.

payments for the 4WEB Medical Ankle Truss System (ATS). According to the applicant, the ATS is a tibiotalocalcaneal (TTC) fusion system with a premarket authorized TTC nail to manage ankle bone defects that occur after a failed ankle arthrodesis or arthroplasty.

Please refer to the online application posting for ATS, available at *https://mearis.cms.gov/public/publications/ntap/NTP221014QPJ43*, for additional detail describing the technology.

According to the applicant, the ATS received Breakthrough Device designation from FDA on October 4, 2022 for use with a premarket authorized tibiotalocalcaneal (TTC) nail as part of a TTC fusion system to manage ankle bone defects that may be associated with the following indications: failed ankle arthrodesis, failed ankle arthroplasty. The anatomical landmarks necessary for the design and creation of ATS Power Mobility Devices (PMDs) must be present and identifiable on appropriate radiography scans. The ATS is intended for use with autograft and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft. The applicant stated that it is seeking 510(k) clearance from FDA for the same indication.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify the ATS. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the ATS beginning in FY 2024.

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for the ATS, the applicant searched the FY 2021 MedPAR file for cases reporting the ICD–10–PCS codes listed in the following table, which describe open fusion of the ankle joint with any device but autologous tissue substitute. The applicant used the inclusion/exclusion criteria described in the following table. The applicant provided two analyses to demonstrate that the technology meets the cost criterion, the first using 100 percent of all identified cases, and the second using 75 percent of all identified cases. The applicant followed the order of operations described in the following table.

Under the first analysis (100 percent of all cases), the applicant identified 1,278 cases mapping to 49 MS–DRGs (see Table 10.1.A.—4WEB Medical Ankle Truss System Codes—FY 2024 associated with this proposed rule for a complete list of MS–DRGs provided by the applicant). The applicant calculated a final inflated average case-weighted standardized charge per case of $212,292, which exceeded the average case-weighted threshold amount of $100,961.

Under the second analysis (75 percent of all cases) the applicant identified 959 claims mapping to 20 MS–DRGs (see Table 10.1.A.—4WEB Medical Ankle Truss System Codes—FY 2024 associated with this 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 $205,198, which exceeded the average case-weighted threshold amount of $101,243.

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 the ATS meets the cost criterion.

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4WEB ANKLE TRUSS SYSTEM COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
ICD-10-PCS Code	0SGF03Z Fusion of Right Ankle Joint with Sustained Compression Internal Fixation Device, Open Approach 0SGF04Z Fusion of Right Ankle Joint with Internal Fixation Device, Open Approach 0SGF05Z Fusion of Right Ankle Joint with External Fixation Device, Open Approach 0SGF0JZ Fusion of Right Ankle Joint with Synthetic Substitute, Open Approach 0SGF0KZ Fusion of Right Ankle Joint with Nonautologous Tissue Substitute, Open Approach 0SGG03Z Fusion of Left Ankle Joint with Sustained Compression Internal Fixation Device, Open Approach 0SGG04Z Fusion of Left Ankle Joint with Internal Fixation Device, Open Approach 0SGG05Z Fusion of Left Ankle Joint with External Fixation Device, Open Approach 0SGG0JZ Fusion of Left Ankle Joint with Synthetic Substitute, Open Approach 0SGG0KZ Fusion of Left Ankle Joint with Nonautologous Tissue Substitute, Open Approach
List of MS-DRGs	Please see Table 10.1.A. - 4WEB Medical Ankle Truss System Codes - FY 2024 associated with this proposed rule for the complete list of MS-DRGs provided by the applicant for each scenario
Inclusion/Exclusion Criteria	For scenario 1 and 2, the applicant identified cases using the ICD-10-PCS codes listed previously. Scenario 1: 100% of cases identified Scenario 2: 75% of all cases identified 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	Per the applicant, use of the 4WEB Ankle Truss System is not expected to replace any of the devices utilized in these cases and the charges for these devices would be minimal. However, the applicant removed 50% of charges associated with the service category Medical/Surgical Supplies and Devices, which include revenue centers 027x and 0624. The applicant stated that it believes it is appropriate to reduce these charges by a percentage to account for any devices used to promote fusion. The applicant explained that while the charges for these devices would be minimal, to provide a conservative estimate of the overall charges per case, the analysis removed 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 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 estimated hospital per-patient cost of the new technology ($19,500) by the national cost-to-charge ratio for Implantable Devices (0.281) from the FY 2023 IPPS/LTCH PPS final rule.

We note the following concern regarding the cost criterion. To identify potentially eligible cases, the applicant searched the FY 2021 MedPAR file using only the listed ankle fusion procedure codes, but we note that that the proposed indication for this device is for use in failed ankle fusions and failed arthroplasties. We therefore question whether searching for the ankle fusion procedure codes in combination with diagnosis complication codes reported to identify the previous failure such as category T84, M97.21, or M97.22 would more accurately identify eligible cases.

Subject to the applicant adequately addressing this concern, we would agree that the technology meets the cost criterion and are proposing to approve the ATS 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 this proposed rule, the estimated cost of this technology to the hospital on a per-patient basis is $19,500, which is the cost of a single implant. We note 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 are proposing that the maximum new technology add-on payment for a case involving the use of the ATS would be $12,675 for FY 2024 (that is, 65 percent of the average cost of the technology).

We are inviting public comments on whether the 4WEB Medical Ankle Truss System meets the cost criterion and our proposal to approve new technology add-on payments for the 4WEB Medical Ankle Truss 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.

(2) 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 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.

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, 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 is seeking FDA approval for both the atrial leadless pacemaker (Aveir™ AR Leadless Pacemaker) and the dual chamber leadless pacemaker (Aveir™ Dual-Chamber Leadless Pacemaker) for the same indications. We note 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 appears 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 appears 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 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 invite public comment on the eligibility of the Aveir™ AR Leadless Pacemaker under the alternative pathway.

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). We note that the applicant also submitted a request for approval for a unique ICD–10–PCS procedure code for Aveir™ AR Leadless Pacemaker beginning in FY 2024. 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.

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 question 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 is 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 are 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 question which technology the cases identified in the MedPAR data represent. We question 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, we would agree that the technology meets the cost criterion and are proposing 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 has not provided an estimate for the cost of the Aveir™ AR Leadless Pacemaker at the time of this proposed rule. We expect the applicant to submit cost information prior to the final rule, and we will 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 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 invite 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.

(3) 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 is seeking FDA approval for the Aveir™ Dual-Chamber Leadless Pacemaker for the same indications listed on the Breakthrough Device designation.

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. We note that 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. 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 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.

We have the following concern regarding the cost criterion. It is 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 are 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 question which technology the cases identified in the MedPAR data represent. We question 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, we would agree with the applicant that the technology meets the cost criterion and are therefore proposing 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 has not provided an estimate for the cost of the Aveir™ Dual-Chamber Leadless Pacemaker at the time of this proposed rule. We expect the applicant to submit cost information prior to the final rule, and we will 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 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 invite 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.

(4) 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.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify the CTE with CHIRP System. 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.

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 this 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 this 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.

We agree with the applicant that the technology meets the cost criterion and are therefore proposing 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 this proposed rule, the total cost of the CTE with CHIRP System to the hospital is approximately $1,654 per knee. This includes $1,309 for the CTE and $345 for the Canary Medical Home Base Station. We note 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 note that the Home Base Station is provided to the patient to set up and connect to their home Wi-Fi prior to surgery. We therefore believe the relevant inpatient costs for the add-on payment would include only the cost of the CTE.[151] We note 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 are proposing 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 percent of the average cost of the technology).

We invite 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.

(5) Ceribell Delirium Monitor

Ceribell, Inc. submitted an application for new technology add-on payments for the Ceribell Delirium Monitor for FY 2024. Per the applicant, the Ceribell Delirium 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). According to the applicant, the software utilizes a machine learning model to analyze EEG signals to detect features indicative of delirium in order to provide more effective diagnosis of delirium.

Please refer to the online application posting for the Ceribell Delirium Monitor, available at *https://mearis.cms.gov/public/publications/ntap/NTP221014R4HKQ,* for additional detail describing the technology.

According to the applicant, the Ceribell Delirium Monitor received Breakthrough Device designation from FDA on August 11, 2022 for the following proposed indication: The Ceribell Delirium Monitor software is intended to analyze features associated with diffuse slowing electroencephalogram (EEG) patterns that may be indicative of delirium. The Ceribell Delirium Monitor software is intended to aid in the screening and monitoring of delirium with clinical assessments in adult patients aged 65 and older in critical care settings within hospitals. The applicant stated that it is seeking market authorization from FDA under the De Novo pathway for the same indication. We note that the Ceribell EEG Headband and Ceribell Pocket EEG are not included on the Breakthrough Device designation and it therefore appears 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.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify the Ceribell Delirium Monitor. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the Ceribell Delirium Monitor beginning in FY 2024. The applicant provided a list of diagnosis codes that may be used to currently identify the indication for

[151] *https://canarymedical.com/clinicians/additional-information-for-clinicians/.*

the Ceribell Delirium Monitor 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, to identify potential cases representing patients who may be eligible for the Ceribell Delirium Monitor, the applicant searched the FY 2021 MedPAR file for claims with charges in the revenue codes 020X (Intensive Care Unit) and 021X (Coronary Care Unit) for patients age 65 or older, based on the expected FDA label and because the technology can be utilized for any patient in intensive or critical care units. The applicant used the inclusion/exclusion criteria described in the following table and provided two analyses to demonstrate that it meets the cost criterion, the first using 100 percent of all cases identified, and the second using 75 percent of all cases identified. The applicant followed the order of operations described in the following table for each scenario.

Under the first analysis (100 percent of all identified cases), the applicant identified 2,538,587 claims mapping to 731 MS–DRGs (see Table 10.6.A.—Ceribell Delirium Monitor Codes—FY 2024 associated with this 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 $105,176, which exceeded the average case-weighted threshold amount of $85,580.

Under the second analysis (75 percent of all identified cases) the applicant identified 1,904,914 claims mapping to 89 MS–DRGs (see Table 10.6.A.—Ceribell Delirium Monitor Codes—FY 2024 associated with this proposed rule for a complete list of MS–DRGs provided by the applicant) and calculated a final inflated average case-weighted standardized charge of $102,354, which exceeded the average case-weighted threshold amount of $85,363.

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 Ceribell Delirium Monitor meets the cost criterion.

CERIBELL DELIRIUM MONITOR COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of MS-DRGs	Analysis 1: Please see Table 10.6.A. - Ceribell Delirium Monitor Codes - FY 2024 associated with this proposed rule for a complete list of MS-DRGs provided by the applicant. Analysis 2: Please see Table 10.6.A. - Ceribell Delirium Monitor Codes - FY 2024 associated with this proposed rule for a complete list of MS-DRGs provided by the applicant.
Inclusion/Exclusion Criteria	For both analyses (100% and 75% of cases), the applicant identified cases by using revenue codes 020X (Intensive Care Unit) and 021X (Coronary Care Unit) with the restriction that the age of the beneficiary must be 65 years of age or older. 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 any charges for the prior technology. With regard to charges related to the technology, in analyzing the FY 2021 MedPAR data, the applicant removed 50% of charges associated with revenue codes 020X and 021X. Per the applicant, the use of the technology is expected to help diagnose delirium 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 Delirium 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, 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 agree that the technology meets the cost criterion and therefore are proposing to approve the Ceribell Delirium 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.

The applicant has not provided an estimate for the cost of the Ceribell Delirium Monitor at the time of this proposed rule. We expect the applicant to submit cost information prior to the final rule, and we will provide an update regarding the new technology add-on payment amount for the technology, if approved, in the final rule. The applicant stated that the operating costs of the technology will be comprised of the Ceribell Delirium Monitor software, which is the subject of the Breakthrough Device designation, and the Ceribell EEG headband, which is required for each patient to utilize the Ceribell Delirium Monitor software. However, as discussed previously, it seems that only the software would be eligible for the new technology add-on payment under the alternative pathway as it is the subject of the Breakthrough Device designation. Moreover, we note that the Ceribell EEG headband appears to have been 510(k)-cleared by FDA on August 21, 2017,[152] and is therefore no longer new. Therefore, it appears any add-on payment for the Ceribell Delirium Monitor would include only the cost of the software. We welcome comment on including only the cost of the software in determining the add-on payment amount for the Ceribell Delirium Monitor. Any new technology add-on payment for the Ceribell Delirium Monitor would be subject to our policy under § 412.88(a)(2) where we limit new technology add-on payment to the lesser of 65 percent of

[152] *https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171459.pdf.*

the average cost of the technology, or 65 percent of the costs in excess of the MS–DRG payment for the case.

We invite public comments on whether the Ceribell Delirium Monitor meets the cost criterion and our proposal to approve new technology add-on payments for the Ceribell Delirium Monitor 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.

(6) 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) in order 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 it is seeking 510(k) clearance from FDA for the same indication. We note that the Ceribell EEG Headband and Ceribell Pocket EEG are not included on the Breakthrough Device designation and it therefore appears 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.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify the Ceribell Status Epilepticus Monitor. 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. The applicant provided a list of diagnosis codes that may be used to currently identify the indication for the Ceribell Status Epilepticus Monitor 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 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 this 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 this 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 this 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 this 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 this 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 this 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 this 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 this 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 believed 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 charges of $7,625.

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We agree that the technology meets the cost criterion and therefore are proposing 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 this 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). However, as discussed previously, it seems that only the software would be eligible for the new technology add-on payment under the alternative pathway as it is the subject of the Breakthrough Device designation. We further note, as discussed with regard to the Ceribell Delirium Monitor, that the Ceribell EEG headband appears to have been 510(k)-cleared by FDA since August 2017 [153] and is therefore no longer new. Therefore, it appears any add-on payment for the Ceribell Status Epilepticus Monitor would include only the cost of the software ($1,800). We welcome comment on including only the cost of the software in determining the add-on payment amount for the Ceribell Status Epilepticus Monitor. We note 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 are proposing 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 invite 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 subject to the technology receiving FDA marketing authorization as a Breakthrough Device for the same indication by July 1, 2023.

(7) 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

[153] *https://www.accessdata.fda.gov/cdrh_docs/pdf17/K171459.pdf.*

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.

According to the applicant, there are currently no ICD–10–PCS procedure codes that can be used to uniquely identify EchoGo Heart Failure 1.0. 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. 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 this 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 this 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 this 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 this 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 this 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% 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 this 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.

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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 this 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 this 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 this 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 this 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 this 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 this 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 this 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 this 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 this 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 this 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.
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.

We agree with the applicant that EchoGo Heart Failure 1.0 meets the cost criterion and are therefore proposing 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 this proposed rule, the applicant's anticipated cost per patient for EchoGo Heart Failure 1.0 is $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 note 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 are proposing 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 invite 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.

(8) LimFlow System

LimFlow submitted an application for new technology add-on payments for the LimFlow System for FY 2024. According to the applicant, the LimFlow System is a single-use, medical device system intended for patients with no-option chronic limb-threatening ischemia (CLTI) of the lower extremities and who are at risk of major amputation. The LimFlow System consists of LimFlow's Straight and Conical Stent Grafts that are used in conjunction with a LimFlow Arterial Catheter, a LimFlow Venous Catheter, and a LimFlow Valvulotome. Per the applicant, the LimFlow System is used for transcatheter arterialization of the deep veins (TADV), a minimally invasive procedure that aims to restore blood flow by diverting a stream of oxygenated blood around diseased arteries through tibial veins and into the ischemic foot.

Please refer to the online application posting for the LimFlow System, available at *https://mearis.cms.gov/public/publications/ntap/NTP221012C5JB7*, for additional detail describing the technology and the condition treated by the technology.

According to the applicant, the LimFlow System received Breakthrough Device designation from FDA on October 3, 2017 for use in patients who have chronic limb-threatening ischemia (CLTI) with no suitable endovascular or surgical revascularization options and are at risk of major amputation. The applicant is seeking premarket authorization from FDA for the same indication. According to the applicant, the device will be available on the market immediately upon FDA approval.

The applicant provided a list of ICD–10–PCS codes that, effective October 1, 2018, can be used to uniquely describe procedures involving the use of the LimFlow System under the ICD–10–PCS coding system. Please refer to the online application posting for the complete list of ICD–10–PCS codes provided by the applicant. The applicant stated that the following ICD–10–CM codes may be used to currently identify the indication for LimFlow System under the ICD–10–CM coding system: I70.92 (Chronic total occlusion of artery of the extremities) and I70.231–I70.239 (Atherosclerosis of native arteries of right leg with ulceration), I70.241–I70.249 (Atherosclerosis of native arteries of left leg with ulceration), or I70.261–I70.263 (Atherosclerosis of native arteries of legs with gangrene).

With respect to the cost criterion, the applicant provided two analyses to demonstrate that it meets the cost criterion. Each analysis used the same ICD–10–PCS codes to identify potential cases representing patients who may be eligible for the LimFlow System, but utilized different years of MedPAR data. According to the applicant, it conducted a second analysis using the FY 2020 MedPAR data because of the small number of claims identified in the FY 2021 data.

For the first analysis, the applicant searched the FY 2021 MedPAR file for claims reporting at least one of the ICD–10–PCS codes listed in the following table to identify cases that may be eligible for the LimFlow System. The applicant used the inclusion/exclusion criteria described in the following table. The applicant noted that it imputed 11 cases for all MS–DRGs where the case count was fewer than 11. As a result, all MS–DRGs were imputed to 11 cases except for one MS–DRG which had 12 cases. Under this analysis, the applicant identified 111 claims mapping to 10 MS–DRGs and calculated a final inflated average case-weighted standardized charge per case of $265,409, which exceeded the average case-weighted threshold amount of $110,688.

For the second analysis, the applicant searched the FY 2020 MedPAR file for claims reporting at least one of the ICD–10–PCS codes listed in the following table to identify cases that may be eligible for the LimFlow System. The applicant used the inclusion/exclusion criteria described in the following table. The applicant noted that it imputed 11 cases for all MS–DRGs where the case count was fewer than 11. As a result, all MS–DRGs were imputed to 11 cases. Under this analysis, the applicant identified 99 claims mapping to the nine MS–DRGs listed in the following table and calculated a final inflated average case-weighted standardized charge per case of $262,842, which exceeded the average case-weighted threshold amount of $118,692.

Because the final inflated average case-weighted standardized charge per case exceeded the average case weighted threshold amount in both cohorts, the applicant asserted that the LimFlow System meets the cost criterion.

LIMFLOW SYSTEM COST ANALYSIS	
Data Source and Time Period	Analysis 1: FY 2021 MedPAR file Analysis 2: FY 2020 MedPAR file
List of ICD-10-PCS Codes	041M3JS (Bypass right popliteal artery to lower extremity vein with synthetic substitute, percutaneous approach) 041N3JS (Bypass left popliteal artery to lower extremity vein with synthetic substitute, percutaneous approach) 041P3JS (Bypass right anterior tibial artery to lower extremity vein with synthetic substitute, percutaneous approach) 041Q3JS (Bypass right anterior tibial artery to lower extremity vein with synthetic substitute, percutaneous approach) 041R3JS (Bypass right posterior tibial artery to lower extremity vein with synthetic substitute, percutaneous approach) 041S3JS (Bypass left posterior tibial artery to lower extremity vein with synthetic substitute, percutaneous approach) 041T3JS (Bypass right peroneal artery to lower extremity vein with synthetic substitute, percutaneous approach) 041U3JS (Bypass left peroneal artery to lower extremity vein with synthetic substitute, percutaneous approach)
List of MS-DRGs	Analysis 1 and 2 239 (Amputation for Circulatory System Disorders Except Upper Limb and Toe With MCC) 240 (Amputation for Circulatory System Disorders Except Upper Limb and Toe With CC) 252 (Other Vascular Procedures With MCC) 253 (Other Vascular Procedures With CC) 254 (Other Vascular Procedures Without CC/MCC) 270 (Other Major Cardiovascular Procedures With MCC) 271 (Other Major Cardiovascular Procedures With CC) 853 (Infectious and Parasitic Diseases With O.R. Procedures With MCC) Analysis 1 464 (Wound Debridement and Skin Graft Except Hand for Musculoskeletal and Connective Tissue Disorders With CC) 475 (Amputation for Musculoskeletal System and Connective Tissue Disorders With CC) Analysis 2 981 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC)
Inclusion/Exclusion Criteria	The applicant identified cases by using the ICD-10-PCS codes listed in this table and mapped to MS-DRGs for different years. The applicant included claims that would be used for rate setting (fee-for-service IPPS discharges, plus Maryland hospital discharges). The applicant imputed 11 cases for all MS-DRGs where the case count was fewer than 11. The applicant calculated the average unstandardized charge per case for each MS-DRG.
Charges Removed for Prior Technology	The applicant used a conservative approach and removed all implantable device cost center 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	For Analysis 1 with FY 2021 MedPAR data, 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. For Analysis 2 with FY 2020 MedPAR data, 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 anticipated per patient cost of the LimFlow System to the hospital will be $25,000. The applicant added charges for the new technology by dividing the cost of the technology ($25,000) by the national average cost-to-charge ratio (CCR) for implantable devices of 0.281 from the FY 2023 IPPS final rule (87 FR 48902). Accordingly, the applicant calculated the per treatment charge for the LimFlow System to be $88,967.97.

We agree with the applicant that the LimFlow System meets the cost criterion and are therefore proposing to approve the LimFlow 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 this proposed rule, the applicant anticipated the total cost of the LimFlow System to be $25,000 per patient. The applicant stated that all components of the LimFlow System are single-use and the entire system is an operating cost. According to the applicant, the LimFlow System is sold as a system, as such, the components of the LimFlow System are not priced or sold to hospitals independently. We note 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 are proposing that the maximum new technology add-on payment for a case involving the use of the LimFlow System would be $16,250 for FY 2024 (that is, 65 percent of the average cost of the technology).

We invite public comments on whether the LimFlow System meets the

cost criterion and our proposal to approve new technology add-on payments for the LimFlow 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.

(9) Nelli® Seizure Monitoring System

Neuro Event Labs, Inc. submitted an application for new technology add-on payments for the Nelli® Seizure Monitoring System for FY 2024. Per the applicant, the Nelli® Seizure Monitoring System is a prescription-only device that is designed to be used as an adjunct to seizure monitoring in a hospital inpatient or home setting for adults and children 6 years of age and older. The applicant stated that data is collected while the patient is 'observed' using the system hardware (Personal Recording Unit [PRU]), and the software provides objective summaries of semiological components of identified events (including velocity and acceleration of movements, seizure frequency, seizure duration, heart rate, and respiratory rate) to enable the detection and classification of epileptic events using pretrained artificial intelligence (AI). We note that Neuro Event Labs, Inc. submitted an application for new technology add-on payments for the Nelli® Seizure Monitoring System for FY 2023, as summarized in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28341 through 28342), 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 48960).

Please refer to the online application posting for the Nelli® Seizure Monitoring System, available at *https://mearis.cms.gov/public/publications/ntap/NTP2210147LTUM*, for additional detail describing the technology.

According to the applicant, the Nelli® Seizure Monitoring System received Breakthrough Device designation from FDA on October 9, 2020 for the automated analysis of audio and video data to identify seizure events with a positive motor component in children and adults. The applicant stated that it is seeking 510(k) clearance from FDA with a proposed indication for use as an adjunct to seizure monitoring of adults in healthcare facilities during periods of rest. The device utilizes automated analysis of audio and video (media) data collected via the Personal Recording Unit (PRU) hardware accessory to identify epileptic and non-epileptic seizure events with a positive motor component. Since the indication for which the applicant anticipates receiving 510(k) clearance is included within the scope of the Breakthrough Device designation, it appears that the proposed 510(k) indication is appropriate for consideration for new technology add-on payment under the alternative pathway criteria.

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 the Nelli® Seizure Monitoring System: XXE0X48 (Measurement of brain electrical activity, computer-aided semiologic analysis, new technology group 8). The applicant provided a list of diagnosis codes that may be used to currently identify the indication for the Nelli® Seizure Monitoring System under the ICD–10–CM coding system, as set forth in the Nelli® Seizure Monitoring System Cost Analysis table that follows.

With respect to the cost criterion, the applicant provided two analyses to demonstrate that it meets the cost criterion, with the primary analysis excluding claims from hospitals with 11 or fewer cases, and the second analysis based on all identified claims within the same MS–DRGs identified in the primary analysis, as described in further detail in the following table.

The applicant stated that since the inpatient patient population that the Nelli® Seizure Monitoring System would be used for would also undergo standard video EEG monitoring, the applicant searched the FY 2021 MedPAR file for potential cases representing patients who may be eligible for the Nelli® Seizure Monitoring System using ICD–10–PCS code 4A10X4Z (Monitoring of central nervous electrical activity, external approach) in combination with a list of seizure-related ICD–10–CM codes, as set forth in the table that follows. The applicant stated this approach to identifying cases is similar to the methodology used in a study that assessed the ability of using code-based queries to identify inpatient epilepsy monitoring unit (EMU) admissions from billing records in a large academic medical center over a four-year period, 2016–2019.[154]

The applicant used the inclusion/exclusion criteria and followed the order of operations described in the following table. Under the first analysis, the applicant identified 7,758 claims mapping to the 15 MS–DRGs listed in the following table and calculated a final inflated average case-weighted standardized charge per case of $76,098, which exceeded the average case-weighted threshold amount of $54,698. Under the second analysis, the applicant identified 15,612 claims mapping to the same 15 MS–DRGs and calculated a final inflated average case-weighted standardized charge per case of $104,912, which exceeded the average case-weighted threshold amount of $64,913. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount for both scenarios, the applicant asserted that the Nelli® Seizure Monitoring System meets the cost criterion.

[154] Kamitaki BK, Rishty S, Mani R, et al. Using ICD–10 codes to identify elective epilepsy monitoring unit admissions from administrative billing data: A validation study. Epilepsy Behav. 2020;111:107194. doi:10.1016/j.yebeh.2020.107194.

Nelli® Seizure Monitoring System Cost Analysis	
Data Source and Time Period	FY 2021 MedPAR File
List of ICD-10-CM Codes	G40.XXX Epilepsy G40.0XX, G40.1XX, Focal epilepsy G40.2XX Generalized epilepsy G40.3XX, G40.4XX Epilepsy related to external causes G40.5XX Absence and juvenile myoclonic epilepsy G40.AXX, G40.BXX Other epilepsy, unspecified G40.8XX, G40.9XX R56.01 Post-traumatic seizures R56.9 Unspecified convulsions/ seizure-like activity F44.5 Conversion disorder with psychogenic non-epileptic seizures F44.9 Dissociative and conversion disorder, unspecified R25.0-R25.9 Abnormal involuntary movements R40.4 Transient alteration of awareness R41.0 Disorientation, unspecified R41.82 Altered mental status, unspecified R55 Syncope and collapse R94.01 Abnormal EEG
List of ICD-10-PCS Codes	4A10X4Z (Monitoring of central nervous electrical activity, external approach)
List of MS-DRGs	004 Tracheostomy with MV >96 Hours or PDX except Face, Mouth and Neck without Major O.R. Procedure 025 Craniotomy and Endovascular Intracranial Procedures with MCC 056-057 Degenerative Nervous System Disorders with/without MCC 064 Intracranial Hemorrhage or Cerebral Infarction with MCC 070-071 Nonspecific Cerebrovascular Disorders with CC/MCC 100-101 Seizures with/without MCC 312 Syncope and Collapse 689 Kidney and Urinary Tract Infections with MCC 870 Septicemia or Severe Sepsis with MV >96 Hours 871 Septicemia or Severe Sepsis without MV >96 Hours with MCC 880 Acute Adjustment Reaction and Psychosocial Dysfunction 884 Organic Disturbances and Intellectual Disability
Inclusion/Exclusion Criteria	Scenario 1: The applicant selected claims from hospitals with 11 or more cases reporting 4A10X4Z (Monitoring of central nervous electrical activity, external approach) in combination with one or more of the ICD-10-CM codes listed in this table, as the applicant only had provider specific data for these hospitals. The applicant then calculated the average unstandardized charge per case for each MS-DRG. Scenario 2: The applicant included all claims (including those from hospitals with fewer than 11 cases) using the same ICD-10-PCS and ICD-10-CM codes, and for the same MS-DRGs identified, as in the first scenario. The applicant then 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, as there is no technology being replaced when the Nelli® Seizure Monitoring System is used in a hospital inpatient setting.
Standardized Charges	The applicant used the standardization formula provided in 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 20.47% 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 non-capital cost (cost of the analysis for the real time AI analysis during hospital visit) of the new technology ($1,000) by the national average cost-to-charge ratio of 0.359 for "Other Services" from the FY 2023 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

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We agree with the applicant that the Nelli® Seizure Monitoring System meets the cost criterion and are therefore proposing to approve the Nelli® Seizure Monitoring 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 this proposed rule, the applicant anticipated the total cost of the Nelli® Seizure Monitoring System to the hospital to be $1,000 per patient for the cost of the analysis (real time AI analysis during hospital visit) and seminological report produced following patient assessment. We note 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. The applicant based the cost per case of its technology on two pricing

models that it currently uses in Europe. The applicant stated the first pricing model consists of a 300 € (approximately $330 USD) per day charge for the technology. The applicant stated that this results in a typical cost to the hospital of around $1,000 USD (excluding capital costs) for an average patient stay of 3 days in an EMU. The applicant stated that the second pricing model is a single 1,000 € per-patient fee for measurement of readings and producing the report, regardless of the number of days the system is used. Therefore, based on the information provided by the applicant, it appears that the average cost per case for the use of the Nelli® Seizure Monitoring System is $1,000 USD. 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 proposing that the maximum new technology add-on payment for a case involving the use of the Nelli® Seizure Monitoring System would be $650 for FY 2024 (that is, 65 percent of the average cost of the technology).

We invite public comments on whether the Nelli® Seizure Monitoring System meets the cost criterion and our proposal to approve new technology add-on payments for the Nelli® Seizure Monitoring 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.

(10) NUsurface® Meniscus Implant

Active Implants, LLC. submitted an application for new technology add-on payments for the NUsurface® Meniscus Implant for FY 2024. According to the applicant, the NUsurface® Meniscus Implant is a flexible, discoid anatomic-shaped medial meniscus replacement implant intended for patients with persistent medial knee compartment pain following medial meniscus surgery. Per the applicant, the implant design mimics that of the native meniscus, replacing the biomechanical characteristics and distributing load (that is, weight) across the medial compartment to protect the articular cartilage of the knee, alleviating knee pain and restoring normal knee kinematics.

Please refer to the online application posting for the NUsurface® Meniscus Implant, available at *https://mearis.cms.gov/public/publications/ntap/NTP221014466YN*, for additional detail describing the NUsurface® Meniscus Implant and knee meniscus disorders.

According to the applicant, the NUsurface® Meniscus Implant received Breakthrough Device designation from FDA on September 13, 2019, for middle-aged patients for whom nonsurgical care and partial medial meniscectomy surgery failed to relieve knee pain, especially in patients with more than one meniscectomy. A patient indicated for use of the device has a debilitated knee pain condition that impacts day-to day functioning and quality of life. The applicant stated that it is seeking De Novo classification from FDA for the same indication.

The applicant stated that, effective October 1, 2022, the following ICD–10–PCS codes can be used to uniquely describe procedures involving the use of the NUsurface® Meniscus Implant for the indication that is the subject of this application: XRRG0M8 (Replacement of right knee joint with synthetic substitute, medial meniscus, open approach, new technology group 8) and XRRH0M8 (Replacement of left knee joint with synthetic substitute, medial meniscus, open approach, new technology group 8).

With respect to the cost criterion, the applicant did not provide a complete cost analysis. According to the applicant, it determined the cases eligible mapped to MS–DRG 489 (Knee Procedures without Principal Diagnosis of Infection without CC/MCC). However, to determine the average charge per case for the technology, instead of using charges per case from a claims database such as the MedPAR file for cases assigned to MS–DRG 489, the applicant used the costs of the technology converted to charges, and then doubled rather than standardized the charges. The applicant then inflated the charges based on the inflation factor used to calculate outlier threshold charges in the FY 2023 IPPS/LTCH PPS final rule. The applicant then added more charges for the technology to the inflated charges. In essence, the applicant presented the charges per case based on the cost of the technology as converted to charges, and then almost tripled these charges. We further note that the charges for the technology as presented by the applicant are lower than the threshold for MS–DRG 489. Because the applicant did not present an analysis based on the average charge per case, we are unable to assess whether the average charge per case exceeds the threshold for MS–DRG 489. In addition, it seems cases eligible for the use of the technology (medial meniscus replacement) may map to additional MS–DRGs for other knee procedures, such that those cases should also be considered in the cost analysis. CMS requested a revised cost analysis utilizing data to identify potential cases eligible for the technology and to demonstrate that it meets the cost criterion. However, we did not receive a revised analysis in time for the development of this proposed rule. Therefore, because the applicant has not provided sufficient information to demonstrate that the NUsurface® Meniscus Implant meets the cost criterion, we are proposing to disapprove new technology add-on payments for the NUsurface® Meniscus Implant for FY 2024. However, in the event we receive updated information to establish that the NUsurface® Meniscus Implant meets the cost criterion, we are providing the following information regarding the new technology add-on payment amount.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total device costs of the NUsurface® Meniscus Implant to the hospital to be $9,795 per patient, which is the cost of the NUsurface® definitive implant ($7,295), and the NUsurface® trial implants ($2,500) which are disposable and used to determine the definitive implant size. We note that the applicant also included $2,026 in related costs for O.R. time and procedure-related costs. As we have discussed in prior rulemaking, when determining a new technology add-on payment, we provide payment based on the cost of the actual technology (such as the drug or device itself) and not for additional costs related to the use of the device (86 FR 45146). Therefore, we are not including these costs in the relevant costs for purposes of determining the new technology add-on payment amount. We note 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 would 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. In the event we receive supplemental information to establish that the technology meets the cost criterion, and we were to approve new technology add-on payments for the NUsurface® Meniscus Implant in the final rule, the maximum new technology add-on payment for a case involving the use of the NUsurface® Meniscus Implant would be $6,366.75 ($9,795 × 0.65) for FY 2024 (that is, 65

percent of the average cost of the NUsurface® Meniscus Implant).

We invite public comments on whether the NUsurface® Meniscus Implant meets the cost criterion and our proposal to disapprove new technology add-on payments for the NUsurface® Meniscus Implant for FY 2024. In the event we receive updated information to establish that the NUsurface® Meniscus Implant meets the cost criterion, any approval for new technology add on payments would be 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.

(11) 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. 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,[155] 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, 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 is the expected date when the Phagenyx® System will be commercially available.

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 this 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.

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[155] List of Breakthrough Devices with Marketing Authorization: *https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program*.

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 this 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.

We agree with the applicant that the Phagenyx® System meets the cost criterion and are therefore proposing 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 this 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 note 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 are proposing 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 invite 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.

(12) 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. According to the applicant, 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 note 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 note that a device must be designated under FDA's Breakthrough Devices Program to be eligible under the alternative pathway. 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.

We agree with the applicant that SAINT Neuromodulation System meets the cost criterion and are therefore proposing 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 this 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 note 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 are proposing 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 invite 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.

(13) Selux NGP System

Selux Diagnostics, Inc. submitted an application for new technology add-on payments for the Selux Next-Generation Phenotyping (NGP) System for FY 2024. Per the applicant, the Selux NGP System is a phenotypic antimicrobial susceptibility testing (AST) system, intended to assist medical professionals in the identification of in vitro susceptibility or resistance to specific antimicrobial agents. According to the applicant, the technology is intended for use with bacteria separated from monomicrobial positive blood cultures and sterile body fluid culture samples from non-charcoal-containing types of BACTEC, BacT/ALERT, VIRTUO and VersaTREK blood culture bottles. Per the applicant, the Selux NGP System supports antimicrobial susceptibility testing on a subset of aerobic and facultative anaerobic gram-negative and gram-positive species. The Selux NGP System consists of an automated sample preparation instrument, the Positive Blood Culture (PBC) Separator; automated instruments for preparing and processing AST panels, the Inoculator and Analyzer; a computer workstation running Selux Site Software that integrates the instruments; and reagents and consumables required to perform AST testing. The Selux Site Software includes algorithmic models based on machine learning that enables the system to determine the susceptibilities of an organism to the variety of antimicrobials under test.

Please refer to the online application posting for the Selux NGP System, available at *https://mearis.cms.gov/public/publications/ntap/NTP221017CVJ8C*, for additional detail describing the technology and how it is used.

According to the applicant, the Selux NGP System received Breakthrough Device designation from FDA on September 21, 2021, with the indication that the Selux Positive Blood Culture Separator and Selux System is intended for use with bacteria separated from monomicrobial positive blood cultures and sterile body fluid culture samples from non-charcoal-containing types of BACTEC, BacT/ALERT, VIRTUO and VersaTREK blood culture bottles. Per the applicant, the Selux NGP System is seeking FDA premarket approval from FDA for the same indication. The applicant noted that it is concurrently seeking FDA authorization for in vitro diagnostic (IVD) use in the clinical microbiology laboratory for automated quantitative AST by minimal inhibitory concentration (MIC) of isolated colonies

for aerobic and facultative anaerobic gram-negative Enterobacterales and non-Enterobacterales. We note that, the applicant used ''the Selux NGP System'' as the name of technology, which is different from ''Direct-from-Positive Blood Culture Rapid AST System'' as in the FDA Breakthrough Device designation letter. We would appreciate additional clarification on whether the Selux NGP System is the same as ''Direct-from-Positive Blood Culture Rapid AST System''. 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.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify the Selux NGP System. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the Selux NGP System beginning in FY 2024. The applicant provided a list of ICD–10–CM codes that may be used to currently identify the indication for the Selux NGP 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 provided multiple analyses to demonstrate that the technology meets the cost criterion. The applicant searched the FY 2021 MedPAR file to identify eligible cases, with the first analysis using all cases assigned to a list of MS–DRGs to which the technology would most commonly map, the second analysis identifying potential cases using ICD–10–CM diagnosis codes representing patients who may be eligible for the Selux NGP System, and the third analysis combining the results of the first 2 analyses. Each analysis followed the order of operations described in the following table.

For the first analysis, the applicant limited the analysis to all cases in a subset of MS–DRGs to which the vast majority of cases are projected to map. Please see Table 10.20.A.—Selux NGP System Codes—FY 2024 associated with this proposed rule for a complete list of MS–DRGs provided by the applicant. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 1,543,757 claims mapping to 34 MS–DRGs and calculated a final inflated average case-weighted standardized charge per case of $86,399, which exceeded the average case-weighted threshold amount of $69,947.

For the second analysis, the applicant searched for cases using a list of bacteremia or sepsis ICD–10–CM diagnosis codes in any position (primary or secondary) that may be eligible for the technology. Please see Table 10.20.A.—Selux NGP System Codes—FY 2024 associated with this proposed rule for a complete list of ICD–10–CM diagnosis codes provided by the applicant. Under this analysis, the applicant identified 446,137 claims mapping to 593 MS–DRGs, with the highest percentage of cases (43 percent) mapping to MS–DRG 871, and calculated a final inflated average case-weighted standardized charge per case of $146,538, which exceeded the average case-weighted threshold amount of $90,279.

For the third analysis, the applicant combined the results from the first and second analyses. The applicant used the inclusion/exclusion criteria described in the following table. Under this analysis, the applicant identified 1,679,957 claims mapping to 595 MS–DRGs, with the highest percentage of cases mapping to MS–DRG 871 (32 percent) and MS–DRG 177 (25 percent), and calculated a final inflated average case-weighted standardized charge per case of $95,625, which exceeded the average case-weighted threshold amount of $72,865.

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 Selux NGP System meets the cost criterion.

SELUX NGP SYSTEM COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR File
List of ICD-10-CM Codes	Scenario 1: Not applicable. Used all cases from a subset of MS-DRGs Scenario 2: Please see Table 10.20.A. – Selux NGP System Codes - FY 2024 associated with this proposed rule for the list of ICD-10-CM diagnosis codes. Scenario 3: Combined the results of scenario 1 and 2. Please see Table 10.20.A. – Selux NGP System Codes - FY 2024 associated with this proposed rule
List of MS-DRGs	Scenario 1: please see Table 10.20.A. – Selux NGP System Codes - FY 2024 associated with this proposed rule for the list of MS-DRGs. Scenario 2: Please see Table 10.20.A. – Selux NGP System Codes - FY 2024 associated with this proposed rule for the list of MS-DRGs. Scenario 3: Please see Table 10.20.A. – Selux NGP System Codes - FY 2024 associated with this proposed rule for the list of MS-DRGs.
Inclusion/Exclusion Criteria	Scenario 1: The applicant limited the analysis to all cases in a subset of MS-DRGs to which the vast majority of cases are projected to map. These MS-DRGs were selected as likely to have blood testing for use with the Selux NGP System. Scenario 2: The applicant searched for cases using a list of bacteremia or sepsis ICD-10-CM diagnosis codes in any position (primary or secondary) that may be eligible for the technology. Scenario 3: This scenario combined the results of the first two scenarios. If an MS-DRG was in both scenarios, the applicant used the results from the first scenario and disregarded the results from the second scenario (as the first scenario included all cases). If the MS-DRG was only in the second scenario, then the applicant used the results from the second scenario when it combined the results.
Charges Removed for Prior Technology	The applicant stated since the technology is not expected to remove the need for prior technologies or costs associated with prior technologies, no direct or indirect charges 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 20.5% 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 to the hospital is $149.87 per patient. The applicant added charges for the new technology by dividing the average cost of the new technology by the national average cost-to-charge ratio of 0.107 for laboratory cost center from the FY 2023 IPPS/LTCH PPS final rule. The applicant did not add indirect charges related to the new technology.

We agree with the applicant that the Selux NGP System meets the cost criterion and are therefore proposing to approve the Selux NGP 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 this proposed rule, the applicant anticipated the total cost of the Selux NGP System to the hospital to be $149.87 per patient per test, including the capital component (Positive Blood Culture Separator, Inoculator, and Analyzer ($14.83)) and the operating components (Selux AST Gram Negative and Selux AST Gram Positive Kit ($80.00), Selux AST Positive Blood Culture Kit ($50.00), Selux ASTAnalyzer Reagent Kit ($4.79), and Selux AST Waste Kit ($0.25)). Because section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services or technologies under the payment system established under that subsection, which establishes the system for payment of the operating costs of inpatient hospital services, 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 (86 FR 45145). Based on the information from the applicant, it appears that the costs of the Positive Blood Culture Separator, Inoculator, and Analyzer are capital costs. Therefore, these components are not eligible for new technology add-on payment because, as discussed in prior rulemaking and noted previously, we only make new technology add-on payments for operating costs (72 FR 47307 through 47308). Based on the operating costs from the applicant at the time of this proposed rule, the total operating cost of the Selux NGP System to the hospital is $135.04 per patient per test.

The applicant stated that total cost per patient will vary depending on the estimated number of tests that the hospital expects that it will perform. To account for the variability of institution and patient status and calculate the average usage of the Selux NGP System during a patient stay, the applicant analyzed the Premier Healthcare Database (Ph.D.-AC) Linked to Closed Claims (Ph.D.-CC), Microbiology data (available for a subset from 2009 to current). The database includes information on over 490,000 patient journeys. The applicant applied the following criteria to optimize the data: removing negative blood cultures; removing unclear results (incomplete information); including only inpatient stays; excluding patients who have more than one organism identified; excluding patients with organisms that not non-fastidious; and filtering out results of anything besides susceptible, intermediate and resistant (S, I, and R). Per the applicant, the output of the calculation illustrated that on average, each patient with a positive blood culture result would receive 1.2 AST tests using the Selux NGP System per

stay. The average cost per patient would therefore be $162.05 (the cost per test of $135.04 × 1.2 tests on average, per patient).

We note 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 are proposing that the maximum new technology add-on payment for a case involving the use of the Selux NGP System would be $105.33 for FY 2024 (that is, 65 percent of the average cost of the technology, $162.05).

We invite public comments on whether the Selux NGP System meets the cost criterion and our proposal to approve new technology add-on payments for the Selux NGP 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.

(14) DETOUR System

Endologix, Inc., submitted an application for new technology add-on payments for the DETOUR System for fiscal year (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 stated that it is seeking premarket approval from FDA for the same indication. According to the applicant, the device will be available on the market immediately upon FDA approval.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify the DETOUR System. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for the DETOUR System beginning in FY 2024. 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 this 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 this 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.

We agree with the applicant that the DETOUR System meets the cost criterion and propose 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.

The applicant has not provided an estimate for the cost of the DETOUR System at the time of this proposed rule. We expect the applicant to submit cost information prior to the final rule, and we will 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 invite 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.

(15) 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 is 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 note that the premarket approval indication does not include limitation to neurogenic claudication as noted in the Breakthrough Device designation. We note 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 stated that effective October 1, 2021, the following ICD–10–

PCS procedure codes 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) and XRHD018 (Insertion of Posterior Spinal Motion Preservation Device into Lumbosacral 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 note that ICD–10–CM code M48.061 is 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 this 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 this 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 this 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.

We agree with the applicant that the TOPS™ System meets the cost criterion and are therefore proposing 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 this 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 note 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 are proposing 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 invite 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.

(16) Total Ankle Talar Replacement

4WEB Medical, Inc. submitted an application for new technology add-on payments for the Total Ankle Talar Replacement for FY 2024. Per the applicant, the Total Ankle Talar Replacement is a patient specific, metallic spacer that is a solid, polished replica of a patient's physiologic talus and intended to articulate to the surrounding native bone anatomy (that is, calcaneus and navicular). However, the dome is mapped so that it matches that of a third-party ankle system. The applicant stated that the device is intended to allow for restoration of function due to losses attributed to talar dysfunction.

Please refer to the online application posting for the Total Ankle Talar Replacement, available at *https://mearis.cms.gov/public/publications/ntap/NTP221014C88U0*, for additional details describing the technology.

According to the applicant, the Total Ankle Talar Replacement has not yet received Breakthrough Device designation from FDA, but the applicant is seeking the designation for use with a premarket authorized total ankle arthroplasty system as part of an ankle arthroplasty system to manage talar dysfunction that may be associated with the following indications: failed ankle arthroplasties, talar trauma, tumors or lesions, ankle arthritis/degenerative joint disease, ankle arthrodesis or malunion, talar osteomyelitis/infection or ankle/foot deformities. The applicant stated that it is seeking 510(k) clearance from FDA for the same indication and anticipates receiving FDA marketing authorization before July 1, 2023.

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify the use of the Total Ankle Talar Replacement. The applicant submitted an application for a unique ICD–10–PCS code for FY 2024.

With respect to the cost criterion, to identify potential cases representing patients who may be eligible for the Total Ankle Talar Replacement, the applicant searched the FY 2021 MedPAR file for cases reporting one of the ICD–10–PCS codes listed in the table in this section. Using the inclusion/exclusion criteria described in the following table, the applicant identified 187 claims mapping to 17 MS–DRGs as 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 $199,539, which exceeded the average case-weighted threshold amount of $98,577. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the Total Ankle Talar Replacement meets the cost criterion.

TOTAL ANKLE TALAR REPLACEMENT COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of ICD-10-PCS Codes	0SRH0JZ Replacement of right tarsal joint with synthetic substitute, open approach 0SRJ0JZ Replacement of left tarsal joint with synthetic substitute, open approach 0SRH0KZ Replacement of right tarsal joint with nonautologous tissue substitute, open approach 0SRJ0KZ Replacement of left tarsal joint with nonautologous tissue substitute, open approach 0QRL0JZ Replacement of right tarsal with synthetic substitute, open approach 0QRM0JZ Replacement of left tarsal with synthetic substitute, open approach 0QRL0KZ Replacement of right tarsal with nonautologous tissue substitute, open approach 0QRM0KZ Replacement of left tarsal with nonautologous tissue substitute, open approach
List of MS-DRGs	253 (Other Vascular Procedures with CC), 469 (Major Hip and Knee Joint Replacement or Reattachment of Lower Extremity with MCC or total Ankle Replacement), 477 (Biopsies of Musculoskeletal System and Connective Tissue with MCC), 481 (Hip and Femur Procedures Except Major Joint with CC), 492 (Lower extremity and humerus procedures except hip, foot and femur with MCC), 493 (Lower extremity and humerus procedures except hip, foot and femur with CC), 494 (Lower Extremity and Humerus Procedures Except Hip, Foot and Femur without CC/MCC), 495 (Local Excision and Removal of Internal Fixation Devices Except Hip and Femur with MCC) 496 (Local Excision and Removal of Internal Fixation Devices Except Hip and Femur with CC) 497 (Local Excision and Removal of Internal Fixation Devices Except Hip and Femur without CC/MCC), 504 (Foot Procedures with CC) 622 (Skin Grafts and Wound Debridement For Endocrine, Nutritional and Metabolic Disorders with MCC) 628 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with MCC) 629 (Other Endocrine, Nutritional and Metabolic O.R. Procedures with CC) 853 (Infectious and Parasitic Diseases with O.R. Procedures with MCC) 981 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with MCC) 982 (Extensive O.R. Procedures Unrelated to Principal Diagnosis with CC)
Inclusion/Exclusion Criteria	The applicant searched for cases reporting one of the ICD-10-PCS codes listed previously. The applicant noted that all the MS-DRGs in its analysis had fewer than 11 cases. Therefore, 11 cases were utilized for each MS-DRG in its analysis for a total of 187 cases (17 MS-DRGs x 11 cases = 187 cases).
Charges Removed for Prior Technology	Per the applicant, the use of the Total Ankle Talar Replacement implant is expected to replace other devices. The applicant removed 50% of direct charges associated with Medical/Surgical Supplies and Devices (revenue centers 027x, and 0624). The applicant stated that the financial impact of utilizing the Total Ankle Talar Replacement implant on hospital resources compared to prior technologies is minimal. The applicant therefore 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 Total Ankle Talar Replacement implant by dividing the estimated hospital per-patient cost of the new technology ($19,500) by the national cost-to-charge ratio for Implantable Devices (0.281) as provided in the CMS charge threshold template. This resulted in estimated charges for the new technology of $69,395. No other hospital charges were assumed to be required for implanting the Total Ankle Talar Replacement.

We note the following concerns regarding the cost criterion. The applicant stated that the technology is a replica of the patient's physiologic talus and mapped to fit a third-party ankle system. However, the applicant included tarsal joint replacement procedure codes (for example, 0SRH0JZ, 0SRJ0JZ, 0SRH0KZ, 0SRJ0KZ) in addition to talar replacement codes, when searching for eligible cases, and we question whether these tarsal joint replacement procedure codes are applicable since this joint is in the foot (and not the ankle). We question whether only cases for talar replacement should be included.

Subject to the applicant adequately addressing these concerns, we would agree that the technology meets the cost criterion and are proposing to approve the Total Ankle Talar Replacement 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 same indication by July 1, 2023.

Based on preliminary information from the applicant at the time of this proposed rule, the applicant anticipated the total cost of the Total Ankle Talar Replacement to the hospital to be $19,500 per patient, which represents one implant. We note 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 are proposing that

the maximum new technology add-on payment for a case involving the use of the Total Ankle Talar Replacement would be $12,675 for FY 2024 (that is, 65 percent of the average cost of the technology).

We are inviting public comments on whether the Total Ankle Talar Replacement meets the cost criterion and our proposal to approve new technology add-on payments for the Total Ankle Talar Replacement for FY 2024, subject to the technology receiving Breakthrough Device Designation and FDA marketing authorization as a Breakthrough Device for the same indication by July 1, 2023.

(17) Transdermal GFR Measurement System Utilizing Lumitrace

MediBeacon, Inc. submitted an application for new technology add-on payments for Transdermal Glomerular Filtration Rate (GFR) Measurement System utilizing Lumitrace for FY 2024. According to the applicant, the Transdermal GFR Measurement System utilizing Lumitrace is a three-component system consisting of (1) an optical skin sensor, (2) a monitor and (3) MB–102 (also known as relmapirazin/Lumitrace), which is a proprietary fluorescent tracer agent that glows in the presence of light and is removed from the blood exclusively by the GFR mechanism of the kidney. The technology is intended to measure Glomerular Filtration Rate (GFR) in patients with impaired or normal renal function during clinical conditions where the real time measurement of GFR (versus estimated measures) is clinically useful to patient management.

Please refer to the online application posting for Transdermal GFR Measurement System utilizing Lumitrace, available at *https://mearis.cms.gov/public/publications/ntap/NTP221013VQ6RT*, for additional detail describing the technology.

According to the applicant, the Transdermal GFR Measurement System utilizing Lumitrace received Breakthrough Device designation from FDA on October 16, 2018 for measuring GFR in patients with impaired or normal renal function, and the applicant is seeking premarket approval from FDA for the same indication. According to the applicant, the Transdermal GFR Measurement System will be available on the market immediately after FDA approval.

The applicant stated that, effective October 1, 2019, the following ICD–10–PCS code may be used to uniquely identify procedures involving the Transdermal GFR Measurement System utilizing Lumitrace: XT25XE5 (Monitoring of kidney using fluorescent pyrazine, external approach, new technology group 5).

With respect to the cost criterion, the applicant searched the FY 2021 MedPAR file for potential cases representing patients who may be eligible for Transdermal GFR Measurement System utilizing Lumitrace using a combination of ICD–10–CM/PCS codes representing the clinical scenarios in the inpatient hospital setting involving the potential for or presence of acute or chronic kidney injury where measurement of the GFR in patients with impaired or normal renal function may facilitate clinical management, as listed in the following table. Using the inclusion/exclusion criteria described in the following table, the applicant identified 497,297 claims mapping to 687 MS–DRGs. Please see Table 10.26.A.—Transdermal GFR Measurement System utilizing Lumitrace Codes—FY 2024 associated with this proposed rule for a complete list of codes 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 $230,414 which exceeded the average case-weighted threshold amount of $130,279. Because the final inflated average case-weighted standardized charge per case exceeded the average case-weighted threshold amount, the applicant asserted that the Transdermal GFR Measurement System utilizing Lumitrace meets the cost criterion.

Transdermal GFR Measurement System utilizing Lumitrace COST ANALYSIS	
Data Source and Time Period	FY 2021 MedPAR file
List of ICD-10-CM Codes	Please see Table 10.26.A. - Transdermal GFR Measurement System utilizing Lumitrace Codes - FY 2024 associated with this proposed rule for a complete list of ICD-10-CM diagnosis codes provided by the applicant.
List of ICD-10-PCS Codes	0TY Kidney transplant procedures 021 Heart and great vessels-bypass 02Q Hear and great vessels-repair 02Y Heart transplant 5A1D90Z Continuous renal replacement therapy
List of MS-DRGs	Please see Table 10.26.A. - Transdermal GFR Measurement System utilizing Lumitrace Codes - FY 2024 associated with this proposed rule for a complete list of MS-DRGs provided by the applicant.
Inclusion/Exclusion Criteria	The applicant identified potential cases by including MS-DRGs that had at least one case matching the selection criteria, based on the presence of specific ICD-10-CM diagnosis codes and select ICD-10-PCS procedure codes. The applicant stated that the ICD-10 codes were selected based on input from renal physicians or specialists to represent the clinical scenarios in the inpatient hospital setting where measurement of the GFR in patients with impaired or normal renal function may facilitate clinical management. Per the applicant, managed care cases, claims submitted only for GME payments, claims with ancillary costs of zero, and claims that were statistical outliers within the MS-DRGs were excluded. Only cases with three or more days in the intensive care unit were included in the analysis.
Charges Removed for Prior Technology	According to the applicant, the MediBeacon Transdermal Glomerular Filtration Rate Measurement System which includes a sensor, a fluorescent tracer agent relmapirazin, and the monitor do not replace an existing technology. Therefore, the applicant did not remove indirect charges related to 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 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. The applicant did not add indirect charges related to the new technology.

We agree with the applicant that the Transdermal GFR Measurement System utilizing Lumitrace meets the cost criterion and propose to approve Transdermal GFR Measurement System utilizing Lumitrace 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 has not provided an estimate for the cost of Transdermal GFR Measurement System utilizing Lumitrace at the time of this proposed rule. The applicant stated that there would be three components for the cost of the technology: the operating cost of the optical skin sensor, the operating cost of the relmapirazin (fluorescent tracer) that glows in the presence of light and is removed from the blood exclusively by the GFR mechanism of the kidney, and the capital cost of the monitor that converts the measured fluorescence time dependent curve to a measured GFR (mGFR). Because section 1886(d)(5)(K)(i) of the Act requires that the Secretary establish a mechanism to recognize the costs of new medical services or technologies under the payment system established under that subsection, which establishes the system for payment of the operating costs of inpatient hospital services, 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 (86 FR 45145). As noted, the applicant stated that the cost of the monitor that converts the measured fluorescence time dependent curve to a mGFR is a capital cost. We expect the applicant to submit cost information prior to the final rule, and we will 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 Transdermal GFR Measurement System utilizing Lumitrace 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 invite public comments on whether the Transdermal GFR Measurement System utilizing Lumitrace meets the cost criterion and our proposal to approve new technology add-on payments for Transdermal GFR Measurement System utilizing Lumitrace 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.

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). 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. If the FDA marketing authorization is received on or after July 1, 2023, no new technology add-on payments will be made for cases involving the use of DefenCath™ for FY 2023. We note 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 note 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.

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 is 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 codes 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 this 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 this 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 this 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 this 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 this 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. Therefore, the applicant assumed the per treatment charge for taurolidine/heparin will be $103,328.80. The applicant did not add indirect charges related to the new technology.

We agree with the applicant that taurolidine/heparin meets the cost criterion based on the analysis presented. We also welcome additional information on using additional codes and/or criteria to better target cases of taurolidine/heparin for the cost criterion.

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 are proposing 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 are proposing 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 this proposed rule, according to the applicant, the Wholesale Acquisition Cost of taurolidine/heparin is $1,170 per three milliliter vial taurolidine/heparin. The applicant notes 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 will 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 anticipates the cost of taurolidine/heparin to the hospital per patient to be $22,815. We would be 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 note 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 are proposing 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 invite 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.

(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™. Due to the timing of receipt of FDA approval, we are interested in additional information on whether the technology is considered a QIDP under this NDA.

According to the applicant, there are currently no ICD–10–PCS procedure codes that distinctly identify the administration of REZZAYO™. The applicant submitted a request for approval for a unique ICD–10–PCS procedure code for REZZAYO™ beginning in FY 2024.

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 this 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.

We agree with the applicant that REZZAYO™ meets the cost criterion and are therefore proposing 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 has not provided an estimate for the cost of REZZAYO™ at the time of this 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 estimates 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 expect the applicant to submit cost information prior to the final rule, and we will 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 invite 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.

(3) SUL–DUR (Sulbactam/Durlobactam)

Entasis Therapeutics, Inc. submitted an application for new technology add-on payments for SUL–DUR for FY 2024. According to the applicant, SUL–DUR 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 SUL–DUR, 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, SUL–DUR received QIDP designation for the treatment of HABP/VABP and bloodstream infections due to Acinetobacter baumannii. The applicant stated that it is 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. We note that, under the eligibility criteria for approval under the alternative pathway for certain antimicrobial products, only the use of SUL–DUR for the treatment of HABP/VABP and bloodstream infections due to Acinetobacter baumannii, and the FDA QIDP designation it received for that use, are relevant for purposes of the new technology add-on payment application for FY 2024. We also note that, as an application submitted under the alternative pathway for certain antimicrobial products at § 412.87(d), SUL–DUR 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).

According to the applicant, there are currently no ICD–10–PCS procedure codes to distinctly identify SUL–DUR. The applicant submitted a request for a new unique ICD–10–PCS procedure code for SUL–DUR to be considered at the March 2023 ICD–10 Coordination and Maintenance Committee meeting. The applicant provided a list of diagnosis codes that may be used to currently identify the indication for SUL–DUR 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 note 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 believe the relevant ICD–10–CM codes to identify the QIDP-designated indications are: 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.

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 SUL–DUR. 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, SUL–DUR is 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, SUL–DUR 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.—SUL–DUR Codes—FY 2024 associated with this 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 exceeds the average case-weighted threshold amount in both analyses, the

applicant asserted that SUL–DUR meets the cost criterion.

SUL-DUR 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. - SUL-DUR 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 SUL-DUR. 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 SUL-DUR 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.

We agree with the applicant that SUL–DUR meets the cost criterion and are therefore proposing to approve SUL–DUR 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. As an application submitted under the alternative pathway for certain antimicrobial products at § 412.87(d), SUL–DUR 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). If SUL–DUR 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 would be made for cases involving the use of SUL–DUR 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 SUL–DUR is $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 are 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 note 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 propose that the maximum new technology add-on payment for a case involving the use of SUL–DUR 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 invite public comments on whether SUL–DUR meets the cost criterion and our proposal to approve new technology add-on payments for SUL–DUR 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.

8. Proposal To Modify New Technology Add-On Payment Application Eligibility Requirements Related to FDA Application Status and To Move FDA Marketing Authorization Deadline 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 proposed 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 market authorization status and the status of any relevant required designations.

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 proposing modifications to both the new technology add-on payment eligibility requirements and the date by which applicants must receive FDA marketing authorization in order to be eligible for consideration. Specifically, we are proposing 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 market 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 would 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 market authorization request to FDA at the time of submission of the new technology add-on payment application would 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 would 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 are proposing 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 market authorization request before submitting an application for new technology add-on payments. We propose that, for the purposes of this policy, submission of a request for marketing authorization by the 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 market authorization request at the time of submission of its new technology add-on payment application to CMS. We believe that requiring an FDA acceptance or filing letter would provide the clearest and most effective means of documenting that the applicant has submitted a complete request to FDA and are therefore proposing to require this approach to documentation. Under this proposal, the applicant would also indicate on the new technology add-on payment application whether the FDA request has an active status with FDA. We note that applicants for technologies that have already received FDA market 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 are proposing 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.

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 market 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 clinical indications and the clinical data that often only becomes available after receiving FDA market authorization would 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 are proposing to require that applicants 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 believe 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 are proposing 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, under this proposal, we would 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 would also neither summarize nor respond to public comments received regarding these withdrawn or ineligible applications in the final rule.

We note that we are 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) (proposed to be redesignated as § 412.87(f)(3)), as finalized in the FY 2021 IPPS/LTCH PPS final rule (85 FR 58740). However, we are proposing to amend proposed redesignated § 412.87(f)(3) to revise the current cross-reference to § 412.87(e)(2) in light of the previously discussed proposed amendments.

We are seeking public comment on our proposals 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 market 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.

III. Proposed 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 proposed FY 2024 hospital wage index based on the statistical areas appears under section III.A.2. of the preamble of this proposed 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 proposed adjustment for FY 2024 is discussed in section II.B. of the Addendum to this proposed rule.

As discussed in section III.I. of the preamble of this proposed 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 proposed budget neutrality adjustment for FY 2024 is discussed in section II.A.4.b. of the Addendum to this proposed 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 proposing to apply to the FY 2024 wage index appears under sections III.E. and F. of the preamble of this proposed rule.

2. Core-Based Statistical Areas (CBSAs) for the Proposed 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 the August 15, 2017, OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04 which superseded the April 10, 2018 OMB Bulletin No. 18–03. 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, the September 14, 2018, OMB Bulletin No. 18–04 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 would 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 proposed 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 Proposed FY 2024 Wage Index

The proposed 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 proposed 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 proposed 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 proposed 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.

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 proposed FY 2024 wage index includes FY 2020 data submitted to us as of January 30, 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.

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–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, 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 the COVID–19 PHE did differentially impact the wages paid by individual hospitals over time, 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 note that we have not identified 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 believe the FY 2020 wage data is the best available wage data to use for FY 2024 and are proposing to use the FY 2020 wage data for FY 2024.

We welcome comment from the public with regard to the FY 2020 wage data. We note, 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*.

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 (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. 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. If data elements for some of these providers are corrected, we intend 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.

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 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 rule, 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. In summary, we calculated the FY 2024 wage index using the Worksheet S–3, Parts II and III wage data of 3,103 hospitals.

For the proposed 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 proposed 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:

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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

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 Proposed FY 2024 Unadjusted Wage Index

The method used to compute the proposed 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 are not proposing 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 are not proposing 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 proposed 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 proposed 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 proposed 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 are not proposing 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, the proposed FY 2024 unadjusted national average hourly wage is the following:

Proposed FY 2024 Unadjusted National Average Hourly Wage	$50.33

E. Proposed 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

For FY 2024, we are proposing 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 proposed rule (which is available via the internet on the CMS website), which contains the proposed 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 proposed 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 proposed FY 2024 wage index. For the proposed FY 2024 wage index, we are using 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 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 proposed FY 2024 occupational mix adjusted national average hourly wage is the following:

Proposed FY 2024 Occupational Mix Adjusted National Average Hourly Wage	$50.27

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 are required to submit their completed 2022 surveys to their MACs by June 30 2023. The preliminary, unaudited CY 2022 survey data will be 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.

F. Analysis and Implementation of the Proposed Occupational Mix Adjustment and the Proposed FY 2024 Occupational Mix Adjusted Wage Index

As discussed in section III.E. of the preamble of this proposed 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 proposed 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	$44.43
National LPN and Surgical Technician	$26.90
National Nurse Aide, Orderly, and Attendant	$18.53
National Medical Assistant	$19.51
National Nurse Category	$37.36

The proposed 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 69 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 Proposed Occupational Mix Adjusted Wage Indexes to the Proposed Unadjusted Wage Indexes by CBSA	
Number of Urban Areas Wage Index Increasing	229 (55.6%)
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	124 (30.1 %)
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	78 (18.9 %)
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	8 (17 %)
Number of Rural Areas Wage Index Decreasing by 5 Percent or More	0 (0%)
Largest Positive Impact for an Urban Area	7.14 %
Largest Positive Impact for a Rural Area	4.12 %
Largest Negative Impact for an Urban Area	-5.54 %
Largest Negative Impact for a Rural Area	-2.56 %
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. Proposed 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 proposed 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 proposed rule), we

estimate that 596 hospitals would 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 proposed 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 (D.D.C. 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.[156] 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' treatment of hospitals with dual § 412.103 and MGCRB reclassifications. The commenter stated that CMS' 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 the FY 2023 IPPS/LTCH PPS final rule (87 FR 49002), commenters urged CMS to discontinue the policy of excluding the wage data of § 412.103 hospitals from the rural floor calculation. 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 statutory framework.

In this proposed rule, CMS has taken the opportunity to revisit the case law, prior public comments, and the relevant statutory language. After doing so, CMS now agrees—for the reasons expressed by the U.S. Courts of Appeals for the Second and Third Circuit, 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. While CMS has previously treated section 1886(d)(8)(E) reclassifications as one among many reclassifications provided for under section 1886(d) 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 are influenced by the fact that courts have largely adopted this interpretation of section 1886(d)(8)(E), 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 also 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 acknowledge that this interpretation of section 1886(d)(8)(E) 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) 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 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 solicit comments on our proposed interpretation of section 1886(d)(8)(E) and section 1886(d)(3)(E)(i).

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 propose to change that policy, consistent with our new proposed interpretation of section 1886(d)(8)(E), 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 would also resolve the concerns about the rural floor raised in comments discussed previously. As far

[156] 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 would 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.

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 solicit 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), 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) 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 increase 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 proposed 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. Proposed 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 will 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 propose changing the rural wage index calculation methodology consistent with that proposed reinterpretation. We acknowledge the ongoing risk of the pending lawsuits cited previously, and recognize the challenge should we need to implement any future remedy in a budget neutral manner.

Beginning with FY 2024, we are proposing 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

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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 would no longer be treated as an inbound reclassification (calculation 3 of the current policy), but would instead be included in all calculations in which geographically rural hospitals are included (calculations 1–3 of the proposed policy). ''Dual reclass'' hospitals would 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 proposed 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 are proposing 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 acknowledge that these proposals would 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)—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 proposed 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 would no longer be affected by this policy, as we are proposing 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 would 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 are proposing 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 are proposing 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 are proposing 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) requires CMS to treat a reclassified hospital as being located in the rural area of the state, and section 1886(d)(8)(B) 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.

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) 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 proposed rule, States that would be all-urban States as defined in section 1886(d)(3)(E)(iv)(IV) of the Act, and thus hospitals in such States would 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 proposed 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 would 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 this FY 2024 IPPS/LTCH PPS proposed rule, we are not proposing any changes to the frontier floor policy for FY 2024. In this proposed rule, 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 note that while Nevada meets the criteria of a frontier State, all hospitals within the State are projected to receive a wage index value greater than 1.0000 prior to the application of the frontier floor policy for FY 2024.

The areas affected by the rural and frontier floor policies for the proposed FY 2024 wage index are identified in Table 2 associated with this proposed rule, which is available via the internet on the CMS website.

4. Proposed 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 being used 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.[157] 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 proposed 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 are proposing to continue the low wage index hospital policy and the related budget neutrality adjustment (discussed in this section of this rule). We may decide to take a different approach in the final rule, depending on public comments or developments in the court proceedings.

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 are proposing 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 proposed 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 proposed rule, the table displays the 25th percentile wage index value across all hospitals for FY 2024.

[157] 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).

FY 2024 25th Percentile Wage Index Value	0.8615

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 would 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).

For FY 2024, we would 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 would be updated, as appropriate, based on the final rule data. We refer readers to the Addendum of this proposed rule for further information regarding the budget neutrality calculations.

H. FY 2023 Wage Index Tables

In this FY 2024 IPPS/LTCH PPS proposed 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 proposed rule for a discussion of the wage index tables for FY 2024.

I. Proposed 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). We note that rural hospitals reclassifying under the MGCRB to another State's rural area are not eligible for the rural floor, because the rural floor may apply only to urban, not rural, hospitals.

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 proposed 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. At the time this proposed rule was drafted, the MGCRB had completed its review of FY 2024 reclassification requests. Based on such reviews, there are 621 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 262 hospitals approved for wage index reclassifications in FY 2022 that will continue for FY 2024, and 266 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, based upon the review at the time of the proposed rule, 1,149 (approximately 35 percent) hospitals are in a MGCRB reclassification status for FY 2024 (with 196 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' 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.

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 outmigration adjustment. In addition, in that rule, we adopted a minor procedural change that would allow 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 would 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 outmigration 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 outmigration adjustment would be denied, and the hospital would 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 would 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 outmigration adjustment under section 1886(d)(13)(G) of the Act.

J. Proposed 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). 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 outmigration 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 are proposing 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 are not proposing 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).)

Table 2 associated with this proposed 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 proposed 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 proposed rule for instructions on accessing IPPS tables that are posted on the CMS websites identified in this proposed 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 412.103. We also refer readers to section III.G.1. of the preamble of this proposed 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 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 proposed rule, we are proposing 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 are proposing 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 are also proposing in section V.C.2 of the preamble of this proposed rule to make 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 proposing to amend § 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 proposed § 412.92(b)(2)(vi), the effective date for rural reclassification for such hospital would 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 proposed rule for complete details on these proposals.

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) is 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, is 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 are given the opportunity to examine Table 2 associated with this 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 note 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 plan to post 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 is 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, is also the deadline for hospitals to dispute data corrections made by CMS of which the hospital is 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 do 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 are 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 will be 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 will have 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' 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 time table discussed in section III.L.1. of the preamble of this proposed 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. Proposed 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 and 86 FR 45529–45530). 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 this proposed rule, for FY 2024, we are not proposing to make any further changes to the labor-related share. For FY 2024, we are proposing 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 proposed 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 are not proposing 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 proposed rule and available via the internet on the CMS website, reflect the proposed national labor-related share. Table 1C, in section VI. of the Addendum to this FY 2024 IPPS/LTCH PPS proposed rule and available via the internet on the CMS website, reflects the proposed 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 proposing to apply 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 proposing to apply the wage index to a proposed labor-related share of 67.6 percent of the national standardized amount.

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, 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 disproportionate patient percentage 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 those 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 uncompensated care. The 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.

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 2 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 (including a Pickle 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.[158] 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, 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), minus a statutory adjustment of 0.2 percentage point for FYs 2018 and 2019.

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 for 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 the regulations at 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 in order 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. Therefore, hospitals must receive empirically justified Medicare DSH payments in a fiscal year in order to receive an additional Medicare uncompensated care payment for that year. Specifically, section 1886(r)(2) of the Act states that, in addition to the payment made to a subsection (d) hospital under section 1886(r)(1) of the Act, the Secretary shall pay to such subsection (d) hospitals an additional amount. Because section 1886(r)(1) of the Act refers to empirically justified Medicare DSH payments, the additional payment under section 1886(r)(2) of the Act is limited to hospitals that receive empirically justified Medicare DSH payments in accordance with section 1886(r)(1) of the Act for the applicable fiscal year.

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 provided 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

[158] *https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/Mar07_EntireReport.pdf.*

that are available). For this proposed rule, we estimated DSH status for all hospitals using the most recent available SSI ratios and information from the most recent available Provider Specific File. We note that FY 2020 SSI ratios available on the CMS website were the most recent available SSI ratios at the time of developing this proposed rule.[159] If more recent data on DSH eligibility become available before the final rule, we would use such data in the 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 have specified our policies for several specific classes of hospitals within the scope of section 1886(r) of the Act.

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).

• *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, and if they receive interim empirically justified Medicare DSH payments in a fiscal year, they also will receive interim uncompensated care payments for that fiscal year on a per discharge basis, subject as well 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 Federal rate is exceeded by the updated hospital-specific rate from certain specified base years (76 FR 51684). 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), 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 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 proposed 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, which began on January 1, 2019. Under the Maryland TCOC Model, which 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.

• *Sole community hospitals* (*SCHs) that are paid under their hospital-specific rate* are not eligible for Medicare DSH and uncompensated care payments. (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

[159] *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/dsh.*

solicitation for applications for additional hospitals to participate in the demonstration program. The period of performance for this 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 would extend until 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 also excluded from receiving interim and final uncompensated care payments. At the time of development of this proposed rule, we believe 26 hospitals may participate in the demonstration program at the start of FY 2024.

C. Empirically Justified Medicare DSH Payments

As we have 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 program to pay a designated percentage of these payments, without revising 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 did not believe that it was necessary to develop any new operational mechanisms for making such payments. Therefore, in the FY 2014 IPPS/LTCH PPS final rule (78 FR 50626), we implemented this provision by advising Medicare Administrative Contractors (MACs) to simply adjust the interim claim payments to the requisite 25 percent of what would have otherwise been paid. 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 that 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 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 the applicable 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.

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 three factors. These three factors represent our estimate of 75 percent of the amount of Medicare DSH payments that would otherwise have been paid, an adjustment to this amount for the percent change in the national rate of uninsurance compared to the rate of uninsurance in 2013, and each eligible hospital's estimated uncompensated care amount relative to the estimated uncompensated care amount for all eligible hospitals. In this section of this proposed rule, we discuss the data sources and methodologies for computing each of these factors, our final policies for FYs 2014 through 2023, and our proposed policies for FY 2024.

1. Proposed 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 the new payment provision; and (2) the amount of empirically justified Medicare DSH payments that are made for the fiscal year, which takes into account the requirement to pay 25 percent of what would have otherwise been paid under section 1886(d)(5)(F) of the Act. In other words, this factor represents our estimate of 75 percent (100 percent minus 25 percent) of our estimate of Medicare DSH payments that would otherwise be made, in the absence of section 1886(r) of the Act, for the fiscal year.

In this FY 2024 IPPS/LTCH PPS proposed rule, in order to determine Factor 1 in the uncompensated care payment formula for FY 2024, we are proposing to 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) of determining 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 has applied in previous years, these estimates will not be revised or updated subsequent to the publication of our final projections in the FY 2024 IPPS/LTCH PPS final rule.

Therefore, in order to determine the two elements of proposed Factor 1 for FY 2024 (Medicare DSH payments prior to the application of section 1886(r)(1) of the Act, and empirically justified Medicare DSH payments after application of section 1886(r)(1) of the Act), for this proposed rule, we used the most recently 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 IPPS Impact File. The determination of the amount of DSH payments is partially based on OACT's Part A benefits projection model. One of the results 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''.

For purposes of calculating Factor 1 and modeling the impact of this FY 2024 IPPS/LTCH PPS proposed rule, we used the Office of the Actuary's January 2023 Medicare DSH estimates, which were based on data from the September 2022 update of 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 publication of the FY 2023 IPPS/LTCH PPS final rule. Because SCHs that are projected to be paid under their hospital-specific rate are excluded from the application of section 1886(r) of the Act, these hospitals also were excluded from the January 2023 Medicare DSH estimates. Furthermore, because section 1886(r) of the Act specifies that the uncompensated care payment is in addition to the empirically justified Medicare DSH payment (25 percent of DSH payments that would be made without regard to section 1886(r) of the Act), Maryland hospitals, which are not eligible to receive DSH payments, were also excluded from the Office of the Actuary's January 2023 Medicare DSH estimates. The 26 hospitals that are anticipated to participate in the Rural Community Hospital Demonstration Program in FY 2024 were also excluded from these estimates, because under the payment methodology that applies during the third 5-year extension period, these hospitals are not eligible to receive empirically justified Medicare DSH payments or uncompensated care payments.

For this proposed rule, using the data sources as previously discussed, the Office of the Actuary's January 2023 estimate of Medicare DSH payments for FY 2024 without regard to the application of section 1886(r)(1) of the Act, is approximately $13.621 billion. Therefore, also based on the 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, is 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) of the regulations, Factor 1 is the difference between these two OACT estimates. Therefore, we are proposing that Factor 1 for FY 2024 would be $10,216,040,319.50, which is equal to 75 percent of the total amount of estimated Medicare DSH payments for FY 2024 ($13.621 billion minus $3.405 billion). We note that consistent with our approach in previous rulemakings, OACT intends to use more recent data that may become available for purposes of projecting the final Factor 1 estimates for the FY 2024 IPPS/LTCH PPS final rule.

We note 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 the Factor 1 estimates for the final rules are generally consistent with those used for the Midsession Review of the President's Budget. As we have in the past, 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 expect that the Midsession Review will have updated economic assumptions and actuarial analysis, which will be used for the development of Factor 1 estimates in the final rule.

For a general overview of the principal steps involved in projecting future inpatient costs and utilization, we refer 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.'' 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. We also refer 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*).

In this proposed rule, we include information regarding the data sources, methods, and assumptions employed by the actuaries in determining the OACT's estimate of Factor 1. In summary, we indicate the historical HCRIS data

update OACT used to identify Medicare DSH payments, we explain that the most recent Medicare DSH payment adjustments provided in the IPPS Impact File were used, and we provide the components of all the 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 includes a description of the ''Other'' and ''Discharges'' assumptions, and also provides additional information regarding how we address the Medicaid and CHIP expansion.

The Office of the Actuary's estimates for FY 2024 for this proposed 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	0.9850	0.9804	12.997
2022	1.025	0.943	0.997	1.0011	0.9647	12.539
2023	1.043	0.975	1.005	1.0484	1.0715	13.435
2024	1.028	0.976	1.005	1.0055	1.0139	13.621

*Rounded.

In this table, the discharges column shows the changes in the number of Medicare fee-for-service (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 pandemic. The discharge figure for FY 2023 is based on preliminary data. The discharge figure for FY 2024 is an assumption based on recent trends recovering back to the long-term trend and assumptions related to how many beneficiaries will be enrolled in Medicare Advantage (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 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 recent trends recovering back to the long-term trend. 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 shows the increase 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 January 30, 2023, the Biden Administration announced its plan to end the national emergency declaration and PHE declaration on May 11, 2023. Based on the most recent available data, Medicaid enrollment is estimated to change as follows: 12.3 percent in FY 2021, 8.1 percent in FY 2022, 2.0 percent in FY 2023, and −11.1 percent in FY 2024. In the future, the assumptions regarding Medicaid enrollment may change based on actual enrollment in the States.

For a discussion of general issues regarding Medicaid projections, we refer readers to the 2018 Actuarial Report on the Financial Outlook for Medicaid, which is available on the CMS website at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/MedicaidReport*. 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, use fewer hospital services. Specifically, based on the most recent available data at the time of developing this proposed rule, the 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-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	3.0	-0.2	0.0	2.8

Note: All numbers are the final inpatient hospital updates for the applicable year, except for the FY 2024 percentages, which are based on the 4th quarter 2022 IHS Global Inc. (IGI) forecast, the most recent forecast available at the time of development of this proposed rule. We refer readers to section V.B. of the preamble of this proposed rule for a complete discussion of the proposed changes in the inpatient hospital update for FY 2024.

2. Calculation of Proposed 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), minus 0.2 percentage point for FYs 2018 and 2019. In FY 2020 and subsequent fiscal years, there is no longer a reduction. 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 CBO estimates to determine the percent change in the rate of uninsurance beginning in FY 2018. 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. We are proposing 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 represents the government's official estimates of economic activity (spending) within the health sector. The information contained in the NHEA has been used to study numerous topics related to the health care sector, including, but not limited to, 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; and comparisons to other countries' health 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 are 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, we continue to believe 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*.

In order 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 population of the United States. (We refer readers to the website at *https://www.census.gov/programs-surveys/cps.html*.) The enhanced CPS, available from SHADAC (available at *http://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 2019 estimate 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.[160] 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 rate of uninsurance in both CY 2023 and CY 2024. On an annual basis, OACT projects enrollment and spending trends for the coming 10-year period. The most recent projections are for 2021 through 2030. Those projections used the latest NHEA historical data that were available at the time of their construction (that is, through 2020). The NHEA projection methodology accounts for expected changes in enrollment across all of 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 2021 Medicare Trustees Report,[161] 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 2021 Medicare Trustees Report. Greater detail 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. Proposed Factor 2 for FY 2024

Using these data sources and the previously described methodologies, at the time of developing this proposed rule, OACT has estimated that the uninsured rate for the historical, baseline year of 2013 was 14 percent and for CYs 2023 and 2024 is 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 has certified these estimates. We refer readers to OACT's Memorandum on Certification of Rates of Uninsured prepared for this 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.[162]

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, in order 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, we are proposing to continue to apply the weighted average approach used in past fiscal years in order to estimate the rate of uninsurance for FY 2024.

The 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. We note that we may 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. For example, (1) more recent data may become available regarding the impacts of the expiration of the Families First Coronavirus Response Act's continuous enrollment provision for Medicaid (which, once no longer in effect, will permit states to actively begin disenrolling beneficiaries no longer eligible for the program starting on April 1, 2023); (2) the Inflation Reduction Act's extension of enhanced Marketplace premium tax credits through 2025; and (3) the impacts associated with the Internal Revenue Services' 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). The calculation of the proposed Factor 2 for FY 2024 is 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. $1 - |((0.14 - 0.092)/0.14)| = 1 - 0.3429 = 0.6571$ (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 in order to determine Factor 2. Therefore, we are proposing that Factor 2 for FY 2024 would be 65.71 percent.

The proposed FY 2024 uncompensated care amount is equivalent to proposed Factor 1 multiplied by proposed Factor 2, which is $10,216,040,319.50 * 0.6571 = $6,712,960,093.94.

We are inviting public comments on our proposed Factor 2 for FY 2024.

3. Calculation of Proposed 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

[160] 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*.

[161] *https://www.cms.gov/files/document/2022-medicare-trustees-report.pdf*.

[162] OACT Memorandum on Certification of Rates of Uninsured. March 3, 2023. Available at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInPatientPPS/dsh.html*.

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 FYs 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 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 currently 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 1 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 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. Although 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, 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. 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, 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. For IHS and Tribal hospitals and Puerto Rico hospitals, we finalized the use of a low-income insured days proxy to determine Factor 3 for FY 2021(85 FR 58825).

In the FY 2021 IPPS/LTCH PPS final rule, 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 (85 FR 58825 through 58828). 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, 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 (86 FR 45236 through 45243). 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 governs both the selection of the data to be used in calculating Factor 3, and also 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, 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 (86 FR 45237). In the FY 2022 IPPS/LTCH PPS final rule, 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 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 final 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 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 on 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.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, 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, 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 (79 FR 50021). In the FY 2015 IPPS/LTCH PPS final rule, 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 (79 FR 50021 and 50022). 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 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 most recent audited cost reports for hospitals that are projected to be DSH-eligible. We stated that we continue to believe these thresholds are 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 are proposing to follow the same methodology as applied in FY 2023 and that is described in the

previous section of this proposed 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 this FY 2024 IPPS/LTCH PPS proposed rule, we are using reports from the December 2022 HCRIS extract to calculate Factor 3. We intend 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, 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 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 proposed rule for a further discussion of these payments. We note that we are not proposing any changes to the methodology for determining supplemental payments, and we will calculate the supplemental payments to eligible IHS/Tribal and Puerto Rico hospitals consistent with the methodology described in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49047 through 49051) and in the regulation 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 (FY) 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 will 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 will 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 will 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 will use the hospital's FY 2017 report if it spans some of the FY 2018 time period. In other words, we will 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 uncompensated care costs (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 by a scaling factor.

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, will 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 will 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 will 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.

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, will 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 the final rule is developed. However, at cost report settlement, we will 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 will 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 will 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 will also apply a scaling factor, as described previously.

Under the CCR trim methodology, for purposes of this FY 2024 proposed 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.

For a hospital that is subject to the trim for potentially aberrant data and are ultimately determined to be DSH-eligible at cost report settlement, its uncompensated care payment will 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 will 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 will 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 will reflect the uncompensated care costs reported on the hospital's FY 2024 cost report, while the denominator will 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 will apply a scaling factor, as discussed previously, to the Factor 3 calculation for the hospital. 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.

For purposes of the FY 2024 IPPS/LTCH PPS final rule, we intend to use data from the March 2023 HCRIS extract for this calculation, which will be the latest quarterly HCRIS extract that is publicly available at the time of the development of that 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 note that MACs follow normal timelines and procedures. 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 is not available for the March HCRIS extract, then that amended and/or reopened report data will not be part of the FY 2024 IPPS/LTCH PPS final rule's Factor 3 calculation. We note that the March HCRIS data extract will be available during the comment period for this proposed rule if providers want to verify that their amended and/or reopened data is reflected in the March HCRIS extract.

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 are proposing to calculatethe 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 continue 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, we believe 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 note that including discharge data from FY 2022 to compute this 3-year average is consistent with the proposed use of FY 2022 Medicare claims in the IPPS ratesetting, as discussed in section I.E. of the preamble of this FY 2024 IPPS/LTCH PPS proposed rule. Under this proposal, the resulting 3-year average of the number of discharges would be used to calculate a per discharge payment amount that will 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 will 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 are requesting 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. In the FY 2021 IPPS/LTCH PPS final rule (85 FR 58833 and 58834), we finalized a voluntary process 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 FY 2023 discharges. 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 the FY 2023 IPPS/LTCH final rule for a more detailed discussion of the steps for

determining the operating and capital Federal payment rate and the outlier payment calculation (87 FR 49431 through 49432). 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 will not change how the total uncompensated care payment amount will be reconciled at cost report settlement.

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 proposed 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 have 60 days from the date of public display of this 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 this 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). 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 will 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. All other comments submitted in response to our proposals 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 note 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 the 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), we believe 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 are proposing to no longer have the 15 business day time 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 are inviting public comments on this proposal.

V. Other Decisions and Changes to the IPPS for Operating System

A. Proposed 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 directs us 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. Proposed Changes for FY 2024

As discussed in section II.C. of the preamble of this proposed rule, based on our analysis of FY 2022 MedPAR claims data, we are proposing to make changes to a number of MS–DRGs, effective for FY 2024. Specifically, we are proposing 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 new 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).

In light of the proposed changes to the MS–DRGs for FY 2024, according to the regulations under § 412.4(d), we have evaluated the MS–DRGs using the general postacute care transfer policy criteria and data from 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 note that while CMS is proposing the

reassignment of procedure codes from MS–DRGs 252, 253, and 254 to proposed new MS–DRGs 278 and 279, we do not consider this proposed revision to constitute a material change that would warrant reevaluation of the postacute care status of MS–DRGs 252, 253, and 254. We note 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.

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 propose 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.

Using the December 2022 update of the FY 2022 MedPAR file, we have developed the following chart which sets forth the most recent analysis of the postacute care transfer policy criteria completed for this proposed rule with respect to each of these proposed new or revised MS–DRGs. For the FY 2024 final rule, we intend to update this analysis using the most recent available data at that time.

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LIST OF PROPOSED NEW OR REVISED MS-DRGs SUBJECT TO REVIEW OF POSTACUTE CARE TRANSFER POLICY STATUS FOR FY 2024

Proposed New or Revised MS-DRG	MS-DRG Title	Total Cases	Postacute Care Transfers (55th percentile: 1,042.5)	Short-Stay Postacute Care Transfers	Percent of Short-Stay Postacute Care Transfers to all Cases (55th percentile: 10.58201%)	FY 2023 Postacute Transfer Policy Status	Proposed Postacute Care Transfer Policy Status
166	OTHER RESPIRATORY SYSTEM O.R. PROCEDURES WITH MCC	7,756	4,105	1,324	17.07%	Yes	Yes
167	OTHER RESPIRATORY SYSTEM O.R. PROCEDURES WITH CC	4,203	1,358	257	6.11% *	Yes	Yes**
168	OTHER RESPIRATORY SYSTEM O.R. PROCEDURES WITHOUT CC/MCC	1,462	204 *	0	0.00% *	Yes	Yes**
173	ULTRASOUND ACCELERATED AND OTHER THROMBOLYSIS WITH PRINCIPAL DIAGNOSIS PULMONARY EMBOLISM	1,537	552 *	31	2.02% *	New	No
212	CONCOMITANT AORTIC AND MITRAL VALVE PROCEDURES	892	618 *	241	27.02%	New	No
275	CARDIAC DEFIBRILLATOR IMPLANT WITH CARDIAC CATHETERIZATION AND MCC	3,468	1,629	291	8.39% *	New	No
276	CARDIAC DEFIBRILLATOR IMPLANT WITH MCC	3,832	1,780	411	10.73%	New	Yes
277	CARDIAC DEFIBRILLATOR IMPLANT WITHOUT MCC	4,106	903 *	141	3.43% *	New	Yes**
278	ULTRASOUND ACCELERATED AND OTHER THROMBOLYSIS OF PERIPHERAL VASCULAR STRUCTURES WITH MCC	516	281 *	66	12.79%	New	No
279	ULTRASOUND ACCELERATED AND OTHER THROMBOLYSIS OF PERIPHERAL VASCULAR STRUCTURES WITHOUT MCC	972	296 *	42	4.32% *	New	No
321	PERCUTANEOUS CARDIOVASCULAR PROCEDURES WITH INTRALUMINAL DEVICE WITH MCC OR 4+ ARTERIES/INTRALUMINAL DEVICES	40,805	11,818	1,077	2.64% *	New	No
322	PERCUTANEOUS CARDIOVASCULAR PROCEDURES WITH INTRALUMINAL DEVICE WITHOUT MCC	56,680	5,328	565	1.00% *	New	No
323	CORONARY INTRAVASCULAR LITHOTRIPSY WITH INTRALUMINAL DEVICE WITH MCC	2,081	704 *	106	5.09% *	New	No
324	CORONARY INTRAVASCULAR LITHOTRIPSY WITH INTRALUMINAL DEVICE WITHOUT MCC	2,161	281 *	18	0.83% *	New	No
325	CORONARY INTRAVASCULAR LITHOTRIPSY WITHOUT INTRALUMINAL DEVICE	405	64 *	3	0.74% *	New	No
397	APPENDIX PROCEDURES WITH MCC	1,186	401 *	45	3.79% *	New	No
398	APPENDIX PROCEDURES WITH CC	3,820	700 *	111	2.91% *	New	No
399	APPENDIX PROCEDURES WITHOUT CC/MCC	3,071	221 *	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.

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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 this 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 are proposing that proposed new MS–DRG 277 also would be subject to the MS–DRG special payment methodology, effective for FY 2024. For the FY 2024 final rule, we intend to update this analysis using the most recent available data at that time.

LIST OF PROPOSED NEW OR REVISED MS-DRGs SUBJECT TO REVIEW OF SPECIAL PAYMENT POLICY STATUS FOR FY 2024

Proposed 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	Proposed Special Payment Policy Status
166	OTHER RESPIRATORY SYSTEM O.R. PROCEDURES WITH MCC	8.373703179	$41,407	$82,393	No	No
167	OTHER RESPIRATORY SYSTEM O.R. PROCEDURES WITH CC	3.459079009	$45,832	$42,031	No	No
168	OTHER RESPIRATORY SYSTEM O.R. PROCEDURES WITHOUT CC/MCC	1.835816638	$45,547	$32,756	No	No
276	CARDIAC DEFIBRILLATOR IMPLANT WITH MCC	6.304841426	$182,624	$133,031	New	Yes
277	CARDIAC DEFIBRILATOR IMPLANT WITHOUT MCC	3.329316171	$186,031	$106,900	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.

The proposed postacute care transfer and special payment policy status of these MS–DRGs is reflected in Table 5 associated with this proposed rule, which is listed in section VI. of the Addendum to this proposed rule and available on the CMS website.

B. Proposed Changes in the Inpatient Hospital Update for FY 2024 (§ 412.64(d))

1. Proposed 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 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 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 are proposing 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 is estimated to be 3.0 percent. We also are proposing that if more recent data subsequently become 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. We also refer commenters to the discussion at Appendix B to this proposed rule.

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 are proposing a productivity adjustment of 0.2 percent. Similar to the proposed market basket update, for this proposed rule, the estimate of the proposed FY 2024 productivity adjustment is based on IGI's fourth quarter 2022 forecast. As noted previously, we are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2024 productivity adjustment for the final rule.

Based on these data, we have determined four proposed applicable percentage increases to the standardized amount for FY 2024, as specified in the following table:

PROPOSED 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
Proposed Market Basket Rate-of-Increase	3.0	3.0	3.0	3.0
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	-0.75	-0.75
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	-2.25	0.0	-2.25
Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.2	-0.2	-0.2	-0.2
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.8**	**0.55**	**2.05**	**-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 proposed rule, section 4102 of the Consolidated Appropriations Act, 2023 (Pub. L. 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 proposed rule for further discussion of the MDH program.

For FY 2024, we are proposing 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. As previously discussed, we are proposing that if more recent data subsequently become 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.

2. Proposed 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.

PROPOSED 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
Proposed Market Basket Rate-of-Increase	3.0	3.0
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	-2.25
Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.2	-0.2
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.8**	**0.55**

Based on IGI's fourth quarter 2022 forecast of the 2018-based IPPS market basket update with historical data through third quarter 2022, for this FY 2024 proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as discussed previously, for Puerto Rico hospitals we are proposing 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, there are two possible applicable percentage increases that could be applied to the standardized amount. Based on these data, we have 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 are proposing 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 are proposing 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 $\times$ 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 are proposing that if more recent data subsequently become 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.

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 a 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. Proposed 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) [163] and meeting other criteria at § 412.92(a).

[163] 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.

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, we are proposing 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. This 90-day timeframe will 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. 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 are also proposing 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 are proposing 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 are not proposing 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 are not proposing any change to the effective date for an SCH application that does not involve a merger.

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 note that we are not proposing 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 seek comment on the need for such a proposal, which we may consider for future rulemaking as appropriate.

Therefore, we are proposing to revise § 412.92 by adding a new proposed 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 would 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 would 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 proposing to make conforming changes to the existing regulations at § 412.92(b) by adding an exception referencing proposed 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 proposing a technical correction to paragraph (b)(1)(v) by revising the word ''forward'' to ''forwards''.

As discussed, we are also proposing to make 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 proposing to amend § 412.103(d)(1) and to add new § 412.103(d)(3) to provide that, subject to the hospital meeting the requirements set forth at proposed § 412.92(b)(2)(vi), the effective date for rural reclassification for such hospital would be as of the effective date determined under § 412.92(b)(2)(vi).

D. Rural Referral Centers (RRCs) Proposed 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 would 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 proposed national median CMI value for FY 2024 is based on the CMI values of all urban hospitals nationwide, and the proposed 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 proposed values are based on discharges occurring during FY 2022 (October 1, 2021 through September 30, 2022), and include bills posted to CMS' records through December 2022. We believe that this is the best available data for use in calculating the proposed 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 this FY 2024 IPPS/LTCH PPS proposed rule, we are proposing 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 are set forth in the table in this section of this rule. We intend 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.

Region	Proposed Case-Mix Index Value
1. New England (CT, ME, MA, NH, RI, VT)	1.5284
2. Middle Atlantic (PA, NJ, NY)	1.5771
3. East North Central (IL, IN, MI, OH, WI)	1.6712
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	1.7382
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	1.6569
6. East South Central (AL, KY, MS, TN)	1.6593
7. West South Central (AR, LA, OK, TX)	1.8334
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	1.86195
9. Pacific (AK, CA, HI, OR, WA)	1.8116

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. For FY 2024, we are proposing 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), which are the latest cost report data available at the time this proposed rule was developed. We believe that this 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. Therefore, we are proposing 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 proposed number of discharges as set forth in the table in this section of this rule. We intend to update these numbers in the FY 2024 final rule based on the latest available cost report data.

Region	Proposed Number of Discharges
1. New England (CT, ME, MA, NH, RI, VT)	8,644
2. Middle Atlantic (PA, NJ, NY)	9,251
3. East North Central (IL, IN, MI, OH, WI)	7,542
4. West North Central (IA, KS, MN, MO, NE, ND, SD)	7,202
5. South Atlantic (DE, DC, FL, GA, MD, NC, SC, VA, WV)	9,970
6. East South Central (AL, KY, MS, TN)	8,259
7. West South Central (AR, LA, OK, TX)	5,593
8. Mountain (AZ, CO, ID, MT, NV, NM, UT, WY)	8,031
9. Pacific (AK, CA, HI, OR, WA)	8,501

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 proposed 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. 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:

Low-Volume Hospital Payment Adjustment =

$0.25 - [0.25/3300] \times$ (number of total discharges $- 500$) =

$(95/330) -$ (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 proposed rule, we are proposing 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.

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 4102 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 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 are proposing 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 proposed rule.

4. Proposed Payment Adjustment for FY 2024 and Proposed 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:

Low-Volume Hospital Payment Adjustment =

$0.25 - [0.25/3300] \times$ (number of total discharges $- 500$) =

$(95/330) -$ (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 are proposing to continue using the previously specified continuous, linear sliding scale formula to determine the low-volume hospital payment adjustment for FY 2024. We are also proposing 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 are proposing 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 are proposing 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 as the low-volume hospital payment adjustment policy in effect for FYs 2005 through 2010, as described previously.

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 proposed 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 proposed 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 are proposing 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 are proposing 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) in order 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.

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:

- Section 102 of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (Pub. L. 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.
- 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.
- 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).

Therefore, we are proposing 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 Pub. L. 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 section 102 of the Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023, section 102 of the Further Continuing Appropriations and Extensions Act, 2023, and section 4102 of the Consolidated Appropriations and Extensions 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.

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, in order 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). 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 this proposed rule, we are clarifying 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. 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 18) 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 clarification focuses 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].

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. 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.*''

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 explain the reasons in detail in this section of this rule. However, first, we are acknowledging 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 note 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 believe that the ''current year numerator'' referred to on Worksheet E, Part A line 20 is line 15, not line 12. This is in contrast to 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 propose 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.*

We are not proposing 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 intend 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.

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 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 in order 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 are proposing 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 are proposing 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 are proposing 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 are proposing to add a new paragraph (d) at 42 CFR 419.92 to implement these provisions.

4. Notice of Closure of Teaching Hospital and Opportunity To Apply for Available Slots

a. Background

Section 5506 of the Affordable Care Act (Pub. L. 111–148), as amended by the Health Care and Education Reconciliation Act of 2010 (Pub. L. 111–152) (collectively, the Affordable Care Act), authorizes the Secretary to redistribute residency slots after a hospital that trained residents in an approved medical residency program closes. Specifically, section 5506 of the Affordable Care Act amended the Act by adding subsection (vi) to section 1886(h)(4)(H) of the Act and modifying language at section 1886(d)(5)(B)(v) of the Act, to instruct the Secretary to establish a process to increase the FTE resident caps for other hospitals based upon the FTE resident caps in teaching hospitals that closed on or after a date that is 2 years before the date of enactment (that is, March 23, 2008). In the CY 2011 Outpatient Prospective Payment System (OPPS) final rule with comment period (75 FR 72212), we established regulations at 42 CFR 413.79(o) and an application process for qualifying hospitals to apply to CMS to receive direct GME and IME FTE resident cap slots from the hospital that closed. We made certain modifications to those regulations in the FY 2013 IPPS/LTCH PPS final rule (77 FR 53434), and we made changes to the section 5506 application process in the FY 2015 IPPS/LTCH PPS final rule (79 FR 50122 through 50134). The procedures we established apply both to teaching hospitals that closed on or after March 23, 2008, and on or before August 3, 2010, and to teaching hospitals that close after August 3, 2010.

b. Notice of Closure of St. Vincent Charity Medical Center Located in Cleveland, OH and the Application Process—Round 20

CMS has learned of the closure of St. Vincent Charity Medical Center, located in Cleveland, OH (CCN 360037).

Accordingly, this notice serves to notify the public of the closure of this teaching hospital and initiate another round of the section 5506 application and selection process. This round will

be the 20th round (''Round 20'') of the application and selection process. The table in this section of this rule contains the identifying information and IME and direct GME FTE resident caps for the closed teaching hospital, which are part of the Round 20 application process under section 5506 of the Affordable Care Act.

TABLE V.G.-01: ST. VINCENT CHARITY MEDICAL CENTER FTE RESIDENT CAPS

CCN	Provider Name	City and State	CBSA Code	Terminating Date	IME FTE Resident Cap (including+/-Sec. 422 of the MMA[1] and Sec. 5503 of the Affordable Care Act [2] adjustments)	Direct GME FTE Resident Cap (including +/- Sec. 422 of MMA adjustment)
360037	St. Vincent Charity Medical Center	Cleveland, OH	17460	November 11, 2022	65.83 – 3.57 sec. 422 reduction – 5.53 sec. 5503 reduction = 56.73[3]	72.86 – 8.20 sec. 422 reduction = 64.66[4]

[1] Section 422 of the MMA, Pub. L. 108-173, redistributed unused IME and direct GME residency slots effective July 1, 2005.
[2] Section 5503 of the Affordable Care Act of 2010, Pub. L. 111–148 and Pub. L. 111–152, redistributed unused IME and direct GME residency slots effective July 1, 2011.
[3] St. Vincent Charity Medical Center's 1996 IME FTE resident cap is 65.83. Under section 422 of the MMA, the hospital received a reduction of 3.57 to its IME FTE resident cap, and under section 5503 of the Affordable Care Act, the hospital received a reduction of 5.53 to its IME FTE resident cap: 65.83 – 3.57 – 5.53 – 56.73.
[4] St. Vincent Charity Medical Center's 1996 direct GME FTE resident cap is 72.86. Under section 422 of the MMA, the hospital received a reduction of 8.20 to its direct GME FTE resident cap: 72.86 – 8.20 = 64.66.

c. Application Process for Available Resident Slots

The application period for hospitals to apply for slots under section 5506 of the Affordable Care Act is 90 days following notice to the public of a hospital closure (77 FR 53436). Therefore, hospitals that wish to apply for and receive slots from the FTE resident caps of closed St. Vincent Charity Medical Center, located in Cleveland, OH, must submit applications using the electronic application intake system, Medicare Electronic Application Request Information System™ (MEARIS™), with application submissions for Round 20 due no later than July 10, 2023. The Section 5506 application can be accessed at: *https://mearis.cms.gov/public/home*.

CMS will only accept Round 20 applications submitted via MEARIS™. Applications submitted through any other method will not be considered. Within MEARIS™, we have built in several resources to support applicants:

- Please refer to the ''Resources'' section for guidance regarding the application submission process at: *https://mearis.cms.gov/public/resources*.
- Technical support is available under ''Useful Links'' at the bottom of the MEARIS™ web page.
- Application related questions can be submitted to CMS using the form available under ''Contact'' at: *https://mearis.cms.gov/public/resources*.

Application submission through MEARIS™ will not only help CMS track applications and streamline the review process, but it will also create efficiencies for applicants when compared to a paper submission process.

We have not established a deadline by when CMS will issue the final determinations to hospitals that receive slots under section 5506 of the Affordable Care Act. However, we review all applications received by the deadline and notify applicants of our determinations as soon as possible.

We refer readers to the CMS Direct Graduate Medical Education (DGME) website at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/DGME.html.* Hospitals should access this website for a list of additional section 5506 guidelines for the policy and procedures for applying for slots, and the redistribution of the slots under sections 1886(h)(4)(H)(vi) and 1886(d)(5)(B)(v) of the Act.

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 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 this FY 2024 IPPS/LTCH PPS proposed rule, we are proposing the rates for CY 2022. Consistent with the use of HCRIS data for past calendar years, we are proposing 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 this 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 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 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

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 this section, we propose 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. We propose 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 propose 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 propose 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 propose 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 propose 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 note 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) 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.

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 are not proposing any changes to the regulations text at 42 CFR 413.87.

I. Proposed 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 in order 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).[164]

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 42 CFR 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 are proposing 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 are proposing to use to adjust the case count for purposes of the relative weight calculations, as described in section II.D. of the preamble of this proposed 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 this proposed 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 are proposing to use to adjust the case count for purposes of the relative weight calculations, we are proposing 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 this proposed rule for further discussion of these proposed methodology changes.

Consistent with our calculation of the proposed adjustor for the relative weight

[164] *https://www.fda.gov/news-events/expanded-access/expanded-access-keywords-definitions-and-resources.*

calculations, for this proposed rule we propose 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 42 CFR 412.312 (for capital IPPS payments), we propose 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 propose to update the value of the adjustor based on more recent data for the final rule.

J. Hospital Readmissions Reduction Program

1. Statutory Basis for the Hospital Readmissions Reduction Program

Section 1886(q) of the Act establishes 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.

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.

There are no proposals or updates in this proposed rule for the Hospital Readmissions Reduction Program. We refer readers to section I.G.5 of the proposed rule for an updated estimate of the financial impact of 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 (that is, July 1, 2019, through June 30, 2022).

K. Hospital Value-Based Purchasing (VBP) Program: Proposed 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 December 2022 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 are publishing proxy value-based incentive payment adjustment factors in Table 16 associated with this proposed rule (which is available via the internet on the CMS website). We note that these proposed proxy adjustment factors will not be used to adjust hospital payments. These proposed proxy value-based incentive payment adjustment factors were calculated using the historical baseline and performance periods for the FY 2023 Hospital VBP Program. These proxy factors were calculated using the December 2022 update to the FY 2022 MedPAR file. The slope of the linear exchange function used to calculate these proxy factors was 2.6516107025, and the estimated amount available for value-based incentive payments to hospitals for FY 2024 is approximately $1.7 billion. We intend to include an update to this table, as Table 16A, with the FY 2024 IPPS/LTCH PPS final rule, to reflect changes based on the March 2023 update to the FY 2022 MedPAR file. 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 are not proposing any changes to these policies in this proposed rule.

b. Proposal to Codify 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. We are proposing in this proposed rule 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. We believe this proposal 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 invite public comment on this proposal.

c. Proposed Substantive Measure Modifications

(1) Proposed Substantive Measure Updates to the Medicare Spending per Beneficiary (MSPB)—Hospital Measure (CBE #2158) Beginning With the FY 2028 Program Year

We are proposing to adopt substantial measure updates to the MSPB Hospital measure (CBE #2158) in the Hospital VBP Program beginning with the FY 2028 program year. 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 the MSPB Hospital measure provides important data on resource use (addressing the Meaningful Measures Framework priority of making care affordable), which is why we are proposing 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.[165]

We presented the three substantive updates to the MSPB Hospital measure (CBE #2158) to the consensus-based entity (CBE) [166] 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).[167] 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.[168] Following re-endorsement, we included the updated measure in CMS's ''List of Measures Under Consideration (MUC) for December 1, 2021.'' [169] The re-evaluated MSPB Hospital measure (MUC2021–131) underwent Measure Applications Partnership (MAP) 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.[170]

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 are proposing 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 are proposing 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 proposed rule where we discuss our defined baseline and performance periods for this updated measure under the Hospital VBP Program. We are also proposing that the performance standards calculation methodology for the updated MSPB Hospital measure would be the same as that which we currently use for the measure. The performance standards for

[165] Medicare Spending Per Beneficiary (MSPB) Measure Methodology. Available at: *https://qualitynet.cms.gov/inpatient/measures/mspb/methodology*.

[166] 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.

[167] The submission materials, including the testing results, are available at: *https://www.qualityforum.org/ProjectMeasures.aspx?projectID=86056&cycleNo=2&cycleYear=2020*.

[168] 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*.

[169] 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*.

[170] 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*.

the updated measure for the FY 2028 program year are not yet available.

We invite public comment on this proposal.

(2) Proposed 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

We are proposing 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. 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 this measure provides important data on resource use (addressing the Meaningful Measures Framework priority of making care affordable), which is why we are proposing 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 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'' [171] with identification number MUC2021–118. The MAP reviewed the re-evaluated 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.[172] The CBE re-endorsed the original measure in July of 2021,[173] 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 would 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 describe the same updates we are proposing 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 would 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 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 are proposing 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 are proposing 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 proposed rule where we discuss our defined baseline and performance periods for this updated measure under the Hospital VBP Program. We are also proposing that the performance standards calculation methodology for the updated THA/TKA Complications measure would 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 invite public comment on this proposal.

3. Proposed 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

[171] 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.*

[172] 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.*

[173] 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.*

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. Proposed New Measure 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 patients.[174] 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.[175] 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.[176] 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.[177]

In a 2001 study by Rivers et al.,[178] 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.[179]

(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 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 significant reductions in hospital length of stay, re-admission rates and mortality have been observed.[180] [181] Additional information about this measure is available on the CMS Measures Inventory Tool (CMIT) website.[182]

We believe 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

[174] 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*.

[175] 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*.

[176] 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.

[177] 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.

[178] 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.

[179] 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.

[180] 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.

[181] 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.

[182] Severe Sepsis and Septic Shock: Management Bundle (Composite Measure) *https://cmit.cms.gov/cmit/#/MeasureView?variantId=778&sectionNumber=1*.

of safety cultures.[183] We also believe 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.[184] 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.[185] 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.[186] 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.[187] 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 believe 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.[188] We believe 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 would 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 for hospitals to report. However, in light of our high priority to address patient safety, we are proceeding with the proposal to adopt the Severe Sepsis and Septic Shock: Management Bundle measure at this time. 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.[189] 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 in order 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

[183] The National Healthcare System Action Alliance To Advance Patient Safety. HHS. Available at: *ahrq.gov/cpi/about/otherwebsites/action-alliance.html*.

[184] 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*.

[185] 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.

[186] Ibid.

[187] Chaudhary N, Donnelly, J, Wang H (2018). Critical Care Medicine 46(6):p 878–883, June 2018. | DOI: 10.1097/CCM.0000000000003020.

[188] 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.

[189] Hospital IQR Program, Inpatient Specifications Manual v5.14. *https://qualitynet.cms.gov/files/6391eabf76962e0016ad91ba?filename=HIQR_SpecsMan_v5.14.zip*.

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 are proposing 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

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 are proposing 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 proposed rule where we discussed our proposed baseline periods and performance periods for this measure if adopted for the Hospital VBP Program.

We invite public comment on this proposal.

b. Summary of Previously Adopted Measures for the FY 2024 and FY 2025 Program Years, and Previously Adopted Measures and Newly Proposed 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. We are not proposing any changes to the FY 2024 and FY 2025 measure sets. The Hospital VBP Program measure set for the FY 2024 and FY 2025 years would 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

We are proposing substantive measure updates to the MSPB and THA/TKA Complication measures. We are also proposing to adopt the Severe Sepsis and Septic Shock: Management Bundle. Table V.K.-02 summarizes the previously adopted and newly proposed Hospital VBP Program measures for the FY 2026 through FY 2030 program years:

TABLE V.K.-02: SUMMARY OF PREVIOUSLY ADOPTED MEASURES AND NEWLY PROPOSED 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 proposed rule, we are proposing to adopt 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 proposed rule, we are proposing to adopt 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 proposed rule, we are proposing to adopt substantive updates to the MSPB Hospital measure beginning with the FY 2028 program year.

c. Proposed 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 proposed rule where the Hospital IQR Program is proposing to make updates to the administration and submission requirements of the HCAHPS Survey measure beginning with the FY 2027 payment determination. We are also proposing 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 in order 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.

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 proposed rule. There would be no changes to the HCAHPS Survey measure patient eligibility or exclusion criteria. We note 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, this proposal to adopt technical changes does 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 invite public comment on this proposal.

4. Previously Adopted and Newly Proposed 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), FY 2022 IPPS/LTCH PPS final rule (86 FR 45284 through 45290), and 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. Proposed 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 proposed rule, we are proposing the Severe and Septic Shock: Management Bundle measure beginning with the FY 2026 program year. We are proposing to adopt a 12-month baseline period and a 12-month performance period for that measure. Therefore, for the FY 2026 program year, we are proposing 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 propose 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. We display these proposed 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 Proposed 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 proposing to adopt.

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 December 31, 2019 (87 FR 49111 through 49113).

**In accordance with 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 voluntarily submitted for scoring purposes under the Hospital VBP Program.

TABLE V.K.-04: PREVIOUSLY ADOPTED AND NEWLY PROPOSED 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 proposing to adopt the Severe Sepsis and Septic Shock: Management Bundle measure beginning with the FY 2026 program year.

TABLE V.K.-05: PREVIOUSLY ADOPTED AND NEWLY PROPOSED 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, mortality, and CMS PSI 90 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 PROPOSED 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 proposing to adopt the substantive updates to the MSPB measure for the FY 2028 program year.
**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, mortality, and CMS PSI 90 measures. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).

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TABLE V.K.-07: NEWLY PROPOSED 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, mortality, and CMS PSI 90 measures. For more detailed information, we refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45297 through 45299).

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, FY 2014 IPPS/LTCH PPS final rule, and 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. We are issuing 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 are being 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 proposed rule.

(2) Technical Correction to the Previously Established and Estimated 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. Although the asterisk in this table denotes that the performance standards for the Safety domain measures were calculated using CY 2019 data, the numbers for the five hospital-associated infection (HAI) measures incorrectly displayed performance standards using CY 2021 data. We are therefore issuing a correction to display the correct performance standards 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 Newly Established 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. We are therefore issuing 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 of this proposed rule.

c. Previously Established and Estimated 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. The previously established and estimated performance standards for the measures in the FY 2026 program year have been updated and are set out in Tables V.K.-09, V.K.-10, V.K.-11, and V.K.-12.

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*.**	0.668	0
CLABSI*.**	0.833	0
CDI*	0.433	0
MRSA Bacteremia*	0.866	0
Colon and Abdominal Hysterectomy SSI*	0.757	0
SEP-1***	83.94	58
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 proposed performance standards for the HAI measures in this proposed rule represent estimates based on the most recently available data, and we intend to update the numerical values in the FY 2024 IPPS/LTCH PPS final rule. These estimates are based on 10/1/2021-9/30/2022 data.

*** We note that the numerical values for the proposed performance standards for the SEP-1 measure displayed in this proposed rule represent estimates based on the most recently available data, and we intend to update the numerical values in the FY 2024 IPPS/LTCH PPS final rule. These estimates are based on 4/1/2021- 3/31/2022 data.

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	55.29	76.53	85.59
Communication with Doctors	56.88	76.92	85.98
Responsiveness of Hospital Staff	33.8	59.62	76.92
Communication about Medicines	36.6	58.13	69.65
Hospital Cleanliness & Quietness	39.84	62.68	77.24
Discharge Information	61.75	85.57	91.14
Care Transition	20.57	48.68	60.86
Overall Rating of Hospital	34.15	67.64	83.3

* We note that the numerical values for the proposed performance standards for the HCAHPS Survey in this proposed rule represent estimates based on the most recently available data, and we intend to update the numerical values in the FY 2024 IPPS/LTCH PPS final rule. These estimates are based on 10/1/2021-9/30/2022 data.

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 in order 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 proposed substantive updates to the MSPB measure would not change if the substantive measure updates are adopted. 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 in order 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). We refer readers to section V.K.5.b.(3) of this proposed rule where we announce that we are issuing 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.

6. Proposed 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. We are proposing modifications to the existing scoring methodology to reward excellent care in underserved populations.

b. Proposal To Revise 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.[190] [191] Research shows that patients experiencing worse health outcomes often face barriers to accessing health care services and have access to fewer healthcare providers.[192] [193] 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.[194] 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 Under Medicare's Value-Based Purchasing Programs, 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.[195] Patients with dual 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

[190] 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.*

[191] 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: *http://nap.nationalacademies.org/21858.*

[192] 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.*

[193] Thompson, T., McQueen, A., Croston, M., Luke, A., Caito, N., Quinn, K., Funaro, J., & Kreuter, M.W. (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.*

[194] 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.*

[195] 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: *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files/171041/ASPESESRTCfull.pdf.*

likely to be medically complex, and have greater social needs compared to other beneficiaries.[196] Patients with DES are one of the most vulnerable populations.[197] [198] Despite the multitude of indicators available for assessing vulnerability and health risks, dual eligibility remains the strongest predictor of negative health outcomes.[199]

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] [200]+) 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.[201] 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.[202] 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, we are proposing to add Health Equity Adjustment bonus points to a hospital's Total Performance Score (TPS) that would 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.

We propose 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 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.[203]

We propose 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 would award to a hospital for each domain would 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 would 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 propose 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 would use the total number of inpatient stays from January 1, 2024 through December 31, 2024. A logistic exchange function would 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 propose that the HEA bonus points would 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 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 proposed methodology for the calculation of the HEA bonus points is

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[196] Johnston, K.J., & Joynt Maddox, K.E. (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.*

[197] Johnston, K.J., & Joynt Maddox, K.E. (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.*

[198] Wadhera, R.K., Wang, Y., Figueroa, J.F., Dominici, F., Yeh, R.W., & Joynt Maddox, K.E. (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.*

[199] 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.*

[200] 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.

[201] Health Equity Strategic Pillar. Centers for Medicare & Medicaid Services. *https://www.cms.gov/pillar/health-equity.*

[202] 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.*

[203] 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.*

described in sections V.K.6.b.(3) and V.K.6.b.(4) of this proposed rule. By providing HEA bonus points to hospitals that serve higher proportions of patients with DES and perform well on quality measures, we believe we can begin to bridge performance gaps and better address the social needs of patients, in alignment with our National Quality Strategy.[204] 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 this proposal would 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 this proposal aligns with the broader CMS health equity goals to close gaps in health care quality and promote the highest quality outcomes for all people.[205]

We are proposing 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 proposed rule are similar to the health equity adjustment finalized in the Shared Savings Program. Additionally, a similar health equity adjustment is being proposed in the FY 2024 Skilled Nursing Facility Value-Based Purchasing (SNF VBP) Program's Prospective Payment System (PPS) proposed rule.

(2) Determining the Underserved Multiplier and Measure Performance Scaler

At this time, for purposes of the Hospital VBP Program's proposed health equity adjustment, 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 are proposing to only use DES data at this time. As DES is a strong indicator of poorer healthcare outcomes in Medicare's VBP programs,[206] we believe it can serve as an appropriate underserved multiplier on its own in the Hospital VBP Program. If adopted as proposed, we would 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 are seeking comment on the use of these additional indicators in section V.K.6.b.(7) of this proposed rule.

The measure performance scaler points would be available to all hospitals that exhibit high quality care across the entire patient population. Each domain would be assessed independently such that a hospital that performs in the top or middle third of performance for one domain would 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 would receive measure performance scaler points for all domains. Alternatively, a hospital which is in the bottom third of performance for all four domains would 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 proposal.

The underserved multiplier would 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.[207] These data would 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 are proposing 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 would then be applied to this dual proportion. We would 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 proposed rule. Unlike the Shared Savings Program's policy, we note that we are not proposing 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 in order to give every hospital an opportunity to participate in this proposed scoring change.

Through the proposed HEA bonus points, we seek to improve outcomes by providing incentives to hospitals to strive for high performance 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 proposal. While we recognize and discuss in this proposed 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

[204] 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.*

[205] 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.*

[206] 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.*

[207] 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.*

population'' throughout this proposal. 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.[208]

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 would 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 proposed rule, the combination of the measure performance scaler and the underserved multiplier would 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 are also proposing to codify at 42 CFR 412.160 of our regulations the definitions of these new scoring methodology terms, and we are proposing 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) Proposed 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 are proposing 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 would be 12.

We propose 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, we are also proposing that the number of HEA bonus points that could then be added to a hospital's TPS for a program year would 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 proposed 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, we propose that the maximum number of HEA bonus points that could be added to the TPS would be 10 points. Under this proposal, no hospital could earn more than a 110 maximum final TPS that includes the HEA bonus points. We refer readers to section V.K.6.b.(6) of this proposal and to our proposed regulations at 42 CFR 412.160 where we propose to modify the TPS maximum to 110. This proposed maximum at 110 would 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) Proposed Calculation Steps and Examples

In this section, 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 would be as follows:

Step One—Calculate the Number of Measure Performance Scaler Points for Each Hospital

We propose to first assign a measure performance scaler to each domain based on a hospital's domain level scores. We would assign point values to hospitals for each domain based on their performance on the measures in that domain. A hospital would 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

Table V.K.–13 displays the measure performance scaler that three example hospitals would receive for each domain based on their performance.

[208] 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 : 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 propose to calculate an underserved multiplier for each hospital, which we propose 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 would 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 would have the opportunity for the most HEA bonus points. Thus, we are proposing to utilize a logistic exchange function to calculate the underserved multiplier for scoring hospitals such that there would be a lower rate of increase at the beginning and the end of the curve.

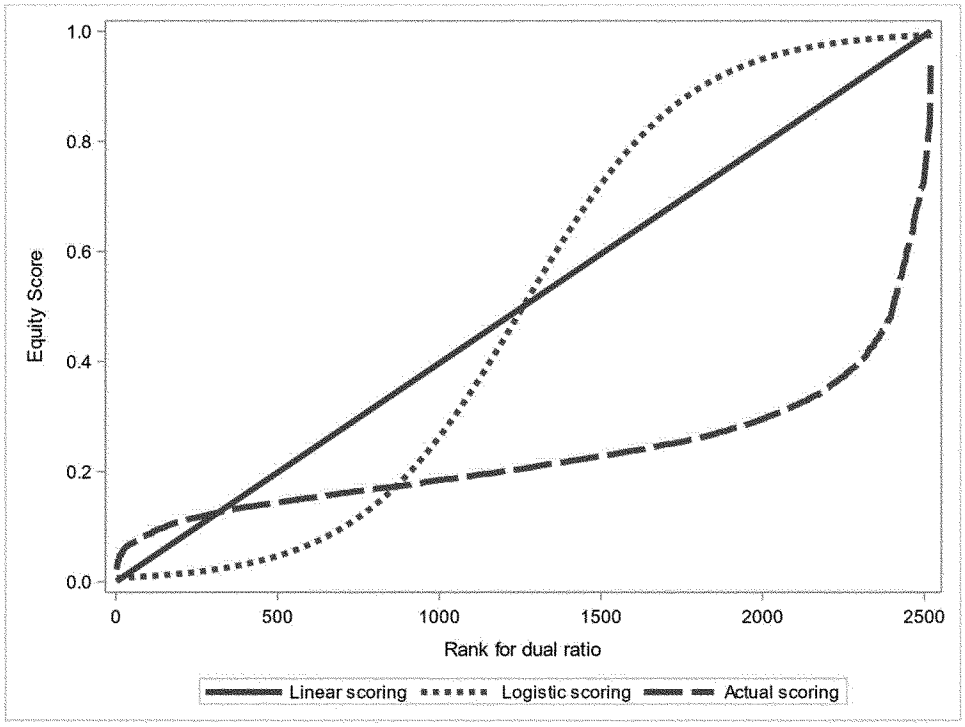
The underserved multiplier calculation would thus be:

Underserved Multiplier = Logistic Function (Number of Inpatient Stays for Patients with DES/Total Medicare Inpatient Stays)

To determine the proportion of the number of inpatient stays for patients with DES, we propose 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 would 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 are proposing to utilize a logistic exchange function to calculate the underserved multiplier for scoring hospitals such that there would 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 would ensure that there would be very few differences in the points awarded between hospitals with similar proportions of patients served. For example, there would 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 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 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 are proposing 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) in order 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 would earn 16 measure performance scaler points, which would 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.

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

Step Four—Add Health Equity Adjustment Bonus Points to the Total of the Weighted Domain Scores To Calculate the TPS

Finally, we are proposing that we would 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 would remain as outlined in our regulations at 42 CFR 412.165(b)(4), and the HEA bonus points would be the hospital's TPS for the program year. We are not proposing 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 note that we are proposing 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 proposed 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 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 invite public comment on this proposed scoring change which we are also proposing to codify in our regulations at 42 CFR 412.160 and 412.165(b).

(5) Impact Analysis of Proposed Scoring Methodology Change

We conducted analyses 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. 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 in order to contextualize the request for additional information in section V.K.6.b.(7) of this proposal. 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.[209] A logistic 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 are proposing 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 proposed 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 would increase with the addition of the HEA bonus points.

Our analysis finds that both the proposed and alternative HEA scoring

[209] 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 voluntarily submitted for scoring purposes under the Hospital VBP Program.

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 proposal 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 are seeking feedback on the alternative scoring method in section V.K.6.b.(7) of this proposed rule for future consideration.

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 proposed 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 are proposing 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 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.[210] [211] Therefore, we believe 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 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.[212] [213] 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.[214] [215] [216] [217] [218]

[210] 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.

[211] 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.*

[212] Center for Health Disparities Research University of Wisconsin. (2022). Neighborhood Atlas. Available at: *https://www.neighborhoodatlas.medicine.wisc.edu/.*

[213] 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: *http://dx.doi.org/10.5888/pcd13.160221.*

[214] 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.*

[215] 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.*

[216] Cheng, E., Soulos, P.R., Irwin, M.L., et al. (2021). Neighborhood and Individual

Many rural areas also have relatively high levels of neighborhood disadvantage and high ADI levels. We believe 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.[219] 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 hope to utilize the ADI in the Hospital VBP Program in future years as data becomes more readily available through new measures in the Program in order 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.[220] 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 does 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 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.

(6) Proposal To Modify 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. We are proposing 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. A TPS maximum of 110 would 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 proposing to modify the TPS range will afford even top-performing hospitals the opportunity to receive up to an additional 10 HEA bonus points.

We are also proposing 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 this proposal will make it easier for interested parties to find these updated policies.

We invite public comment on this proposal.

(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.[221] We believe the proposed scoring methodology embodies this commitment, but recognize it is only a first step.

Therefore, we invite 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.

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*.

[217] 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*.

[218] 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*.

[219] 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*.

[220] 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*.

[221] 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*.

• 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 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 in order 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?

b. 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.

We are not proposing any changes to these domain weights.

c. 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 in order 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).

We are not proposing any changes to these domain weights.

d. 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.

We are not proposing any changes to these policies.

e. 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 Proposed Minimum Numbers of Cases

The previously adopted minimum numbers of cases for the Hospital VBP 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 are proposing to maintain the same minimum number of cases as the current measures.

We are proposing to codify at 42 CFR 412.165(a)(1)(i) these minimum numbers of cases. We believe this proposal will make it easier for interested parties to find these policies.

TABLE V.K.-18: PREVIOUSLY ADOPTED AND NEWLY PROPOSED 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 proposed rule, we are proposing to adopt the Severe Sepsis and Septic Shock: Management Bundle measure beginning with the FY 2026 program year.

We invite comment on these proposals.

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.

We are not proposing any changes to the Hospital VBP Program ECE policy.

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.[222]

[222] 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.*

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 *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.

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[223] #**
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 are not proposing 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 are not proposing 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 the COVID–19 on hospitalized individuals on the CMS PSI 90 measure, although the Public Health Emergency is scheduled to end in CY 2023.[224]

We are not proposing any changes in this proposed rule.

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 2021, by 7 percent, 5 percent, and 14 percent respectively.[225] 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.[226] 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

[223] 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.

[224] 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/*.

[225] Centers for Disease Control and Prevention. (2022). Current HAI Progress Report. Available at: *https://www.cdc.gov/hai/data/portal/progress-report.html#2018*.

[226] 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

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.[227] 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.[228] 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.[229] [230]

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 in the FY 2023 IPPS/LTCH PPS proposed rule (87 FR 28452) we are seeking 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 & 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. We would appreciate 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 proposed rule, the Hospital IQR Program is proposing to adopt three additional eCQMs, which we seek 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 invite public comment on the adoption of these six eCQMs in the HAC Reduction Program.

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 invite public comment on potential future measures as well as on how the HAC Reduction Program can further promote patient safety. Specifically, we invite 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?

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 are not proposing 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,

[227] 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*.

[228] 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*.

[229] 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*.

[230] 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*.

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 are not proposing any changes to these processes.

(2) Proposal To Adopt a Validation Reconsideration Process

In this proposed rule, we are proposing to add a validation reconsideration process to the HAC Reduction Program, giving hospitals the opportunity to request reconsideration of their final validation scores. 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 proposed 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 are proposing 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 would 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.

The process, if finalized, would 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 are proposing to notify hospitals that failed the HAC Reduction Program validation requirement for the CDC NHSN HAI measures via a notification letter sent by certified mail. The letter would instruct hospitals 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 would 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 would provide hospitals an email acknowledgement, following receipt of a request for validation reconsideration, using the contact information provided in the validation reconsideration request. We would 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 would 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 would 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 are proposing to 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 would not abstract medical records that were not submitted during the initial validation process. We would 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 would abstract data elements from the medical record submitted by the hospital as part of our review of its reconsideration request. After the reconsideration process was complete, we would 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 would 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 Scores, are subject to a 1-percent payment reduction under the HAC Reduction Program. We note that the proposed HAC Reduction Program reconsideration process is limited to reconsideration as to the data validation requirements of the program. We are not proposing 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 invite public comment on this proposal.

(3) Proposal To Update the Targeting Criteria for Hospitals Granted an Extraordinary Circumstances Exception (ECE)

As proposed in the Hospital IQR program in section IX.C.11.b of this proposed rule, we are proposing to update our targeting criteria for validation of hospitals granted an extraordinary circumstances exception (ECE) in the HAC Reduction Program. Specifically, we are proposing 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 propose to add a new criterion to the five established targeting criteria used to select the up to 200 additional hospitals. We propose that a hospital subject to validation who 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 would not receive the penalty of the maximum Winsorized *z*-scores, the worst scores, for measures validated. This exception would not except a hospital from participation in the HAC Reduction Program, and the hospital would 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 adopting this additional criterion would promote alignment with what is being proposed in Hospital IQR Program. Hospitals that meet this criterion would 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 more or more quarters and does not meet the 75 percent threshold.

Specifically, we propose 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 proposal would align targeting criteria 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). Our proposal would also allow us to appropriately address instances in which hospitals, with an ECE for one or more quarters for the data period validated, would 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 invite public comment on this proposal.

M. 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 proposed rule, we summarize the status of the demonstration program, and the current methodologies for implementation and calculating budget neutrality.

We are also proposing 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 proposing to include the reconciled amount of demonstration costs for FY 2018 in the FY 2024 IPPS/LTCH final rule. We expect all finalized cost reports for this earlier year to be available by that time.

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) of Public Law 108–173, 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 of 2021) follows upon the previous extensions under the Affordable Care Act (Pub. L. 111–148) and the Cures Act (Pub. L. 114–255). Section 410A of Public Law 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 Affordable Care Act, 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.

3. 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 of 2021, we have continued upon the general budget neutrality methodology used in previous years, as previously described in the citations to earlier IPPS final rules. In this proposed rule, we outline the methodology to be used 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 are estimating the costs of the demonstration for the upcoming fiscal year, and proposing to 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 proposed market basket percentage increase for FY 2024, which can be found at section V.B.1 of the preamble to this proposed 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) in order 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 proposed applicable percentage increase, per section V.B.1 of the preamble of this proposed 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 proposed rule, the resulting amount is $37,658,408, 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. If updated data become available prior to the final rule, we will use them as appropriate to estimate the costs for the demonstration program for FY 2024 in accordance with our methodology for determining the budget neutrality estimate. We will also incorporate any statutory change that might affect the methodology for determining hospital costs either with or without the demonstration.

(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 proposed rule, not all of the finalized cost reports are available for the 29 hospitals that completed cost report periods beginning in FY 2018 under the demonstration payment methodology. We expect all of these finalized cost reports to be available by the time of the final rule, and thus we are proposing to include the difference between the actual cost of the demonstration for FY 2018 as determined from finalized cost reports within the budget neutrality offset amount in the FY 2024 final rule.

(3) Total Proposed Budget Neutrality Offset Amount for FY 2024

Therefore, for this FY 2024 IPPS/LTCH PPS proposed rule, the proposed budget neutrality offset amount for FY 2024 is the amount determined under section V.M.3.c.(1). of the preamble of this proposed rule, representing the difference applicable to FY 2023 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 $37,658,408.

However, we note, that the overall amount might change if there are any revisions prior to the final rule to the data used to formulate this estimate. We also expect to revise the budget neutrality offset amount upon calculating the actual costs of the demonstration for FY 2018, after

receiving all of the finalized cost reports for that fiscal year.

VI. Proposed 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) × (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. Proposed Annual Update for FY 2024

The proposed 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 proposed 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 we propose to revise the capital DSH regulations in response to this court ruling. Specifically, we are proposing 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 propose 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.

VII. Proposed Changes for Hospitals Excluded From the IPPS

A. Proposed 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 this FY 2024 IPPS/LTCH PPS proposed rule, based on IGI's 2022 fourth quarter forecast, we estimate that the 2018-based IPPS operating market basket percentage increase for FY 2024 is 3.0 percent (that is, the estimate of the market basket rate-of-increase). 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, RNCHIs, and short-term acute care hospitals located in the U.S. Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa is 3.0 percent, in accordance with the applicable regulations at 42 CFR 413.40. However, we are proposing that if more recent data becomes 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.

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 is 3.0 percent, which is based on IGI's fourth quarter 2022 forecast. Furthermore, we are proposing that if more recent data becomes 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.

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 proposed 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 proposed 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 proposed 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), 42 CFR 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 and/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 proposed 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.

Therefore, we propose not 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.

VIII. Proposed 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 proposed 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 extends 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 proposed rule for our discussion on our proposal to use the most recent data available for the FY 2024 LTCH PPS ratesetting, including the FY 2022 MedPAR claims and FY 2021 cost report data.

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 would be 766 MS–DRG, and by extension, MS–LTC–DRG, groupings based on the proposed changes, as discussed in section II.E. of the preamble of this proposed 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 format, 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 proposed 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).

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. Proposed 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 proposed rule, we are proposing to update the MS–LTC–DRG classifications effective October 1, 2023 through September 30, 2024 (FY 2024) consistent with the proposed changes to specific MS–DRG classifications presented in section II.F. of the preamble of this proposed rule. Accordingly, the proposed MS–LTC–DRGs for FY 2024 are the same as the MS–DRGs being proposed for use under the IPPS for FY 2024. In addition, because the proposed MS–LTC–DRGs for FY 2024 are the same as the proposed MS–DRGs for FY 2024, the other proposed changes that affect MS–DRG (and by extension MS–LTC–DRG) assignments under proposed GROUPER Version 41, as discussed in section II.E. of the preamble of this proposed rule, including the proposed changes to the MCE software and the ICD–10–CM/PCS coding system, are also applicable under the LTCH PPS for FY 2024.

3. Proposed 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 proposed 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 proposed methodology). For FY 2024, we are proposing to continue to use applicable LTCH cases to establish the same volume-based categories to calculate the FY 2024 MS–LTC–DRG relative weights.

b. Proposed Development of the MS–LTC–DRG Relative Weights for FY 2024

In this section, we present our proposed methodology for determining the MS–LTC–DRG relative weights for FY 2024. We first list and provide a brief description of our proposed steps for determining the FY 2024 MS–LTC–DRG relative weights. We then, later in this section, discuss in greater detail each proposed 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, we are proposing to return 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). Our historical LTCH ratesetting methodologies do not separately account for the impact of COVID–19 on the ratesetting data, which we believe is appropriate for FY 2024 as discussed in further detail in section I.E. of the preamble of this proposed rule. 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 proposed 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 this FY 2024 IPPS/LTCH PPS proposed rule, consistent with our proposal in section I.E. of the preamble of this 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 are proposing 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.

To calculate the FY 2024 MS–LTC–DRG relative weights under the dual rate LTCH PPS payment structure, we are proposing to 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 December 2022 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 FY 2022 MedPAR file, we identified 164 LTCH PPS standard Federal payment rate cases for this LTCH. Of these 164 cases, 116 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, we are proposing to remove 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 proposed rule, we also are proposing to remove 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 proposed 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 December 2022 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 December 2022 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 proposed steps to calculate the proposed 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 proposed calculation of the proposed 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 proposed 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, consistent with our existing relative weight methodology, in determining the proposed FY 2024 MS–LTC–DRG relative weights, we are proposing to remove 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, we are proposing to continue 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 proposed rule, based on the best available data (that is, the December 2022 update of the FY 2022 MedPAR file), we identified 235 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 proposed rule, the number of MS–LTC–DRGs with less than 25 applicable LTCH cases was evenly divisible by 5. Therefore, each quintile contained 47 MS–LTC–DRGs (235/5 = 47). We are proposing that in the final rule, if the number of MS–LTC–DRGs with less than 25 applicable LTCH cases in the best available data is not evenly divisible by 5, we would employ 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, we are proposing to make adjustments to the resulting low-volume MS–LTC–DRGs to preserve monotonicity, as discussed in Step 7 of our proposed methodology.

To determine the FY 2024 relative weights for the low-volume MS–LTC–DRGs, consistent with our historical practice, we are proposing to use 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 proposed 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 proposed rule, we are providing the list of the composition of the proposed 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 proposed 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 proposed calculation of the proposed 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, we are proposing to continue 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 proposed 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 proposed calculation of the proposed FY 2024 MS–LTC–DRG relative weights, consistent with our historical approach, we are proposing to adjust 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, we are proposing to make 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 proposed 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 propose to continue 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 proposed rule, we are proposing to continue 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, we propose to calculate the proposed 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 are proposing to continue 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 proposed 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 proposed 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, its 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 proposed MS–LTC–DRG relative weights, consistent with our historical methodology, we are proposing to continue 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 proposed 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 proposed 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 December 2022 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 proposed 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, we are proposing to crosswalk each no-volume proposed MS–LTC–DRG to another proposed MS–LTC–DRG for which we calculated a relative weight (determined in accordance with the methodology as previously described). Then, the ''no-volume'' proposed MS–LTC–DRG is assigned the same relative weight (and average length of stay) of the proposed MS–LTC–DRG to which it was crosswalked (as described in greater detail in this section of this proposed rule).

Of the 766 proposed MS–LTC–DRGs for FY 2024, we identified 430 MS–LTC–DRGs for which there were no trimmed applicable LTCH cases. The 430 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 402 MS–LTC–DRGs that for which, we are proposing to assign a relative weight using our existing ''no-volume'' MS–LTC–DRG methodology (that is, $430 - 11 - 2 - 15 = 402$). We are proposing to assign relative weights to each of the 402 no-volume MS–LTC–DRGs based on clinical similarity and relative costliness to 1 of the remaining 336 ($766 - 430 = 336$) 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 336 MS–LTC–DRGs to which we cross-walked each of the 402 ''no-volume'' MS–LTC–DRGs.) Then, in general, we are proposing to assign the 402 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 December 2022 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 proposed 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 proposed 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 proposed 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 proposed 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 proposed rule for proposed MS–LTC–DRG 061 (Ischemic stroke, precerebral occlusion or transient ischemia with thrombolytic agent with MCC). We determined that proposed MS–LTC–DRG 064 (Intracranial hemorrhage or cerebral infarction with MCC) is similar clinically and based on resource use to proposed MS–LTC–DRG 061. Therefore, we are proposing to assign the same relative weight (and average length of stay) of proposed MS–LTC–DRG 064 of 1.4526 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 proposed 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, we are proposing to use 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, we are proposing to establish 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 proposing to established 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 proposing to establish 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 proposing to establish 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, we are proposing to continue to apply budget neutrality adjustments in determining the proposed FY 2024 MS–LTC–DRG relative weights so that our proposed update of the MS–LTC–DRG classifications and relative weights for FY 2024 are made in a budget neutral manner. For FY 2024, we are proposing to apply 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 proposed 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 proposed budget neutrality factor that accounts for the application of the 10-percent cap policy (step 11).

In this proposed rule, to ensure budget neutrality for the proposed 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 are proposing to continue 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 proposed 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 proposed normalization factor for FY 2024, we propose to use 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 proposed FY 2024 GROUPER (that is, Version 41 for FY 2024) and the proposed 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 proposed MS–LTC–DRG relative weights for FY 2024, each recalibrated MS–LTC–DRG uncapped relative weight is multiplied by the proposed normalization factor of 1.30980 (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 proposed 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 proposed rule, for FY 2024, we propose to determine 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 proposed 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 proposed FY 2024 MS–LTC–DRG relative weights, each uncapped normalized relative weight is then multiplied by a proposed budget neutrality factor of 0.9962866 (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 proposed 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, we are proposing to limit the reduction to 10-percent. Under this policy, we do not apply the 10 percent cap to the proposed low-volume MS–LTC–DRGs identified in Step 3 or the proposed no-volume MS–LTC–DRGs identified in Step 8.

Therefore, in this step, for each proposed 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 proposed normalization and proposed 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 proposed capped FY 2024 MS–LTC–DRG relative weight that would be equal to 90 percent of that MS–LTC–DRG's FY 2023 relative weight (that is, we set the proposed FY 2024 relative weight equal to the FY 2023 weight $\times$ 0.90).

In section II.E. of the preamble of this proposed rule, we discuss our proposed 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 are not proposing any changes to this policy for FY 2024, and as such any proposed new or renumbered MS–LTC–DRGs for FY 2024 would not be eligible for the 10-percent cap, if finalized.

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 are proposing to continue to apply a budget neutrality adjustment to the MS–LTC–DRG relative weights so that the proposed 10-percent cap on relative weight reductions (step 10) is implemented in a budget neutral manner. Therefore, we are proposing to determine the proposed 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 proposed capped relative weights for FY 2024 (determined in Step 10) and proposed GROUPER Version 41; (b) simulate estimated total FY 2024 LTCH PPS standard Federal payment rate payments for applicable LTCH cases using the proposed uncapped relative weights for FY 2024 (determined in Step 9) and proposed 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 proposed FY 2024 MS–LTC–DRG relative weights, each capped relative weight is then multiplied by a proposed budget neutrality factor of 0.9984223 (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 proposed rule

and is available via the internet on the CMS website, lists the proposed MS–LTC–DRGs and their respective proposed relative weights, proposed geometric mean length of stay, and proposed 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 proposed MS–LTC–DRG relative weights prior to the application of the proposed 10 percent cap on MS–LTC–DRG relative weight reductions and corresponding proposed cap budget neutrality factor.

C. Proposed Changes to the LTCH PPS Payment Rates and Other Proposed Changes to the LTCH PPS for FY 2024

1. Overview of Development of the Proposed 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 are proposing to 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 proposed rule, we present our proposed policies related to the annual update to the LTCH PPS standard Federal payment rate for FY 2024.

The proposed update to the LTCH PPS standard Federal payment rate for FY 2024 is presented in section V.A. of the Addendum to this proposed rule. The components of the proposed 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 proposed rule). We are proposing to make 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 proposed rule).

2. Proposed 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. Proposed 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 proposed rule, we are proposing to 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. Proposed 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, applies a 2.0 percentage points reduction 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 proposed rule.)

d. Proposed Annual Market Basket Update Under the LTCH PPS for FY 2024

Consistent with our historical practice, we estimate the market basket increase and the productivity adjustment based on IGI's forecast using the most recent available data. Based on IGI's fourth quarter 2022 forecast, the proposed FY 2024 market basket update for the LTCH PPS using the 2017-based LTCH market basket is 3.1 percent. The proposed productivity adjustment for FY 2024 based on IGI's fourth quarter 2022 forecast is 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 are proposing to reduce the FY 2024 market basket increase by the FY 2024 productivity adjustment. To determine the proposed market basket increase for LTCHs for FY 2024, as reduced by the proposed productivity adjustment, consistent with our established methodology, we subtracted the proposed FY 2024 productivity adjustment from the proposed FY 2024 market basket increase. (For additional details on our established methodology for adjusting the market basket increase by the productivity adjustment, we refer readers to the FY 2012 IPPS/LTCH PPS final rule (76 FR 51771).)

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. Therefore, for LTCHs that fail to submit quality reporting data under the LTCH QRP, the proposed 3.1 percent market basket increase to the LTCH PPS standard Federal payment rate for FY 2024 would be reduced by the proposed 0.2 percentage point productivity adjustment as required under section 1886(m)(3)(A)(i) of the Act and by the additional 2.0 percentage points reduction required by section 1886(m)(5) of the Act.

In this FY 2024 IPPS/LTCH PPS proposed rule, in accordance with the statute, we are proposing to reduce the proposed FY 2024 market basket 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 are proposing 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 most recent estimate of 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 are proposing 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 are proposing 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 are proposing 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 are also proposing 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 this proposed rule).

IX. Proposed Quality Data Reporting Requirements for Specific Providers

A. Overview

In section IX. of the preamble of this proposed rule, we are seeking comment on and proposing 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).

B. Proposed 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).[231] 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 1.1 million deaths in the United States as of March 27, 2023.[232] In recognition of the ongoing significance and complexity of COVID–19, the Secretary has 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.[233] HHS announced plans to let the PHE expire on May 11, 2023 and 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.[234]

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,[235] 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 in order 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,[236] Moderna,[237] and Janssen.[238] 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.[239] The FDA issued approval for the Moderna vaccine, marketed as Spikevax, on January 31, 2022 [240] and an EUA for the Novavax adjuvanted vaccine on July 13, 2022.[241] The FDA also issued EUAs for single booster doses of the then authorized COVID–19 vaccines. As of November 19, 2021,[242] [243] [244] 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.[245] FDA first authorized the use of a booster dose of bivalent or ''updated'' COVID–19 vaccines from Pfizer-BioNTech and Moderna in August 2022.[246]

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

[231] 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*.

[232] Centers for Disease Control and Prevention. COVID Data Tracker. Accessed March 27, 2023. Available at: *https://covid.cdc.gov/covid-data-tracker/#datatracker-home*.

[233] 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*.

[234] 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*.

[235] 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*.

[236] 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*.

[237] 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*.

[238] 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*.

[239] 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*.

[240] 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*.

[241] 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*.

[242] 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*.

[243] 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*.

[244] 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*.

[245] 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*.

[246] 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*.

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.[247] 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.[248] 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.[249] 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.[250] In the presence of high 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.[251] 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.[252] 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.[253] 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.[254] The FDA issued EUAs for booster doses of two bivalent COVID–19 vaccines, one from Pfizer-BioNTech [255] and one from Moderna,[256] 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.[257] 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.[258] [259] 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.[260] 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.[261]

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

[247] 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*.

[248] 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://cdc.gov.mmwr/volumes/70/wr/mm7037e1.htm?s_cid=mm7037e1_w.

[249] 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*.

[250] 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 online at: *https://pubmed.ncbi.nlm.nih.gov/34551224/*.

[251] 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/*.

[252] Centers for Disease Control and Prevention. (August 2021). Variants of the Virus. Available at: *https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html*.

[253] Food and Drug Administration. (November 2022). COVID–19 Bivalent Vaccine Boosters.

[254] 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*.

[255] 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*.

[256] 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*.

[257] 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*.

[258] 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/*.

[259] 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/*.

[260] 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*.

[261] 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-preliminary-analysis-pacltc-workgroup.pdf*.

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 receive primary series and booster vaccine doses 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 propose 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 propose to 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 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 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). 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.[262] 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.[263] 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 would 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.[264] 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)[265] 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 would be 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:[266]

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

[262] 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.*

[263] 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.*

[264] 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.*

[265] 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.*

[266] 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.*

contraindications as defined by the CDC.[267] There are no changes to the denominator exclusions.

The numerator would 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.* For example, for the proposed updated measure, HCP would be 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 meet one of the following criteria:

1. Individuals who received an updated bivalent [268] booster dose, or

2a. Individuals who received their last booster dose less than 2 months ago, or

2b. Individuals who completed their primary series [269] less than 2 months ago.

We note that for purposes of NHSN surveillance, the CDC used this definition of up to date during quarter 4 2022 surveillance period (September 26, 2022–December 25, 2022).

We refer readers to *https://www.cdc.gov/nhsn/nqf/index.html* for more details on the measure specifications.

We are proposing that public reporting of the modified version of the COVID–19 Vaccination Coverage among HCP measure would 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.[270] The applicable authorities of the Hospital IQR Program,[271] PCHQR Program,[272] and LTCH QRP [273] 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.[274] We adopted this measure during the FY 2022 IPPS/LTCH PPS rule cycle, 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 are not proposing any changes to the data submission or reporting process, we are proposing that reporting of the updated measure would 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 would 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 would be used to calculate the measure. Each quarter, the CDC would calculate a single quarterly COVID–19 HCP vaccination coverage rate for each provider, which would be calculated by taking the average of the data from the three weekly rates submitted by the provider for that quarter. CMS would 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)). We note that while the measure requires reporting for a minimum of one week each month, the current hospital Conditions of Participation (CoP) require more frequent reporting. With the announcement that the PHE will be ending on May 11, 2023,[275] reporting under the Hospital CoP may be reduced to a lesser frequency. CMS plans to communicate any future changes to CoP through a Quality Safety & Oversight memoranda and other communications materials when new policies are finalized.

We invite public comment on this proposal.

C. Proposed 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

[267] 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.*

[268] 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.

[269] 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.

[270] 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.*

[271] Sec. 1886(b)(3)(B)(viii)(IX)(aa) of the Act.

[272] Sec. 1866(k)(3)(A) of the Act.

[273] Sec. 1886(m)(5)(D)(i) of the Act.

[274] *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.

[275] 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.*

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 82 FR 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 are not proposing any changes to these policies in this 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 are not proposing any changes to these policies in this proposed rule. However, as discussed in subsection 7.d. of this section of the proposed rule, we are proposing to codify our measure retention and removal policies in our regulations.

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.[276] 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.[277]

We are not proposing any changes to these policies in this proposed rule.

5. Proposed New Measures for the Hospital IQR Program Measure Set

We are proposing 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.

a. Proposed 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.[278] Pressure injuries commonly lead to further patient harm, including local infection, osteomyelitis, anemia, and sepsis,[279] in addition to causing pain and discomfort to patients.[280] Development of a pressure injury can increase the length of a patient's hospital stay by an average of four days.[281] Hospital-acquired pressure injuries are associated with 1.5 to 2.0 times greater risk of 30, 60, and 90-day readmissions.[282] 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).[283]

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

[276] 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.*

[277] 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.*

[278] 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.*

[279] 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.

[280] 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.

[281] 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.

[282] 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.*

[283] AHRQ. (2019). Never Events. *https://psnet.ahrq.gov/primer/never-events.*

pressure injuries, including nutrition.[284] 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.[285] [286] 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 would 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.[287]

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).[288]

An older version of this measure was reviewed by the consensus-based entity (CBE) convened Measure Applications Partnership (MAP) 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 this proposal. 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.[289] 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). The MAP noted that risk adjustment may be necessary to ensure the measure does not disproportionately penalize facilities who 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.[290]

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

[284] 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.

[285] 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.

[286] 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.*

[287] Wound Management & Prevention: Volume 64—Issue 11—November 2018 ISSN 1943–2720 Index: Ostomy Wound Manage. 2018;64(11):30–41' Definition Inpatient hospitalizations.

[288] 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.*

[289] 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.*

[290] *Ibid.*

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.[291] [292] [293] [294] [295] 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/pre-rulemaking-eh-cah-ecqms*) 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 are proposing 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 proposed 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 proposed rule for a discussion of a similar proposal to adopt this measure in the Medicare Promoting Interoperability Program.

We invite public comment on this proposal.

b. Proposed 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.[296] 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.[297] 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.[298] [299] Both worsening renal function and injury requiring dialysis have lasting negative impacts including loss of kidney function, uremic complications, and symptoms associated with drug toxicity and volume overload.[300] [301] [302] 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.[303] 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 while reducing patient quality of life.[304] About 30 percent of patients with AKI may require ongoing dialysis in the outpatient setting after hospital discharge.[305] Survivors of AKI also have significantly lower health-related quality of life (HRQOL) compared to the general population.[306] HRQOL is a predictor of mortality among AKI survivors after adjusting for clinical risk variables.[307]

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

[291] 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.*

[292] 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/.*

[293] 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.

[294] 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.

[295] 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.

[296] Levey, A.S., & James, M.T. (2017). Acute Kidney Injury. *Annals of internal medicine, 167*(9), ITC66–ITC80.

[297] 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.

[298] Hoste, E.A., & Schurgers, M. (2008). Epidemiology of acute kidney injury: how big is the problem? Critical care medicine, 36(4 Suppl), S146–S151.

[299] Wilson, F.P., Yang, W., & Feldman, H.I. (2013). Predictors of death and dialysis in severe AKI: the UPHS–AKI cohort. Clinical journal of the American Society of Nephrology: CJASN, 8(4), 527–537.

[300] Hoste, E., & De Corte, W. (2011). Clinical consequences of acute kidney injury. *Contributions to nephrology, 174,* 56–64.

[301] Levey, A.S., & James, M.T. (2017). Acute Kidney Injury. *Annals of internal medicine, 167*(9), ITC66–ITC80.

[302] 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.

[303] 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.

[304] 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.

[305] 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.

[306] 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.

[307] 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.

Disease: Improving Global Outcomes (KDIGO) guidelines suggest careful management of hemodynamic status, fluids, and vasoactive medications for the prevention of AKI.[308] Literature suggests early AKI treatment such as nephrotoxic avoidance, drug dose adjustment, and attention to fluid balance are also effective preventive measures.[309] [310] Using electronic health record (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.[311] 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.[312] Accurately monitoring the rate at which AKI occurs in the hospital setting would 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).[313]

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.[314] 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 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/pre-rulemaking-eh-cah-ecqms*) 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.

[308] 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.

[309] Perazella M. A. (2012). Drug use and nephrotoxicity in the intensive care unit. *Kidney international, 81*(12), 1172–1178.

[310] 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.

[311] 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.*

[312] 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.

[313] 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.*

[314] 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.*

We are proposing 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 proposed 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 proposed rule for a discussion of a similar proposal to adopt this measure in the Medicare Promoting Interoperability Program.

We invite public comment on this proposal.

c. Proposed 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.[315] 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.[316] 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.[317]

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.[318] 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.[319]

A large body of research links CT scans to a higher risk of developing cancer.[320] [321] [322] [323] [324] 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.[325] 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.[326] One study estimated that the percentage of cancers in the U.S. attributable to CT scans may be as high as two percent.[327] 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.[328] 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 would 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.[329] We are also proposing to adopt the Excessive Radiation eCQM to support the National Quality Strategy goal of promoting safety by reducing preventable harm to patients.[330] 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,[331] The Society of Interventional Radiology,[332] The Society of Cardiovascular CT,[333]

[315] Harvard Health Publishing. (2021). Radiation Risk from Medical Imaging. Available at: *https://www.health.harvard.edu/cancer/radiation-risk-from-medical-imaging*.

[316] *Ibid.*

[317] *Ibid.*

[318] *Ibid.*

[319] 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*.

[320] 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*.

[321] 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.

[322] 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.

[323] 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.

[324] 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.

[325] Harvard Health Publishing. (2021). Radiation Risk from Medical Imaging. Available at: *https://www.health.harvard.edu/cancer/radiation-risk-from-medical-imaging*.

[326] 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*.

[327] *Ibid.*

[328] Centers for Medicare & Medicaid Services. 2022 MUC List. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports*.

[329] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy*.

[330] CMS Quality Strategy. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy*.

[331] American College of Radiology. (2015). Development and Revision Handbook. *https://www.acr.org/-/media/ACR/Files/Practice-Parameters/DevelopmentHandbook.pdf*.

[332] Stecker, Michael S. et al. Guidelines for Patient Radiation Dose Management. Journal of Vascular and Interventional Radiology. 2009. Volume 20, Issue 7, S263–S273.

[333] 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.

cardiovascular imaging societies,[334] Image Wisely 2020,[335] and the FDA.[336]

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.[337] 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 would encourage shared decision-making between providers and patients.[338]

(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 translation software would be available to all reporting entities free of charge and would be accessible by creating a secure account through the measure developer's website. Education materials would provide step-by-step instructions on how hospitals can create an account and then link their EHR and PACS data to the translation software. Reporting entities and their vendors would 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 is the number of diagnostic CT scans that have a size-adjusted radiation dose greater than the 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.[339]

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.[340]

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 Code (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/pre-rulemaking-eh-cah-ecqms*) for more details on the measure specifications.

(5) Data Submission and Reporting

We are proposing 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 proposed 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 proposed rule for more information on our proposal to adopt the Excessive Radiation eCQM in the Medicare Promoting Interoperability Program.

We invite public comment on this proposal.

6. Refinements to Current Measures in the Hospital IQR Program Measure Set

We are proposing to modify three measures within 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 the 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 proposed rule.

[334] 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*.

[335] Image Wisely 2020. Available at: *https://www.imagewisely.org/*.

[336] FDA. (2019). Computed Tomography (CT). *https://www.fda.gov/radiation-emitting-products/medical-x-ray-imaging/computed-tomography-ct#6*.

[337] 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*.

[338] *Ibid.*

[339] Centers for Medicare & Medicaid Services. 2022 MUC List. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports*.

[340] *Ibid.*

a. Proposed 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.[341] 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.[342] 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.[343]

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.[344]

In this proposed rule, we are proposing 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 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 are proposing 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.[345] The Congressional Budget Office estimates that by 2030, 62 percent of beneficiaries will be covered by MA plans.[346] MA coverage also varies across counties and states (ranging between one to 59 percent) with lower enrollment in rural states.[347] Including MA beneficiaries in hospital outcome measures would help ensure that hospital quality is measured across all Medicare beneficiaries. We further believe that the addition of MA beneficiaries to FFS would 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 would address interested parties' concerns about differences in quality for MA and FFS beneficiaries by ensuring hospital outcomes are measured across all Medicare beneficiaries.[348] [349]

(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 would 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. 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)

[341] 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.*

[342] 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/.*

[343] 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.*

[344] 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.

[345] 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/.*

[346] *Ibid.*

[347] *Ibid.*

[348] 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/.*

[349] 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.*

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.[350]

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 are proposing is the addition of MA admissions into the cohort; all other specifications would 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.[351] The modified measure with expanded cohort is expected to be submitted for CBE re-endorsement in Fall 2024.

(4) Data Submission and Reporting

Under this proposal, hospitals would 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 routinely collect, that can be feasibly extracted from hospital EHRs, and that can be utilized as part of specific quality outcome measures.[352] 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 would need to submit the core clinical data elements included in the Hybrid HWM measure, as described for measure calculation,[353] 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 would 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 is the only change to the Hybrid HWM measure being proposed. We are proposing 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 invite public comment on this proposal.

b. Proposed 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.[354] Some readmissions are unavoidable, for example, those that

[350] 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*.

[351] 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*.

[352] 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*.

[353] 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*.

[354] 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*.

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.[355] [356] [357] [358] 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.[359]

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.[360]

In this proposed rule, similar to our proposal for the Hybrid HWM measure, we are proposing 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 are proposing 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.[361] The Congressional Budget Office projects that by 2030, 62 percent of beneficiaries will be covered by MA plans.[362] MA coverage also varies across counties and states (ranging between one to 59 percent) with lower enrollment in rural states.[363] Including MA beneficiaries in CMS hospital outcome measures would 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 would 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 would address stakeholder concerns about differences in quality for MA and FFS beneficiaries by ensuring hospital outcomes are measured across all Medicare beneficiaries.[364] [365]

(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 propose 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

[355] 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/.*

[356] 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/.*

[357] 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.*

[358] 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 targeted care bundle. *J Hosp Med.* 2009;4(4):211–218. Accessed December 8, 2022. Available at: *https://pubmed.ncbi.nlm.nih.gov/19388074/.*

[359] 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.*

[360] 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.

[361] 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/.*

[362] *Ibid.*

[363] *Ibid.*

[364] 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/.*

[365] 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.*

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.[366]

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 current Hybrid HWR measure is the addition of MA admissions into the cohort; all other specifications remain the same. We refer readers to the Hybrid Hospital-Wide Readmission Measure with Electronic Health Record Extracted Risk Factors (Version 1.2) 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.[367] 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 would 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 would need to submit the core clinical data elements included in the Hybrid HWR measure, as described for measure calculation,[368] 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.[369] 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 would 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 is the only proposed change to the Hybrid HWR measure. We are proposing 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 invite public comment on this proposal.

7. Proposed Measure Removals for the Hospital IQR Program Measure Set and Proposed Codification of Measure Removal Factors

We are proposing 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

[366] 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*.

[367] Centers for Medicare & Medicaid Services Measures Inventory Tool (CMIT). Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=4597&sectionNumber=3*.

[368] 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*.

[369] 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*.

Gestation (PC–01) measure beginning with the CY 2024 reporting period/FY 2026 payment determination.

We are also proposing 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 in the subsequent sections.

a. Proposed 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 would 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 Complication (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 this proposed rule, we are proposing 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 is proposing to adopt the re-evaluated measure to replace the original version of the measure that is in the Hospital VBP Program. Therefore, we are proposing 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 would 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 proposed rule for more information on the proposal 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 would 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 would 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 would 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),[370] which is

[370] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy*.

why we are proposing 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 are proposing 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 invite public comment on this proposal.

b. Proposed 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 this proposed rule, we are proposing 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 is being proposed for adoption by the Hospital VBP Program in section V.K. of this proposed rule, and we are proposing 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 would 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 proposed rule 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 would 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 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 would help achieve that goal. As discussed in section V.K. of the preamble of this proposed 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 are proposing 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 are proposing 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 invite public comment on this proposal.

c. Proposed 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.[371] 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.[372]

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 PC–01 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 (PC–01) measure was used widely in the 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 are proposing to remove PC–01, 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.

[371] 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.*

[372] 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.*

Therefore, we are proposing to remove the Elective Delivery (PC–01) measure beginning with the CY 2024 reporting period/FY 2026 payment determination.

We invite public comment on this proposal.

d. Proposed 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 propose 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.[373] 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 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 are proposing to codify our existing measure retention and removal policies in our regulations at 42 CFR 412.140(g)(1) through (3).

We invite public comment on this proposal.

8. Summary of Previously Finalized and Proposed Hospital IQR Program Measures

a. Summary of Previously Finalized and Proposed 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.

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[373] 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 FY 2012 IPPS/LTCH PPS final rule (76 FR 51609 through 51610). We incorporate these rationales by reference.

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	N/A
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		
Hybrid HWR**	Hybrid Hospital-Wide All-Cause Readmission Measure (HWR)	2879
Hybrid HWM***	Hybrid Hospital-Wide All-Cause Risk Standardized Mortality Measure (HWM)	3502

Short Name	Measure Name	CBE #
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	N/A
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 proposed rule, we are proposing 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). We are proposing to revise these measures beginning with the FY 2027 payment determination in this proposed rule. 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 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 Proposed Hospital IQR Program Measures for the FY 2026 Payment Determinations

This table summarizes the previously finalized and proposed Hospital IQR Program measure set for the FY 2026 payment determination, including the proposed 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	N/A
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
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

Short Name	Measure Name	CBE #
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
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 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 proposed Hospital IQR Program measure set for the FY 2027 payment determination including the proposed 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	N/A
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
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

Short Name	Measure Name	CBE #
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	N/A
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 proposed rule, we are proposing to revise 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 proposed rule, we are proposing to revise 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 proposed rule, we are proposing 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 proposed rule, we are proposing to adopt 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 proposed rule, we are proposing 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 proposed Hospital IQR Program measure set for the FY 2028 payment determination, including the proposed 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	N/A
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

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	N/A
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 proposed rule, we are proposing to revise 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 proposed rule, we are proposing 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 proposed rule, we are proposing to revise 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 proposed rule, we are proposing to adopt 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 proposed rule, we are proposing to adopt 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 proposed rule, we are proposing 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.

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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, we seek public feedback on these measures as we consider how best to develop the Hospital IQR Program's measure set.

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.[374] 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.[375] 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.[376]

As the population ages, care can become more complex,[377] with patients often developing multiple chronic conditions. The CDC estimates that 68.4 percent of Medicare beneficiaries have two or more chronic conditions.[378] 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.[379]

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.[380] 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.[381] 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.[382] 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.[383]

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[384] to the older adult and their family or other caregivers.[385] 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.[386] 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.[387]

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 are also requesting 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.[388] A major

[374] 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.

[375] *Ibid.*

[376] *Ibid.*

[377] 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.

[378] Lochner KA, Cox CS. Prevalence of Multiple Chronic Conditions Among Medicare Beneficiaries, United States, 2010. Prev Chronic Dis 2013;10:120137. DOI: *http://dx.doi.org/10.5888/pcd10.120137*.

[379] Salive, M.E. (2013). Multimorbidity in older adults. Epidemiologic reviews, 35(1), 75–83.

[380] 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.

[381] 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.

[382] 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.

[383] *Ibid.*

[384] 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.*

[385] Institute for Healthcare Improvement. (2020). Age-friendly health systems: Guide to using the 4Ms in the care of older adults. Available at: *https://241684.fs1.hubspotusercontent-na1.net/hubfs/241684/AgeFriendlyHealthSystems_GuidetoUsing4MsCare_FINAL_July2020.pdf.*

[386] *Ibid.*

[387] *Ibid.*

[388] 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/.*

challenge presented in the geriatric population is that care is not a single structural element or process.[389] 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.[390] [391] Orchestrating all these elements results in better outcomes, and improving their implementation would be an essential first step to improve geriatric outcomes.[392]

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.[393] More specifically, the measures align with the Meaningful Measures Framework priority focus on patient-centered care.[394] 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.'' [395] 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.[396]

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.[397] 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.[398] 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.[399] 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.[400]

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.[401] 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.[402]

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.[403] 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.[404] 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.

[389] *Ibid.*

[390] 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%20Sites_FINAL.pdf.*

[391] 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.

[392] *Ibid.*

[393] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy.*

[394] *Ibid.*

[395] 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.*

[396] 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.*

[397] Centers for Medicare & Medicaid Services. 2022 MUC List. Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[398] 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.*

[399] *Ibid.*

[400] *Ibid.*

[401] *Ibid.*

[402] *Ibid.*

[403] *Ibid.*

[404] *Ibid.*

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.[405] 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. 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.[406] 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.[407] The MAP Coordinating Committee had concerns related to the subjectiveness of attestation based measures, noting a preference for outcome or process measures.[408] 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.[409]

(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.

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[405] *Ibid.*

[406] *Ibid.*

[407] *Ibid.*

[408] *Ibid.*

[409] *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.

Attestation Domains	Attestation Statements: Select All That Apply (Note: Attestation of all statements would be required to qualify for the measure numerator)
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.
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.

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(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 invite public comment on the potential future use of this measure in the Hospital IQR Program.

(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.

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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.
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.

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(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 invite public comment on the potential use of this measure in the Hospital IQR Program.

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 invite 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 this proposed rule?
- 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 in order 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?

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.

We are not proposing any changes to these policies in this proposed rule.

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.

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 are not proposing any changes to these policies in this 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 are not proposing any changes to these policies in this 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 are not proposing any changes to these policies in this 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 are not proposing any changes to this policy in this 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 are not proposing any changes to this policy in this 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 are not proposing any changes to this policy in this 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 are not proposing any changes to this policy in this 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 proposed rule where we propose to modify 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 are not proposing any changes to these policies in this 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 are not proposing any changes to these policies in this 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) Proposed 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.[410] Hospitals must survey patients throughout each month of the year.[411] 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,[412] and re-endorsed the measure in 2010, 2015, and 2019.[413]

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

[410] 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.

[411] *Ibid.*

[412] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalHCAHPS.*

[413] CMS. Hospital Consumer Assessment of Healthcare Providers and Systems Survey (HCAHPS). Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=91&sectionNumber=1.*

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 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 are not proposing changes to the HCAHPS Survey's content in this proposed rule.

(b) Proposed Addition of Three New Modes of Survey Implementation

In this proposed rule, we are proposing 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 are proposing 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, mail followed by phone mode; 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 invite public comment on this proposed update.

(c) Proposed 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 are proposing 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 would, however, still encourage patients to respond to the survey rather than proxies.

We invite public comment on this proposed update.

(d) Proposed 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 are therefore proposing to extend the data collection period for the HCAHPS Survey from 42 to 49 days, beginning with January 2025 discharges.

We invite public comment on the proposed change in the length of the data collection period.

(e) Proposed 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 in order 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.[414] 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 invite public comment on our proposal to limit the number of supplemental items. We welcome suggestions for alternative limits below 12 supplemental items.

(f) Proposed 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.[415] 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 propose 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 invite public comment on the proposed requirement to administer the survey in Spanish. We also welcome suggestions for additional translations beyond the existing translations in Spanish, Chinese, Russian, Vietnamese, Portuguese, German, Tagalog, and Arabic.

(g) Proposed Removal of Two Administration Methods

In this proposed rule, we are proposing 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. In order to streamline HCAHPS oversight and training, we propose 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 would 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 order to streamline HCAHPS oversight and training, we are also proposing 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 would 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*.

(h) Data Collection

The HCAHPS Survey would 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 proposed rule. There would be no changes to HCAHPS patient eligibility or exclusion criteria (we note 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 invite public comments on these proposals.

i. Request for Information on Potential Addition of Patients With a Primary Psychiatric Diagnosis to the HCAHPS Survey Measure

We are soliciting 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 seek 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 request 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

[414] 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*.

[415] HCAHPS Quality Assurance Guidelines V18.0. *https://www.hcahpsonline.org/en/quality-assurance/*.

found in the HCAHPS Quality Assurance Guidelines, V18.0 at *https://hcahpsonline.org/en/quality-assurance/.*

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 would 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 are not proposing any changes to these policies in this 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 are not proposing any changes to these policies in this 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 are not proposing any changes to these policies in this proposed rule.

11. Validation of Hospital IQR Program Data

In this proposed rule, we are proposing to update our targeting criteria for validation of hospitals granted an extraordinary circumstances exception (ECE). Specifically, we are proposing 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.

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) 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 would 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. Proposed Addition of Targeting Criterion for Validation

In this proposed rule, beginning with validations of CY 2024 reporting period data for the FY 2027 payment determination, we propose to add a new criterion to the six established targeting criteria used to select up to 200 additional hospitals for validation. We propose that a hospital with less than four quarters of data subject to validation due to receiving an extraordinary circumstance exception (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 are proposing 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 would 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 propose 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.

This proposal would 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). Our proposal would also 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.

We invite public comment on our proposal.

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 are not proposing any changes to this policy in this 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 are not proposing any changes to these policies in this 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 this proposed rule for a discussion of our previously finalized eCQM reporting and submission policies.

We are not proposing any changes to these policies in this 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 are not proposing any changes to these policies in this 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 are not proposing any changes to these policies in this 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 are not proposing any changes to these policies in this 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 are not proposing any changes to our measure removal or retention policies.

In this proposed rule, we are proposing 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 also refer readers to section IX.B. of the preamble of this proposed rule where we are proposing modifications of the COVID–19 Vaccination Among Healthcare Personnel (HCP) measure in the PCHQR, Hospital Inpatient Quality Reporting, and Long-Term Care Hospital Quality Reporting Programs.

3. Proposal To Adopt 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.[416] [417] [418] [419] [420] [421] [422] [423] [424] [425] 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.[426] [427] [428] [429] [430] [431]

[416] 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.

[417] 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.*

[418] 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.

[419] 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.*

[420] 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.*

[421] 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.*

[422] 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.

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[425] 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.*

[426] 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.*

[427] 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.*

[428] 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.

[429] 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.*

[430] 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.

[431] 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.

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.[432] [433] [434] [435] [436] Data indicate that, even after accounting for factors such as socioeconomic conditions, members of racial and ethnic minority groups reported experiencing lower quality healthcare.[437] 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.[438] Additionally, inequities in the drivers of health affecting these groups, such as poverty and healthcare access, are interrelated and influence a wide range of health and quality-of-life outcomes and risks.[439]

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.[440] [441] [442] 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.[443] 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.[444] [445] [446] 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.[447] 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.[448] 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.[449] 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 are proposing to adopt an attestation-based structural measure, Facility Commitment to Health Equity, beginning with the FY 2026 program year.

The first pillar of our strategic priorities[450] reflects our deep

[432] 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.*

[433] 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.*

[434] 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.*

[435] 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.*

[436] 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.

[437] 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.

[438] 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.

[439] Department of Health and Human Services. (2021). Healthy People 2020: Disparities. Available at: *www.healthypeople.gov/2020/about/foundation-health-measures/Disparities.*

[440] 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.*

[441] 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.*

[442] 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/.*

[443] 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.*

[444] 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.

[445] 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.

[446] 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.

[447] 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.

[448] 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.*

[449] 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.*

[450] 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.*

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 hospitals 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 hospital 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 hospitals to act on any one data element or domain, but instead encourages hospitals 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 hospitals in leveraging available data, pursuing focused quality improvement activities, and promoting efficient and effective use of resources.

The five questions of the proposed structural measure are adapted from the CMS Office of Minority Health's Building an Organizational Response to Health Disparities framework, which focuses on data collection, data analysis, culture of equity, and quality improvement.[451] The proposed 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.[452] 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.[453] 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.''

b. Overview of Measure

The Facility Commitment to Health Equity measure would assess 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 would affirmatively attest for the PCH to receive credit for that domain.

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[451] 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*.

[452] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy*.

[453] 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*. We note that Meaningful Measures 2.0 is still under development.

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 hospital to receive a point for the domain in the numerator)
Domain 1: Equity is a Strategic Priority	
Hospital 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 hospital strategic plan identifies priority populations who currently experience health disparities. (B) Our hospital strategic plan identifies health equity goals and discrete action steps to achieving these goals. (C) Our hospital strategic plan outlines specific resources which have been dedicated to achieving our equity goals. (D) Our hospital 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 hospital is an important step in identifying and eliminating health disparities. Please attest that your hospital engages in the following activities.	(A) Our hospital 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 hospital has training for staff in culturally sensitive collection of demographic and/or social determinant of health information. (C) Our hospital 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 hospital engages in the following activities.	(A) Our hospital 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 hospital 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 hospital engages in the following activities.	(A) Our hospital senior leadership, including chief executives and the entire hospital board of trustees, annually reviews our strategic plan for achieving health equity. (B) Our hospital senior leadership, including chief executives and the entire hospital board of trustees, annually reviews key performance indicators stratified by demographic and/or social factors.

* 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."

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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 would be required to attest. For a PCH to affirmatively attest ''yes'' to a domain, and receive credit for that domain, the PCH would evaluate and determine whether it engages in each of the sub-elements that comprise the domain. PCHs would 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 would be represented in the denominator as a point, for a total of 5 points (one per domain).

For example, for Domain 1 (''Hospital commitment to reducing healthcare disparities is strengthened when equity is a key organizational priority''), a PCH would 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 would affirmatively attest to Domain 1 and receive one (1) point for that attestation. A PCH would 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 would not be able to affirmatively attest to Domain 1 and would not receive a point for that attestation.

The numerator would 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 would receive the maximum 5 points.

Specifications for the measure are available on the CMS Measure Methodology page with the file name ''Facility Commitment to Health Equity Measure Specifications'' at: *https://cmit.cms.gov/cmit/#/*.

d. Data Submission and Reporting

We are proposing that PCHs would be required 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 would follow the submission and reporting requirements for web-based measures for the PCHQR Program posted on the QualityNet website. We also refer readers to section IX.D.10.a. of the preamble of this proposed rule for details on our previously finalized data submission requirements and deadlines.

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.[454] The CBE-convened Measure Applications Partnership (MAP) 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.[455] 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.[456] 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.[457] 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.[458] 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.[459]

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 would assess PCH progress in providing high-quality healthcare for all patients, regardless of social risk factors or demographic characteristics.

f. Consensus-Based Entity Endorsement

We have not submitted this measure for consensus-based entity (CBE)[460] 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

We are proposing to publicly display the PCH-specific results for the Facility Commitment to Health Equity measure and refer readers to Table IX.D.–02 in section IX.D.9. of the preamble for the proposed public display requirements.

We invite public comment on this proposal.

[454] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[455] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[456] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[457] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[458] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[459] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[460] 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.

4. Proposal To Adopt the Screening for Social Drivers of Health Measure Beginning With Voluntary Reporting in the FY 2026 Program Year and Mandatory Reporting in 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.[461] 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.[462] 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 Program (87 FR 70054 through 70055).

These measures would 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 PCH's quality of care.[463] [464] [465] [466] 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 proposed rule.

a. Background

Health disparities manifest primarily as worse health outcomes in population groups where access to care is inequitable.[467] [468] [469] [470] [471] Such differences persist across geography and healthcare settings irrespective of improvements in quality of care over time.[472] [473] [474] Assessment of HRSNs is an essential mechanism for capturing the interaction between social, community, and environmental factors associated with health status and health outcomes.[475] [476] [477] 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.[478] [479] While

[461] 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.

[462] 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.*

[463] 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.*

[464] 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.*

[465] 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/.*

[466] 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/.*

[467] 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/.*

[468] 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.*

[469] 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.*

[470] 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.

[471] 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.*

[472] 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.*

[473] 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/.*

[474] 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_care/everyone_project/team-based-approach.pdf.*

[475] 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.*

[476] 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.*

[477] 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.

[478] 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.

[479] Khullar, D., Schpero, W.L., Bond, A.M., Qian, Y., & Casalino, L.P. (2020). Association Between

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 proposed measures, but only 24 percent of hospitals screening for all five HRSNs.[480]

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).[481] [482] [483] [484] 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.[485] [486] 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.[487] [488] 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.[489] [490] [491] [492] The persistent 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.[493] [494] 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.[495] Additionally, associations between disproportionate health risk, hospitalization, and adverse health outcomes have been highlighted and magnified by the COVID–19 pandemic.[496] [497]

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.[498] 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.[499] [500] [501]

These five evidence-based HRSN domains, which informed development of the two social drivers of health

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*.

[480] 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.

[481] 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*.

[482] 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*.

[483] 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*.

[484] 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*.

[485] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*.

[486] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*.

[487] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*.

[488] 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.

[489] 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.

[490] Khullar, D., MD. (2020, September 8). Association Between Patient Social Risk and Physician Performance American academy of Family Physicians. (2020). Addressing Social Determinants of Health in Primary Care team-based approach for advancing health equity.

[491] 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*.

[492] 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.

[493] 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*.

[494] 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*.

[495] 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.

[496] 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.

[497] 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.

[498] 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*.

[499] 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*.

[500] 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*.

[501] 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/*.

measures, are described in Table IX.D.–02.

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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.[502,503] 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 services.[504,505] Food insecurity is associated with high-cost healthcare utilization including emergency department (ED) visits and hospitalizations.[506,507,508]
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.[509,510] 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.[511] Housing instability is associated with higher rates of chronic illnesses, injuries, and complications and more frequent utilization of high-cost healthcare services.[512,513]

[502] 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.
[503] 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/.
[504] 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/.
[505] 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.
[506] 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/.
[507] 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.
[508] 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.
[509] 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.
[510] Hill-Briggs, F. (2021). Social Determinants of Health and Diabetes: A Scientific Review. Diabetes Care. Available at: https://pubmed.ncbi.nlm.nih.gov/33139407/.
[511] 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.
[512] 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.
[513] 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.

Domain	Description
Transportation Needs	Unmet transportation needs include limitations that impede transportation to destinations required for all aspects of daily living.[514] 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 more frequent utilization of high-cost healthcare services including emergency medical services, EDs, and hospitalizations.[515,516,517,518]
Utility Difficulties	Inconsistent availability of electricity, water, oil, and gas services is directly associated with housing instability and food insecurity.[519] Specifically, interventions that increase or maintain access to such services have been associated with individual and population-level health improvements.[520]
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.[521] 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.[522,523]

[514] 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.
[515] 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.
[516] 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/.
[517] 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.
[518] 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.
[519] 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.
[520] 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.
[521] 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.
[522] 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.
[523] 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.

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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.[524] [525] [526] [527] [528]

For data collection of this measure, PCHs could 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.[529] [530] 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.[531] The AHC Model was tested across varied care-delivery sites in diverse geographic locations across the U.S.[532] 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.[533] Moreover, the screening instrument can be implemented in a variety of places where patients seek healthcare, including cancer hospitals.[534]

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,[535] 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 proposed 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.''[536] 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.[537]

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 proposed rule) would be 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 would 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 would 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 could enable us to set appropriate performance targets for PCHs.

b. Overview of Measure

The Screening for Social Drivers of Health measure would 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 would 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/#/*.

(1) Cohort

The Screening for Social Drivers of Health measure would 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

[524] 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*.

[525] 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*.

[526] 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*.

[527] 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*.

[528] 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.

[529] 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.

[530] 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.

[531] More information on the HRSN Screening Tool is available at: *https://innovation.cms.gov/files/worksheets/ahcm-screeningtool.pdf*.

[532] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*.

[533] 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/*.

[534] 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. Available at: *https://innovation.cms.gov/media/document/ahcm-screeningtool-companion*.

[535] Centers for Medicare & Medicaid Services. Meaningful Measures Framework. Available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/CMS-Quality-Strategy*.

[536] 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.

[537] 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*.

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 would 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 would 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

We are proposing that PCHs would 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 would 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.[538] [539] SIREN contains descriptions of the content and characteristics of various tools, including information about intended populations, completion time, and number of questions. We would encourage PCHs to consider 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 of HRSN information in an interoperable fashion so that these data can be shared across the care continuum to support coordinated care.

We are proposing that PCHs would 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 would follow the established submission and reporting requirements for web-based measures for the PCHQR Program posted on the QualityNet website. We also refer readers to section IX.10.a. of the preamble of this proposed rule for details on our previously finalized data submission, deadline and sampling requirements across measure types.

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.[540] 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.[541] 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.[542] 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.[543] 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.[544]

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 would 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

[538] 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.

[539] 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.

[540] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[541] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[542] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[543] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[544] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

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

We are proposing to publicly display the PCH-specific results for the Screening for the Social Drivers of Health measure and refer readers to Table IX.D.–04 in section IX.D.9. of the preamble for the proposed public display requirements.

We invite public comment on this proposal.

5. Proposal To Adopt the Screen Positive Rate for Social Drivers of Health Beginning With Voluntary Reporting in the FY 2026 Program Year and Mandatory Reporting in the FY 2027 Program Year

a. Background

The impact of social risk factors on health outcomes has been well-established in the literature.[545] [546] [547] [548] [549] 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.[550] 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.[551] [552] [553] 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 proposed 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.[554] [555] [556] The Screen Positive Rate for Social Drivers of Health measure would 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 would 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).[557] We refer readers to section IX.D.4. of the preamble of this proposed rule where we previously discussed the identification process resulting in the selection of these five domains.

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.[558] [559] 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.[560] 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

[545] 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*.

[546] 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.

[547] 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.

[548] 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*.

[549] 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*.

[550] 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*.

[551] 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*.

[552] 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.

[553] 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*.

[554] 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*.

[555] 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.

[556] 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*.

[557] 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*.

[558] 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.

[559] 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.

[560] RTI International. (2020). Accountable Health Communities (AHC) Model Evaluation. Available at: *https://innovation.cms.gov/data-and-reports/2020/ahc-first-eval-rpt*.

planning.[561] [562] [563] 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 in order 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.[564]

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 would 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.'' [565] Under CMS' Meaningful Measures Framework, the Screen Positive Rate for Social Drivers of Health measure would address the quality priority of ''Work with Communities to Promote Best Practices of Healthy Living'' through the Meaningful Measures Area of ''Equity of Care.'' [566] Development of this measure also aligns with our strategic pillar to advance health equity by addressing the health disparities that underlie our health system.[567]

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 would benefit from connection via the PCH to targeted community-based services.[568] The measure would 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 would 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 would provide 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 would consist 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 would consist 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 would 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 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 would 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

We are proposing that PCHs would be required 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 in the FY 2026 program year and mandatory reporting in the FY 2027 program year. PCHs would follow the established submission and reporting requirements for web-based measures for the PCHQR Program posted on the QualityNet website. We also refer readers to section IX.D.10.a. of the preamble of this proposed rule for details on our previously finalized data submission requirements and deadlines.

[561] 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*.

[562] De Marchis, E., Knox, M., Hessler, D., WillardGrace, 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.

[563] 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*.

[564] 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.

[565] 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*.

[566] 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*.

[567] 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*.

[568] 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.

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.[569] 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.[570] 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.[571] 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).[572] 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.[573]

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 would 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

We are proposing 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 section IX.D.9. of the preamble for the proposed public display requirements.

We invite public comment on this proposal.

6. Proposal To Adopt 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.[574] One study found that Americans report having a serious illness conversation with their clinician only 11 percent of the time.[575] 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.[576]

[569] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[570] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[571] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[572] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[573] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[574] 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.

[575] Hamel, Liz, et al. *Views and Experiences with End-of-Life Medical Care in the U.S.* 2017.

[576] 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.*

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.[577] Care inconsistent with preferences is associated with a lower quality of care and higher medical costs.[578]

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.[579] 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: [580]

- 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 would assess goals of care discussion documentation among patients with cancer who die while receiving care at the reporting PCH. We are proposing that on an annual basis, PCHs would 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 would focus 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 would require 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 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 would be the number of patients meeting the criteria for inclusion in the measure's population in the reporting period.

(3) Numerator

The numerator would be 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 would require any documentation in one or more patient goals fields. To meet the requirements for inclusion in the numerator, the documentation in the EHR would 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

We are proposing that PCHs would be required 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 would follow the submission and reporting requirements for web-based measures for the PCHQR Program posted on the QualityNet website. We also refer readers to section IX.D.10.a. of the preamble of this

[577] 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.

[578] 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.

[579] American Society of Clinical Oncology Quality Oncology Practice Initiative: Quality Clinical Data Registry Measures. 2014. *http://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.

[580] Alliance of Dedicated Cancer Centers. Improving Goal Concordant Care Initiative Implementation Planning Guide. September 2020.

proposed rule for details on our previously finalized data submission, deadline and sampling requirements across measure types.

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.[581] 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.[582] 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).[583] 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.[584]

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

We are proposing 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 section IX.D.9. of the proposed preamble for the public display requirements.

We invite public comment on this proposal.

7. Summary of Previously Adopted and Newly Proposed PCHQR Program Measures for the FY 2026 Program Year and Subsequent Years

As previously discussed in sections IX.D.3, IX.D.4., and IX.D.5. of the preamble of this proposed rule, we are proposing to adopt one health equity-focused measure beginning with the FY 2026 program year, the Facility Commitment to Health Equity measure, and two health equity-focused measures beginning with voluntary reporting in the FY 2026 program year and mandatory reporting in the FY 2027 program year, the Screening for Social Drivers of Health measure and the Screen Positive Rate for Social Drivers of Health measure. We are also proposing to adopt the Documentation of Goals of Care Discussions Among Cancer Patients measure beginning with the FY 2026 program year and refer readers to section IX.D.6. of the preamble of this proposed rule. For ease of reference, Table IX.D.–03 summarizes the previously adopted and the newly proposed measures for the PCHQR Program measures for the FY 2026 program year and subsequent years.

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[581] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[582] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[583] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

[584] Available at: *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

TABLE IX.D.-03: PREVIOUSLY ADOPTED MEASURES AND PROPOSED MEASURES FOR 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 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**

*Indicates proposed update to this previously finalized measure.

**Indicates new measures proposed in this proposed rule.

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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 are not proposing 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 are not proposing any changes to our previously finalized public display requirements.

b. Proposal To Begin 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 are proposing 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 would make these data publicly available following a 30-day period in which PCHs would have an opportunity to review the data. We would announce the exact timeframe on a CMS website and our applicable listservs.

We invite public comment on the proposal.

c. Summary of Previously Finalized and Proposed Public Display Requirements for the PCHQR Program

Our previously finalized and proposed public display requirements for the PCHQR Program measures are shown in the following Table IX.D.–04:

TABLE IX.D.-04: PREVIOUSLY FINALIZED AND PROPOSED PUBLIC DISPLAY REQUIREMENTS FOR THE PCHQR PROGRAM

Summary of Previously Finalized and Proposed 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 proposed in this proposed 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. Proposed 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.[585] Hospitals must survey patients throughout each month of the year.[586] 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,[587] and re-endorsed the measure in 2010, 2015, and 2019.[588]

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 are not proposing changes to the HCAHPS Survey's content in this proposed rule.

(2) Proposed Addition of Three New Modes of Survey Implementation

In this proposed rule, we are proposing 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 are proposing 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 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, mail followed by phone mode; web followed by mail, or phone, or both) result in overall higher response rates and better representation

[585] HHS: HCAHPS: Patients' Perspectives of Care Survey, available at: *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalHCAHPS*.

[586] *Ibid.*

[587] *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/HospitalHCAHPS*.

[588] HCAHPS (Hospital Consumer Assessment of Healthcare Providers and Systems) Survey. Available at: *https://cmit.cms.gov/cmit/#/MeasureView?variantId=91&sectionNumber=1*.

of younger, Spanish language-preferring, racial and ethnic minority, and maternity care patients.

We invite public comment on this proposed update.

(3) Proposed 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 are proposing 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 would, however, still encourage patients to respond to the survey rather than proxies.

We invite public comment on this proposed update.

(4) Proposed 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 are therefore proposing to extend the data collection period for the HCAHPS Survey from 42 to 49 days, beginning with January 2025 discharge.

We invite public comment on the proposed change in the length of the data collection period.

(5) Proposed 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 in order 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.[589] 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 invite public comment on our proposal to limit the number of supplemental items. We welcome suggestions for alternative limits below 12 supplemental items.

(6) Proposed 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 in order to accommodate patient populations.[590] 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 propose 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 invite public comment on the proposed requirement to administer the survey in Spanish. We also welcome suggestions for additional translations beyond the existing translations in Spanish, Chinese, Russian, Vietnamese, Portuguese, German, Tagalog, and Arabic.

(7) Proposed Removal of an Administration Method

In this proposed rule, we are proposing 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. In order to streamline HCAHPS oversight and training, we propose 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, PCHs would 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 to the previously discussed proposals, we encourage 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.*

[589] 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.*

[590] HCAHPS Quality Assurance Guidelines V18.0. *https://www.hcahpsonline.org/en/quality-assurance/.*

(8) Data Collection

The HCAHPS Survey would 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 the proposed rule. There would 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 invite public comments on these proposals.

(9) Public Reporting

The scoring of the proposed updated HCAHPS Survey would be the same as the current HCAHPS Survey. Detailed information on how the measure would be scored for purposes of public reporting can be found on the HCAHPS website at: *https://hcahpsonline.org/en/hcahps-star-ratings/*.

We invite public comments on these proposals.

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 are not proposing 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 this proposed rule, we are proposing to modify one measure in the LTCH QRP as described in section IX.E. of the preamble of this proposed rule. Second, we are proposing to adopt two new measures, and remove two existing measures. Third, we are seeking information on principles CMS could use to select and prioritize LTCH QRP quality measures in future years. Fourth, we are providing an update on our efforts to close the health equity gap. Fifth, we are proposing to change the LTCH QRP data completion thresholds. Finally, we are proposing to begin public reporting of four measures. These proposals are further specified in this section of this rule.

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 Proposals

In this proposed rule, we include LTCH QRP proposals for FY 2025 and FY 2026 program years. Beginning with the FY 2025 LTCH QRP, we are proposing to (1) modify the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure; (2) adopt the Discharge Function Score,[591] 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 are proposing 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. Proposed 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,[592] 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 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 propose 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 proposed rule. We invite public comment on our proposal to modify the HCP COVID–19 Vaccine measure, beginning with the FY 2025 LTCH QRP.

b. Proposed 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.[593] 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.[594] 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.[595] [596]

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 are proposing to remove it in section IX.E.4.c of this proposed rule. While there is an additional outcome measure addressing functional status [597] 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.[598] 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.[599] [600] [601] Nonetheless,

[591] 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.*

[592] 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.*

[593] 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.*

[594] 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.*

[595] 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.

[596] 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.

[597] The measure is Change in Mobility Among Long-Term Care Hospital Patients Requiring Ventilator Support.

[598] 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.

[599] 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.

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,[602] [603] [604] [605] rehospitalization rates,[606] [607] [608] discharge to community,[609] [610] and falls.[611]

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.[612] [613] [614] [615] [616] 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,[617] [618] [619] 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.[620] [621]

We are proposing to adopt the Discharge Function Score (DC Function) measure[622] 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 are proposing to remove in section IX.E.4.c. of the preamble of this proposed rule the proposed measure would be calculated using standardized patient assessment

[600] 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.

[601] 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.

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[603] 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.

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[606] 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.

[607] 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.

[608] 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.

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[610] 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.

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[615] 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.

[616] 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.

[617] 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.

[618] 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.

[619] 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.

[620] 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.

[621] 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.

[622] 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*.

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.[623] 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 this proposed rule). Unlike the existing functional outcomes measures, this 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.[624] Specifically, the measure (1) considers two dimensions of function [625] (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 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.

(a) 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 this 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.[626] 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 this 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

[623] Meaningful Measures 2.0 can be found at *https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization.*

[624] 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).

[625] 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.*

[626] ''Expected functional capabilities'' is defined as the predicted discharge function score.

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.*[627]

(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.

Therefore, after consideration of other available measures, we find that the exception under section 1899B(e)(2)(B) of the Act applies and are proposing 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.

[627] 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.*

(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)[628] and *Technical Expert Panel (TEP) for Cross-Setting Function Measure Development Summary Report* (January 2022 TEP)[629] 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.[630] 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 convened MAP workgroups who 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 this 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. One 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 resident 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 resident-setting 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,*[631] 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

[628] 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.*

[629] 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.*

[630] 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.*

[631] 2022–2023 MAP Final Recommendations. *https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx.*

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.*[632]

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 this proposed measure statistical imputation allows missing values (for example, the ANA codes) to be replaced 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*[633] for measure specifications and additional details.

We invite public comment on our proposal to adopt the DC Function measure, beginning with the FY 2025 LTCH QRP.

c. Proposed 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 are proposing 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.[634] 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 proposed 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,[635] 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).[636] [637] [638] 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,[639] and for CY 2021, LTCHs had an average score of 99.4 percent, with nearly 63 percent of LTCHs scoring 100 percent.[640] 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 proposed 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.[641] 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,

[632] 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.*

[633] 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.*

[634] 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.*

[635] 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.*

[636] 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.*

[637] 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.*

[638] 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.*

[639] 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.*

[640] 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.*

[641] ''Expected functional capabilities'' is defined as the predicted discharge function score.

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, we are proposing to remove it from the LTCH QRP beginning with the FY 2025 LTCH QRP. We are also proposing 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 proposed 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 invite 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.

d. Proposed 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 are proposing 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 propose 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,[642] 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).[643] [644] [645] 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,[646] and for CY 2021, 61 percent of LTCHs scored 100 percent.[647]

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 are proposing 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 will 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 invite 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.

e. Proposed 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 March 15, 2023, the U.S. has reported 103,801,821 cumulative cases of COVID–19, and 1,121,512 total deaths due to COVID–19.[648] 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 rate.[649] Older adults, in general, are prone to both acute and chronic infections owing to reduced immunity, and are a high-risk population.[650] Adults age 65 and older comprise over 75 percent of total COVID–19 deaths despite representing 13.2 percent of reported cases.[651] COVID–19 has

[642] 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.*

[643] 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.*

[644] 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.*

[645] 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.*

[646] 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.*

[647] 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.*

[648] Centers for Disease Control and Prevention. COVID Data Tracker. 2023. *https://covid.cdc.gov/covid-data-tracker.*

[649] 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.*

[650] 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.

[651] Centers for Disease Control and Prevention. Demographic Trends of COVID–19 Cases and

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.[652]

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.[653] 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 [654] (Pfizer-BioNTech or Moderna), and 84 percent for those receiving a viral vector vaccine [655] (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.[656] 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.[657]

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.[658] [659] [660] 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.[661] Additionally, a second vaccine booster dose has been shown to reduce risk of severe outcomes related to COVID–19, such as hospitalization or death.[662] 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.[663] [664]

(a) Measure Importance

Despite the availability and demonstrated effectiveness of COVID–19 vaccinations, significant gaps continue to exist in vaccination rates.[665] 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).[666] 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.[667] Variations are also present when examining vaccination rates by race, gender, and geographic location.[668] 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 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.[669] Disparities have been found in vaccination rates between rural and urban areas, with lower vaccination rates found in rural areas.[670] [671] Data

Deaths in the US Reported to CDC. COVID Data Tracker. 2023. *https://covid.cdc.gov/covid-data-tracker/#demographics*.

[652] 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*.

[653] 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.

[654] A person is fully vaccinated with an mRNA vaccine when they receive two doses of a primary series.

[655] A person is fully vaccinated with a viral vector vaccine after receiving one dose of a primary series.

[656] 1 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*

[657] 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).

[658] 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.

[659] 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.

[660] 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.

[661] 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*.

[662] 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*.

[663] 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.

[664] 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.

[665] 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*.

[666] 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*.

[667] 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/*.

[668] 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.

[669] 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*.

[670] 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/

Continued

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.[672] 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.[673]

We are proposing 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. This 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.[674]

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).[675] 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.

mmwr.mm7109a2. PMID: 35239636; PMCID: PMC8893338.

[671] 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.

[672] Centers for Disease Control and Prevention. Vaccination Equity. COVID Data Tracker; 2023. *https://covid.cdc.gov/covid-data-tracker/#vaccination-equity*.

[673] Centers for Disease Control and Prevention. Vaccination Equity. COVID Data Tracker; 2023. *https://covid.cdc.gov/covid-data-tracker/#vaccination-equity*.

[674] *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*.

[675] 87 FR 25070.

(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),[676] 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. One 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.[677] Similarly, the MAP Rural Health Advisory Group met on December 8, 2022 and expressed that the measure is important for rural communities.[678]

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.[679]

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.''[680] Despite the MAP Coordinating Committee's vote, we believe it is still important to propose the Patient/Resident COVID–19 Vaccine measure for the LTCH QRP. As we stated in section VI.C.2.b.(3) of this proposed rule, 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 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.*[681]

(5) Quality Measure Calculation

The proposed Patient/Resident COVID–19 Vaccine measure is a process

[676] 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.*

[677] 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.*

[678] 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.*

[679] 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.*

[680] National Quality Forum Measure Applications Partnership. 2022–2023 MAP Final Recommendations. *https://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=98102.*

[681] 2022–2023 MAP Final Recommendations. *https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports.*

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.[682] 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 proposed rule. For additional technical information about this proposed measure, we refer readers to the draft measure specifications document titled *Patient-Resident-COVID-Vaccine-Draft-Specs.pdf*[683] on the LTCH QRP Measures Information web page.

We invite public comments on the proposal to adopt the Patient/Resident COVID–19 Vaccine measure beginning with the FY 2026 LTCH QRP.

5. Principles for Selecting and Prioritizing LTCH QRP Quality Measures and Concepts Under Consideration for Future Years: Request for Information (RFI)

a. Background

We have established a National Quality Strategy (NQS)[684] for quality programs which supports a resilient, high-value healthcare system promoting quality outcomes, safety, equity, and accessibility for all individuals. The CMS NQS is foundational for contributing to improvements in health care, enhancing patient outcomes, and informing consumer choice. To advance these goals, leaders from across CMS have come together to move toward a building-block approach to streamline quality measures across our quality programs for the adult and pediatric populations. This ''Universal Foundation''[685] of quality measures will focus provider attention and reduce provider burden, as well as identify disparities in care, prioritize development of interoperable, digital quality measures, allow for cross-comparisons across programs, and help identify measurement gaps. The development and implementation of the Preliminary Adult and Pediatric Universal Foundation Measures will promote the best, safest, and most equitable care for individuals as we all come together on these critical quality areas.

In alignment with the CMS NQS, the LTCH QRP endeavors to move toward a more parsimonious set of measures while continually improving the quality of health care for beneficiaries. The purpose of this RFI is to gather input on existing gaps in LTCH QRP measures and to solicit public comment on fully developed LTCH measures that are not part of the LTCH QRP, fully developed quality measures in other programs that may be appropriate for the LTCH QRP, and measurement concepts that could be developed into LTCH QRP measures, to fill these measurement gaps in the LTCH QRP. While we will not be responding to specific comments submitted in response to this RFI in the FY 2024 IPPS/LTCH PPS final rule, we intend to use this input to inform future policies.

This RFI consists of three sections. The first section discusses a general framework or set of principles that CMS could use to identify future LTCH QRP measures. The second section draws from an environmental scan conducted to identify measurement gaps in the current LTCH QRP, and measures or measure concepts that could be used to fill these gaps. The final section solicits public comment on (1) the set of principles for selecting measures for the LTCH QRP, (2) identified measurement gaps, and (3) measures that are available for immediate use, or that may be adapted or developed for use in the LTCH QRP.

b. Guiding Principles for Selecting and Prioritizing Measures

CMS has identified a set of principles to guide future LTCH QRP measure set development and maintenance. These principles are intended to ensure that measures resonate with beneficiaries and caregivers, do not impose undue burden on providers, comply with CMS statutory requirements and PAC program goals, and can be readily operationalized. Specifically, measures incorporated into the LTCH QRP should meet the following four objectives:

- Actionability—Optimally, LTCH QRP measures should focus on structural elements, healthcare processes, and outcomes of care that have been demonstrated through clinical evidence or other best practices to be amenable to improvement and feasible for LTCHs to implement.
- Comprehensiveness and Conciseness—QRP measures should assess performance of all LTCH core services using the smallest number of measures that comprehensively assess the value of care provided in LTCH settings. Parsimony in the QRP measure set minimizes provider burden resulting from data collection and submission.
- Focus on Provider Responses to Payment—The LTCH PPS shapes incentives for care delivery. LTCH performance measures should neither exacerbate nor induce unwanted responses to the payment systems. As feasible, measures should mitigate adverse incentives of the payment system.
- Compliance with CMS Statutory Requirements and Key Program Goals—Measures must comply with the governing statutory authorities and our policy to align measures with our policy initiatives, such as the Meaningful Measures Framework.

c. Gaps in LTCH QRP Measure Set and Potential New Measures

CMS conducted an environmental scan that utilized the previously listed principles and identified measurement gaps in the domains of cognitive function, behavioral and mental health, patient experience and patient satisfaction, and chronic conditions and pain management. We discuss each of these in more detail in this section of this rule.

(1) Cognitive Function

Illnesses associated with limitations in cognitive function, which may include stroke, traumatic brain injuries, dementia, and Alzheimer's disease, affect an individual's ability to think, reason, remember, problem-solve, and make decisions. Section 1886(m)(5)(F) of the Act requires LTCHs to submit data on quality measures under section 1899B(c)(1) of the Act, and cognitive function and changes in cognitive function are key dimensions of clinical care that are not currently represented in the LTCH QRP.

Two sources of information on cognitive function currently collected in LTCHs include the Brief Interview for

[682] 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).

[683] Patient-Resident-COVID-Vaccine-Draft-Specs.pdf. *https://www.cms.gov/files/document/patient-resident-covid-vaccine-draft-specs.pdf.*

[684] Schreiber M, Richards AC, Moody-Williams J, Fleisher LA. The CMS National Quality Strategy: A Person-centered Approach to Improving Quality. Centers for Medicare & Medicaid ServicesBblog. June 6, 2022. *https://www.cms.gov/blog/cms-national-quality-strategy-person-centered-approach-improving-quality.*

[685] 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.

Mental Status (BIMS) and Confusion Assessment Method (CAM©).[686] Both the BIMS and CAM have been incorporated into the LCDS as standardized patient assessment data elements. Scored by providers via direct observation, the BIMS is used to determine orientation and the ability to register and recall new information. The CAM assesses the presence of delirium and inattention, and level of consciousness.

Alternative sources of information on cognitive function include the Patient-Reported Outcomes Measurement Information Set (PROMIS) Cognitive Function forms and the PROMIS Neuro-Quality of Life (QoL) measures.[687] [688] Developed and tested with a broad range of patient populations, PROMIS Cognitive Function assesses cognitive functioning using items related to patient perceptions regarding performance of cognitive tasks, such as memory and concentration, and perceptions of changes in these activities. The Neuro-QoL, which was specifically designed for use in patients with neurological conditions, assesses patient perceptions regarding oral expression, memory, attention, decision-making, planning, and organization.

The BIMS, CAM, PROMIS Cognitive Function short forms, and PROMIS Neuro-QoL include items representing different aspects of cognitive function, from which quality measures may be constructed. Although these instruments have been subjected to feasibility, reliability, and validity testing, additional development and testing would be required prior to transforming the concepts reflected in the BIMS and CAM (for example, temporal orientation, recall) into fully specified measures for implementation in the LTCH QRP.

This RFI is requesting comment on the availability of cognitive functioning measures outside of the LTCH QRP that may be available for immediate use in the LTCH QRP, or that may be adapted or developed for use in the LTCH QRP, using the BIMS, CAM, PROMIS Cognitive Function short forms, and PROMIS Neuro-QoL, or other instruments. In addition to comment on specific measures and instruments, CMS seeks input on the feasibility of measuring improvement in cognitive functioning during an LTCH stay, which typically averages between 25 and 30 days;[689] the cognitive skills (for example, executive functions) that are more likely to improve during an LTCH stay; conditions for which measures of maintenance—rather than improvement in cognitive functioning—are more practical; and the types of interventions that have been demonstrated to assist in improving or maintaining cognitive functioning.

(2) Behavioral and Mental Health

Estimates suggest that one in five Medicare beneficiaries has a serious mental illness and nearly 8 percent have a ''common mental health disorder.'' [690] Substance use disorders (SUDs) are also not uncommon among Medicare beneficiaries. Research estimates that approximately 1.7 million Medicare beneficiaries (8 percent) reported a SUD in the past year, with 77 percent attributed to alcohol use and 16 percent to prescription drug use.[691] In some instances, such as following a traumatic injury that requires ventilator support, patients may develop depression, anxiety, and/or SUDs. In other instances, patients may have been dealing with mental or behavioral health or SUD issues long before their post-acute admission. Left unmanaged, however, these conditions could make it difficult for affected patients to actively participate in their rehabilitation and treatment regimen, thereby contributing to poor health outcomes.

Information on the availability and appropriateness of behavioral health measures in PAC is limited, and the 2021 National Impact Assessment of the CMS Quality Measures Report [692] identified PAC program measurement gaps in the areas of behavioral and mental health. Among the mental health quality measures in current use, the Home Health QRP assesses the extent to which patients have been screened for depression and, if positive, a follow-up plan is documented.[693] Although it may be possible to adapt this depression screening measure for use in other PAC settings, this process measure does not directly assess performance in the management of depression and related mental health concerns.

Other instruments that may be adapted to assess management of mental or behavioral health in PAC settings include the Consumer Assessment of Healthcare Providers and Systems (CAHPS) Experience of Care and Health Outcomes Survey (ECHO), which consists of a series of questions that may be used to understand patients' perspectives concerning mental health services received;[694] the PROMIS [695] suite of instruments that may be used to monitor and evaluate mental health and quality of life; the National Institutes of Health (NIH) Toolbox for the Assessment of Neurological and Behavioral Health Function,[696] which was commissioned by the NIH Blueprint for Neuroscience Research and includes both stand-alone measures and batteries of measures to assess emotional function and psychological well-being.

Like mental health issues, SUDs have been under-studied in the LTCH/PAC settings, even though they are among the fastest-growing disorders in the community-dwelling older adult population.[697] [698] Left untreated, SUDs can lead to overdose deaths, emergency department visits, and hospitalizations. The Substance Abuse and Mental Health Services Administration

[686] Centers for Medicare & Medicaid Services. Long-Term Care Hospital Continuity Assessment Record and Evaluation (CARE) Data Set Version 5.0. Effective October 1, 2022. *https://www.cms.gov/files/document/ltch-care-data-set-version-50-planned-discharge-final.pdf.*

[687] HealthMeasures. List of Adult Measures: Available Neuro-QoL™ Measures for Adult Self-Report. *https://www.healthmeasures.net/explore-measurement-systems/neuro-qol/intro-to-neuro-qol/list-of-adult-measures.*

[688] HealthMeasures. List of Adult Measures: Available PROMIS® Measures for Adults. *https://www.healthmeasures.net/explore-measurement-systems/promis/intro-to-promis/list-of-adult-measures.*

[689] Medicare Payment Advisory Commission. March 2022 Report to the Congress; Chapter 10. *https://www.medpac.gov/wp-content/uploads/2022/03/Mar22_MedPAC_ReportToCongress_Ch10_SEC.pdf.*

[690] Figueroa JF, Phelan J, Orav EJ, Patel V, Jha AK. Association of Mental Health Disorders with Health Care Spending in the Medicare Population. JAMA Netw Open. 2020;3(3):e201210. doi: 10.1001/jamanetworkopen.2020.1210. PMID: 32191329; PMCID: PMC7082719.

[691] Parish W, Mark T, Weber E, Steinberg D. Substance Use Disorders Among Medicare Beneficiaries: Prevalence, Mental and Physical Comorbidities, and Treatment Barriers. Am J Prev Med. 2022 Aug;63(2):225–232. doi: 10.1016/j.amepre.2022.01.021. PMID: 35331570.

[692] Centers for Medicare & Medicaid Services. 2021 National Impact Assessment of the Centers for Medicare & Medicaid Services (CMS) Quality Measures Report. June 2021. *https://www.cms.gov/files/document/2021-national-impact-assessment-report.pdf.*

[693] Centers for Medicare & Medicaid Services. Depression Screening Conducted and Follow-Up Plan Documented. January 29, 2021. *https://cmit.cms.gov/cmit/#/MeasureView?variantId=3102&sectionNumber=1.*

[694] Agency for Healthcare Research and Quality. CAHPS Mental Health Care Surveys. May 2022. *https://www.ahrq.gov/cahps/surveys-guidance/echo/index.html.*

[695] HealthMeasures. Intro to PROMIS®. August 5, 2022. *https://www.healthmeasures.net/explore-measurement-systems/promis/intro-to-promis.*

[696] HealthMeasures. NIH Toolbox®. *https://www.healthmeasures.net/explore-measurement-systems/nih-toolbox.*

[697] Desai A, Grossberg G. Substance Use Disorders in Postacute and Long-Term Care Settings. Psychiatr Clin North Am. 2022 Sep;45(3):467–482. doi: 10.1016/j.psc.2022.05.005. PMID: 36055733.

[698] Sorrell JM. Substance Use Disorders in Long-Term Care Settings: A Crisis of Care for Older Adults. J Psychosoc Nurs Ment Health Serv. 2017 Jan 1;55(1):24–27. doi: 10.3928/02793695–20170119–08. PMID: 28135388.

(SAMHSA) was established by Congress in 1992 to make substance use and mental disorder information, services, and research more accessible. As part of its work, SAMHSA developed the Screening, Brief Intervention, and Referral to Treatment (SBIRT) approach to support providers in using early intervention with at-risk substance users before more severe consequences occur, and has a number of resources available.[699]

CMS seeks feedback on these and other measures or instruments that may be directly applied, adapted, or developed for use in the LTCH QRP. Further, CMS seeks comments on the degree to which measures have been or will require validation and testing prior to application in the LTCH QRP. We seek input on the availability of data, the manner in which data could be collected and reported to CMS, and the burden imposed on LTCHs.

(3) Patient Experience and Patient Satisfaction

Patient experience measures focus on how patients experienced or perceived selected aspects of their care, whereas patient satisfaction measures focus on whether a patient's expectations were met. Information on patient experience of care is typically collected via a number of instruments that rely on patient self-reported data. The most prominent among these is the CAHPS suite of surveys, although CAHPS instruments have not been developed for use in LTCHs. However, CMS developed the LTCH Experience of Care Survey,[700] which measures patient experience in terms of goal setting, interaction and communication with staff, respect and privacy received, cleanliness of the facility, and other domains.

One patient satisfaction measure that has been developed for use by SNFs and could potentially be adapted for use by LTCHs is the CoreQ: Short Stay Discharge Measure (CoreQ: SS DC). The CoreQ: SS DC, which underwent 2017–2018 pre-rulemaking for the SNF QRP [701] and 2021–2022 pre-rulemaking for the SNF Value-Based Purchasing (VBP) program,[702] assesses the level of satisfaction among SNF short-stay (less than 100 days) patients.

CMS seeks comment on the feasibility and challenges of adapting existing patient experience and patient satisfaction measures and instruments, such as the LTCH Experience of Care Survey and the CoreQ, for use in the LTCH QRP. CMS seeks input on the extent to which patient experience measures offer LTCHs sufficient information to assist in quality improvement, and the challenges of collecting and reporting patient experience and patient satisfaction data.

(4) Chronic Conditions and Pain Management

Despite the availability of measures focused on clinical care and, specifically, on ventilator support for patients with respiratory conditions, LTCH QRP measures do not directly address aspects of care rendered to populations with chronic conditions, such as chronic kidney disease or cardiovascular disease. Existing measures also fail to capture LTCH actions concisely for pain management even though pain has been demonstrated to contribute to falls with major injury and restrictions in mobility and daily activity. However, a host of other factors also contribute to these measure domains, making it difficult to directly link provider actions to performance. Instead, a measure of provider actions in reducing pain interference in daily activities, including the ability to sleep, would be a more concise measure of pain management. Beginning October 1, 2022, LTCHs began collecting new standardized patient assessment data elements under the LTCH QRP, including items that assess pain interference with: (1) daily activities; (2) sleep; and (3) participation in therapy, providing an opportunity to develop more concise measures of provider performance (84 FR 42536 through 42588).

Through this RFI CMS is seeking input on measures of chronic condition and pain management for patients that may be used to assess LTCH performance. Additionally, CMS seeks general comment on the feasibility and challenges of measuring and reporting LTCH performance on existing QRP measures, such as Discharge to the Community and Potentially Preventable 30-day post-discharge readmissions, for subgroups of patients defined by type of chronic condition. As examples, measures could assess rates of discharge to community or 30-day post-discharge readmissions among patients admitted to an LTCH with chronic obstructive pulmonary disease (COPD) or chronic renal failure.

d. Solicitation of Comments

We invite 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 solicit 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 seeks input on data available to develop measures, approaches for data collection, perceived challenges or barriers, and approaches for addressing challenges.

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

[699] Substance Abuse and Mental Health Services Administration. Resources for Screening, Brief Intervention, and Referral to Treatment (SBIRT). April 14, 2022. *https://www.samhsa.gov/sbirt/resources.*

[700] Centers for Medicare & Medicaid Services. Long-term Care Hospital (LTCH) Experience of Care. Updated October 12, 2022. *https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/ltch-quality-reporting/ltch-experience-of-care-.*

[701] Centers for Medicare & Medicaid Services. List of Measures under Consideration for December 1, 2017. *https://www.cms.gov/files/document/2017amuc-listclearancerpt.pdf.*

[702] Centers for Medicare & Medicaid Services. List of Measures under Consideration for December 1, 2021. *https://www.cms.gov/files/document/measures-under-consideration-list-2021-report.pdf.*

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.'' [703] 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* [704] are in line with Executive Order 13985, ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.'' [705] 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.

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).[706] 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, 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.[707] 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.[708] 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.[709] Measure stratification is important for understanding differences in outcomes across different groups. 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.'' [710] 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 and we think this learning opportunity would benefit post-acute care providers. The goals of the confidential reporting are to provide LTCHs with their results; educate LTCHs and offer the opportunity to ask questions; and solicit feedback from LTCHs for future enhancements to the methods.

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. With 30 percent to 55 percent of health outcomes attributed to SDOH,[711] a measure capturing and addressing SDOH could encourage SNFs 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 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.[712]

[703] Centers for Medicare and Medicaid Services. Health Equity. *https://www.cms.gov/pillar/health-equity.* October 3, 2022.

[704] Centers for Medicare & Medicaid Services. CMS Framework for Health Equity 2022–2032. *https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf.*

[705] 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.*

[706] 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.*

[707] Turner A. The Business Case for Racial Equity: A Strategy for Growth. April 24, 2018. W.K. Kellogg Foundation and Altarum. *https://altarum.org/RacialEquity2018.*

[708] 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.*

[709] 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.*

[710] 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.*

[711] World Health Organization. Social Determinants of Health. *https://www.who.int/westernpacific/healthtopics/social-determinants-of-health.*

[712] Jacobs DB, Schreiber M, Seshamani M, Tsai D, Fowler E, Fleisher LA. Aligning Quality Measures

Continued

As we move this important work forward, we will continue to take input from interested parties.

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. Proposed 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 proposed rule, we are proposing to adopt the DC Function measure beginning with the FY 2025 LTCH QRP. We are proposing 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 invite public comments on this proposal.

c. Proposed 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 the proposed rule, we are proposing 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 are proposing 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 are also proposing to add a new item to the LCDS in order for LTCHs to report this 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.[713]

We invite public comments on this proposal.

d. Proposal to Increase the 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.[714]

We are now proposing that, beginning with the FY 2026 program year, 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, this proposal would contribute to further alignment of data completion thresholds across the PAC settings.

We believe LTCHs should be able to meet this proposed requirement for the LTCH QRP because our data shows that LTCHs are already in compliance with, or exceeding, this proposed threshold. The complete list of items required under the LTCH QRP is updated annually and posted on the LTCH QRP Measures Information page.[715]

We are proposing that LTCHs would be required to comply with the proposed new completion threshold beginning with the FY 2026 LTCH QRP program year. 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 are also proposing to update § 412.560(f)(1) of our regulations to reflect this new policy (see the regulation text in this proposed rule).

We invite 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 program year.

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. Proposed 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 are proposing 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

across CMS—The Universal Foundation. N Engl J Med. 2023 Mar 2;338:776–779. doi: 10.1056/NEJMp2215539. PMID: 36724323.

[713] *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.*

[714] 79 FR 50312 through 50313.

[715] 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.*

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 are proposing 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 are proposing 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 invite 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.

c. Proposed Public Reporting of the Discharge Function Score Measure Beginning With the FY 2025 LTCH QRP

We are proposing 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). If finalized as proposed, 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 are proposing 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 invite 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.

d. Proposed 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 are proposing 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). If finalized as proposed, 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 are proposing 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 invite 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.

F. Proposed Changes to the Medicare Promoting Interoperability Program

1. Statutory Authority for the Medicare Promoting Interoperability Program for Eligible Hospitals and 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 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 Federal fiscal year (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), 413.70(a)(5) and (6), and part 495.

2. EHR Reporting Periods

a. Proposed 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 IPPS/LTCH PPS final rule (86 FR 45460 through 45462). We believe that maintaining a 180-day EHR reporting period for an additional year would 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 are proposing that the EHR reporting period in CY 2025 would be a minimum of any continuous 180-day period within CY 2025. 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 are proposing corresponding

revisions to the definition of EHR reporting period for a payment adjustment year at 42 CFR 495.4.

We invite public comment on this proposal.

The continued efforts toward promoting interoperability and health information exchange are key goals of the Medicare Promoting Interoperability Program, therefore we are considering increasing the length of the EHR reporting period in CY 2026 for eligible hospitals and CAHs to report. We believe that increasing the length of the EHR reporting period in future rulemaking would encourage eligible hospitals and CAHs to prepare to produce more comprehensive and reliable data on the quality measures they are required to report, especially given that, beginning with the CY 2023 EHR reporting period, eligible hospitals and CAHs are required to submit four calendar quarters of data for each of the required eCQMs (87 FR 49365). We believe a longer EHR reporting period in future years would provide eligible hospitals and CAHs increased opportunities to identify areas that may require investigation and corrective action that are important for the continued improvement of interoperability and health information exchange. This information would also help CMS identify gaps in reporting to provide additional support to eligible hospitals and CAHs in demonstrating effective use of CEHRT in furtherance of meaningful use. Although we are not making any proposals for the EHR reporting period in CY 2026 at this time, we will continue to monitor CEHRT utilization by eligible hospitals and CAHs to determine if a longer EHR reporting period would be feasible.

b. Proposed 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 42 CFR 495.4, paragraphs (2)(vii) and (viii), we specify 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, 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, these rules provide that 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 1 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 are proposing to change the rule for eligible hospitals that have not successfully demonstrated they are a meaningful EHR user in a prior year. CMS has made technological modifications to the data submission process for the Medicare Promoting Interoperability Program, including registration and attestation. 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 CMS through the QualityNet help desk at *QnetSupport@cms.hhs.gov* or 1–866–288–8912 for instructions.

According to the Office of the National Coordinator for Health Information Technology (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. We therefore believe that few eligible hospitals or CAHs will be new participants in the Medicare Promoting Interoperability Program, and that few eligible hospitals or CAHs are likely to be affected by this change.[716] 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 believe this proposal is feasible. Therefore, beginning with the EHR reporting period in CY 2025, we are proposing 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.

We are proposing that for all eligible hospitals (new and returning participants), the EHR reporting period in CY 2025 would apply for purposes of the FY 2027 payment adjustment year. Eligible hospitals and CAHs would 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 would mean that for eligible hospitals that have not successfully demonstrated they are meaningful EHR users in a prior year, there would 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 would not have to attest to meaningful use no later than October 1, 2025. Instead, similar to eligible

[716] 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.*

hospitals that have demonstrated meaningful use, these eligible hospitals would attest during the 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 would be applied for the FY 2027 payment adjustment year. We are proposing corresponding revisions to the definition of EHR reporting period for a payment adjustment year at 42 CFR 495.4.

We invite comment on 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. Proposed 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 are proposing 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 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 note 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 without charge to download or use at *https://jamanetwork.com/journals/jama/fullarticle/2788984*.

Therefore, we are proposing 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. Under this proposal, an attestation of ''no'' would result in the eligible hospital or CAH not meeting the measure and not satisfying the definition of a meaningful EHR user under 42 CFR 495.4, which would subject the eligible hospital or CAH to a downward payment adjustment. We refer readers to Table IX.H.-03. in this proposed rule for a description of the measure.

We invite public comment on this proposal.

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 42 CFR 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.H.-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).

In this proposed rule, we are not proposing any changes to the scoring methodology for the EHR reporting period in CY 2024. We refer readers to Table IX.F.–01. in this proposed 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 PERIOD 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 proposed rule do not include the points that would be redistributed in the event an exclusion is claimed for a given measure. We are not proposing 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 proposed 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 REDISTRIBITION 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. Proposed 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.F.–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.F.–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 42 CFR 495.24(e)(3). For more information regarding the previous codification of the objectives, measures, and other policies under 42 CFR 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.F.–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.

We have reviewed the descriptions of the calculation considerations in Table IX.F.–07. and believe some are not applicable to certain measures. We believe 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 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 are proposing 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)''. The following measures would 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 believe this proposal would reduce potential confusion regarding which measures require calculations related to unique patients or actions. We have included the proposed changes in Table IX.F.–03.

We invite public comment on this proposal.

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 at 42 CFR 495.24(f), regarding the Stage 3 objectives and measures for eligible hospitals and CAHs attesting to CMS for 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 42 CFR 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 are proposing to update the regulatory text at § 495.40 to make it consistent with 42 CFR 495.24(f).

We invite public comment on this proposal.

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 proposals made in this proposed rule. Table IX.F.–04. lists the 2015 Edition certification criteria required to meet the objectives and measures.

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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	Proposed 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 proposal made in this FY 2024 IPPS/LTCH PPS proposed 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.

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7. Clinical Quality Measurement for Eligible Hospitals and CAHs Participating in the Medicare Promoting Interoperability Program

a. Proposed 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 42 CFR 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 proposed 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) Proposed 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 proposed rule, we are proposing to adopt three new eCQMs for the Medicare Promoting Interoperability Program, beginning with the CY 2025 reporting period. Specifically, we propose 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 propose 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 proposed rule for more information about these three measures and our policy reasons for proposing them. Table IX.F.-07. in this proposed 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 proposed in this proposed rule to add to the eCQM measure set, beginning with the CY 2025 reporting period.

We invite public comment on these proposals.

b. Proposed 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 are not proposing 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).

We are proposing that, if our proposals 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 detailed in section IX.C. of the preamble of this proposed rule are finalized, these measures would be available for eligible hospitals and CAHs to select as one of their three self-selected eCQMs for the CY 2025 reporting period and subsequent years.

We invite public comment on this proposal.

X. Other Provisions Included in This Proposed Rule

A. Medicare Program—Special Requirements for Rural Emergency Hospitals (REHs)

1. Background

This proposed 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 are proposing 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 proposed rule.

We also are proposing to update certain definitions in the survey and certification regulations to address REHs. Specifically, we are proposing 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 propose 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 propose 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 propose 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.

5. Proposed Special Requirements for REHs (§ 488.70)

We propose 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 proposed 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 are not proposing any additional information submissions at this time.

6. Proposed Requirements for Providers (§ 489.102) (Advance Directives)

We propose to add REHs to the applicable provisions at § 489.102(a) and add a new § 489.102(b)(5).

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 payer) 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 physician-owned hospitals. 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 varies with 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.[717] Following the issuance of these reports, the Congress held hearings and began to consider policies to limit the growth of these facilities.[718] Section 6001(a) of the Affordable Care Act effectively eliminated the exceptions for physician ownership in hospitals, although hospitals with physician ownership and a Medicare provider agreement on December 31, 2010, are ''grandfathered'' to continue using the rural provider exception, if applicable, and whole hospital exception.

(2) Prohibition on Facility Expansion

Section 6001(a)(3) of the Affordable Care Act amended the rural provider and whole hospital exceptions to provide that a hospital 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 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 either 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

[717] 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.*

[718] 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.

applicable hospital are set forth at § 411.362(c)(2) and the requirements for a high Medicaid facility are set forth at § 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 § 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 clarify certain aspects of the process for requesting an exception from the prohibition on facility expansion (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 to 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 exception to the prohibition on expansion of facility capacity (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 to 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 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 the expansion of applicable hospitals (85 FR 86257).

2. Proposals

a. Process for Requesting an Exception From the Prohibition on Expansion of Facility Capacity

As described in section X.B.1.b.(1). of the preamble of this proposed rule, in order to satisfy the requirements of the rural provider or 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 would prohibit 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 proposed 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 proposed 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 proposed rule as an ''expansion exception''). The regulations at existing § 411.362(c) set forth the expansion exception process.

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, in order 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 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 high Medicaid facility. Put another way, it is our position that, under section 1877(i)(3)(A)(i) of the Act and existing § 411.362(c)(1), meeting the criteria for an applicable hospital or 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).) We note also that 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 interpret the requirement to provide for community input ''with respect to [an] application'' to require CMS to permit *any* input related to the expansion exception request—not just input related to whether the requesting hospital meets the criteria for an applicable hospital or 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 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 believe that modification and clarification of our regulations at existing § 411.362(c) is warranted. Therefore, we are proposing 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 and whole hospital exceptions. Under our proposals, existing § 411.362(c), as well as certain related definitions in existing § 411.362(a), would be renumbered at § 411.363. We believe 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 are proposing 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 are proposing at new § 411.363(a) to include 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 are proposing 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 are proposing 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) Eligibility To Request an Expansion Exception and Publication in the **Federal Register**

We are proposing 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 either an applicable hospital or high Medicaid facility, which are renumbered at § 411.363(c) and (d), respectively. We are proposing 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 proposed rule.

As explained in section X.B.2.b. of the preamble of this proposed rule, we are proposing 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 for hospitals that meet the criteria for a high Medicaid facility. The regulation at proposed § 411.363(b)(2)(i) would implement the statutory restriction on the Secretary's ability to permit an expansion that would result in a hospital's facility capacity exceeding 200 percent of its baseline facility capacity and apply the restriction to any hospital requesting an expansion exception. (See section 1877(i)(C)(ii) of the Act.) Therefore, even if the hospital meets the criteria for an applicable hospital or high Medicaid facility, it would not be eligible to request another expansion exception 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. Any prior expansion exception approval(s) must be considered when determining the maximum facility capacity of the hospital if the request is approved. To illustrate, 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 another 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.

The regulation at proposed § 411.363(b)(2)(ii) would implement section 1877(i)(3)(B) of the Act, 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 CY 2012 OPPS/ASC final rule, after receiving no comments on our proposals 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). 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 (*Id.*). As discussed in section X.B.2.b of this 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, as of January 1, 2021, a high Medicaid facility is 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. Even though we reversed the regulatory extension of the restriction on frequency of expansion exception requests for hospitals that meet the criteria for a high Medicaid facility, in CY 2021 OPPS/ASC final rule, we nonetheless limited a high Medicaid facility to applying for expansion exception only when it does not have another expansion exception request pending with CMS. We did so to preserve CMS resources and continue to maintain an orderly and efficient expansion exception process (85 FR 86256). Historically, CMS has worked with requesting hospitals for several weeks or months following the initial submission in order 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 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 are proposing at § 411.363(b)(2)(ii) that a hospital—whether it otherwise meets the criteria for an applicable hospital or high Medicaid facility—would not be eligible to request an expansion exception 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 regulation, CMS would not consider an expansion exception request submitted by a hospital that is not eligible to request the expansion exception. CMS would consider an expansion exception request submitted by a hospital that is eligible to request the expansion exception, provided that the request includes all information required under proposed § 411.363. In processing an expansion exception request, we would first determine whether the requesting hospital is eligible to request the expansion exception. This would include providing an opportunity for community input regarding whether the requesting hospital meets the criteria for an applicable hospital or high Medicaid facility (depending on the specific request). If the hospital meets the criteria for an applicable hospital or high Medicaid facility, and is not otherwise precluded from making an expansion exception request under proposed § 411.363(b), 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. (See section X.B.2.a.(3). of the preamble of this proposed rule for a discussion of the factors that CMS considers.) Because community input would be relevant to both the determination that a requesting hospital meets the criteria for an applicable hospital or high Medicaid facility (depending on the specific request) and our decision whether to approve or deny the expansion exception request, 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. In the **Federal Register** notice, we would seek community input on both whether the requesting hospital meets the criteria for an applicable hospital or 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.

Following publication of the notice of the expansion exception request in the **Federal Register**, receipt of community input, 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 high Medicaid facility (depending on the specific request). We are proposing to codify this part of the process at proposed § 411.363(h). If CMS determines that the requesting hospital meets the criteria for an applicable hospital or 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 the basis for its decision. We are proposing to codify this part of the process at proposed § 411.363(i)(1). Other data and information relevant to the basis for 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 or intends to expand, 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 are also proposing a nonsubstantive revision to the introductory language at existing § 411.362(c)(2) and (3). Currently, these regulations state the criteria that an applicable hospital or high Medicaid facility, respectively, must satisfy. To more closely conform to our regulations

in 42 CFR part 411, subpart J, we are proposing to use the word ''meets'' in place of ''satisfies'' in the introductory language of these regulations, which would be renumbered at § 411.363(c) and (d) under our proposal.

(3) CMS Decision To Approve or Deny an Expansion Exception Request

Proposed § 411.363(i)(2) identifies factors that CMS would always consider when deciding whether to approve or deny an expansion exception request. 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, any county in which the hospital provides inpatient or outpatient hospital services as of the date the hospital submits the expansion exception request, or any county in which the hospital plans to provide inpatient or outpatient hospital services if CMS approves the request. 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) does not limit CMS to the enumerated factors in making its decision. For example, 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. 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. (See section X.B.2.a.(4). of this proposed rule for a discussion of the relevance of the specialty of a hospital or the services it provides, and section X.B.2.b. of the preamble of this proposed rule for a discussion of a hospital's ability to relocate ''original'' operating rooms, procedure rooms, and beds from its main campus without triggering the physician self-referral law's referral and billing prohibitions.)

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** notice of 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 are proposing to revise for clarity and renumber at § 411.363(k). If CMS determines that the requesting hospital does not meet the criteria for an applicable hospital or 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 high Medicaid facility. If CMS determines that the requesting hospital meets the criteria for an applicable hospital or high Medicaid facility (depending on the specific request), 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 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 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. We are proposing 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. This would include determinations regarding whether a hospital meets the criteria for an applicable hospital or high Medicaid facility and decisions regarding whether to approve or deny a hospital's request. The regulation, if finalized, would be renumbered 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 in order for CMS to consider the request. We are proposing 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 are not proposing 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 are proposing to renumber this regulation at § 411.363(e)(2)(i). We are proposing 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 also require an electronic mail address for correspondence with the contact person. We are also proposing to clarify that the request must include an address for receipt of hard copy mail by the contact person. Finally, we are proposing to renumber this regulation at § 411.363(e)(2)(iii).

We are proposing to revise existing § 411.362(c)(4)(ii)(B) and renumber this regulation at § 411.363(e)(2)(ii). As proposed, the 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. It is important to our ability to thoroughly consider an expansion exception request to understand where the expansion facility capacity would be located—which would be the main campus of the hospital in all instances if we finalize our proposals to reinstate certain program integrity restrictions as described in section X.B.2.b. of the

preamble of this proposed rule—as well as other counties where the hospital may be relocating ''original'' operating rooms, procedure rooms, and beds from its main campus to expand its inpatient and outpatient services.

Under existing § 411.362(c)(4)(ii)(D), an expansion exception request must include a statement identifying the hospital as an applicable hospital or 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 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 are proposing that the first element of existing § 411.362(c)(4)(ii)(D) (identification as an applicable hospital or high Medicaid facility and supporting document regarding satisfaction of the criteria for such) would apply only to the calculations and comparisons required to show that a hospital is an applicable hospital or high Medicaid facility. We are also proposing 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 as explained in section X.B.2.a.(2). of the preamble of this proposed rule. We are proposing 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. 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 are proposing 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).

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 believe 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 if the request is approved. Therefore, we are proposing 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 previously-approved expansion facility capacity and whether it plans to use expansion facility capacity to provide specialty services if the request is approved. We are proposing to include this revised requirement at § 411.363(e)(2)(vi) (renumbered from existing § 411.362(c)(4)(ii)(E)).

Finally, we are proposing 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 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 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 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. Knowing whether a requesting hospital has used or failed to use previously-approved expansion facility capacity in this way, as well as whether the requesting hospital has previously-approved but unused expansion facility capacity available to it, is pertinent to our decision to approve or deny the current request.

Finally, we are proposing 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 are proposing 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 are proposing 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. 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 high Medicaid facility. Our current regulations do not define the ''community'' in which the requesting hospital is located. To eliminate uncertainty, we are proposing 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. Certain exceptions to the physician self-referral law's prohibitions identify the geographic area served by a hospital to define the location where certain activity may occur (for example, the location of a recruited physician's medical practice). We believe 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. Under proposed § 411.363(f)(2), 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 high Medicaid facility (depending on the specific request) and to hospitals located in the requesting hospital's community. Thus, individuals and entities in the requesting hospital's community that wish to provide input related to the expansion exception request would be aware of the request. We recognize 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. If we finalize this proposal, 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.

The type of community input that we will accept is not restricted in any way (76 FR 74522). However, to support the two-step process for first determining whether a requesting hospital is eligible to request an expansion exception and, if so, deciding whether to approve or deny the request, we are proposing to revise existing § 411.362(c)(5) and renumber it at § 411.363(f)(3) to 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. (See section X.B.2.a.(3). of the preamble of this proposed rule for a discussion of the factors.) 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, 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 received hundreds of pages of community input on others. If we finalize our proposals to revise the expansion exception process, we believe that the community input would be more robust 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 high Medicaid facility (80 FR 55852). Therefore, to provide adequate time for interested parties to develop and submit community input, we are proposing 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 do not believe that an extension of the 30-day period for the requesting hospital to submit a rebuttal statement is necessary, but seek comment regarding whether we should extend this timeframe to 60 days to provide the requesting hospital additional time to review any community input in light of our proposals in this proposed rule.

(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 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 high Medicaid facility (depending on the specific request) 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). 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. 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.

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 finalize 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 that the Secretary announce his determination that HCRIS contains sufficiently complete inpatient Medicaid discharge data through notice-and-comment rulemaking, we are nonetheless proposing 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 October 1, 2023 (the anticipated effective date of the revised regulations if our proposals are finalized). As we stated in the CY 2012 OPPS/ASC final rule, we believe that requiring the use of HCRIS data 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 HCRIS data for all expansion exception requests would 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. And, as commenters pointed out in response to our proposals in the CY 2015 OPPS/ASC proposed rule, in some states, external data sources may not contain data sufficient for requesting hospitals to make the comparisons required under the statute and our existing regulations because those states do not require all hospitals to report their Medicaid inpatient admission data (79 FR 66991). Even so, we do not believe that it is necessary to continue to permit the use of external data sources for purposes of the expansion exception process. We anticipate that requiring the use of HCRIS data for all comparison calculations would have little practical impact on whether a requesting hospital meets the criteria for an applicable hospital or high Medicaid facility, and do not believe that a requesting hospital would be prejudiced by this requirement. It is unlikely that a hospital that elects not to participate in Medicare would nonetheless participate in its state Medicaid program, and a hospital that participates in Medicaid (which an applicable hospital or high Medicaid facility almost certainly would) should have a higher percentage of Medicaid inpatient admissions than a comparison hospital that does not participate in Medicaid. 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 are proposing 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 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.

Based on our understanding of congressional intent with respect to the expansion exception process, we do not believe that the Congress anticipated, much less intended, that a hospital willing to expand its number of operating rooms, procedure rooms, and beds in a community in which there is a clear need for additional capacity would be foreclosed from doing so if one or more of the other hospitals in that 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. 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 believe that our proposal to permit only the use of HCRIS data 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.

We are also proposing to revise the terminology used in our regulations to describe the comparisons that a hospital requesting an expansion exception must make in order to show that it is an applicable hospital or high Medicaid facility. We are doing 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 Medicaid inpatient admissions for ''any other'' hospital in the county. Our 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 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 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 are proposing to revise the references in our regulations to refer to ''each'' or ''each other'' hospital (where appropriate). We are not proposing 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 are proposing 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. For purposes of this proposed regulation, 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. With respect to requests submitted on or after October 1, 2023 (the anticipated effective date of the revised regulations if our proposals are 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 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 requesting hospital is located. For purposes of this proposed regulation, 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. With respect to requests submitted on or after October 1, 2023 (the anticipated effective date of the revised regulations if our proposals are 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.

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 high Medicaid facility, we are proposing at § 411.363(c)(6) and (d)(4), respectively, to consider the location of a hospital to be the county or State, as applicable, 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/Ambulatory Surgical Center (ASC) final rule, in addition to expanding the permissible data sources a hospital may use to show that it meets the criteria for either an applicable hospital or high Medicaid facility, we also amended the expansion exception process to increase the period of time after which an exception request will be deemed complete when an external data source is used by a requesting hospital or in the public comments to determine whether a hospital meets the criteria for either an applicable hospital or 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 are proposing that only filed Medicare hospital cost report data from HCRIS may be used to show that the requesting hospital meets the criteria for either an applicable hospital or high Medicaid facility, we do not believe that we would need the full 180 days currently provided for at existing § 411.362(c)(5)(ii) to deem an expansion exception request complete. Therefore, we are proposing 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 30-day rebuttal period, regardless of whether the requesting hospital submits a rebuttal statement, if CMS receives written comments from the community. The proposed regulation would be renumbered at § 411.363(g), which would also include our 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 believe 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 is eligible to request the expansion exception under proposed § 411.363(b) and whether CMS should approve or deny the request. We note that our proposals would not affect expansion exception requests submitted before the effective date of the revised regulations, if finalized.

(8) Summary of the Expansion Exception Process as Proposed

To facilitate comments on the proposals set forth in this section X.B.2.a., we believe it is helpful to provide a brief, high-level summary of the expansion exception process as proposed. We note that, in many respects, the existing expansion exception process includes the same steps. Under our proposals, a hospital would submit its expansion exception request to CMS. CMS would confirm that the request includes all required information and that the hospital is not precluded from requesting the expansion exception under proposed

§ 411.363(b)(2). CMS would confirm the accuracy of the required calculations (as we do currently). If the requesting hospital has performed the required calculations incorrectly, it is CMS' practice to inform the hospital of the error(s) and work with the hospital to ensure the required calculations are performed correctly. We would continue this practice under the proposed expansion exception process. After these steps are completed, if the hospital does not withdraw the expansion exception request, CMS would publish notice of the expansion exception request in the **Federal Register**. Community input could be submitted during the stated comment period. If CMS receives community input on the expansion exception request, it would be provided to the requesting hospital. The hospital would have 30 days to submit a rebuttal statement if it chooses to do so. CMS would then consider the information included in the expansion exception request, community input (if any), and rebuttal statement (if any), as well as other information available to CMS that may be relevant to: (1) its determination whether the hospital meets the criteria for an applicable hospital or high Medicaid facility and (2) its decision whether to approve or deny the expansion exception request. CMS would publish notice of its determination whether the requesting hospital meets the criteria for an applicable hospital or high Medicaid facility in the **Federal Register**. If CMS determines that the requesting hospital meets the criteria for an applicable hospital or high Medicaid facility, CMS would also publish notice of its decision to approve or deny the expansion exception request in the same **Federal Register** notice.

b. Program Integrity Restrictions on Approved Facility Expansion

As discussed in sections X.B.1.b. and X.B.2.a. of the preamble of this proposed rule, in the CY 2012 OPPS/ASC final rule, we issued regulations setting forth the expansion exception process at § 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 exception process 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 as noted in sections X.B.1.b. and X.B.2.a. of the preamble of this proposed rule. 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.*).

Section 1877(i)(3)(B) of the Act provides that the expansion exception process shall permit an applicable hospital to apply for an exception to the prohibition on expansion of facility capacity up to once every 2 years. In extending this provision to high Medicaid facilities, 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 exception to the prohibition on expansion of facility capacity (76 FR 74524). We did not receive any public comments regarding the frequency of exception requests. Until January 1, 2021, under our regulations, both applicable hospitals and high Medicaid facilities could request an exception to the prohibition on expansion of facility capacity up to once every 2 years from the date of a CMS decision on the hospital's most recent request.

Section 1877(i)(3)(C)(ii) of the Act provides that the Secretary shall not permit an increase in an applicable hospital's facility capacity 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 applicable hospital's baseline facility capacity. In adopting a parallel limit on the increase in facility capacity that a high Medicaid facility may request, we noted that, in response to our request for comment on whether the 200 percent limit would be sufficient to balance the intent of the general prohibition on facility expansion with the purpose of the exception process—which is to provide the opportunity to expand in areas where a sufficient need for access to high Medicaid facilities is demonstrated—commenters supported our proposal regarding the amount of permitted increase and at least one commenter specifically supported the parallel treatment of high Medicaid facilities (76 FR 74524). Until January 1, 2021, under our regulations, a 200 percent limitation applied to both applicable hospitals and high Medicaid facilities.

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 extending this limitation on the location of expansion facility capacity to high Medicaid facilities, we explained 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). We did not receive any public comments regarding the location of the permitted increase. Until January 1, 2021, under our regulations, expansion facility capacity could occur only in facilities on the hospital's main campus.

In the CY 2021 OPPS/ASC final rule, we revised the regulations that set forth the expansion exception process with respect to high Medicaid facilities to remove certain regulatory restrictions that are not included in section 1877(i) of the Act (85 FR 86256). As of January 1, 2021, a high Medicaid facility may request an exception to the prohibition on expansion of facility capacity more frequently than once every 2 years; may request to expand its facility capacity beyond 200 percent of the hospital's baseline number of operating rooms, procedure rooms, and beds; and, if its request is granted, is not restricted to locating approved expansion facility capacity on the hospital's main campus. Under our existing regulations, an applicable hospital remains subject to the statutory limitation on the frequency of requests for an expansion exception (no more than once every 2 years); may not request to expand its facility capacity beyond 200 percent of the hospital's baseline facility capacity; and, if its request is granted, is restricted to locating approved expansion facility capacity on the hospital's main campus. 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 prohibit expansion of physician-owned hospitals generally. As previously 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 in order to eliminate burden under the former Patients over Paperwork initiative. Commenters opposed to our proposal 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 physician-owned hospitals present a risk of program or patient abuse—through cherry-picking patients, avoiding Medicaid and uninsured patients, and treating fewer medically complex patients—and unrestricted expansion of such hospitals could exacerbate the risk (85 FR 86256 through 86257). Despite the program integrity concerns identified by commenters on the CY 2021 OPPS/ASC proposals, the regulations were revised to remove a perceived burden on high Medicaid facilities because the program integrity restrictions are not expressly required in section 1877(i) of the Act.

We recently reviewed the CY 2021 OPPS/ASC regulatory revisions, including the comments on our then-proposals, 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 to the expansion of physician-owned hospitals generally that we received in conjunction with an expansion exception request decided 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 physician-owned hospital expansion. Following this recent review, 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. 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 are applied 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, 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 are proposing 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 are proposing 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 are also proposing to renumber this regulation at § 411.363(j). We note 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 September 30, 2023 (the day before the anticipated effective date of the revised regulations if our proposals are finalized). We are not proposing any change to these program integrity restrictions with respect to applicable hospitals, which have consistently applied to such hospitals under our regulations since January 1, 2012. In addition to the regulation at proposed § 411.363(j), the program integrity restriction on the maximum aggregate expansion of a hospital is also implemented at proposed § 411.363(b)(2)(i), which provides that a hospital is not eligible to request an expansion exception 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, those hospitals would be ineligible to submit a future expansion exception request on or after the effective date of the revised regulations if our proposal is finalized. 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 meet the eligibility requirements for making an expansion exception request at proposed § 411.363(b) at the time of the request.

The program integrity restriction on the location of expansion facility capacity at proposed § 411.363(j) would require that any approved expansion occur only on the main campus of the hospital. However, nothing in our existing physician self-referral regulations or our proposals in this section X.B.2.b. would affect 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 Frequently Asked Question (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 existing 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,[719] from a POH's main campus to a remote location. However, because the regulation at existing 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.

Our policy has not changed since the publication of the FAQ. 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 or 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 existing § 411.362 no later than September 23, 2011. Section 1877(i)(1)(A) of the Act and existing § 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 (emphasis added). Put another way, for a hospital to bill Medicare (or another individual, entity, or third-party payer) 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 other than the main campus of a hospital.

Finally, as discussed in section X.B.2.a.(2). of the preamble of this proposed rule, 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 are also proposing, 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). The proposed regulation provides that a hospital is not eligible to 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. Applicable hospitals have been subject to this limitation under our regulations since the effective date of our CY 2012 OPPS/ASC final rule, and we are not proposing any substantive change to the application of the limitation on applicable hospitals. However, we are proposing to slightly revise the language of existing § 411.362(c)(1) and renumber it at § 411.363(b)(2)(ii) as described in this section X.B.2.b. As noted, the limitation would apply uniformly to all hospitals requesting an expansion exception.

c. Technical and Grammatical Revisions

We are proposing certain technical and grammatical revisions to the existing regulations in § 411.362 and the proposed regulations in § 411.363. First, we are proposing 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 in this section X.B.2. of the preamble of this proposed rule, we are also proposing to substitute the word ''approved'' for the current reference to ''granted'' at § 411.362(b)(2). We are proposing to use the same phrasing of ''exception from the prohibition on facility expansion'' wherever that language appears in the regulation. We are proposing to use defined acronyms, such as HCRIS, where those terms appear following the initial designation of the acronym. In addition, we are specifying at proposed § 411.363(l) that the references to section 1869 and 1878 in existing § 411.362(c)(8) are references to the Social Security Act. For consistency with our regulations in this subpart J, we are proposing to revise the term ''Web site'' to ''website'' wherever the term appears in existing § 411.362. We are also proposing to change numbers to words and vice versa where those conventions are correct in the Code of Federal Regulations. Finally, we are proposing minor changes to correct grammatically the wording of certain regulations. For example, we are proposing to restate the regulation at existing § 411.362(c)(2)(iii) and renumber it at § 411.363(b)(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.''

C. Proposed 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 are proposing to correct these technical errors.

[719] 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.

Specifically, in § 411.353(d) we are proposing to amend paragraph (d) by removing the parenthetical phrase ''§ 1003.101 of this title.'' and adding in its place ''§ 1003.110 of this title.'' Also, we are also proposing 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.''.

D. Safety Net Hospitals—Request for Information

1. Background

Consistent with President Biden's Executive Order 13985 on ''Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' [720] and Executive Order 14091 on ''Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,'' [721] 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.[722]

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.[723] 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.[724] 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 healthcare, 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.[725] 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 have provided emergency care to many of the country's most at-risk patients and have leveraged their position as trusted providers to drive vaccine uptake in their communities.[726]

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 has pointed specifically to the greater share of patients insured by public programs, which it stated typically pay lower rates for the same 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.[727] Moreover, the financial pressures on many safety-net hospitals have been further exacerbated by the impacts of the COVID–19 pandemic.[728] In response to the challenges posed by COVID–19, HHS has authorized several targeted distributions from the Provider Relief Fund to safety-net hospitals and other hospitals that serve vulnerable populations.[729]

In its June 2022 Report to Congress, MedPAC expressed concern over the financial position of safety-net hospitals.[730] 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.'' [731] 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.[732] 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.[733] [734]

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

[720] *https://www.federalregister.gov/documents/2021/01/25/2021-01753/advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government.*

[721] 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*).

[722] *https://www.cms.gov/sites/default/files/2022-04/Health%20Equity%20Pillar%20Fact%20Sheet_1.pdf.*

[723] *https://www.cms.gov/sites/default/files/2022-04/Health%20Equity%20Pillar%20Fact%20Sheet_1.pdf.*

[724] *https://www.ncbi.nlm.nih.gov/books/NBK224519/.*

[725] *https://www.ncbi.nlm.nih.gov/books/NBK224521/.*

[726] *https://www.nejm.org/doi/full/10.1056/NEJMp2114010.*

[727] *https://www.medpac.gov/wp-content/uploads/2022/06/Jun22_MedPAC_Report_to_Congress_v2_SEC.pdf.*

[728] *https://www.nejm.org/doi/full/10.1056/NEJMp2114010.*

[729] *https://www.hrsa.gov/provider-relief/payments-and-data/targeted-distribution.*

[730] 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.*

[731] *https://www.medpac.gov/wp-content/uploads/2022/06/Jun22_MedPAC_Report_to_Congress_v2_SEC.pdf.*

[732] *https://www.nytimes.com/2020/07/01/nyregion/Coronavirus-hospitals.html*; *https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2768602.*

[733] *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3272769/.*

[734] *https://www.healthaffairs.org/do/10.1377/forefront.20180503.138516/full/.*

hospitals.[735] 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.

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. In the next two sections, we discuss two potential approaches: the Safety-Net Index, 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

The Safety-Net Index (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.

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,[736] 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

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.[737] 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 calculating the Medicare share of total 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).

When calculating the SNI, the following circumstances may be encountered: new hospitals (for example, hospitals that begin participation in 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 are soliciting 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 refer readers to section IV.E.3. of the preamble this proposed rule for a discussion of how these circumstances are addressed in the uncompensated care payment methodology.

For MedPAC's SNI calculation, we are also soliciting 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

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. Recently, the Office of the Assistant Secretary for Planning and Evaluation (ASPE) 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

[735] *https://www.medpac.gov/wp-content/uploads/2022/06/Jun22_MedPAC_Report_to_Congress_v2_SEC.pdf.*

[736] 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 proposed rule).

[737] 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 are available for this FY 2024 proposed rule.)

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.[738]

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.[739] [740] [741] [742] [743]

Many rural areas also have relatively high levels of neighborhood disadvantage and high ADI levels.

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 in order to support care improvement for underserved beneficiaries (87 FR 69845 through 69849).[744]

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 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

We are interested in public feedback on the challenges faced by safety-net hospitals, and potential approaches to help safety-net hospitals meet those challenges. We welcome all feedback on this issue, and ask 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 existing statutory authority, please 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?

[738] 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.

[739] 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.*

[740] 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.*

[741] 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.*

[742] 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.*

[743] 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.*

[744] 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.

++ 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?

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 referred to as the Disclosures proposed rule). The Disclosures 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. The Disclosures proposed rule 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 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). However, these concerns about PEC and REIT are not limited to SNFs but extend to other provider and supplier types. Given the linkage discussed in the Disclosure proposed rule between PEC and REIT ownership and a decline in nursing home quality, we believe it is very important for us to collect this information from all providers and suppliers that complete the Form CMS–855A so as 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.[745]

For the foregoing reasons and to assist these entities in completing the Form CMS–855A, we propose in this FY 2024 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; however, as we stated in the Disclosures proposed rule, these definitions may be modestly different from definitions of the same terms used in other settings. Accordingly, we seek comment from all provider and supplier types that complete the Form CMS–855A on the propriety of the PEC and REIT definitions first proposed in the Disclosures proposed rule. We welcome any suggested revisions thereto and particularly seek comment on whether our proposed definition of PEC should include publicly-traded private equity companies. Moreover, we would appreciate public feedback regarding any other types of private ownership besides PECs and REITs about which CMS should consider collecting information from providers and suppliers as part of the enrollment process.

We note that there are two principal categories of legal authorities for this proposal:

• Section 1866(j) of the Act furnishes specific authority regarding the enrollment process for providers and suppliers.

• Sections 1102 and 1871 of the Act provide general authority for the Secretary to prescribe regulations for the efficient administration of the Medicare program.

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 proposed rule. MedPAC recommendations for the IPPS for FY 2024 are addressed in Appendix B to this proposed 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-Fee-for-Service-Payment/AcuteInpatientPPS/index*. Following is a listing of the IPPS-related data files that are available.

Commenters interested in discussing any data files used in construction of this proposed rule should contact Michael Treitel at (410) 786–4552.

1. CMS Wage Data Public Use File

This file contains the hospital hours and salaries from Worksheet S–3, parts II and III from FY 2020 Medicare cost reports used to create the proposed FY

[745] *https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-855a.*

2024 IPPS wage index. Multiple versions of this file are created each year. For a discussion of the release of different versions of this file, we refer readers to section III.L. of the preamble of this proposed rule.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html*. Periods Available: FY 2007 through FY 2024 IPPS Update.

2. CMS Occupational Mix Data Public Use File

This file contains the CY 2019 occupational mix survey data to be used to compute the occupational mix adjusted wage indexes. Multiple versions of this file are created each year. For a discussion of the release of different versions of this file, we refer readers to section III.L. of the preamble of this proposed rule.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html*. Period Available: FY 2024 IPPS Update.

3. Provider Occupational Mix Adjustment Factors for Each Occupational Category Public Use File

This file contains each hospital's occupational mix adjustment factors by occupational category. Two versions of these files are created each year to support the rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html*.

Period Available: FY 2024 IPPS Update.

4. Other Wage Index Files

CMS releases other wage index analysis files after each proposed and final rule. Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Wage-Index-Files.html*. Periods Available: FY 2005 through FY 2024.

5. FY 2024 IPPS FIPS CBSA State and County Crosswalk

This file contains a crosswalk of State and county codes used by the Federal Information Processing Standards (FIPS), county name, and a list of Core Based Statistical Areas (CBSAs).

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the FY 2024 proposed rule home page or the FY 2024 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*.

Period Available: FY 2024 IPPS Update.

6. HCRIS Cost Report Data

The data included in this file contain cost reports with fiscal years ending on or after September 30, 1996. These data files contain the highest level of cost report status.

Media: internet at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Downloadable-Public-Use-Files/Cost-Reports/Cost-Reports-by-Fiscal-Year*.

(We note that data are no longer offered on a CD. All of the data collected are now available free for download from the cited website.)

7. Provider-Specific File

This file is a component of the PRICER program used in the MAC's system to compute DRG/MS–DRG payments for individual bills. The file contains records for all prospective payment system eligible hospitals, including hospitals in waiver States, and data elements used in the prospective payment system recalibration processes and related activities. Beginning with December 1988, the individual records were enlarged to include pass-through per diems and other elements.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspMedicareFeeSvcPmtGen/psf_text*.

Period Available: Quarterly Update.

8. CMS Medicare Case-Mix Index File

This file contains the Medicare case-mix index by provider number based on the MS–DRGs assigned to the hospital's discharges using the GROUPER version in effect on the date of the discharge. The case-mix index is a measure of the costliness of cases treated by a hospital relative to the cost of the national average of all Medicare hospital cases, using DRG/MS–DRG weights as a measure of relative costliness of cases. Two versions of this file are created each year to support the rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*, or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

Periods Available: FY 1985 through FY 2024.

9. MS–DRG Relative Weights (Also Table 5—MS–DRGs)

This file contains a listing of MS–DRGs, MS–DRG narrative descriptions, relative weights, and geometric and arithmetic mean lengths of stay for each fiscal year. Two versions of this file are created each year to support the rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*, or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or the fiscal year final rule home page desired).

Periods Available: FY 2005 through FY 2024 IPPS Update.

10. IPPS Payment Impact File

This file contains data used to estimate payments under Medicare's hospital inpatient prospective payment systems for operating and capital-related costs. The data are taken from various sources, including the Provider-Specific File, HCRIS Cost Report Data, MedPAR Limited Data Sets, and prior impact files. The data set is abstracted from an internal file used for the impact analysis of the changes to the prospective payment systems published in the **Federal Register**. Two versions of this file are created each year to support the rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Historical-Impact-Files-for-FY–1994-through-Present*, or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

Periods Available: FY 1994 through FY 2024 IPPS Update.

11. AOR/BOR File

This file contains data used to develop the MS–DRG relative weights. It contains mean, maximum, minimum, standard deviation, and coefficient of variation statistics by MS–DRG for length of stay and standardized charges. The BOR file are ''Before Outliers

Removed'' and the AOR file is ''After Outliers Removed.'' (Outliers refer to statistical outliers, not payment outliers.) Two versions of this file are created each year to support the rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*, or for the more recent data files, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of page, click on the specific fiscal year proposed rule home page or fiscal year final rule home page desired).

Periods Available: FY 2005 through FY 2024 IPPS Update.

12. Prospective Payment System (PPS) Standardizing File

This file contains information that standardizes the charges used to calculate relative weights to determine payments under the hospital inpatient operating and capital prospective payment systems. Variables include wage index, cost-of-living adjustment (COLA), case-mix index, indirect medical education (IME) adjustment, disproportionate share, and the Core-Based Statistical Area (CBSA). The file supports the rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the FY 2024 proposed rule home page or the FY 2024 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*.

Period Available: FY 2024 IPPS Update.

13. MS–DRG Relative Weights Cost Centers File

This file provides the lines on the cost report and the corresponding revenue codes that we used to create the 19 national cost center cost-to-charge ratios (CCRs) that we used in the relative weight calculation.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the FY 2024 proposed rule home page or the FY 2024 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*.

Period Available: FY 2024 IPPS Update

14. Hospital Readmissions Reduction Program Supplemental File

The Hospital Readmissions Reduction Program Supplemental File is only available and updated for the final rule, when the most recent data is available. Therefore, we refer readers to the FY 2023 IPPS/LTCH PPS final rule supplemental file, which has the most recent finalized payment adjustment factor components and is the same data as would have been used to create the FY 2024 IPPS/LTCH PPS proposed rule supplemental file.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the FY 2024 proposed rule home page or the FY 2024 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*.

Period Available: FY 2024 IPPS Update.

15. Medicare Disproportionate Share Hospital (DSH) Supplemental File

This file contains information on the calculation of the uncompensated care payments for DSH eligible hospitals as well as the supplemental payments for eligible IHS and Tribal hospitals and hospitals located in Puerto Rico for FY 2024. Variables include the data used to determine a hospital's share of uncompensated care payments, total uncompensated care payments, estimated per claim uncompensated care payment amounts, and if applicable, supplemental payment amounts. The file supports the rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the FY 2024 proposed rule home page or the FY 2024 final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*.

Period Available: FY 2024 IPPS Update.

16. New Technology Thresholds File

This file contains the cost thresholds by MS–DRG that are generally used to evaluate applications for new technology add-on payments for the fiscal year that follows the fiscal year that is otherwise the subject of the rulemaking. (As discussed in section II.G. of this proposed rule, we use the proposed threshold values associated with the proposed rule for that fiscal year to evaluate the cost criterion for 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.) Two versions of this file are created each year to support rulemaking.

Media: internet at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Index.html* (on the navigation panel on the left side of the page, click on the applicable fiscal year's proposed rule or final rule home page) or *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Acute-Inpatient-Files-for-Download.html*.

Periods Available: For FY 2024 and FY 2025 applications.

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 this proposed rule, we are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs). The following ICRs are listed in the order of appearance within the preamble (see sections II. through X. of the preamble of this proposed 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 proposed 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. ICRs for Payments for Low-Volume Hospitals

As discussed in section V.E. of the preamble of this proposed 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 that section 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. 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 x $80.74). The information collection request under OMB control number 0938–NEW will be submitted to OMB for approval.

3. ICRs Relating to the Hospital Readmissions Reduction Program

In section V.J. of the preamble of this proposed rule, we discuss proposed policies for the Hospital Readmissions Reduction Program. In this proposed rule, we are not proposing any changes to the Hospital Readmissions Reduction Program for FY 2024. 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 would 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.

4. ICRs for the Hospital Value-Based Purchasing (VBP) Program

In section V.K. of the preamble of this proposed rule, we discuss updates to the Hospital VBP Program. Specifically, in this proposed rule, we are proposing to adopt substantial measure updates to the Medicare Spending per Beneficiary (MSPB) 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. We are also proposing to adopt the Severe Sepsis and Septic Shock measure beginning with the FY 2026 program year. Additionally, we are proposing to adopt technical changes to the to the form and manner of the administration of the HCAHPS Survey measure. We are also proposing a scoring methodology change that adjusts for treating a high proportion of underserved patients, defined by dual eligibility, and rewards hospitals for providing excellent care to this population beginning with the FY 2026 program year. We are also requesting feedback on potential Additional Changes to the Hospital VBP Program that would address health equity. Lastly, we are proposing to modify the Total Performance Score (TPS) maximum to be 110, resulting in numeric score range of 0 to 110.

Data collections for the Hospital VBP Program are associated with the Hospital Inpatient Quality Reporting Program under OMB control number 0938–1022, the National Healthcare Safety Network under OMB control number 0920–0666, and the Hospital Consumer Assessment of Healthcare Providers and Systems (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 anticipate any change in burden associated with these proposed measures. There is also no change in burden due to the proposed scoring methodology change because the proposal does not require hospitals to submit any additional information but instead changes how hospitals are scored based on the information already being submitted.

5. 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 this proposed rule, we are not proposing to add or remove any measures from the HAC Reduction Program.

In section V.L.6.a.(2). of the preamble of this proposed rule, we are proposing 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. This reconsideration process would 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 proposal.

In section V.L.6.a.(3). of the preamble of this proposed rule, we are proposing 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. Because we are neither proposing to modify the number of hospitals that will be selected for validation nor the number of records each selected hospital will be required to submit, we are not proposing any changes to our currently approved burden estimates as a result of this proposal.

6. 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 this proposed rule, we describe the burden changes regarding collection of information under OMB control number 0938–1022, for IPPS hospitals.

For more detailed information on our proposals for the Hospital IQR Program, we refer readers to section IX.C. of the preamble of this proposed rule. We are proposing 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 Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Inpatient) eCQM. We are proposing 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. We are proposing to modify the COVID–19 Vaccination Coverage among Healthcare Personnel measure beginning with the Q4 2023 reporting period/FY 2025 payment determination. We are proposing to remove the Elective Delivery measure beginning with the CY 2024 reporting period/FY 2026 payment determination. We are proposing to remove two Medicare FFS claims-based measures: the 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 impacting the FY 2030 payment determination, and the Medicare Spending Per Beneficiary (MSPB)—Hospital measure beginning with the CY 2026 reporting period/FY 2028 payment determination. We are proposing 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. Lastly, we are proposing to modify data collection and reporting requirements for the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey measure beginning with the FY 2027 payment determination.

Our proposal to remove the Elective Delivery measure beginning with the CY 2024 reporting period/FY 2026 payment determination will result in a change of collection of information burden as detailed in this section. The remaining policies being proposed would 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.[746] 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 proposed 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 Proposed 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 proposed rule, we discuss the proposal to remove 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 160,650 hours (51 hours × 3,150 hospitals) at a cost of $7,206,759 (160,650 hours × $44.86) related to this proposal.

c. Information Collection Burden Estimate for the Proposed 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 Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Inpatient) eCQM.

In sections IX.C.5.a., b., and c. of the preamble of this proposed rule, we are proposing to adopt three new eCQMs: (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—beginning with the CY 2025 reporting period/FY 2027 payment determination. Current Hospital IQR Program policy requires hospitals 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 49299 through 49302). In other words, although these new eCQMs are being

[746] 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.*

added to the eCQM measure set, hospitals are not required to report more than a total of six eCQMs. 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 1 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 of submitting eCQMs 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.

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 proposed rule).

d. Information Collection Burden Estimate for the Two Hybrid Measure Refinement Proposals

In sections IX.C.6.a. and b. of this proposed rule, we are proposing to modify 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 proposed modifications of both measures would 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 proposing any changes in burden associated with the proposed 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 Healthcare Personnel (HCP) measure for the Hospital IQR Program (86 FR 45374 through 45382). In section IX.B. of this proposed rule, we are proposing 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 quarter 4 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 proposing any updates to the form, manner, and timing of data submission for this measure, there would be no increase in burden associated with the proposal. Furthermore, the modified COVID–19 Vaccination Coverage among HCP measure would 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) (NCVIA).

f. Information Collection Burden for the Proposed Removal of Two Claims-Based Measures

In sections IX.C.7.a. and b. of the preamble of this proposed rule, we are proposing to remove 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 would 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 Proposed Modification of Validation Targeting Criteria Beginning With the FY 2027 Payment Determination

In section IX.C.11.b. of the preamble of this proposed rule, we are proposing 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.

Because we are neither proposing to modify 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 proposing any changes to our currently approved burden estimates as a result of this proposal.

h. Information Collection Burden for the Proposed 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 proposed rule, we are proposing 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 proposing 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 proposal to remove 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 proposals 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.[747] 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 will submit the revised information collection estimates to OMB for approval under OMB control number 0938–0981.

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 proposed rule will result in a total decrease of 160,650 hours at a savings of $7,206,759 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 proposed 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 and 0938–0981.

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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 hospital	Proposed 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	160,650	N/A	-160,650
	Total Change in Information Collection Burden Hours: -160,650							
	Total Cost Estimate: Updated Hourly Wage ($44.86) x Change in Burden Hours (-160,650) = **-$7,206,759**							

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	Proposed Annual burden (hours) across hospitals	Previously finalized annual burden (hours) across hospitals	Net difference in annual burden hours
Adopt Proposed 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: +13,976							
	Total Cost Estimate: Updated Hourly Wage ($20.71) x Change in Burden Hours (+13,976) = **$289,443**							

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[747] *https://aspe.hhs.gov/reports/valuing-time-us-department-health-human-services-regulatory-impact-analyses-conceptual-framework.*

7. 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. In this proposed rule, we describe the collection of information impact under the same OMB control number for PPS-exempt cancer hospitals (PCHs).

In the proposed rule, we are proposing 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 in the FY 2026 program year and mandatory reporting beginning with the FY 2027 program year. We are also proposing updates to the data collection and reporting for the HCAHPS survey measure (NQF #0166) beginning with the FY 2027 program year. Our burden estimates associated with these proposed policies are described later in this section.

We are also proposing policies which will not affect the information collection burden associated with the PCHQR Program. As discussed in section IX.B. of the preamble of this proposed rule, we are proposing to modify the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure beginning with the FY 2025 program year. In addition, as discussed in section IX.D.9.b. of the preamble of this proposed rule, we are proposing to begin public reporting of the Surgical Treatment Complications for Localized Prostate Cancer (PCH–37) measure with the FY 2025 Program Year.

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.[748] 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 proposed rule for the PCHQR Program.

a. Information Collection Burden Estimate for the Proposed Adoption of 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 proposed rule, we are proposing to adopt the Documentation of Goals of Care Discussions Among Cancer Patients measure beginning with the FY 2026 program year. PCHs would 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 would 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 proposed rule).

b. Information Collection Burden Estimate for the Proposed Facility Commitment to Health Equity Structural Measure Beginning With the FY 2026 Program Year

In section IX.D.3. of the preamble of this proposed rule, we are proposing to adopt 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 would be the same for PCHs.

PCHs would 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 proposed rule).

c. Information Collection Burden for the Proposed Screening for Social Drivers of Health Measure Beginning With the FY 2026 Program Year

In section IX.D.4. of the preamble of this proposed rule, we are proposing to adopt the Screening for Social Drivers of Health measure beginning with voluntary reporting in 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 would be the same for PCHs. As discussed in the preamble of this proposed rule, PCHs would 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 would 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

[748] 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.*

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 would screen 50 percent of patients. For the FY 2027 program year, we assume 100 percent of PCHs would screen 100 percent of patients. For the FY 2026 program year, we estimate that 828 total patients would 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 proposed rule).

d. Information Collection Burden for the Proposed 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 proposed rule, we are proposing to adopt the Screen Positive Rate for Social Drivers of Health measure with voluntary reporting in 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 would not need to provide any additional information for this measure (87 FR 49386). We believe the estimated burden would 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 Proposed 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 proposed rule, we are proposing updates to the data collection and reporting for the HCAHPS survey measure beginning with the FY 2027 program year. Specifically, we are proposing 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 proposal to remove 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 will submit the revised information collection estimates to OMB for approval under OMB control number 0938–0981.

f. Information Collection Burden Estimate for the Proposal To Modify 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 finalized to adopt the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure for the PCHQR Program (86 FR 45428 through 45434). In section IX.B. of the preamble of this proposed rule, we are proposing 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 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 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 Proposal 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 proposed rule, we are proposing to

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 proposal.

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 proposed 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 all proposals). Under OMB control number 0938–0981 (expiration date September 30, 2024), we estimate that the policies promulgated in this proposed 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 numbers 0938–1175 and 0938–0981.

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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**	**Proposed 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 (135) = **$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**	**Proposed 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	Proposed Annual burden (hours) across 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**								

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8. 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.

We believe that 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 proposed rule, we are proposing 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 proposed rule, we are proposing that LTCHs submit data on one modified quality measure, the HCP COVID–19 Vaccine measure beginning with the FY 2025 LTCH QRP. LTCHs would 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 are not proposing any updates to the form, manner, and timing of data submission for this measure, there would be no increase in burden associated with the proposal. We refer readers to the FY 2022 IPPS/LTCH PPS final rule (86 FR 45448 through 45449) for these proposed policies.

In section IX.E.4.a. of the preamble of this proposed rule, we propose the DC Function measure beginning with the FY 2025 LTCH QRP. This assessment-based quality measure would be calculated using data from the LCDS that are already reported to the Medicare program for payment and other quality reporting purposes. There would be no additional burden for LTCHs because the proposal would not require LTCHs to report new data elements.

In section IX.E.4.b and IX.E.4.c. of the preamble of this proposed rule, we propose to remove the Application of Functional Assessment/Care Plan and Functional Assessment/Care Plan measures beginning with the FY 2025 LTCH QRP. We estimate that the proposed removal of these two measures would result in a decrease of 0.1 hour (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.[749] 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. We believe that the removal of the measure would 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. We believe that 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 $79.56/hr; LVN 2.5 percent at $49.86/hr; and SLP 2.5 percent at $82.52/hr.

Specifically, we believe that 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

[749] *https://www.bls.gov/oes/current/oes_nat.htm.*

collected for CY 2021, we estimate 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 this proposed rule, we propose 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. Because LTCHs have been required to submit LCDS assessments in this manner since October 1, 2012, there would be no increase in burden to LTCH providers associated with the proposal.

In section IX.E.4.d. of the preamble of this proposed rule, we propose to adopt the Patient/Resident COVID–19 Vaccine measure beginning with the FY 2026 LTCH QRP. The proposed measure would 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 would be added to the LCDS in order to allow for collection of this measure and would 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 estimate 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.

We believe that 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 proposed in this proposed 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).

	Per LTCH		All LTCHs	
Proposal	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 this proposed rule	(3.91)	(386.1234)	(1,292.31)	(127,420.728)

9. ICRs for the Medicare Promoting Interoperability Program

a. Historical Background

In section IX.F. of the preamble of this proposed rule, we discuss several proposed policies 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 this proposed rule, we describe the burden changes regarding collection of information under OMB control number 0938–1278 for eligible hospitals and CAHs. The collection of information burden analysis in this proposed 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 proposed policies for the Medicare Promoting Interoperability Program, we refer readers to section IX.F. of the preamble of this proposed rule. We are proposing several policies which will not affect the information collection burden associated with the Medicare Promoting Interoperability Program. We are proposing 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 (CMT) in Adults eCQM. We are also proposing 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. Lastly, we are proposing to establish an EHR reporting period of a minimum of any continuous 180-day period in CY 2025.

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.[750] 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 proposed 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 Proposed 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 eCQM

In sections IX.F.7.a.(2). of the preamble of this proposed rule, we are proposing adoption of 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) in Adults 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.

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 proposed rule).

c. Information Collection Burden Estimate for the Proposed Modification to the SAFER Guides Measure

In section IX.F.3. of the preamble of this proposed rule, we are proposing 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. In the CY 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 proposing to modify the information that eligible hospitals and CAHs will be required to submit but are instead requiring an attestation of ''yes'', we are not proposing any changes to our currently approved burden estimates as a result of this proposal.

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 proposed rule).

d. Information Collection Burden for the Proposal To Establish 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 proposed rule, we are proposing to establish an EHR reporting period of a minimum of any continuous 180-day period in CY 2025. Because we are not proposing to modify the type or amount of data each eligible hospital and CAH will be required to submit, we are not proposing any changes to our currently approved burden estimates as a result of this proposal.

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 proposed rule will not result in a change in burden. We continue to estimate an annual burden of 6.6 hours per eligible hospital and CAH as well as an additional 4 hours annually for CAHs to report eCQMs.

10. ICRs Regarding Special Requirements for Rural Emergency Hospitals (REHs) (§ 488.70)

The proposed special requirements for REHs 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. The estimated burden related to this proposed regulation is discussed below.

a. Sources of Data Used in Estimates of Burden Hours and Cost Estimates

For the estimated costs contained in the analysis below, 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.[751] 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

We are proposing 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 proposed 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

[750] U.S. Bureau of Labor Statistics. Occupational Outlook Handbook, Medical Records and Health Information Technicians. Accessed on January 13, 2023. Available at: *https://www.bls.gov/ooh/healthcare/medical-records-and-health-information-technicians.htm.*

[751] 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 8, 2023.

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).[752]

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 above. 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 [753] This wage, 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.

11. ICRs for Physician-Owned Hospitals

As discussed in section X.B. of the preamble of this proposed rule, we are proposing to make changes pertaining to the process for physician-owned hospitals requesting an exception from the prohibition against facility expansion and program integrity restrictions on approved facility expansion.

Specifically, we are proposing to make 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 hardcopy 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 or plans to provide inpatient or outpatient hospital services if CMS approves the request, 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); (4) providing information regarding whether and how the hospital has used any expansion facility capacity approved in a prior request and whether it plans to use expansion facility capacity to provide specialty services if the request is approved; (5) providing information regarding the requesting hospital's need for additional operating rooms, procedure rooms, or beds to serve Medicaid, uninsured, and underserved populations; and (6) providing information regarding the need 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. In addition, we are proposing to require electronic submission of requests following instructions posted on the CMS website and eliminate 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 proposing to eliminate the use of external data sources for determining whether a hospital meets the criteria for an applicable hospital or high Medicaid facility. Finally, we are proposing to reinstate, with respect to high Medicaid facilities, the program integrity restrictions on the frequency of expansion exception requests at proposed § 411.362(c)(1)(ii)(B), which provides that a hospital is not eligible to make an expansion exception request 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.

We do not believe any of these proposals would result in any changes in burden under the PRA. The proposed changes to the information being submitted are 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 proposed changes will affect the annual number of respondents. We are not proposing 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 would have little practical impact on whether a requesting hospital meets the criteria for an applicable hospital or high Medicaid facility. Also, although our regulations have permitted high Medicaid facilities to 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 the proposed information collection would normally be subject to the PRA, we 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 high Medicaid facility. As stated in the CY 2021 OPPS 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

[752] *https://www.federalregister.gov/d/2022-23918/p-4515.*

[753] *https://www.bls.gov/oes/current/oes119111.htm.*

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 explained 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 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), the proposed collection would be exempt as it affects less than 10 entities in a 12-month period. Although we believe the proposed information collection would be 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 a request, we use a 2021 wage rate of $71.17 for lawyers from the Bureau of Labor Statistics,[754] and we double that wage to account for overhead and benefits. The total estimated annual cost is $960.79.

12. ICRs for Disclosures of Ownership and Additional Disclosable Parties Information

As explained in section X.E. of the preamble of this proposed rule, we propose that the private equity company (PEC) and real estate investment trust (REIT) definitions that we proposed in the Disclosures proposed rule (published on February 15, 2023)[755] and referenced in section X.E. of the preamble of this proposed rule apply to all providers and suppliers completing the Form CMS–855A enrollment application (OMB Control No. 0938–0685)), not merely skilled nursing facilities. This is consistent with our proposal 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.[756]

There would be five types of Form CMS–855A transactions via which we believe providers and suppliers would report PEC and REIT data: (1) initial enrollment applications; (2) change of ownership applications; (3) revalidation applications; (4) reactivation applications; and (5) change of information applications.

Form CMS–855A applications are typically completed by the provider's or supplier's office staff. Consequently, we will use the following categories and hourly wage rates from the U.S. Bureau of Labor Statistics' (BLS) May 2021 National Occupational Employment and Wage Estimates for all salary estimates (*http://www.bls.gov/oes/current/oes_nat.htm*):

TABLE XII.B-06: NATIONAL OCCUPATIONAL EMPLOYMENT AND WAGE ESTIMATES

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefits and Overhead ($/hr)	Adjusted Hourly Wage ($/hr)
Office and Administrative Support Workers, All Other	43-9199	20.47	20.47	40.94

Based on our internal data, we estimate that the following number of Form CMS–855A applications would be submitted reporting PEC or REIT data: (1) 6,462 initial applications; (2) 3,105 changes of ownership; (3) 3,133 revalidations; (4) 610 reactivations; and (5) 27,000 changes of information. Furthermore, we project that it would take an average of 12 minutes to furnish the PEC and REIT data, though we recognize that this will vary by Form

[754] 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.*

[755] Medicare and Medicaid Programs; Disclosures of Ownership and Additional Disclosable Parties Information for Skilled Nursing Facilities and Nursing Facilities (88 FR 9820).

[756] *https://www.cms.gov/regulations-and-guidance/legislation/paperworkreductionactof1995/pra-listing/cms-855a.*

CMS–855A transaction type and the amount of the data the particular provider or supplier must disclose.

We note that while the 12-minute estimate is consistent with our time-per-response projection in the aforementioned Form CMS–855A PRA package, the (1) number of affected providers and suppliers and (2) total hour and cost projections are not. After further consideration, we believe these two estimates we made in the PRA package are significantly too low. In the final PRA package associated with our Form CMS–855A revision, we will revise these numbers to reflect the figures outlined in the previous paragraph, which we believe are more accurate. The reinstated information collection request under the OMB control number 0938–0685 will be sent to OMB for approval.

TABLE XII.B-07: HOUR AND BURDEN ESTIMATES FOR PEC AND REIT PROVISIONS

	OMB Control No.	Number of Respondents	Number of Responses	Burden per Response (hours)	Total Annual Burden (hours)	Hourly Labor Cost of Reporting ($) (includes 100% fringe benefits) *	Total Cost ($)
Initial Form CMS-855A Applications	0938-0685	6,462	6,462	0.2	1,292	40.94	52,894
Form CMS-855A Change of Ownership	0938-0685	3,105	3,105	0.2	621	40.94	25,424
Form CMS-855A Revalidation Applications	0938-0685	3,133	3,133	0.2	627	40.94	25,669
Form CMS-855A Reactivation Applications	0938-0685	610	610	0.2	122	40.94	4,995
Form CMS-855A Change of Information Applications	0938-0685	27,000	27,000	0.2	5,400	40.94	221,076
TOTALS	**N/A**	**40,310**	**40,310**	**N/A**	**8,062**	**40.94**	**330,058**

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 proposed 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 proposed figures for the standardized amounts, offsets, and budget neutrality factors. Therefore, in this proposed rule, we are setting forth the rate-of-increase percentage for updating the target amounts for certain hospitals excluded from the IPPS that would 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 proposed 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 proposed 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 proposed 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 proposing to make 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 proposed 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 proposed 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 proposed rule are listed in section VI. of this Addendum and are available on the CMS website.

II. Proposed 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 proposing to use for determining the proposed prospective payment rates for FY 2024.

In summary, the proposed 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 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 proposed rule for a complete discussion on the FY 2024 inpatient hospital update. The table that follows shows these four scenarios:

PROPOSED 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**
Proposed Market Basket Rate-of-Increase	3.0	3.0	3.0	3.0
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.75	-0.75
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-2.25	0	-2.25
Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.2	-0.2	-0.2	-0.2
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.8**	**0.55**	**2.05**	**-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 proposed 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.E.2.d. of the preamble of this proposed rule and 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. of the preamble of this proposed 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 proposed 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 proposing to apply 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 proposing to apply a uniform, national budget neutrality adjustment to the FY 2024 wage index for the rural floor.

For FY 2024, we are proposing to continue 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 Proposed 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 in order 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, we are proposing to continue to use the national labor-related and nonlabor-related shares (which are based on the 2018-based hospital 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 proposed rule, we are proposing to continue to use 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 proposing to apply 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 proposed 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 proposed rule and are available 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, we are proposing to calculate 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 proposing to use the 2018-based IPPS operating and capital market baskets for FY 2024. As discussed in section IV.B. of the preamble of this proposed 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 proposing to reduce the FY 2024 market basket percentage increase (which for this proposed rule is based on IGI's fourth quarter 2022 forecast of the 2018-based IPPS market basket) by the productivity adjustment, as discussed elsewhere in this proposed rule.

Based on IGI's fourth quarter 2022 forecast of the hospital market basket percentage increase (as discussed in Appendix B of this proposed rule), the forecast of the hospital market basket percentage increase for FY 2024 for this proposed rule is 3.0 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 proposed 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 proposed 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 proposed FY 2024 update factors is set forth in Appendix B of this proposed rule.

4. Methodology for Calculation of the Average Standardized Amount

The methodology we used to calculate the proposed 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 proposed 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 proposing to adjust 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 proposed 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, in order 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), in order 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 proposing to remove 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 proposing to not remove 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), we are proposing to include 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, we also are proposing 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.

• 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 proposing to continue to apply a proposed 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 hospital VBP payment adjustment (for FY 2024, this proposed proxy would be 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) on each side of the comparison, 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 proposing to apply 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 proposed rule for a complete discussion on the Hospital Readmissions Reduction Program and section V.G. of the preamble of this proposed 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. In order 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), we are proposing to include 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 are proposing to consider 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 proposing to include 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 proposed rule and later in this section, we are proposing to continue 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 proposing to include estimated uncompensated care payments in this comparison.

Similarly, for MDHs, as discussed in section IV.G. of the preamble of this proposed 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 proposing to continue to take into consideration uncompensated care payments in the computation of payments under the Federal rate and the hospital-specific rate for MDHs.

• We are proposing to include 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 proposed 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. Proposed Reclassification and Recalibration of MS–DRG Relative Weights Before Proposed 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.E. of the preamble of this proposed 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 proposing to make 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 proposed rule, 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 proposed proxy FY 2024 hospital readmissions payment adjustments and proposed proxy FY 2024 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2023 labor-related share percentages, the proposed FY 2024 relative weights before applying the 10 percent cap, and the FY 2023 pre-reclassified wage data, and applied the same proposed proxy FY 2024 hospital readmissions payment adjustments and proposed proxy FY 2024 hospital VBP payment adjustments applied previously.

Because this payment simulation uses the proposed FY 2024 relative weights (before applying the 10 percent cap), consistent with our proposal in section IV.I. of the preamble to this proposed rule, we applied the proposed 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 proposing to apply 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 proposed rule for a complete discussion on the proposed adjustor for certain cases that group to MS–DRG 018 and to section II.E.2.b. of the preamble of this proposed rule, for a complete discussion of the proposed 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 proposed budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, we are proposing to apply 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 proposed FY 2024 budget neutrality factors.

b. Proposed Budget Neutrality Adjustment for Reclassification and Recalibration of MS–DRG Relative Weights With Cap

As discussed in section II.E.2.d of this proposed 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.E.2.d of the preamble of this proposed 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 proposed 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 proposed proxy FY 2024 hospital readmissions payment adjustments and the proposed proxy FY 2024 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2023 labor-related share percentages, the proposed FY 2024 relative weights after applying the 10-percent cap, and the FY 2023 pre-reclassified wage data, and applied the same proposed proxy FY 2024 hospital readmissions payment adjustments and proposed 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 proposed rule and our historical policy, and as discussed in the preceding section, we applied the proposed adjustor for certain cases that group to MS–DRG 018 in our simulation of these payments.

In addition, we applied the proposed 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 proposed budget neutrality adjustment factor and applied this factor to the standardized amount. As discussed in section IV. of this Addendum, we are proposing to apply 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 proposed FY 2024 budget neutrality factors.

c. Updated Wage Index—Proposed 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, we are proposing to adjust 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 proposed rule.

To compute a proposed 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 proposed 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 proposed proxy FY 2024 hospital readmissions payment adjustment and the proposed proxy FY 2024 hospital VBP payment adjustment.
- Aggregate payments using the proposed FY 2024 relative weights and the proposed FY 2024 pre-reclassified wage indexes, applied the proposed 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 proposed proxy FY 2024 hospital readmissions payment adjustments and proposed proxy FY 2024 hospital VBP payment adjustments applied previously.

In addition, we applied the proposed MS–DRG reclassification and recalibration budget neutrality adjustment factor before the proposed 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 proposed 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 proposed budget neutrality factors.

d. Reclassified Hospitals—Proposed 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 proposed rule, beginning with FY 2024 we are proposing to include hospitals with § 412.103 reclassification along with geographically rural hospitals in all rural wage index calculations, and only to exclude ''dual reclass'' hospitals (hospitals with simultaneous § 412.103 and MGCRB reclassifications) when implicated by 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 proposing to 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 proposed rule, we acknowledge that these proposals would have significant effects on wage index values. In addition, as a result of this proposed 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 proposed budget neutrality adjustment factor for FY 2024, we used FY 2022 discharge data to simulate payments and compared the following:

- Aggregate payments using the proposed FY 2024 labor-related share percentage, the proposed FY 2024 relative weights, and the proposed 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 proposed proxy FY 2024 hospital readmissions payment adjustments and the proposed proxy FY 2024 hospital VBP payment adjustments.
- Aggregate payments using the proposed FY 2024 labor-related share percentage, the proposed FY 2024 relative weights, and the proposed FY 2024 wage data after such reclassifications, and applied the same proposed proxy FY 2024 hospital readmissions payment adjustments and the proposed 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 proposed rule, which is available via the internet on the CMS website. This table reflects reclassification crosswalks proposed for FY 2024, and applies the proposed policies explained in section III. of the preamble of this proposed rule. Based on this comparison, we computed a proposed 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 proposed FY 2024 budget neutrality factors.

The proposed FY 2024 budget neutrality adjustment factor was applied to the proposed standardized amount after removing the effects of the FY 2023 budget neutrality adjustment factor. We note that the proposed 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 proposed rule. We finally note, in the absence of the proposed policies discussed in section III.G.1 of this proposed 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) when implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act), the reclassification budget neutrality factor would be 0.985756.

e. Proposed Rural Floor Proposed 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) is 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 proposed 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, we are proposing to calculate 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 (share a border with) to 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 proposed FY 2024 rural Puerto Rico wage index is calculated based on the average of the proposed 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 proposed rule, we are proposing 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) when implicated by 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 proposing to 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 proposed rule, we acknowledge that these proposals would have significant effects on wage index values. In addition, as a result of this proposed 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 proposed national rural floor budget neutrality adjustment factor. The national adjustment was applied to the national wage indexes to produce proposed rural floor budget neutral wage indexes. Please see the table later in this section for a summary of the proposed FY 2024 budget neutrality factors. We note, in the absence of the proposed policies discussed in section III.G.1. of this proposed 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) when implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act), the rural floor budget neutrality factor would be 0.992537.

As further discussed in section III.G.2. of this proposed 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 proposed rule for a complete discussion regarding the imputed floor.

f. Proposed Continuation of the Low Wage index Hospital Policy—Proposed Budget Neutrality Adjustment

As discussed in section III.G.3. of the preamble of this proposed rule, we are proposing to continue 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 proposed rule, consistent with our current methodology for implementing wage index budget neutrality under section 1886(d)(3)(E) of the Act, we are proposing to make 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 proposed 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 proposed FY 2024 relative weights, and the proposed FY 2024 wage index for each hospital before adjusting the wage indexes under the low wage index hospital policy, and applied the proposed proxy FY 2024 hospital readmissions payment adjustments and the proposed proxy FY 2024 hospital VBP payment adjustments; and
- Aggregate payments using the FY 2024 labor-related share percentage, the proposed FY 2024 relative weights, and the proposed FY 2024 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy, and applied the same proposed proxy FY 2024 hospital readmissions payment adjustments and the proposed proxy FY 2024 hospital VBP payment adjustments applied previously.

This proposed FY 2024 budget neutrality adjustment factor was applied to the standardized amount.

g. Permanent Cap Policy for Wage Index Budget Neutrality Adjustment—Proposed Budget Neutrality Adjustment

As noted previously, in section III.N. of the preamble to this proposed 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 proposed FY 2024 labor-related share percentages, the proposed FY 2024 relative weights, the proposed FY 2024 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy, and applied the proposed proxy FY 2024 hospital readmissions payment adjustments and the proposed proxy FY 2024 hospital VBP payment adjustments.
- Aggregate payments with the 5-percent cap using the proposed FY 2024 labor-related share percentages, the proposed FY 2024 relative weights, the proposed FY 2024 wage index for each hospital after adjusting the wage indexes under the low wage index hospital policy, and applied the same proposed proxy FY 2024 hospital readmissions payment adjustments and the proposed proxy FY 2024 hospital VBP payment adjustments applied previously.

We note, Table 2 associated with this proposed rule contains the wage index by provider before and after applying the low wage index hospital policy and the proposed cap.

h. Proposed Rural Community Hospital Demonstration Program Adjustment

In section V.L. of the preamble of this proposed 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 proposed 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 proposed 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 $37,658,408. 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 proposed 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 proposed FY 2024 budget neutrality factors, as discussed in the previous sections.

Summary of Proposed FY 2024 Budget Neutrality Factors	
MS-DRG Reclassification and Recalibration Budget Neutrality Factor	1.001376
Cap Policy MS-DRG Weights Budget Neutrality Factor	0.999925
Wage Index Budget Neutrality Factor	1.000943
Reclassification Budget Neutrality Factor	0.980959
*Rural Floor Budget Neutrality Factor	0.981145
Low Wage Index Hospital Policy Budget Neutrality Factor	0.997371
Cap Policy Wage Index Budget Neutrality Factor	0.996562
Rural Demonstration Budget Neutrality Factor	0.999619

*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. Proposed 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 proposing to incorporate 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) Proposed 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 Proposed 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), we are proposing to continue 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 proposed rule, we are proposing to determine a projection of outlier payment reconciliations for the FY 2024 outlier threshold calculation, by advancing the methodology by 1 year. Specifically, we are proposing to use 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, we are proposing to use the same methodology from FY 2020 to incorporate a projection of operating outlier payment reconciliations for the FY 2024 outlier threshold calculation.

For this 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 propose 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*.

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. For this 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. 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 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). The total Federal operating payments based on the December 2022 HCRIS was $88,729,603,026.

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. For FY 2024, the proposed ratio is a negative 0.007806 percent ((-$6,925,967/$88,729,603,026) × 100), which, when rounded to the second digit, is −0.01 percent. This percentage amount would be used to adjust the outlier target 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 Medicare claims data in the MedPAR file used to model the outlier threshold, we are proposing to target 5.1 percent minus the percentage determined in Step 4 in determining the outlier threshold. Using the FY 2018 cost reports based on the December 2022 HCRIS extract, 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 proposed methodology. Therefore, for FY 2024, we are proposing to incorporate a projection of outlier reconciliation dollars by targeting an outlier threshold at 5.11 percent [5.1 percent − (− .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 the Addendum to this proposed rule, we provide the FY 2024 outlier threshold as calculated for this proposed rule both with and without including this proposed 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 is 0.949 (1 − 0.051).

We are inviting public comment on our proposed 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.

(b) Proposed 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 are proposing 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 are proposing 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.

For this 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 are proposing 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.

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 are proposing 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. To do so, we are proposing 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. Based on the December 2022 HCRIS, 5 hospitals had an outlier reconciliation amount recorded on Worksheet E, Part A, Line 93 for total capital outlier reconciliation dollars of negative $383,169. 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 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). The total Federal capital payments based on the December 2022 HCRIS was $8,027,006,104.

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. For FY 2024, the proposed ratio is a negative .00477 percent ((−$383,169/$8,027,006,104) × 100), which, when rounded to the second digit, is 0.00 percent. 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 are proposing 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 proposed methodology would be lower than the percentage of capital outlier payments otherwise determined using the shared outlier threshold.

For this FY 2024 proposed rule, the estimated percentage of FY 2024 capital outlier payments otherwise determined using the shared outlier threshold is 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 FY 2024, 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 are proposing 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 are inviting 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.

(2) Proposed 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 proposed FY 2024 outlier threshold, we simulated payments by applying proposed 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 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).

In order to determine the proposed 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 are proposing 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 proposing 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).
- Because this payment simulation uses the proposed FY 2024 relative weights, consistent with our proposal discussed in section IV.I. of the preamble to this proposed rule, we applied the proposed 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 this proposed rule, based on the information available at this 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, such that modifications to our usual ratesetting methodologies (including the methodology for calculating the outlier threshold) would be warranted. Therefore, we are proposing 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 are proposing to use the same methodology as FY 2020 to determine the charge inflation factor. That is, for FY 2023, we are proposing 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 this proposed rule we are proposing to use 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 this FY 2024 IPPS/LTCH PPS proposed rule) to compute the proposed charge inflation factor. We are proposing 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 proposed methodology, to compute the 1-year average annual rate-of-change in charges per case, we compared the average covered charge per case of $78,089.49 ($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.

In this proposed rule, we are proposing 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 this proposed rule. We are proposing to apply the following edits to providers' CCRs in the PSF. We believe these edits are appropriate in

order 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 are also proposing 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 are proposing 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, we are proposing 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 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 this 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:

- 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 proposed 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 proposed 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.

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 proposed 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 proposed 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 proposed 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 are proposing 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 are proposing 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 are proposing to include estimated FY 2024 uncompensated care payments in the computation of the proposed outlier fixed-loss cost threshold. Specifically, we are proposing 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 are proposing 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 are proposing 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 are proposing to incorporate an estimate of FY 2024 outlier reconciliation in the methodology for determining the outlier threshold. As noted previously, for this 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 are proposing 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 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 reflects 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 note that, if calculated without applying our proposed methodology for incorporating an estimate of outlier reconciliation in the determination of the outlier threshold, the proposed threshold would be $40,808. We are proposing 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.

(3) Other Proposed 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 4.16 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 are proposing to reduce the FY 2024 standardized amount by 5.1 percent to account for the projected proportion of payments paid as outliers.

The proposed outlier adjustment factors that would be applied to the operating standardized amount and capital Federal rate based on the proposed FY 2024 outlier threshold are as follows:

	Operating Standardized Amounts	Capital Federal Rate*
National	0.949	0.958

*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 the Addendum of this proposed rule.

We are proposing to apply 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 1.205 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 proposed 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 proposed statewide average capital CCRs. As previously stated, the proposed 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 proposed 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 6.73 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 proposed rule. We will provide an estimate of actual FY 2023 outlier payments in the FY 2025 IPPS/LTCH PPS proposed rule.

5. Proposed 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 proposing to apply to all hospitals, except hospitals located in Puerto Rico, for FY 2024. The proposed 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 proposed 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 proposing to apply 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 proposed standardized amounts reflecting the proposed applicable percentage increases for FY 2024.

The proposed 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 proposed FY 2024 national standardized amounts. The second through fifth columns display the changes from the FY 2023 standardized amounts for each proposed 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.

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CHANGES FROM FY 2023 STANDARDIZED AMOUNTS TO THE PROPOSED 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)	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
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 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
Proposed FY 2024 Update Factor	1.027	1.00375	1.01925	0.996
Proposed FY 2024 MS-DRG Reclassification and Recalibration Budget Neutrality Factor Before Cap	1.001376	1.001376	1.001376	1.001376
Proposed FY 2024 Cap Policy MS-DRG Weight Budget Neutrality Factor	0.999925	0.999925	0.999925	0.999925
Proposed FY 2024 Wage Index Budget Neutrality Factor	1.000943	1.000943	1.000943	1.000943
Proposed FY 2024 Reclassification Budget Neutrality Factor	0.980959	0.980959	0.980959	0.980959
Proposed FY 2024 Lowest Quartile Budget Neutrality Factor	0.997371	0.997371	0.997371	0.997371
Proposed FY 2024 Cap Policy Wage Index Budget Neutrality Factor	0.996562	0.996562	0.996562	0.996562
Proposed FY 2024 RCH Demonstration Budget Neutrality Factor	0.999619	0.999619	0.999619	0.999619
Proposed FY 2024 Operating Outlier Factor	0.949	0.949	0.949	0.949
Proposed National Standardized Amount for FY 2024 if Wage Index is Greater Than 1.0000; Labor/Non-Labor Share Percentage (67.6/32.4)	**Labor: $4,410.86 Nonlabor: $2,114.08**	**Labor: $4,314.32 Nonlabor: $2,067.81**	**Labor: $4,378.68 Nonlabor: $2,098.66**	**Labor: $4,282.14 Nonlabor: $2,052.39**
Proposed 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: $4,045.46 Nonlabor: $2,479.48**	**Labor: $3,956.92 Nonlabor: $2,425.21**	**Labor: $4,015.95 Nonlabor: $2,461.39**	**Labor: $3,927.41 Nonlabor: $2,407.12**

B. Proposed 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 proposed labor-related and nonlabor-related shares that we are proposing to use 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. Proposed 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 proposed rule, we are proposing to apply 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 proposing to apply 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 proposed 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 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 Proposed 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 proposed 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 × (l + 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 proposed 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
Proposed Market Basket Rate-of-Increase	3.0	3.0	3.0	3.0
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0	0	-0.75	-0.75
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0	-2.25	0	-2.25
Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.2	-0.2	-0.2	-0.2
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.8**	**0.55**	**2.05**	**-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 proposed 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 proposed 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.E.2.d. of the preamble this proposed 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 proposed 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. Proposed 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 are proposing to use 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 Proposed Federal Hospital Inpatient Capital-Related Prospective Payment Rate Update for FY 2024

In the discussion that follows, we explain the factors that we are proposing to use to determine the capital Federal rate for FY 2024. In particular, we explain why the proposed FY 2024 capital Federal rate would increase approximately 4.50 percent, compared to the FY 2023 capital Federal rate. As discussed in the impact analysis in Appendix A to this proposed rule, we estimate that capital payments per discharge would increase approximately 6.3 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 proposed update factor for FY 2024 under that framework is 3.5 percent based on a projected 2.6 percent increase in the 2018-based CIPI, a proposed 0.0 percentage point adjustment for intensity, a proposed 0.0 percentage point adjustment for case-mix, a proposed 0.0 percentage point adjustment for the DRG reclassification and recalibration, and a proposed 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 proposed rule, we describe the policy adjustments that we are proposing to apply 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, the proposed 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 proposed 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, we are proposing to make 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 proposing 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 proposed rule, we are proposing to continue 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 proposing to use 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, we are proposing to make 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 proposed 3.5 percent capital update factor under the capital update framework for FY 2024, as shown in the following table.

PROPOSED FY 2024 UPDATE FACTOR TO THE CAPITAL FEDERAL RATE

Capital Input Price Index*	2.6
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 Proposed Update	3.5

*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 are proposing to incorporate the estimated outlier reconciliation payment amounts into the outlier threshold model, as we did for FY 2023. (For more details on our proposal to incorporate outlier reconciliation payment amounts into the outlier threshold model, please see section II.A. of this Addendum to this proposed 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 would equal 4.16 percent of inpatient capital-related payments based on the proposed 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 would not change the estimated percentage of FY 2024 capital outlier payments. Therefore, accounting for estimated capital outlier reconciliation, the estimated outlier payments for capital-related PPS payments would equal 4.16 percent (4.16 percent − 0.00 percent) of inpatient capital-related payments based on the proposed capital Federal rate in FY 2024. Accordingly, we are proposing to apply an outlier adjustment factor of 0.9584 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 proposed FY 2024 outlier adjustment of 0.9584 is a 1.43 percent change from the FY 2023 outlier adjustment of 0.9449. Therefore, the proposed net change in the outlier adjustment to the capital Federal rate for FY 2024 is 1.0143 (0.9584/0.9449) so that the proposed outlier adjustment would increase the FY 2024 capital Federal rate by approximately 1.43 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 proposed 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. Therefore, as discussed in section III.G.3. of the preamble of this proposed rule, this policy was applied in FYs 2020 through 2023, and we are proposing to continue to apply this policy in FY 2024. 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 proposing 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 proposing 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. 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 proposed 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 proposed changes to the wage index and other proposed wage index policies for FY 2024 discussed previously, which directly affect the GAF, we are proposing to continue to compute a budget neutrality adjustment for changes in the GAFs in two steps. We discuss our proposed 2-step calculation of the proposed 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 proposed FY 2024 GAFs without incorporating the proposed continuation of the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy. To achieve budget neutrality for these proposed changes in the GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 0.9977 for FY 2024. Next, we compared estimated aggregate capital Federal rate payments based on the proposed FY 2024 GAFs with and without the proposed continuation of 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 proposed FY 2024 MS–DRG classifications and relative weights (after application of the 10-percent cap discussed later in this section) and the proposed FY 2024 GAFs (both with and without the proposed continuation of the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy). (We note, for this calculation the proposed GAFs included the imputed floor, out-migration and Frontier state adjustments.) To achieve budget neutrality for the effects of the proposed continuation of the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy on the proposed FY 2024 GAFs, we calculated an incremental GAF budget neutrality adjustment factor of 0.9934. 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 proposed budget neutrality factor for the proposed continuation of 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 proposed budget neutrality factors in the discussion that follows, and this proposed factor is not included in the calculation of the proposed combined GAF/DRG adjustment factor described later in this section. (We note that the proposed FY 2024 GAFs reflect the proposed changes to the rural wage index methodology discussed in section III.G.1. of the preamble to this proposed rule. As discussed, beginning in FY 2024, we are proposing 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) when implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. We are also proposing 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).

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 proposed 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 proposed 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 proposed FY 2024 GAFs without the proposed continuation of the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy. The proposed incremental adjustment factor for DRG classifications and changes in relative weights prior to the application of the 10-percent cap is 1.0016. Next, we compared estimated aggregate capital Federal rate payments based on the proposed 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 proposed 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 proposed FY 2024 GAFs without the proposed continuation of the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy. The proposed 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 proposed FY 2024 MS–DRG reclassification and recalibration (including the 10-percent cap), based on the calculations described previously, we are proposing to apply an incremental budget neutrality adjustment factor of 1.0015 (1.0016 × 0.9999) for FY 2024 to the capital Federal rate. We note that all the values are calculated with unrounded numbers.

The proposed incremental adjustment factor for the proposed FY 2024 MS–DRG reclassification and recalibration (1.0015) and for proposed changes in the FY 2024 GAFs due to the proposed update to the wage data, wage index reclassifications and redesignations, and application of the rural floor policy (0.9977) is 0.9992 (1.0015 × 0.9977). This incremental adjustment factor is built permanently into the capital Federal rates. To achieve budget neutrality for the effects of the proposal to continue 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 proposed budget neutrality adjustment factor of 0.9934 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 proposed continuation of 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 proposed incremental GAF/DRG adjustment factor of 0.9992 accounts for the proposed MS–DRG reclassifications and recalibration (including application of the 10-percent cap on relative weight decreases) and for proposed changes in the GAFs that result from proposed 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 proposed lowest quartile/cap adjustment factor of 0.9934 accounts for changes in the GAFs that result from our proposal to continue the 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. Proposed 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 proposing to establish an update of 3.5 percent in determining the FY 2024 capital Federal rate for all hospitals. As a result of this proposed update and the proposed budget neutrality factors discussed earlier, we are proposing to establish a national capital Federal rate of $505.54 for FY 2024. The proposed national capital Federal rate for FY 2024 was calculated as follows:

- The proposed FY 2024 update factor is 1.0350; that is, the proposed update is 3.5 percent.
- The proposed FY 2024 GAF/DRG budget neutrality adjustment factor that is applied to the capital Federal rate for proposed changes in the MS–DRG classifications and relative weights (including application of the 10-percent cap on relative weight decreases) and proposed 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 0.9992.
- The proposed 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 proposal to continue 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 0.9934.
- The proposed FY 2024 outlier adjustment factor is 0.9584.

We are providing the following chart that shows how each of the proposed factors and adjustments for FY 2024 affects the computation of the proposed FY 2024 national capital Federal rate in comparison to the FY 2023 national capital Federal rate. The proposed FY 2024 update factor has the effect of increasing the capital Federal rate by 3.5 percent compared to the FY 2023 capital Federal rate. The proposed GAF/DRG budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.08 percent. The proposed FY 2024 lowest quartile/cap budget neutrality adjustment factor has the effect of decreasing the capital Federal rate by 0.38 percent compared to the FY 2023 capital Federal rate. The proposed FY 2024 outlier adjustment factor has the effect of increasing the capital Federal rate by 1.43 percent compared to the FY 2023 capital Federal rate. The combined effect of all the proposed changes would increase the national capital Federal rate by approximately 4.50 percent, compared to the FY 2023 national capital Federal rate.

COMPARISON OF FACTORS AND ADJUSTMENTS: FY 2023 CAPITAL FEDERAL RATE AND THE PROPOSED FY 2024 CAPITAL FEDERAL RATE

	FY 2023	Proposed FY 2024	Change	Percent Change
Update Factor[1]	1.0250	1.0350	1.0350	3.50
GAF/DRG Adjustment Factor[1]	1.0012	0.9992	0.9992	-0.08
Quartile/Cap Adjustment Factor[2]	0.9972	0.9934	0.9962	-0.38
Outlier Adjustment Factor[3]	0.9449	0.9584	1.0143	1.43
Capital Federal Rate	$483.79	$505.54	1.0450	4.50[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 proposed 0.9992 GAF/DRG budget neutrality adjustment factor for FY 2024 is a net change of 0.9992 (or -0.08 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 proposed FY 2024 lowest quartile/cap budget neutrality adjustment factor is 0.9934/0.9972 or 0.9962 (or -0.38 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 proposed FY 2024 outlier adjustment factor is 0.9584/0.9449 or 1.0143 (or 1.43 percent).

[4] Percent change may not sum due to rounding.

B. Calculation of the Proposed 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 proposed 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 proposed fixed-loss amount of $40,732.

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 proposed rule, we are proposing to use 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 fourth quarter 2022 forecast, for this proposed rule, we are forecasting the 2018-based CIPI to increase 2.6 percent in FY 2024. This reflects a projected 3.1 percent increase in vintage-weighted depreciation prices (building and fixed equipment, and movable equipment), and a projected 4.2 percent increase in other capital expense prices in FY 2024, partially offset by a projected 1.1 percent decrease in vintage-weighted interest expense prices in FY 2024. The weighted average of these three factors produces the forecasted 2.6 percent increase for the 2018-based CIPI in FY 2024.

We are also proposing that if more recent data become available (for example, a more recent estimate of the percentage increase in the 2018-based CIPI), we would use such data, if appropriate, to determine the FY 2024 percentage increase in the 2018-based CIPI for the final rule.

IV. Proposed 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 this FY 2024 IPPS/LTCH PPS proposed rule, based on IGI's 2022 fourth quarter forecast, we estimate that the 2018-based IPPS operating market basket rate-of-increase for FY 2024 is 3.0 percent. Based on this estimate, the proposed FY 2024 rate-of-increase percentage that will be applied to the FY 2023 target amounts in order to calculate the proposed FY 2024 target amounts for children's hospitals, the 11 cancer hospitals, RNCHIs, 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 will be 3.0 percent, in accordance with the applicable regulations at 42 CFR 413.40. We are also proposing that if more recent data subsequently become available (for example, a more recent estimate of the market basket rate-of-increase), we would use such data, if appropriate, to calculate the final IPPS operating market basket rate-of-increase for FY 2024.

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 proposed 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. Proposed Changes to the Payment Rates for the LTCH PPS for FY 2024

A. Proposed LTCH PPS Standard Federal Payment Rate for FY 2024

1. Overview

In section VIII. of the preamble of this proposed 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 proposed 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 proposed 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 Proposed FY 2024 LTCH PPS Standard Federal Payment Rate

Consistent with our historical practice and § 412.523(c)(3)(xvii), for FY 2024 we are proposing to apply the annual update to the LTCH PPS standard Federal payment rate from the previous year. Furthermore, in determining the proposed LTCH PPS standard Federal payment rate for FY 2024, we also are proposing to make certain regulatory adjustments, consistent with past practices. Specifically, in determining the proposed FY 2024 LTCH PPS standard Federal payment rate, we are proposing to apply 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 to this proposed rule.

In this proposed rule, we are proposing to establish an annual update to the LTCH PPS standard Federal payment rate of 2.9 percent (that is, the most recent estimate of the LTCH PPS market basket increase of 3.1 percent less the proposed productivity adjustment of 0.2 percentage point). Therefore, in accordance with § 412.523(c)(3)(xvii), we are proposing to apply an update factor of 1.029 to the FY 2023 LTCH PPS standard Federal payment rate of $46,432.77 to determine the proposed 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, the proposed 3.1 percent update to the LTCH PPS standard Federal payment rate for FY 2024 would be reduced by the proposed 0.2 percentage point productivity adjustment as required under section 1886(m)(3)(A)(i) of the Act and the additional 2.0 percentage points reduction required by section 1886(m)(5) of the Act. Accordingly, we are proposing 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 an update factor of 1.009) for FY 2024 for LTCHs that fail to submit the required quality reporting data for FY 2024 as required under the LTCH QRP. Consistent with § 412.523(d)(4), we are proposing to apply an area wage level budget neutrality factor to the FY 2024 LTCH PPS standard Federal payment rate of 1.0035335, based on the best available data at this time, to ensure that any proposed changes to the area wage level adjustment (that is, the proposed 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) would not result in any change (increase or decrease) in estimated aggregate LTCH PPS standard Federal payment rate payments. Accordingly, we are proposing to establish an LTCH PPS standard Federal payment rate of $47,948.15 (calculated as $46,432.77 × 1.029 × 1.0035335) 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 proposing to establish an LTCH PPS standard Federal payment rate of $47,016.21 (calculated as $46,432.77 × 1.009 × 1.0035335) for FY 2024.

B. Proposed 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 proposed FY 2024 LTCH PPS standard Federal payment rate wage index values that would 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 the Addendum to this proposed rule and available via the internet on the CMS website.

2. Proposed 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 the August 15, 2017 OMB Bulletin No. 17–01. On September 14, 2018, OMB issued OMB Bulletin No. 18–04, which superseded the April 10, 2018 OMB Bulletin No. 18–03. 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, the September 14, 2018 OMB Bulletin No. 18–04 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 the September 14, 2018 OMB Bulletin No. 18–04, 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 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 are not proposing 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. Proposed 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 this proposed rule, consistent with our historical practice, we are proposing that the LTCH PPS labor-related share for FY 2024 is 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 are proposing 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 is 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 baskets). Since the FY 2024 relative importance for capital-related costs is 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, we are proposing 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 are also proposing that if more recent data become available after the publication of this 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.

4. Proposed 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, we are proposing to continue to employ our historical practice of using the same data we are proposing to use to compute the proposed FY 2024 acute care hospital inpatient wage index, as discussed in section III. of the preamble of this proposed 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, we are proposing to compute 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. We are also proposing to continue 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 we are proposing to continue 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 are proposing to use to determine the proposed 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 proposed 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 the Addendum to this proposed rule.

Based on the FY 2020 IPPS wage data that we are proposing to use to determine the proposed FY 2024 LTCH PPS standard Federal payment rate area wage index values in this proposed rule, there are no rural areas without IPPS hospital wage data. Therefore, it is not necessary to use our established methodology to calculate a proposed 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 the Addendum to this proposed rule.

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 proposed 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 proposed rule at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

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 proposed 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 proposed rule at: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html.*

6. Proposed 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 a proposed 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 to this proposed rule, consistent with, § 412.525(c)(2), we include the application of the 5-percent cap on wage index decreases in the determination of the proposed area wage level budget neutrality factor. Specifically, we are proposing to determine 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 proposed FY 2024 wage index values (including application of the 5 percent cap on wage index decreases) and the proposed FY 2024 labor-related share of 68.4 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 to this proposed rule and the labor-related share is discussed in section V.B.3. of this Addendum to this proposed rule.)

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 proposed FY 2024 updates to the area wage level adjustment (calculated in Step 2) to determine the proposed 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 proposed FY 2024 updates to the area wage level adjustment budget neutrality factor from Step 3 to determine the proposed FY 2024 LTCH PPS standard Federal payment rate after the application of the proposed FY 2024 annual update.

In section I.E. of the preamble of this proposed rule, we discuss our proposal to use the most recent data available for the FY 2024 LTCH PPS ratesetting, including the FY 2022 MedPAR file. Consistent with this proposal, we used claims from the FY 2022 MedPAR file in calculating the proposed 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 proposed 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 FY 2022 MedPAR file, we identified 164 LTCH PPS standard Federal payment rate cases for this LTCH. Of these 164 cases, 116 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, we are proposing to remove claims from CCN 312024 when determining the FY 2024 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor.

For this proposed rule, using the steps in the methodology previously described, we determined a proposed FY 2024 LTCH PPS standard Federal payment rate area wage level adjustment budget neutrality factor of 1.0035335. Accordingly, in section V.A. of the Addendum to this proposed rule, we applied the proposed area wage level adjustment budget neutrality factor of 1.0035335 to determine the proposed FY 2024 LTCH PPS standard Federal payment rate, in accordance with § 412.523(d)(4).

C. Proposed 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 update 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 proposed 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, we are proposing to continue 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).)

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. Proposed 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 also are 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. Proposed LTCH Total CCR Ceiling

Consistent with our historical practice, we are proposing to use the best available data to determine the LTCH total CCR ceiling for FY 2024 in this proposed rule. Specifically, in this proposed rule, we are proposing to use our established methodology for determining the LTCH total CCR ceiling based on IPPS total CCR data from the December 2022 update of the Provider Specific File (PSF), which is the most recent data available. Accordingly, we are proposing an LTCH total CCR ceiling of 1.287 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. Consistent with our historical practice, we are proposing to use the best available data, if applicable, to determine the LTCH total CCR ceiling for FY 2024 in the final rule. (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).)

c. Proposed 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 proposed rule, we are proposing to use our established methodology for determining the LTCH statewide average CCRs, based on the most recent complete IPPS ''total CCR'' data from the December 2022 update of the PSF. We are proposing LTCH PPS statewide average total CCRs for urban and rural hospitals that would be effective for discharges occurring on or after October 1, 2023, through September 30, 2024, in Table 8C listed in section VI. of the Addendum to this proposed rule (and available via the internet on the CMS website). Consistent with our historical practice, we also are proposing to use the best available data, if applicable, to determine the LTCH PPS statewide average total CCRs for FY 2024 in the final rule.

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 and Nevada have 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 December 2022. Therefore, consistent with our existing methodology, we are proposing to use the national average total CCR for rural IPPS hospitals for rural Connecticut and Nevada 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 (0.455) and furthermore implies costs greater than charges, as with Connecticut and Nevada, we are proposing to use 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, we are proposing to continue 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 proposing to use 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)).

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. Proposed 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. Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2024

In this section of this Addendum, we discuss our proposed methodology for determining the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2024. As we state later in this section, the proposed fixed-loss amount we determined for FY 2024 is significantly higher than the fixed-loss amount we finalized for FY 2023 (87 FR 49449). As we explain later in this section, we are soliciting comments on our proposed methodology and the assumptions underlying it, and will consider these comments when finalizing our methodology in the final rule.

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 (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 FY 2022 MedPAR file, we identified 164 LTCH PPS standard Federal payment rate cases for this LTCH. Of these 164 cases, 116 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, we are proposing to remove claims from CCN 312024 when determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2024.

(1) Proposed Charge Inflation Factor for Use in Determining the Proposed 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 the Addendum to this proposed rule), 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 this section of this Addendum, we describe our charge inflation factor methodology.

Step 1—Identify LTCH PPS Standard Federal Payment Rate Cases

The first step in our methodology is to identify LTCH PPS standard Federal payment rate cases from the MedPAR claim files for the two most recently available Federal fiscal year time periods. For both fiscal years, consistent with our historical methodology for determining payment rates for the LTCH PPS, we remove any claims submitted by LTCHs that were all-inclusive rate providers as well as any Medicare Advantage claims. For both fiscal years, we also remove claims from providers that only had claims in one of the fiscal years.

Step 2—Remove Statistical Outliers

The next step in our methodology is to remove all claims from providers whose growth in average charges was a statistical outlier. 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. To perform this statistical trim, we first calculate each provider's average charge in both fiscal years. Then, we calculate a charge growth factor for each provider by dividing its average charge in the most recent fiscal year by its average charge in the prior fiscal year. Then we remove all claims for providers whose calculated charge growth factor was outside 3 standard deviations from the mean provider charge growth factor.

Step 3—Calculate the Charge Inflation Factor

The final step in our methodology is to use the remaining claims to calculate a national charge inflation factor. We first calculate the average charge for those remaining claims in both fiscal years. Then we calculate the national charge inflation factor by dividing the average charge in the more recent fiscal year by the average charge in the prior fiscal year.

Following the methodology described previously, we computed a proposed charge inflation factor based on the most recently available data. Specifically, we used the December 2022 update of the FY 2022 MedPAR file and the December 2021 update of the FY 2021 MedPAR as the basis of the LTCH PPS standard Federal payment rate cases for the two most recently available Federal fiscal year time periods, as described previously in our methodology. Therefore, we trimmed the December 2022 update of the FY 2022 MedPAR file and the December 2021 update of the FY 2021 MedPAR file as described in steps 1 and 2 of our methodology. To compute the 1-year average annual rate-of-change in charges per case, we compared the average covered charge per case of $247,014 ($12,380,602,491/50,121 cases) from FY 2021 to the average covered charge per case of $280,522 ($11,570,133,996/41,245 cases) from FY 2022. This rate-of-change was 13.5651 percent, which results in a 1-year charge inflation factor of 1.135651, and a 2-year charge inflation factor of 1.289703 (calculated by squaring the 1-year factor). We propose 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 proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2024.

(2) Proposed CCRs for Use in Determining the Proposed 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 the Addendum to this proposed rule), 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 this section of this Addendum, we describe our CCR adjustment factor methodology.

Step 1—Assign Providers Their Historical CCRs

The first step in our methodology is to identify providers with LTCH PPS standard Federal payment rate cases in the most recent MedPAR claims file (excluding all-inclusive rate providers and providers with only Medicare Advantage claims). For each of these providers, we then identify the CCR from the most recently available PSF. For each of these providers we also identify the CCR from the PSF that was made available one year prior to the most recently available PSF.

Step 2—Trim Providers With Insufficient CCR Data

The next step in our methodology is to remove from the CCR adjustment factor calculation any providers for which we cannot accurately measure changes to their CCR using the PSF data. We first remove any provider whose CCR was missing in the most recent PSF or prior year PSF. We next remove any provider assigned the statewide average CCR for their State in either the most recent PSF or prior year PSF. We lastly remove any provider whose CCR was not updated between the most recent PSF and prior year PSF (determined by comparing the effective date of the records).

Step 3—Remove Statistical Outliers

The next step in our methodology is to remove providers whose change in their CCR is a statistical outlier. To perform this statistical trim, for those providers remaining after application of Step 2, we calculate a provider-level CCR growth factor by dividing the provider's CCR from the most recent PSF by its CCR in the prior year's PSF. We then remove any provider whose CCR growth factor was outside 3 standard deviations from the mean provider CCR growth factor. These statistical outliers are removed prior to calculating the CCR adjustment factor because we believe that they may represent aberrations in the data that would distort the measure of average annual CCR change.

Step 4—Calculate a CCR Adjustment Factor

The final step in our methodology is to calculate, across all remaining providers after application of Step 3, an average case-weighted CCR from both the most recent PSF and prior year PSF. The provider case counts that we use to calculate the case-weighted average are determined from claims for LTCH standard Federal rate cases from the most recent MedPAR claims file. We note when determining these case counts, consistent with our historical methodology for determining the MS–LTC–DRG relative weights, we do not count short-stay outlier claims as full cases but instead as a fraction of a case based on the ratio of covered days to the geometric mean length of stay for the MS–LTC–DRG grouped to the case. We calculate the national CCR adjustment factor by dividing the case-weighted CCR from the most recent PSF by the case-weighted CCR from the prior year PSF.

Following the methodology described previously, we computed a CCR adjustment factor based on the most recently available data. Specifically, we used the December 2022 PSF as the most recently available PSF and the December 2021 PSF as the PSF that was made available one year prior to the most recently available PSF, as described in our methodology. In addition, we used claims from the December 2022 update of the FY 2022 MedPAR file in our calculation of average case-weighted CCRs described in Step 4 of our methodology. Specifically, following the methodology described previously and, for providers with LTCH PPS standard Federal payment rate cases in the December 2022 update of the FY 2022 MedPAR file, we identified their CCRs from both the December 2021 PSF and December 2022 PSF. After performing the trims outlined in our methodology, we used the LTCH PPS standard Federal payment rate case counts from the FY 2022 MedPAR file (classified using proposed Version 41 of the GROUPER)

to calculate case-weighted average CCRs. Based on this data, we calculated a December 2021 national average case-weighted CCR of 0.235395 and a December 2022 national average case-weighted CCR of 0.229631. We then calculated the proposed national CCR adjustment factor by dividing the December 2022 national average case-weighted CCR by the December 2021 national average case-weighted CCR. This results in a proposed 1-year national CCR adjustment factor of 0.975513. When calculating the proposed 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 December 2022 PSF or whose CCR was missing in the December 2022 PSF. For all other providers, we multiplied their CCR from the December 2022 PSF by the proposed 1-year national CCR adjustment factor of 0.975513.

(3) Proposed Fixed-Loss Amount for LTCH PPS Standard Federal Payment Rate Cases for FY 2024

In this proposed rule, for FY 2024, using the best available data and the steps described previously, we calculated a proposed 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 proposed payment rates and policies for these cases presented in this proposed rule). Consistent with our historical practice, we are proposing to 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 December 2022 update of the FY 2022 MedPAR file adjusted for charge inflation and adjusted CCRs from the December 2022 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 proposing a fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2024 of $94,378 that would result in estimated outlier payments projected to be equal to 7.975 percent of estimated FY 2024 payments for such cases. We also are proposing to continue 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 proposed adjusted LTCH PPS standard Federal payment rate payment and the proposed fixed-loss amount for LTCH PPS standard Federal payment rate cases of $94,378).

The proposed fixed-loss amount for FY 2024 ($94,378) is significantly higher than the fixed-loss amount for FY 2023 ($38,518). Each year the fixed-loss amount is determined prospectively based on the best available data at the time. There is typically a 2-year lag between the ratesetting year and the claims data available for ratesetting. For example, as described previously, we used standard Federal payment rate cases from the FY 2022 MedPAR file to compute the proposed fixed-loss amount for FY 2024. The average estimated cost per discharge for LTCH PPS standard Federal payment rate cases has risen considerably in recent years, primarily due to a significant increase in billed charges. The average charge per standard Federal payment rate case increased approximately 11 percent and 14 percent in FY 2021 and FY 2022, respectively. Using the FY 2021 and FY 2022 MedPAR files, we estimate that actual high cost outlier payments accounted for 11.1 and 11.7 percent of total LTCH PPS standard Federal payment rate payments in FY 2021 and FY 2022, respectively. These percentages are much higher than the budget neutral target of 7.975 percent that we modelled, using the best available data at the time, when determining the FY 2021 fixed-loss amount of $27,195 (85 FR 59056) and the FY 2022 fixed-loss amount of $33,015 (86 FR 45566). Using the FY 2021 and FY 2022 MedPAR files, we currently estimate that for actual high cost outlier payments to have accounted for 7.975 percent of total LTCH PPS standard Federal payment rate payments in FY 2021 and FY 2022, the fixed-loss amounts would have needed to been set at approximately $47,550 and $60,650, respectively. Furthermore, as discussed in Appendix A to this proposed rule, we currently model that high cost outlier payments in FY 2023 will account for 12.7 of total LTCH PPS standard Federal payment rate payments. Based on this model, we estimate that the FY 2023 fixed-loss amount would have needed to have been set at approximately $75,000 to meet the requirement that high cost outlier payments account for 7.975 percent of total LTCH PPS standard Federal payment rate payments in FY 2023.

For the reasons discussed previously, we believe a large increase to the fixed-loss amount is warranted to ensure that estimated outlier payments in FY 2024 return to our statutorily required budget neutral target of 7.975 percent. However, we acknowledge that the proposed increase is substantial. Therefore, we are soliciting comments on our proposed methodology for determining the fixed-loss amount for FY 2024. As described previously, our methodology for modelling the fixed-loss amount requires certain assumptions. For example, through our charge inflation factor, we assume that billed charges will continue to increase, in general, at the rate observed in the most recently available data. Similarly, through our CCR adjustment factor, we assume that CCRs for LTCHs will continue to change, in general, at the rate observed in the most recently available data. We are seeking comments on all aspects of our proposed methodology, including the assumptions underlying the methodology for modelling the fixed-loss amount, and whether there are any modifications to the methodology or the assumptions underlying it that may 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. We remind the reader that 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 will consider comments received when finalizing our methodology for determining the fixed-loss amount for LTCH PPS standard Federal payment rate cases for FY 2024 in the final rule.

4. Proposed 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 proposed rule, we are proposing 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 proposed 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 proposed 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, consistent with past practice, we are proposing 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 proposed IPPS fixed-loss amount. That is, we are proposing a fixed-loss amount for site neutral payment rate cases of $40,732, which is the same proposed FY 2024 IPPS fixed-loss amount discussed in section II.A.4.i.(2). of the Addendum to this proposed rule. Accordingly, for FY 2024, we are proposing to calculate a 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 proposed fixed-loss amount for site neutral payment rate cases of $40,732).

In establishing a 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, we are proposing to continue this policy.

As discussed earlier, consistent with the IPPS HCO payment threshold, we estimate the proposed 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, we are proposing to apply 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 proposed HCO budget neutrality adjustment would not be applied to the HCO portion of the site neutral payment rate amount (81 FR 57309).

E. Proposed 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 statutory changes to the Medicare DSH payment adjustment methodology in the calculation of the ''IPPS comparable amount'' and the ''IPPS equivalent amount'' under the LTCH PPS, we stated 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 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).

For FY 2024, as discussed in greater detail in section IV.E.2.b. of the preamble of this proposed 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 65.71 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 49.28 percent (the product of 75 percent and 65.71 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 74.28 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 + 49.28 percent = 74.28 percent).

Therefore, for FY 2024, we are proposing 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 are proposing that, if more recent data became available, we would use that data to determine this factor in the final rule.

F. Computing the Proposed 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 proposed FY 2024 values are shown in Tables 12A through 12B listed in section VI. of the Addendum to this proposed rule 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 proposed FY 2024 factors are shown in the chart in section V.C. of this Addendum) in accordance with § 412.525(b). In this proposed rule, we are proposing to establish an LTCH PPS standard Federal payment rate for FY 2024 of $47,948.15, as discussed in section V.A. of the Addendum to this proposed rule. We illustrate the methodology to adjust the proposed LTCH PPS standard Federal payment rate for FY 2024, applying our proposed 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 proposed FY 2024 LTCH PPS wage index value of 1.0431 (as shown in Table 12A listed in section VI. of the Addendum to this proposed rule). The Medicare patient case is classified into proposed MS–LTC–DRG 189 (Pulmonary Edema & Respiratory Failure), which has a proposed relative

weight for FY 2024 of 0.9410 (as shown in Table 11 listed in section VI. of the Addendum to this proposed rule). 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 proposed Federal prospective payment for this Medicare patient case in FY 2024, we computed the wage-adjusted Federal prospective payment amount by multiplying the unadjusted proposed FY 2024 LTCH PPS standard Federal payment rate ($47,948.15) by the proposed labor-related share (68.4 percent) and the proposed wage index value (1.0431). This wage-adjusted amount was then added to the proposed nonlabor-related portion of the unadjusted proposed LTCH PPS standard Federal payment rate (31.6 percent; adjusted for cost of living, if applicable) to determine the adjusted proposed LTCH PPS standard Federal payment rate, which is then multiplied by the proposed MS–LTC–DRG relative weight (0.9410) to calculate the total adjusted proposed LTCH PPS standard Federal prospective payment for FY 2024 ($46,449.34). The table illustrates the components of the calculations in this example.

Unadjusted Proposed LTCH PPS Standard Federal Prospective Payment Rate	$47,948.15
Proposed Labor-Related Share	x 0.684
Proposed Labor-Related Portion of the LTCH PPS Standard Federal Payment Rate	= $32,796.53
Proposed Wage Index (CBSA 16984)	x 1.0431
Proposed Wage-Adjusted Labor Share of the LTCH PPS Standard Federal Payment Rate	= $34,210.06
Proposed Nonlabor-Related Portion of the LTCH PPS Standard Federal Payment Rate ($47,948.15 x 0.316)	+ $15,151.62
Adjusted Proposed LTCH PPS Standard Federal Payment Amount	= $49,361.68
Proposed MS-LTC-DRG 189 Relative Weight	x 0.9410
Total Adjusted Proposed LTCH PPS Standard Federal Prospective Payment	= $46,449.34

VI. Tables Referenced in This Proposed Rule Generally Available on the CMS Website

This section lists the tables referred to throughout the preamble of this proposed 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 proposed 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 proposed 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 proposed rule, we are making 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 this proposed 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 proposed rule should contact Michael Treitel at (410) 786–4552.

The following IPPS tables for this proposed 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 Proposed Rule Home Page'' or ''Acute Inpatient-Files-for Download.''

Table 2.—Case-Mix Index and Wage Index Table by CCN—FY 2024 Proposed Rule
Table 3.—Proposed Wage Index Table by CBSA—FY 2024 Proposed Rule
Table 4A.—Proposed List of Counties Eligible for the Out-Migration Adjustment under Section 1886(d)(13) of the Act—FY 2024 Proposed Rule
Table 4B.—Proposed Counties Redesignated Under Section 1886(d)(8)(B) of the Act (LUGAR Counties)—FY 2024 Proposed Rule
Table 5.—Proposed List of Medicare Severity Diagnosis-Related Groups (MS–DRGs), Relative Weighting Factors, and Geometric and Arithmetic Mean Length of Stay—FY 2024
Table 6A.—New Diagnosis Codes—FY 2024
Table 6B.—New Procedure Codes—FY 2024
Table 6C.—Invalid Diagnosis Codes—FY 2024
Table 6E.—Revised Diagnosis Code Titles—FY 2024
Table 6G.1.—Proposed Secondary Diagnosis Order Additions to the CC Exclusions List—FY 2024
Table 6G.2.—Proposed Principal Diagnosis Order Additions to the CC Exclusions List—FY 2024
Table 6H.1.—Proposed Secondary Diagnosis Order Deletions to the CC Exclusions List—FY 2024
Table 6H.2.—Proposed Principal Diagnosis Order Deletions to the CC Exclusions List—FY 2024
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

Table 6J.2.—Proposed Deletions to the CC List—FY 2024

Table 6P.—ICD–10–CM and ICD–10–PCS Codes for Proposed MS–DRG and MCE Changes—FY 2024 (Table 6P contains multiple tables, 6P.1a. through 6P.9a that include the ICD–10–CM and ICD–10–PCS code lists relating to specific proposed MS–DRG and MCE changes or other analyses). In addition, Table 6P.10—Potential MS–DRG Changes With Application of the NonCC Subgroup Criteria and Detailed Data Analysis—FY 2024 (Table 6P.10 contains multiple tables, 6P.10a through 6P.10f that include the list of MS–DRGs and data analyses relating to application of the NonCC subgroup criteria). These tables are referred to throughout section II.C. of the preamble of this proposed rule.

Table 8A.—Proposed FY 2024 Statewide Average Operating Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals (Urban and Rural)

Table 8B.—Proposed FY 2024 Statewide Average Capital Cost-to-Charge Ratios (CCRs) for Acute Care Hospitals

Table 10.—Codes Provided by FY 2024 New Technology Add-On Payment Applicants for Their Cost Analyses

Table 16.—Proxy Hospital Value-Based Purchasing (VBP) Program Adjustment Factors for FY 2024

Table 18.—Proposed FY 2024 Medicare DSH Uncompensated Care Payment Factor 3

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–P:

Table 8C.—Proposed FY 2024 Statewide Average Total Cost-to-Charge Ratios (CCRs) for LTCHs (Urban and Rural)

Table 11.—Proposed 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.—Proposed LTCH PPS Wage Index for Urban Areas for Discharges Occurring From October 1, 2023, Through September 30, 2024

Table 12B.—Proposed LTCH PPS Wage Index for Rural Areas for Discharges Occurring From October 1, 2023, Through September 30, 2024

TABLE 1A.—PROPOSED 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 = 2.8 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0. 55 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 2.05 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
$4,410.86	$2,114.08	$4,314.32	$2,067.81	$4,378.68	$2,098.66	$4,282.14	$2,052.39

TABLE 1B.—PROPOSED 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 = 2.8 Percent)		Hospital Submitted Quality Data and is NOT a Meaningful EHR User (Update = 0.55 Percent)		Hospital Did NOT Submit Quality Data and is a Meaningful EHR User (Update = 2.05 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
$4,045.46	$2,479.48	$3,956.92	$2,425.21	$4,015.95	$2,461.39	$3,927.41	$2,407.12

TABLE 1C.—PROPOSED 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 = 2.8)		Hospital is NOT a Meaningful EHR User and Wage Index Less Than or Equal to 1 (Update = 0.55)	
	Labor	Nonlabor	Labor	Nonlabor	Labor	Nonlabor
National[1]	Not Applicable	Not Applicable	$4,045.46	$2,479.48	$3,956.92	$2,425.21

[1] For FY 2024, there are no CBSAs in Puerto Rico with a national wage index greater than 1.

TABLE 1D.—PROPOSED CAPITAL STANDARD FEDERAL PAYMENT RATE—FY 2024

	Rate
National	$505.54

TABLE 1E.—PROPOSED LTCH PPS STANDARD FEDERAL PAYMENT RATE--FY 2024

	Full Update (2.9 Percent)	Reduced Update* (0.9 Percent)
Standard Federal Rate	$47,948.15	$47,016.21

* 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 proposed rule is necessary in order 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 proposed 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 proposed changes in this proposed rule, such as the proposed updates to the IPPS and LTCH PPS rates, and the proposals 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 proposed changes would 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. Proposed 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 proposed rule, we are proposing to update the national standardized amount for inpatient hospital operating costs by the proposed applicable percentage increase of 2.8 percent (that is, a 3.0 percent market basket update with a proposed reduction of 0.2 percentage point for the productivity adjustment). We are also proposing to apply the proposed applicable percentage increase (including the market basket update and the proposed 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 would receive a proposed applicable percentage increase of 2.05 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 would receive a proposed applicable percentage increase of 0.55 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 would receive a proposed 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. Proposed 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.8. of this proposed rule, beginning with new technology add-on payment applications for FY 2025, we are proposing, for technologies that are not already 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 are also proposing 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 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. Proposed 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, 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 proposed 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 proposing to continue the low wage index hospital policy and the related budget neutrality adjustment.

d. Proposed Modification to the Rural Wage Index Calculation Methodology

As discussed in section III.G.1 of the preamble of this proposed 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 proposing 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 proposed rule, as required by section 1886(r)(2) of the Act, we are proposing to update our estimates of the three factors 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 IHS and Tribal hospitals and hospitals located in Puerto Rico to help prevent undue long-term financial disruption to these hospitals due to discontinuing use of the low-income insured days proxy in the uncompensated care payment methodology for these providers.

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 proposed 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 in order 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 proposed rule, we propose 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. Proposed Update to the LTCH PPS Payment Rates

As described in section VIII.C.2. of the preamble of this proposed rule, in order to update payments to LTCHs using the best available data, we are proposing to update the LTCH PPS standard Federal payment rate by 2.9 percent (that is, a 3.1 percent market basket update with a proposed 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 proposed rule, would receive a proposed update of 0.9 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, and links the quality data submission 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, and links 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 in order 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 Proposed 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 are proposing to codify those requirements at 42 CFR 488.70. We are also proposing 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 proposed 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 facilitate compliance with the process for requesting an expansion exception, we are proposing to revise 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 proposing to reinstate, 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 proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $100 million or more in any 1 year, or adversely and

materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities ; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in the Executive order.

A regulatory impact analysis (RIA) must be prepared for rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1)) greater than $100 million or more in any one year. Based on our estimates, OMB's Office of Information and Regulatory Affairs has determined this rulemaking exceeds the $100 million threshold under section 3(f)(1). Accordingly, 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 proposed regulations, and the Departments have provided the following assessment of their impact.

We estimate that the proposed changes for FY 2023 acute care hospital operating and capital payments would redistribute amounts in excess of $100 million to acute care hospitals. The proposed applicable percentage increase to the IPPS rates required by the statute, in conjunction with other proposed payment changes in this proposed rule, would result in an estimated $2.7 billion increase in FY 2024 payments, primarily driven by: (a) a combined $3.2 billion increase in FY 2024 operating payments, including uncompensated care payments, low volume hospital payments, and FY 2024 capital payments and (b) a decrease of $ 0.466 million resulting from estimated changes in new technology add-on payments. These proposed 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 a decrease in payments by approximately $24 million in FY 2024 relative to FY 2023.

Our operating payment impact estimate includes the proposed 2.8 percent hospital update to the standardized amount (which includes the proposed 3.0 percent market basket update reduced by the proposed 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 proposed 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 proposed 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 proposed 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 proposed changes in this proposed 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 proposed changes would ensure that the outcomes of the prospective payment systems are reasonable and equitable, while avoiding or minimizing unintended adverse consequences.

Because this proposed rule contains a range of policies, we refer readers to the section of the proposed rule where each policy is discussed. These sections include the rationale for our decisions, including the need for the proposed policy.

D. Limitations of Our Analysis

The following quantitative analysis presents the projected effects of our proposed policy changes, as well as statutory changes effective for FY 2024, on various hospital groups. We estimate the effects of individual proposed 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 proposed policies in the discussion of those proposed 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 25 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 3,130 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 1,426 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 proposed changes to the prospective payment systems for these IPPS-excluded hospitals and units are not included in this proposed rule. The impact of the proposed 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 Proposed Policy Changes Under the IPPS for Operating Costs

1. Basis and Methodology of Estimates

In this proposed rule, we are announcing proposed policy changes and payment rate updates for the IPPS for FY 2024 for operating costs of acute care hospitals. The proposed FY 2024 updates to the capital payments to acute care hospitals are discussed in section I.I. of this Appendix.

Based on the overall proposed percentage change in payments per case estimated using our payment simulation model, we estimate that total FY 2024 operating payments would increase by 2.8 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 proposed changes to each system. This section deals with the proposed 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 proposed changes in this proposed rule. As discussed in section I.E. of the preamble to this proposed rule, we believe that the FY 2022 claims data is the best available data for purposes of the proposed FY 2024 ratesetting and this impact analysis reflects the use of that data. However, there are other proposed changes for which we do not have data available that would allow us to estimate the payment impacts using this model. For those proposed 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 proposed changes in payments per case presented in this section are taken from the FY 2022 MedPAR file, as discussed previously in this proposed rule, and the most current Provider-Specific File (PSF) that is used for payment purposes. Although the analyses of the proposed 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 proposed 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 proposed 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 proposed payments under the capital IPPS, and the impact of proposed 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 proposed changes:

- The effects of the application of the proposed applicable percentage increase of 2.8 percent (that is, a proposed 3.0 percent market basket update with a proposed reduction of 0.2 percentage point for the productivity adjustment), and the proposed applicable percentage increase (including the proposed market basket update and the proposed productivity adjustment) to the hospital-specific rates.
- The effects of the proposed changes to the relative weights and MS–DRG GROUPER.
- The effects of the proposed 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 proposed FY 2024 wage index.
- The effects of the geographic reclassifications by the MGCRB (as of publication of this proposed rule) that will be effective for FY 2024.
- The effects of the proposed rural floor with the application of the national budget neutrality factor to the wage index and the proposed change to the rural wage index and rural floor methodology.
- The effects of the proposed imputed floor wage index adjustment. This provision is not budget neutral.
- The effects of the proposed 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 proposed FY 2024 policies relative to payments based on FY 2023 policies.

To illustrate the impact of the proposed 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 update. Therefore, we are proposing that, 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 2.05 percent. At the time this impact was prepared, 63 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 proposed 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 percentage increase determined without regard to section 1886(b)(3)(B)(ix), (xi), or (xii) of the Act. Therefore, we are proposing that 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 0.55 percent. At the time this impact analysis was prepared, 132 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 proposed 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 proposed applicable percentage increase of −0.2 percent, which reflects a one-quarter reduction of the market basket update for failure to submit quality data and a three-quarter reduction of the market basket update for being identified as not a meaningful EHR user. At the time this impact was prepared, 32 hospitals are estimated to not receive the full market basket rate-of-increase for FY 2023 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 proposed policy change, statutory or otherwise, is then added incrementally to this baseline, finally arriving at an FY 2024 model incorporating all of the proposed changes. This simulation allows us to isolate the effects of each change.

Our comparison illustrates the proposed 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 proposing to update the standardized amounts for FY 2024 using a proposed applicable percentage increase of 2.8 percent. This includes the FY 2024 proposed IPPS operating hospital market basket increase of 3.0 percent with a proposed 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 a proposed update of 2.05 percent.

This update includes a reduction of one-quarter of the market basket update for failure to submit these data. Hospitals that do comply with the quality data submission requirements but are not meaningful EHR users would receive a proposed update of 0.55 percent, which includes a reduction of three-quarters of the market basket update. Furthermore, hospitals that do not comply with the quality data submission requirements and also are not meaningful EHR users would receive a proposed 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 2.8 percent, if the hospital submits quality data and is a meaningful EHR user.

A second significant factor that affects the proposed 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 proposed 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 3,130 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 2,414 hospitals located in urban areas and 716 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 1,319, respectively.

The next three groupings examine the impacts of the proposed 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 1,903 nonteaching hospitals in our analysis, 949 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 proposed 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 127 RRCs, 256 SCHs, 115 MDHs, 120 hospitals that are both SCHs and RRCs, and 20 hospitals that are both MDHs and RRCs. Of the hospitals that are reclassified from urban to rural, there are 492 RRCs, 45 SCHs, 30 MDHs, 41 hospitals that are both SCHs and RRCs, and 12 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.

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TABLE I.—IMPACT ANALYSIS OF PROPOSED CHANGES TO THE IPPS FOR OPERATING COSTS FOR FY 2024

	Number of Hospitals[1]	Proposed Hospital Rate Update (1)[2]	Proposed FY 2024 Weights and DRG Changes with Application of Budget Neutrality (2)[3]	Proposed FY 2024 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2024 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Imputed Floor, Frontier State Wage Index and Outmigration Adjustment (6)[7]	All Proposed FY 2024 Changes (7)[8]
All Hospitals	3,130	2.8	0.0	0.0	0.0	0.0	0.4	2.8
By Geographic Location:								
Urban hospitals	2,414	2.8	0.0	0.0	-0.2	0.0	0.4	2.8
Rural hospitals	716	2.7	0.1	-0.3	2.2	-0.5	0.1	3.3
Bed Size (Urban):								
0-99 beds	648	2.7	-0.1	-0.2	-0.9	0.3	0.6	2.5
100-199 beds	693	2.8	0.1	0.0	-0.4	0.4	0.4	2.9
200-299 beds	415	2.8	0.1	0.0	0.0	0.3	0.5	3.1
300-499 beds	405	2.8	0.0	0.0	0.2	0.5	0.3	3.4
500 or more beds	251	2.7	-0.1	0.0	-0.4	-0.5	0.4	2.3
Bed Size (Rural):								0.0
0-49 beds	362	2.6	0.0	-0.1	1.3	-0.4	0.2	2.9
50-99 beds	190	2.7	0.2	0.0	1.8	-0.4	0.2	3.6
100-149 beds	86	2.7	0.2	-0.2	2.3	-0.4	0.1	3.6
150-199 beds	45	2.8	0.2	-0.5	2.1	-0.6	0.0	3.1
200 or more beds	33	2.8	0.0	-0.7	3.2	-0.7	0.2	3.3
Urban by Region:								
New England	108	2.8	0.0	-0.4	0.7	-0.6	0.9	-0.2
Middle Atlantic	292	2.8	0.1	1.0	0.5	-0.1	1.0	4.5
East North Central	372	2.8	0.0	-0.5	-0.4	-0.7	0.1	1.7
West North Central	156	2.8	-0.1	-0.3	-0.6	-0.7	0.6	1.5
South Atlantic	403	2.8	0.0	-0.1	-0.8	-0.8	0.4	1.9
East South Central	138	2.8	0.0	0.0	-0.7	-0.7	0.1	2.5
West South Central	359	2.8	0.0	-0.1	-0.9	-0.7	0.1	1.9
Mountain	176	2.8	-0.1	-0.3	-0.8	-0.6	0.4	0.1
Pacific	360	2.7	0.0	0.1	0.8	3.2	0.1	6.4
Puerto Rico	50	2.7	0.2	-1.9	-1.6	-0.1	0.1	2.2
Rural by Region:								
New England	19	2.8	0.0	-1.2	0.9	-0.6	0.2	1.9
Middle Atlantic	47	2.8	0.0	-0.2	6.4	-0.7	0.0	7.0
East North Central	113	2.8	0.0	-0.3	1.4	-0.4	0.0	2.8
West North Central	85	2.7	0.1	-0.1	0.5	-0.2	0.3	2.9
South Atlantic	107	2.7	0.3	0.2	2.2	-0.6	0.1	3.1
East South Central	140	2.7	0.2	-0.8	2.6	-0.7	0.0	3.2
West South Central	135	2.7	0.1	-0.1	2.6	-0.6	0.0	3.1
Mountain	46	2.4	0.0	0.0	0.1	-0.1	0.8	2.2
Pacific	24	2.8	0.3	-0.2	3.8	-0.4	0.0	5.1
By Payment Classification:								
Urban hospitals	1,811	2.8	0.0	0.0	-1.0	0.5	0.6	3.2
Rural areas	1,319	2.8	0.0	0.0	1.0	-0.5	0.2	2.4
Teaching Status:								

	Number of Hospitals[1]	Proposed Hospital Rate Update (1)[2]	Proposed FY 2024 Weights and DRG Changes with Application of Budget Neutrality (2)[3]	Proposed FY 2024 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2024 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Imputed Floor, Frontier State Wage Index and Outmigration Adjustment (6)[7]	All Proposed FY 2024 Changes (7)[8]
Nonteaching	1,903	2.8	0.0	-0.1	0.1	0.5	0.3	3.2
Fewer than 100 residents	949	2.8	0.0	0.0	0.1	0.0	0.5	2.9
100 or more residents	278	2.7	0.0	0.1	-0.2	-0.3	0.4	2.5
Urban DSH:								
Non-DSH	365	2.8	-0.2	0.1	-1.0	-0.5	0.9	2.3
100 or more beds	1,093	2.8	0.1	0.0	-1.0	0.6	0.6	3.4
Less than 100 beds	353	2.8	0.1	0.0	-0.9	0.7	0.5	2.8
Rural DSH:								
Non-DSH	110	2.7	-0.2	0.1	0.6	-0.8	0.2	1.2
SCH	257	2.7	0.2	0.0	0.3	-0.1	0.0	3.1
RRC	709	2.8	0.0	-0.1	1.0	-0.5	0.2	2.5
100 or more beds	32	2.7	-0.1	0.5	0.0	-0.7	0.1	2.4
Less than 100 beds	211	2.7	0.1	-0.1	2.4	-0.7	0.2	3.6
Urban teaching and DSH:								
Both teaching and DSH	639	2.8	0.1	0.0	-1.0	0.3	0.7	3.1
Teaching and no DSH	61	2.8	-0.3	0.5	-1.0	-0.5	1.0	2.8
No teaching and DSH	807	2.8	0.1	0.0	-0.9	1.4	0.3	3.9
No teaching and no DSH	304	2.8	-0.2	-0.2	-1.0	-0.5	0.7	1.9
Special Hospital Types:								
RRC	127	2.8	0.0	-0.6	2.7	-0.6	0.3	3.1
RRC with Section 401 Rural Reclassification	492	2.8	-0.1	0.0	0.9	-0.6	0.2	2.3
SCH	256	2.7	0.1	0.0	0.4	-0.1	0.1	3.0
SCH with Section 401 Rural Reclassification	45	2.8	0.2	0.0	0.1	0.0	0.0	3.1
SCH and RRC	121	2.7	0.2	-0.2	1.1	-0.3	0.1	3.2
SCH and RRC with Section 401 Rural Reclassification	41	2.8	-0.1	0.0	0.1	0.1	0.0	2.7
MDH	115	2.7	0.0	-0.2	1.7	-0.5	0.5	3.5
MDH with Section 401 Reclassification	30	2.8	0.2	-0.2	0.6	-0.3	0.0	3.3
MDH and RRC	20	2.8	0.2	-0.1	0.9	-0.3	0.1	3.0
MDH and RRC with Section 401 Reclassification	12	2.8	0.2	0.0	0.6	0.0	0.1	3.0
Type of Ownership:								
Voluntary	1,921	2.8	0.0	0.1	0.1	-0.1	0.5	2.8
Proprietary	777	2.8	0.1	-0.3	-0.3	0.6	0.2	2.8
Government	431	2.7	0.1	0.0	-0.4	0.1	0.1	3.0
Medicare Utilization as a Percent of Inpatient Days:								
0-25	994	2.7	0.1	0.1	-0.6	0.4	0.2	3.2
25-50	1,946	2.8	0.0	-0.1	0.3	-0.2	0.5	2.6
50-65	138	2.7	0.0	0.1	-0.1	1.0	0.6	3.5
Over 65	25	2.5	0.1	0.3	1.0	-0.2	0.0	3.8
Medicaid Utilization as a Percent of Inpatient Days:								
0-25	2,065	2.8	-0.1	-0.1	0.0	-0.3	0.4	2.5
25-50	947	2.8	0.1	0.1	-0.1	0.3	0.4	3.2
50-65	86	2.6	0.6	0.6	-0.8	3.1	0.1	6.4
Over 65	32	2.6	0.9	0.4	-1.3	4.8	0.0	8.8
FY 2024 Reclassifications:								
All Reclassified Hospitals	1,134	2.8	0.0	0.0	0.9	-0.3	0.2	2.5
Non-Reclassified Hospitals	1,996	2.8	0.0	0.0	-1.1	0.4	0.6	3.2
Urban Hospitals Reclassified	939	2.8	0.0	0.0	0.9	-0.3	0.2	2.5

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	Number of Hospitals[1]	Proposed Hospital Rate Update (1)[2]	Proposed FY 2024 Weights and DRG Changes with Application of Budget Neutrality (2)[3]	Proposed FY 2024 Wage Data with Application of Wage Budget Neutrality (3)[4]	FY 2024 MGCRB Reclassifications (4)[5]	Proposed Rural Floor with Application of National Rural Floor Budget Neutrality (5)[6]	Application of the Proposed Imputed Floor, Frontier State Wage Index and Outmigration Adjustment (6)[7]	All Proposed FY 2024 Changes (7)[8]
Urban Non-Reclassified Hospitals	1,490	2.8	0.0	0.0	-1.5	0.5	0.7	3.1
Rural Hospitals Reclassified Full Year	304	2.8	0.2	-0.3	2.7	-0.5	0.0	3.3
Rural Non-Reclassified Hospitals Full Year	397	2.6	0.1	-0.3	1.1	-0.4	0.3	3.5
All Section 401 Rural Reclassified Hospitals	660	2.8	0.0	0.0	0.8	-0.5	0.2	2.3
Other Reclassified Hospitals (Section 1886(d)(8)(B))	57	2.7	0.1	-0.4	4.1	-0.7	0.2	3.7

[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 proposed hospital rate update, including the proposed 2.8 percent update to the national standardized amount and the hospital-specific rate (the proposed 3.0 percent market basket update reduced by 0.2 percentage point for the proposed productivity adjustment).

[3] This column displays the payment impact of the proposed changes to the Version 41 GROUPER, the proposed 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 proposed recalibration budget neutrality factors of 1.001376 and 0.999925.

[4] This column displays the payment impact of the proposed 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 proposed wage budget neutrality factor. The proposed wage budget neutrality factor is 1.000943.

[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 proposed geographic budget neutrality factor of 0.980959.

[6] This column displays the effects of the proposed rural floor and the proposed 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 proposed rural floor budget neutrality factor applied to the wage index is 0.981145.

[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 Proposed Hospital Update (Column 1)

As discussed in section V.A. of the preamble of this proposed rule, this column includes the proposed hospital update, including the proposed 3.0 percent market basket update reduced by the proposed 0.2 percentage point for the productivity adjustment. As a result, we are proposing to make a 2.8 percent update to the national standardized amount. This column also includes the proposed update to the hospital-specific rates which includes the proposed 3.0 percent market basket update reduced by the proposed 0.2 percentage point for the productivity adjustment. As a result, we are proposing to make a 2.8 percent update to the hospital-specific rates.

Overall, hospitals would experience a 2.8 percent increase in payments primarily due to the combined effects of the proposed hospital update to the national standardized amount and the proposed hospital update to the hospital-specific rate.

b. Effects of the Proposed Changes to the MS–DRG Reclassifications and Relative Cost-Based Weights With Recalibration Budget Neutrality (Column 2)

Column 2 shows the effects of the proposed changes to the MS–DRGs and relative weights with the application of the proposed 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 in order 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 proposed 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.E. of the preamble of this proposed rule, for FY 2024, we calculated the proposed MS–DRG relative weights using the FY 2022 MedPAR data grouped to the proposed Version 41 (FY 2024) MS–DRGs. The proposed reclassification changes to the GROUPER are described in more detail in section II.G. of the preamble of this proposed rule.

The ''All Hospitals'' line in Column 2 indicates that proposed changes due to the MS–DRGs and relative weights would result in a 0.0 percent change in payments with the application of the proposed recalibration budget neutrality factor of 1.001376 and the proposed recalibration cap budget neutrality factor of 0.999925 to the standardized amount.

c. Effects of the Proposed Wage Index Changes (Column 3)

Column 3 shows the impact of the proposed updated wage data, with the application of the proposed 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 proposed 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 proposed 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 proposed payment parameters constant in this simulation. That is, Column 3 shows the proposed 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 proposed FY 2024 pre-reclassification wage index with the proposed 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 proposed 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 proposed 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 2023, we are proposing to calculate the proposed wage budget neutrality factor to ensure that payments under updated wage data and the proposed 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 proposed FY 2023 wage budget neutrality factor is 1.000943 and the overall proposed payment change is 0 percent.

Column 3 shows the impacts of updating the wage data. Overall, the new wage data and the proposed labor-related share, combined with the proposed 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 5.3 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 proposed 5.3 percent increase in the national average hourly wage. Of the 3,071 hospitals with wage data for both FYs 2023 and 2024, 1,337 or 43.5 percent would experience an average hourly wage increase of 5.3 percent or more.

The following chart compares the shifts in wage index values for hospitals due to proposed 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 proposed 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 proposed pre-reclassified wage index figures in the following chart may illustrate a somewhat larger or smaller proposed change than would occur in a hospital's payment wage index and total payment.

The following chart shows the projected impact of proposed changes in the area wage index values for urban and rural hospitals.

Proposed FY 2023 Percentage Change in Area Wage Index Values	Number of Hospitals	
	Urban	Rural
Increase 10 percent or more	7	1
Increase greater than or equal to 5 percent and less than 10 percent	74	0
Increase or decrease less than 5 percent	2,212	685
Decrease greater than or equal to 5 percent and less than 10 percent	79	9
Decrease 10 percent or more	4	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). The proposed 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 proposed rule, this column also reflects the proposed 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) when implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. Consistent with this proposal, beginning with FY 2024 we are also proposing to 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.

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 proposing to apply an adjustment of 0.980959 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 proposed 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 2.2 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 proposed rule and available via the internet on the CMS website reflects the reclassifications for FY 2024.

e. Effects of the Proposed 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 proposed rule, section 4410 of Public Law 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 proposed rural floor.

As discussed in section III.G.1 of this proposed rule, this column also reflects the proposed 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) when implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. Consistent with this proposal, beginning with FY 2024 we are also proposing to include the data of all § 412.103 hospitals (including those that have an MGCRB reclassification) 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 proposed FY 2024 rural floor budget neutrality factor to be applied to the wage index of 0.981145, which would reduce wage indexes by −1.9 percent compared to the rural floor provision not being in effect.

Column 5 shows the projected impact of the proposed 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 proposed change to the rural floor and rural wage index methodology. The column compares the proposed post-reclassification FY 2024 wage index of providers before the rural floor adjustment and the proposed post-reclassification FY 2024 wage index of providers with the rural floor adjustment based on the OMB labor market area delineations and with the proposed change to the rural floor and the rural wage index methodology applied.

We estimate that 596 hospitals would receive the rural floor in FY 2024. All IPPS hospitals in our model would have their wage indexes reduced by the proposed rural floor budget neutrality adjustment of 0.981145. We project that, in aggregate, rural hospitals would experience a 0.5 percent decrease in payments as a result of the application

of the proposed rural floor budget neutrality 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 nonrural 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 3.2 percent increase in payments primarily due to the application of the rural floor in California.

f. Effects of the Application of the Proposed Imputed Floor, Proposed Frontier State Wage Index and Proposed 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 $249 million. There are an estimated 81 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 43 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 $58 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 159 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 $46 million.

g. Effects of All FY 2024 Proposed Changes (Column 7)

Column 7 shows our estimate of the proposed changes in payments per discharge from FY 2023 and FY 2024, resulting from all changes reflected in this proposed rule for FY 2024. It includes combined effects of the year-to-year change of the previous columns in the table.

The proposed average increase in payments under the IPPS for all hospitals is approximately 2.8 percent for FY 2024 relative to FY 2023 and for this row is primarily driven by the proposed changes reflected in Column 1. Column 7 includes the proposed annual hospital update of 2.8 percent to the national standardized amount. This proposed annual hospital update includes the proposed 3.0 percent market basket update reduced by the proposed 0.2 percentage point productivity adjustment. Hospitals paid under the hospital-specific rate would receive a 2.8 percent hospital update. As described in Column 1, the proposed annual hospital update for hospitals paid under the national standardized amount, combined with the proposed 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 2.8 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 proposed 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 are proposing to 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 0.2 percent. Therefore, our estimate of the proposed changes in payments per discharge from FY 2023 and FY 2024 in Column 7 reflects the estimated −0.2 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 proposed 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 proposed applicable percentage increase and proposed changes to policies related to MS–DRGs, geographic adjustments, and outliers are estimated to increase by 2.8 percent for FY 2024. Hospitals in urban areas would experience a 2.8 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 3.3 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.

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TABLE II.--IMPACT ANALYSIS OF PROPOSED 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 Proposed Average FY 2024 Payment Per Discharge (3)	Proposed FY 2024 Changes (4)
All Hospitals	3,130	15,696	16,143	2.8
By Geographic Location:				
Urban hospitals	2,414	16,082	16,535	2.8
Rural hospitals	716	11,694	12,083	3.3
Bed Size (Urban):				
0-99 beds	648	12,041	12,340	2.5
100-199 beds	693	12,759	13,132	2.9
200-299 beds	415	14,335	14,775	3.1
300-499 beds	405	15,880	16,420	3.4
500 or more beds	251	20,038	20,501	2.3
Bed Size (Rural):				
0-49 beds	362	9,903	10,188	2.9
50-99 beds	190	11,536	11,955	3.6
100-149 beds	86	11,325	11,730	3.6
150-199 beds	45	12,631	13,025	3.1
200 or more beds	33	13,673	14,119	3.3
Urban by Region:				
New England	108	17,934	17,900	-0.2
Middle Atlantic	292	18,773	19,619	4.5
East North Central	372	15,322	15,578	1.7
West North Central	156	15,379	15,614	1.5
South Atlantic	403	13,774	14,041	1.9
East South Central	138	13,345	13,679	2.5
West South Central	359	14,011	14,280	1.9
Mountain	176	16,193	16,205	0.1
Pacific	360	20,339	21,642	6.4
Puerto Rico	50	9,051	9,251	2.2
Rural by Region:				
New England	19	17,282	17,606	1.9
Middle Atlantic	47	11,666	12,483	7
East North Central	113	11,868	12,199	2.8
West North Central	85	12,146	12,496	2.9
South Atlantic	107	10,752	11,087	3.1
East South Central	140	10,415	10,749	3.2
West South Central	135	9,817	10,121	3.1
Mountain	46	13,781	14,087	2.2
Pacific	24	16,070	16,893	5.1
By Payment Classification:				
Urban hospitals	1,811	14,676	15,151	3.2
Rural areas	1,319	16,892	17,306	2.4
Teaching Status:				
Nonteaching	1,903	12,171	12,558	3.2
Fewer than 100 residents	949	14,412	14,836	2.9
100 or more residents	278	23,149	23,723	2.5
Urban DSH:				
Non-DSH	365	12,573	12,859	2.3
100 or more beds	1,093	15,222	15,735	3.4
Less than 100 beds	353	11,095	11,404	2.8
Rural DSH:				
Non-DSH	110	15,109	15,283	1.2
SCH	257	12,911	13,307	3.1
RRC	709	17,508	17,938	2.5
100 or more beds	32	17,973	18,402	2.4
Less than 100 beds	211	9,587	9,932	3.6
Urban teaching and DSH:				

	Number of Hospitals (1)	Estimated Average FY 2023 Payment Per Discharge (2)	Estimated Proposed Average FY 2024 Payment Per Discharge (3)	Proposed FY 2024 Changes (4)
Both teaching and DSH	639	16,571	17,087	3.1
Teaching and no DSH	61	13,835	14,228	2.8
No teaching and DSH	807	12,330	12,805	3.9
No teaching and no DSH	304	11,896	12,124	1.9
Special Hospital Types:				
RRC	127	12,161	12,540	3.1
RRC with Section 401 Rural Reclassification	492	18,361	18,780	2.3
SCH	256	12,164	12,525	3
SCH with Section 401 Rural Reclassification	45	14,992	15,450	3.1
SCH and RRC	121	13,761	14,195	3.2
SCH and RRC with Section 401 Rural Reclassification	41	16,385	16,823	2.7
MDH	115	10,028	10,382	3.5
MDH with Section 401 Reclassification	30	12,884	13,304	3.3
MDH and RRC	20	11,476	11,817	3
MDH and RRC with Section 401 Reclassification	12	13,701	14,115	3
Type of Ownership:				
Voluntary	1,921	15,748	16,194	2.8
Proprietary	777	13,700	14,085	2.8
Government	431	18,054	18,592	3
Medicare Utilization as a Percent of Inpatient Days:				
0-25	994	17,875	18,447	3.2
25-50	1,946	14,923	15,317	2.6
50-65	138	12,463	12,899	3.5
Over 65	25	8,582	8,910	3.8
Medicaid Utilization as a Percent of Inpatient Days:				
0-25	2,065	14,228	14,580	2.5
25-50	947	18,163	18,740	3.2
50-65	86	21,090	22,430	6.4
Over 65	32	21,087	22,936	8.8
FY 2024 Reclassifications:				
All Reclassified Hospitals	1,134	16,585	17,004	2.5
Non-Reclassified Hospitals	1,996	14,789	15,264	3.2
Urban Hospitals Reclassified	939	17,185	17,622	2.5
Urban Nonreclassified Hospitals	1,490	14,864	15,332	3.1
Rural Hospitals Reclassified Full Year	304	11,774	12,157	3.3
Rural Non-Reclassified Hospitals Full Year	397	11,580	11,985	3.5
All Section 401 Reclassified Hospitals:	660	18,005	18,425	2.3
Other Reclassified Hospitals (Section 1886(d)(8)(B))	57	10,962	11,364	3.7

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4. Impact Analysis of Table III: Provider Deciles by Beneficiary Characteristics

Advancing health equity is the first pillar of CMS's 2022 Strategic Framework.[757] 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 proposed rule contains a range of policies and there is a section of the proposed rule where each policy is discussed. Each section includes the rationale for our decisions, including the need for the proposed policy. The information contained in Table III is provided solely to demonstrate the quantitative effects of our proposed policies across a number of health equity dimensions and does not form the basis or rationale for the proposed 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

[757] Available at: *https://www.cms.gov/files/document/2022-cms-strategic-framework.pdf.*

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.

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. 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.

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.[758] 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.[759] 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.[760] 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

[758] *https://aspe.hhs.gov/sites/default/files/migrated_legacy_files//195046/Social-Risk-in-Medicare%E2%80%99s-VBP-2nd-Report-Executive-Summary.pdf.*

[759] *Available at: https://health.gov/healthypeople/priority-areas/social-determinants-health.*

[760] 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.*

proposed rule, where we discuss our proposal 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.

d. Behavioral Health

Beneficiaries with behavioral health diagnoses often face co-occurring physical illnesses, but often experience difficulty accessing care.[761] The combination of physical and behavioral health conditions can exacerbate both conditions and result in poorer outcomes than one condition alone.[762] Additionally, the intersection of behavioral health and health inequities is a core aspect of CMS' Behavioral Health Strategy.[763] 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.[764] Disabled beneficiaries often have complex healthcare needs and difficulty accessing care. Compared to people without disabilities, people with disabilities generally have less access to health care, have more depression and anxiety, engage more often in risky health behaviors such as smoking, and are less physically active.[765] 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.[766] 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.[767] [768] 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.[769] 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.[770] [771] [772] [773] [774] 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.

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[769] *https://www.neighborhoodatlas.medicine.wisc.edu/.*

[770] 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.*

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TABLE III. PROVIDER DECILES BY BENEFICIARY CHARACTERISTICS

Beneficiary Characteristics	Decile Group[775]	Percentile Range of Group	Decile Value Range	Estimated Average Payment Per Discharge (FY 2023)	Proposed Estimated Average Payment Per Discharge (FY 2024)	% Change
All Hospitals				$15,696	$16,143	2.8%
% Of Beneficiaries Who Are White	1	0 to 10	0.1% - 46.6%	20,285	21,209	4.6%
	2 to 5	>10 to 50	46.6% - 85.0%	17,058	17,534	2.8%
	6 to 9	>50 to 90	85.0% - 95.1%	13,869	14,230	2.6%
	10	>90 to 100	95.1% - 98.2%	11,587	11,878	2.5%
% Of Beneficiaries Who Are Black	1	0 to 10	0.0% - 0.4%	12,892	13,190	2.3%
	2 to 5	>10 to 50	0.4% - 4.2%	14,385	14,807	2.9%
	6 to 9	>50 to 90	4.2% - 24.3%	16,429	16,896	2.8%
	10	>90 to 100	24.3% - 95.9%	18,431	18,930	2.7%
% Of Beneficiaries Who Are Hispanic	1	0 to 10	0.3% - 1.1%	12,096	12,475	3.1%
	2 to 5	>10 to 50	1.1% - 2.6%	13,907	14,246	2.4%
	6 to 9	>50 to 90	2.6% - 20.4%	17,141	17,585	2.6%
	10	>90 to 100	20.4% - 96.1%	17,971	19,121	6.4%
% Of Beneficiaries Who Are Asian or Pacific Islander	1	0 to 10	0.0% - 0.2%	10,529	10,855	3.1%
	2 to 5	>10 to 50	0.2% - 0.8%	12,930	13,273	2.7%
	6 to 9	>50 to 90	0.8% - 5.0%	16,308	16,692	2.4%
	10	>90 to 100	5.0% - 95.3%	21,573	22,599	4.8%
	1	0 to 10	0.1% - 0.2%	12,183	12,403	1.8%
	2 to 5	>10 to 50	0.2% - 0.3%	15,117	15,482	2.4%

[775] 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

Beneficiary Characteristics	Decile Group[775]	Percentile Range of Group	Decile Value Range	Estimated Average Payment Per Discharge (FY 2023)	Proposed Estimated Average Payment Per Discharge (FY 2024)	% Change
% Of Beneficiaries Who Are American Indian or Alaska Native	6 to 9	>50 to 90	0.3% - 1.3%	17,042	17,648	3.6%
	10	>90 to 100	1.3% - 48.0%	15,457	15,807	2.3%
% Of Beneficiaries Who Are Multiracial	1	0 to 10	0.1% - 1.5%	13,228	13,652	3.2%
	2 to 5	>10 to 50	1.5% - 2.1%	15,216	15,615	2.6%
	6 to 9	>50 to 90	2.1% - 3.1%	16,426	16,911	3.0%
	10	>90 to 100	3.1% - 10.7%	16,809	17,349	3.2%
% Of Beneficiaries Who Are Dual (All) Enrolled During The Month Of Discharge	1	0 to 10	0.2% - 11.0%	13,358	13,537	1.3%
	2 to 5	>10 to 50	11.0% - 24.3%	14,601	14,918	2.2%
	6 to 9	>50 to 90	24.3% - 48.6%	17,042	17,609	3.3%
	10	>90 to 100	48.6% - 100.0%	19,891	21,081	6.0%
% Of Beneficiaries Who Are LIS Enrolled During The Month Of Discharge	1	0 to 10	0.2% - 12.9%	13,286	13,462	1.3%
	2 to 5	>10 to 50	12.9% - 26.9%	14,771	15,090	2.2%
	6 to 9	>50 to 90	26.9% - 51.1%	16,883	17,462	3.4%
	10	>90 to 100	51.1% - 100.0%	19,859	21,017	5.8%
% Of Beneficiaries Who Are Dual (All) or LIS Enrolled During The Month Of Discharge	1	0 to 10	0.2% - 12.9%	13,286	13,462	1.3%
	2 to 5	>10 to 50	12.9% - 27.0%	14,770	15,088	2.2%
	6 to 9	>50 to 90	27.0% - 51.1%	16,888	17,469	3.4%
	10	>90 to 100	51.1% - 100.0%	19,872	21,023	5.8%
% Of Beneficiaries With a Z code reported related to SDOH	1	0 to 10	0.1% - 0.4%	12,754	13,128	2.9%
	2 to 5	>10 to 50	0.4% - 1.7%	15,249	15,703	3.0%
	6 to 9	>50 to 90	1.7% - 6.1%	16,464	16,891	2.6%
	10	>90 to 100	6.1% - 61.4%	17,507	18,127	3.5%
% Of Beneficiaries With a Behavioral Health Diagnosis	1	0 to 10	2.9% - 37.4%	17,641	18,164	3.0%
	2 to 5	>10 to 50	37.4% - 48.8%	16,475	16,960	2.9%
	6 to 9	>50 to 90	48.8% - 58.8%	14,787	15,170	2.6%
	10	>90 to 100	58.8% - 100.0%	14,176	14,727	3.9%
% Of Beneficiaries who come from rural areas	1	0 to 10	0.0% - 1.0%	16,908	17,454	3.2%
	2 to 5	>10 to 50	1.0% - 15.7%	16,051	16,480	2.7%

Beneficiary Characteristics	Decile Group[775]	Percentile Range of Group	Decile Value Range	Estimated Average Payment Per Discharge (FY 2023)	Proposed Estimated Average Payment Per Discharge (FY 2024)	% Change
	6 to 9	>50 to 90	15.7% - 93.6%	15,218	15,655	2.9%
	10	>90 to 100	93.6% - 100.0%	11,638	12,042	3.5%
% Of Beneficiaries With ESRD coverage	1	0 to 10	0.1% - 0.7%	11,218	11,531	2.8%
	2 to 5	>10 to 50	0.7% - 3.8%	13,812	14,127	2.3%
	6 to 9	>50 to 90	3.8% - 8.2%	16,798	17,290	2.9%
	10	>90 to 100	8.2% - 81.3%	20,582	21,454	4.2%
% Of Beneficiaries with Disability	1	0 to 10	3.2% - 16.5%	14,164	14,485	2.3%
	2 to 5	>10 to 50	16.5% - 26.2%	15,431	15,780	2.3%
	6 to 9	>50 to 90	26.2% - 38.4%	16,337	16,909	3.5%
	10	>90 to 100	38.4% - 100.0%	16,915	17,695	4.6%
% Of Beneficiaries who live in an area with ADI >= 85	1	0 to 10	0.1% - 0.8%	18,821	19,365	2.9%
	2 to 5	>10 to 50	0.8% - 12.5%	16,043	16,497	2.8%
	6 to 9	>50 to 90	12.5% - 45.9%	14,450	14,858	2.8%
	10	>90 to 100	45.9% - 100.0%	11,639	12,018	3.3%

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G. Effects of Other Policy Changes

In addition to those proposed policy changes discussed previously that we are able to model using our IPPS payment simulation model, we are proposing to make various other changes in this proposed rule. As noted in section I.D. of this Appendix A, 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 proposed rule. Generally, we have limited or no specific data available with which to estimate the impacts of these proposed changes using that payment simulation model. For those proposed 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 proposed changes are discussed in this section.

1. Effects of Policy Changes Relating to New Medical Service and Technology Add-On Payments

a. Proposed FY 2024 Status of Technologies Approved for FY 2023 New Technology Add-On Payments

In section II.E.5. of the preamble of this proposed rule, we are proposing to continue to make new technology add-on payments for the 11 technologies listed in the following table in FY 2024 because these technologies would still be considered new for purposes of new technology add-on payments. Under § 412.88(a)(2), the new technology add-on payment for each case 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, our estimates in this proposed rule are based on the applicant's estimate at the time they submitted their original application and the increase in new technology add-on payments for FY 2024 as if every claim that would qualify for a new technology add-on payment would receive the maximum add-on payment. In the following table are estimates for the 11 technologies for which we are proposing to continue to make new technology add-on payments in FY 2024:

FY 2024 ESTIMATES FOR NEW TECHNOLOGY ADD-ON PAYMENTS PROPOSED TO CONTINUE FOR FY 2024

Technology Name	Estimated Cases	Proposed 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. Proposed FY 2024 Applications for New Technology Add-On Payments

In sections II.E.6. and 7. of the preamble to this proposed rule, we discuss 39 technologies for which we received applications for add-on payments for new medical services and technologies for FY 2024. We note that of the 54 applications (27 alternative and 27 traditional) we received, 15 applicants withdrew their application (7 alternative and 8 traditional) prior to the issuance of this proposed rule. As explained in the preamble to this proposed 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 proposed 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 proposed rule, and must also still meet the cost criterion.

As also discussed in section II.E.7. of the preamble of this proposed rule, we are proposing to approve 19 alternative pathway applications submitted for FY 2024 new technology add-on payments. We note, the one technology we are not proposing to approve has not provided an adequate cost analysis and we are therefore unable to determine eligibility for new technology add-on payments.

Based on preliminary information from the applicants at the time of this proposed rule, we estimate that total payments for the 20 technologies that applied under the alternative pathway, if approved, would be in excess of approximately $263 million for FY 2024. Total estimated FY 2024 payments for new technologies that are designated as a QIDP are approximately $213 million, and the total estimated FY 2024 payments for new technologies that are part of the Breakthrough Device program are approximately $50.5 million. Because cost or volume information has not yet been provided for 7 of the 20 technologies under the alternative pathway, including 1 of the

QIDP applicants, we have not included those technologies in the estimate. We did not receive any LPAD applications for add-on payments for new technologies for FY 2024. We note that the estimated payments may be updated in the final rule based on revised or additional information CMS receives prior to the final rule.

We have not yet determined whether any of the 19 technologies that applied under the traditional pathway discussed in section II.E.6. of the preamble of this proposed rule will meet the criteria for new technology add-on payments for FY 2024. Consequently, it is premature to estimate the potential payment impact of these 19 technologies for any potential new technology add-on payments for FY 2024. We note that, as in past years, if any of the technologies that applied under the traditional pathway are found to be eligible for new technology add-on payments for FY 2024, we would discuss the estimated payment impact for FY 2024 in the FY 2024 IPPS/LTCH PPS final rule.

2. Effects of the Proposed Changes to Medicare DSH Uncompensated Care Payments and Supplemental Payments for Indian Health Service Hospitals and Tribal Hospitals and Hospitals Located in Puerto Rico for FY 2024

As discussed in section IV.E. of the preamble of this proposed 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 and any additional statutory adjustment (Factor 2), is available to make additional payments to each hospital that qualifies for Medicare DSH payments and that has 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 proposed rule, we are proposing to establish the amount to be distributed as uncompensated care payments (UCP) to DSH eligible hospitals, which is $6,712,960,093.94. This figure represents 75 percent of the amount that otherwise would have been paid for Medicare DSH payment adjustments adjusted by a proposed Factor 2 of 65.71 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 $90.3 million in supplemental payments in FY 2024, as determined based on the difference between each hospital's FY 2022 UCP (reduced by negative 6.70 percent, which is the projected change between the proposed 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 proposed rule, the total uncompensated care payments and supplemental payments equal approximately $6.803 billion. For FY 2024, we are using three 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 proposed rule. For a discussion regarding the methodology for calculating the supplemental payments, we refer readers to section IV.D. of the preamble of this proposed rule.

To estimate the impact of the combined effect of the proposed 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 proposed uncompensated care payments and the proposed supplemental payments estimated in this FY 2024 IPPS/LTCH PPS proposed 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 proposed Factor 2 of 65.71 percent and multiplied by a Factor 3 calculated using the methodology described previously. For this proposed 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 2,395 hospitals that are projected to be eligible for DSH in FY 2024. It did not include hospitals that had terminated their participation in the Medicare program as of February 3, 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 proposed 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:

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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 Proposed Uncompensated Care Payments and Proposed Supplemental Payments** ($ in millions) (3)	Dollar Difference: FY 2023 - FY 2024 ($ in millions) (4)	Percent Change*** (5)
Total	**2,395**	**$6,971**	**$6,803**	**-$167**	**-2.40%**
By Geographic Location					
Urban Hospitals	1,921	6,592	6,420	-172	-2.61
Large Urban Areas	1,007	4,073	3,974	-99	-2.43
Other Urban Areas	914	2,519	2,446	-73	-2.89
Rural Hospitals	474	379	383	4	1.17
Bed Size (Urban)					
0 to 99 Beds	356	259	257	-2	-0.76
100 to 249 Beds	792	1,491	1,465	-26	-1.76
250+ Beds	773	4,842	4,698	-144	-2.97
Bed Size (Rural)					
0 to 99 Beds	368	207	212	4	2.07
100 to 249 Beds	93	127	124	-3	-2.47
250+ Beds	13	44	48	3	7.34
Urban by Region					
New England	90	176	177	2	0.88
Middle Atlantic	232	765	744	-21	-2.77
South Atlantic	315	762	726	-36	-4.70
East North Central	101	357	345	-12	-3.44
East South Central	331	1,713	1,659	-54	-3.18
West North Central	123	428	414	-14	-3.28
West South Central	234	1,401	1,393	-8	-0.59
Mountain	138	292	288	-4	-1.28
Pacific	314	611	593	-18	-2.96
Puerto Rico	43	87	81	-6	-6.42
Rural by Region					
New England	7	11	11	-1	-7.22
Middle Atlantic	30	12	13	1	10.83
South Atlantic	72	43	46	3	7.91
East North Central	29	25	24	-1	-3.62
East South Central	80	107	112	5	4.96
West North Central	120	81	78	-3	-3.72
West South Central	107	81	81	0	0.25
Mountain	23	14	13	-1	-4.32
Pacific	6	6	6	0	-6.73
By Payment Classification					
Urban Hospitals	1,417	4,057	3,948	-109	-2.69
Large Urban Areas	815	2,751	2,679	-72	-2.60
Other Urban Areas	602	1,306	1,268	-38	-2.88
Rural Hospitals	978	2,914	2,856	-58	-2.00
Teaching Status					
Nonteaching	1,323	1,830	1,805	-25	-1.36

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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 Proposed Uncompensated Care Payments and Proposed Supplemental Payments** ($ in millions) (3)	Dollar Difference: FY 2023 - FY 2024 ($ in millions) (4)	Percent Change*** (5)
Fewer than 100 residents	797	2,476	2,392	-84	-3.39
100 or more residents	275	2,665	2,606	-59	-2.20
Type of Ownership					
Voluntary	1,499	4,014	3,902	-112	-2.79
Proprietary	532	1,005	994	-11	-1.10
Government	363	1,950	1,906	-44	-2.24
Medicare Utilization Percent****					
0 to 25	876	3,985	3,864	-121	-3.03
25 to 50	1,441	2,951	2,900	-50	-1.70
50 to 65	69	33	37	4	10.54
Greater than 65	9	2	2	0	1.88
Medicaid Utilization Percent****					
0 to 25	1,392	3,194	3,140	-54	-1.69
25 to 50	882	3,074	2,960	-114	-3.71
50 to 65	88	441	441	0	-0.04
Greater than 65	33	262	262	1	0.21

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 $6,803 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 proposed 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.

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 a proposed decrease in Factor 1. The proposed Factor 1 has decreased from the FY 2023 final rule's Factor 1 of $10.461 billion to this proposed rule's Factor 1 of $10.216 billion. The proposed Factor 2 is 65.71 percent, which is the same as the FY 2023 IPPS/LTCH PPS final rule's Factor 2. In addition, we note that there is a slight increase in the number of projected DSH eligible hospitals to 2,395 at the time of the development for this proposed rule compared to the projected 2,368 DSHs in the FY 2023 IPPS/LTCH PPS final rule (87 FR 49472). Based on the proposed changes, the impact analysis found that, across all projected DSH eligible hospitals, proposed FY 2024 uncompensated care payments and proposed supplemental payments are estimated at approximately $6.803 billion, or a proposed decrease of approximately 2.40 percent from FY 2023 uncompensated care payments and supplemental payments (approximately $6.971 billion). While the proposed changes would 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 proposed 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 2.40 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 2.40 percent indicates that a hospital type is projected to have a smaller decrease or an increase 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 an increase in uncompensated care payments compared to the decrease their urban counterparts are projected to experience. Overall, rural hospitals are projected to receive a 1.17 percent increase in payments, while urban hospitals are projected to receive a 2.61 percent decrease in payments, which is a slightly larger decrease than the overall hospital average.

By bed size, rural hospitals with 250+ beds are projected to receive a 7.34 percent payment increase, smaller rural hospitals with 0–99 beds are projected to receive a 2.07 percent payment increase while rural hospitals with 100–249 beds are projected to receive a slightly larger than average decrease of 2.47 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 2.97 percent. In contrast, smaller urban hospitals with 0–99 beds and urban hospitals with 100–249 beds are projected to receive a 0.76 and 1.76 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 increases in payments. Regionally, 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, as well as hospitals located in Puerto Rico are projected to receive larger than average decreases in payments, while urban hospitals in the West South Central and Mountain regions are projected to receive smaller than average decreases in payments. Urban hospitals in New England are projected to receive an increase in payments.

By payment classification, although hospitals in urban payment areas overall are expected to receive a 2.69 percent decrease in uncompensated care payments and supplemental payments, hospitals in large urban payment areas are projected to receive a decrease in payments of 2.60 percent. In contrast, hospitals in rural areas are projected to receive a decrease in payments of 2.00 percent.

Teaching hospitals with fewer than 100 residents are projected to receive a larger than average payment decrease of 3.39 percent. Nonteaching hospitals and teaching hospitals with 100+ residents are projected to receive smaller than average payment decreases of 1.36 percent and 2.20 percent respectively. Proprietary and government hospitals are projected to receive smaller than average decreases of 1.10 and 2.24 percent respectively, while voluntary hospitals are expected to receive a larger than average payment decrease of 2.79 percent. Hospitals with less than 25 percent Medicare utilization and hospitals with 25 to 50 percent Medicare utilization are projected to receive decreases of 3.03 and 1.70 percent, respectively, while hospitals with 50–65 percent and hospitals with greater than 65 percent Medicare utilization are projected to receive increases of 10.54 percent and 1.88 percent, respectively. Hospitals with greater than 65 percent Medicaid utilization are projected to receive increases in uncompensated care payments and supplemental payments of 0.21 percent. 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 1.69 and 0.04 percent respectively, while hospitals with 25–50 percent Medicaid utilization are projected to receive a larger than average decrease of 3.71 percent.

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 $90.3 million in FY 2024.

3. Effects of the Proposed Changes to Indirect Medical Education and Direct Graduate Medical Education Payments

Under section V.G.2. of the preamble of this proposed rule, we are proposing to clarify policy on 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 propose to clarify how to determine if the hospital increased its current year allowable FTE count, and to clarify 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 proposed 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.

4. Effects of Proposed Changes for Reasonable Cost Payments for Nursing and Allied Health Programs

a. Waiver of Cap

Under section V.H. of the preamble of this proposed rule, we propose 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.

b. Training in New REH Facility Type

As discussed in section V.G.3. of the preamble of this proposed 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 proposed 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 are proposing 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 are proposing 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. If a hospital 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.

5. Effects of Requirements Under the Hospital Readmissions Reduction Program for FY 2024

In section V.J. of the preamble of this proposed rule, we note that we are not proposing to add, modify, or remove any policies for the FY 2024 Hospital Readmissions Reduction Program; 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 proposed rule illustrate the estimated financial impact of the Hospital Readmissions Reduction Program payment adjustment methodology by hospital characteristic. 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, 2018, and June 30, 2021 (that is, the FY 2023 Hospital Readmissions Reduction Program's applicable period).[776] 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 budget neutrality. In the FY 2024 IPPS/LTCH PPS final rule, we will provide 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 (that is, July 1, 2019, through June 30, 2022).

The results in Table I.G.–01 include 2,910 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 between July 1, 2018, and June 30, 2021. 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.–01 indicates the percentage of penalized hospitals among those eligible to receive a penalty by hospital characteristic. For example, 80.79 percent of eligible hospitals characterized as non-teaching hospitals are expected to be penalized. Among teaching hospitals, 88.65 percent of eligible hospitals with fewer than 100 residents and 91.18 percent of eligible hospitals with 100 or more residents are expected to be penalized. The fourth column in Table I.G.–01 estimates the financial impact on hospitals by hospital characteristic. Table I.G.–01 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, 2020, through September 30, 2021 (FY 2021). For example, the penalty as a share of payments for non-teaching hospitals is 0.60 percent. This means that total penalties for all non-teaching hospitals are 0.60 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.–01.

[776] Although the FY 2023 performance period is July 1, 2018, through June 30, 2021, 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, 2018, through December 1, 2019, and July 1, 2020, through June 30, 2021.

TABLE I.G.-01: 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	2,910	2,448	84.12	0.53
By Geographic Location[e] (n= 2,907)				
Urban hospitals	2,208	1,891	85.64	0.52
1-99 beds	526	372	70.72	0.55
100-199 beds	646	574	88.85	0.64
200-299 beds	390	344	88.21	0.58
300-399 beds	284	265	93.31	0.57
400-499 beds	116	107	92.24	0.52
500 or more beds	246	229	93.09	0.42
Rural hospitals	699	555	79.40	0.56
1-49 beds	336	243	72.32	0.40
50-99 beds	201	162	80.60	0.57
100-149 beds	83	75	90.36	0.58
150-199 beds	46	43	93.48	0.60
200 or more beds	33	32	96.97	0.60
By Teaching Status[f] (n= 2,907)				
Non-teaching	1,754	1,417	80.79	0.60
Fewer than 100 residents	881	781	88.65	0.54
100 or more residents	272	248	91.18	0.42
By Ownership Type (n= 2,907)				
Government	416	334	80.29	0.42
Proprietary	686	558	81.34	0.70
Voluntary	1,805	1,554	86.09	0.51
By Safety-net Status[g] (n= 2,907)				
Safety-net hospitals	569	488	85.76	0.40
Non-safety-net hospitals	2,338	1,958	83.75	0.56
By Disproportionate Share Hospital (DSH) Patient Percentage[h] (n= 2,907)				
0-24	1,178	944	80.14	0.61
25-49	1,420	1,243	87.54	0.50
50-64	187	159	85.03	0.42
65 and over	122	100	81.97	0.35
By Medicare Cost Report (MCR) Percentage[i] (n= 2,906)				
0-24	646	546	84.52	0.38
25-49	2,022	1,711	84.62	0.55
50-64	213	174	81.69	0.89
65 and over	25	14	56.00	0.55
By Region (n= 2,910)				
New England	125	111	88.80	0.79
Middle Atlantic	322	294	91.30	0.58
East North Central	463	391	84.45	0.56
West North Central	236	181	76.69	0.28
South Atlantic	490	438	89.39	0.58
East South Central	261	230	88.12	0.62
West South Central	448	365	81.47	0.48
Mountain	217	154	70.97	0.42
Pacific	348	284	81.61	0.39

Source: The table results are based on the data used to calculate the FY 2023 payment adjustment factors of open, non-Maryland, subsection (d) hospitals only. The FY 2023 payment adjustment factors are based on discharges from July 1, 2018, through December 1, 2019, and July 1, 2020, through June 30, 2021. 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

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June 30, 2020, from the Hospital Readmissions Reduction Program (HRRP) 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 2022 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 2023 Hospital Inpatient Prospective Payment System (IPPS) Final 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 (HRRP) 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, 2020, through September 31, 2021 (FY 2021), 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=2,907, missing=3), and MCR percentage (n=2,906; missing=4).

[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 Proposed 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 proposed 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 proposed 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 December 2022 update to the FY 2022 MedPAR file.

The proposed estimated impacts of the FY 2024 program year by hospital characteristic, found in Table V.G.-05, are based on historical TPSs. We used the FY 2021 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 December 2022 update to the FY 2022 MedPAR file. The proxy adjustment factors can be found in Table 16 associated with this proposed rule (available via the internet on the CMS website).

TABLE I.G.-01 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	**2,526**	**0.025%**
	Urban Area	1,977	0.012%
	Rural Area	549	0.074%
	Missing		.
	Urban Hospitals	**1,977**	**0.012%**
	0-99 beds	347	0.036%
	100-199 beds	623	0.000%
	200-299 beds	388	0.036%
	300-499 beds	386	0.026%
	500 or more beds	233	-0.055%
	Rural Hospitals	**549**	**0.074%**
	0-49 beds	205	0.080%
	50-99 beds	191	0.014%
	100-149 beds	78	0.068%
	150-199 beds	43	0.199%
	200 or more beds	32	0.236%
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	0.064%
	Pacific	308	-0.026%
	Rural By Region	**549**	**0.074%**
	New England	18	0.113%
	Middle Atlantic	44	-0.075%
	South Atlantic	86	0.022%
	East North Central	97	0.033%
	East South Central	97	0.186%
	West North Central	70	0.062%
	West South Central	78	0.175%
	Mountain	35	0.015%
	Pacific	24	0.003%
BY MCR PERCENT:			
	0-25	591	-0.025%
	25-50	1,787	0.045%
	50-65	147	-0.009%
	Over 65	1	-0.433%
	Missing	.	.
BY DSH PERCENT:			
	0-25	972	0.038%
	25-50	1,298	0.024%
	50-65	156	0.004%
	Over 65	100	-0.044%
	Missing	.	.
BY TEACHING STATUS:			
	Non-Teaching	1,418	0.026%
	Teaching	1,108	0.025%

The actual FY 2024 program year's TPSs would 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 would be used for the updated impact analysis in the final rule, if the proposals, as previously described, for FY 2024 are not finalized.

b. Estimated Effects for the FY 2026 Program Year Applying Proposed Scoring Methodology Change

The estimated effects of the proposed 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 proposed HEA scoring option increases the number of hospitals gaining compared to the existing scoring methodology. ''Gaining'' means both those who are receiving a larger bonus and those who are receiving a smaller penalty under the proposed health equity scoring change than they would receive in the existing scoring methodology. Through these analyses, we found that the hospital-weighted average payment adjustment is positive even though the Program remains revenue neutral. The increase in the number of hospitals gaining occurs primarily among safety net hospitals compared to non-safety net. Additionally, the distribution of Total Performance Scores 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 proposed 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 this proposed rule, we are not proposing to

add or remove any measures from the HAC Reduction Program, nor are we proposing any changes to reporting or submission requirements which would have any 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. 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, 2021 and December 31, 2021. To analyze the results by hospital characteristic, we used the FY 2023 Final 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 this proposed rule will result in any significant economic impacts because the reconsideration request form would 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 2,946 non-Maryland hospitals with a 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, 531 hospitals out of 1,756 hospitals characterized as non-teaching hospitals would be subject to a payment reduction. Among teaching hospitals, 152 out of 909 hospitals with fewer than 100 residents and 46 out of 272 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, 30.2 percent of the 1,756 hospitals characterized as non-teaching hospitals, 16.7 percent of the 909 teaching hospitals with fewer than 100 residents, and 16.9 percent of the 272 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]	2,946	736	25
By Geographic Location (n = 2,937)[d]			
Urban hospitals	**2,291**	**477**	**20.8**
1-99 beds	572	214	37.4
100-199 beds	664	130	19.6
200-299 beds	403	57	14.1
300-399 beds	288	35	12.2
400-499 beds	117	12	10.3
500 or more beds	247	29	11.7
Rural hospitals	**646**	**252**	**39**
1-49 beds	284	140	49.3
50-99 beds	200	70	35
100-149 beds	83	22	26.5
150-199 beds	46	11	23.9
200 or more beds	33	9	27.3
By Safety-Net Status[e] (n = 2,937)			
Non-safety net	2,341	559	23.9
Safety-net	596	170	28.5
By DSH Percent[f] (n = 2,937)			
0-24	1,194	275	23
25-49	1,409	349	24.8
50-64	193	62	32.1
65 and over	141	43	30.5
By Teaching Status[g] (n =2,937)			
Non-teaching	1,756	531	30.2
Fewer than 100 residents	909	152	16.7
100 or more residents	272	46	16.9
By Ownership (n = 2,937)			
Voluntary	1,829	419	22.9
Proprietary	710	159	22.4
Government	398	151	37.9
By MCR Percent[h] (n = 2,931)			
0-24	719	172	23.9
25-49	2,014	487	24.2
50-64	187	60	32.1
65 and over	11	5	45.5
By Region[i] (n= 2,946)			
New England	128	33	25.8
Mid-Atlantic	325	77	23.7
South Atlantic	488	100	20.5
East North Central	472	112	23.7
East South Central	247	76	30.8
West North Central	237	57	24.1
West South Central	449	144	32.1
Mountain	222	55	24.8
Pacific	378	82	21.7

Source: FY 2024 HAC Reduction Program proposed 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, 2021, through December 31, 2021. Hospital Characteristics are based on the FY 2023 Final 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 = 2,946). 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 = 2,937).

[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 = 2,931).

[i] All hospitals had data for Region (n = 3,067). For the 6 hospitals that were not in the FY 2023 Proposed Rule Impact File region data were identified using the hospital CCN.

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In section V.L.6.a.(3) of the preamble of this proposed rule, we are proposing to update our targeting criteria for validation of hospitals granted an

extraordinary circumstances exception (ECE) in the HAC Reduction Program. Specifically, we are proposing 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. We do not believe the proposal to modify 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 would not exceed the total maximum number of hospitals that would 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 proposed rule for FY 2024, we discussed our 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 116–260 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 proposed rule, the resulting amount applicable to FY 2024 is $37,658,408, which we are proposing as 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 will continue this general procedure. At this time, for the FY 2024 proposed rule, not all of the finalized cost reports are available for the 29 hospitals that completed cost report periods beginning in FY 2018 under the demonstration payment methodology. If all of these cost reports are available, we will include in the budget neutrality offset amount in the FY 2024 final rule the amount by which the actual costs of the demonstration, as determined from these cost reports, differed from the estimated costs identified in the FY 2018 final rule.

9. Effects of Continued Implementation of the Frontier Community Health Integration Project (FCHIP) Demonstration

In section VII.B.2. of the preamble of this proposed 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 in order 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 proposed 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 located 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 are not proposing 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 Proposed Changes for Rural Emergency Hospitals

Section X.A. of the preamble of this proposed 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 proposed 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 on the basis of 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 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.[777] For these facilities, the 3 percent threshold would be about $219,000, nearly 500 times our

[777] ''How Many Hospitals Might Convert to a Rural Emergency Hospital (REH)?'' July 2021. Pink, GH et al. Findings Brief—NC Rural Health Research Program.

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 Proposed Changes for Physician-Owned Hospitals

The physician-owned hospital provisions are discussed in section X.B. of the preamble of this proposed rule. Section X.B.2.a. of the preamble of this proposed rule describes our proposals to revise 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. We expect that our proposed clarifications and technical revisions along with the proposed factors we will consider when making a decision on an expansion exception request would 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. We anticipate that requiring the use of HCRIS data for all comparison calculations would have little practical impact on whether a requesting hospital meets the criteria for an applicable hospital or high Medicaid facility, nor would a requesting hospital be prejudiced by this requirement.

Section X.B.2.b. of the preamble of this proposed rule describes our proposal to reinstate, 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 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 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.

H. Effects on Hospitals and Hospital Units Excluded From the IPPS

As discussed in section II.A.4. of the Addendum to this proposed rule, consistent with our proposed use of the PSF, there were 96 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 10 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 proposed rate updates discussed in this proposed rule. The impacts of the proposed 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 proposed 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 fourth quarter 2022 forecast of the 2018-based IPPS market basket increase, we are estimating the proposed FY 2024 update to be 3.0 percent (that is, the estimate of the market basket rate-of-increase), as discussed in section V.A. of the preamble of this proposed rule. We are proposing 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 (proposed 0.2 percentage point reduction for FY 2024), resulting in a proposed 2.8 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 proposed 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 proposed update is the percentage increase in the 2018-based IPPS operating market basket for FY 2024, estimated at 3.0 percent.

The impact of the proposed 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 proposed rule, we used data from the December 2022 update of the FY 2022 MedPAR file and the December 2022 update of the Provider-Specific File (PSF) that was used for payment purposes. Although the analyses of the proposed changes to the capital prospective payment system do not incorporate cost data, we used

the December 2022 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 proposed rule.

Due to the interdependent nature of the IPPS, it is very difficult to precisely quantify the impact associated with each proposed 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 December 2022 update of the FY 2022 MedPAR file, we simulated payments under the capital IPPS for FY 2023 and the proposed 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 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 proposed rule, the proposed update to the capital Federal rate is 3.5 percent for FY 2024.
- In addition to the proposed FY 2024 update factor, the proposed FY 2024 capital Federal rate was calculated based on a proposed GAF/DRG budget neutrality adjustment factor of 0.9992, a proposed budget neutrality factor for the proposed continuation of the lowest quartile hospital wage index adjustment and the 5-percent cap on wage index decreases policy of 0.9934, and a proposed outlier adjustment factor of 0.9584.

2. Results

We used the payment simulation model previously described in section I.I. of Appendix A of this proposed rule to estimate the potential impact of the proposed changes for FY 2024 on total capital payments per case, using a universe of 3,130 hospitals. As previously described, the individual hospital payment parameters are taken from the best available data, including the December 2022 update of the FY 2022 MedPAR file, the December 2022 update to the PSF, and the most recent available cost report data from the December 2022 update of the FY 2021 HCRIS. In Table III, we present a comparison of estimated total payments per case for FY 2023 and estimated proposed total payments per case for FY 2024 based on the proposed FY 2024 payment policies. Column 2 shows estimates of payments per case under our model for FY 2023. Column 3 shows estimates of proposed payments per case under our model for FY 2024. Column 4 shows the total proposed percentage change in payments from FY 2023 to FY 2024. The change represented in Column 4 includes the proposed 3.50 percent update to the capital Federal rate and other proposed 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 6.3 percent compared to capital payments per case in FY 2023. This expected increase is primarily due to the 3.50 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 proposed rule, we are proposing 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 proposal, geographically urban hospitals with 100 or more beds reclassified as rural under § 412.103 would be eligible for capital DSH payments beginning in FY 2024. The CMS' Office of the Actuary estimates this proposed change in policy would 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 proposed changes in GAFs, and are generally consistent with the projected changes in payments due to proposed changes in the wage index (and proposed policies affecting the wage index), as shown in Table I in section I.F. of Appendix A of this proposed rule. We note that the proposed FY 2024 GAFs reflect the proposed changes to the rural wage index methodology. As discussed in section III.G.1. of the preamble to this proposed rule, beginning in FY 2024, we are proposing 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) when implicated by the hold harmless provision at section 1886(d)(8)(C)(ii) of the Act. We are also proposing 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.

The net impact of these changes is an estimated 6.3 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 would experience an increase in capital IPPS payments per case in FY 2024 as compared to FY 2023. Capital IPPS payments per case would increase by an estimated 6.3 percent for hospitals in urban areas while payments to hospitals in rural areas would increase by 5.9 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 3.3 percent increase for the Mountain region to a 9.7 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 2.0 percent increase for the Mountain rural region to a 16.8 percent increase for the Middle Atlantic region. These regional differences are primarily due to the proposed changes in the GAFs, which reflect the proposed changes to the rural wage index methodology, and estimated

changes in capital DSH payments. We note that the proposed 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 and government hospitals are expected to experience the highest increase in capital payments per case from FY 2023 to FY 2024 of 6.4 percent. Meanwhile, proprietary hospitals are expected to experience an increase in capital payments per case from FY 2023 to FY 2024 of 5.3 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 proposed rule for FY 2024, we show the proposed average capital payments per case for reclassified hospitals for FY 2024. Urban reclassified hospitals are expected to experience an increase in capital payments of 7.8 percent; urban nonreclassified hospitals are expected to experience an increase in capital payments of 4.4 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 proposing a change to our capital DSH policy under which geographically urban hospitals with 100 or more beds reclassified as rural under § 412.103 would be eligible for capital DSH payments beginning in FY 2024. Rural reclassified hospitals are expected to experience an increase in capital payments of 5.7 percent; rural nonreclassified hospitals are expected to experience an increase in capital payments of 6.2 percent.

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TABLE III.-- COMPARISON OF TOTAL PAYMENTS PER CASE

[FY 2023 PAYMENTS COMPARED TO PROPOSED FY 2024 PAYMENTS]	Number of Hospitals	Average FY 2023 Payments/ Case	Proposed Average FY 2024 Payments/ Case	Change
All Hospitals	3,130	1,087	1,155	6.3
By Geographic Location:				
Urban hospitals	2,414	1,119	1,189	6.3
Rural hospitals	716	763	808	5.9
Bed Size (Urban):				
0-99 beds	648	881	912	3.5
100-199 beds	693	938	992	5.8
200-299 beds	415	1,030	1,097	6.5
300-499 beds	405	1,109	1,188	7.1
500 or more beds	251	1,330	1,411	6.1
Bed Size (Rural):				
0-49 beds	362	652	688	5.5
50-99 beds	190	735	784	6.7
100-149 beds	86	744	789	6.0
150-199 beds	45	833	876	5.2
200 or more beds	33	903	954	5.6
Urban by Region:				
New England	108	1,197	1,249	4.3
Middle Atlantic	292	1,248	1,354	8.5
East North Central	372	1,049	1,107	5.5
West North Central	156	1,076	1,125	4.6
South Atlantic	403	971	1,019	4.9
East South Central	138	944	995	5.4
West South Central	359	1,023	1,075	5.1
Mountain	176	1,132	1,169	3.3
Pacific	360	1,449	1,589	9.7
Puerto Rico	50	605	628	3.8
Rural by Region:				
New England	19	1,057	1,083	2.5
Middle Atlantic	47	744	869	16.8
East North Central	113	756	795	5.2
West North Central	85	772	809	4.8
South Atlantic	107	708	748	5.6
East South Central	140	722	758	5.0
West South Central	135	690	724	4.9
Mountain	46	871	888	2.0
Pacific	24	980	1,073	9.5

[FY 2023 PAYMENTS COMPARED TO PROPOSED FY 2024 PAYMENTS]	Number of Hospitals	Average FY 2023 Payments/ Case	Proposed Average FY 2024 Payments/ Case	Change
By Payment Classification:				
Urban hospitals	1,811	1,071	1,120	4.6
Rural areas	1,319	1,107	1,197	8.1
Teaching Status:				
Nonteaching	1,903	901	953	5.8
Fewer than 100 residents	949	1,026	1,091	6.3
100 or more residents	278	1,471	1,565	6.4
Urban DSH:				
Non-DSH	365	956	992	3.8
100 or more beds	1,093	1,105	1,156	4.6
Less than 100 beds	353	822	850	3.4
Rural DSH:				
Non-DSH	110	1,013	1,051	3.8
SCH	257	781	842	7.8
RRC	709	1,148	1,247	8.6
100 or more beds	32	1,218	1,277	4.8
Less than 100 beds	211	648	687	6.0
Urban teaching and DSH:				
Both teaching and DSH	639	1,168	1,219	4.4
Teaching and no DSH	61	1,011	1,056	4.5
No teaching and DSH	807	954	1,003	5.1
No teaching and no DSH	304	927	957	3.2
Special Hospital Types:				
RRC	127	891	933	4.7
RRC with Section 401 Rural Reclassification	492	1,213	1,318	8.7
SCH	256	746	788	5.6
SCH with Section 401 Rural Reclassification	45	876	964	10.0
SCH and RRC	121	847	893	5.4
SCH and RRC with Section 401 Rural Reclassification	41	1,017	1,100	8.2
MDH	115	652	698	7.1
MDH with Section 401 Reclassification	30	728	775	6.5
MDH and RRC	20	712	752	5.6
MDH and RRC with Section 401 Reclassification	12	822	882	7.3
Type of Ownership:				
Voluntary	1,921	1,090	1,160	6.4
Proprietary	777	1,001	1,054	5.3
Government	431	1,186	1,262	6.4
Medicare Utilization as a Percent of Inpatient Days:				
0-25	994	1,196	1,277	6.8
25-50	1,946	1,050	1,113	6.0
50-65	138	897	948	5.7
Over 65	25	582	627	7.7
Medicaid Utilization as a Percent of Inpatient Days:				
0-25	2,065	1,010	1,064	5.3
25-50	947	1,216	1,305	7.3
50-65	86	1,401	1,539	9.9
Over 65	32	1,427	1,613	13.0
FY 2024 Reclassifications:				
All Reclassified Hospitals	1,134	1,111	1,195	7.6
Non-Reclassified Hospitals	1,996	1,063	1,114	4.8
Urban Hospitals Reclassified	939	1,150	1,240	7.8
Urban Non-Reclassified Hospitals	1,490	1,082	1,130	4.4
Rural Hospitals Reclassified Full Year	304	775	819	5.7
Rural Non-Reclassified Hospitals Full Year	397	746	792	6.2
All Section 401 Rural Reclassified Hospitals	660	1,181	1,281	8.5
Other Reclassified Hospitals (Section 1886(d)(8)(B))	57	755	809	7.2

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J. Effects of Proposed Payment Rate Changes and Policy Changes Under the LTCH PPS

1. Introduction and General Considerations

In section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule, we set forth the proposed annual update to the payment rates for the LTCH PPS for FY 2024. In the preamble of this proposed rule, we specify the statutory authority for the proposals that are presented, identify the proposed policies for FY 2024, and present rationales for our proposals as well as alternatives that were considered. In this section of Appendix A to this proposed rule, we discuss the impact of the proposed changes to the payment rate, factors, and other payment rate policies related to the LTCH PPS that are presented in the preamble of this proposed 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 proposed 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 proposals to remove 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 proposed rule). Moreover, in the claims data used for this proposed 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 proposed payment rate, factors, and policies presented in this proposed rule, the proposed 2.9 percent annual update to the LTCH PPS standard Federal payment rate, the proposed update to the MS–LTC–DRG classifications and relative weights, the proposed 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 has provided a waiver of the application of the site neutral payment rate for LTCH cases admitted during the COVID–19 PHE period. At the time of development of this proposed rule, the COVID–19 PHE is set to expire 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 proposed rule, we estimate that overall LTCH PPS payments in FY 2024 would decrease by approximately 0.9 percent (or approximately $24 million) based on the proposed rates and factors presented in section VII. of the preamble and section V. of the Addendum to this proposed rule.

Based on the FY 2022 LTCH cases that were used for the analysis in this proposed 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 proposed for FY 2024. Taking this into account along with other changes that would 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 would increase by approximately 10.8 percent (or approximately $35 million). This projected increase in payments to LTCH PPS site neutral payment rate cases is primarily due to the proposed updates to the IPPS rates and payments reflected in our estimate of the IPPS comparable per diem amount, as well as an estimated increase in costs for these cases determined using the charge and CCR adjustment factors described in section V.D.3.b. of the Addendum to this proposed rule. We note that we estimate payments to site neutral payment rate cases in FY 2024 will represent approximately 14 percent of estimated aggregate FY 2024 LTCH PPS payments.

Based on the FY 2022 LTCH cases that were used for the analysis in this proposed 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 2.5 percent (or approximately $59 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 4.7 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 proposed rule.

Based on the 333 LTCHs that were represented in the FY 2022 LTCH cases that were used for the analyses in this proposed rule presented in this Appendix, we estimate that aggregate FY 2023 LTCH PPS payments will be approximately $2.645 billion, as compared to estimated aggregate FY 2024 LTCH PPS payments of approximately $2.622 billion, resulting in an estimated overall decrease in LTCH PPS payments of approximately $24 million. We note that the estimated $24 million decrease 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 proposed policies in this proposed rule.

The LTCH PPS standard Federal payment rate for FY 2023 is $46,432.77. For FY 2024, we are proposing to establish an LTCH PPS standard Federal payment rate of $47,948.15 which reflects the proposed 2.9 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 1.0035335 (discussed in section V.B.6. of the Addendum to this proposed 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 proposing to establish an LTCH PPS standard Federal payment rate of $47,016.21. This proposed 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 proposed annual update of 2.9 percent to the LTCH PPS standard Federal payment rate is projected to result in an increase of 2.8 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 2.8 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 2.8 percent.

For FY 2024, we are proposing to update 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 proposing to establish a labor-related share of 68.4 percent for FY 2024, based on the most recent available data (IGI's fourth quarter 2022 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 proposing to apply an area wage level budget neutrality factor of 1.0035335 to ensure that the proposed changes to the area wage level adjustment would 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 proposed 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 12.7 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 4.7 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 in section V.D.3.b. of the Addendum to this proposed 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 proposed methodology described in section V.D.3.b. of the Addendum to this proposed rule. We lastly note, as discussed in section V.D.3.b. of the Addendum to this proposed rule, we are soliciting comments on our proposed methodology for determining the fixed-loss amount for FY 2024 and will consider these comments when finalizing our methodology in the 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.

As we discuss in detail throughout this proposed rule, based on the best available data, we believe that the provisions of this proposed rule relating to the LTCH PPS, which are projected to result in an overall decrease in estimated aggregate LTCH PPS payments, 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 1.5 percent decrease in estimated payments for LTCH PPS standard Federal payment rate cases for LTCHs located in a rural area, primarily due to a projected decrease in high cost outlier payments. 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 Proposed LTCH PPS Payment Rate Changes and Policy Changes

a. Proposed 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 a decrease in aggregate LTCH PPS payments in FY 2024 of approximately $24 million. This estimated decrease in payments reflects the projected decrease in payments to LTCH PPS standard Federal payment rate cases of approximately $59 million and the projected increase in payments to site neutral payment rate cases of approximately $35 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 proposed 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 proposed 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 proposed 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 proposed provider impact analysis for the changes that affect LTCH PPS payments for LTCH PPS standard Federal payment rate cases.

b. Proposed 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 proposed 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 proposed rates, factors, and the policies in this proposed rule (as discussed in section VII. of the preamble of this proposed rule and section V. of the Addendum to this proposed rule). As discussed elsewhere in this proposed 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 proposed 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. Proposed 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 proposed 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 proposed FY 2024 LTCH PPS standard Federal payment rate, we used the proposed FY 2024 standard Federal payment rate of $47,948.15 (or $47,016.21 for LTCHs that failed to submit quality data as required under the requirements of the LTCH QRP). In each case, we applied the applicable proposed 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 proposed FY 2024 LTCH PPS payments, we used the proposed FY 2024 LTCH PPS labor-related share (68.4 percent), the proposed FY 2024 wage index values from Tables 12A and 12B listed in section VI. of the Addendum to this

proposed rule (which are available via the internet on the CMS website), the proposed FY 2024 HCO fixed-loss amount for LTCH PPS standard Federal payment rate cases of $94,378 (as discussed in section V.D.3. of the Addendum to this proposed rule), and the proposed FY 2024 COLA factors (shown in the table in section V.C. of the Addendum to this proposed rule) to adjust the proposed FY 2024 nonlabor-related share (31.6 percent) for LTCHs located in Alaska and Hawaii. We noted 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 proposed rule. We also noted 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 proposed methodology described in section V.D.3.b. of the Addendum to this proposed 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 proposed 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 proposed 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 proposed annual update to the standard Federal rate (as discussed in section V.A.2. of the Addendum to this proposed 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 proposed changes to the area wage level adjustment (that is, the updated hospital wage data and labor-related share) and the application of the corresponding proposed budget neutrality factor (as discussed in section V.B.6. of the Addendum to this proposed 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 proposed changes.

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TABLE IV: IMPACT OF PROPOSED 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	41,311	56,202	54,782	2.8	0.0	-2.5
BY LOCATION:							
RURAL	18	1,540	43,580	42,925	2.7	-0.5	-1.5
URBAN	314	39,771	56,690	55,242	2.8	0.0	-2.6
BY PARTICIPATION DATE:							
BEFORE OCT. 1983	10	883	50,694	48,318	2.9	0.0	-4.7
OCT. 1983 - SEPT. 1993	36	5,134	64,761	63,320	2.8	0.4	-2.2
OCT. 1993 - SEPT. 2002	132	16,790	55,540	54,223	2.8	-0.1	-2.4
AFTER OCTOBER 2002	154	18,504	54,690	53,229	2.8	-0.1	-2.7
BY OWNERSHIP TYPE:							
VOLUNTARY	54	4,708	59,267	56,466	2.8	0.0	-4.7
PROPRIETARY	269	36,064	55,514	54,298	2.8	0.0	-2.2
GOVERNMENT	9	539	75,466	72,486	2.7	1.2	-3.9
BY REGION:							
NEW ENGLAND	10	1,168	46,518	44,684	2.9	-0.1	-3.9
MIDDLE ATLANTIC	19	2,594	66,522	65,589	2.8	0.5	-1.4
SOUTH ATLANTIC	61	8,507	54,669	52,906	2.8	0.1	-3.2
EAST NORTH CENTRAL	47	5,817	58,151	55,892	2.8	-0.3	-3.9
EAST SOUTH CENTRAL	31	3,059	52,513	50,601	2.8	-0.4	-3.6
WEST NORTH CENTRAL	22	2,314	55,816	52,266	2.8	-0.4	-6.4
WEST SOUTH CENTRAL	92	10,582	47,076	46,634	2.8	0.1	-0.9
MOUNTAIN	27	2,278	54,705	54,601	2.8	-0.6	-0.2
PACIFIC	23	4,992	75,912	74,520	2.7	0.3	-1.8
BY BED SIZE:							
BEDS: 0-24	27	1,694	52,910	51,903	2.8	0.0	-1.9
BEDS: 25-49	157	15,362	51,246	50,127	2.8	-0.2	-2.2
BEDS: 50-74	80	10,718	54,892	53,524	2.8	0.0	-2.5
BEDS: 75-124	47	8,710	64,581	62,689	2.8	0.0	-2.9
BEDS: 125-199	17	3,679	61,861	59,602	2.8	0.3	-3.7
BEDS: 200+	4	1,148	57,897	57,640	2.7	0.6	-0.4

[1] Estimated FY 2024 LTCH PPS payments for LTCH PPS standard Federal payment rate criteria based on the proposed payment rate and factor changes applicable to such cases presented in the preamble of and the Addendum to this proposed 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 proposed 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.

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d. Results

Based on the FY 2022 LTCH cases (from 333 LTCHs) that were used for the analyses in this proposed rule, we have prepared the following summary of the impact (as shown in Table IV) of the LTCH PPS payment rate and proposed policy changes for LTCH PPS standard Federal payment rate cases presented in this proposed 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 2.5 percent, on average, for all LTCHs from FY 2023 to FY 2024 as a result of the proposed payment rate and policy changes applicable to LTCH PPS standard Federal payment rate cases presented in this proposed rule. This estimated 2.5 percent decrease in LTCH PPS payments per discharge was determined by comparing estimated FY 2024 LTCH PPS payments (using the proposed payment rates and factors discussed in this proposed 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 proposing an annual update to the LTCH PPS standard Federal payment rate for FY 2024 of 2.9 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 proposed budget neutrality factor for changes to the area wage level adjustment of 1.0035335 (discussed in section V.B.6. of the Addendum to this proposed rule), based on the best available data at this time, to ensure that any proposed changes to the area wage level adjustment would 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 proposed rule, for most categories of LTCHs (as shown in Table IV, Column 6), the estimated payment increase due to the proposed 2.9 percent annual update to the LTCH PPS standard Federal payment rate is projected to result in approximately a 2.8 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 proposed 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 2.5 percent. The projected decrease for rural and urban hospitals, respectively, is 1.5 and 2.6.

(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 2.4 percent and 2.7 percent, respectively. LTCHs that began participating in the Medicare program between October 1983 and September 1993 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, 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 4.7 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 a decrease in payments to LTCH PPS standard Federal payment rate cases of 2.2 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 4.7 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 3.9 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 6.4 percent in the West North Central region to a decrease of 0.2 percent in the Mountain region. These regional variations are primarily due to the proposed 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 would experience the largest decrease in payments for LTCH PPS standard Federal payment rate cases, 3.7 percent. LTCHs with greater than 200 beds are projected to experience the smallest decrease in payments of 0.4 percent. The remaining bed size categories are projected to experience a decrease in payments in the range of 1.9 to 2.9 percent.

4. Effect on the Medicare Program

As stated previously, we project that the provisions of this proposed rule would 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 $59 million (or approximately 2.5 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 proposed rule would 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 $35 million (or approximately 10.8 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 14 percent of total estimated FY 2024 LTCH PPS payments.) Therefore, we project that the provisions of this proposed rule would result in a decrease in estimated aggregate LTCH PPS payments for all LTCH cases in FY 2024 relative to FY 2023 of approximately 24 million (or approximately 0.9 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 proposed 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.

L. Effects of Requirements for the Hospital Inpatient Quality Reporting (IQR) Program

In section IX.C. of the preamble of this proposed rule, we discuss our current requirements and proposed 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 proposed rule, we are proposing: (1) removal of the 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; (2) adoption of the Hospital Harm—Pressure Injury electronic clinical quality measure (eCQM) beginning with the CY 2025 reporting period/FY 2027 payment determination; (3) adoption of the Hospital Harm—Acute Kidney Injury eCQM beginning with the CY 2025 reporting period/FY 2027 payment determination; (4) adoption of the Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Hospital Level—Inpatient) eCQM beginning with CY 2025 reporting period/FY 2027 payment determination; (5) modification of 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) modification of 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) modification of the COVID–19 Vaccination Coverage among Healthcare Personnel (HCP) measure beginning with the Q4 CY 2023 reporting period/FY 2025 payment determination; (8) removal of the 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 impacting the FY 2030 payment determination; (9) removal of the Medicare Spending Per Beneficiary (MSPB)—Hospital measure beginning with the CY 2026 reporting period/FY 2028 payment determination; (10) modification of 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) modification of 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 table in section XII.B.6. of the preamble of this proposed rule, we estimate a total information collection burden decrease for 3,150 IPPS hospitals of 146,674 hours at a savings of $6,917,315 annually associated with our proposed policies 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 proposed rule, we are proposing adoption of 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 those proposed provisions, we believe that costs are multifaceted and include not only the burden associated with reporting, but also the costs associated with implementing and maintaining Hospital IQR Program measures in hospitals' EHR systems for all of the eCQMs available for use in the Hospital IQR Program (83 FR 41771).

In section IX.B. of this proposed rule, we are proposing to modify 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. 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 would 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 proposals to remove or modify existing measures, we do not believe any of these proposals will result in any additional economic impact beyond those discussed in section XII.B.6. (Collection of Information). Similarly, we do not believe the proposal 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 would 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.

M. Effects of Requirements for the PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

In section IX.D of the preamble of this proposed 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 proposed rule, we are proposing: (1) adoption of the Documentation of Goals of Care Discussions Among Cancer Patients measure beginning with the FY 2026 program year, (2) adoption of the Facility Commitment to Health Equity measure beginning with the FY 2026 program year; (3) adoption of the Screening for Social Drivers of Health measure with voluntary reporting in the FY 2026 program year and mandatory reporting beginning in the FY 2027 program year; (4) adoption of the Screen Positive Rate for Social Drivers of Health measure with voluntary reporting in the FY 2026 program year and mandatory reporting beginning in the FY 2027 program year; (5) updates to the data collection and reporting for the HCAHPS Survey Measure (NQF #0166) beginning with the FY 2027 program year; (6) modification of the COVID–19 Vaccination Coverage Among Healthcare Personnel (HCP) measure beginning with the FY 2025 program year; and (7) to begin 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 proposed 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 proposed 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 proposed 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 proposed rule, we are proposing to adopt the Documentation of Goals of Care Discussions Among Cancer Patients measure beginning with the FY 2026 program year. This measure would 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 would 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) 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 proposed rule, we are proposing to adopt the Facility Commitment to Health Equity measure. In order for PCHs to receive a point for each of the five domains in the measure, affirmative attestations are required for each of the elements within a domain. For PCHs that are unable to attest affirmatively for an element, there are likely to be additional costs associated with activities such as updating hospital policies, engaging senior leadership, participating in new quality improvement activities, performing additional data analysis, and training staff. The extent of these costs would vary from PCH to PCH depending on what activities the PCH is already performing, size, and the individual choices each PCH makes in order to meet the criteria necessary to attest affirmatively.

In section IX.D.4 of the preamble of this proposed rule, we are proposing to adopt the Screening for Social Drivers of Health measure with voluntary reporting in the FY 2026 program year and mandatory reporting beginning in 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 would 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 proposed rule, we are proposing to modify 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 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 would 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 proposals will result in any additional economic impact.

N. Effects of Proposed Requirements for the Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

In section IX.G. of the preamble of this proposed rule, we are proposing to modify one measure, adopt two measures and remove two measures from the LTCH QRP. Specifically, we propose 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 propose 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 propose to begin publicly displaying data for the quality measures TOH-Patient, TOH–Provider, DC Function, and Patient/Resident COVID–19 Vaccine measures. We propose to increase the LTCH QRP data completion thresholds for the LCDS items beginning with the FY 2026 LTCH QRP. Finally, we are seeking information on principles for selecting and prioritizing LTCH QRP quality measures and concepts for measure development and provide 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 are not proposing any updates to the form, manner, and timing of data submission for this measure, there would be no increase in burden associated with the proposal.

The effect of the remaining proposals for the LTCH QRP would 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 proposed 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 program years compared to our currently approved information collection burden estimates. We refer readers to section XII.B.8. of the preamble of this proposed 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.

O. Effects of Requirements Regarding the Medicare Promoting Interoperability Program

In section IX.F. of the preamble of this proposed rule, we are proposing 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 electronic clinical quality measure (eCQM) beginning with the CY 2025 reporting period; (2) adoption of the Hospital Harm—Acute Kidney Injury eCQM Hospital Harm—Pressure 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 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) establishing an EHR reporting period of a minimum of any continuous 180-day period in CY 2025. As discussed in section XII. of the preamble of this proposed rule, we do not estimate a change in total information collection burden associated with our proposed policies.

In section IX.F.7.a.(2). of the preamble of this proposed rule, we are proposing to adopt 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 those proposed provisions, we believe that costs are multifaceted and include not only the burden associated with reporting but also the costs associated with implementing and maintaining program measures in hospitals' EHR systems for all of the eCQMs available for use in the Medicare Promoting Interoperability Program (83 FR 41771).

In section IX.F.3. of the preamble of this proposed rule, we are proposing 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. In the CY 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). If this proposal is finalized, eligible hospitals and CAHs would 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 would spend performing each self-assessment or the staff they would utilize. Therefore, we estimate the time required to conduct each self-assessment would range from approximately 30 minutes per guide to approximately 20 minutes per recommendation.[778] Across the nine SAFER Guides and 165 recommendations within them, the estimated time to complete all nine self-assessments would 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. Table I.O.-01 provides the detail of our calculated cost to conduct SAFER Guide self-assessments.

[778] Toward More Proactive Approaches to Safety in the Electronic Health Record Era. Available at *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8136246/*. Accessed December 14, 2022.

[779] *http://www.bls.gov/oes/current/oes_nat.htm.* Accessed December 14, 2022.

Table I.O.-01. Cost Per Eligible Hospital and CAH to Conduct SAFER Guides Self-Assessment

Eligible Hospital/CAH Staff Title	BLS Labor Category (Occupation Code)[1]	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 I.O.-01, 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) in order to attest ''yes'' to the measure. We invite comment on our assumptions regarding the economic impact of the proposed 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.[780]

P. Alternatives Considered

This proposed rule contains a range of policies. It also provides descriptions of the statutory provisions that are addressed, identifies the proposed policies, and presents rationales for our decisions and, where relevant, alternatives that were considered.

1. Alternatives Considered to the Proposed Hospital Wage Index Calculations

As discussed in section III.G.1. of the preamble of this proposed rule, we are proposing 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) when implicated by 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 proposing 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. As also discussed in section III.G.1 of the preamble of this proposed rule, we acknowledge that these proposals would have significant effects on wage index values. In addition, as a result of this proposed change, both the geographic reclassification budget neutrality adjustment and the rural floor budget neutrality adjustment are significantly larger than in prior years.

In the past, such as in response to the FY 2020 IPPS/LTCH PPS proposed rule, commenters have strongly supported policies that ''curb . . . the manipulative practice of some hospitals abusing the rural floor provision to inappropriately influence the rural floor wage index value, which many commenters stated exacerbates the wage index disparity between urban and rural hospitals'' (84 FR 42333). Commenters stated that ''the use of urban to rural reclassifications to artificially inflate the rural floor has stretched the rural floor provision beyond its original intent . . . hospitals should not be penalized and bear the burden of declining reimbursement due to other hospitals manipulating their state wage index (84 FR 42334).

Considering the commenters' support for policies that limited the extent to which hospitals could manipulate the rural floor wage index value, 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, given that the Courts have repeatedly held unlawful CMS 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, the ongoing risk of the pending lawsuits cited previously, and the recognition of the challenge should we need to implement any future remedy in a budget neutral manner, we determined that it was necessary to propose 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 Proposed 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

[780] *https://www.eisneramper.com/safer-guides-healthcare-organizations-0822/.* Accessed December 14, 2022.

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 as provide data to patients and caregivers through transparency of data. Therefore, these proposed measures have the potential to generate actionable data on COVID–19 vaccination rates.

3. Alternatives Considered to the Proposed 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 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. 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.

4. Alternatives Considered for the Proposed 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,[781] and no longer provide meaningful distinctions in improvements in performance. Therefore, no alternatives were considered.

As discussed previously, these proposals for the LTCH QRP will result in an overall decrease in burden for LTCHs, and we believe the importance of the information necessitates these provisions.

Q. Overall Conclusion

1. Acute Care Hospitals

Acute care hospitals are estimated to experience an increase of approximately $2.7 billion in FY 2024, including operating, capital, low-volume hospital payments, and new technology changes. The estimated change in operating payments is approximately $2.7 billion (discussed in section I.F. and I.G. of this Appendix). The estimated change in capital payments is approximately $0.446 billion (discussed in section I.I. of this Appendix). The estimated change in new technology add-on payments is approximately −$0.466 billion as discussed in section I.G. of this Appendix. The change in new technology add-on payments reflects the net impact of new applications under the alternative pathways and continuing new technology add-on payments. 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 would experience a 6.2 percent increase in capital payments per case, as shown in Table III. of section I.I. of this Appendix. We project that there would be a $446 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 proposed rule, constitute a regulatory impact analysis.

2. LTCHs

Overall, LTCHs are projected to experience a decrease in estimated payments in FY 2024. In the impact analysis, we are using the proposed rates, factors, and policies presented in this proposed 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 decrease approximately $24 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.

R. 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 will review the rule, we assume that the total number of unique commenters on last year's proposed rule will be the number of reviewers of this proposed rule. We acknowledge that this assumption may understate or overstate the costs of reviewing the rule. It is possible that not all commenters reviewed last 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 this rule. We welcome any comments on the approach in estimating the number of entities which will review this proposed 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 1,631 number of timely pieces of correspondence on the FY 2023 IPPS/LTCH proposed rule as our estimate for the number of reviewers of this 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

[781] 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.*

and regulatory text. We seek comments on this assumption.

Using the wage information from the BLS for medical and health service managers (Code 11–9111), we estimate that the cost of reviewing the proposed 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 22.14 hours for the staff to review half of this proposed rule. For each IPPS hospital or LTCH that reviews this proposed rule, the estimated cost is $2,550.97 (22.14 hours × $115.22). Therefore, we estimate that the total cost of reviewing this proposed rule is $4,160,663.37 ($2,550.97 × 1,631 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 proposed 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 proposed changes to the IPPS presented in this proposed 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 proposed rule are estimated at $2.7 billion.

TABLE V.—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES UNDER THE IPPS FROM FY 2023 TO FY 2024

Category	Transfers
Annualized Monetized Transfers	$2.7 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 proposed rule under the LTCH PPS is projected to result in a decrease in estimated aggregate LTCH PPS payments in FY 2024 relative to FY 2023 of approximately $24 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 proposed 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 proposed 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 savings to the Federal Government associated with the policies for LTCHs in this proposed rule are estimated at $24 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	-$24 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 proposed 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 proposed 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

proposed rule would have a significant economic impact on a substantial number of small entities. For example, the majority of the 3,130 IPPS hospitals included in the impact analysis shown in ''Table I.—Impact Analysis of Proposed Changes to the IPPS for Operating Costs for FY 2024,'' on average are expected to see increases in the range of 2.8 percent, primarily due to the proposed hospital rate update, as discussed in section I.G. of this Appendix. On average, the proposed rate update for these hospitals is estimated to be 2.8 percent.

The 333 LTCH PPS hospitals included in the impact analysis shown in ''Table IV: Impact of Proposed 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 2.5 percent, primarily due to the 4.7 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 proposed rule contains a range of proposed policies. It provides descriptions of the statutory provisions that are addressed, identifies the proposed 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 proposed rule constitutes our regulatory flexibility analysis. We are soliciting public comments on our estimates and analysis of the impact of our proposals on small entities. Public comments that we receive and our responses will be presented in the final rule.

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 603 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 (362 hospitals) and 50–99 beds (190 hospitals) are expected to experience an increase in payments from FY 2023 to FY 2024 of 2.9 percent and 3.6 percent, respectively, primarily driven by the proposed hospital rate update and the proposed 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 proposed 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 a decrease in payments from FY 2023 to FY 2024 of 1.5 percent, primarily due to the projected 4.7 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 proposed 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 proposed 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 proposed 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 this 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 proposed 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. Proposed FY 2024 Inpatient Hospital Update

As discussed in section IV.A. of the preamble to this proposed 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 this FY 2024 IPPS/LTCH PPS proposed rule, in accordance with section 1886(b)(3)(B) of the Act, we are proposing 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 is 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 this FY 2024 IPPS/LTCH PPS proposed rule, based on IGI's fourth quarter 2022 forecast, we are proposing a productivity adjustment of 0.2 percentage point for FY 2024. We are also proposing that if more recent data subsequently become 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.

Therefore, 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 are proposing four possible applicable percentage increases that could be applied to the standardized amount, as shown in the following table.

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
Proposed Market Basket Rate-of-Increase	3.0	3.0	3.0	3.0
Proposed Adjustment for Failure to Submit Quality Data under Section 1886(b)(3)(B)(viii) of the Act	0.0	0.0	-0.75	-0.75
Proposed Adjustment for Failure to be a Meaningful EHR User under Section 1886(b)(3)(B)(ix) of the Act	0.0	-2.25	0.0	-2.25
Proposed Productivity Adjustment under Section 1886(b)(3)(B)(xi) of the Act	-0.2	-0.2	-0.2	-0.2
Proposed Applicable Percentage Increase Applied to Standardized Amount	**2.8**	**0.55**	**2.05**	**-0.2**

B. Proposed 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).

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 proposed 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 proposing the same four possible applicable percentage increases in the previous table for the hospital-specific rate applicable to SCHs and MDHs.

C. Proposed 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 proposed rule.

In addition, as discussed in section IV.A.2. of the preamble of this proposed 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.

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, for this FY 2024 proposed rule, in accordance with section 1886(b)(3)(B) of the Act, as previously discussed, for Puerto Rico hospitals, we are proposing 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, there are two possible applicable percentage increases that can be applied to the standardized amount. Based on these data, we are proposing 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, we are proposing 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 are proposing 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 × 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 are proposing that if more recent data subsequently become 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.

D. Proposed 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 proposed rule, we are proposing 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 proposed rule, the current estimate of the IPPS operating market basket percentage increase for FY 2024 is 3.0 percent. We are proposing that if more recent data subsequently become available, we would use such data, if appropriate, to determine the FY 2024 market basket update for the FY 2024 IPPS/LTCH PPS final rule.

E. Proposed 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 proposed rule, we are proposing to update the LTCH PPS standard Federal payment rate for FY 2024 by 2.9 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 proposing to reduce 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 proposing to establish an update factor of 1.029 in determining the LTCH PPS standard Federal rate for FY 2024. For LTCHs that fail to submit quality data for FY 2024, we are proposing to establish an annual update to the LTCH PPS standard Federal rate of 0.9 percent (that is, the proposed annual update for FY 2024 of 2.9 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 a proposed update factor of 1.009 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 proposed rule, the proposed update to the LTCH PPS standard Federal payment rate of 2.9 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 B. 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 3.0 percent.

For FY 2024, consistent with policy set forth in section VII. of the preamble of this proposed rule, for LTCHs that submit quality data, we are recommending an update of 2.9 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 0.9 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 an update to 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 seek comments on approaches CMS could take. We are proposing an applicable percentage increase for FY 2024 of 2.8 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 proposed update to the capital rate is discussed in section III. of the Addendum to this proposed 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 proposed 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 proposed rule for a further discussion of Medicare DSH and uncompensated care payments.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this proposed rule, and, when we proceed with a subsequent document(s), we will respond to those comments in the preamble to that document.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on March 22, 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, and Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services proposes to amend 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 meets all of following:

(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 paragraph (c) of this section, are readily available and accessible to the requesting hospital, comparison hospitals, and CMS.

(iv) Maintains or generates data that, for purposes of the process described in paragraph (c) of 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) *Eligibility to request 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; or

(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 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 paragraph (c) of this section, a hospital is located in the county and State in which the main campus of the hospital is located.

(d) *Criteria for 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 paragraph (d) of this section, 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 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) All of the following information for the hospital requesting an exception:

(A) Name.

(B) Address.

(C) National Provider Identification number(s) (NPI).

(D) Tax Identification Number(s) (TIN).

(E) CMS Certification Number(s) (CCN).

(ii)(A) The name of the county in which the main campus of the hospital requesting an exception is located; and

(B) 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.

(iii) The following information for the contact person who will be available to discuss the request with CMS on behalf of the hospital:

(A) Name.

(B) Title.

(C) Address to receive hard copy mail.

(D) Electronic mail address.

(E) Daytime telephone number.

(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, if available, supporting documentation 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 all of the following:

(A) The hospital's calculations of its baseline number of operating rooms, procedure rooms, and beds.

(B) The hospital's 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.

(D) The additional number of operating rooms, procedure rooms, and beds by which the hospital requests to expand.

(E) Whether the hospital plans to use expansion facility capacity to provide specialty services (for example, maternity or psychiatric services) if the request is approved.

(vii) Information regarding the need 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;

(C) In any county in which the hospital provides inpatient or outpatient hospital services as of the date the hospital submits the request; and

(D) In any county in which the hospital plans to provide inpatient or outpatient hospital services if CMS approves the request.

(3) 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 and hospitals located in the requesting hospital's community as defined in paragraph (f)(3) 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 is eligible to request the expansion exception under paragraph (b) of this section 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.

(C) The counties in which the hospital plans to provide inpatient or outpatient hospital services if CMS approves the request.

(iii) Community input must be received no later than 60 days after CMS publishes notice of the hospital's request in the **Federal Register**.

(A) Such input must take the form of written comments.

(B) The written comments must be submitted according to the instructions in the **Federal Register** notice of the hospital's request.

(C) If CMS receives written comments from the community, the hospital has 30 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—

(i) The end of the 60-day comment period if CMS does not receive written comments from the community.

(ii) The end of the 30-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 30-day rebuttal period, regardless of whether the hospital submits a rebuttal statement, if CMS receives written comments from the community.

(h) *Eligibility determination.* Based on the information described in paragraph (e) of this section, CMS will first determine whether the hospital is eligible to make the request for an exception from the prohibition on facility expansion under paragraph (b) of this section.

(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 the basis for its decision.

(2) *Basis for decision.* 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 following:

(A) The county in which the main campus of the hospital is located.

(B) Any county in which the hospital provides inpatient or outpatient hospital services as of the date the hospital submits the request.

(C) Any county in which the hospital plans to provide inpatient or outpatient hospital services if CMS approves 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 decisions.* Not later than 60 days after receiving a complete request—

(1) If CMS determines that the hospital is not eligible to make the request for an exception from the prohibition on facility expansion under paragraph (b) of this section, CMS will publish in the **Federal Register** notice of such determination; or

(2) If CMS determines that the hospital is eligible to make the request for an exception from the prohibition on facility expansion under paragraph (b) of this section, 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).

* * * * *

§ 412.108 [Amended]

■ 12. 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''.

■ 13. 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. Under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific factor.

■ 14. 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'' 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 product of the measure performance scaler and the underserved multiplier.

* * * * *

Measure performance scaler means the sum of the points awarded to a hospital for each domain based on its unweighted domain score for the domain for the applicable fiscal year as calculated under § 412.165(b)(3).

* * * * *

Total Performance Score means the numeric scores awarded to each hospital based on its performance under the Hospital VBP Program with respect to a fiscal year as follows:

(1) For performance years before FY 2026, ranging from 0 to 100 for program years before FY 2026.

(2) For performance years on or after 2026, ranging from 0 to 110 for program years on or after FY 2026.

Underserved multiplier means a logistic function applied to the proportion of the hospital's patients with dual eligibility status out of the hospital's total Medicare inpatient population during the calendar year that is 2 years prior to the applicable fiscal year.

* * * * *

■ 15. 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 program years before FY 2026, the hospital's Total Performance Score divided by 100; or

(B) For program years on or after FY 2026, the hospital's Total Performance Score divided by 110.

(iii) The linear exchange function slope.

* * * * *

■ 16. Section 412.164 is amended by adding paragraph (c) 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 quality measures specified under section 1866(o)(2) of the Act for the Hospital VBP Program measure set 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.* The benefits of removing a measure from the Hospital VBP Program will be assessed on a case-by-case basis. Under this case-by-case approach, a measure will not be removed solely on the basis of meeting any specific factor.

(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**.

■ 17. 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) For program years on or after FY 2026, CMS will determine the health equity adjustment bonus points the hospital has earned for the fiscal year as follows:

(i) CMS will calculate the measure performance scaler 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.

(D) Sum the points awarded under paragraph (b)(5)(i) of this section.

(ii) CMS will calculate the underserved multiplier for the hospital for the fiscal year.

(iii) CMS will calculate the health equity adjustment bonus points by multiplying the measure performance scaler calculated under paragraph (b)(5)(i) of this section and the underserved multiplier calculated under paragraph (b)(5)(ii) of this section.

(iv) CMS will cap the total number of health equity adjustment bonus points that could be added to a hospital's Total Performance Score for a program year at 10.

(6) After the domain scores are weighted:

(i) For program years before FY 2026, the sum of the weighted domain scores is the hospital's Total Performance Score for the fiscal year.

(ii) For program years on or after FY 2026, the sum of the weighted domain scores and the health equity adjustment bonus points is the hospital's Total Performance Score for the fiscal year.

* * * * *

§ 412.320 [Amended]

■ 18. Section 412.320 is amended in paragraph (a)(1)(iii) by adding the phrase ''and before October 1, 2023,'' after ''October 1, 2006,''.

■ 19. 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 program year.

(B) The threshold set at 100 percent completion of measures data and standardized patient assessment data collected using the LCDS on at least 90 percent of the assessments LTCHs submit through the CMS designated data submission system beginning with the FY 2026 program year.

(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

■ 20. The authority citation for part 419 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395l(t), and 1395hh.

■ 21. 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

■ 22. The authority citation for part 488 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

§ 488.1 [Amended]

■ 23. 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,''.

■ 24. 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.

TABLE 1 TO § 488.2—Continued

Section	Subject
1913	Medicaid requirements for hospitals that provide nursing facility (NF) care.
1919	Medicaid requirements for NFs.

§ 488.18 [Amended]

■ 25. 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)''.

■ 26. 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

■ 27. 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.

■ 28. 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

■ 29. The authority citation for part 495 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 30. 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.

* * * * *

■ 31. 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: April 4, 2023.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2023–07389 Filed 4–10–23; 4:15 pm]

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Part III

Department of Energy

10 CFR Parts 429 and 430
Energy Conservation Program: Test Procedure for Fans and Blowers; Final Rule

DEPARTMENT OF ENERGY

10 CFR Parts 429 and 430

[EERE–2021–BT–TP–0021]

RIN 1904–AF17

Energy Conservation Program: Test Procedure for Fans and Blowers

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule.

SUMMARY: The U.S. Department of Energy (''DOE'') establishes a test procedure for fans and blowers, including air circulating fans, and incorporates by reference the relevant industry test standards for: measuring the fan electrical input power and determining the fan energy index of fans and blowers other than air-circulating fans; and measuring the fan airflow in cubic feet per minute per watt of electric power input of air-circulating fans. In this final rule, DOE also establishes supporting definitions, requirements for alternative efficiency determination methods, and sampling requirements.

DATES: The effective date of this rule is May 31, 2023. All representations of energy efficiency and energy use, including those made on marketing materials and product labels, must be made in accordance with this test procedure beginning October 30, 2023. To the extent the test procedure established in this document is required only for the evaluation and issuance of newly established efficiency standards, use of the test procedure is not required until the implementation date of such new standards. The incorporation by reference of certain materials listed in the rule is approved by the Director of the Federal Register on May 31, 2023.

ADDRESSES: The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as those containing information that is exempt from public disclosure.

A link to the docket web page can be found at *www.regulations.gov/docket/EERE-2021-BT-TP-0021.* The docket web page contains instructions on how to access all documents, including public comments, in the docket.

For further information on how to review the docket, contact the Appliance and Equipment Standards Program staff at (202) 287–1445 or by email: *ApplianceStandardsQuestions@ee.doe.gov.*

FOR FURTHER INFORMATION CONTACT:

Mr. Jeremy Dommu, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–2J, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–9879. Email: *ApplianceStandardsQuestions@ee.doe.gov.*

Ms. Amelia Whiting, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW, Washington, DC 20585–0121. Telephone: (202) 586–2588. Email: *amelia.whiting@hq.doe.gov.*

SUPPLEMENTARY INFORMATION:

DOE incorporates by reference the following industry standards into 10 CFR part 431:

ANSI/AMCA Standard 210–16 (AMCA 210–16), ''Laboratory Methods of Testing Fans for Certified Aerodynamic Performance Rating,'' August 26, 2016. (Co-published as ASHRAE 51–16).

ANSI/AMCA Standard 214–21 (AMCA 214–21), ''Test Procedure for Calculating Fan Energy Index for Commercial and Industrial Fans and Blowers,'' March 1, 2021.

ANSI/AMCA Standard 230–23 (AMCA 230–23), ''Laboratory Methods of Testing Air Circulating Fans for Rating and Certification,'' February 10, 2023.

ANSI/AMCA Standard 240–15 (AMCA 240–15), ''Laboratory Methods of Testing Positive Pressure Ventilators for Aerodynamic Performance Rating,'' May 9, 2015.

Copies of AMCA 210–16, AMCA 214–21, AMCA 230–23, and AMCA 240–15 can be obtained from the Air Movement and Control Association International (AMCA), 30 West University Drive, Arlington Heights, IL 60004–1893, (847) 394–0150, or by going to *www.amca.org.*

ISO 5801:2017(E), ''Fans—Performance testing using standardized airways,'' Third Edition, September 2017.

ISO 80079–36:2016, ''Explosive atmospheres—Part 36: Non-electrical equipment for explosive atmospheres—Basic method and requirements,'' Edition 1.0, February 2016.

Copies of ISO 5801:2017(E) and ISO 80079–36:2016 can be obtained from the International Organization for Standardization (ISO), Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, or by going to *www.iso.org.*

UL 705 (UL 705–2022), ''Standard for Safety for Power Ventilators,'' Edition 7, July 19, 2017 (including revisions through August 19, 2022).

Copies of UL 705–2022 can be obtained from Underwriters Laboratories (UL), 333 Pfingsten Road, Northbrook, IL 60062 or *www.shopulstandards.com.*

For a further discussion of these standards, see section IV.N of this document.

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I. Authority and Background

On August 19, 2021, DOE published a coverage determination classifying fans and blowers as covered equipment under 42 U.S.C. 6311(2)(A) and 6312(b). 86 FR 46579 (''August 2021 Final Coverage Determination''). DOE does not currently have a test procedure or energy conservation standard for fans and blowers. The following sections discuss DOE's authority to establish a test procedure for fans and blowers and relevant background information regarding DOE's consideration of test procedures for this equipment.

A. Authority

The Energy Policy and Conservation Act, as amended (''EPCA''),[1] authorizes DOE to regulate the energy efficiency of a number of consumer products and certain industrial equipment. (42 U.S.C. 6291–6317) Title III, Part C[2] of EPCA, added by Public Law 95–619, Title IV, section 441(a), established the Energy Conservation Program for Certain Industrial Equipment, which sets forth a variety of provisions designed to improve energy efficiency. EPCA provides that DOE may include a type of industrial equipment, including fans and blowers, as covered equipment if it determines that to do so is necessary to carry out the purposes of Part A–1. (42 U.S.C. 6311(2)(B)(ii) and (iii); 42 U.S.C. 6312(b)) EPCA specifies the types of equipment that can be classified as industrial equipment. (42 U.S.C. 6311(2)(B)) The purpose of Part A–1 is to improve the efficiency of electric motors and pumps and certain other industrial equipment in order to conserve the energy resources of the Nation. (42 U.S.C. 6312(a)) As stated, on August 19, 2021, DOE published a final determination in which DOE determined that fans and blowers meet the three statutory criteria for classifying industrial equipment as covered (42 U.S.C. 6311(2)(A)), because fans and blowers are a type of industrial equipment which: (1) in operation consume, or are designed to consume, energy; (2) are to a significant extent distributed in commerce for industrial or commercial use; [3] and (3) are not covered under 42 U.S.C. 6291(a)(2). 86 FR 46579, 46585–46588. DOE also determined that coverage of fans and blowers is necessary to carry out the purposes of Part A–1. 86 FR 46579, 46588.

The energy conservation program under EPCA consists essentially of four parts: (1) testing, (2) labeling, (3) Federal energy conservation standards, and (4) certification and enforcement procedures. Relevant provisions of EPCA include definitions (42 U.S.C. 6311), test procedures (42 U.S.C. 6314), labeling provisions (42 U.S.C. 6315), energy conservation standards (42 U.S.C. 6313), and the authority to require information and reports from manufacturers (42 U.S.C. 6316; 42 U.S.C. 6296).

The Federal testing requirements consist of test procedures that manufacturers of covered equipment must use as the basis for: (1) certifying to DOE that their equipment complies with the applicable energy conservation standards adopted pursuant to EPCA (42 U.S.C. 6316(a); 42 U.S.C. 6295(s)), and (2) making other representations about the efficiency of that equipment (42 U.S.C. 6314(d)). Similarly, DOE must use these test procedures to determine whether the equipment complies with relevant standards promulgated under EPCA. (42 U.S.C. 6316(a); 42 U.S.C. 6295(s))

Federal energy efficiency requirements for covered equipment established under EPCA generally supersede State laws and regulations concerning energy conservation testing, labeling, and standards. (42 U.S.C. 6316(a); 42 U.S.C. 6297). DOE may, however, grant waivers of Federal preemption for particular State laws or regulations, in accordance with the procedures and other provisions of EPCA. (42 U.S.C. 6316(b)(2)(D))

Under 42 U.S.C. 6314, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered equipment. EPCA requires that any test procedures prescribed or amended under this section must be reasonably designed to produce test results which reflect energy efficiency, energy use or estimated annual operating cost of a given type of covered equipment during a representative average use cycle (as determined by the Secretary) and requires that test procedures not be unduly burdensome to conduct. (42 U.S.C. 6314(a)(2))

B. Background

As discussed, on August 19, 2021, DOE published in the **Federal Register** a final coverage determination classifying fans and blowers as covered equipment. 86 FR 46579. DOE determined that the term ''blower'' is interchangeable with the term ''fan.'' 86 FR 46579, 46583. DOE defines a fan (or blower) as a rotary bladed machine used to convert electrical or mechanical power to air power, with an energy output limited to 25 kilojoule (''kJ'') per kilogram (''kg'') of air. It consists of an impeller, a shaft and bearings and/or driver to support the impeller, as well as a structure or housing. A fan (or blower) may include a transmission, driver, and/or motor controller. 10 CFR 431.172.

Prior to the August 2021 Final Coverage Determination, DOE published a notice of intent to establish an Appliance Standards and Rulemaking Federal Advisory Committee (''ASRAC'') Working Group (''Working

[1] All references to EPCA in this document refer to the statute as amended through the Energy Act of 2020, Public Law 116–260 (Dec. 27, 2020), which reflect the last statutory amendments that impact Parts A and A–1 of EPCA.

[2] For editorial reasons, upon codification in the U.S. Code, Part C was redesignated Part A–1 and hereafter referred to as ''Part A–1.''

[3] DOE notes that distribution for residential use does not preclude coverage as covered equipment so long as to a significant extent the equipment is of a type that is also distributed in commerce for industrial and commercial use.

Group'') for fans and blowers. 80 FR 17359 (April 1, 2015). The Working Group [4] commenced negotiations at an open meeting on May 18, 2015, and held 16 meetings and three webinars to discuss scope, metrics, test procedures, and standard levels for fans.[5] The Working Group concluded its negotiations on September 3, 2015, and, by consensus vote,[6] approved a term sheet containing recommendations for DOE on the scope of a test procedure, and energy conservation standards for fans. The term sheet containing the Working Group recommendations (''term sheet'') is available in the fans energy conservation standard rulemaking docket. (Docket No. EERE–2013–BT–STD–0006, No. 179) [7] ASRAC approved the term sheet on September 24, 2015. (Docket No. EERE–2013–BT–NOC–0005, Public Meeting Transcript, No. 58 at p. 29)

On January 10, 2020, DOE received a notice of petition from the Air Movement and Control Association (''AMCA''), Air Conditioning Contractors of America, and Sheet Metal & Air Conditioning Contractors of America (''the Petitioners'') requesting that DOE establish test procedures for certain categories of commercial and industrial fans based on an industry test method in development, AMCA 214. DOE published a notice of this petition with a request for public comment on April 23, 2020; [8] 85 FR 22677 (''April 2020 Notice of Petition''). As part of the April 2020 Notice of Petition, DOE sought data and information pertinent to whether amended test procedures would (1) accurately measure energy efficiency, energy use, or estimated annual operating cost of fans during a representative average use cycle; and (2) not be unduly burdensome to conduct. 85 FR 22677, 22679.

On October 1, 2021, DOE published a request for information pertaining to potential test procedures for fans and blowers. 86 FR 54412 (''October 2021 RFI''). In the October 2021 RFI, DOE identified a variety of issues on which it sought input to determine whether, and if so how, potential test procedures for fans and blowers, including air circulating fans, would: (1) comply with the requirements in EPCA that test procedures be reasonably designed to produce test results that reflect energy use during a representative average use cycle, and (2) not be unduly burdensome to conduct. *Id.* In response to requests from stakeholders,[9] DOE extended the comment period 14 days to November 15, 2021. 86 FR 59308 (Oct. 27, 2021).

DOE published a notice of proposed rulemaking (''NOPR'') for the test procedure on July 25, 2022. 87 FR 44194 (hereafter, the ''July 2022 NOPR''). DOE held a public meeting related to this NOPR on August 2, 2022 (hereafter, the ''NOPR public meeting''). DOE received several comments [10] requesting a comment extension ranging from 15 to 60 days, some commenters also requested a second public meeting/workshop. In particular, the Air-Conditioning, Heating, and Refrigeration Institute (''AHRI'') commented that the complexity of the commercial fans rulemaking warrants additional time for stakeholder feedback and recommended that DOE reconsider the request for an open meeting and reopen the comment period so that all stakeholders have ample opportunity for discourse on the implementation of an incredibly complex rule, adding that the 60-day comment period was not sufficient. (AHRI, No. 40 at pp. 3–4, 5) DOE determined that the length of the comment period provided a meaningful opportunity to comment on the NOPR and did not provide an extension.[11]

DOE received comments in response to the July 2022 NOPR from the interested parties listed in Table I–1.

TABLE I–1—LIST OF COMMENTERS WITH WRITTEN SUBMISSIONS IN RESPONSE TO THE JULY 2022 NOPR

Commenter(s)	Reference in this final rule	Comment No. in the docket	Commenter type
Association of Home Appliance Manufacturers	AHAM	35	Trade Association.
Air-Conditioning, Heating, and Refrigeration Institute	AHRI	40	Trade Association.
Air Movement and Control Association International	AMCA	13, 41	Trade Association.
Appliance Standards Awareness Project, American Council for an Energy-Efficient Economy, Natural Resources Defense Council.	Efficiency Advocates	32	Efficiency Organizations.
California Investor-Owned Utilities: Pacific Gas and Electric Company, San Diego Gas and Electric, and Southern California Edison.	CA IOUs	37	Utilities.
California Energy Commission	CEC	30	Manufacturer.
ebm-papst Inc	ebm-papst	31	Manufacturer.
Greenheck Group	Greenheck	39	Manufacturer.

[4] The Working Group was comprised of representatives from AAON, Inc.; AcoustiFLO LLC; AGS Consulting LLC; AMCA; AHRI, Appliance Standards Awareness Project; Berner International Corp; Buffalo Air Handling Company; Carnes Company; Daikin/Goodman; ebm-papst; Greenheck; Morrison Products Inc.; Natural Resources Defense Council; Newcomb & Boyd; Northwest Energy Efficiency Alliance; CA IOUs; Regal Beloit Corporation; Rheem Manufacturing Company; Smiley Engineering LLC representing Ingersoll Rand/Trane; SPX Cooling Technologies/CTI; The New York Blower Company; Twin City Companies, Ltd; U.S. Department of Energy; and United Technologies/Carrier.

[5] Details of the negotiation sessions can be found in the public meeting transcripts that are posted to the docket for the energy conservation standard rulemaking at: *www.regulations.gov/docket?D=EERE-2013-BT-STD-0006.*

[6] At the beginning of the negotiated rulemaking process, the Working Group defined that before any vote could occur, the Working Group must establish a quorum of at least 20 of the 25 members and defined consensus as an agreement with less than 4 negative votes. Twenty voting members of the Working Group were present for this vote. Two members (Air-Conditioning, Heating, and Refrigeration Institute and Ingersoll Rand/Trane) voted no on the term sheet.

[7] The references are arranged as follows: (commenter name, comment docket ID number, page of that document). If one comment was submitted with multiple attachments, the references are arranged as follows: (commenter name, comment docket ID number. Attachment number, page of that document). The attachment number corresponds to the order in which the attachment appears in the docket. The parenthetical reference provides a reference for information located in DOE Docket No. EERE–2021–BT–TP–0021. If the information was submitted to a different DOE docket, the DOE docket number is additionally specified in the reference.

[8] At the time of the petition, AMCA 214–21 was available as a draft version (AMCA 214).

[9] AMCA requested a 21-day extension (AMCA, No. 2 at p. 1).

[10] AMCA and AHRI, No. 19 at p. 1; AHAM, No. 20 at p. 1; CA IOUs, No. 21 at pp. 1–2; NEEA, No. 22 at p. 1, JCI, No. 23 at p. 1; AHAM, No. 24 at p. 1.

[11] DOE posted a copy of the pre-**Federal Register** publication of the fans and blowers test procedure NOPR on the DOE website and notified stakeholder organizations via email on June 24, 2022, which provided stakeholders approximately 30 days for review of that copy in addition to the 60-day comment period that was announced in the notice published in the **Federal Register** on July 25, 2022. A public meeting was held on August 2, 2022, and the written comment period closed on September 23, 2022.

TABLE I–1—LIST OF COMMENTERS WITH WRITTEN SUBMISSIONS IN RESPONSE TO THE JULY 2022 NOPR—Continued

Commenter(s)	Reference in this final rule	Comment No. in the docket	Commenter type
Johnson Controls	JCI	34	Manufacturer.
Morrison Products Inc	Morrison	42	Manufacturer.
New York Blower	New York Blower	33	Manufacturer.
Northwest Energy Efficiency Alliance	NEEA	36	Efficiency Organization.
Robinson Fans Holdings	Robinson	43	Manufacturer.
Trane Technologies	Trane	38	Manufacturer.

A parenthetical reference at the end of a comment quotation or paraphrase provides the location of the item in the public record.[12] To the extent that interested parties have provided written comments that are substantively consistent with any oral comments provided during the NOPR public meeting, DOE cites the written comments throughout this final rule. DOE identified one oral comment from Nidec Motor Corporation (''Nidec'') regarding stability determination that is summarized and addressed in section III.E.16.a.; one comment from ASAP generally supporting the test procedure rulemaking summarized and addressed in section III.A; one comment from Daikin related to embedded fans exclusions summarized and addressed in section III.B.3.b; and one comment from Loren Cook Company (''Loren Cook'') related to test burden summarized and addressed in section III.E.12 of this document. All other comments provided during the webinar are substantively addressed by written comments.

In addition, DOE notes that it received several comments [13] that were not related to the test procedure and instead relate to potential energy conservation standards. DOE will address these comments in a separate rulemaking pertaining to energy conservation standards.

On November 21, 2022, AMCA, as well as AMCA members (ebm-papst, Big Ass Fans, Greenheck, New York Blower, and Twin City Fan), ASAP, and NEEA met with DOE to discuss several items related to the fan and blower test procedure during an ex-parte meeting. (AMCA No. 45, at pp. 1–12)

II. Synopsis of the Final Rule

In this final rule, DOE adopts a test procedure for fans and blowers in subpart J of 10 CFR part 431 and modifies 10 CFR part 429, as follows:

- Establishes the scope of the test procedure for fans and blowers as to include standalone and embedded fans and blowers (*i.e.,* fans and blowers incorporated into other equipment) that are either: axial inline fans; axial panel fans; centrifugal housed fans; centrifugal unhoused fans; centrifugal inline fans; radial-housed fans; power roof/wall ventilators (''PRVs''); or air circulating fans with input power greater than or equal to 125 W; and excluding some fans that are embedded in other products or equipment; and excluding radial housed unshrouded fans with a diameter less than 30 inches or a blade width of less than 3 inches; safety fans; induced flow fans; jet fans; cross-flow fans; fans manufactured exclusively to be powered by internal combustion engines; fans that create a vacuum of 30 inches water gauge (''in. wg'') or greater; and fans designed and marketed to operate at or above 482 degrees Fahrenheit (250 degrees Celsius). In addition, for fans and blowers other than air circulating fans, the test procedure only applies to duty points with fan shaft input power equal to or greater than 1 horsepower and fan air power equal to or less than 150 horsepower.
- Defines ''axial inline fan,'' ''axial panel fan,'' ''centrifugal housed fan,'' ''centrifugal unhoused fan,'' ''centrifugal inline fan,'' ''radial-housed fan,'' ''power roof ventilator,'' ''cross-flow fan,'' ''induced flow fan,'' ''jet fan,'' ''basic model,'' ''safety fan,'' ''air circulating fan,'' and related terms.
- Adopts through reference in newly adopted appendix A to subpart J of 10 CFR part 431 (''appendix A'') certain provisions of ANSI/AMCA 214–21, ''Test Procedure for Calculating Fan Energy Index for Commercial and Industrial Fans and Blowers'' (''AMCA 214–21''), with modifications, as the test procedure for determining FEP and FEI of fans and blowers other than circulating fans;
- Adopts through reference in newly adopted appendix B to subpart J of 10 CFR part 431 (''appendix B'') certain provisions of ANSI/AMCA 230–23, ''Laboratory Methods of Testing Air Circulating Fans for Rating and Certification,'' with modifications, as the test procedure for determining efficacy in cubic feet per minute (''CFM'') per watt (''W'') (''CFM/W'');
- Adopts through reference certain provisions of the following industry standards referenced by AMCA 214–21: ANSI/AMCA 210–16, (''AMCA 210–16'') ''Laboratory Methods of Testing Fans for Certified Aerodynamic Performance Rating'' and ISO 5801:2017(E), ''Fans Performance testing using standardized airways'' (ISO 5801:2017).
- Establishes fan and blower sampling requirements and provisions related to determining represented values in 10 CFR 429.69;
- Establishes an alternative efficiency determination method (''AEDM'') for fans and blowers in 10 CFR 429.70; and

The adopted requirements are summarized in Table II–1.

[12] The parenthetical reference provides a reference for information located in the docket of DOE's rulemaking to develop test procedures for fans and blowers. (Docket No. EERE–2021–BT–TP–0021, maintained at *www.regulations.gov.*) The references are arranged as follows: (commenter name, comment docket ID number, page of that document).

[13] *See* AHRI, No. 40 at pp. 7, 8, 9–10, 12–14; CA IOUs, No. 37 at pp. 1–3.

TABLE II–1—SUMMARY OF ADOPTED REQUIREMENTS

Topic	Location in CFR	Adopted requirements	Applicable preamble discussion
Scope	10 CFR 431.174	Establish the scope of the test procedure for fans and blowers as to include standalone and embedded fans and blowers (*i.e.,* fans and blowers incorporated into other equipment) that are either: axial inline fans; axial panel fans; centrifugal housed fans; centrifugal unhoused fans; centrifugal inline fans; radial-housed fans; power roof/wall ventilators; or air circulating fans with input power greater than or equal to 125 W; and excluding some fans that are embedded in other products or equipment; and excluding radial housed unshrouded fans with diameter less than 30 inches or a blade width of less than 3 inches; safety fans; induced flow fans; jet fans; cross-flow fans; fans manufactured exclusively to be powered by internal combustion engines; fans that create a vacuum of 30 in. wg or greater; and fans designed and marketed to operate at or above 482 degrees Fahrenheit (250 degrees Celsius). In addition, for fans and blowers other than air circulating fans, the test procedure is applicable to duty points with fan shaft input power equal to or greater than 1 horsepower and fan air power equal to or less than 150 horsepower.	Section III.B.
Definitions	10 CFR 431.172	Define ''axial inline fan,'' ''axial panel fan,'' ''centrifugal housed fan,'' ''centrifugal unhoused fan,'' ''centrifugal inline fan,'' ''radial-housed fan,'' ''power roof ventilator,'' ''cross-flow fan,'' ''induced flow fan,'' ''jet fan,'' ''basic model,'' ''safety fan,'' ''air circulating fan,'' and related terms.	Section III.C.
Test Procedure	10 CFR 431.174	Establish FEI as the metric for fans and blowers other than air circulating fans; incorporate by reference AMCA 214–21, AMCA 210–16, and provide additional instructions for determining the FEI (and other applicable performance characteristics) for fans and blowers other than air circulating fans. Establish the efficacy (CFM/W) as the metric for air circulating fans; incorporate by reference AMCA 230–23 and provide additional instructions for determining the efficacy (and other applicable performance characteristics) for air circulating fans.	Sections III.D, III.E, III.F and III.G.
Sampling Plan	10 CFR 429.69	Specify the minimum number of fans or blowers to be tested to rate a basic model and determine representative values.	Section III.J.
AEDM	10 CFR 429.70	Establish requirements for applying an alternative energy use determination method.	Section III.I.

DOE's test method for fans and blowers includes measurements of pressure, flow rate, and fan shaft or electrical input power, all of which are required to calculate FEP, FEI, and efficacy (CFM/W) as applicable, as well as other quantities to characterize rated fan and blower performance (*e.g.,* speed). DOE has determined that the relevant sections of AMCA 214–21, AMCA 210–16, and AMCA 230–23, in conjunction with the additional provisions adopted in this test procedure, would produce test results that reflect the energy efficiency and energy use of a fan or blower during a representative average use cycle. (42 U.S.C. 6314(a)(2)) Additionally, DOE has determined that the test procedure, which is based on the relevant industry testing standard, would not be unduly burdensome to conduct. (42 U.S.C. 6314(a)(2)) DOE's analysis of the burdens associated with the proposed test procedure is presented in section III.M of this document.

The effective date for the test procedure adopted in this final rule is 30 days after publication of this document in the **Federal Register**. Representations of energy use or energy efficiency must be based on testing in accordance with the test procedure beginning 180 days after the publication of this final rule.

III. Discussion

In the following sections, DOE establishes test procedures and related definitions for fans and blowers in subpart J of part 431, sampling plans for this equipment, an alternative efficiency determination method (''AEDM'') for this equipment, and enforcement provisions for this equipment. In the following sections, DOE provides relevant background information, discusses and responds to relevant public comments, and presents the adopted requirements.

A. General

ASAP commented in general support of the July 2022 NOPR. (Public Meeting transcript, No. 18 at p. 5)

AHRI commented that in the Table of Contents of the NOPR, DOE lists a section ''C. Deviation from the Process Rule;'' however, no such section can be found in the NOPR. AHRI noted that according to Section 3(a) of 10 CFR part 430, subpart C, appendix A, DOE may,

as necessary, deviate from [the Process Rule] to account for specific circumstances of a particular rulemaking, and interested parties will receive notice of the deviation and explanation. AHRI recommended that DOE reopen the comment period to include the missing ''Section C. Deviation from the Process Rule'' that includes an explanation for the deviation so that the public can respond and provide meaningful comments. AHRI stated that DOE has failed to be transparent in the NOPR in providing no notice or explanation of any deviation from the applicable guidance of appendix A. (AHRI, No. 40 at pp. 2–3)

AHAM commented that DOE did not provide notice and explanation for deviations from the Process Rule, although the table of contents included such section. Nevertheless, AHAM noted that it is clear that DOE deviated from the Process Rule at least with regard to the comment period, although DOE did not explain why. AHAM commented that instead of the process rule's required 75-day comment period for test procedures, DOE provided only 60 (which has become DOE's common practice regardless of the particular rulemaking). AHAM stated that DOE declined several parties' requests to extend that comment period despite substantive reasons necessitating more time and reasonable extension requests that would not meaningfully extend DOE's rulemaking process requested. In addition, AHAM commented that a longer comment period was required for manufacturers to test products using DOE's proposed tests. In addition, AHAM noted that AHAM members struggled to understand whether the proposed test procedure would implicate consumer fans and/or fans used in home appliances in the allotted time. AHAM stated that denying reasonable requests for modest comment period extensions will not ultimately streamline DOE's efforts and will result in increased resource needs for the Department to respond to stakeholder meeting requests and supplemental documents, which would lengthen the rulemaking process. AHAM commented that in the future, DOE should allow for reasonable extensions to comment periods in order to increase the quality of responses to its requests for comment and the overall accuracy of its final rules. (AHAM, No. 35 at pp. 7–8)

AMCA noted that incorporating air circulating fans in the test procedure NOPR at a time when AMCA 230 was undergoing revisions added considerable time and efforts in addition to having to review the expected material and AMCA commented that DOE denied multiple stakeholder requests for a 30-day extension. AMCA further commented that an ex-parte meeting after the pre-publication of the NOPR and before the publication of the NOPR would have benefited stakeholders and potentially improved the NOPR. (AMCA No. 41 at p. 2)

DOE did not deviate from 10 CFR part 430, subpart C, appendix A (''appendix A''), applicable to fans and blowers under 10 CFR 431.4, and did not include such discussion in the July 2022 NOPR. DOE notes however that a section title for this section was not deleted from the table of contents and should have been deleted.

In addition, appendix A does not prescribe any mandatory comment period for test procedure NOPRs. A 60-day period is the typical period that DOE provides for all NOPRs, which exceeds the 45-day minimum required by EPCA. (*See* 42 U.S.C. 6314(b)(2)) As previously noted, the pre-publication version of the NOPR was publicly available for 30 days for stakeholders to review prior to publication of the NOPR. As such, the timing and sequence of this rulemaking has been conducted consistent with the provisions in appendix A. Additionally, the intent of the pre-publication version of a document is to provide stakeholders with additional time to review and prepare comments. Further, DOE provided opportunity for written comments and subsequent ex-parte meeting, as previously discussed, and comments from all stakeholders were considered in finalizing this test procedure pertaining to fans and blowers as discussed in section III of this document.

AHRI commented that the proposed test procedure will exacerbate supply chain issues, contradicting Executive Order 14017.[14] AHRI commented that supply chain disruptions have been lowering the competitiveness of the HVAC industry and hindering AHRI manufacturing capabilities. AHRI commented that trade distortions and the COVID–19 pandemic have resulted in shortages of essential components and led to delays and costly inflation at every stage of the manufacturing supply chain. AHRI commented that the immediacy of the implementation of a test procedure change serves to exacerbate near-term supply chain disruptions, and that these issues are made worse with ongoing labor shortages, and added together, disrupt domestic production, and result in temporary shutdowns, reduced sales, increased consumer costs, and delayed delivery of critical products.[15] AHRI further provided a description of current supply issues experienced by its members and commented that such regulatory burdens by DOE and others have left manufacturers in an almost constant state of redesign and testing. AHRI added that innovation is no longer as important as just modifying products to meet what AHRI described as new and ever-changing regulatory burdens. (AHRI, No. 40 at pp. 15–17)

DOE has determined that establishing a test procedure will not impact the availability of current models. The test procedure does not establish any energy conservation standards and does not result in any non-compliant fans. Section III.M of this document discusses DOE's analysis of testing costs and burden as a result of establishing this test procedure.

Morrison commented that the proposed new metric and testing plans was inconsistent with 2015 ASRAC WG term sheet agreement and disregarded the 11 years of work that went into this challenging and groundbreaking rulemaking effort. (Morrison No. 42 at p.1) As discussed in section III.G.1 of this document, DOE did not propose a new metric in the July 2022 NOPR. Further in this final rule, DOE is adopting a minimum sample size of one unit in line with the term sheet as discussed in section III.J of this document.

B. Scope of Applicability

This rulemaking applies to fans and blowers. A fan or blower is defined as a rotary bladed machine that is used to convert electrical or mechanical power to air power with an energy output limited to 25 kilojoule (''kJ'')/kilogram (''kg'') of air. 10 CFR 431.172. It consists of an impeller, a shaft and bearings and/or a driver to support the impeller, as well as a structure or housing. *Id.* A fan or blower may include a transmission, driver, and/or motor controller. *Id.* As discussed, DOE has classified fans and blowers as covered equipment. 86 FR 46579. ''Covered equipment'' consists of certain industrial equipment, which is classified by the Secretary according to section 6312(b) and excludes covered

[14] Executive Order on America's Supply Chains, February 24, 2021. Available at: *www.whitehouse.gov/briefing-room/presidential-actions/2021/02/24/executive-order-on-americas-supply-chains.*

[15] AHRI referenced appendix A of the Supply Chain Disruptions Affect Viability of U.S. Manufacturing Sector white paper, published by AHRI, AHAM, NAFEM, and NEMA. Available at *www.nema.org/docs/default-source/advocacy-document-library/joint-association-supply-chain-white-paper.pdf?sfvrsn=1763ed3b_2.*

products, other than industrial equipment that is a component of a covered product. (42 U.S.C. 6311(1) and (2)(A)(iii)) DOE explained in the coverage determination that fans and blowers, the subjects of this rulemaking, do not include ceiling fans and furnace fans, as defined at 10 CFR 430.2. *See* 86 FR 46579, 46586. DOE also noted that distribution for residential use does not preclude coverage as covered equipment so long as to a significant extent the equipment is of a type that is also distributed in commerce for industrial and commercial use. *Id.* at fn. 26.

In the August 2021 Final Coverage Determination, DOE did not establish definitions for specific categories of fans and blowers. DOE stated that it would consider specific categories of fans and blowers and the scope of applicability of test procedures and energy conservation standards in its respective rulemakings. 86 FR 46579, 46585.

This section discusses the fans and blowers that DOE includes in the scope of applicability of the test procedure, as well as exemptions.

1. Fans and Blowers Inclusions

This section discusses fans and blowers, other than air circulating fans, proposed for inclusion in the scope of applicability of the test procedure. Air circulating fans are discussed in section III.B.4 of this document.

The Working Group recommended that the test procedure be applicable to certain classifications of fans and blowers, listed in Table III–8 of this document. (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #1 at p. 1) The Working Group did not provide definitions for the specified classifications of the fans and blowers identified for inclusion in the scope of a test procedure. AMCA 214–21 provides terms and associated definitions for certain classifications of fans and blowers that correspond to the Working Group recommendation. The Working Group further recommended that the test procedure apply only to the fan operating points (*i.e.,* duty points) with a fan shaft power equal to or greater than 1 horsepower (''hp'') and fan air power [16] equal to or less than 150 hp. The Working Group recommended that air power be calculated using static pressure for unducted fans (''static air power'') and total pressure for ducted fans (''total air power'').[17] (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #5 at p. 4)

In the July 2022 NOPR, DOE noted that on February 24, 2022, the California Energy Commission (''CEC'') published a proposed rulemaking for fans and blowers that includes terms and definitions that correspond to the Working Group recommendations.[18] The CEC proposed to cover the following fan categories: axial inline, axial panel, centrifugal housed, centrifugal unhoused, centrifugal inline, radial housed, and power roof/wall ventilators, and to define these terms largely based on the definitions in AMCA 214–21, with revisions to indicate a fan's intended application and if a fan's inlet or outlet can be (optionally, as applicable) ducted. In addition, the CEC proposal considers fans and blowers that have a rated fan shaft power greater than or equal to 1 horsepower, or, for fans without a rated shaft input power, an electrical input power greater than or equal to 1 kW, and a fan output power less than or equal to 150 horsepower.[19] 87 FR 44194, 44199.

In the July 2022 NOPR, DOE proposed to include all fans and blowers that are included within the scope of AMCA 210–16 (referenced by AMCA 214–21) and proposed that the test procedure would be applicable to the following fans and blowers, with exclusions discussed in sections III.B.2 and III.B.3 of this document: (1) axial inline fan; (2) axial panel fan; (3) centrifugal housed fan; (4) centrifugal unhoused fan; (5) centrifugal inline fan; (6) radial-housed fan; and (7) power roof/wall ventilator (''PRV'').[20] 87 FR 44194, 44200. (See section III.C.1 of this document for definitions of these terms)

AMCA supported the proposed standalone fan inclusions and did not provide comments regarding embedded fans. (AMCA, No. 41 at p. 5) New York Blower commented that the fans and blowers proposed for inclusion in the DOE test procedure are appropriate. (New York Blower, No. 33 at p. 6)

DOE did not receive any other comments on this issue and includes all fans and blowers within the scope of AMCA 210–16 (referenced by AMCA 214–21) in the scope of the DOE test procedure. As such, DOE specifies that the test procedure is applicable to the following fans and blowers, with exclusions discussed in sections III.B.2 and III.B.3 of this document: (1) axial inline fan; (2) axial panel fan; (3) centrifugal housed fan; (4) centrifugal unhoused fan; (5) centrifugal inline fan; (6) radial-housed fan; and (7) PRV.

In the July 2022 NOPR, DOE proposed that the scope of the test procedure cover fans and blowers with a fan shaft input power equal to or greater than 1 horsepower and a fan static or total air power equal to or less than 150 horsepower. DOE proposed the lower 1 hp limit to match the technical applicability of the AMCA 214–21 and AMCA 210–16 test procedures. DOE proposed the upper air power limit at this time because fans that operate above the proposed upper limit are typically custom orders and are too large to be tested in a laboratory setting. In addition, DOE noted that these limits are in line with the Working Group recommendations and the CEC scope. 87 FR 44194, 44200–44201.

In the July 2022 NOPR, DOE tentatively determined that the 1 hp fan shaft power lower limit may not be a practical unit of measurement for all fans because some fans are designed such that the measurement of the shaft input power is not feasible, and the only feasible measurement is the FEP, which is measured in units of kW. For example, some fans incorporate the bare shaft and the motor in the same enclosed housing and do not provide access to the fan shaft (*i.e.,* between the motor and the fan), where the measurement of the fan shaft power would be conducted. DOE relied on the motor efficiency equations provided in section 6.4.2.3 of AMCA 214–21 to convert the fan shaft power into electrical input power [21] and has tentatively determined that 0.89 kW is appropriate to establish a standardized equivalent to the 1 hp fan shaft input power limit. Additionally, section 6.5.3.1.3 ''Fan Efficiency Requirements'' of ANSI/ASHRAE/IES 90.1, ''Energy Standard for Buildings except Low-Rise Residential Buildings (2019)'' (''ASHRAE 90.1–2019'') relies on the value of 0.89 kW as the corresponding

[16] The air power of a fan is the fan's output power. It is proportional to the product of the fan airflow rate and the fan pressure.

[17] The terms ''ducted'' and ''unducted'' refer to the recommended test configuration used when conducting a fan test. Appendix C of the term sheet specifies which fan categories are typically ducted (*i.e.,* tested using a ducted outlet and for which the FEI is calculated on a total pressure basis): axial cylindrical housed, centrifugal housed (excluding inline and radial), inline and mixed flow, radial housed; and which fan types are considered unducted (*i.e.,* tested with a free outlet and for which the FEI is calculated on a static pressure basis): panel, centrifugal unhoused (excluding inline and radial), and power roof ventilators.

[18] All documents related to this rulemaking can be found in the rulemaking Docket 22–AAER–01 accessible at: *www.energy.ca.gov/rules-and-regulations/appliance-efficiency-regulations-title-20/appliance-efficiency-proceedings-11.*

[19] *See* Proposed regulatory language for Commercial and Industrial Fans and Blowers available in the following Docket: 22–AAER–01 at: *efiling.energy.ca.gov/Lists/DocketLog.aspx?docketnumber=22-AAER-01.*

[20] PRVs include: Centrifugal PRV exhaust fans; Centrifugal PRV supply fans; and Axial PRVs, as defined in AMCA 214–21.

[21] The electrical input power is equal to the fan shaft input power divided by the motor efficiency.

threshold to a value of 1 hp of shaft input power. Accordingly, DOE proposed that the test procedure would be applicable to a fan or blower with duty points [22] with the following characteristics: (1) a fan shaft input power equal to or greater than 1 horsepower and a fan static or total air power equal to or less than 150 horsepower, or (2) a FEP equal to or greater than 0.89 kW and a fan static or total air power equal to or less than 150 horsepower. 87 FR 44194, 44200.

In addition, AMCA 214–21 distinguishes between fans that use a total pressure basis [23] and fans that use a static pressure basis.[24] In the July 2022 NOPR, DOE proposed to establish the 150 hp upper limit in terms of total air power for fans and blowers that use a total pressure basis FEI and would be required to be tested with a ducted outlet according to the proposed provisions adopted through reference to AMCA 214–21. For fans and blowers that use a static pressure basis FEI and would be required to be tested using a free outlet under the provisions of AMCA 214–21, DOE proposed to establish the air power limit in terms of static air power. 87 FR 44194, 44200–44201.

Finally, to define total air power, DOE proposed to rely on the definition of ''fan output power'' in AMCA 210–16. DOE proposed to define ''total air power'' as the total power delivered to air by the fan; it is proportional to the product of the fan airflow rate, the fan total pressure, and the compressibility coefficient and is calculated in accordance with section 7.8.1 of AMCA 210–16. *See* the definition of ''fan output power'' in Section 3.1.31 of AMCA 210–16 and calculation formulas in section 7.8.1 of AMCA 210–16. DOE also proposed to define ''static air power'' as the static power delivered to air by the fan; it is proportional to the product of the fan airflow rate, the fan static pressure, and the compressibility coefficient and is calculated in accordance with section 7.8.1 of AMCA 210–16, using static pressure instead of total pressure. 87 FR 44194, 44201.

In response to the July 2022 NOPR, AMCA commented in support of the basis of the proposed power limits based on fan air power, fan shaft input power and fan electrical input power. In terms of scope, AMCA added that fans deliver air power, defined generally as pressure multiplied by volume flow rate. AMCA stated that by limiting the top end of the scope to air power, as opposed to electrical input power, a less efficient fan is not allowed to escape regulation by consuming a larger amount of electrical input power to deliver a similar amount of air power. Regarding the low side of the scope related to power, for bare fans, AMCA commented that shaft input power is the appropriate measure because there is no driver. For fans tested wire-to-air, AMCA commented that the appropriate measure is electrical input power. (AMCA, No. 41 at p. 5)

Morrison commented in support of the proposed power limits (Morrison, No. 42 at p. 2)

New York Blower commented that the proposed power limits were appropriate. New York Blower commented that the limits are configured in a manner that captures products at the low end of fan powers and does not allow less efficient products at the high end to escape regulation by being less efficient. However, New York Blower noted that the July 2022 NOPR implies that if a fan is capable of operating within the scope of regulation, it should be regulated under all possible operating conditions. New York Blower commented that such approach would remove the upper limit of scope considering that practically any fan could be slowed down enough to operate within the proposed scope. Instead, New York Blower commented that for applications that operate at the high end of the proposed scope, fan performance is typically attached to the fan and that these types of fans are not sold as a distributed product—like a fan in a box—but configured and applied to the application. Thus, for these fans, New York Blower recommended that the industry be regulated for fans configured and identified as operating within scope and for identical products operating outside the scope, the product not be regulated. (New York Blower, No. 33 at p. 7)

ebm-papst commented that testing of larger fans becomes exponentially more burdensome and recommended that DOE exempt all fans that have at least one duty point at an air power above 150 horsepower. Otherwise, according to ebm-papst, many speed adjustable industrial fans become subject to this regulation even if just a small portion of the operating map is below 150 hp or air power. (ebm-papst, No. 31 at p. 1)

Robinson commented that they are not in favor of the inclusion of duty points within the power range. Robinson commented that custom fan equipment is often selected at a duty point well beyond the horsepower limitation, but included within the operational requirements are operating duty points that fall within the horsepower range. Robinson asked if the manufacturer is only required to make a representation regarding that single duty point. Robinson added that in some instances, customers cannot obtain a desired duty point through speed control, and therefore duty points must be attained through damper control. Inclusion of these appurtenances in testing will significantly multiply testing requirements to make an assertation regarding FEP, FEI, etc. and result in over-designed fans. (Robinson, No. 43 at p. 4)

The CA IOUs commented that DOE should rely on the best efficiency point (''BEP'') [25] as the criteria for whether a fan falls within the power input range and air horsepower to determine if a fan is within the scope of the test procedure. The CA IOUs commented that DOE proposed that the test procedure applies to a fan or blower with duty points greater than one horsepower and equal to or less than 150 horsepower. Therefore, fans with a single duty point of less than 150 air horsepower would be within the scope of this rulemaking. The CA IOUs asserted that fans with variable speed drives, regardless of size, are bound to have duty points less than 150 horsepower. The CA IOUs also stated that there are also many small fans, particularly forward-curved fans, with a few points and shaft input power greater than one horsepower at the extreme right end of the fan curve. The CA IOUs recommended that DOE change this exclusion to fans where the BEP is less than or equal to one horsepower or greater than 150 hp. (CA IOUs, No. 37 at p. 10)

As noted, the Working Group recommended that the test procedure be only applicable to the fan operating points with a fan shaft power equal to or greater than 1 horsepower (''hp'') and fan air power equal to or less than 150 hp. (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #5 at p. 4) In line with this approach, DOE adopts the power limits as proposed in the July 2022 NOPR and corresponding definitions of static air power (''fan static air power'') and total airpower

[22] A duty point is characterized by a given airflow and pressure and has a corresponding operating speed.

[23] This includes: centrifugal housed fans, radial housed fans, centrifugal inline fans, centrifugal PRVs Supply, and Axial Inline fans. (*See* Table 7.1 of AMCA 214–21.)

[24] This includes: Centrifugal unhoused fans, Centrifugal PRVs Exhaust, Axial Panel fans, Axial PRVs. (*See* Table 7.1 of AMCA 214–21.)

[25] The BEP represents the flow and pressure values at which the fan total efficiency (ratio of total air power to fan shaft input power) is maximized when operating a given speed.

(fan total air power''). DOE further clarifies that the test procedure is only applicable to the fan or blower duty points with the following characteristics: (1) a fan shaft input power equal to or greater than 1 horsepower and a fan static or total air power equal to or less than 150 horsepower, or (2) a FEP equal to or greater than 0.89 kW and a fan static or total air power equal to or less than 150 horsepower. When determining the duty points of a basic model, to establish whether a fan includes duty points that meet the scope requirements in terms of power limit, DOE will refer to published data, marketing literature, and other publicly available information about the range of operation (*i.e.,* flow, speed, and pressure) of each basic model. If the manufacturer only includes 1 single duty point in the fan operating range, then the manufacturer is only required to make a representation at that one point. In addition, DOE follows the Working Group recommendation for establishing the scope power limit as proposed in the July 2022 NOPR. Finally, the limit recommended by the Working Group recommendation was set to capture the design points that represent the majority of the market and therefore corresponds to a limit in terms design point not BEP. (EERE–2013–BT–STD–0006, Public Meeting Transcript, No. 161 at pp. 96, 100–101) In line with this Working Group recommendation, DOE is not relying on BEP to establish the scope of the test procedure.

Regarding fans that are designed to operate outside of the power limits but that may include duty points that fall in the scope, DOE notes that the manufacturer would be required to test such a fan at the duty points that fall in the scope of the test procedure. Regarding testing with accessories, DOE addresses this issue in section III.E.12 of this document.

2. Fans and Blowers Exclusions

The Working Group recommended the exclusion of circulating fans (also known as air circulating fans), induced flow fans, jet fans, and cross-flow fans. (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #2 at pp. 2–3) The Working Group also recommended the exclusion of safety fans due to low operating hours and specific design features that impair efficiency (*e.g.,* high tip clearance), and a subset of radial fans that are used for material handling applications [26] (*e.g.,* to move paper dust, sand, etc.).[27] (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #2 at pp. 2–3) Table III–1 of this document presents the exclusions recommended by the Working Group.

TABLE III–1—FAN CATEGORIES RECOMMENDED FOR EXCLUSION BY THE WORKING GROUP

Fan category recommended for exclusion by the working group *	Definition in AMCA 214–21
Radial housed unshrouded fan with diameter less than 30 inches or a blade width of less than 3 inches.	Included in the definition ''radial housed fan'' as noted in Table III-1.
Safety fan	Not defined in AMCA 214–21.
Induced flow fan	''Induced flow fan'' means a type of laboratory exhaust fan with a nozzle and windband; the fan's outlet airflow is greater than the inlet airflow due to induced airflow. All airflow entering the inlet exits through the nozzle. Airflow exiting the windband includes the nozzle airflow plus the induced airflow.
Jet fan	''Jet fan'' means a fan designed and marketed specifically for producing a high velocity air jet in a space to increase its air momentum. Jet fans are rated using thrust. Inlets and outlets are not ducted but may include acoustic silencers.
Cross-flow fan	''Cross-flow fan'' means a fan with a housing that creates an airflow path through the impeller in a direction at right angles to its axis of rotation and with airflow both entering and exiting the impeller at its periphery. Inlets and outlets can optionally be ducted.**

* **Note:** The Working Group also recommended the exclusion of circulating fans (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #2 at pp. 2–3), which are defined in AMCA 214–21 as a fan that is not a ceiling fan that is used to move air within a space that has no provision for connection to ducting or separation of the fan inlet from its outlet. The fan is designed to be used for the general circulation of air. Circulating fans are discussed in Section III.B.4 of this document.

** Excluded from AMCA 214–21 and defined in ANSI/AMCA Standard 208, ''Calculation of the Fan Energy Index for calculating FEI'' (''AMCA 208–18'').

The Petitioners requested that the scope of any future DOE test procedure be consistent with the scope described in the term sheet and requested the exclusion of fans that cannot be tested per AMCA 210–16 (*i.e.,* the physical test method referenced in AMCA 214–21).[28] The Petitioners also requested that the scope of the test procedure be consistent with ASHRAE 90.1–2019. (Docket No. EERE–2020–BT–PET–0003, The Petitioners, No. 1, attachment ''AMCA Petition to DOE Cover Letter and Petition [sic] 2020110'' at pp. 7–8)

Table III–2 of this document compares the scope exclusions requested by the Petitioners in accordance with the commercial and industrial fan and blower requirements in ASHRAE 90.1–2019 and the scope of exclusions as recommended by the Working Group (other than embedded fans and blowers). In the July 2022 NOPR, DOE reviewed the fan and blower exclusions to section 6.5.3.1.3 of ASHRAE 90.1–2019 ''Fan Efficiency Requirements'' as listed in Table III–2 of this document and tentatively determined that these exclusions are covered by the exclusions recommended by the Working Group. 87 FR 44194, 44201–44202.

[26] Specifically, radial housed unshrouded fans, which means a radial housed fan for which the impeller blades are attached to a backplate and hub (*i.e.,* open radial blade), or to a hub only (*i.e.,* open paddle wheel), and with an open front at the impeller's inlet. These are different than radial shrouded fans, for which the impeller blades are attached to a backplate and to a ring or ''shroud'' at the impeller's inlet.

[27] The discussions of the Working Group related to these exclusions can be found in the meeting transcripts, available in the fan's energy conservation standard rulemaking docket. (Docket No. EERE–2013–BT–STD–0006, Public Meeting Transcript, No. 161 at pp. 63–70; Public Meeting Transcript, No. 85 at pp. 60–62).

[28] For example, circulating fans, ceiling fans, desk fans, jet tunnel fans, and induced flow fans (*e.g.,* used in laboratory exhaust systems). This is consistent with the scope of the term sheet.

TABLE III–2—EXCEPTIONS TO SECTION 6.5.3.1.3 OF ASHRAE 90.1–2019 ''FAN EFFICIENCY REQUIREMENTS''

[Other than for embedded fans and blowers]

Exceptions to section 6.5.3.1.3 of ASHRAE 90.1–2019 ''fan efficiency requirements''	Included in the exclusions recommended by the working group?
Fans that are not embedded fans with a motor nameplate horsepower of less than 1.0 hp or with a fan nameplate electrical input power of less than 0.89 kW.	Yes.
Ceiling fans	Yes (NOTE: ceiling fans are not within the scope of the definition of fans and blowers).
Fans used for moving gases at temperatures above 482 degrees Fahrenheit.	Yes (safety fans).
Fans used for operation in explosive atmospheres	Yes (safety fans).
Reversible fans used for tunnel ventilation	Yes (jet fans, safety fans).
Fans outside the scope of AMCA 208–18	Yes (AMCA 208–18 references the scope of AMCA 210–16).
Fans that are intended to operate only during emergency conditions	Yes (safety fans).

In the July 2022 NOPR, DOE noted that in its proposed rulemaking for commercial and industrial fans and blowers, the CEC proposed to exclude the following categories of fans: (1) safety fans (*see* section III.C.2 of this document for more details on this definition); (2) ceiling fans as defined in 10 CFR 430.2; (3) circulating fans; (4) induced flow fans; (5) jet fans; (6) cross-flow fans; (7) embedded fans as defined in ANSI/AMCA 214–21; [29] (8) fans mounted in or on motor vehicles or other mobile equipment; (9) fans that create a vacuum of 30 in. wg or greater; [30] and (10) air curtain unit.[31] 87 FR 44194, 44202. *See* Table III–3 and section III.B.3 for a discussion of embedded fans and air curtain units and section III.B.5 for a discussion of fans mounted in or on motor vehicles or other mobile equipment.

TABLE III–3—FANS RECOMMENDED FOR EXCLUSION BY THE WORKING GROUP AND THE CORRESPONDING CEC PROPOSED EXCLUSIONS

Fans recommended for exclusion by the working group *	Corresponding term and definition proposed for exclusion in CEC proposed regulatory text
Radial housed unshrouded fan with diameter less than 30 inches or a blade width of less than 3 inches.	Not excluded by the CEC proposed regulatory text.
Safety fan	''Safety Fan'' *See* section III.C.2 of this document.
Induced flow fan	''Induced flow fan'' means a type of laboratory exhaust fan with nozzle and windband; the fan's outlet airflow is greater than the inlet airflow due to induced airflow. All airflow entering the inlet exits through the nozzle. Airflow exiting the windband includes the nozzle airflow as well as the induced airflow.
Jet fan	''Jet fan'' means a fan designed and marketed specifically to produce a high-velocity air jet in a space to increase its air momentum. Jet fans are rated using thrust. Inlets and outlets are not ducted but may include acoustic silencers.
Cross-flow fan	''Cross-flow fan'' means a fan with a housing that creates an airflow path through the impeller, in a direction at right angles to the axis of rotation and with airflow both entering and exiting the impeller at the periphery. Inlets and outlets can optionally be ducted.

* **Note:** The Working Group also recommended the exclusion of circulating fans, which are also excluded from the CEC proposed regulation and defined as a fan that is not a ceiling fan that is used to move air within a space, that has no provision for connection to ducting or separation of the fan inlet from its outlet. The fan is designed to be used for the general circulation of air. Circulating fans are discussed in section III.B.4 of this document.

In the July 2022 NOPR, DOE reviewed the exclusions recommended by the Working Group, the exclusions requested by the Petitioners, the exclusions provided in the proposed CEC regulations, and comments received and proposed to exclude from the proposed DOE test procedure the following fans and blowers: (1) radial housed unshrouded fans with a diameter less than 30 inches or a blade width of less than 3 inches; (2) safety fans; (3) induced flow fans; (4) jet fans; and (5) cross-flow fans. 87 FR 44194, 44202.

AMCA commented in support of the proposed exclusions of (1) radial housed unshrouded fans with a diameter less than 30 inches or a blade width of less than 3 inches; (2) safety fans; (3) induced flow fans; (4) jet fans; and (5) cross-flow fans. AMCA noted that these are consistent with the ASRAC term sheet. (AMCA, No. 41 at p. 6)

DOE did not receive any other comments on these exclusions and thus excludes from the DOE test procedure

[29] As defined in ANSI/AMCA 214–21: ''A fan that is part of a manufactured assembly where the assembly includes functions other than air movement.''

[30] CEC proposed excluding these fans because AMCA 214–21 is not applicable to this equipment. *See* CEC's Initial Statement of Reason, available at *efiling.energy.ca.gov/Lists/DocketLog.aspx?docketnumber=22-AAER-01*.

[31] When the NOPR was issued, the CEC defined an air curtain unit as equipment providing a directionally controlled stream of air moving across the entire height and width of an opening that reduces the infiltration or transfer of air from one side of the opening to the other and/or inhibits the passage of insects, dust, or debris. 87 44194, 44260 fn 25.

the following fans and blowers: (1) radial housed unshrouded fans with a diameter less than 30 inches or a blade width of less than 3 inches; (2) safety fans; (3) induced flow fans; (4) jet fans; and (5) cross-flow fans.

In the July 2022 NOPR, DOE also stated that it was considering including an exclusion, consistent with the findings of the CEC, for fans that create a vacuum of 30 in. wg or greater. DOE tentatively determined that a test using AMCA 210–16 may not result in a measurement of energy use or energy efficiency during a representative average use cycle for fans that are exclusively used to create a vacuum rather than produce airflow. 87 FR 44194, 44203.

In response to the July 2022 NOPR, the CEC recommended excluding fans that create a vacuum of 30 in. wg or greater because these fans have different operating conditions (run in stall) and will require a different way to measure their efficiency. (CEC, No. 30 at p. 2)

The CA IOUs requested that DOE exclude fans that create a vacuum of 30 in. wg or greater from the proposed scope. The CA IOUs explained that typically, fans that create a high vacuum operate in the unstable range and must be reinforced with heavy housings and oversized bearings to handle unstable operating conditions. The CA IOUs stated that DOE may consider the 30 in. wg. too low and if so, requested DOE find an appropriate level. (CA IOUs, No. 37 at . 8)

DOE has determined that a test using AMCA 210–16 may not result in a measurement of energy use or energy efficiency during a representative average use cycle for fans that are exclusively used to create a vacuum rather than produce airflow. As noted by the CEC and the CA IOUs, these fans operate in the stalling region (or unstable range). Further as noted by the CEC, such fans would require a different way to measure their efficiency. Therefore, in this final rule, DOE excludes fans that create a vacuum of 30 in. wg or greater. Additionally, as discussed in section III.C.2 of this document, DOE excludes fans that designed and marketed to operate at or above 482 degrees Fahrenheit (250 degrees Celsius).

3. Embedded Fans and Blowers Exclusions

In addition to the specific exclusions discussed in the prior section, DOE also proposed excluding certain ''embedded'' fans from the scope of the test procedure. Fans can be distributed in commerce as standalone equipment or can be distributed in commerce incorporated into other equipment that requires a fan to operate. 87 FR 44194, 44203.

Section 3.25.3 of AMCA 214–21 defines a ''standalone fan'' as ''a fan in at least a minimum testable configuration. This includes any driver, transmission or motor controller if included in the rated fan. It also includes any appurtenances included in the rated fan, and it excludes the impact of any surrounding equipment whose purpose exceeds or is different than that of the fan.'' [32] Section 3.25.4 of AMCA 214–21 defines the term ''embedded fan'' as ''a fan that is part of a manufactured assembly where the assembly includes functions other than air movement.''

The Working Group recommended excluding certain embedded fans. *See* Table III–4 of this document. (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendations #2 and #3 at pp. 2–4)

TABLE III–4—EMBEDDED FANS RECOMMENDED FOR EXCLUSION BY THE WORKING GROUP

Fans embedded in:
Single-phase central air conditioners and heat pumps rated with a certified cooling capacity less than 65,000 British thermal units per hour (''Btu/h''), that are subject to DOE's energy conservation standard at 10 CFR 430.32(c).
Three-phase, air-cooled, small commercial packaged air-conditioning and heating equipment rated with a certified cooling capacity less than 65,000 Btu/h, that are subject to DOE's energy conservation standard at 10 CFR 431.97(b).
Residential furnaces that are subject to DOE's energy conservation standard at 10 CFR 430.32(y).
Transport refrigeration (*i.e.,* Trailer refrigeration, Self-powered truck refrigeration, Vehicle-powered truck refrigeration, Marine/Rail container refrigerant), and fans exclusively powered by internal combustion engines.
Vacuum cleaners.*
Heat Rejection Equipment:
• Packaged evaporative open circuit cooling towers.
• Evaporative field-erected open circuit cooling towers.
• Packaged evaporative closed-circuit cooling towers.
• Evaporative field-erected closed-circuit cooling towers.
• Packaged evaporative condensers.
• Field-erected evaporative condensers.
• Packaged air-cooled (dry) coolers.
• Field-erected air-cooled (dry) coolers.
• Air-cooled steam condensers.
• Hybrid (water saving) versions of all of the previously listed equipment that contain both evaporative and air-cooled heat exchange sections.
Air curtains.
Air-cooled commercial package air conditioners and heat pumps (CUAC, CUHP) with a certified cooling capacity between 5.5 tons (65,000 Btu/h) and 63.5 tons (760,000 Btu/h) that are subject to DOE's energy conservation standard at 10 CFR 431.97(b).**
Water-cooled and evaporatively-cooled commercial air conditioners and water-source commercial heat pumps that are subject to DOE's energy conservation standard at 10 CFR 431.97(b).**
Single package vertical air conditioners and heat pumps that are subject to DOE's energy conservation standard at 10 CFR 431.97(d).**
Packaged terminal air conditioners (PTAC) and packaged terminal heat pumps (PTHP) that are subject to DOE's energy conservation standard at 10 CFR 431.97(c).**
Computer room air conditioners that are subject to DOE's energy conservation standard at 10 CFR 431.97(e).**

[32] Additionally, AMCA 214–21 defines a minimum testable configuration as ''A fan having at least an impeller; shaft and bearings and/or driver to support the impeller; and its structure or its housing.'' *See* Section 3.53 of AMCA 214–21.

TABLE III–4—EMBEDDED FANS RECOMMENDED FOR EXCLUSION BY THE WORKING GROUP—Continued

Fans embedded in:
Variable refrigerant flow multi-split air conditioners and heat pumps that are subject to DOE's energy conservation standard at 10 CFR 431.97(f).**

* Although the term sheet specifies ''vacuum,'' the term was intended to designate vacuum cleaners. (Docket No. EERE–2013–BT–STD–0006; AHRI, Public Meeting Transcript, No. 166 at p. 11).
** The recommendation only applies to supply and condenser fans embedded in this equipment.

Stated more generally, the exclusions recommended by the Working Group would exclude from the scope of the test procedure fans that are embedded in regulated equipment for which the DOE metric captures the energy consumption of the fan.[33]

The Working Group further recommended for fans embedded in non-regulated equipment, and/or embedded in regulated equipment other than listed in Appendix B of the term sheet, and/or any fans that are not supply and condenser fans in regulated equipment listed in Appendix B of the term sheet, that the first manufacturer of a testable configuration [34] would be responsible for certifying the standalone fan performance to DOE. (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #4 at p. 4) [35]

The Petitioners requested that the scope of any DOE test procedure be consistent with the scope of the term sheet. The Petitioners also requested the test-procedure scope for commercial fans be consistent with ASHRAE 90.1–2019, and additionally exclude embedded fans that are part of equipment listed in section 6.4.1.1 of ASHRAE 90.1–2019. ASHRAE 90.1–2019 (*See* Table III–6 of this document). (Docket No. EERE–2020–BT–PET–0003, The Petitioners, No. 1, attachment ''AMCA Petition to DOE Cover Letter and Petition [sic] 2020110'' at pp. 7–8)

The additional exclusions for embedded fans that are part of equipment listed in section 6.4.1.1 of ASHRAE 90.1–2019 as requested by AMCA are included in the fan and blower exclusions to section 6.5.3.1.3 of ASHRAE 90.1–2019, ''Fan Efficiency Requirements,'' and presented in Table III–5 of this document.

TABLE III–5—EMBEDDED FAN AND BLOWER EXCLUSIONS TO SECTION 6.5.3.1.3 OF ASHRAE 90.1–2019 ''FAN EFFICIENCY REQUIREMENTS''

Embedded fan and blower exclusions to section 6.5.3.1.3 of ASHRAE 90.1–2019, ''fan efficiency requirements''	Included in the exclusion recommended by the working group?
Embedded fans and fan arrays with a combined motor nameplate horsepower of 5 hp or less or with a fan system electrical input power of 4.1 kW or less.	No.
Embedded fans that are part of equipment listed under section 6.4.1.1.	*See* Table III-7.
Embedded fans included in equipment bearing a third party-certified seal for air or energy performance of the equipment package.	No.

TABLE III–6—EQUIPMENT LISTED IN SECTION 6.4.1.1 OF ASHRAE 90.1–2019 ''MINIMUM EQUIPMENT EFFICIENCIES—LISTED EQUIPMENT—STANDARD RATING AND OPERATING CONDITIONS''

Fans embedded in:	Included in the embedded fan exclusions recommended by the working group?
Electrically Operated Unitary Air Conditioners	Partially. This category includes equipment above 760,000 Btu/h. The exclusions in the term sheet apply only to fans embedded in equipment above 65,000 Btu/h and below 760,000 Btu/h (equivalent to 5.5 tons and 63.5 tons, respectively as stated in the term sheet). In addition, the term sheet specifies that the exclusions would apply only to embedded ''supply and condenser fans.''
Electrically Operated Air-Cooled Unitary Heat Pumps	Partially. This category includes equipment above 760,000 Btu/h. The exclusions in the term sheet apply only to fans embedded in equipment below 760,000 Btu/h. In addition, the term sheet specifies that the exclusion would apply only to embedded ''supply and condenser fans.''
Air-, water-, and evaporatively cooled Condensing Units	Yes, these fans are below 1 hp. In addition, it is specified in Table 6.8.1–1 of ASHRAE 90.1–2019 that this category only includes equipment greater than or equal to 135,000 Btu/h.
Water-Chilling Packages	No.
Electrically Operated Packaged Terminal Air Conditioners, Packaged Terminal Heat Pumps, Single-Package Vertical Air Conditioners, and Single-Package Vertical Heat Pumps.	Yes. However, the term sheet specifies that the exclusion would apply only to embedded ''supply and condenser fans.''

[33] The Working Group created a subgroup to propose potential embedded fan exclusions, which were subsequently voted on by the Working Group. The information used by the subgroup to develop the proposal is available in the fans energy conservation standard rulemaking docket. (Docket No. EERE–2013–BT–STD–0006, No. 125.2)

[34] AMCA 214–21 defines the ''minimal testable configuration'' as a fan having at least an impeller; shaft and bearings and/or driver to support the impeller; and its structure or its housing.

[35] As part of this recommendation, the Working Group also recommended that if a manufacturer purchases a standalone fan to incorporate in a product or in equipment, that manufacturer must ensure that the design operating range (or design point) of the embedded fan is within the certified operating range of the standalone fan and disclose the design operating range (or design point) of the embedded fan to the end-user. This issue does not relate to the test procedure and is not discussed in this document.

TABLE III–6—EQUIPMENT LISTED IN SECTION 6.4.1.1 OF ASHRAE 90.1–2019 ''MINIMUM EQUIPMENT EFFICIENCIES—LISTED EQUIPMENT—STANDARD RATING AND OPERATING CONDITIONS''—Continued

Fans embedded in:	Included in the embedded fan exclusions recommended by the working group?
Room Air-conditioners and Air-conditioner Heat pumps	Yes. These fans are below 1 hp.
Warm-Air Furnaces and Combination Warm-Air Furnaces/Air-Conditioning Units, Warm-Air Duct Furnaces, and Unit Heaters.	No.
Gas- and Oil-Fired Boilers	Partially. Some of these fans are below 1 hp.
Heat-Rejection Equipment	Yes.
Electrically Operated Variable-Refrigerant-Flow Air Conditioners	Yes. However, the term sheet specifies that the exclusion would apply only to embedded ''supply and condenser fans.''
Electrically Operated Variable-Refrigerant-Flow and Applied Heat Pumps.	Partially. This category includes ground water source and ground source equipment that is not regulated by DOE and that was not included in the term sheet exclusions. In addition, the term sheet specifies that the exclusion would apply only to embedded ''supply and condenser fans.''
Floor-Mounted Air Conditioners and Condensing Units Serving Computer Rooms.	Partially. This category includes equipment greater than or equal to 760,000 Btu/h, which are not regulated by DOE.
Commercial Refrigerators, Commercial Freezers, and Refrigeration	Yes. These fans are below 1 hp.
Vapor-Compression-Based Indoor Pool Dehumidifiers	Yes. These fans are below 1 hp.
Electrically Operated direct-expansion dedicated outdoor air system Units, Single-Package and Remote Condenser, without Energy Recovery.	No.
Electrically Operated direct-expansion dedicated outdoor air system Units, Single-Package and Remote Condenser, with Energy Recovery.	No.
Electrically Operated Water-Source Heat Pumps	Partially. This category includes ground water source and ground source equipment that is not regulated by DOE and was not included in the term sheet exclusions. In addition, the term sheet specifies that the exclusion would apply only to embedded ''supply and condenser fans.''
Heat Pump and Heat Recovery Chiller Packages	No.
Ceiling-Mounted Computer-Room Air Conditioners	Partially. The term sheet only excludes embedded fans in computer room air conditioners that are subject to DOE energy conservation standards.
Walk-In Cooler and Freezer Display Door	Yes. These fans are below 1 hp.
Walk-In Cooler and Freezer Non-Display Door	Yes. These fans are below 1 hp.
Walk-In Cooler and Freezer Refrigeration System	Yes. These fans are below 1 hp.

In the July 2022 NOPR, DOE noted that in its proposed regulation, the CEC proposed to exclude embedded fans, as defined in AMCA 214–21, including embedded fans in air curtain units.[36] In its staff report, the CEC stated that its proposal would exclude fans embedded in regulated and non-regulated equipment where the main function is other than the movement of air, as long as the fan is not sold or offered for sale as a standalone product.[37] As reasons for exclusion, the CEC stated that these fans are either manufactured by an original equipment manufacturer (OEM), who embeds the fan in a piece of equipment where the main function is something other than the movement of air, or because they are manufactured for the purpose of being embedded into an appliance after market.[38] The CEC also discussed the potential complexity of testing embedded fans and the accuracy of the results. See section III.E.9 of this document for further discussion related to testing 87 FR 44194, 44206–44207.

In the July 2022 NOPR, DOE proposed to exclude fans embedded in equipment listed in Table III–4 of this document, as long as the fan is not distributed in commerce as a standalone product, consistent with the Working Group term sheet scope recommendations related to embedded fans. (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendations #2 and #3 at pp. 2–4) DOE noted that the equipment listed in Table III–4 of this document includes equipment that is separately regulated by DOE (''covered equipment'') as well as non-covered equipment (*i.e.,* transportation refrigeration equipment, vacuum cleaners, heat rejection equipment, and air curtains). 87 FR 44194, 44207. The rest of this section discusses the comments received on each proposed exclusion and DOE's decision for this final rule.

Greenheck commented that DOE should consider adopting the ASAP/NRDC/ACEEE proposal to CEC[39] regarding the issue of embedded fans in equipment. Greenheck commented that the recommendation includes a two-phase rulemaking approach allowing for expeditious rulemaking in phase one for fans, while continuing to provide additional opportunities for energy savings in phase two for built-up equipment that includes embedded fans. Greenheck commented that including embedded fans in the scope adds significant complexity and a two-phase approach would provide time for additional investigation of all impacts for embedded fans. In addition, Greenheck noted that equipment incorporating fans are already tested at a component level, or as an entire system to AHRI test standards, building energy codes, and in some cases, DOE test standards (*e.g.,* dedicated outdoor air systems equipment). Further,

[36] *See* Proposed regulatory language for Commercial and Industrial Fans and Blowers, Docket No. 22–AAER–01 at *efiling.energy.ca.gov/Lists/DocketLog.aspx?docketnumber=22-AAER-01.* **Note:** Since the publication of the July 2022 NOPR, on September 9, 2022, the CEC has published Express terms with implemented amendments to the proposed regulation for Commercial and Industrial Fans and Blowers Efficiency.

[37] *See* CEC Commercial and Industrial Fans and Blowers Staff Report, Docket No. 22–AAER–01, TN #241951 at p. 16.

[38] *Id.*

[39] *See: efiling.energy.ca.gov/GetDocument.aspx?tn=224830.*

Greenheck commented that it, as well as other manufacturers of equipment that include a combination of fans, heating, cooling, filtration, energy recovery, and/or other components, publishes performance data for embedded fans as installed in the equipment. Greenheck commented that performance data for the fan in the minimum testable configuration is typically not available and to comply with the scope of the DOE NOPR, manufacturers would have to retest embedded fans in their minimum testable configuration. Greenheck commented that the testing burden is significant and will force manufacturers to prioritize their resources on the testing required to comply with this regulation, rather than improving the overall efficiency of the equipment. Greenheck asserted that the embedded fans are only a portion of the overall energy consumption of these products and that regulating the equipment holistically like AHRI 920 for direct-expansion dedicated outdoor air systems (''DX–DOASes'') will result in the largest reduction in energy consumption. (Greenheck, No. 39 at pp. 5–6)

AHAM opposed the development of test procedures, energy conservation standards, and/or certification requirements for categories of commercial and industrial fans and blowers that are component parts of home appliances and supported a finished-product approach to energy efficiency regulation. AHAM commented that expanding the test procedure or coverage to embedded fans used in home appliances could push finished product manufacturers to more expensive components and increase the cost of appliances and equipment, while not necessarily improving the energy performance of the finished product and potentially impacting the efficacy of products such as range hoods. AHAM added that it would significantly increase burden on manufacturers if manufacturers of products that incorporate embedded fans are suddenly forced to certify compliance with standards for component parts, including the testing, paperwork, and record-keeping requirements that accompany certification and the risks associated with enforcement. AHAM commented that the manufacturer additional burden would not be outweighed by a corresponding benefit. Further, AHAM stated a concern that for both for embedded fans and air circulating fans, the proposed efficiency requirements could drive performance challenges due to reduced air flow. AHAM commented that given that many products using fans are used to improve indoor air quality, such as range hoods/downdraft fans, this is an undesirable result, which could impact consumer health and safety for the long term. In addition, for air circulating fans, AHAM commented that this would reduce the performance of the primary function of the fan. AHAM also commented that for covered products, there is no benefit to requiring embedded fans to meet an energy conservation standard or to be tested. AHAM stated that those products are already regulated by DOE and many manufacturers turn to more efficient designs that include components, such as more efficient fans to meet more stringent energy conservation standards. (AHAM, No. 35 at pp. 6–7)

AHRI commented that DOE is proposing changes to the scope of test procedures for commercial fans that would include fans destined for particular applications in finished goods. AHRI stated disagreement with DOE's plan to expand the existing scope of coverage of commercial fans to include these products. AHRI commented that embedded fan testing, and ultimately energy conservation standards, would save minimal, if any, energy and would create needless testing, paperwork, and record-keeping requirements that would raise costs for consumers. In addition, AHRI commented that the foreword of AMCA 214–21 notes, ''AMCA Standard 214 primarily is for fans that are tested alone or with motors and drives; it does not apply to fans tested embedded inside of other equipment.'' AHRI commented that there is no normative procedure for applying a stand-alone fan metric to embedded applications and therefore recommended to only include stand-alone fans in this regulation. (AHRI, No. 40 at p. 8) In addition, AHRI commented that there are a variety of safety standards affected by air flow in addition to the performance standards. AHRI commented that testing of all legacy equipment because of a fan change will be cost and resource prohibitive. AHRI added that if a replacement fan is not compliant then, in most cases, an engineered-to-fit substitution would be required, along with requisite reliability, robustness assurance actions, and safety standard compliance. AHRI commented that costs, risks, and time required to retest heating, ventilation, air-conditioning and refrigeration (''HVACR'') and water heating equipment would all be prohibitive and could be impractical if the HVACR and water heating equipment are out of production. Further, AHRI commented that manufacturers would be forced to rebuild an out-of-production unit solely for the purpose of testing the new fan or risk abandoning a reasonable repair path for consumers. AHRI further stated that there may be instances where such part substitution makes sense, but that is not a reasonable basis for a broad scope to a component's test procedure. (AHRI, No. 40 at pp. 9–10)

JCI commented that the proposed changes will likely result in elimination of current fans for those products ''outside the scope'' of this rulemaking as an unintended consequence as fan manufactures will seek to standardize designs and eliminate options. Therefore, per the recommendation of the term sheet, JCI recommends that all embedded fans be excluded from the scope of this rulemaking. JCI further commented that there also appears to be a major design limitation as there are few if any existing outdoor condenser fan designs, which have a FEI > 1.0. JCI stated that this issue by itself presents a major design and test hurdle as direct drive plenum fans are not designed to be utilized in a traditional outdoor, condenser exhaust configuration such as a rooftop unit. (JCI, No. 34 at p. 2)

DOE notes that this final rule does not establish any certification requirements and energy conservation standards for fans and blowers and would not require any fan replacements or redesigns and would not result in any changes in fan performance, or in the elimination of fan models, or in the need to retest HVARC equipment, or added certification burden. In addition, as discussed in section III.B.3.b of this document, DOE is implementing exclusions for fans embedded in covered equipment where the DOE metric already captures the energy use of the fans, such as supply and condenser fans embedded in DX–DOASes subject to any DOE test procedures in appendix B to subpart F of part 431. Finally, as discussed in section III.E.9 of this document, DOE determined that some fan manufacturers test embedded fans as standalone fans and therefore DOE has determined that there is value in establishing a standardized test method for these fans.

AHRI commented that as DOE has indicated in a prior notice of proposed determination and request for comment on small electric motors, DOE should maintain consistency in its rulemaking process and seek to establish regulatory coverage over equipment rather than the components in such equipment. (AHRI, No. 40 at p. 9)

Trane commented that if changing an embedded fan necessitates the re-optimization or redesign of Trane's

products, it will be forced to make trade-offs within the design of the product itself in order to maintain the most cost-competitive price point. Trane stated that for products which must already meet an energy performance metric that captures the fans, including the majority of fans in large commercial unitary air conditioners and air compressors, this will mean an energy-neutral change to the overall performance of the product. As an example, if a Trane large commercial air conditioner must be redesigned to accommodate a larger supply fan, downgrades to the compressors and/or heat exchangers would have to be made in order to control costs. The new product would have a similar Integrated Energy Efficiency Ratio (IEER)—washing out the energy savings from the supply fan—but would be larger, more expensive, and sub-optimal. (Trane, No. 38 at p. 3)

DOE notes that this final rule does not establish any energy conservation standards for fans and blowers and would not impact the efficiency and performance of fans embedded in covered equipment or products. In addition, EPCA provides that no standard prescribed for small electric motors (*i.e.,* those regulated in 10 CFR part 431, subpart X) shall apply to any such motor that is a component of a covered product under EPCA or of covered equipment under EPCA. (42 U.S.C. 6317(b)(3)) EPCA does not establish any such prohibition for fans and blowers. DOE further notes that EPCA does not establish any such prohibition for electric motors either. *See* 42 U.S.C. 6313(b)(1) (providing that standards for electric motors be applied to electric motors manufactured ''alone or as a component of another piece of equipment'').

AHRI commented that requests have been made to lower the power threshold from less than or equal to 1hp, to less than or equal to 0.25hp, which would include a large swath of fans used in residential products, including residential central air conditioners and heat pumps. AHRI stated that in order to regulate ''industrial equipment articles'' that are component parts of consumer products, DOE must determine that ''such articles are, to a significant extent, distributed in commerce other than as component parts for consumer products.'' (42 U.S.C. 6312(c)(1)) AHRI commented that in general, DOE regulates products as a whole and not by component. Although DOE has previously regulated furnace fans and electric motors, AHRI commented that DOE did so under unique authority provided in the sections of EPCA specific to those products and equipment.[40] AHRI commented that under the general industrial component requirement to show that embedded fans are distributed in commerce other than as component parts in a consumer product, DOE does not have the authority to regulate fans that are embedded in consumer products. (AHRI, No. 40 at pp. 5–6)

As discussed, on August 19, 2021, DOE published a final determination classifying certain fans and blowers as covered equipment and determining that fans and blowers meet the three statutory criteria for classifying industrial equipment as covered (42 U.S.C. 6311(2)(A)), including that fans and blowers are to a significant extent distributed in commerce for industrial or commercial use. *See* 86 FR 46579, 46586–46588. Further, ''covered equipment'' consists of certain industrial equipment, which in turn excludes covered products, other than industrial equipment that is a component of a covered product. (42 U.S.C. 6311(1) and (2)(A)(iii) DOE also noted, in a footnote, that distribution for residential use does not preclude coverage as covered equipment so long as to a significant extent the equipment is of a type that is also distributed in commerce for industrial and commercial use. *See* 86 FR 46579, 46586. As such, DOE disagrees with AHRI's assessment of DOE's authority. DOE can regulate fans and blowers embedded in a covered product.

a. Fans and Blowers Embedded in Non-Covered Equipment

Consistent with the Working Group term sheet scope recommendation (Docket No. EERE–2013–BT–STD–0006–0179, Recommendation #2 at p. 2), DOE proposed to exclude fans that are exclusively embedded in transport refrigeration (*i.e.,* trailer refrigeration, self-powered truck refrigeration, vehicle-powered truck refrigeration, and marine/rail container refrigeration) from the scope of the test procedure. 87 FR 44194, 44207.

In response to the July 2022 NOPR, the CEC recommended excluding fans mounted in motor vehicles or other mobile equipment since the fans are smaller in size and, although they require electricity to operate, the source of electrical power is generated by the engine of the motor and not the public electrical grid. The CEC noted that Table III–8 of the July 2022 NOPR may provide the exclusion for these fans, but that the wording was unclear (CEC, No. 30 at p. 2)

DOE did not receive any additional comments on this exclusion. Further, because DOE is not adopting a definition of ''exclusively embedded fan'' (see section of this III.B.3.c document) in this final rule, DOE excludes fans that are embedded in transport refrigeration and removed the term ''exclusively'' as proposed in the July 2022 NOPR. In addition, DOE discusses the exclusion of fan powered by combustion engines in section III.B.5 of this document.

In the July 2022 NOPR, consistent with the Working Group term sheet scope recommendation (Docket No. EERE–2013–BT–STD–0006–0179, Recommendation #2 at p. 2), DOE proposed to exclude fans exclusively embedded in vacuum cleaners from the scope of the test procedure. 87 FR 44194, 44207.

In response to the July 2022 NOPR, AHAM agreed that fans embedded in consumer/residential vacuum cleaners should be exempt from the scope. (AHAM, No. 35 at p. 5)

AHAM commented that it opposes including fans embedded in consumer home appliances, whether those products are DOE ''covered products'' or not, in the scope of the test procedure and/or energy conservation standards. AHAM noted that fans embedded in most home appliances would not be implicated by DOE's currently proposed definition of embedded fans because most are under 1 horsepower. However, AHAM noted that a lower threshold of 0.25 hp would include fans used in a number of covered products.[41] AHAM added that there are a few products that might use fans that meet DOE's definition and AHAM objects to those fans being considered commercial and industrial fans. AHAM is concerned that coverage of such fans could negatively impact the product performance of products such as range hoods/downdraft fans that are critical for improving indoor air quality in homes. AHAM commented that DOE should exclude embedded fans used in residential products such as range hoods/downdraft fans and hand dryers as well as dryer booster fans and fans used in commercial clothes dryers.

[40] AHRI commented that DOE is required by EPCA to consider and prescribe new energy conservation standards or energy use standards for electricity used for purposes of circulating air through duct work. *Id.* 42 U.S.C. 6295(f)(4)(D); *Id.* 42 U.S.C. 6313(b)(1) (covering electric motors ''alone or as a component of another piece of equipment'').

[41] These products include but are not limited to: residential refrigerator/freezers, clothes washers and dryers, dishwashers, room air conditioners, portable air conditioners, dehumidifiers, and (in the future) room air cleaners.

Additionally, AHAM is concerned that commercial clothes washers could be implicated even by the 1 horsepower limitation and requested that DOE specifically exclude fans used in commercial clothes washers from the scope of its regulation. (AHAM, No. 35 at pp. 4–5)

In this final rule, DOE excludes fans that are embedded in vacuum cleaners from the scope of the test procedure, as proposed. Further because DOE is not adopting a definition of ''exclusively embedded fan'' (see section III.B.3.c of this document), DOE removes the use of the term ''exclusively'' as proposed in the July 2022 NOPR. DOE notes that this final rule establishes a test procedure for fans and blowers and does not adopt any energy conservation standards. This final rule will not have any impacts on the performance of the fan of the larger equipment in which the fan is embedded. In addition, as noted in section III.B of this document, DOE establishes a lower shaft input power limit of 1 hp (0.89 kW of electrical input power) and that the lower power limit of 1 horsepower (0.89 kW) excludes most fans used in regulated and non-regulated consumer products, including range hoods. Finally, as discussed in section III.B.3.b of this document, DOE is implementing exclusions for fans embedded in covered equipment where the DOE metric already captures the energy use of the fans.

In the July 2022 NOPR, consistent with the Working Group term sheet scope recommendations (Docket No. EERE–2013–BT–STD–0006–0179, Recommendation #2 at p. 2), DOE also proposed to exclude fans exclusively embedded in heat rejection equipment from the scope of the test procedure (*See* Table III–4 of this document for a list of the heat rejection equipment). DOE noted that fans used in heat rejection equipment are primarily fabricated in-house by the heat rejection equipment manufacturer and that these fans are not sold in a standalone configuration.[42] 87 FR 44194, 44207.

In response to the July 2022 NOPR, Trane commented that DOE should align with the CEC proposed regulation in which the definition of embedded fans includes fans used in heat rejection equipment. Trane commented that heat rejection fans for HVAC systems are not designed for specific flow of air, and thus a metric based on air flow is not valid for heat rejection fans such as condenser fans. Trane noted that because a heat rejection fan's purpose is to reject heat from a system, these fans are designed in conjunction with a heat exchanger solely for optimizing removal of heat from a system. Trane commented that enforcing fan efficiency requirements on these definite purpose fans will require re-optimization of the heat rejection system that will not impact overall system efficiency and building energy consumption. Trane stated that this would impact manufacturer design cost, manufacturing cost, and end customer cost with no measurable energy benefit or payback. (Trane, No. 38 at p. 2)

Trane added that in order to align with CEC and the definitions of AMCA 214–21, DOE should add to the list of exclusions: (1) Air cooled chillers; and (2) Unitary package units above 760k btu (whose system metric is covered in ASHRAE 90.1–2019). (Trane, No. 38 at p. 2)

The CA IOUs recommended that DOE exclude all condenser fans from the scope of the test procedure. The CA IOUs explained that DOE proposed to accept the Cooling Tower Institute's recommendation to exclude heat rejection fans on various unregulated equipment and agreed with this decision as these fans would be difficult or impossible to test using the underlying procedures. Furthermore, the CA IOUs stated that improving the fan's efficiency would not necessarily improve the system's efficiency because of its embedment in a larger system. The CA IOUs commented that the same logic would apply to condenser fans in other types of equipment (*e.g.,* chillers and unregulated commercial unitary air conditioners). (CA IOUs, No. 37 at p. 10)

Daikin commented that fans used in air-cooled condensers have the same issues as fans used in cooling towers and other heat rejection equipment. (Public Meeting, No. 18 at p. 16) DOE notes that the Working Group did not list chillers and air-cooled condensers, and specifically limited the exemption to regulated commercial unitary air conditioners with a certified cooling capacity between 5.5 tons (65,000 Btu/h) and 63.5 tons (760,000 Btu/h). As previously noted, the embedded fan exclusions recommended by the Working Group would exclude from the scope of the test procedure fans that are embedded in regulated equipment for which the DOE metric captures the energy consumption of the fan. In line with the approach taken by the Working Group, and as discussed in section III.B.3.b of this document, DOE is implementing exclusions for fans embedded in covered equipment where the DOE metric already captures the energy use of the fans. Chillers are currently not a covered equipment and DOE does not regulate commercial unitary air conditioners with a certified cooling capacity above 760,000 Btu/h. Air cooled condensers are also not regulated by DOE. Although fans used in these equipment may face similar issues than fans used in heat rejection equipment, both pieces of equipment were not specifically listed for exemption by the Working Group. Therefore, DOE is not excluding fans used in these categories of equipment. Further, DOE excludes other condenser fans in several types of covered equipment, if the DOE metric captures the energy use of these fans. (*See* section III.B.3.b of this document.) In addition, in this final rule, DOE is not establishing any energy conservation standards and the adoption of a test procedure will not impose fan efficiency requirements. For these reasons, DOE is maintaining the exclusion of fans embedded in heat rejection equipment as proposed in the July 2022 NOPR. Further, because DOE is not adopting a definition of ''exclusively embedded fan'' (see section of this III.B.3.c document), DOE removes the use of the term ''exclusively'' as proposed in the July 2022 NOPR.

In addition, in the July 2022 NOPR, DOE proposed that fans embedded in air curtains be excluded from the scope of the proposed test procedure. 87 FR 44194, 44207. In response to the July 2022 NOPR, The CEC commented in support of the proposed exclusion of air curtains. (CEC, No. 30 at p. 2) DOE did not receive any additional comments on this issue and is excluding fans in air curtains as proposed.

b. Fans and Blowers Embedded in Covered Equipment

In the July 2022 NOPR, DOE also proposed that the test procedure would exclude fans in covered equipment in which the fan energy use is already captured in the equipment specific test procedures. DOE proposed to adopt an exclusion for fans embedded in equipment listed in Table III–4,[43] as long as the fan is not distributed in commerce as a standalone product. DOE proposed to additionally exclude fans embedded in DX–DOASes to reflect the DOE proposed test procedure and metric for DX–DOASes that, if adopted,

[42] In some cases, the heat rejection equipment manufacturer may purchase the impeller and assemble the fan in a housing which is tied to the structure of the heat rejection equipment.

[43] DOE notes that while the Working Group recommended to exclude fans in residential furnaces that are subject to DOE's energy conservation standard at 10 CFR 430.32(y), furnace fans are excluded from the definition of ''fan and blower'' and therefore do not need to be listed as a proposed exclusion.

would incorporate fan energy use.[44] DOE noted that the proposed exclusions were consistent with the recommendations of the Working Group. DOE also noted that the proposed approach would avoid regulating fans for which existing DOE regulations account for their energy use by excluding such fans from the test procedure if distributed exclusively embedded in the listed equipment. DOE proposed that to the extent a fan is distributed in commerce as a stand-alone fan, and therefore is not limited to use in specific equipment, or embedded in equipment in which its energy use is not addressed in a DOE test procedure, such a fan would be subject to the DOE test procedure. 87 FR 44194, 44207. Table III–7 of this document summarizes the embedded fans proposed for exclusion from the scope of the test procedure.

TABLE III–7—EMBEDDED FANS EXCLUDED FROM THE SCOPE OF THE TEST PROCEDURE

Fans embedded in:
DX–DOASes subject to any DOE test procedures in appendix B to subpart F of part 431.*
Single-phase central air conditioners and heat pumps rated with a certified cooling capacity less than 65,000 British thermal units per hour (''Btu/h''), that are subject to DOE's energy conservation standard at 10 CFR 430.32(c).
Three-phase, air-cooled, small commercial packaged air-conditioning and heating equipment rated with a certified cooling capacity less than 65,000 Btu/h, that are subject to DOE's energy conservation standard at 10 CFR 431.97(b).
Transport refrigeration (*i.e.,* Trailer refrigeration, Self-powered truck refrigeration, Vehicle-powered truck refrigeration, Marine/Rail container refrigerant), and fans exclusively powered by combustion engines.
Vacuum cleaners.
Heat Rejection Equipment:
• Packaged evaporative open circuit cooling towers.
• Evaporative field-erected open circuit cooling towers.
• Packaged evaporative closed-circuit cooling towers.
• Evaporative field-erected closed-circuit cooling towers.
• Packaged evaporative condensers.
• Field-erected evaporative condensers.
• Packaged air-cooled (dry) coolers.
• Field-erected air-cooled (dry) coolers.
• Air-cooled steam condensers.
• Hybrid (water saving) versions of all of the previously listed equipment that contain both evaporative and air-cooled heat exchange sections.
Air curtains.
** Air-cooled commercial package air conditioners and heat pumps (CUAC, CUHP) with a certified cooling capacity between 5.5 tons (65,000 Btu/h) and 63.5 tons (760,000 Btu/h) that are subject to DOE's energy conservation standard at 10 CFR 431.97(b).
** Water-cooled and evaporatively-cooled commercial air conditioners and water-source commercial heat pumps that are subject to DOE's energy conservation standard at 10 CFR 431.97(b).
** Single package vertical air conditioners and heat pumps that are subject to DOE's energy conservation standard at 10 CFR 431.97(d).
** Packaged terminal air conditioners (PTAC) and packaged terminal heat pumps (PTHP) that are subject to DOE's energy conservation standard at 10 CFR 431.97(c).
** Computer room air conditioners that are subject to DOE's energy conservation standard at 10 CFR 431.97(e).
** Variable refrigerant flow multi-split air conditioners and heat pumps that are subject to DOE's energy conservation standard at 10 CFR 431.97(f).

** DX–DOASes are not currently subject to a DOE test procedure. However, there is an ongoing rulemaking to establish a test procedure for DX–DOASes that DOE anticipates will be finalized before the final rule of the fans and blowers rulemaking. Information about this rulemaking can be found at *www.regulations.gov* under Docket No. EERE–2017–BT–TP–0018.

* The exclusion only applies to supply and condenser fans embedded in this equipment.

NEEA commented in support of DOE's definitions and scope for inclusion and exemptions of embedded fans, but recommended DOE establish a consistent approach to ensure fan efficiency is accounted for in other regulated products. NEEA commented that this would include a similar methodology for each product, even if the exact conditions are not the same across all products. Conceptually, NEEA stated that this could function as a checklist to ensure fans are appropriately accounted for: (1) the total fan energy use is accounted for in the ''average period of use'' of that product (*e.g.,* economizing fan energy use for CUAC); (2) the testing conditions represent the operating conditions of the fan (*e.g.,* representative static pressure for packaged HVAC); (3) the benefits of variable speed fans and right sizing of a fan are accounted for (*i.e.,* will these energy saving measures increase the regulated rating). (NEEA, No. 36 at pp. 7–8)

DOE accounts for fan energy use on a product-by-product basis. Any consideration of fan energy use in other covered product or equipment would be addressed in the test procedure rulemakings specific to each such product or equipment.

AHRI recommended that DOE exclude fans embedded in commercial water heaters and boilers from the rulemaking. AHRI commented that the metric for commercial water heaters includes the embedded fan's energy, meeting the criteria which was the basis for limited exclusions in regulated products recommended by the Working Group. AHRI commented that the test procedure and energy conservation standards for commercial boilers do not capture the fan power. However, AHRI commented that the actual energy savings potential from applying the proposed fan regulation to a boiler or water heater fan itself is likely to be small and the total energy consumption of the equipment may be increased due to effects on combustion. In addition, AHRI stated that the complexity of integrating a new fan system into a boiler or water heater is considerable as fans are integral parts of the combustion

[44] *See* 86 FR 72874, 72889–72890 (December 23, 2021).

systems, raising costs that are ultimately passed on to consumers. AHRI commented that the appropriate approach is to work through the commercial boiler test standard's consensus process and find a path to incorporate the electrical energy used in a boiler system into the test procedure and the equipment ratings to include electrical power consumption from the fan is currently being drafted. AHRI added that it estimates the market of the commercial boiler and water heater industries is small, with annual shipments of approximately 20,000 boiler units and under 2,000 hot water supply boilers. In addition, AHRI noted that fans used in commercial storage water heaters are virtually all under 1 horsepower and only exceed 1 horsepower in commercial boilers and hot water supply boilers with input rates exceeding two million Btu/h. For hot water supply boilers, AHRI commented that approximately 12 percent of models exceed 2 million Btu/h, or approximately 250 boilers per year nationally.[45] Based on these shipments, AHRI estimated that the potential 30-year electricity savings from commercial boiler fans would be on the order of 0.016 quads nationally and noted a potential that fan changes will result in increased standby losses and reduction in thermal efficiency that would result in a net energy loss. AHRI added that given the small degree of energy savings and the small shipment volume relative to the significant redesign, testing, and certification costs associated with incorporating a new fan, it is highly unlikely that there are significant positive consumer benefits. (AHRI, No. 40 at pp. 11–12)

As noted by AHRI, the metric for commercial water heaters includes the embedded fan's energy, meeting the proposed criteria to identify the embedded fan exemption. However, as AHRI noted, fans in this equipment are below 1 hp shaft power and therefore are already excluded based on the adopted power limits discussed in section III.B.1 of this document. Therefore, DOE did not propose and is not adopting to specifically list this equipment in the list of covered equipment for which the fan is excluded from the test procedure. For embedded fans in commercial boilers, as noted by AHRI, only the larger units would incorporate fans that meet the scope criteria discussed in section III.B.1 of this document. However, as noted by AHRI, the current DOE test procedure for commercial boilers does not capture the fan energy use; therefore, DOE did not propose and is not adopting to list this equipment as part of the covered equipment for which the fan is excluded from the test procedure. Instead, DOE is exempting fans embedded in the equipment listed in Table III–7, as proposed in the July 2022 NOPR and continues to exclude fans in covered equipment in which the fan energy use is already captured in the equipment specific test procedures. Further, because DOE is not adopting a definition of ''exclusively embedded fan'' (see section of this III.B.3.c document), DOE removes the use of the term ''exclusively'' as proposed in the July 2022 NOPR. In addition, DOE notes that this final rule does not adopt energy conservation standards or certification requirements and any impacts from setting potential energy conservation standards (including equipment redesign and consumer benefits) will be analyzed as part of any separate energy conservation standard rule.

Daikin commented that it was appropriate to exempt embedded fans in DOE-regulated products and added that DOE should also exempt fans in equipment that are regulated by IECC and [ASHRAE] 90.1 (Public Meeting transcript, No. 18 at p. 15–16)

As noted previously, DOE is exempting fans embedded in the equipment listed in Table III–7, as proposed in the July 2022 NOPR and continues to exclude fans in covered equipment in which the fan energy use is already captured in the equipment specific test procedures. In addition, DOE is not exempting fans that are in equipment that are regulated by IECC and ASHRAE 90.1, consistent with the term sheet. Instead, DOE excludes fans embedded in equipment listed in Table III–7, consistent with the Working Group term sheet scope recommendations related to embedded fans.

c. Exclusively Embedded Fans

In the July 2022 NOPR, DOE further clarified that DOE proposed to exclude embedded fans that are not distributed in commerce as standalone fans. DOE acknowledged that in a number of instances, a standalone fan purchased by a manufacturer for incorporation into a unit of listed equipment may be indistinguishable based on physical features from a fan that is purchased by a manufacturer for incorporation into non-listed equipment or from a fan used as a standalone fan. DOE noted that during the ASRAC negotiations, AHRI conducted a survey of its members to determine the number of fans purchased versus manufactured by the equipment manufacturer. (Docket No. EERE–2013–BT–STD–0006, AHRI, No. 125.3 at p. 1) AHRI estimated that over 80 percent of all fans that are used as components across all commercial regulated equipment are manufactured by the equipment manufacturer. *Id.* This percentage was higher for commercial air-conditioning and heat pump equipment and was estimated to be between 94 and 99 percent. 87 FR 44194, 44208.

In order to provide additional specificity as to the fans that would be subject to the embedded fan exclusion, in the July 2022 NOPR, DOE proposed to use the term ''exclusively embedded fans'' to designate the fans covered by the embedded fan exclusion. DOE proposed to define ''exclusively embedded fan'' as: a fan or blower that is manufactured and incorporated into a product or equipment manufactured by the same manufacturer and that is exclusively distributed in commerce embedded in another product or equipment. Based on this information, DOE tentatively determined that the vast majority of fans used as components in regulated commercial HVACR equipment would meet the proposed definition of exclusively embedded fan and would not be subject to the test procedure as proposed in the July 2022 NOPR. DOE further provided examples illustrating how the proposed definition of exclusively embedded fan would impact whether a fan must be tested and certified to DOE. 87 FR 44194, 44208.

In response to the July 2022 NOPR, ebm-papst commented that it does not believe it to be common practice that original equipment manufacturers (''OEMs'') fabricate fans in the literal sense. ebm-papst added that very few OEMs, if any, in the U.S. fabricate their own impellers and that in its experience no American OEMs fabricate their own fan motors or their own electronic fan speed controller. However, ebm-papst added that it is common practice for OEMs to purchase major sub-components from independent suppliers, such as ebm-papst. (ebm-papst, No. 31 at p. 6)

Morrison commented that 95 percent of fans it manufactures are used in HVAC equipment. (Morrison, No. 42 at p. 3)

As noted in the July 2022 NOPR, DOE relied on data from AHRI to estimate the share of embedded fans that are manufactured in-house by OEMs vs. purchased and notes that these

[45] AHRI cited U.S. Department of Energy, Technical Support Document: Energy Efficiency Program for Consumer Products and Commercial and Industrial Equipment: Commercial Water Heating Equipment, April 18, 2016, Figure 3.10.26, p. 3–29).

estimates may not reflect individual manufacturer practices.

In response to the July 2022 NOPR, DOE received several comments related to the proposed definition of ''exclusively embedded fan''.

AHRI stated support for the AMCA 214–21 definition of an embedded fan as ''a fan that is part of a manufactured assembly where the assembly includes functions other than air movement.'' (AHRI, No. 40 at p. 8)

NEEA commented in support of DOE's proposals related to embedded fans and supports the definition of exclusively embedded fans, which adds additional clarity to what is included or excluded from regulation. (NEEA, No. 36 at p. 7)

The Efficiency Advocates supported DOE's proposal regarding embedded fans. The Efficiency Advocates commented that generally fans can be sold as standalone products or they may be embedded within a piece of equipment that requires the fan to operate. The Efficiency Advocates commented that in the NOPR, DOE defines ''exclusively embedded'' fans and excludes various types of exclusively embedded fans consistent with the Working Group recommendations. The Efficiency Advocates stated that these exclusions, summarized in Table III–8 of the July 2022 NOPR, essentially apply only to embedded fans in regulated equipment for which the DOE metric captures the energy consumption of the fan. The Efficiency Advocates support this approach to help ensure that inefficient fans are not embedded into products for which energy use is not captured by a DOE efficiency metric. (Efficiency Advocates, No. 32 at p. 2)

Morrison commented that the exclusively embedded fans it manufactures have a clearly identified label with a unique part number and are exclusive per the manufacturer, with full traceability through the sales order process to a ship-to site. Morrison stated a concern about double regulation for parts that are instrumental to the equipment's already existing regulation and now an added layer of regulation that adds to the cost of products but provides no additional energy savings. (Morrison, No. 42 at p. 4) Morrison added that the fans it manufactures are built to order for the customer and are application-specific designs with unique part numbers on the label that identify the customer and location. Morrison stated that all shipments have a unique Sales Order that confirms the ship-to location and part number and would be traceable to the OEM's appliance. Morrison commented that the fans it manufactures are assembled into an appliance and nearly all are in the covered product category that has a metric inclusive of the fan energy. In addition, Morrison pointed out that this proposed added layer of test for standalone fans before embedding amounts to duplicate regulation and double counting of the energy savings, and that these fans are currently tested by the OEMs in the appliance and would not need the added cost of regulation as a fan. (Morrison, No. 42 at p. 3)

AHAM commented that embedded fans used in covered products should be excluded. AHAM commented that it is critical that those fans be excluded regardless of whether they are imported or sold for inclusion in a domestically manufactured product or are imported as part of that product. AHAM requested that should DOE include fans that are embedded in consumer products, DOE ensure that all embedded fans—whether sold for incorporation into the product or imported already in the product—are treated the same. Otherwise, AHAM commented that domestically manufactured products could be at a disadvantage, which is contrary to the Administration's goals to increase domestic manufacturing. (AHAM, No. 35 at p. 5)

AHRI commented that all embedded fans, and replacement fans for these finished goods, regardless of whether they are domestically produced or imported as part of the product, should be exempt. Under DOE's proposal, AHRI commented that finished goods manufactured overseas would be treated differently from those manufactured domestically. AHRI stated that, as proposed, a manufacturer would be able to buy and embed a standalone fan and not be subject to the regulation if the finished product was imported. However, AHRI added, a domestic manufacturer buying a fan for manufacture domestically would be subject to the proposed rule, as written, and DOE has not considered the burden this places on domestic manufacturers. (AHRI, No. 40 at pp. 7–8)

Morrison commented that the exemption for exclusively embedded fans would lead to trade-restrictive issues. Morrison commented that using a scenario of covered equipment with an exempted embedded fan: (1) If the OEM produces the testable fan configuration, then those fans are exempt from fan regulation (2) But if an identical fan construction is delivered as a testable configuration by a supplier to an OEM factory in the U.S., then the fan is considered a standalone fan and therefore will be in the scope of the regulation and testing will be required (3) On the other hand, if the U.S. OEM has a joint venture north or south of the border, then it can receive and install unregulated fans there and sell the unit back in the U.S. without any fan regulation (4) Another scenario is possible with the OEM factory in a foreign country and under that scenario, the embedded fan is exempt from fan regulation. Morrison commented that this would appear to promote the use of offshore production and would not just favor foreign-made equipment but would encourage more use of imported equipment. (Morrison, No. 42 at p. 3) Similarly, ebm-papst did not support the proposed definition of standalone fans in the NOPR and provided the following scenario: If an OEM fabricates the testable fan configuration itself, the fans will be exempt from fan regulation. However, ebm-papst stated, if an identical fan construction is supplied as a testable configuration by a supplier to an OEM factory in the U.S., then the fan will become a standalone fan and therefore will be in the scope of the regulation. ebm-papst added that if the U.S.-based OEM owns a factory outside of the U.S., then it will be permitted to receive and install unregulated fans there, and sell the unit in the U.S. ebm-papst further commented that if the OEM factory is in a foreign country altogether, then the embedded fan will be exempt from the fan regulation. ebm-papst commented that the proposed exclusions would be a restraint of domestic trade, while favoring foreign OEM factories. (ebm-papst, No. 31 at p.2)

ebm-papst requested clarification regarding the proposed approach to exclude embedded fans if they are fabricated by the OEM, while all external fabricators would be burdened by the regulation. (ebm-papst, No. 31 at p. 1) ebm-papst requested that DOE ensure that all embedded fans—whether sold for incorporation into the product or imported already in the product—be treated the same. Otherwise, ebm-papst commented that domestically manufactured products could be at a disadvantage, which is contrary to the Administration's goals to increase domestic manufacturing. Further, ebm-papst commented that there are no unique physical features that could be used to distinguish a fan that is exclusively designed for use in equipment listed in Table III 8 of the NOPR. However, ebm-papst opposes the attempt to treat exclusively embedded fans differently, merely due to potential differences in the fans' supply chains. (*Id.* at p. 6)

As noted previously, the proposed exclusions for certain embedded fans listed in Table III–8 of the July 2022 NOPR, would only apply to fans that are manufactured in-house by the manufacturer of the equipment or to fans that are imported already embedded in equipment listed in Table III–8 of the July 2022. Fans purchased by OEMs in the U.S. to be incorporated into equipment listed in Table III–8 of the July 2022 NOPR would not be excluded, while fans purchased and incorporated by an OEM outside of the U.S. would be excluded. As noted by the stakeholders, the proposed definition of exclusively embedded fans could therefore disadvantage domestic fan suppliers. For this reason, DOE is not establishing a definition of ''exclusively embedded fan''. As this time, DOE is not differentiating the embedded fan listed for exclusion in Table III–7 depending on whether it is exclusively distributed in commerce embedded in another product or equipment listed in that table (*i.e.,* depending on whether it is manufactured and incorporated into a product or equipment manufactured by the same manufacturer). By removing the proposed ''exclusively embedded fan'' definition, all embedded fans, whether sold for incorporation into the product or already incorporated in the product, would be exempted if embedded in equipment listed in Table III–7 of this document. In the future, DOE may consider an approach to provide additional specificity as to how to identify fans that would be sold for incorporation in equipment listed in in Table III–7 of this document.

JCI requested clarifications on how DOE will verify the performance of a fan or blower in a finished-goods unit in the field. JCI asked if the fans would have to be removed from equipment and sent to a lab for testing. (JCI, No. 34 at p. 2)

DOE's regulations apply to the point of manufacture and not to the equipment as installed in the field. If the fan is embedded in another equipment, testing would be performed in accordance with the provisions described in section III.E.9 of the document.

AHAM commented that it does not support an approach that would require OEMs to certify embedded fans used in their finished products and that would hold OEMs responsible for certification, testing and record-keeping for the fans embedded in their products. AHAM commented that the fan manufacturers should bear this burden given that they have the expertise and facilities to conduct the testing, etc. (AHAM, No. 35 at p. 7)

DOE notes that the fan manufacturer would be responsible for testing and certifying the fan. If the OEM is also the fan manufacturer (and fabricates the fan in-house), then that OEM would be responsible for testing and certifying the fan if included in the scope of the test procedure.

4. Air Circulating Fans

In the July 2022 NOPR, DOE noted that AMCA 230–15 (with errata) did not include any limitation in terms of input power of the air circulating fans that can be tested in accordance with the test procedure. DOE further noted that the AMCA committee was considering limiting the scope of AMCA 230–15 (with errata) to air circulating fans with input power of 125 W and above to focus on commercial and industrial fan applications and exclude residential fans, such as tower fans and bladeless fans. 87 FR 44194, 44210.

In the July 2022 NOPR, DOE tentatively determined that the proposed test procedure would provide a representative measurement of energy use or energy efficiency during a representative average use cycle for all air circulating fans. Therefore, at the time, DOE proposed to include all categories of air circulating fans in the scope of the proposed test procedure; *i.e.,* including equipment with input power less than 125 W. DOE noted that should additional information justify excluding fans with input power less than 125 W from the scope (or any other power limit that may be justified), DOE may consider applying a power limit in the final rule as considered by the AMCA committee and supported by stakeholders. In addition, DOE noted that it may consider specifying that 125 W corresponds to the air circulating fan's input power at maximum speed. 87 FR 44194, 44210.

The Efficiency Advocates stated support for including air circulating fans within the test procedure scope, so that published efficiency information for these products is based on a standardized test procedure and to allow DOE to consider future potential energy conservation standards. (Efficiency Advocates, No. 32 at p. 2)

AMCA commented that the stakeholders of residential circulating fans are not represented by AMCA and have not previously been involved in the fans-and-blowers rulemaking. Additionally, AMCA noted that the demarcation of the scope of the AMCA 230 test standard under revision will start above 125 W. AMCA questioned if DOE has alerted stakeholders of residential circulating fans that they are in the process of being regulated as it would be fair to enable them to weigh in on the proposed test procedure. (AMCA, No. 41 at p. 5) AMCA recommended the exclusion of ACFH with less than 125–W nameplate electrical power, which is the demarcation between the published IEC Standard 60879:2019, ''Comfort fans and regulators for household and similar purpose,'' [46] and AMCA 230 (next revision). AMCA commented that fans covered by IEC 60879 generally are mass-produced, mass-imported, mass-sales residential products, which are made by stakeholders that have not been represented in any U.S. fan-regulation activity to date, such as ASRAC, California Title 20, or model/state energy codes. (AMCA, No. 41 at pp. 7–8)

ebm-papst recommended limiting the scope of the circulation fan test procedure to fans with nameplate power ratings of at least 125 W in an effort to keep the focus of this rulemaking on commercial and industrial fans. ebm-papst added that the scope of EU 327/2011 is limited at 125 W and that lower-power circulation fans are in the scope of IEC 60879. (ebm-papst, No. 31 at p. 6)

Since the publication of the July 2022 NOPR, AMCA published AMCA 230–23, and this latest version of the industry standard only covers air circulating fans with input power greater than or equal to 125 W. Further, to date, stakeholders representative of the market of circulating fans with input power less than 125 W s have not commented on this rulemaking. In addition, in the NOPR, DOE did not review IEC 60879:2019, which stakeholders indicated would be the most appropriate industry test procedure for these fans. For these reasons, at this time, DOE is limiting the scope of the test procedures to air circulating fans with input power greater than or equal to 125 W, as measured by the test procedure at high speed.

AHAM commented that consumer fans such as desk fans, box fans, pedestal fans, should not be included in the scope of commercial and industrial fans and blowers. AHAM commented that this would be in direct contradiction to EPCA, and consumer fans have different average representative uses than commercial and industrial fans. AHAM urged DOE

[46] IEC 60879:2019 specifies the performance-measuring methods of comfort fans and regulators for household and similar purposes, including conventional fans, tower fans, and bladeless fans, their rated voltage being not more than 250 V for single-phase fans and 480 V for other fans, and their rated power input being less than 125 W.

to either specifically exclude consumer air circulating fans from the scope of coverage and noted that a 125 W limit would be an effective way to distinguish consumer fans so long as the 125–W threshold applies to the fan rating alone and not to the entire product or the fan and motor. AHAM noted this could implicate products like residential fan-heaters and stated it was unclear whether the relevant definitions in the applicable AMCA and IEC 60879 standards would take the products out of scope. As such, AHAM requested that DOE make it clear that all residential/consumer fans are exempt. AHAM added that it was their understanding that DOE's proposal did not include bladeless circulation fans in the scope of air circulating fans based on the proposed definitions. AHAM agrees that such fans should not be included. AHAM added that DOE should treat other consumer fans the same way, *i.e.,* no consumer fan should be included in the scope of the commercial and industrial fan test procedure or energy conservation standards). (AHAM, No. 35 at p. 6)

AHAM commented against DOE's proposal to include consumer (residential) air circulating fans and embedded fans used in consumer (residential) products in the scope of its commercial and industrial fans and blowers test procedure. AHAM commented that this would be contrary to EPCA, DOE's coverage determination, and essential EPCA public policy. AHAM commented that consumer fans and fans used in consumer products are, by definition, not commercial/industrial fans or blowers. AHAM added that Congress's intent was to include only commercial and industrial fans and blowers under the scope of ''fans'' and ''blowers'' in 42 U.S.C. 6311(2)(B). First, AHAM noted that fans and blowers are listed as types of industrial equipment, which indicates an intent to cover commercial and industrial equipment, not residential/consumer products. Second, AHAM added that in EPCA, fans and blowers are not included in Part A, which is for Consumer Products other than Automobiles. Third, AHAM stated that fans and blowers by definition are industrial equipment, which EPCA defines as equipment that ''to any significant extent, is distributed in commerce for industrial or commercial use, without regard to whether such article is in fact distributed in commerce for industrial or commercial use.'' (42 U.S.C. 6311(2)(A)(ii)) In particular, AHAM commented that residential air circulating fans by definition are clearly consumer products—they are not, ''to any significant extent'' distributed in commerce for industrial or commercial use and are distributed for use in homes. AHAM commented that fans such as desk fans, box fans, and pedestal fans that are used in homes are regularly distributed in commerce for personal use or consumption by individuals. AHAM commented that if particular SKUs are labeled as consumer fans and, in fact, are primarily marketed and distributed into the very different commercial/industrial sectors, then they can be dealt with through compliance and enforcement efforts rather than by over-incorporation of all consumer fans into test procedures and standards. AHAM noted that commercial clothes washers also appear in the same list of ''covered equipment.'' (42 U.S.C. 6311(1)(H)) AHAM commented that despite the fact that commercial and residential clothes washers share similar construction and are often both used by individual consumers, EPCA differentiates them. Thus, AHAM stated it was evident that Congress intended to include only truly commercial/industrial fans and blowers in the scope of industrial equipment. AHAM added that DOE's proposal to include embedded fans used in consumer products and residential/consumer air circulating fans in the scope of the commercial and industrial fans and blowers rulemaking is inconsistent with its previous decision for these products. AHAM commented that DOE's final determination of coverage stated that ''[t]o qualify as 'industrial equipment,' fans and blowers must be, to a significant extent, distributed in commerce for industrial and commercial use.'' (42 U.S.C. 6311(2)(A)(ii)) AHAM noted that in footnote 26 of the final coverage determination, DOE notes that distribution for residential use does not preclude coverage as covered equipment so long as to a significant extent the equipment is of a type that is also distributed in commerce for industrial and commercial use. However, AHAM commented that is not the case with fans embedded in consumer products (whether they are DOE covered products or not) or fans used in homes to circulate air. Thus, AHAM commented that DOE should not be including either type of fan under the scope of the commercial and industrial fans and blowers test procedure or energy conservation standards. AHAM commented that DOE's proposal is not consistent with its own guidance on the consumer/commercial distinction in EPCA.[47] Specifically, AHAM noted that residential/consumer fans are typically smaller than commercial and industrial fans because they are meant to circulate air in smaller spaces and have lower wattage, have different durability requirements, and have different safety requirements. AHAM commented that UL 507: Standard for Electric Fans applies to consumer fans and some commercial fans, but that there are also additional safety requirements for commercial fans (*e.g.,* OSHA requirements) and UL 507 specifically excludes certain fans. AHAM further noted that there are industrial technical guidance requirements such as ISO13348 (''Industrial fans—Tolerances, methods of conversion and technical data presentation'')[48] that distinguish household and industrial fans. Finally, AHAM noted that residential fans as a product type are primarily used in residential applications. AHAM commented that the same was true for fans embedded in consumer products. (AHAM, No. 35 at pp. 1–4)

AMCA commented in support of AHAM's comment regarding the scope of the [air] circulating fan coverage extending below 125 W. (AMCA, No. 41 at p. 4)

DOE notes that air circulating fans are tested in a configuration that measures electrical input power to the fan, inclusive of the motor, and that the existing test procedures (*i.e.,* AMCA 230–23 or IEC 60879:2019) do not allow measuring the mechanical shaft power to the fan, exclusive of the motor. Therefore, DOE has determined that a limit in terms of electrical input power (applicable to the fan and motor) is more appropriate. Regarding DOE's authority to regulate fans and blowers that are distributed in commerce for residential use, as noted previously (*See* section III.B of this document), DOE has determined that distribution for residential use does not preclude coverage as covered equipment so long as to a significant extent the equipment is of a type that is also distributed in commerce for industrial and commercial use. EPCA defines ''industrial equipment'' as any article of equipment[49] ''of a type'' that ''to any

[47] AHAM referenced the following: *www1.eere.energy.gov/buildings/appliance_standards/pdfs/cce_faq.pdf.*

[48] *See www.iso.org/standard/45118.html.*

[49] The types of equipment are ''(in addition to electric motors and pumps, commercial package air conditioning and heating equipment, commercial refrigerators, freezers, and refrigerator-freezers, automatic commercial ice makers, commercial clothes washers, packaged terminal air-conditioners, packaged terminal heat pumps, warm air furnaces, packaged boilers, storage water heaters, instantaneous water heaters, and unfired

significant extent, is distributed in commerce for industrial or commercial use'' and ''is not a covered [consumer] product [ ] without regard to whether such article is in fact distributed in commerce for industrial or commercial use.'' 42 U.S.C. 6311(2)(A). Accordingly, any equipment that meets the definition of air circulating fan, has an input power greater than or equal to 125 W, as measured by the test procedure at high speed, and is of a type that, to any significant extent, is distributed in commerce for industrial or commercial use is included in the scope of the test procedure, regardless of whether it is sold for use in commercial, industrial, or residential settings. In addition, as previously stated, DOE is not setting test procedures for air circulating fans with input power less than 125 W and DOE believes this would exclude most fans used in residential applications.

Morrison commented that air circulating fans should be covered in a separate rulemaking as their utility, function, and testing process are different from other fans and blowers. Morrison added that this should be done so the appropriate fan manufacturers are engaged in this process to reduce adding burden and complexity to this rulemaking. (Morrison, No. 42 at p. 1)

AMCA recommended that air circulating fans that are not ceiling fans be handled with a separate rulemaking. AMCA commented that this would provide stakeholders of covered fans less than 125 W an opportunity to participate and provide separation between residential and commercial/industrial products. (AMCA, No. 41 at p. 17) In addition, AMCA commented that such request seemed practical and fair seem practical and fair, especially for the circulating fan stakeholders that were not in the scope of the ASRAC process, and which are in the final stages of revising the AMCA 230 test standard for circulating fans. AMCA requested DOE to allow that standard committee to complete its work before issuing the final rule on this test procedure. Already, with the final rule for the ceiling fan test procedure causing problems for the AMCA 230 revision, AMCA commented that it would really hurt the standard to have it out of synch with the fans and blowers test procedure sections that cover circulating fans. (AMCA, No. 41 at pp. 3–4

Greenheck commented that the inclusion of air circulating fans in the fans and blowers test procedure is problematic as they are a completely different type of equipment and utilize different industry test standards, procedures, and metrics as defined in AMCA 230–15. Greenheck commented that the inclusion of air circulating fans makes the test procedure rulemaking confusing and contradictory. (Greenheck, No. 39 at p. 8)

DOE notes that although the test procedures for fans and blowers other than air circulating fans, and air circulating fans are combined in a single notice, DOE is adopting separate test procedures for each category of equipment and explicitly indicates the scope of application of each test procedure. In addition, as noted previously, DOE is not setting test procedures for air circulating fans with input power less than 125 W. Therefore, DOE is continuing to include air circulating fans in the same rulemaking docket as fan and blowers. Although DOE is including air circulating fans in the same rulemaking as fans and blowers other than air circulating fans, DOE notes that this final rule establishes the test procedures for fans and blowers other than air circulating fans and the test procedures for air circulating fans as separate appendices. In addition, as previously stated, DOE is not setting test procedures for air circulating fans with input power less than 125 W. In addition, as discussed in section III.D of this document, DOE is incorporating by reference the latest version of AMCA 230–23, which addresses AMCA's concerns about this rulemaking being completed before AMCA 230–23 published.

AHRI commented that DOE expanded the scope of the NOPR to include fans that were not discussed in the 2015 ASRAC negotiations. In addition, AHRI commented that the October 2021 RFI was narrowly limited to one classification of fans, the air circulating fan heads (''ACFH''). (AHRI, No. 40 at pp. 4–5)

DOE notes that neither the term sheet nor the scope of the RFI limits DOE's authority to initiate a rulemaking on additional categories of fans and blowers. DOE proposed a test procedure for air circulating fans in the July 2022 NOPR and considered comments received in response to the NOPR in determining the test procedure established in this final rule.

5. Non-Electric Drivers

Some fans operate with non-electric drivers, such as engines or generators, and such fans may be used in non-stationary applications or stationary applications. The Working Group recommended that DOE exclude fans that are exclusively powered by internal combustion engines from the test procedure and related energy conservation standards. (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #2 at p. 2)

AMCA 214–21 does not provide for the testing of fans and blowers powered by internal combustion engines. In order to measure the energy efficiency or energy use of non-electric drivers during a representative average use cycle, separate test methods would be necessary for each type of driver (*e.g.,* engine, generators). DOE is not currently aware of a relevant industry test procedure and does not have information regarding the test set-up required to test fans powered by internal combustion engines. As such, in the July 2022 NOPR, DOE did not propose test procedures for fans and blowers powered exclusively by an internal combustion engine, [50] regardless of whether such fan or blower is used in a stationary or non-stationary application. 87 FR 44194, 44210.

Certain bare shaft fans can be powered by either electric drivers (*i.e.,* motors) or non-electric drivers. In the July 2022 NOPR, DOE tentatively determined that to the extent such a fan can be powered by an electric driver, the proposed test procedure would provide for measurement of the energy efficiency or energy use during a representative average use cycle when powered by an electric driver. As such, DOE proposed that such a fan would be subject to the test procedure. 87 FR 44194, 44210–44211.

The CEC commented in support of the exclusion of fans that are operated by an internal combustion engine that is used for personal (consumer), commercial, or industrial transportation only. The CEC recommended defining the term ''fan combustion engines,'' since it is unclear if the term ''fan combustion engine'' is meant to be that of a turbo fan engine, a fan driven by an internal combustion engine in any context, or the fans driven by an internal combustion engine used for the purpose of personal (consumer), commercial, or industrial transportation. (CEC, No. 30 at p. 3)

hot water storage tanks) as follows: (i) compressors; (ii) fans; (iii) blowers; (iv) refrigeration equipment; (v) electric lights and lighting power supply circuits; (vi) electrolytic equipment; (vii) electric arc equipment; (viii) steam boilers; (ix) ovens; (x) kilns; (xi) evaporators; (xii) dryers; and (xiii) other motors.'' 42 U.S.C. 6311(2)(B).

[50] DOE notes that the July 2022 NOPR included a typographical error in Table III–8 of the NOPR, stating ''fans exclusively powered by fan combustion engines'' instead of ''fans exclusively powered by an internal combustion engine.''

AMCA stated its support for the exclusion of fans and blowers that are exclusively powered by internal combustion engines from the scope of this test procedure because such fans include Positive Pressure Ventilators (''PPV''), which are portable fans for fire-rescue operations and excluded from having FEI ratings calculated using AMCA 214–21. (AMCA, No. 41 at p. 8)

AMCA noted that to help distinguish fans powered by combustion engines, PPVs are portable tube-axial fans and can be powered by batteries, combustion engines, and hydraulics while having no provisions for duct installations. AMCA added that PPVs sometimes are confused with floor-drying fans, which are housed centrifugal fans, whereas PPVs are not supplied in bare shaft configuration. (AMCA, No. 41 at p. 8)

New York Blower commented that fans with internal combustion engines are extremely rare and not likely to increase due to regulation and that exclusion of these fans seems appropriate. New York Blowers stated that it is possible at lower power ranges that there might be a significant quantity of products and consequently, units driven by internal combustion applications that they are not aware of. Aside from a clutch mechanism to keep the fan disengaged from the motor when idling, New York Blower commented that it does not know of any distinguishing feature of the fan that would indicate the fan would be driven by an internal combustion engine. (New York Blower, No. 33 at p. 9)

Robinson stated a lack of awareness of any physical features of a fan design that would distinguish those as exclusively powered by internal combustion engines other than the presence of an internal combustion engine or potentially a fluid clutch. (Robinson, No. 43 at p. 6)

Morrison commented that many fans for internal combustion engines are specific designs intended for direct attachment to the engine and others have low voltage motors consistent with vehicle electrical systems. Morrison commented that such fans should be part of the equipment regulation (autos, buses, trucks, generators, and heavy equipment) as opposed to being included in this effort as detailed in the ASRAC term sheet. In addition, Morrison noted that these fans have low-voltage motors and heavy construction features. (Morrison, No. 42 at p. 4)

DOE notes that the July 2022 NOPR included a typographical error in Table III–8 of the NOPR, stating ''fans exclusively powered by fan combustion engines'' instead of ''fans exclusively powered by an internal combustion engine.'' In this final rule, consistent with the July 2022 NOPR, and as recommended by stakeholders, DOE excludes fans and blowers powered exclusively by an internal combustion engine, regardless of whether such fan or blower is used in a stationary or non-stationary application from the scope of the test procedure. DOE is not adopting additional definitions as the reference to internal combustion engines clearly specifies the fans excluded from the scope of the test procedure. As noted by stakeholders such fans can be distinguished based on the presence of a clutch mechanism or designs intended for direct attachment to the engine.

6. Replacement Fans and Blowers

The Working Group did not address the issue of replacement parts in the term sheet. (Docket EERE–2013–BT–TP–0055, No. 179, Appendix F at p. 19). In the July 2022 NOPR, DOE proposed to include all fans and blowers that: (1) meet the criteria for scope of inclusion as described in section III.A.1 of that document, and (2) are not proposed for exclusion as listed in section III.A.2 of that document or Table III–8 of the July 2022 NOPR, regardless of whether that fan is a replacement fan. 87 FR 44194, 44211.

Morrison commented that replacement blowers for HVAC appliances need to be fully excluded for safety reasons as appliance limit controls may cause malfunction that could result in loss of life and/or property. (Morrison, No. 42 at p. 2)

AHAM commented that replacement fans, as well as those that are not considered covered products, should be excluded from the scope of the test procedure and applicable standards. (AHAM, No. 35 at p. 5)

AHRI commented that any potential regulation should consider the impact on replacement fans and added that the consequences of a replacement fan made non-compliant because of these new regulations could be catastrophic. AHRI commented that in many cases, such as supply-air fans with air flow through gas fired heat exchangers, hot-water, coils or electric resistance units, a variety of safety standards in addition to performance standards are affected. AHRI commented that the testing of all legacy equipment because of a fan change will be cost- and resource-prohibitive, and that if a replacement fan is not compliant, in most cases, an unsafe, engineered-to-fit substitution would be required. AHRI asserted that the costs, risks, and time required to retest the HVACR and water-heating equipment would all be prohibitive and that testing would also be impractical if the HVACR and water heating equipment is out of production. AHRI added that manufacturers would be forced to rebuild an out-of-production unit solely for the purpose of testing a new fan. AHRI concluded by stating that there may be instances in which such part substitution makes sense, but that is not a reasonable basis for a broad, minimum standard. (AHRI, No. 40 at p. 13)

Trane commented that replacement fans should be exempt if embedded fans fall under regulation. Trane encouraged DOE to align with the CEC regulation that provides an exemption for ''embedded fans as defined in ANSI/AMCA 214–21, including embedded fans sold exclusively for replacement of another embedded fan.'' Trane commented that fans embedded in equipment such as residential or commercial HVAC have downstream or upstream impacts on airflow distribution. Trane commented that many applications of this equipment have heating coils and/or natural gas heat exchangers that are developed, tested and certified for safety. Trane stated that when a fan is changed in the field at the application point, an exact model should be used for replacement to comply with safety requirements to ensure that no equipment failure results that may compromise the safety of the building occupants. Trane commented that, additionally, fan efficiency challenges the ability to replace ''like for like'' fans. Trane commented that more-efficient fans are often larger than less efficient ones and as such, this may increase associated product size. Trane noted that while a similar impeller-diameter fan may be available at a higher efficiency, it is imperative to consider that differing fan types have different non-impeller fan geometries and constraints, such that the overall fan footprint increases dramatically. Trane commented that with space constraints being a constant pressure, new products may be too large to replace smaller existing ones without significant design changes and associated costs that would serve to dissuade building owners from purchasing the more efficient fans contained in new products and instead repair existing, less efficient products. Trane commented that retrofit curbs can be used, but they generally come with associated pressure drop, which negates any efficiency improvement associated with the more efficient fan. (Trane, No. 38 at p. 3)

DOE includes all fans and blowers that meet the criteria for scope inclusion

as described in section III.B.1 of this document and are not listed for exclusion in section III.B.2 of this document or Table III–7 of this document, regardless of whether that fan is a replacement fan. At this time, DOE is not adopting energy conservation standards for fans and blowers, and the test procedure would not impact the availability of current models. The test procedure does not set any energy conservation standards and does not result in any non-compliant fans. DOE will consider the impacts from setting potential energy conservation standards on replacement fans (*e.g.,* costs, design, safety, and availability) as part of any potential energy conservation standards rulemaking.

7. Material Handling and Heavy Industrial Processing Fans and Blowers

In response to the July 2022 NOPR, Robinson commented that fans that provide mass transfer or are subjected to significant wear will not benefit from a switch to highly efficient aerodynamic designs. In fact, stated Robinson, shorter equipment life was highly likely and end use customers would bear the additional cost of replacement. For this reason, Robinson stated it does not support the inclusion of fans that provide mass transfer or are subjected to wear (whether abrasion or corrosion). (Robinson, No. 43 at p. 5)

At this time, DOE is not adopting energy conservation standards for fans and blowers, and the test procedure would not impact the availability of current models. The test procedure does not set any energy conservation standards and does not result in any non-compliant fans. In addition, as noted in the July 2022 NOPR, based on input from AMCA during the ASRAC negotiations, DOE has determined that radial housed unshrouded fans with a diameter less than 30 inches or a blade width of less than 3 inches are designed for materials-handling applications. These fans have specific design features (*e.g.,* built to resist the impact and erosive wear from large quantities of various materials passing through the fan housing) that generally limit the opportunity for improved efficiency. (Docket No. EERE–2013–BT–STD–0006, Public Meeting Transcript, No. 85 at p. 60). 87 FR 44194, 44202–44203. Furthermore, testing these fans based on the test method for clean air fans would not provide a measurement of energy use or energy efficiency that is representative of an average use cycle. For these reasons, as discussed in section III.B.2 of this document, DOE is excluding radial housed unshrouded fans with a diameter less than 30 inches or a blade width of less than 3 inches at this time.

Robinson further commented that the proposed rule would create an extreme challenge for the heavy industrial processing industry (*e.g.,* mining, refining, metal making, rock product processing, food production, chemical processing, and much more) in the United States. Robinson commented that specialty heavy industrial process fans are significantly different from fans used in commercial or light industrial applications as they operate in heavy industrial process facilities that are constrained by significant regulations as well as engineering requirements. Robinson stated that this means that the design of the whole process, which requires each part to play a specific application, is quite complicated and under multiple reviews. Robinson commented that the fans, as part of the process, are often designed to perform at several load points, as the design and then the actual operation of the plant may experience variability. Robinson also noted that the fans are placed throughout the heavy industrial process and, depending upon the role of each specific fan, will be forced to handle particulate, extreme temperatures, dramatic temperature changes, moisture, corrosive matter, and other items in the air stream. Robinson noted that the most efficient fan designs are only able to operate in clean air applications (*i.e.,* where they draw in outside air and blow it into a part of the heavy industrial process) and that the number of clean air fans in any heavy industrial process and the amount of energy they consume, relative to the rest of the process, is small. Instead, Robinson commented that fans handling air movement through the more challenging parts of the process are much more likely to consume more energy, but also deal with variables that limit the efficiency improvement of that fan. Robinson added that these fans are connected to the larger whole of the heavy industrial process in which they operate and are subject to the conditions as they change through the entire system. Further, if the end goal is to require fans to all comply with minimum levels of efficiency, Robinson commented that entire industrial processes will need to be retrofitted to allow all of the fans within the process to be clean air handling fans. Robinson commented that not only would this require the reconstruction of entire heavy industrial processing facilities, but also require that each fan be bigger or that there be more fans, which would draw greater energy and therefore be less efficient. Robinson added that it is necessary for many heavy industrial plant precipitators and baghouses (Air Pollution Control—APC devices) to operate in a positive pressure environment to prevent combustion of pollutants captured and collected in the cleaning device hoppers. In these applications, stated Robinson, it is necessary for the fans to be located upstream (or in the dirty air) of the APC device to minimize the risk of fires that would significantly damage the internals of the APC device. Robinson commented that the repair/replacement cost of these devices alone, if damaged by fire, is in the $5 to $10 million range for each, not including the plant lost production time. Robinson commented that the cost of adding additional particulate collection equipment upstream of the existing heavy industrial process fans and APC devices coupled with the added pressure drop of this equipment will offset any efficiency benefits since the existing fans will need to be replaced with larger horsepower fans. In short, Robinson summarized, it would not be surprising if this forced all heavy industrial processing out of the United States. (Robinson, No. 43 at pp. 2–3)

At this time, DOE is not adopting energy conservation standards for fans and blowers, and the test procedure would not impact the availability of current models. The test procedure does not set any energy conservation standards and does not result in any non-compliant fans or necessary redesigns. Any future energy conservation standard rulemaking would, as part of the analyses conducted to support the rulemaking, analyze the markets in which fans and blowers are used, conduct a technology assessment, and evaluate any potential impacts on technological feasibility, practicability to manufacture, install or service, equipment utility or equipment availability, health, and safety as a result of potential standards. In addition, although DOE is not specifically excluding material handling fans and heavy industrial processing fans, DOE notes that the test procedure is limited to fan design points with air power less than 150 hp. In addition, radial housed unshrouded fan with diameter less than 30 inches or a blade width of less than 3 inches, safety fans and fans that designed and marketed to operate at or above 482 degrees Fahrenheit (250 degrees Celsius) are excluded from the scope of the test procedure. As such, DOE notes that any fan that meets the scope criteria

described in section III.B.1 of this document, and is not listed for exemption as discussed in section III.B.2 and III.B.3 of this document would be in the scope of the test procedure.

C. Definitions

This section discusses DOE's adopted definitions for specific terms used in the test procedure for fans and blowers.

1. Fan and Blower Categories

The classification of fans and blowers recommended by the Working Group for coverage under a test procedure and the corresponding terms and definitions in AMCA 214–21 and the proposed CEC regulations [51] are presented in Table III–8 of this document.

TABLE III–8—SCOPE RECOMMENDED BY THE WORKING GROUP, CORRESPONDING TERMS AND DEFINITIONS

Working group scope recommendations	Corresponding term and definition in AMCA 214–21	Corresponding CEC definitions
Axial cylindrical housed fan.	''Axial inline fan'' means a fan with an axial impeller and a cylindrical housing with or without turning vanes.	''Axial-inline fan'' means a fan with an axial impeller and a cylindrical housing with or without turning vanes. Inlets and outlets can optionally be ducted.
Panel fan	''Axial panel fan'' means an axial fan, without cylindrical housing, that is mounted in a panel, an orifice plate or ring.	''Axial-panel fan'' means a fan with an axial impeller mounted in a short housing, non-cylindrical, that can be a panel, ring, or orifice plate. The housing is typically mounted to a wall separating two spaces, and the fans are used to increase the pressure across this wall. Inlets and outlets are not ducted.
Centrifugal housed fan, excluding inline fan and radial fan.	''Centrifugal housed fan'' means a fan with a centrifugal or mixed flow impeller in which airflow exits into a housing that is generally scroll-shaped to direct the air through a single fan outlet. A centrifugal housed fan does not include a radial impeller*.	''Centrifugal housed fan'' means a fan with a centrifugal or mixed flow impeller in which airflow exits into a housing that is generally scroll-shaped to direct the air through a single fan outlet. Inlets and outlets can optionally be ducted. It does not include a radial impeller.
Centrifugal unhoused fan, excluding radial fan.	''Centrifugal unhoused fan'' means a fan with a centrifugal or mixed flow impeller in which airflow enters through a panel and discharges into free space. Inlets and outlets are not ducted. This fan type also includes fans designed for use in fan arrays that have partition walls separating the fan from other fans in the array**.	''Centrifugal unhoused fan'' means a fan with a centrifugal or mix-flow impeller in which airflow enters through a panel and discharges into free space. Inlets and outlets are not ducted. This fan type also includes fans designed for use in fan arrays that have partition walls separating the fan from other fans in the array.
Inline and mixed-flow fan.	''Centrifugal inline fan'' means a fan with a centrifugal or mixed flow impeller in which airflow enters axially at the fan inlet and the housing redirects radial airflow from the impeller to exit the fan in an axial direction.	''Centrifugal inline fan'' means a fan with a centrifugal or mixed-flow impeller in which airflow enters axially at the fan inlet and the housing redirects radial airflow from the impeller to exit the fan in an axial direction. Inlets and outlets can optionally be ducted.
Radial housed fan	''Radial-housed fan'' means a fan with a radial impeller in which airflow exits into a housing that is generally scroll-shaped to direct the air through a single fan outlet. Inlets and outlets can optionally be ducted.	''Radial-housed fan'' means a fan with a radial impeller in which airflow exits into a housing that is generally scroll-shaped to direct the air through a single fan outlet. Inlets and outlets can optionally be ducted.
Power roof ventilator	''Power roof/wall ventilator (PRV)'' means a fan with an internal driver and a housing to prevent precipitation from entering the building. It has a base designed to fit over a roof or wall opening, usually by means of a roof curb.	''Power roof ventilator (PRV)'' or ''power wall ventilator (PWV)'' means a fan with an internal driver and a housing to prevent precipitation from entering the building. It has a base designed to fit over a roof or wall opening, usually by means of a roof curb.

* The inclusion of ''scroll-shaped'' in this definition excludes inline fans.
** Radial fans are housed and therefore not included in this definition.

In the July 2022 NOPR, DOE proposed to utilize the terminology and definitions specified in AMCA 214–21 to define the categories of fans and blowers proposed in the scope of applicability of the test procedure and tested using AMCA 210–16 as follows: (1) axial inline fan; (2) centrifugal housed fan; (3) centrifugal unhoused fan; (4) centrifugal inline fan; (5) radial-housed fan; and (6) PRVs. DOE proposed to modify the definition of ''axial panel fan'' as provided in AMCA 214–21 to distinguish these fans from air circulating axial panel fans, as follows: an axial panel fan is an axial fan, without cylindrical housing, that includes a panel, orifice plate, or ring with brackets for mounting through a wall, ceiling, or other structure that separates the fan's inlet from its outlet. 87 FR 44194, 44211–44212.

In the July 2022 NOPR, DOE noted that the CEC definitions are similar to the AMCA 214–21 definitions. DOE noted that the inclusion of additional language in the CEC definitions to indicate a fan's intended application or whether a fan's inlet or outlet is (optionally, as relevant) ducted was informative, but did not further distinguish the terms. In addition, for axial panel fans, DOE noted that the CEC definitions specified that the housing is typically mounted to a wall separating two spaces, and the fans are used to increase the pressure across this wall. DOE stated that the CEC description distinguishes axial panel fans from axial air circulating panel fans, which do not have provisions for connection to ducting or separation of the fan inlet from its outlet. However, DOE noted that the CEC distinction was based on how the fan was installed and not on a physical design feature of the fan. Therefore, DOE proposed to rely on physical features and to define axial panel fans instead. 87 FR 44194, 44211–44212.

[51] *See* Proposed regulatory language for Commercial and Industrial Fans and Blowers available in the following Docket: 22–AAER–01 at: *efiling.energy.ca.gov/Lists/DocketLog.aspx?docketnumber=22-AAER-01.*

In addition, to support the exclusions proposed in the July 2022 NOPR and clarify which fans would fall under the proposed exclusions, DOE proposed to adopt definitions of the terms ''induced flow fan'' and ''jet fan'' as established in AMCA 214–21 and ''cross-flow fan'' as defined in AMCA 208–18. *Id.* at 87 FR 44212.

In response to the July 2022 NOPR, New York Blower commented that the definitions in AMCA 214–21 are adequate. (New York Blower, No. 33 at p. 10) AMCA commented in support of the DOE-proposed definitions of axial inline fan, centrifugal housed fan, centrifugal unhoused fan, centrifugal inline fan, radial-housed fan, and power roof ventilator, which are consistent with definitions found in AMCA 214–21. However, AMCA noted that there would be additional alignment with the CEC's resultant definitions for the Title 20 fan regulation if DOE were to add, ''inlets and outlets can optionally be ducted'' to the definitions of axial inline fan, centrifugal housed fan, and centrifugal inline fan. In addition, AMCA commented in support of the DOE-proposed definitions of induced flow fan, jet fan, and cross-flow fan, as they are consistent with definitions found in AMCA 214–21 and AMCA 208–18. (AMCA, No. 41 at p.9)

As noted previously, DOE did not include the additional language for the CEC definitions as DOE notes that although it provides additional description of optional features of the equipment, or of the equipment installation configuration, the additional language does not describe the equipment's unique physical characteristics and therefore does not further distinguish the definitions. Therefore, DOE adopts the definitions of (1) axial inline fan; (2) centrifugal housed fan; (3) centrifugal unhoused fan; (4) centrifugal inline fan; (5) radial-housed fan; (6) PRVs; (7) induced flow fan; (7) jet fan; and (8) cross-flow fan as proposed.

AMCA noted that DOE may want to consider revising the definition of axial panel fan to state, ''without cylindrical or box housing,'' as in the definition of air circulating axial panel fan. (AMCA, No. 41 at p. 9)

DOE agrees with AMCA that adding ''or box housing'' would align the definitions of axial panel fan and air circulating axial panel fan. However, DOE notes that this is not specified in the AMCA 214–21 definitions and unlike for air circulating fans heads where AMCA 230–23 includes a separate definition of box fans and distinguishes these fans from air circulating axial panel fan, AMCA 214–21 does not distinguish box fans using a separate definition. DOE retains the proposed definition to continue to align with AMCA 214–21.

2. Safety Fans

In the July 2022 NOPR, DOE proposed a definition of safety fan to support the exclusion of safety fans from the scope of the test procedure, as discussed in section III.B.2 of this document. 87 FR 44194, 44213.

In the July 2022 NOPR, DOE reviewed the following definition of safety fan as proposed by the CEC: (1) a fan that is designed and marketed to operate only at or above 482 degrees Fahrenheit (250 degrees Celsius); (2) a reversible axial fan in cylindrical housing that is designed and marketed for use in ducted tunnel ventilation that will reverse operations under emergency ventilation conditions; (3) a fan bearing an Underwriter Laboratories (UL) or Electric Testing Laboratories listing for ''Power Ventilators for Smoke Control Systems''; (4) an open discharge exhaust fan with integral discharge nozzles which develop or maintain a minimum discharge velocity of 3,000 feet per minute (''fpm''); (5) a fan constructed in accordance with AMCA type A or B spark resistant construction as defined in ANSI/AMCA Standard 99–16 Standards Handbook; (6) a fan designed and marketed for use in explosive atmospheres and tested and marked according to EN 13463–1:2001 Non-electrical Equipment for Potentially Explosive Atmospheres; or (7) an electric-motor-driven Positive Pressure Ventilator as defined in ANSI/AMCA Standard 240–15 Laboratory Methods of Testing Positive Pressure Ventilators for Aerodynamic Performance Rating.[52] In the July 2022 NOPR, based on a review of the existing industry and regulatory definitions of ''safety fan,'' DOE tentatively determined that the definition proposed by the CEC (at the time) was representative of the equipment considered ''safety fans.'' 87 FR 44194, 44214.

In the July 2022 NOPR, DOE proposed to adopt a definition in line with the definition proposed by the CEC with the following edits. Regarding item (1) of the CEC definition: DOE proposed not to include the term ''only'' from ''a fan that is designed and marketed to operate only at or above 482 degrees Fahrenheit (250 degrees Celsius)'' because DOE tentatively determined that a fan that can operate at or above a certain temperature can also operate below. Regarding item (4) DOE tentatively determined that the definition of safety fans is equivalent to ''laboratory exhaust fans'' as defined in section 3.52 of AMCA 214–21: fans designed and marketed specifically for exhausting contaminated air vertically away from a building using a high-velocity discharge. DOE noted it was considering replacing item (4) with ''laboratory exhaust fans'' and to define it in accordance with AMCA 214–21. DOE also reviewed item (6) and noted that the referenced industry standard is no longer current and has been replaced. In 2008, the International Electrotechnical Commission System for Certification to Standards Relating to Equipment for Use in Explosive Atmospheres replaced EN 13463–1 by ISO 80079–36, ''Explosive atmospheres—Part 36: Non-electrical equipment for explosive atmospheres—Basic method and requirements.'' [53] The latest version of ISO 80079–36 is the 2016 edition. Therefore, DOE proposed to reference ISO 80079–36:2016, instead of EN 13463–1:2001. *Id.*

In response to the July 2022 NOPR, the CEC recommended that DOE incorporate the following definition of safety fan: safety fan means (1) a reversible axial fan in cylindrical housing that is designed and marketed for use in ducted tunnel ventilation that will reverse operations under an emergency ventilation condition; (2) a fan for use in explosive atmospheres tested and marked according to EN ISO Standards 80079–36:2016, Explosive atmospheres—Part 36: Non-electrical equipment for explosive atmospheres—Basic method and requirements; (3) a Positive Pressure Ventilator; or (4) a fan bearing a listing for ''Power Ventilators for Smoke Control Systems'' in compliance with ANSI/UL 705 Power Ventilators (dated August 23, 2021). Specifically, the CEC recommended removing fans that are designed and marketed to operate only at or above 482 degrees Fahrenheit (250 degrees Celsius) from the safety fan definition and instead listed together with the exclusions as proposed in Table III–8 of the July 2022 NOPR. The CEC commented that fans that are designed and marketed to operate only at or above 482 degrees Fahrenheit (250 degrees Celsius) can be designed for uses other than safety and are subject to different performance requirements, for example fans used for industrial processes that require operation at higher temperatures. The CEC also

[52] *See* CEC Docket No. 22–AAER–01, TN #241950, Proposed regulatory language for Commercial and Industrial Fans and Blowers, at pp. 7–8.

[53] *See www.intertek.com/blog/2019-03-14-hazloc/*.

recommended that laboratory exhaust fans not be included in the definition for safety fan, nor be included as a separate exclusion from the proposed scope of applicability of the test procedure. The CEC noted that although laboratory exhaust fans exhaust possible dangerous gasses, the fans are used for routine non-emergency lab procedures and are fully capable of achieving efficient operation without compromising the purpose for which they are installed. (CEC, No. 30 at pp. 2–3)

In response to the July 2022 NOPR, AMCA provided a comparison of the CEC safety fan definition as provided in the Title 20 express terms, noting elements that differed or were consistent with the proposed safety fan definition. AMCA commented that in Title 20 express terms,[54] the CEC removed the high-temperature section from the safety fan definition and inserted it in the list of fan-type exemptions instead. AMCA added that the rationale for this is that high-temperature fans are not always safety-related; they also are specified for commercial-kitchen exhaust and other demanding applications. (AMCA, No. 41 at p. 6, 12) AMCA recommended that DOE move item (1) of the DOE proposed safety fan definition to the list of explicit exemptions. Regarding item (4) of the DOE proposed definition, AMCA noted that it submitted comments to the CEC recommending that the CEC should seek to clean up some of the language because AMCA felt that the 3,000-fpm criterion could provide a loophole for fans that provide 3,000 fpm but are not used for safety purposes and was intended to describe a ''laboratory exhaust fan'' without naming it. AMCA commented that the 3,000-fpm discharge velocity with integral discharge nozzles appears to reference similar verbiage in ANSI/AIHA Z9.5, Laboratory Ventilation, and recommended exhaust velocities for safely exhausting contaminants without re-entrainment and added that laboratory exhaust fans would be considered safety fans regardless of exhaust velocity for the simple fact they service laboratories requiring numerous safety protocols for the protection of occupants and the surrounding area. For this reason, AMCA noted that in its comment to the CEC, AMCA commented that the CEC proposed regulatory language and supporting information indicated laboratory exhaust fans should be excluded and proposed using the term ''laboratory exhaust fan.'' AMCA recommended that the CEC add the ANSI/AMCA Standard 214–21 definition for safety fans: ''Laboratory exhaust fan means a fan designed and marketed specifically for exhausting contaminated air vertically away from a building using a high-velocity discharge.'' AMCA commented that rather than agree to AMCA's attempt to remove perceived loopholes from the proposed exemption, CEC removed the exemption altogether. AMCA commented that it would prefer to have this exemption remain in the DOE test procedure. In addition, AMCA recommended the removal of item (5) of the DOE proposed definition of safety fan. As AMCA commented to CEC, while AMCA recognizes the spark-resistant-construction types defined in ANSI/AMCA Standard 99–16, Standards Handbook, the definitions are not consistent with industry standards, and exempting spark resistant fans also is somewhat of a loophole in that a fan should be able to be designed to different types of spark-resistant construction with no impact on performance. For these reasons, AMCA recommended striking this item, and, if there were no other uses of AMCA 99, striking the citation of ANSI/AMCA Standard 99–16 in the referenced-documents portion of this NOPR. (AMCA, No. 41 at p. 12)

New York Blower stated support for the safety fan definition proposed by AMCA. (New York Blower, No. 33 at p. 10)

Robinson requested clarification regarding why AMCA Class C spark resistant construction was not included. (Robinson, No. 43 at p. 6)

Regarding fans designed and marketed to operate only at or above 482 degrees Fahrenheit (250 degrees Celsius), DOE's research confirms CEC's comment that some fans designed and marketed to operate only at or above 482 degrees Fahrenheit (250 degrees Celsius) can be designed for uses other than safety (*e.g.,* manufacturing). Therefore, in this final rule, DOE is removing this category from the definition of safety fans and listing these fans as a separate exclusion instead. In addition, DOE is adopting its proposal to remove the term ''only'' from ''a fan that is designed and marketed to operate only at or above 482 degrees Fahrenheit (250 degrees Celsius)'' because DOE has determined that a fan that can operate at or above a certain temperature can also operate below.

As discussed in the July 2022 NOPR, DOE tentatively determined that ''open discharge exhaust fans with integral discharge nozzles which develop or maintain a minimum discharge velocity of 3,000 FPM'' as listed in the CEC definition of safety fans are equivalent to ''laboratory exhaust fans'' as defined in section 3.52 of AMCA 214–21: fans designed and marketed specifically for exhausting contaminated air vertically away from a building using a high-velocity discharge. 87 FR 44194, 44214. Therefore, DOE is using the term ''laboratory exhaust fans'' and describes these fans in accordance with the AMCA 214–21 definition. In addition, DOE did not propose to include these fans in the scope of applicability of the test procedure and at this time. See 87 FR 44194, 44214. DOE is keeping these fans in the definition of safety fans, such that they are excluded from the scope of applicability. In addition, as noted in the NOPR, this would align with the recommended definition of safety fan provided in appendix D of the term sheet,[55] which includes fans designed for use in toxic, highly corrosive, or flammable environments [or in environments] with abrasive substances. 87 FR 44194, 44213 For these reasons, although DOE notes that such fans may be used for other in non-emergency situations, DOE is including laboratory exhaust fans as part of safety fans.

DOE reviewed the definition recommended by the CEC and notes that it no longer includes fans constructed in accordance with AMCA type A or B spark resistant construction as defined in the ANSI/AMCA Standard 99–16 Standards Handbook. In addition, as highlighted by CEC, DOE understands that such designations are no longer consistent with industry standards. DOE has determined that spark resistant fans used in explosive atmospheres are already included under fans tested and marked according to EN ISO Standards 80079–36:2016, Explosive atmospheres—Part 36: Non-electrical equipment for explosive atmospheres—Basic method and requirements. Therefore, DOE is removing this category from the definition of safety fans and is not incorporating AMCA 99–16 by reference.

In the July 2022 NOPR, DOE proposed to include fans bearing an Underwriter Laboratories (UL) or Electric Testing Laboratories listing for ''Power Ventilators for Smoke Control Systems'' in the definition of safety fans. 87 FR 44194, 44214. As previously noted, the CEC-recommended safety fan definition

[54] DOE notes that this refers to the CEC Express Terms for Commercial and Industrial Fans and Blowers document available at: *efiling.energy.ca.gov/GetDocument.aspx?tn=245898&DocumentContentId=80074*.

[55] The Working Group stated that the definition recommended in appendix D may be subject to potential edits necessary to accomplish the same intent.

further specifies referencing ANSI/UL 705 Power Ventilators (dated August 23, 2021). DOE has determined that this additional specification included in the CEC definition is necessary to identify fans included in this description. In addition, DOE notes that a more recent ANSI-approved version of ANSI/UL 705 Power Ventilators is available (dated August 19, 2022) and, therefore, DOE is adding this language into the safety fan definition and incorporating by reference the latest version of UL 705 available.

In summary, DOE defines safety fan as: (1) a reversible axial fan with cylindrical housing that is designed and marketed for use in ducted tunnel ventilation that will reverse operation under an emergency ventilation condition; (2) a fan for use in explosive atmospheres tested and marked according to EN ISO Standards 80079–36:2016, Explosive atmospheres—Part 36: Non-electrical equipment for explosive atmospheres—Basic method and requirements; (3) an electric-motor-driven Positive Pressure Ventilator as defined in ANSI/AMCA Standard 240–15, Laboratory Methods of Testing Positive Pressure Ventilators for Aerodynamic Performance Rating; (4) a fan bearing a listing for ''Power Ventilators for Smoke Control Systems'' in compliance with ANSI/UL 705 Power Ventilators (dated August 19, 2022); or (5) a laboratory exhaust fan designed and marketed specifically for exhausting contaminated air vertically away from a building using a high-velocity discharge.

3. Definitions Related To Heat Rejection Equipment

As stated in the July 2022 NOPR, DOE proposed to exclude from the scope of the test procedure fans and blowers embedded in heat rejection equipment, specifically fans and blowers embedded in packaged evaporative open circuit cooling towers; evaporative field-erected open circuit cooling towers; packaged evaporative closed-circuit cooling towers; evaporative field-erected closed-circuit cooling towers; packaged evaporative condensers; field-erected evaporative condensers; packaged air-cooled (dry) coolers; field-erected air-cooled (dry) coolers; air-cooled steam condensers; and hybrid (water saving) versions of such listed equipment that contain both evaporative and air-cooled heat exchange sections. In the July 2022 NOPR, DOE proposed to define each of these equipment types according to the recommendations of the Working Group. 87 FR 44194, 44217. DOE did not receive any comments on these definitions and adopts them as proposed.

4. Air Circulating Fans

In the July 2022 NOPR, DOE proposed definitions for air circulating fans and related terms using the definition being considered by the AMCA 230 committee at the time. DOE proposed to define air circulating fans as ''a fan that has no provision for connection to ducting or separation of the fan inlet from its outlet using a pressure boundary, operates against zero external static pressure loss, and is not a jet fan.'' 87 FR 44194, 44215. Further, DOE proposed to define an unhoused ACFH as follows: ''An air circulating fan without housing, having an axial impeller with a ratio of fan-blade span (in inches) to maximum rate of rotation (in revolutions per minute) less than or equal to 0.06. The impeller may or may not be guarded.'' DOE also proposed to define a housed ACFH as an air circulating fan with an axial or centrifugal impeller, and a housing. 87 FR 44194, 44216.

DOE further proposed definitions for the four categories of housed air circulating fans. DOE proposed to adopt the definitions of air circulating axial panel pan, box fan, cylindrical air circulating fan, and housed centrifugal air circulator as considered by the AMCA 230 committee, with the following clarifications: (1) replace ''air circulating fan'' considered by the AMCA 230 committee by ''housed air circulating fan head'' to explicitly indicate that each of these fans are housed ACFHs; (2) replace the term ''circulator'' as used by the AMCA 230 committee with ''circulating fan'' for consistency in terminology; and (3) remove the examples of additional terms used commonly by industry. *Id.*

In response to the July 2022 NOPR, AMCA commented that it submitted a comment on July 7, 2022, that included definitions of air circulating fans and related terms that were approved by the AMCA 230 committee, and that this submission was not included in the July 2022 NOPR. (AMCA, No. 41 at pp. 12–13) AMCA further commented that the AMCA 230 committee supported the proposal to use the categories defined in revisions under way for the AMCA 230 standard, namely housed ACFH, unhoused ACFH, and ceiling fans. (AMCA, No. 41 at p. 7)

Although AMCA submitted the comment prior to the publication date of the July 2022 NOPR, DOE notes that the comments were not received early enough to be incorporated at the time of drafting and were made on the pre-publication version of the NOPR, which is intended to provide stakeholders additional time to review and prepare comments (see discussion related to this comment in section III.A.).[56] However, DOE reviewed the definitions included in the additional comments provided by AMCA (AMCA, No. 13 at pp. 6–9) and these match the definitions considered by the AMCA 230 committee as discussed in the July 2022 NOPR. In addition, these definitions align with those published in AMCA 230–23. DOE therefore concludes that the proposed definitions align with the latest definitions published in AMCA 230–23 and adopts the definitions of air circulating fans and related terms as proposed.

5. Outlet Area

In the July 2022 NOPR, DOE noted that section 5.5.4 of AMCA 230–15 (with errata) defined the discharge area of an air circulating fan as the area of a circle having a diameter equal to the blade tip diameter. DOE noted that this definition was only applicable to unhoused ACFHs as the discharge area of a housed ACFH is determined based on the surface area at the exit of the housing and is not based on the fan blade tip diameter. DOE proposed a definition for fan outlet area specific to air circulating fans as (*i.e.,* ''air circulating fan outlet area''): (1) for unhoused ACFHs, the area of a circle having a diameter equal to the blade tip diameter; (2) for housed ACFHs, the inside area perpendicular to the airstream, measured at the plane of the opening through which the air exits the fan. In the July 2022 NOPR, DOE further noted that the AMCA 230 committee is considering revising the definition of discharge area to include housed ACFHs, and to replace the term ''discharge area'' by ''fan outlet area,'' which is a more commonly used term. 87 FR 44194, 44217.

Generally, DOE further specified that for all definitions related to air circulating fans, DOE was aware that the revisions being considered by the AMCA 230 committee are subject to change and could further be revised in the next version of AMCA 230. DOE added that should the revised version of AMCA 230 publish prior to the publication of any DOE test procedure final rule, DOE intended, after considering stakeholder feedback received in response to the proposals in the July 2022 NOPR, to revise the definitions in line with the latest AMCA 230 standard, provided the updates in

[56] The comment was submitted on July 6, 2022. See *www.regulations.gov/comment/EERE-2021-BT-TP-0021-0013* and the October 2021 RFI comment period ended on November 15, 2022, as discussed in section I.B of this document.

this standard are consistent with the definitions DOE proposed in the July 2022 NOPR or the updates are related to topics that DOE has discussed and for which DOE has solicited comments in the July 2022 NOPR. *Id.*

AMCA commented that it agreed with DOE's use of outlet area for air circulating fans where the outlet area is smaller than the discharge area, as this solves one potential issue with the discharge-area definition in AMCA 230–15. However, AMCA stated that DOE's proposed use of air circulating-fan outlet area creates an issue with historical test data. AMCA commented that the Bioenvironmental and Structural System (BESS) Laboratory's historical performance data for air circulating-panel, box, and tube fans is based on area determined using impeller diameter (not the cross-sectional outlet area of the housing). As the BESS Lab data is the largest set of publicly available, third-party air circulating-fan performance data, it is likely DOE based much of its analysis on this historical performance data. For all potential future users of the data, the AMCA 230 technical committee proposes the following definitions, which will be included in the upcoming edition of AMCA 230: (1) discharge area: area of a circle having a diameter equal to the blade tip diameter; and (2) fan outlet area: the gross inside area measured at the plane of the outlet opening. In addition, AMCA commented that the revised AMCA 230 would specify that the airflow rate and efficiency calculations for unhoused air circulating fan heads must use the discharge area, while airflow rate and efficiency calculations for housed air circulating fan heads must use the lesser of the values for fan outlet area and discharge area. (AMCA, No. 41 at pp. 13–14)

DOE reviewed the definitions of discharge area and fan outlet area provided by AMCA and concluded that the AMCA definition of discharge area aligns with the proposed definition of outlet area for unhoused air circulating fans and that the definition of fan outlet area aligns with the proposed definition of outlet area for housed air circulating fans. To align with industry terminology, DOE distinguishes between fan discharge area and fan outlet area as characterized by AMCA. DOE notes that the distinction is not based on the presence or absence of housing, but rather in the physical area considered. In addition, to further distinguish between housed and unhoused air circulating fans, DOE is adopting the additional instructions in section 8.4 of AMCA 230–23 to specify that the airflow rate and efficiency calculations for unhoused air circulating fan heads must use the discharge area while airflow rate and efficiency calculations for housed air circulating fan heads must use the lesser of the values for fan outlet area and discharge area. DOE has determined that including this distinction as part of the test instructions, rather than in the definitions ensures alignment with industry terminology and reflects current testing practices.

For fans and blowers other than air circulating fans, in the July 2022 NOPR, DOE noted that Annex H of AMCA 210–16 includes requirements for determining where the fan outlet area is measured for different fan categories and references AMCA 99–16, which includes further diagrams to aid in the determination of the outlet area. DOE tentatively determined that for fans and blowers other than air circulating fans, the current definition in AMCA 214–21 and the existing requirements in Annex H of AMCA 210–16 were sufficient to determine the outlet area and did not propose any edits. 87 FR 44194, 44217.

Robinson commented that the definition of outlet area provided by AMCA 99–16 is the industry standard and that the only time this is potentially questioned was when there is more than one outlet plane. Otherwise, Robinson commented that it did not see an issue with the definition of fan outlet and fan outlet area. (Robinson, No. 43 at p. 7) In this final rule, DOE makes no changes to how the fan outlet area is determined for fans and blowers other than air circulating fans, based on Annex H of AMCA 210–16, which references AMCA 99–16. Robinson noted a potential improvement of the definition may be needed in the case when there is more than one outlet plane. However, Robinson did not provide additional details and at this time, DOE is not changing how the fan outlet area is determined for fans and blowers other than air circulating fans.

6. Air Curtains

In the July 2022 NOPR, DOE proposed to exclude fans and blowers embedded in air curtains and noted that the CEC defined an air curtain unit as equipment providing a directionally controlled stream of air moving across the entire height and width of an opening that reduces the infiltration or transfer of air from one side of the opening to the other and/or inhibits the passage of insects, dust, or debris. However, DOE did not propose a definition for this equipment. 87 FR 44194, 44207–44208 at fn. 25.

The CEC recommends defining ''air curtain unit'' as follows: Air curtain unit means equipment that produces a directionally controlled stream of air with a minimum width-to-depth aspect ratio of 5:1 and a discharge that is not intended to be connected to unitary ductwork. The controlled stream of air is designed to span the height and width of an opening and reduce the infiltration or transfer of air from one side of the opening to the other and/or inhibit the passage of insects, dust, or debris. (CEC, No. 30 at p. 2)

DOE did not propose a definition for air curtain. As noted in the July 2022 NOPR, air curtains are used in entrances to buildings or openings between two spaces conditioned at different temperatures. Air curtains include fans packaged with a motor, filter, outlet section (a nozzle, discharge grille, etc.), and in some cases a mounting plate, and/or an electric heater or water heater. 87 FR 44194, 44207. DOE did not find any ambiguity in identifying this equipment and as such, is not adopting a definition of air curtain at this time.

7. Basic Model

The basic model concept allows manufacturers to group like models for the purpose of making representations of energy efficiency and/or energy use, including for the purpose of demonstrating compliance with DOE's energy conservation standards to the extent DOE has established such standards. The concept of basic model may allow manufacturers to reduce the amount of testing they must do to rate the energy use or efficiency of their products. DOE's current regulations provide equipment-specific basic model definitions, which typically state that models within the same basic model group have ''essentially identical'' energy or water use characteristics; as well as a general definition that provides (with some exceptions noted in the regulatory text) that a basic model means ''all units of a given type of product (or class thereof) manufactured by one manufacturer, having the same primary energy source, and which have essentially identical electrical, physical, and functional characteristics that affect energy consumption, energy efficiency, water consumption, or water efficiency.'' *See for example* 10 CFR 430.2; 431.62, 431.152, 431.192, 431.202, 431.222, and 431.292.

In the July 2022 NOPR, DOE proposed a definition of a basic model specific to fans as follows: ''all units of fans and blowers manufactured by one manufacturer, having the same primary energy source, and having essentially identical electrical, physical, and

functional (*e.g.,* aerodynamic) characteristics that affect energy consumption. In addition: (1) all variations of blade pitches of an adjustable-pitch axial fan may be considered a single basic model; and (2) all variations of impeller widths and impeller diameters of a given full-width impeller and full-diameter impeller centrifugal fan may be considered a single basic model.'' DOE further proposed to define ''full-width impeller'' and ''full-diameter impeller'' as ''the maximum impeller width and the maximum impeller diameter with which a given fan basic model is distributed in commerce.'' 87 FR 44194, 44213.

In general, Morrison commented that the definition of a basic model is acceptable but noted the considerable number of basic models—in the thousands in many categories. (Morrison, No. 42 at p. 4) In general, AMCA stated acceptance of the definition of a basic model, but noted there will be a very large number of basic models being registered in the CCMS. AMCA provided an example of one axial-fan product line, for which 60 basic models resulted from the variety of blade spans, hub diameters, blade counts, and blade pitches. (AMCA, No. 41 at pp. 9–10)

NEEA commented that in the definition of a basic model, DOE assumes that a fan experiences similar impeller trimming to a pump. NEEA commented that in practice, however, fans are rarely if ever trimmed from the full-impeller diameter so identifying this feature is not necessary. NEEA noted that by contrast, features like hub diameter are specific to fans, but do not exist in pumps and DOE should consider them in defining a basic model for fans. (NEEA, No. 36 at p. 6)

Fan and blower manufacturers may offer for sale the same bare shaft fan assembled, packaged, or integrated with different motor, transmission, and control combinations. Based on DOE's proposed basic model definition, the same bare shaft fan, sold with different combinations of motor, transmission, and controls (or as a bare shaft fan) could be grouped under the same basic model. In addition, fan manufacturers would be able to elect to group similar individual fan models within the same basic model under the same ratings to reduce testing burden, provided that all representations regarding the energy use of fans within that basic model are identical and based on the most consumptive unit. *See* 76 FR 12422, 12428–12429 (March 7, 2011).[57] Manufacturers would have the option to certify separate ratings for each combination of bare shaft fan, motor, transmission, and/or control in order to make separate representations of the performance of each specific combination. In view of the substantial number of fans that could be subject to an individual certification requirement for each basic model, DOE notes that the proposed definition of basic model would allow variations of blade pitches of an adjustable-pitch axial fan to be considered a single basic model.

Additionally, DOE proposed that all variations of a given full-size impeller width and full-size impeller diameter may be considered to be part of a single basic model represented by the fan with the full-size impeller width and full-size diameter. 87 FR 44194, 44213. In the July 2022 NOPR, DOE did not propose to group fans with varying hub diameters and is not opting to add this in the definition of basic model at this time and adopts the definition of basic model as proposed in the July 2022 NOPR. See *id.* Further, DOE notes that in comments submitted to the CEC docket, several stakeholders [58] have expressed interest in grouping fans of variations of the same impeller into the same basic model and continues to believe that identifying the variations of impeller in the basic model definition is useful.

The CA IOUs requested that DOE adjust its definition of ''basic model'' to refer to the nominal diameter and width of impellers in place of ''full-width'' and ''full-diameter'' impeller since custom impellers may be adjusted to be larger or smaller than the nominal size. The CA IOUs explained that unlike pumps, fabricated fan impellers have adjustable widths and diameters that can increase or decrease and manufacturers typically make these adjustments to attain precise airflow and pressure at synchronous speed of an induction motor. (CA IOUs, No. 37 at pp. 9–10)

As previously stated, DOE proposed to define ''full-width impeller'' and ''full-diameter impeller'' as ''the maximum impeller width and the maximum impeller diameter with which a given fan basic model is distributed in commerce.'' As such, the impeller would only be adjusted to a smaller size as the larger size would then meet the definition of the full-impeller. Therefore, DOE is not adopting the term ''nominal.''

New York Blower commented that the proposed definition of a basic model for fans, which distinguishes on the basis of energy consumption, contributes to the volume of testing required. Specifically, New York Blower commented that not being able to group a fan series of different sizes and geometric similarity (*i.e.,* ''fan product line'') results in at least each size having to be considered a basic model. New York Blower added that ideally a single size fan or a subset of all the sizes offered to the market could be used to certify an entire fan series. New York Blower commented that this would result in a significant reduction in clerical and administrative activity to report ratings to the DOE to support offering products in the market. New York Blower added that such an approach was used in the Californian Commercial Fans and Blower rulemaking where the ratings of sizes within a product were distinguished as either a tested model or a calculated model. (New York Blower, No. 33 at pp. 5, 10)

New York Blower added that recertifying fans annually that are unlikely to change for years creates an overhead burden to keeping the product on the market, even if a sparse quantity of units are sold into the market. Specifically, New York Blower noted that the fan market, and in particular the industrial fan market, is a build-on-demand market. While there may be some designs that sell a large quantity of units, New York Blower commented that it is more likely that many distinct and different units across the broad spectrum of products and sizes available will be sold and manufactured to the wide variety of customer demands. New York Blower stated that placing an administrative burden and consequent cost on a multitude of products that are rarely sold but needed, valued, and installed efficiently in systems when they are required, created no value to the consumer and provided no energy savings considering the units are infrequently sold. Therefore, New York Blower commented that it would be administratively expedient to be able to reference certification of geometrically similar products to a reference, tested

[57] These provisions would allow manufacturers to group individual models with essentially identical, but not exactly the same, energy performance characteristics into a basic model to reduce testing burden. Under DOE's certification requirements, all the individual models within a basic model identified in a certification report as being the same basic model must have the same certified efficiency rating and use the same test data underlying the certified rating. The March 7, 2011, Final Rule also established that the efficiency rating of a basic model must be based on the least efficient or most energy consuming individual model *(i.e.,* all individual models within a basic model must be at least as energy efficient as the certified rating). 76 FR 12422, 12428–12429.

[58] AMCA and Joint Advocates (ASAP, NEEA, NRDC, ACEEE, and CA IOUs), Comments to the CEC Draft Staff Report, *efiling.energy.ca.gov/GetDocument.aspx?tn=224829* (p.9).)).

fan—similar to the CRP–8 [Certified Rating Program] form and process incorporated in the AMCA CRP program.[59] New York Blower added that an example would be for all sizes of a product line larger than 40 inches in diameter to reference, and be certified by, the 40-inch test results without an AEDM or administrative burden. (New York Blower, No. 33 at p. 10)

Robinson commented that the definition of basic model needs further explanation from the perspective of an industrial process custom fan manufacturer, and that the idea of a basic model makes sense for manufacturers of a standard product line. Robinson commented that it manufactures a number of fan designs that are modified to suit the needs of a customer's specific requirements. In other words, Robinson stated, a given design could operate anywhere between 1 and 150 hp and well beyond with varying efficiency (FEI). Robinson commented that the example provided on page 73 of the NOPR states, ''if a manufacturer offers the same fan model in the following full-impeller sizes: 60, 70, 80 and 90 inches, each full-impeller size would constitute a separate basic model. However, a fan with an impeller trimmed to 69 inches could be grouped with the same 70-inch untrimmed fan.'' Robinson commented that without an AEDM, this sounded like a custom fan manufacturer would have to more or less test everything that falls within the limitations as Robinson does not have catalog equipment. (Robinson, No. 43 at p. 6)

DOE notes that different-size fans would not operate at the same duty points and do not have essentially identical electrical, physical, and functional characteristics that affect energy consumption and energy efficiency. Therefore, an approach as described by New York Blower, where a manufacturer would only certify a subset of sizes within a product line, is not feasible. DOE notes that however, a manufacturer could test a subset of sizes within a product line and apply the fan laws as allowed in Annex E of AMCA 214–21 in order to calculate the performance data of all fans in the same product line without the application of an AEDM, thereby reducing manufacturer burden. With regard to custom fans for which a single made-to-order fan is manufactured, general sampling requirements for all covered equipment at 10 CFR 429.11(b), and § 429.11(b)(2) provides provisions for sampling when only one unit of a basic model is produced.[60] In accordance with these provisions, a single made-to-order product must be tested to ensure it complies with the standard. To reduce testing burden, DOE is adopting AEDM provisions that would allow certification of a made-to-order product in lieu of testing. (See section III.I of this document.) Certification would be based on the test results of the one unit, or AEDM ratings for the model. In addition, DOE notes that this test procedure would not result in any certification requirements.

D. Industry Standards

DOE's established practice is to adopt industry standards as DOE test procedures, unless such methodology would be unduly burdensome to conduct or would not produce test results that reflect the energy efficiency, energy use, water use (as specified in EPCA), or estimated operating costs of that product during a representative average use cycle. 10 CFR 431.4; 10 CFR part 430, subpart C, appendix A, section 8(c).

The Working Group recommended that the test procedure for fans and blowers other than air circulating fans:

(1) For standalone (non-embedded) fans, be based on a physical test performed in accordance with the latest version of AMCA 210 (*i.e.,* available at the time of publication of any test procedure final rule) [61] (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #7 at p. 5);

(2) Establish methods to determine the ''FEP'' either by: the direct measurement of the electrical input power to the fan, or by the measurement of the mechanical input power to the fan (*i.e.,* a fan shaft power test, which captures the performance of the bare shaft fan) [62] and by applying default values (*i.e.,* calculation algorithms) to reflect the additional motor, transmission, or motor controller energy use (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #9 at pp. 5–6); and

(3) Allow the use of equations (''fan laws'') to determine the performance of a bare shaft fan at a non-tested speed, based on the results of a test conducted at a different speed (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #17 at p. 10).

The Working Group also recommended specific test set-up and minimal testable configurations to use for each fan category.[63] (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #7 at p. 5)

The Working Group further made recommendations on calculation algorithms and reference values to use to represent the motor, transmission, and motor controller energy efficiency when testing a fan based on a fan shaft power test. (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendations #10 through #15 at pp. 6–9) Additionally, the Working Group recommended that embedded fans be tested in a standalone fan configuration (*i.e.,* outside of the piece of equipment in which they are embedded). Because some components of embedded fans may not be removable without causing irreversible damage to the equipment, the Working Group recommended non-impeller components of the fan that are geometrically similar to the ones used by the fan as embedded in the larger piece of equipment be used to complete the fan testable configuration. (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #8 at pp. 5–6) The Working Group also recommended calculating FEP as the ratio of the electrical input power of a reference fan (in this case, a fan that is exactly compliant with any future fan energy conservation standards) to the electrical input power of the actual fan for which the FEP is calculated, both established at the same duty point.[64] In addition, the Working Group recommended using either static or total pressure [65] to characterize the duty point of a fan and to calculate the associated reference FEP, depending on the fan category and the test set-up used.[66] (Docket No.

[59] DOE notes that this form is available at *www.amca.org/assets/crpdocument/CRP_8.pdf.*

[60] Section 429.11(b)(2) specifies that if only one unit of the basic model is produced, that unit must be tested and the test results must demonstrate that the basic model performs at or better than the applicable standard(s). If one or more units of the basic model are manufactured subsequently, compliance with the default sampling and representations provisions is required.

[61] Currently the latest version of AMCA 210 is AMCA 210–16.

[62] A bare-shaft fan is a fan without a motor or any other drive.

[63] AMCA 214–21 references AMCA 210–2016 as the physical test method to use for fans and blowers (except ACFHs). AMCA 210–16 describes four fan test set-ups (or ''installation categories'') designated by a letter, depending on the ducting at the inlet and outlet of the fan. ''A'': free inlet, free outlet; ''B'': free inlet, ducted outlet; ''C'': ducted inlet, free outlet; and ''D'': ducted inlet, ducted outlet.

[64] A duty point is characterized by a given airflow and pressure and has a corresponding operating speed.

[65] Fan total pressure is the air pressure that exists by virtue of the state of the air and the rate of motion of the air. It is the sum of velocity pressure and static pressure at a point. If air is at rest, its total pressure will equal the static pressure.

[66] Depending on the fan category, the fan performance is represented using a test set-up with a ducted outlet (*i.e.,* using total pressure) or a free outlet (*i.e.,* using static pressure) to reflect typical usage conditions. Fans with ducts attached to the fan's outlet are typically selected based on their performance at a given airflow and total pressure,

EERE–2013–BT–STD–0006, No. 179, Recommendations #18 and #19 at pp. 10–11) Finally, the Working Group recommended equations and default values to use when calculating the reference FEP of a fan at a given duty point. (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendations #18 through #21 at pp. 10–12)

Since the publication of the term sheet, AMCA has revised and developed test standards consistent with the recommendations of the Working Group:

• In September 2016, AMCA published AMCA 210–16, which updated ANSI/AMCA 210–2007, ''Laboratory Methods of Testing Fans for Certified Aerodynamic Performance Rating,'' to include a wire-to-air test method, which captures the performance of any motor, transmission, or motor controller present in the fan, in addition to the performance of the bare shaft fan (*i.e.,* a measurement of the FEP in kW), in addition to the previously existing methods for conducting laboratory tests to determine fan shaft power in hp, airflow in cubic feet per minute (''CFM''), pressure in in. wg, and at a given speed of rotation in ''RPM.''

• In April 2017, AMCA published ANSI/AMCA Standard 207–2017, ''Fan System Efficiency and Fan System Input Power.'' This publication provides calculation algorithms representing the performance of reference motors, transmissions, and motor controllers. These calculations can be directly applied to the results of a fan shaft power test in accordance with AMCA 210–16 to obtain the FEP of a fan at a given duty point.

• In January 2018, AMCA published ''AMCA 208–18.'' This publication defines FEI as the ratio of the electrical input power of a reference fan to the electrical input power of the actual fan for which FEI is calculated, both established at the same duty point. It provides equations to calculate the FEP of a fan as a function of airflow and pressure (either static or total depending on the fan category considered).

Building on these test standards, AMCA developed a new AMCA 214–21 test method, which was approved by ANSI on March 1, 2021. AMCA 214–21 combines provisions of AMCA 210–16, AMCA 207–17, and AMCA 208–18, as well as portions of AMCA 211–13 (R2018), ''Certified Ratings Program Product Rating Manual for Fan Air Performance'' (''AMCA 211–13'') into a single standard.[67] Consistent with the recommendations of the Working Group, AMCA 214–21 provides methods to establish the FEP either by: (1) the measurement of the electrical input power to the fan (*i.e.,* a ''wire-to-air'' test); or by (2) the measurement of the fan shaft power and the application of calculation algorithms to reflect additional motor, transmission, or control energy use. In each case, the fan power measurements are performed in accordance with AMCA 210–16 or ISO 5801:2017, which is referenced in AMCA 214–21 as an equivalent test procedure to AMCA 210–16. AMCA 214–21 also references laboratory test methods for additional categories of fans such as jet fans, circulating fans, and induced flow fans.[68] Specifically, AMCA 214–21 references AMCA 230–15[69] as the industry test procedure to follow when conducting performance measurements on air circulating fans. In addition, AMCA 214–21 adds specific test instructions to ensure test repeatability and reproducibility. Specifically, AMCA 214–21 defines a single set of test set-ups that must be used when conducting a test to ensure comparability of results (See Table III–9). Further, AMCA 214–21 specifies how to select the speed(s) and duty points at which to conduct the test, as well as which accessories to include in the test (See Table III–10).

TABLE III–9—AMCA 214–21 TEST CONFIGURATIONS

[Table 7.1 of AMCA 214–21]

Fan configuration	Test standard	Required		Optional	
		Test configuration *	FEI pressure basis **	Test configuration	FEI pressure basis
Centrifugal housed	AMCA 210–16	B or D	Total	A or C	Static.
Radial housed	AMCA 210–16	B or D	Total	A or C	Static.
Centrifugal inline	AMCA 210–16	B or D	Total	A or C	Static.
Centrifugal unhoused	AMCA 210–16	A	Static	N/A	N/A.
Centrifugal PRV exhaust	AMCA 210–16	A or C	Static	N/A	N/A.
Centrifugal PRV supply	AMCA 210–16	B	Total	A	Static.
Axial inline	AMCA 210–16	D	Total	C	Static.
Axial panel	AMCA 210–16	A	Static	N/A	N/A.
Axial PRV	AMCA 210–16	A or C	Static	N/A	N/A.
Circulating Fans	AMCA 230–15	E	Total	N/A	N/A.

* Each letter corresponds to a test set-up described in Section 7.1 of AMCA 214–21. A: free inlet, free outlet; B: free inlet, ducted outlet; C: ducted inlet, free outlet; D: ducted inlet, ducted outlet.

** This indicates that reference FEP used in the FEI calculation is established using either static or total pressure as indicated in this table and as determined by the required test configuration.

because both the static pressure and fan velocity pressure are available to overcome system resistance. However, fans with a free outlet are typically selected based on their performance at a given airflow and static pressure, because the velocity pressure cannot be used to overcome system resistance. The Working Group recommended using total pressure for some categories of fans (*i.e.,* axial cylindrical housed fans, centrifugal housed fans, inline and mixed flow fans, and radial housed fans) and static pressure for others (*i.e.,* panel fans, centrifugal unhoused fans, and PRVs).

[67] AMCA 211–13 provides instructions on how to apply fan laws and on how to perform a test when establishing an AMCA-certified rating. Some of these instructions were revised and integrated in AMCA 214.

[68] AMCA 230–15, AMCA 250–12, ''Laboratory Methods of Testing Jet Tunnel Fans for Performance,'' and AMCA 260–20, ''Laboratory Methods of Testing Induced Flow Fans for Rating,'' for testing circulating fans, jet fans, and laboratory exhaust fans with induced flow.

[69] AMCA 230–15 provides methods for conducting laboratory tests to determine the performance characteristics of circulating fans including the FEP in W, speed in RPM, pressure in inches of mercury, airflow in CFM, thrust in pound force (lbf), efficacy in CFM/W, and overall efficiency in lbf/W.

TABLE III–10—AMCA 214–21 TEST OPTIONS

Test description (section 6 of AMCA 214–21)	Driver configuration	Motor controller configuration	Transmission configuration	Test speed(s)	FEP determination method
Wire to air test at all speeds	Motor	With or without a motor controller.	With or without transmission	All speeds**	Section 6.1 of AMCA 214–21.
Wire to air test at selected speeds.	Motor	With or without a motor controller.	With or without transmission	At least two speeds.	Section 6.2 of AMCA 214–21.
Fan shaft power test for fans without a motor*.	None	With or without a motor controller.	Without transmission	At least one speed.	Section 6.3 of AMCA 214–21.
Fan shaft power test for fans with a regulated motor*.	Electric motors subject to standards at 10 CFR 431.25.	With a variable frequency drive in accordance with section 6.4.1.4 of AMCA 214–21 or without a motor controller.	Direct drive, V-belt drive, flexible coupling, or synchronous belt drive.	At least one speed.	Section 6.4 of AMCA 214–21.
Fan shaft power test and motor/motor and controls test*.	Motor	With or without a motor controller.	Direct drive, V-belt drive, flexible coupling, or synchronous belt drive.	At least one speed.	Section 6.5 of AMCA 214–21.

* With or without the use of interpolation or fan laws as provided in Annex E.
** All speeds for which FEP values are generated.

In the July 2022 NOPR, DOE proposed to incorporate by reference AMCA 214–21 as the prescribed test method for evaluating the energy use of fans and blowers, with modifications discussed in section III.E of this document. DOE also proposed to incorporate by reference AMCA 210–16, ISO 5801:2017, and AMCA 230–15 (with errata) (or latest version available at the time of the any final rule),[70] which are the physical test methods referenced in AMCA 214–21 for fans and blowers and air circulating fans. 87 FR 44194, 44121.

In response to the July 2022 NOPR, AMCA commented that AMCA 214–21 itemizes which method of physical testing applies adequately to which fan category and that these physical measurements are perfectly suitable for deriving each of the energy performance ratings considered by this rulemaking. AMCA commented that each of those methods provides for the relevant fan types their fan air performance and input power. AMCA added that AMCA 210 and ISO 5801 were the only appropriate test methods for fans that generate fan static pressure when applied as intended. AMCA added that AMCA 230 is the single appropriate test method for measuring the performance of air circulating fans that operate at zero fan static pressure with at least 125 W electrical input power and noted that air circulating fans below 125 W electrical power are in the scope of IEC 60879, ''Comfort fans and regulators for household and similar purposes.'' AMCA noted that too few AMCA members supply low-power air circulating fans and that AMCA was unable to provide more detailed comments. AMCA added that these industry standards measure input power (W) and that prediction of energy consumption (kWh) requires knowledge of operating hours and load, which are too diverse to develop an average use cycle representing the fan industry at large. AMCA noted that the energy-conservation metric that is being defined by DOE references FEI as defined in AMCA 214–21, and because FEI is calculated for a given duty point, energy consumption is inversely proportional to FEI during any use cycle. (AMCA, No. 41 at pp. 14–15)

AMCA further commented that AMCA 210 and AMCA 230 establish uniform test methods to ensure test procedure repeatability. AMCA added that requirements within the standards, such as maintaining instrument accuracy and calibration, contribute to attaining repeatability. Additionally, to help achieve reproducibility between accredited laboratories, AMCA's laboratory accreditation program requires that AMCA audit instrument calibration, compare air-performance test results from AMCA's laboratory against results obtained in the laboratory under review, and conduct independent readings of certain parameters during the test for verification of instrumentation accuracy. AMCA commented that AMCA 214 specifies calculations based on data from various relevant laboratory methods of test and that AMCA does not recommend any changes to these standards in regard to repeatability and reproducibility. In addition, AMCA noted that: (1) AMCA 210 and ISO 5801 are mature test methods that have been used globally for many years; and (2) thrust-testing per AMCA 230 is straightforward. In addition, AMCA already notes that thrust-testing also is used in the DOE test method for large diameter ceiling fans (LDCFs); and (3) as part of the AMCA Lab accreditation program, the same fan is tested at AMCA accredited labs and retested at the AMCA Lab with strict tolerance limits, similar to what is done in a round robin and AMC added it could provide test data from multiple labs for the same fan. (AMCA, No. 41 at pp. 15–16)

AMCA also noted that AMCA 210–16 will be heading into its ANSI-required review/update cycle later in 2022. AMCA expected this to be a revision cycle, not an affirmation, as affirmations only comprise editorial corrections. AMCA commented that this revision would take some time and recommended that DOE not consider the upcoming revision update to AMCA 210. AMCA commented that since the last revision, public comments have accumulated via AMCA's website; however, AMCA does not recommend any changes with regard to AMCA 214–21 and AMCA 210–16. (AMCA, No. 41 at p. 16)

AMCA also commented that AMCA 230 is nearing the completion of its ANSI-required review/update cycle. AMCA commented that it expects this revision to be completed in the near future. AMCA recommended that DOE reference the updated version of AMCA 230 and advised DOE that AMCA 230's revision is nearing completion with the draft out for committee ballot. AMCA stated it expected AMCA 230 to be published as an ANSI/AMCA standard in late 2022 or early 2023. (AMCA, No. 41 at pp. 16–17)

ebm-papst commented that AMCA 210, ISO 5801, and AMCA 230 (as applicable) provided representative measurements of fan power consumption, which were suitable for determining fan efficiency. ebm-papst recommended adopting AMCA 210–16, AMCA 214–21, and AMCA 230–15

[70] In the July 2022 NOPR, DOE noted that it was aware that AMCA 230–15 is currently undergoing periodic review and may be revised in the future. Should a new version become available at the time of any final rule, DOE would incorporate by reference the latest available version of AMCA 230.

without any changes. (ebm-papst, No. 31 at pp. 7–8)

New York Blower commented that AMCA 214–21 and the corresponding FEI metric reasonably estimated energy efficiency and functioned as a viable measure of changes in energy consumption reflected by differences in the FEI values. New York Blower commented that the representative average use issue had been a troubling one to settle due to the wide variety of applications of fans and an industrial application can easily be considered to be continuous operation at the specified operating conditions for 3,000 hours annually (New York Blower, No. 33 at p. 11)

Trane commented that DOE should reference and adopt AMCA 214–21 as its principal test procedure for commercial fans and blowers. (Trane, No. 38 at p. 2)

Greenheck commented that DOE should adopt the test procedures and standards in AMCA 210,[71] 211, and 214 in lieu of the proposed test procedures detailed in the July 2022 NOPR. Greenheck commented that the proposal by DOE differed from the above AMCA standards in ways that would create an extreme burden on the entire fan industry and result in little benefit to the consumer or a reduction in energy consumption. (Greenheck, No. 39 at pp. 1–2)

Morrison commented that the AMCA 210 and AMCA 214 test procedures captured the performance and energy consumption of fans in a clear manner for the relevant fans other than air circulating fans. (Morrison, No. 42 at p. 4) Morrison commented that AMCA 210 established uniform test methods to ensure test-procedure repeatability and that requirements within the standard, such as maintaining instrument accuracy and calibration, contributed to attaining repeatability. Morrison commented that it does not recommend any changes to these standards in regard to repeatability and reproducibility as AMCA 210 was a mature test method that had been used globally for many years. (*Id.* at p. 5)

As noted by stakeholders, AMCA 210–16, AMCA 214–21, and AMCA 230–23 are established test standards used by industry to establish the performance of fans and blower, including air circulating fans. In addition, as previously noted, AMCA 214–21, which references AMCA 210–16 provides test methods that are consistent with the recommendations of the Working Group for fans and blowers other than air circulating fans. Therefore, in this final rule, DOE incorporates by reference AMCA 210–16 and AMCA 214–21 as proposed in the July 2022 NOPR. In addition, as discussed in the July 2022 NOPR, DOE is replacing the reference to AMCA 230–15 (with errata) with AMCA 230–23.[72] DOE did not propose to incorporate AMCA 211–22, ''Certified Ratings Program Product Rating Manual for Fan Air Performance,'' because it does not specify a test method but rather certification and rating procedures, and thus DOE is not adding this standard. In addition, DOE is modifying certain sections of these industry standards as discussed in section III.E of this document.

In addition, due to the comments received on the proposed metric (*see* section III.G of this document) and the adoption of an efficacy metric in CFM/W rather than FEI for air circulating fans, DOE is only incorporating by reference AMCA 230–23 for air circulating fans instead of referencing both AMCA 230–15 (with errata) and AMCA 214–21 as proposed. As noted in the July 2022 NOPR, AMCA 214–21 references AMCA 210–16 and AMCA 230–15 (with errata) as the physical test method, and further provides provisions for calculating the FEI. 87 FR 44194, 44221. Because DOE is adopting an efficacy metric for air circulating fans and is not opting to determine the FEI of air circulating fans, DOE is no longer referencing AMCA 214–21 for air circulating fans.

As stated, in the July 2022 NOPR, AMCA 214–21 provides methods to establish the FEP of a fan based on fan power measurements which are performed in accordance with AMCA 210–16 or ISO 5801:2017, which is referenced in AMCA 214–21 as an equivalent test procedure to AMCA 210–16. 87 FR 44194, 44218–44219. DOE proposed incorporating by reference AMCA 214–21, which allows testing fans other than air circulating fans in accordance with either AMCA 210–16 or ISO 5801:2017 and DOE requested feedback on whether these test methods produce equivalent test results.[73] 87 FR 44194, 44221–44222.

AMCA commented that the test methods prescribed in ISO 5801 and AMCA 210 produce equivalent results when the appropriate test setup is used. AMCA commented that the technical content of AMCA 210 and ISO 5801 are in agreement. AMCA added that products in AMCA's Certified Ratings Program (CRP) are tested in accordance with both ISO 5801 and AMCA 210, and there is reproducibility between both of these test methods, as has been observed through the CRP over decades. AMCA added that one AMCA member conducted comparative testing in its own ISO 5801 lab (inlet chamber) and compared the results with an AMCA 210 test (inlet chamber/Figure 15) and also with AMCA's labs in Chicago and Malaysia and agreement was excellent between each of these labs. (AMCA, No. 41 at p. 15)

New York Blower commented that it relies on the ISO standard and review process to ensure the purpose of the two standards is to produce a similar result. In general, considering this is a U.S. domestic test procedure, New York Blower recommended the use of AMCA 214–21 as the governing document in the test procedure. (New York Blower, No. 33 at p. 11)

ebm-papst commented that it has conducted intercompany round-robin testing to compare AMCA 210 results with ISO 5801 results and concluded that testing fans by these two standards provides equivalent results. (ebm-papst, No. 31 at p. 8) Similarly, Morrison commented that testing conducted with the same setup in either of these standards produced functionally equivalent results. (Morrison, No. 42 at p. 5)

As noted by AMCA, New York Blower, ebm-papst, and Morrison, AMCA 210–16 and ISO 5801:2017 provide equivalent test results and DOE continues to incorporate by reference AMCA 214–21, which references both AMCA 210–16 and ISO 5801:2017 for testing fans and blowers other than air circulating fans.

In addition, in the July 2022 NOPR, DOE further noted that Section 6.3.1 of AMCA 214–21 provides specific equations to be used for bare shaft fans that can only accommodate a direct-drive transmission (*i.e.,* fans that are directly coupled to the drive) and DOE requested comment on the physical features that could be identified to differentiate bare shaft fans that can accommodate only a direct-drive transmission from other bare shaft fans. 87 FR 44194, 44219, 44222.

AMCA commented that AMCA 99–16, Section 9, can be referenced for common belt and direct-drive fan-drive

[71] DOE notes that Greenheck's comment lists AMCA 210, AMCA 211, and AMCA 214 on page 1 of its comments and seems to include a typo on page 2 where it lists AMCA 11, AMCA 211, and AMCA 214. (Greenheck, No. 39 at pp. 1–2)

[72] In the July 2022 NOPR, DOE noted that it is aware that AMCA 230–15 was undergoing periodic review and may be revised in the future. Should a new version become available at the time of any final rule, DOE would incorporate by reference the latest available version of AMCA 230. 87 FR 44194, 44221.

[73] The July 2022 NOPR included a typographical error in the request for comment on the equivalency of AMCA 210–16 and ISO 5801–2017, which listed AMCA 214–21 instead of AMCA 210–16.

arrangements, auxiliary bearings, shaft(s), and/or pulley(s) typically indicate a belt-drive arrangement. (AMCA, No. 41 at p. 17) Similarly, Morrison commented that common belt and direct-drive fan-drive arrangements could be found in AMCA 99–16. Additionally, the presence of auxiliary bearings, shaft(s), and/or pulley(s) typically indicated a belt-drive arrangement. (Morrison, No. 42 at p. 5)

New York Blower commented that it was possible to convert an arrangement 1 fan (belt drive) to an arrangement 8 fan (direct drive) merely by replacing the drive sheave with a coupling and an extended pedestal to support the motor. New York Blower added that, in reality, the shaft and bearings for the drive system would be redesigned to accommodate the different drive system, but to the casual observer, it would look identical. New York Blower noted that arrangement 4 fans have the impeller mounted directly to the motor and so, technically, it would not be a fan without the motor. In summary, New York Blower commented that it was unable to provide distinguishing physical features to assist in the distinction requested and did not see it conceivable to do so. (New York Blower, No. 33 at p. 12)

DOE concludes that the presence of auxiliary bearings, shaft(s), and/or pulley(s) would indicate a belt drive arrangement and would constitute physical features that would differentiate fans that can operate in a belt drive configuration from bare shaft fans that can only accommodate a direct-drive transmission. Therefore, DOE is not modifying the provisions in section 6.3.1 of AMCA 214–21 which provides specific equations to be used for bare shaft fans that can only accommodate a direct-drive transmission.

E. Adoption and Modification of the Industry Standards

As discussed in section III.D, DOE is adopting through reference certain provisions of AMCA 214–21 and AMCA 230–23 as the prescribed test method for measuring the energy use and energy efficiency of fans and blowers. In the July 2022 NOPR, specifically, for fans and blowers that are not air circulating fans, DOE proposed that testing be performed in accordance with AMCA 214–21, with the modifications discussed in the remainder of this section. For air circulating fans, DOE proposed that testing be performed in accordance with AMCA 230–15 with errata, with the modifications discussed in the rest of this section. 87 FR 44194, 44221–44222

For fans other than air circulating fans, the industry test procedure (AMCA 214–21) provides methods to calculate the FEI and FEP of a fan at each of its duty points based on: (1) the fan electrical input measured by a wire-to-air test; or (2) the fan shaft input power measured by a shaft-to-air test, and the application of calculation algorithms to represents the performance of the motor or motor and controller. The industry test procedure (AMCA 214–21) also provides methods to calculate the FEP or fan shaft input power at untested duty points, based on the performance of test duty points and interpolation methods, including the fan laws. For air circulating fans, the industry test procedure provides methods to calculate the efficacy in CFM/W of a fan at maximum speed based on the fan electrical input measured by a wire-to-air test. The following sections discuss key elements of the test procedure and modifications to AMCA 214–21 and AMCA 230–23.

Regarding AMCA 214–21, AMCA recommended that DOE adopt the speed and size interpolations standardized in AMCA 214–21. (AMCA, No. 41 at p. 16) Morrison recommended that DOE adopt the speed and size interpolations standardized in AMCA 214. Further, Morrison recommended no changes be made to AMCA 214–21 and AMCA 210–16. (Morrison, No. 42 at p. 5) New York Blower requested that fan laws be declared a universally accepted AEDM where no testing would be required to apply these laws to create ratings. (New York Blower, No. 33 at p. 24)

In regards to AMCA, Morrison, and New York Blowers comments, DOE references section 8.2.1 of AMCA 214–21, ''Fan laws and other calculation methods for shaft-to-air testing,'' and section 8.2.3 of AMCA 214–21, ''Calculation to other speeds and densities for wire-to-air testing,'' which allow speed and size interpolations as proposed in the July 2022 NOPR. (*See* 87 FR 44194, 44222.)

Robinson commented that the July 2022 NOPR stated that when applying fan laws, the results of a tested fan are used to calculate the fan shaft power of a non-tested fan at a higher speed or with a larger diameter than the fan tested. Robinson asked whether DOE suggested that compressible fan laws can only be applied to fans that are larger or faster than the tested fan. (Robinson, No. 43 at p. 7)

DOE notes the July 2022 proposed to apply the fan laws as described in section 8.2.1 of AMCA 214–21, ''Fan laws and other calculation methods for shaft-to-air testing,'' which relies on the calculation methods in Annex E of AMCA 214–21.87 FR 44194, 44223. Section E.1.1 specifies the requirements to apply the fan laws including the requirement that the fan must have a greater diameter than the tested fan, (*See* section E.1.1.3 of AMCA 214–21) and must have a fan tip speed that is greater than or equal to the tested fan tip speed.

Motor Efficiency Calculation

For bare shaft fans and fans with an electric motor subject to energy conservation standards at 10 CFR 431.25 (''polyphase regulated motor''), sections 6.3 and 6.4 of AMCA 214–21 specify testing these fans using a shaft-to-air test (*i.e.,* a test that does not include the motor performance). When conducting a shaft-to-air test, the mechanical fan shaft input power is measured and the FEP is then calculated by using a mathematical model to represent the performance of the motor (*i.e.,* its part-load efficiency). The FEP is then used to calculate the FEI of the fan.

AMCA 214–21 provides two different methods to estimate the part-load efficiency of a polyphase regulated motor. A single equation presented in section 5.3 and section 6.3.3 of AMCA 214 is used to calculate the FEP of the reference fan (''FEP_{ref}'') and the actual FEP of bare shaft fans (''FEP_{act}''), while a more complex model based on several equations described in section 6.4.2.3 of AMCA 214 is used to calculate the actual FEP of fans sold with polyphase regulated motors without a variable frequency drive (''VFD''). 87 FR 44194, 44222. DOE proposed to maintain the equation as provided in section 5.3 (which are identical to the equations provided in section 6.3.3 of AMCA 214–21) and in section 6.4.2.3 of AMCA 214–21 to estimate the part-load motor efficiency when calculating FEP_{ref}, FEP_{act} of bare shaft fans,[74] and the FEP_{act} of fans sold with electric motors regulated at 10 CFR 431.25 (and without VFDs). *Id.*

In the July 2022 NOPR, DOE requested comment on the equations provided in section 5.3 and section 6.4.2.3 of AMCA 214–21. Specifically, DOE requested comment on whether applying the method outlined in section 6.4 of AMCA 214–21 and the equations

[74] The NOPR did not explicitly specify ''of bare shaft fans'' in the preamble; however, the discussion did previously mention that the equation in Section 6.3.3 of AMCA 214–21 is identical to the equation in Section 5.3 of AMAC 214–21 and applicable to the calculation of FEP_{act} for bare shaft fans. *See* 87 FR 44194, 44222. In addition, the proposed regulatory text specified testing bare shaft fans per Section 6.3 of AMCA 214–21 (*See* Table 1 to Appendix A to tSubpart J of Part 431), which includes Section 6.3.3 of AMCA 214–21. *See* 87 FR 44194, 44257.

provided in section 6.4.2.3 of AMCA 214–21 could result in a higher value of FEI than the FEI resulting from a wire-to-air test in accordance with Section 6.1 of AMCA 214–21. *Id.*

AMCA supports DOE's proposal to maintain the equations as provided in sections 5.3 and 6.4.2.3 of AMCA 214–21 to estimate the part-load motor efficiency when calculating FEP_{ref}, FEP_{act}, and the FEP_{act} of fans sold with electric motors regulated at 10 CFR 431.25 (and without VFDs). AMCA commented that the method outlined in section 6.4 of AMCA 214–21 will result in slightly higher or slightly lower value of FEI than the one outlined in section 6.1. AMCA agrees with DOE that this difference is extremely small and not significant enough to justify deviating from the established industry test procedure. In addition, AMCA recommended to additionally reference Section 6.3 of AMCA 214–21 and add it to the list of acceptable methods for the case of a bare shaft fan. AMCA stated that because bare shaft fans eventually will be paired with motors compliant with current federal regulations, and DOE has concluded the impact on FEI is not significant, section 6.3 should be mentioned along with section 6.4. AMCA added that if a bare shaft fan is likely to be paired with a regulated motor, the method outlined in AMCA 211–21 Section 6.3 provides a convenient and accurate method of calculating FEI when the specific motor size and type is unknown. (AMCA, No. 41 at pp. 17–18)

Morrison stated its general agreement with AMCA's position that the entire AMCA 214–21 be adopted including use of sections 6.4.2.3 and 6.3 of AMCA 214–21. (Morrison, No. 42 at p. 5)

In the July 2022 NOPR, DOE proposed to rely on Section 6.3 and discusses the equation in section 6.3.3 of AMCA 214–21 for determining the FEP of bare shaft fans. *See* 87 FR 44194, 44223, 44257.

In this final rule, DOE is maintaining the proposed equation as provided in section 5.3 and section 6.3.3 of AMCA 214–21 and maintaining the proposed equations in section 6.4.2.3 of AMCA 214–21 to estimate the part-load motor efficiency when calculating FEP_{ref}, FEP_{act} of bare shaft fans, and the FEP_{act} of fans sold with electric motors regulated at 10 CFR 431.25 (and without VFDs).

1. Combined Motor and Controller Efficiency Calculation

For fans with a polyphase regulated motor and a controller, AMCA 214–21 allows testing these fans using a shaft-to-air test (*i.e.,* a test that does not include the motor and controller performance). When conducting a shaft-to-air test, the mechanical fan shaft input power is measured and the FEP is then calculated by using a mathematical model to represent the performance of the combined motor and controller (*i.e.,* its part-load efficiency). The FEP is then used to calculate the FEI of the fan.

Section 6.4.2.4 of AMCA 214–21, which relies on Annex B, ''Motor Constants if Used With VFD (Normative),'' and Annex C, ''VFD Performance Constants (Normative),'' provides a method to estimate the combined motor and controller part-load efficiency for certain electric motors and controller combinations that meet the requirements in sections 6.4.1.3 and 6.4.1.4 of AMCA 214–21, which specify that the motor must be polyphase regulated motor (*i.e.,* an electric motor subject to energy conservation standards at 10 CFR 431.25).

In the July 2022 NOPR, DOE noted that it had previously developed a similar model to estimate the combined motor and controller part-load performance in support of the commercial and industrial pump test procedure final rule published on January 25, 2016 (''January 2016 Pump TP''), in the case where the motor is a polyphase regulated motor. *See* 81 FR 4086, 4128–4130. As noted in the test procedure NOPR pertaining to commercial and industrial pump published on April 29, 2015 (''April 2015 Pumps NOPR''), the model used in the pump test procedure represents a conservative estimate of part-load motor losses (and efficiency).[75] 80 FR 17585, 17628. As noted in the July 2022 NOPR, DOE noted that such approach minimizes the possibility that using the calculation approach to estimate the motor and controller performance would result in better energy efficiency ratings than when testing the equipment inclusive of the motor and controller. 87 FR 44194, 44223.

In the July 2022 NOPR, DOE compared the motor part-load efficiency resulting from applying the AMCA 214–21 motor and controller equations with the combined motor and controller part-load efficiency obtained when using the equation from the DOE pump test procedure and found that the AMCA model resulted in combined motor and controller part-load efficiency values that were generally higher than the DOE model. In addition, DOE reviewed motor and VFD efficiency data from the AHRI certified product database [76] and found existing motor and VFD combinations that performed at a lower efficiency than predicted by the AMCA 214 model. DOE also reviewed the reference motor and controller (''power drive system'') efficiency provided in IEC 61800–9–2:2017 ''Adjustable speed electrical power drive systems Part 9–2: Ecodesign for power drive systems, motor starters, power electronics and their driven applications—Energy efficiency indicators for power drive systems and motor starters,'' which also provides equations to represent the performance of a motor and controller used with fans, and found that the IEC model predicted values of efficiency that were significantly lower (more than 10 percent on average) than the model included in AMCA 214–21. *Id.*

Based on this analysis, DOE stated its concerns that the equations described in section 6.4.2.4 of AMCA 214–21 may not be appropriately representative, resulting in fan FEI ratings that would be higher than FEI ratings obtained using the wire-to-air test method described in section 6.1 of AMCA 214–21. Therefore, DOE did not propose to allow the use of section 6.4.2.4 of AMCA 214–21. Instead, DOE proposed that fans with a motor and controller be tested in accordance with section 6.1 of AMCA 214–21. DOE indicated that manufacturers would still be able to rely on a mathematical model (including the same mathematical model as described in section 6.4.2.4 of AMCA 214–21, as long as the mathematical model meets the AEDM requirements discussed in Section III.I of this document) in lieu of testing to determine the FEI of a fan with a motor and controller. *Id.*

AMCA commented that, for some manufacturers offering fixed combinations of fan/motor/controller, the testing approach was appropriate and encouraged, while for other manufacturers offering standard fan models that can be paired with any standard, commercially available, regulated motor and standard, commercially available VFD, the testing approach of AMCA 214–21 Section 6.1 was not practical and would inhibit AMCA's ability to offer fan products with high-efficiency motors (above current regulation). AMCA stated its appreciation that DOE would consider AMCA 214–21 section 6.4.2.4 an acceptable method to be used as an AEDM; however, AMCA believed some mistakes were made in DOE's analysis

[75] The efficiency (Eff) of a motor at a given load (x) relates to the motor horsepower (hp) and losses (L) as follows: Eff = (x. hp)/(x.hp + L).)).

[76] AHRI Standard 1210, ''Standard for Performance Rating of Variable Frequency Drives,'' certified data from 2016, 2020, and 202. Available at: *www.ahridirectory.org/NewSearch?programId=71&searchTypeId=3.*

that affected the choice of not directly recognizing the calculation model from this section as an acceptable alternative to testing. AMCA commented that these were mistakes also made previously by AMCA that had not yet been sufficiently publicized to prevent them from recurring. AMCA provided supporting data and analysis to illustrate the representativeness of the equations in section 6.4.2.4. (AMCA, No. 41 at pp. 18–21) Specifically, AMCA commented that the DOE model used in the January 2016 Pump TP represented a conservative estimate of part-load motor losses (and efficiency). AMCA added that the model in AMCA 214–21, section 6.4.2.4, was not intended to be a conservative estimate of losses. Instead, according to AMCA, the model was intended to provide a level playing field between manufacturers that chose to test wire-to-air and those that chose to test fan shaft power and calculate wire-to-air losses. AMCA commented that the model used in the pump test procedure, therefore, should result in higher losses, and AMCA believed DOE's use of the pump model to assess AMCA 214 for the fan rulemaking was not valid. (AMCA, No. 41 at p. 18) Regarding AHRI data, AMCA commented that some motor and efficiency data in the AHRI certified product database previously included VFD models that performed at a lower efficiency than most others in the database. When AMCA interviewed the manufacturer of one of the lower-performing models, the manufacturer confided that the certified efficiency was much lower than the actual tested efficiency, but was intentionally rated lower for unrelated reasons. AMCA analyzed the current AHRI 1210 database and found that 59 percent of AMCA 214 calculations were within +/−1 percent of AHRI data and 96 percent were within +/−3 percent and provided graphical representations comparing the AHRI data to the AMCA 207 model.[77] (AMCA, No. 41 at pp. 18–19) AMCA added that the reference PDS model in IEC 61800–9–2:2017 was not typical of currently available products and that no VFDs nor motors were available at these low efficiency levels in the United States. AMCA noted that the equations representative of typical PDS were available in IEC TS 60034–31:2010, ''Rotating electrical machines—Part 31: Selection of energy-efficient motors including variable speed applications—Application guide.'' AMCA further provided a graphical comparison of its model against the equations available in IEC TS 60034–31:2010 as well as in the Motor Systems Tool published by 4E EMSA and demonstrating alignment between models. (AMCA, No. 41 at pp. 19–20) AMCA added that the next version of IEC 61800–9–2 will be expanded to cover VFD frequencies above 60 Hz which is a common condition for fans. AMCA recommended removing IEC 61800–9–2 from consideration for the CIFB rulemaking until at least Edition 2 of IEC 61800–9–2 has been published. Finally, testing at the AMCA lab and at members' labs has always shown excellent agreement with the AMCA 207 models. Figures 5 and 6 show recent testing on 3 and 10 hp motors covering a vast range of speeds and torques. Again, the AMCA 207 model[78] is labeled as the equivalent ISO 12759–2. (AMCA, No. 41 at p. 21)

New York Blower commented that it supports AMCA's analysis. (New York Blower, No. 33 at p. 13) Morrison stated its general agreement with AMCA's position that the entire AMCA 214–21 be adopted, including use of Section 6.4.2.4 of AMCA 214–21. (Morrison, No. 42 at p. 5)

Greenheck commented in support of including AMCA 214 Section 6.4.2.4 combining motor/controller efficiency. (Greenheck, No. 39 at p. 1) In addition, for embedded fans, Greenheck commented that the requirement for wire-to-air testing poses a specific challenge. Greenheck commented that many products are manufactured without motor controllers/VFDs that are provided by the field. Greenheck commented that the proposed testing requirements would, in these cases, put the certification burden on the installing contractor to validate FEI at that selection as the contractor would be completing the ''fan assembly'' as defined. Greenheck commented that this is an unrealistic expectation and would likely be violated regularly. Greenheck commented that DOE should align the testing procedure with existing AMCA standards that allow for calculation of efficiency for motor transmission and controllers. (Greenheck, No. 39 at p. 6)

Robinson commented that in its experience, the issues with making representative energy efficiency ratings with the presence of VFDs at reduced frequency is difficult without direct torque measurement. Robinson added that motor and VFD suppliers repeatedly refused to provide data to allow for calculation of motor and VFD efficiency and power factor at reduced frequency. (Robinson, No. 43 at p. 8)

As noted in the April 2015 Pumps NOPR, the model used in the pump test procedure represents a conservative estimate of part-load motor losses (and efficiency). 80 FR 17585, 17628. As stated, this approach is intended to minimize the possibility that using the calculation approach to estimate the motor and controller performance would result in better energy efficiency ratings than when testing the equipment inclusive of the motor and controller. As illustrated in AMCA's comment, the model in AMCA 214–21 section 6.4.2.4 was not intended to be a conservative estimate of losses and instead is representative of typical performance. In line with DOE's findings, the analysis provided by AMCA shows that there are many AHRI-certified motor and VFD combinations that have a tested efficiency that is lower than the model in section 6.4.2.4 of AMCA 214–21. Therefore, DOE continues to have concerns that applying the model in section 6.4.2.4 of AMCA 214–21 may result in fan FEI ratings that would be higher than FEI ratings obtained using the wire-to-air test method described in section 6.1 of AMCA 214–21. Therefore, DOE is not allowing the use of section 6.4.2.4 of AMCA 214–21. Instead, DOE requires that fans with motor and controller be tested in accordance with section 6.1 of AMCA 214–21. DOE notes that manufacturers would still be able to rely on a mathematical model (including the same mathematical model as described in section 6.4.2.4 of AMCA 214–21, as long as the mathematical model meets the AEDM requirements discussed in Section III.I of this document) in lieu of testing to determine the FEI of a fan with a motor and controller.

In addition, DOE notes that the fan manufacturer is responsible for certifying the equipment as distributed in commerce and a consumer or installer would not be responsible for additional certification. If a fan manufacturer sells a fan basic model without a controller, they would be responsible for certifying that fan basic model without a controller.

2. Annex A of AMCA 214–21

Annex A provides the reference nominal full-load efficiency values to use for polyphase regulated motors subject to energy conservation standards at 10 CFR 431.25 when calculating the motor part load efficiency in accordance with section 6.4.2.3 of AMCA 214–21. In the July 2022 NOPR, DOE proposed to replace Annex A of AMCA 214–21

[77] The AMCA 207 equations are identical to those found in Section 6.4.2.4 of AMCA 214–21 (*See* discussion in section III.D of this document).).

[78] The AMCA 207 equations are identical to those found in AMCA 214–21 (See discussion in section III.D of this document).)).

with a reference to Table 5 of 10 CFR 431.25. The values in Annex A and Table 5 of 10 CFR 431.25 are identical; however, referencing the Code of Federal Regulations would ensure that the values of polyphase regulated motor efficiencies remain up to date with any potential future updates established by DOE. 87 FR 44194, 44223. DOE did not receive any comment on this issue and is replacing Annex A of AMCA 214–21 by referencing Table 5 of 10 CFR 431.25.

3. Annex E of AMCA 214–21

Annex E of AMCA 214–21 allows a reduction in the number of tests potentially required by allowing the use of fan laws to calculate the fan shaft power of a non-tested fan using results from a fan shaft power test of a fan with a smaller impeller diameter. In the July 2022 NOPR, DOE noted that since the publication of AMCA 214–21, AMCA 211–22, ''Certified Ratings Program Product Rating Manual for Fan Air Performance,'' was published. Annex I of AMCA 211–22 allows the use of fan laws to additionally interpolate the fan shaft power of a non-tested fan using results from a fan shaft power test of two fans with a smaller and larger impeller diameter (*i.e.,* interpolation between two tested sizes). DOE considered adding a reference to Section I.6 of Annex I of AMCA 211–22 and allowing manufacturers to additionally interpolate the fan shaft power of a non-tested fan between two tested fans sizes. Alternatively, DOE considered referencing Annex I of AMCA 211–22 in place of Annex E of AMCA 214–21. In the July 2022 NOPR, DOE requested comments on whether it should add a reference to section I.6 of AMCA 211–22 or replace Annex E of AMCA 214–21 by Annex I of AMCA 211–22. 87 FR 44194, 44223–44224.

In response to the July 2022 NOPR, the CEC commented that it supports the reference of Annex E of AMCA 214–21 only. The CEC recommended that section I.6 of AMCA 211–22 not be added or referenced and recommended that Annex I of AMCA–211–22 not replace Annex E of AMCA 214–21. The CEC stated that although section I.6 of AMCA 211–22 and Annex E of AMCA 214–21 could be used to interpolate and compute the Fan Energy Index (FEI) of the interpolated fan for different diameter fans, Annex E of AMCA 214–22 clearly communicated the requirements for the applicability of the formulas provided in Annex E, including the type of units to be used and its distinct source. Including section I.6 could lead to incorrect data being generated for certification since it lacked clear explanations and would require more information to implement correctly. The CEC added that although Annex I of AMCA 211–22 could replace Annex E of AMCA 214–21, it lacks the detail conditions for the applicability of the formulas presented. The CEC commented that Annex I of AMCA 211–22 lacks connectivity to the main body of the test procedure and does not explain the applicability of the results to sections 6.3, 6.4, and 6.5 of AMCA 214–21. The CEC added that Annex I could lead to incorrect data to be generated for certification and would require more information to implement correctly. For these reasons, the CEC recommended referencing Annex E of AMCA 214–21 only. (CEC, No. 30 at pp. 3–4)

AMCA recommended that DOE add a reference to section I.6 of AMCA 211–22. This section covers interpolation between tested fan sizes when geometric similarity requirements were met and would result in more accurate ratings for non-tested sizes. (AMCA, No. 41 at p. 22) New York Blower stated support for AMCA's analysis of the issue. (New York Blower, No. 33 at p. 13)

As previously stated, DOE is not opting to reference AMCA 214–21 for air circulating fans. DOE reviewed the content of Annex I of AMCA–211–22 and of Annex E of AMCA 214–21 and notes that both appendices include identical equations describing the fan laws, interpolations between tested speeds, and general interpolations between tested fans when a single geometric feature is varied, with the following exceptions: (1) Section I.6 of Annex I of AMCA 211–22 allows the use of fan laws to additionally interpolate the fan shaft power of a non-tested fan using results from a fan shaft power test of two fans with a smaller and larger impeller diameter (*i.e.,* interpolation between two tested sizes), while Section E.3 of Annex E of AMCA 214–21 explicitly prohibits this and requires the use of fan laws instead; (2) the equations in Annex I of AMCA 211–22 include the compressibility coefficients, while the equations in Annex E of AMCA 214–21 assume the flow is incompressible; and (3) the symbols in Annex I of AMCA 211–22 are not consistent with the symbols used in AMCA 214–21. For these reasons, at this time to maintain clarity and consistency with the symbols and terms used through AMCA 214–21, DOE is keeping the reference to Annex E of AMCA 214–21 as proposed in the July 2022 NOPR. In addition, DOE is specifying that the equations in Section E.2 of Annex E of AMCA 214–21 must include the compressibility coefficients as applicable for compressible flows.

4. Section 6.5 of AMCA 214–21 and Annex F

Section 6.5 and Annex F of AMCA 214–21 provide methods to determine the FEP of the actual fan by conducting separate tests for the bare shaft fan and the motor or the combined motor and controller. Annex F specifies the industry test methods [79] to use when testing the motor or the combined motor and controller. As provided in Annex F, the motor and controller, if included, must be tested at the range of speeds and loads over which the fan is to be rated. The measurements result in a map of the input power (kW) versus speed and load and intermediate values can be determined through interpolation (linear interpolation or a polynomial curve fit). The methods in section 6.5 and Annex F of AMCA 214–21 are applicable to any electric motor (including non-DOE regulated motors that meet the definition of electric motor at 10 CFR 431.12) as long as it can be tested per the industry test procedures included in Annex F.

In the July 2022 NOPR, DOE noted that the test procedure for combined motor and controller in AMCA 214–21 deviates from the methods proposed in the December 2021 Electric Motors Test Procedure NOPR. 86 FR 71710, 71743 (December 17, 2021).[80] DOE further noted that for fans combined with regulated motors, the methods described in section 6.5 and Annex F of AMCA 214–21 would be less burdensome than multiple wire-to-air tests; however, it would likely be significantly more burdensome than applying the calculation methods described in section 6.3 of AMCA 24–21, since it would require physical tests of all motors with which the bare shaft fan could be paired. In addition, with the option to allow for an AEDM as discussed in Section III.I of this document, a manufacturer would be able to integrate the methods of Section 6.5 and Annex F of AMCA 214–21 into a mathematical model as long as the proposed AEDM requirements were met. 87 FR 44194, 44224.

Therefore, DOE proposed not to include section 6.5 and Annex F of AMCA 214–21. DOE noted that manufacturers would still be able to rely

[79] CSA C747–09 (R2014), ''Energy efficiency test methods for small motors''; CSA C838–13 (R2018), ''Energy efficiency test methods for three-phase variable frequency drive systems''; IEEE 112–2017, ''IEEE Standard Test Procedure for Polyphase Induction Motors and Generators''; and ANSI/ASHRAE Standard 222–2018, ''Standard Method of Test for Electrical Power Drive Systems.''

[80] Since then, DOE notes that the electric motors test procedure was finalized on October 19, 2022. 87 FR 63588.

on a mathematical model (including potentially the same model as described in section 6.5 of AMCA 214–21, as long as the models meet the AEDM requirements discussed in Section III.I of this document) in lieu of testing to determine the FEI of a fan with a motor or a motor and controller, provided that the mathematical model meets all the AEDM requirements proposed in Section III.I of this document. *Id.*

Greenheck commented that DOE's proposal to not adopt section 6.4.2.4 of AMCA 214–21 [81] invalidated a common practice where manufacturers complete bare shaft testing and combine this data with separate testing of the power drive system (PDS). Greenheck commented that the ability to test a PDS separate from the fan significantly reduced testing burden as a single PDS test could be applied across multiple validation classes and sizes. Greenheck commented that testing a PDS separate from the fan would also necessitate that those manufacturers complete wire-to-air testing for any instances where they wish to demonstrate the improved performance of special motor/drive combinations. According to Greenheck, this exclusion penalized manufacturers for offering a more energy efficient PDS through increased testing requirements. (Greenheck, No. 39 at p. 2)

As noted, the test procedure for combined motor and controller in section 6.5 and Annex F of AMCA 214–21 deviates from the methods finalized by DOE on October 19, 2022. In addition, for fans combined with regulated motors, the methods described in section 6.5 and Annex F of AMCA 214–21 would be less burdensome than multiple wire-to-air tests; however, it would likely be significantly more burdensome than applying the calculation methods described in section 6.3 of AMCA 24–21, since it would require physical tests of all motors with which the bare shaft fan could be paired. In addition, as stated, manufacturers would still be able to rely on a mathematical model (including potentially the same model as described in section 6.5 of AMCA 214–21, as long as the models meet the AEDM requirements discussed in Section III.I of this document) in lieu of testing to determine the FEI of a fan with a motor or a motor and controller, provided that the mathematical model meets all the AEDM requirements proposed in Section III.I of this document. For these reasons, DOE is not including Section 6.5 and Annex F of AMCA 214–21.

5. Annex H and Annex I of AMCA 214–21

Annex H ''Required Reported Values (Normative)'' of AMCA 214–21 provides reporting requirements. In the July 2022 NOPR, DOE did not propose to adopt Annex H. DOE stated that it may consider proposals to establish reporting requirements for fans and blowers under a separate rulemaking. 87 FR 44194, 44224.

Annex I ''Minimum Data Requirements for Published Ratings (Informative)'' provides guidance on what performance information to publish. In the July 2022 NOPR, DOE did not propose to adopt Annex I. DOE proposed to adopt requirements regarding represented values in Section III.J of that document. 87 FR 44194, 44224.

The CEC recommended incorporating by reference Annex H of AMCA 214–21 defining the efficiency boundaries of the fan by maximum airflow, maximum pressure, and maximum fan speed as these terms are defined in that section. (CEC, No. 30 at p. 6)

The CA IOUs commented that they were concerned that DOE's test procedure final rule may preempt aspects of the ongoing Title 20 Appliance Standards rulemaking. Specifically, the CA IOUs noted that DOE did not propose to adopt Annex H ''Required Reported Values (Normative)'' of AMCA 214–21 Test Procedure for Calculating FEI for Commercial and Industrial Fans and Blowers. The CA IOUs commented that DOE stated that it may consider reporting requirements in a separate rulemaking. However, the CA IOUs noted that the CEC has proposed adopting Annex H in its Express Terms to determine Maximum Airflow, Maximum Pressure, and Maximum Fan Speed at which the fan can achieve an FEI greater than or equal to 1.0. Therefore, the CA IOUs requested that DOE adopt appendix H to align with the CEC proposal. (CA IOUs, No. 37 at p. 7)

DOE is not adopting reporting requirements for fans and blowers in this rulemaking. DOE may consider proposals to establish reporting requirements for fans and blowers under a separate rulemaking. DOE notes that 180 days after publication of this final rule, any representations made with respect to energy use or efficiency of fans or blowers must be made based on testing in accordance with the test procedures established in this final rule. Further, in regard to the CA IOUs comments about preemption, EPCA states that section 6297 applies with respect to the equipment described in section 6311(1)(L) beginning on the date on which a final rule establishing an energy conservation standard is issued, except that any State or local standard prescribed or enacted for the equipment before the date on which the final rule is issued shall not be preempted until the energy conservation standard for the equipment takes effect. (42 U.S.C. 6316(a)(10))

6. Section 8.3 of AMCA 214–21

Section 8.3, ''Appurtenances,'' provides guidance on how to characterize fan performance in the case of a fan with additional appurtenances beyond what is required by the test procedure. In the July 2022 NOPR, DOE did not propose to adopt this section as DOE does not propose to establish fan performance with additional appurtenances beyond what is specified in the test procedure.[82] 87 FR 44194, 44224.

DOE did not receive any comment on this issue and is not including section 8.3 of AMCA 214–21, because DOE is not establishing fan performance with additional appurtenances beyond what is required in the test procedure. *See* section III.E.12 of this document.

7. Measurement of PVR Performance

Table 7.1 of AMCA 214–21 requires different test configurations for PRVs that supply air to a building and PRVs that exhaust air from a building. Some PRVs can operate both as supply and exhaust fans. In the July 2022 NOPR, DOE proposed that PRVs that can operate both as supply and exhaust fans be tested in both configurations. 87 FR 44194, 44224.

In response to the July 2022 NOPR, the Efficiency Advocates commented that they support DOE's proposal for PRVs requiring that models capable of operating as both supply and exhaust fans be tested as both as it would help ensure that PRVs are tested and rated in all configurations in which they may be installed. (Efficiency Advocates, No. 32 at p. 3)

AMCA supports testing in both configurations. If a PRV is marketed as being able to operate both as a supply and an exhaust fan, AMCA requires it to be tested and rated as both a supply PRV and an exhaust PRV. (AMCA, No. 41 at p. 22)

New York Blower noted that PRVs that operate both in supply and exhaust

[81] DOE believes this is a typographical error in the comment and should be referencing Section 6.5 of AMCA 214–21 which describes the separate bare shaft fans and PDS testing approach.

[82] Section III.D.7 of the July 2022 NOPR included an erroneous reference to Section 7.3 of AMCA 214–21, which DOE did not propose to adopt at the time. *See* 87 FR 44194, 44224. This error was noted in a comment by AMCA (AMCA, No. 41 at p. 23).

modes clearly display a significant difference in performance, and that it is clearly in the manufacturer's best interest to understand the different performance values. New York Blower added that an unintended consequence of deriving an efficiency level that eliminates a significant portion of a direction of PRV could, as unreasonable as it seems, imply two fans should be installed—each operating in its most efficient direction—to accomplish both supply and exhaust. (New York Blower, No. 33 at p. 13)

DOE requires that PRVs that can operate both as supply and exhaust fans be tested in both configurations. DOE would consider any issues related to efficiency levels, including differences in performance for PRVs that operate both in supply and exhaust modes in its separate energy conservation standards rulemaking.

8. Embedded Fans and Blowers

As discussed in Section III.B.3 of this document, DOE proposed to exclude fans that are embedded in equipment as listed in Table III–7 of this document. DOE explained that other embedded fans were included in the scope of the test procedure to the extent that they meet the test procedure scope criteria presented in Section III.B.1 of this document and do not fall under the exclusions discussed in Section III.B.2 of this document. 87 FR 44194, 44224.

The Working Group recommended that embedded fans be tested in a standalone fan configuration (*i.e.,* outside of the piece of equipment in which they are embedded). (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #8 at p. 5) DOE interprets this recommendation to apply to embedded fans that are not manufactured in a standalone configuration because standalone fans that are purchased by an OEM for incorporation into equipment can be tested prior to being embedded. Because embedded fans included in larger equipment may share structural or functional parts with that equipment, the fan may not be removable without causing irreversible damage to the equipment. To address such embedded fans, the Working Group recommended testing exclusively embedded fans using additional fan components, except for the fan impeller, that are geometrically identical to that of the embedded fan inside the larger piece of equipment. (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #8 at p. 5) In addition, the Working Group recommended that embedded fans be certified over their standalone operating range. (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #4 at p. 4)

In the July 2022 NOPR, DOE stated that fan performance information indicated that OEMs currently test and collect information on embedded fan performance and that OEMs understand a fan's typical operating range in terms of flow and pressure. DOE noted that the AMCA 214–21 foreword states that, ''AMCA Standard 214 primarily is for fans that are tested alone or with motors and drives; it does not apply to fans tested embedded inside of other equipment.'' To test exclusively embedded fans that are not manufactured in a standalone configuration, consistent with the Working Group recommendations, DOE therefore proposed that these fans be tested as standalone fans, outside of the equipment in which they are incorporated. In addition, DOE proposed that if any fan components are not removable without causing irreversible damage to the equipment into which the fan is embedded, the manufacturer must use additional fan components, except for the fan impeller, that are geometrically identical to that of the fan embedded inside the larger piece of equipment for testing. This would result in a range of FEI ratings at every operating point at which the fan is capable of operating, including at the flow and pressure point experienced by the fan when embedded inside the equipment. 87 FR 44194, 44425.

ebm-papst commented that its customers almost exclusively embed all purchased fans into equipment that is currently regulated, slated to be regulated, or not regulated. ebm-papst commented that all fans that it supplies in testable configurations are rated based on wire-to-air tests, either AMCA 210 or ISO 5801. However, ebm-papst commented that fans are often supplied in configurations that are not testable: (1) suppliers other than ebm-papst have supplied forward curve impellers loosely placed in scroll housings, thus initially without bearings/drivers, before the OEM furnishes the motors and thereby finally creates the housed centrifugal fan; (2) forward curve impellers complete with integrated motor supplied without scroll housing, as the eventual housing shape will be part of the larger HVAC unit; or (3) axial propellers complete with integrated motors but without panels, because the OEM has the eventual ''panel'' designed and supplied by the surrounding HVAC unit. Nevertheless, ebm-papst noted that it is common practice and the OEMs' expectation that suppliers document fan air performance. In the case of non-testable configurations, the fans would be tested with inlets, housings, and mounting. (ebm-papst, No. 31 at p. 3)

ebm-papst added that OEM customers expect fan performance representations from their suppliers when they purchase incomplete panel fans and or incomplete plenum fans: (1) motorized propellers are measured and rated in the form of axial panel fans but sold without panels; and (2) motorized impellers are measured and rated in the form of plenum fans but sold without inlet cones/rings and without inlet plates. (*Id.* at p. 7) emb-papst further commented that all ebm-papst fans are rated based on tests in standalone configuration, and that those supplied to OEMs without panels or inlet rings for embedding are tested in their laboratories with standardized components in place. emb-papst commented that the necessary geometries of these necessary peripheral components are comprehensively described for the customers and users. ebm-papst added that fans it supplies incomplete to OEMs can be tested with the missing components, that then are documented. In addition, emb-papst noted that motorized propellers should be tested with fan panels/orifices in place and that motorized impellers should be tested with inlet rings/cones and plates in place. (*Id.* at p. 10)

AMCA commented that fans purchased in a testable configuration typically are tested standalone and rated. According to AMCA, in these cases, a fan supplier can provide performance data of a standalone fan to an OEM. (AMCA, No. 41 at p. 6)

New York Blower commented that its involvement in HVACR equipment is limited. Regardless, New York Blower stated that for applications it had been involved in, New York Blower would consider ventilation and regularly use AMCA 210–16 to conduct the test in a standalone configuration. New York Blower stated that therefore, by reference, AMCA 214–21 would also be applicable. (New York Blower, No. 33 at p. 8)

Morrison commented that embedded fans and replacement fans, especially for HVAC and applications where safety was a consideration, should be excluded from the scope. Morrison added that fans tested as standalone do not have the same performance in the appliance as tested per this test procedure. Morrison stated that testing of fans per AMCA 210 requires many multiples of diameter clear of the inlet and exit to ensure proper airflow development and these conditions are never present in appliances, so optimum performance at the lowest energy may be different than the best FEI selection. (Morrison, No. 42

at p. 2) Morrison added that while fans supplied to HVAC equipment manufacturers may be tested as standalone, many are not as they are custom designed for the appliance and only tested in the appliance. Morrison commented that the goal of fans for HVAC equipment is to have the lowest energy consumed at the desired operating point in the equipment and that will often not correspond with the AMCA 210 or AMCA 214 tested FEI. In other words, according to Morrison, the standalone testing is generally of no value in the effort of identifying the fan with the best efficiency in the appliance. Morrison added that the benefit of standalone testing is very limited as end users need performance of the appliance tested as an appliance ready for customer installation. (*Id.* at pp. 2–3) Morrison further commented that testing embedded fans as standalone fans will add cost but provide no value. Morrison stated that AMCA 210 is a test standard for testing of a fan's performance with no obstruction within recommended distance of the inlet and exit to ensure the fundamental operation of the fan is not changed. Morrison commented this is never the case in embedded fans and in most cases, the most efficient standalone tested fan is not the fan that consumes the lowest energy in an application—this has been presented previously in this rulemaking process and is still a consideration today. Morrison commented that unit level testing or better full system level testing provides greater opportunity for energy savings. (*Id.* at p. 6)

As noted by ebm-papst, it is common practice for OEMs to expect fan performance information from their fan suppliers. As mentioned by ebm-papst and AMCA, fans sold in a testable configuration are tested in a standalone configuration. As specified by ebm-papst, fans supplied incomplete to OEMs can be tested with the missing components (*i.e.,* in a standalone configuration) that then are documented. Such approach aligns with the proposed approach for testing embedded fans that are not manufactured in a standalone configuration and is consistent with common industry practice. Therefore, consistent with the Working Group recommendations, DOE requires that embedded fans that are not manufactured in a standalone configuration be tested as standalone fans, outside of the equipment in which they are incorporated. In addition, in line with the Working Group recommendations and July 2022 NOPR, DOE requires that if any fan components are not removable without causing irreversible damage to the equipment into which the fan is embedded, the manufacturer must use additional fan components, except for the fan impeller, that are geometrically identical to that of the fan embedded inside the larger piece of equipment for testing. This will result in a range of FEI ratings at every operating point at which the fan is capable of operating, including at the flow and pressure point experienced by the fan when embedded inside the equipment. DOE further notes that the July 2022 NOPR omitted the corresponding provisions in the proposed regulatory text and DOE is adding the corresponding provisions in the final regulatory text.

The CA IOUs commented that the proposed test procedure would apply to fans embedded in non-regulated equipment such as air-handlers. The CA IOUs commented that neither proposed regulatory language nor the commentary provided guidance to manufacturers on how to provide fan performance data when the requirements of the NOPR take effect. The CA IOUs commented that Title 24, ASHRAE 90.1, and IECC 2021 require that designers meet a maximum fan system power and that the selected fans meet a minimum FEI. The CA IOUs commented that many manufacturers buy a fan represented as a bare shaft fan and bundle it with a motor, transmission, and/or controller. If the fan manufacturer created this bundle, it would have a different representation than the bare shaft fan. Moreover, many manufacturers build fan arrays (*i.e.,* fans with single-speed motors controlled by a single variable frequency drive controller supplied by the packager). The CA IOUs added that fan arrays are not in the scope of AMCA 214–21. Specifically, the CA IOUs requested clarification on the following issues: (1) Can packaged manufacturers use bare shaft performance data from the fan manufacturer and then apply an AEDM or one of the permitted modeling methods to determine the performance of the package with added motors and controllers? (2) When manufacturers package a fan with a motor, transmission, or speed controller, are they required to perform the same testing as a fan manufacturer? If not, can the manufacturer provide performance data based on testing inside the air handler? (3) How can fan manufacturers present performance data for fan arrays where one controller operates many motors? (CA IOUs, No. 37 at p. 8)

Regarding issue (1), DOE clarifies that if a manufacturer assembles a combined bare shaft fan and motor and controller and chooses to make representations of FEI for the combined equipment that it distributes in commerce, then the manufacturer would need to rate the combined equipment in accordance with DOE test procedures. Regarding items (2) and (3), DOE notes that the test procedure is applicable to the fan tested in a standalone fan configuration and does not apply to fan assemblies.

New York Blower commented that it provides a significant quantity of applications where the fan could be described as embedded in a device or system that provides an end service, such as dust collection and that structural design modifications may be required to install the fan in the resulting system. New York Blower commented that it tests the fan by extracting it from the system, creating a mounting interface to support testing and conduct the test. New York Blower commented that for more integrated systems, such as HVACR applications, this may pose significant challenges. (New York Blower, No. 33 at pp. 13–14)

DOE understands that the example described by New York Blower is of a standalone fan installed in a larger system in the field. Such a fan would be tested in the standalone configuration.

ebm-papst requested clarification regarding an OEM's obligation for air performance testing when a fan is incomplete without components that are part of a surrounding unit. (ebm-papst, No. 31 at p. 1)

As adopted, embedded fans that are not manufactured in a standalone configuration must be tested as standalone fans, outside of the equipment in which they are incorporated. As noted, if any fan components are not removable without causing irreversible damage to the equipment into which the fan is embedded, the manufacturer must use additional fan components, except for the fan impeller, that are geometrically identical to that of the fan embedded inside the larger piece of equipment for testing.

9. Wire-to-Air Performance for Air Circulating Fans

As discussed in the July 2022 NOPR, DOE did not find any circulating fans that were distributed in commerce without an electric motor. However, if an air circulating fan is sold without a motor, it would still meet the definition of an air circulating fan and would be included in the scope of the test procedure. Therefore, in the July 2022 NOPR, DOE proposed that air circulating fans distributed in commerce without an electric motor be tested using an electric motor as recommended

in the manufacturer's catalogs or distributed in commerce with the air circulating fan. If more than one motor is available in a manufacturer's catalogs or distributed in commerce with the air circulating fan, DOE proposed requiring that it be tested using the least efficient motor capable of running the fan at the fan's maximum allowable speed. 87 FR 44194, 44225.

ebm-papst commented that it is not aware of any ACF sold without a motor. (ebm-papst, No. 31 at p. 10)

DOE did not receive any other comments on this topic and thus requires that air circulating fans distributed in commerce without an electric motor be tested using an electric motor as recommended in the manufacturer's catalogs or distributed in commerce with the air circulating fan. If more than one motor is available in manufacturer's catalogs or distributed in commerce with the air circulating fan, DOE requires that it be tested using the least efficient motor capable of running the fan at the fan's maximum allowable speed.

10. Total Pressure Calculation for Air Circulating Fans

In the July 2022 NOPR, DOE noted that AMCA 214–21 specifies that air circulating fans must rely on a FEI based on total pressure (sum of the static pressure and velocity pressure). (*See* Table III–9 of that document.) However, AMCA 230–15 does not specify the measurement or calculation of fan total pressure, which is a required input to the FEI calculation. In the July 2022 NOPR, DOE proposed to add provisions to specify how to calculate fan total pressure and to apply the equations in section A.2 of AMCA 208–18 when calculating the fan total pressure at a given airflow for fans tested per AMCA 230–15. 87 FR 44194, 44225.

ebm-papst commented that complete reports of AMCA 230 tests include all information necessary to calculate fan total pressure of circulation fans. (ebm-papst, No. 31 at p. 10)

As noted by ebm-papst, the information included in an AMCA 230 test report includes all the information needed to calculate the fan total pressure. Although DOE is not adopting FEI as the metric for air circulating fans (which required the determination of total pressure), section 8.7 of AMCA 230–23 includes equations for calculating total pressure (the same as proposed by DOE), and DOE is retaining these provisions by referencing section 8.7 of AMCA 230–23.

11. Appurtenances

Section 7.3 of AMCA 214–21 provides instructions on which appurtenances to include as part of the tested fan. It distinguishes between appurtenances that improve or reduce performance. For appurtenances that improve fan performance (including but not limited to inlet bells, diffusers, stators, or guide vanes), AMCA 214–21 specifies that these appurtenances should be included if always supplied with the fan when distributed in commerce. For appurtenances that reduce fan performance, which include, but are not limited to, safety guards, dampers, filters, or weather hoods, AMCA 214–21 states that if the appurtenance is always supplied with the fan when distributed in commerce, then it shall be tested with the fan. If the appurtenance is not always supplied with the fan when distributed in commerce, it shall not be tested with the fan.

For circulating fans, in the July 2022 NOPR, DOE noted that the AMCA 230 committee was considering adding the following provisions as part of the revised version of AMCA 230: any appurtenances sold with the fan shall be included in the minimum testable configuration. 87 FR 44194, 44225.

In the July 2022 NOPR, DOE reviewed the provisions related to accessories in AMCA 214–21 and as considered by the AMCA 230 committee and tentatively determined that testing using the provisions discussed by the AMCA 230 committee would provide results that are more representative of field conditions because consumers are likely to use the fan with the appurtenances they purchase. Therefore, for fans and blowers, including air circulating fans, DOE proposed to specify that any appurtenances sold with the fan must be included during the test. In the July 2022 NOPR, DOE requested comment on the proposed provisions related to the consideration of appurtenances when testing fans and blowers, including air circulating fans.[83] *Id.*

In response to the July 2022 NOPR, for air circulating fans, AMCA commented that if an air circulating fan is sold or supplied with a guard or other appurtenances, then it should be tested with the guard or other appurtenances, and if the fan is sold or supplied without a guard or appurtenances, then it should be tested without a guard or appurtenances. AMCA added that each combination of circulating fan and appurtenances would be a separate basic model or conservative ratings could be used to combine multiple basic models. AMCA commented that this was feasible due to the relatively limited number of air circulating fan models and combinations of guards/appurtenances offered by manufacturers. (AMCA, No. 41 at p. 23)

For fans and blowers other than air circulating fans, AMCA recommended that DOE use the provisions in section 7.3 of AMCA 214–21. AMCA explained that including appurtenances in the scope of testing would add burden on fan manufacturers. AMCA commented that historical data, in general, has been developed without appurtenances being tested with the fan, so that including appurtenances would negate the validity of all the historical data and the basic models would need to be tested again with multiple samples as proposed. AMCA added that some appurtenances are mutually exclusive, and that numerous accessories can be applied to fans, but it may not be possible, or reasonable, to apply all available appurtenances to a fan for testing. AMCA added that appurtenances that negatively impact fan air performance would clearly, at the margin, reduce the compliant region of the fan-performance map, *i.e.,* the FEI bubble would shrink. AMCA commented that one option might be for manufacturers to create different basic models, *i.e.,* model numbers for those that include certain appurtenances and separate model numbers for those that do not—a solution that would clearly add complexity and significant testing and AEDM costs. Finally, AMCA commented that DOE's analyses to date, such as those in the notice of data availability,[84] have been done without accessories and that changing the basis of analysis to include appurtenances would require the analyses to be completely redone to reasonably estimate the cost impacts and energy savings in a subsequent energy standard. Most importantly, this proposal would alter the definition of minimum testable configuration in AMCA 214–21, which is a ''fan having at least an impeller; shaft and bearings and/or driver to support the impeller; and its structure or its housing.'' AMCA

[83] As previously stated, Section III.D.7 of the July 2022 NOPR included an erroneous reference to Section 7.3 of AMCA 214–21, which DOE did not propose to adopt in the July 2022 NOPR. Instead, as described in Section III.D.12 of the July 2022 NOPR, and consistent with the proposed regulatory text, DOE proposed to apply the same provisions related to appurtenances as considered by the AMCA 230 committee for air circulating fans: any appurtenances sold with the fan shall be included in the minimum testable configuration.

[84] On November 1, 2016, DOE published a notice of data availability that presented an analysis based on the scope and metric recommendations of the term sheet. 81 FR 75742.

recommended that fans be tested in their minimum testable configuration—with considerations for appurtenances that are consistent with section 7.3 of AMCA 214–21. (AMCA, No. 41 at pp. 23–24)

New York Blower commented that adding appurtenances to the fan for the test procedure will increase testing costs. New York Blower added that not all appurtenances can be applied to a fan simultaneously and the proposal to include appurtenances would multiply the number of basic models and result in a high number of fan models offered to the market with different combinations of appurtenances. New York Blower noted the challenge represented by the complexity that would be generated from the multiple product configurations, testing, and administrative burden to support product certification. New York Blower added that the fan is the prime mover from an energy conversion perspective, and that it is unlikely a fan will be redesigned to be more efficient based on the addition of an appurtenance. In addition, New York Blower noted that many appurtenances are not manufactured by fan manufacturers and that it would be an additional burden for a fan manufacturer to engage in appurtenance redesign for a product it may not manufacture. New York Blower added that all the market impact analysis done to date was accomplished using appurtenance-free fan data and cannot be used to draw conclusions on the performance of appurtenance-laden fans in the future. Further, New York Blower commented adding appurtenances adds significant complexity. (New York Blower, No. 33 at pp. 5–6)

In addition, New York Blower commented that the inclusion of appurtenances when testing fans and blowers will increase the required testing to a degree that is unsupportable by the majority of manufacturers in the fan industry. New York Blower added that the fan is the prime energy conversion device and that redesigning the fan to improve efficiency to accommodate appurtenances is unlikely to achieve acceptable results. New York Blower added that the test should be limited to the minimum testable configuration as described in AMCA 214–21 with the appropriate modifications to the fan to represent the fan operating in a system. One example of such, stated New York Blower, would be the installation of an inlet bell to represent an inlet duct. (*Id.* at p. 14)

JCI stated that it shared AMCA's comments regarding the rejection of the currently accepted section 6.4.2.4 [85] of AMCA 214–21 on handling appurtenances, which invalidates industry's significant volume of historical testing. (JCI, No. 34 at p. 2)

Morrison commented that fans and blowers should be tested in their minimum testable configuration and consistent with the considerations for appurtenances that are found in section 7.3 of AMCA 214–21. (Morrison, No. 42 at p. 6)

Robinson commented that the testing procedure expectation placed on the manufacturers of heavy industrial process fans and blowers is burdensome and impracticable. Robinson commented that the challenge is pronounced for heavy industrial process fan manufacturers when it comes to testing with appurtenances. Robinson explained that most heavy industrial processes require several subprocesses, often over the stretch of significant acreage of an industrial plant facility (*i.e.,* paper mill, petroleum refinery, pharmaceutical plant, mining facility, chemical plant, food production plant, etc.). Robinson commented that the air movement equipment required to operate these processes and subprocesses is robust, designed and engineered specifically for each application and installation, and also connected to and affected by all of the appurtenances of the plant's system. Robinson commented it is unknown how a fan manufacturer would test the fan with its appurtenances at any point before full installation and by that time, the fan is fully constructed and sold. Robinson stated that the location and timing of the testing will also be difficult as fans are often sold as part of a new subprocess in the midst of construction or as a replacement for a fan currently operating, which when shut down requires the idling of an entire industrial process. Robinson commented it is unclear to what extent industrial fan manufacturers will have to go in order to comply with this part of the rule. Further, Robinson stated that all historical testing, done over l00 years, has been done without appurtenances, and this rule would render all of that testing useless. (Robinson, No. 43 at p. 3) Robinson added that the inclusion of appurtenances when testing fans and blowers will add exponentially to the testing required. Robinson pointed out that it is customary to certify designs or fan performance based off of test block conditions or with appurtenances in their least restrictive settings. Robinson commented that information provided by suppliers of appurtenances is often inadequate to establish losses at conditions other than design, and for industrial process custom fan manufacturers, this would be a very significant burden as each unique configuration and basic model would be either tested or validated. Robinson added that the addition of appurtenances also brings system effect factors into play, which create significant complications. Robinson added that the test should be limited to the fan only (with or without a motor or drive system) (*Id.* at p. 9)

Greenheck commented that DOE did not propose to adopt the AMCA 214–21 Section 7.3 provisions for appurtenances and has provided a confusing stance on what is to be tested. Greenheck commented that there are several appurtenances, and combinations of appurtenances, available on fan products. Greenheck added that many appurtenances are mutually exclusive and should not or cannot be tested together. Greenheck further commented that appurtenances are generally intended to aid the end customer in accommodating building limitations or overall system design requirements and are not part of the basic fan performance. As currently written, stated Greenheck, the DOE rulemaking appears to require two-sample tests for each appurtenance and appurtenance combination, which represents an additional, significant testing burden for all manufacturers. Greenheck further provided an example to illustrate the high number of appurtenances for a single model, where with the combination of a two-sample test and wire-to-air testing, appurtenances would lead to 6,336 tests for a fan series with 11 sizes. (Greenheck, No. 39 at pp. 2–3)

NEEA commented that the treatment of appurtenances in the definition of a basic model is unclear in the current NOPR. In addition, NEEA noted that in Section III.C.5 of the NOPR, DOE proposed to adopt section 7.3 of AMCA 214–21. However, NEEA noted that DOE used language inconsistent with section 7.3 of AMCA 214–21 and in the proposed regulatory text included in Section VI, DOE provided text that ''replaces the provisions in section 7.3 of AMCA 214–21.'' NEEA commented that DOE's current language has the potential of dramatically increasing the number of basic models, as it does not clearly identify how appurtenances impact a basic model. (NEEA, No. 36 at p. 3)

[85] Although JCI references Section 6.4.2.4 of AMCA 214–21, DOE notes that the appurtenances are addressed in Section 7.3 of AMCA 214–21.

Loren Cook Company commented that there is a burden associated to testing any appurtenances sold on a fan. Loren Cook added that it has several products each with many sizes and have a dozen or more accessories that could affect performance and would result in excessive amount of testing required. (Public Meeting Transcript, No. 18 at pp. 65–66)

For fans and blowers other than air circulating fans, in view of the substantially high number and combinations of appurtenances as noted by AMCA, New York Blower, JCI and Greenheck, and to remain consistent with the definitions of minimum testable configurations as described in AMCA 214–21 [86] as noted by AMCA, DOE requires testing in accordance with section 7.3 of AMCA 214–21, which distinguishes between appurtenances that improve or reduce performance. As such, DOE is no longer replacing the provisions in Section 7.3 of AMCA 214–21. For appurtenances that improve fan performance, which include, but are not limited to inlet bells, diffusers, stators, or guide vanes, AMCA 214–21 specifies that these appurtenances should be included if always supplied with the fan when distributed in commerce. For appurtenances that reduce fan performance, which include, but are not limited to, safety guards, dampers, filters, or weather hoods, AMCA 214–21 states that if the appurtenance is always supplied with the fan when distributed in commerce, then it shall be tested with the fan. If the appurtenance is not always supplied with the fan when distributed in commerce, it shall not be tested with the fan. To align with the adopted definition of ''minimum testable configuration,'' DOE requires testing in accordance with section 7.3 of AMCA 214–21. In addition, DOE clarifies that its regulations would apply to the fan as distributed in commerce and would not account for any potential additional appurtenances added in the field. As noted by AMCA, such approach would permit the preservation of historical data and reduces test burdens.

For air circulating fans, in line with the provisions in Section 6.3 of AMCA 230–23, DOE requires that any appurtenances sold with the fan shall be included in the minimum testable configuration, as proposed.

In addition, in the July 2022 NOPR, DOE noted that for air circulating fans, the AMCA 230 committee was considering additional provisions to include in the next version of AMCA 230 to describe what should be considered as part of the test (*i.e.,* the ''minimum testable configuration''). The committee was considering the following: (1) If sold with the fan, an on/off switch or speed control device would be included in the minimum testable configuration. The power consumption of the on/off switch or speed control device would be included in the active and standby mode power measurements. (2) If multiple control devices are sold with the fan, only the standard fan control device would be used for testing. (3) Optional product features not related to generating air movement would not be energized for the purpose of testing. Optional product features not related to generating air movement include, but are not limited to, misting kits, external sensors not required to operate the fan, and communication devices not required to operate the fan. 87 FR 44194, 44225.

For air circulating fans, in the July 2022 NOPR, DOE tentatively determined that it is unlikely that additional features not related to air movement would remain in the on-position unless intended by the consumer. As such, requiring testing in their ''as-shipped'' configuration would not provide a more representative measure of energy use for air circulating fans. DOE proposed to add clarification that additional features not related to air movement be installed, but either powered off or set at the lowest energy-consuming mode during testing. Further, to avoid confusion as to which controller is used for testing in the case where multiple advanced controllers are offered, DOE proposed to add additional clarification to its specifications for appurtenances. Specifically, DOE proposed to clarify that if the air circulating fan is offered with a default controller, testing would be conducted using the default controller. If the air circulating fan is offered with multiple controllers, testing would be conducted using the minimally functional controller (*i.e.,* ''standard controller''). Testing using the minimally functional controller is consistent with the direction to test with additional features not energized during the power consumption measurement. Controller functions other than the minimal functions (*i.e.,* the functions necessary to operate the air circulating fan blades) are akin to additional features that do not relate to the air circulating fan's ability to create airflow. This proposed addition clarifies which controller to select. These proposals were in line with the additional provisions considered by the AMCA 230 committee at the time. *Id.* at 87 FR 44225–44226.

DOE did not receive any comments on these specific proposals.

Since then, AMCA 230–23 has incorporated these provisions in section 6.3. DOE is referencing the provisions in section 6.3 of AMCA 230–23.

12. Voltage, Phase, and Frequency

This section is only applicable to fans with a motor that are tested wire-to-air, where the electrical power supplied to the fan needs to be specified.

Regarding frequency, fans and blowers can be rated to operate at 50 or 60 Hz, be supplied by single-phase or multi-phase electricity, and can operate at a single rated voltage (*e.g.,* 115 V) or within one or more rated voltage ranges, or a combination of both (*e.g.,* 115/208–230 V). In the July 2022 NOPR, DOE stated that section 7.8 of AMCA 214–21 specifies that for fan electrical power measurement (when conducting a wire-to-air test), the fan must be operated using a 60 Hz supply unless that frequency conflicts with nameplate values. The voltage during the test shall match the highest allowable value that corresponds with the relevant nameplate. 87 FR 44194, 44226.

In the United States, 60 Hz frequency is the most representative, and DOE tentatively determined that fans rated for operation with only 60 Hz power supply would be tested with 60 Hz electricity and that fans capable of operating with 50 Hz and 60 Hz electricity would also be tested with 60 Hz electricity. DOE tentatively determined that it does not need to consider fans rated for operation with only 50 Hz power, since these fans are not relevant in the U.S. market. *Id.*

Regarding the phase to select for testing, DOE proposed to clarify which phase to use during the test as follows. DOE proposed to specify to test fans and blowers, including circulating fans, rated for operation with only a single- or multi-phase power supply with single- or multi-phase electricity, respectively. For fans and blowers, including circulating fans, capable of operating with single- and multi-phase electricity, DOE proposed that such fans must be tested using a multi-phase power supply, which is the most common power supply for industrial and commercial equipment. *Id.*

Regarding the voltage to select for testing, DOE proposed to clarify which voltage to use during the test as follows. For fans and blowers other than air circulating fans, DOE proposed to retain the provisions in section 7.8 of AMCA

[86] DOE is incorporating by reference AMCA 214–21 and relies on the definitions included in Sections 3 of AMCA 214–21, including the definition of minimum testable configuration as proposed in the July 2022 NOPR. *See* 87 FR 44194, 44257.

214–21 to specify testing at the highest rated voltage and align with existing industry standards. *Id.* For air circulating fans, DOE reviewed the provisions related to the supply voltage in the ceiling fan test procedure, which are also tested based on AMCA 230–15 (with errata). Section 3.4.3 and 3.4.4 of 10 CFR part 430, appendix U. DOE proposed the same provisions for air circulating fans that it uses for ceiling fans, with additional language to distinguish how to select the supply voltage for fans tested using single-phase and multi-phase electricity. Specifically, DOE proposed that the supply voltage must be: (1) for air circulating fans tested with single-phase electricity, the supply voltage would be (a) 120 V if the air circulating fan's minimum rated voltage is 120 V or the lowest rated voltage range contains 120 V, (b) 240 V if the air circulating fan's minimum rated voltage is 240 V or the lowest rated voltage range contains 240 V, or (c) the air circulating fan's minimum rated voltage (if a voltage range is not given) or the mean of the lowest rated voltage range, in all other cases; (2) for air circulating fans tested with multi-phase electricity, the supply voltage would be (a) 240 V if the air circulating fan's minimum rated voltage is 240 V or the lowest rated voltage range contains 240 V, or (b) the air circulating fan's minimum rated voltage (if a voltage range is not given) or the mean of the lowest rated voltage range, in all other cases. *Id.*

ebm-papst stated that the electrical power supply (frequency, phase, and voltage) are specified by the fan supplier. ebm-papst commented that any surveillance testing for enforcement of a regulation should be performed at the supplier-specified electrical conditions. ebm-papst commented that DOE restrictions on the permitted power supply would potentially limit the usability of fan performance data for specific projects due the very diverse nature of the fan industry. (ebm-papst, No. 31 at p. 10)

For fans supplied for use in the United States, AMCA advised that the frequency, phase, and voltage be 60 Hz, 1- or 3-phase, and 110 VAC or 230/460 VAC, respectively. AMCA added that the test procedure should conform to U.S. standards for fans sold in the United States. Additionally, AMCA stated that because these are the most prevalent electrical properties of fans sold in the market, the test procedure should be based on those properties. Additionally, AMCA stated support for the adoption of section 7.8 of AMCA 214 and not ''consider[ing] other options such as specifying a voltage for test similar to that proposed . . . for air circulating fans.'' AMCA noted that doing otherwise could negate historical fan data that was tested in accordance with AMCA 214. (AMCA, No. 41 at p. 24)

New York Blower commented in support of testing at 60 Hz. New York Blower commented that fans with application motors can be configured regularly with 1- or 3-phase voltage configurations at a variety of voltage levels. New York Blower stated that if the fan is rated and offered for sale at a variety of motors that require different voltages and phases, then it should be tested as offered. New York Blower added that bare fans can be driven by a torque meter. (New York Blower, No. 33 at p. 15)

Morrison commented that it supports the use of voltage, phase, and frequency for U.S.-targeted products be 110 VAC or 230/460 VAC, 60 Hz, and 1- or 3-phase. (Morrison, No. 42 at p. 6)

Nidec requested clarity on the voltages to consider in the test procedure. (Public Meeting Transcript, No. 18, at p. 56)

The frequency, voltage, and phase selected for testing can impact the determination of the input power and in turn the determination of the FEI or CFM/W metrics. Therefore, DOE specifies how manufacturers must select the frequency, phase, and voltage when testing in accordance with the DOE test procedure and cannot permit testing each fan and at the supplier-specified electrical conditions.

Regarding the frequency, DOE requires that fans rated for operation with only 60 Hz power supply be tested with 60 Hz electricity and that fans capable of operating with 50 Hz and 60 Hz electricity also be tested with 60 Hz electricity. DOE is not adopting provisions for fans rated for operation with only 50 Hz power supply, as these are not relevant to the U.S. market.

Regarding the phase to select for testing, DOE clarifies which phase to use during the test as proposed in the July 2022 NOPR. DOE requires testing fans and blowers, including circulating fans, rated for operation with only a single- or multi-phase power supply with single- or multi-phase electricity, respectively. For fans and blowers, including circulating fans, capable of operating with single- and multi-phase electricity, DOE requires testing using multi-phase power supply, the most common power supply for industrial and commercial equipment.

Regarding the voltage to select for testing, DOE specifies which voltage to use during the test as proposed in the July 2022 NOPR. For fans and blowers other than air circulating fans, DOE retains the provisions in section 7.8 of AMCA 214–21. For air circulating fans, DOE adopts the same provisions as proposed in the July 2022 NOPR, to distinguish how to select the supply voltage for fans using single-phase and multi-phase electricity. DOE's provisions related to voltage are similar to those used for ceiling fans and DOE believes these provide sufficient clarity on how to select the voltage for testing based on the voltage(s) of the air circulating fan as rated by the manufacturer.

13. Test Speeds for Air Circulating Fans

In the July 2022 NOPR, for single speed air circulating fans, DOE proposed to require that testing be conducted at the single available speed. For multi-speed fans with discrete operating speeds, and for variable-speed fans with continuously adjustable speeds, while DOE believed it is preferable to align the DOE test procedure with the accepted industry test procedures—in this case AMCA 230—as much as possible, DOE explained that it did not have data to determine the typical field operating speed(s) of air circulating fans and DOE tentatively determined that testing at each discrete speed (for multi-speed fans) or at each of the five speeds currently specified in AMCA 230–15 (with errata), rather than only requiring testing at the maximum speed, may provide a more holistic representation of an air circulating fan's performance over a range of service levels, which may in turn facilitate easier comparisons for consumers. In addition, DOE proposed to clarify that for variable-speed air circulating fans with a minimum speed that is greater than 20 percent of the maximum speed, the performance data would be captured and reported in five speeds evenly spaced throughout the speed range, including at minimum and maximum speeds.[87] 87 FR 44194, 44227.

In the July 2022 NOPR, DOE added that it was considering several alternative options for specifying the test speeds at which fans with multiple or variable speeds should be tested, including testing a high speed only, or testing in accordance with the speed requirements for large diameter ceiling fans in section 3.5 of 10 CFR part 430, appendix U, which specifies that testing must be conducted at maximum speed and at 40-percent speed or the nearest

[87] If the fan's maximum speed is 1000 RPM and the fan's minimum speed is 400 RPM, then the following speeds should be reported: 400, 550, 700, 850, and 1000 where each speed is equally spaced of 150 RPM or (1000–400)/4.

speed that is not less than 40-percent speed. DOE noted that regardless of the proposed tested speeds, performance data at additional speeds may be captured and reported to better define the shape of the fan performance curve (for example, additional measurements at 20, 60, and 80 percent of maximum speed). *Id.*

AMCA commented that AMCA currently does not have usage data for air circulating fans in the United States. AMCA noted that the AMCA 230 committee recommends rating air circulating fans at only maximum speed. AMCA commented that some small air circulating fans are supplied with solid-state controllers (SSC) for fan-speed reduction and recently, direct-drive air circulating fans with variable-speed EC motors have entered the market. However, AMCA commented that the current market for air circulating fans is predominantly single speed fans. AMCA added that there is no common number of available speeds (2, 3, 4, etc. speed fans) and the discrete speeds vary greatly (~95 to 60 percent of maximum speed). AMCA recommended that only the highest speed be used for the air circulating fan metric because consumers will benefit from comparing fans at a standardized condition and that using the highest speed is the only equitable way to do this for air circulating fans. AMCA stated that rating fans at different non-maximum speeds will cause consumers to be confused and potentially purchase significantly less efficient fans. AMCA provided an example comparison of a single speed fan (Fan 1) and a variable speed model (Fan 2) where both fans are used in agricultural applications and generate the same amount of airflow at maximum speed and Fan 1 consumes half the power of Fan 2 at high speed. AMCA commented that as currently defined in the NOPR, Fan 1 and Fan 2 would have the same proposed ACFEI rating of 1.01. (See Table III–11)

TABLE III–11—AIR CIRCULATING FAN PERFORMANCE COMPARISON

% Max RPM	36%	52%	68%	84%	100%
Airflow (CFM)	2,440	3,145	3,851	4,556	5,262
Fan 1 Power (W)	.....	.....	.....	.....	297.6
Fan 2 Power (W)	38.8	107.6	220	381.4	595.2
Fan 1 ACFEI (proposed)	*	*	*	*	1.01
Fan 2 ACFEI (proposed)	2.15	1.07	0.74	0.59	0.51
Fan 1 (CFM/W)**	.....	.....	.....	.....	17.68
Fan 2 (CFM/W)**	62.89	29.23	17.50	11.95	8.84

* **Note:** the AMCA comment included values at different speeds. However, for a single speed fan, only one speed is applicable.
** DOE added the CFM/W row for additional comparison.

AMCA commented that since air circulating fan heads in agricultural applications are often purchased to generate relatively high air speeds to cool large mammals (cows require 200–400+ fpm of air speed for cooling), the air circulating fans are very likely to run at higher speeds for the majority of their operating hours. In this instance, according to AMCA, the efficiency metric would mislead the consumer to believe that the single speed fan would consume the same amount of electricity as the highly inefficient variable speed fan. (AMCA, No. 41 at p. 26) AMCA added that similar to high-speed small diameter (HSSD) ceiling fans, air circulating fan heads are typically either single speed or do not have common discrete speeds, so speeds other than high speed may not be well defined. Additionally, stated AMCA, there are no data available to estimate a distribution of time spent at speeds other than high speed for use in an efficiency metric. AMCA commented that the operating speed(s) and time spent at each speed will vary greatly based on the application and potentially on the local weather conditions. Finally, commented AMCA, unlike ceiling fans where low speed operation can be used for destratification, the only utility of an air circulating fan is generating elevated air speed, which takes place at higher fan speeds. Therefore, AMCA recommended that similar to HSSD fans, DOE only rate air circulating fans at maximum speed. (AMCA, No. 41 at pp. 25–26)

Big Ass Fan commented that an [air circulating] fan with an ACFEI of 1 at full speed could have a ACFEI of 10 to 20 when the speed is reduced to the 20 to 30 percent range. Big Ass Fan commented that such approach would inflate the ACFEI metric such that a fan could have a ACFEI of 1 at full speed and a weighted average ACFEI of 7. In addition, Big Ass Fan commented that operating at 20 percent speed does not provide any utility as these fans are primarily designed to create air speed to increase the rate of heat loss off the human body, or off of an animal. As such Big Ass fan stated that the ACFEI metric as proposed would be rewarding to speeds that provide no utility and would not represent how the product is used. (Public Meeting Transcript, No. 18 at p. 55)

DOE collected additional speed data on air circulating fan performance data from the BESS certification database [88] and observed that over 80 percent of models are rated at high speed only. While DOE cannot confirm if these fans are single speed, the data seems to indicate that the market is predominantly single speed as stated by AMCA. In addition, as noted by AMCA and Big Ass Fans, a weighted average metric across different speeds may have unintended consequences, inflate the ACFEI metric, and disproportionally favor multi-and variable-speed fans, which would show significantly better ratings even when performing relatively worse than a similar single speed fan at the same airflow and maximum speed. In addition, the latest version of AMCA 230–23 (section 7.2.4.1 of AMCA 230–23) was revised to require testing at the highest speed only (maximum speed). Therefore, at this time, DOE is requiring testing at maximum speed only, which DOE believes is most representative of an average use cycle and would not be unduly burdensome for manufacturers to conduct. DOE notes that for multi-and variable-speed air circulating fans, section 7.2.4.1 of AMCA 230–23 provides that performance data at additional speeds may be captured to better define the shape of the fan performance curve (for example, additional measurements at 20, 60, and 80 percent of maximum speed). DOE adopts to reference these provisions and allows optional representations at lower speeds as allowed in AMCA 230–23.

In the July 2022 NOPR, DOE noted that AMCA 214–21 has provisions to

[88] Additional speed data collected in September 2022 included 435 models of air circulating fans with the following information: Manufacturer, Power Supply, Model Number, Style (*i.e.,* basket, box, panel, or tube), Size (in) (*i.e.,* impeller diameter), Guard configuration, Airflow (CFM), efficacy (CFM/W), Thrust (lbf), Input power (kW), Thrust Efficiency ratio (lbf/kW), 5D Centerline Velocity (fpm), and Speed (high, med, low, % of max). *See bess.illinois.edu.*

calculate performance data at non-tested speeds based on wire-to-air test results at different speeds. *See* section 6.2 of AMCA 214–21, ''Calculated Ratings Based on Wire to Air Testing,'' which references section 8.2.3, ''Calculation to other speeds and densities for wire-to-air testing'' and Annex G, ''Wire-to-Air Measurement—Calculation to Other Speeds and Densities (Normative).'' For air circulating fans, DOE tentatively determined that these sections do not apply because air circulating fans have a more limited range of operating speeds and DOE proposed to test at each speed where performance data is required. In the July 2022 NOPR, DOE noted that AMCA 214–21 also includes an annex that only applies to shaft-to-air tests and allows interpolating performance between tested speeds (Annex E of AMCA 214–21). For air circulating fans, DOE tentatively determined that these sections do not apply because air circulating fans are tested wire-to-air. 87 FR 44194, 44227.

In response to the July 2022 NOPR, AMCA commented that for ACF, only G.2.3 airflow and G.2.5.2 electrical power at zero static pressure apply. (AMCA, No. 41 at p. 27) AMCA commented that Annex E is not needed for air circulating fans because air circulating fans are tested and sold inclusive of motors. *Id.*

As previously stated, DOE is no longer referencing AMCA 214–21 for air circulating fans and DOE is not opting to reference sections 6.2 of AMCA 214–21, which references section 8.2.3 and Annex G; or Annex E of AMCA 214–21.

14. Run-In Requirements

In the July 2022 NOPR, DOE stated that section 7.4 of AMCA 214–21 specifies that all fans shall be run-in for not less than 15 minutes prior to the commencement of data collection and that the AMCA 230 committee was considering similar provisions for air circulating fans. DOE proposed that the minimum run-in requirement of 15 minutes for fans and blowers be applied to air circulating fans. 87 FR 44194, 44235.

Since then, AMCA 230–23 became available and sections 7.1.3 and 7.3 of AMCA 230–23 include a minimum run-in requirement of 15 minutes.

New York Blower commented that the proposed run-in requirements seem appropriate and are similar to current procedures and practices. (New York Blower, No. 33 at p. 17)AMCA and Morrison recommended that the minimum run-in time for any fan should be at least 15 minutes, which is consistent with DOE's proposal. (AMCA, No. 41 at pp. 28–30; Morrison, No. 42 at p. 7)

In this final rule, DOE is requiring that all fans shall be run-in for no less than 15 minutes prior to the commencement of data collection.

15. Determination of Equilibrium and Test Stability

As discussed in the July 2022 NOPR, both AMCA 210–16 and AMCA 230–15 require that steady readings must be obtained prior to the start of test; however, neither test standard provides specific variables with associated tolerances within which equilibrium can be quantified. To ensure repeatable and reproducible results from a test method, it is necessary to specify consistent requirements for determining when a fan is and is not at equilibrium before the commencement of testing. It is also necessary to specify a duration over which equilibrium must be established. 87 FR 44194, 44227–44228.

a. Fans and Blowers Other Than Air Circulating Fans

As discussed in the July 2022 NOPR, DOE reviewed the test chamber and test equipment accuracy requirements listed in section 6 of AMCA 210–16 to determine equilibrium requirements for fans and blowers other than air circulating fans. 87 FR 44194, 44229. DOE proposed that calculations of ambient air density, and measurements of input power (as measured by a reaction dynamometer, torque meter, calibrated motor, or electrical meter), and fan speed would need to fall within the tolerance window listed in Table III–12 prior to initiating the test. *Id.* In DOE's proposal, input power stability would be required on a single input power device. DOE proposed that fan system equilibrium would need to be verified over at least 5 minutes, with measurements for each variable recorded at a maximum of 5 seconds. *Id.*

TABLE III–12—TOLERANCE REQUIREMENTS FOR MEASURED VARIABLES TO ESTABLISH STABILITY FOR FANS AND BLOWERS THAT ARE NOT AIR CIRCULATING FANS AS PROPOSED IN THE JULY 2022 NOPR

Variable	Equilibrium tolerance
Ambient air density	±1 percent of mean.
Input power by reaction dynamometer.	±4 percent of mean.
Input power by torque meter.	±4 percent of mean.
Input power by calibrated motor.	±4 percent of mean.
Input power by electrical meter.	±2 percent of mean or 1 W, whichever is greater.
Fan speed	±1 percent of mean or 1 rpm, whichever is greater.

In the July 2022 NOPR, DOE discussed that ISO 5801 includes more stringent stability tolerance requirements for fan speed; however, DOE stated that since it was proposing requirements for both fan speed and input power, it was suggesting a less stringent tolerance on fan speed. *Id.* DOE requested comment on its proposal for determining if a fan that is not an air circulating fan has reached equilibrium prior to initiating testing, on the minimum duration and maximum interval over which equilibrium would need to be verified, and on which variables proposed in Table III–12 that, if not stable prior to test, would have the greatest impact on measured fan performance. 87 FR 44194, 44229.

During the public meeting associated with the July 2022 NOPR, Nidec commented that motor test methods require [motor] temperature stabilization and that the July 2022 NOPR did not discuss temperature stabilization. (Public Meeting Transcript, No. 18, p. 57) In the July 2022 NOPR, DOE stated that section 7.4 of AMCA 214–21 specifies that all fans shall be run-in for not less than 15 minutes prior to the commencement of data collection. 87 FR 44194, 44235. As discussed in section III.E.15, DOE is requiring that all fans shall be run-in for no less than 15 minutes prior to the commencement of data collection. The purpose of this requirement is to ensure the motor tested with the fan is appropriately warmed up and stable. While DOE has not provided specific temperature stabilization requirements for the motor, DOE expects that laboratories will sufficiently run-in the motor to avoid lengthy testing to demonstrate fan stability. ebm-papst commented that AMCA 210 and ISO 5801 testing has not caused them concerns about equilibrium. (ebm-papst, No. 31 at p. 11)

New York Blower commented that the signals being measured for larger fans have inherent instability. (New York Blower, No. 33 at p. 12) New York Blower also commented that a 5-minute interval between each test determination seems excessive,

particularly based on their experience of testing industrial fans; however, they understand if this is necessary for air circulating fans. (New York Blower, No. 33 at p. 16) In response, DOE notes that its intent in the July 2022 NOPR was that a fan would be considered stable if it met the proposed tolerance requirements over a 5-minute ''stability test'', not that each test would be 5 minutes in duration.

Robinson stated that the equilibrium requirements are reasonable; however, they added that not all laboratories are temperature controlled and therefore the density requirement may not be attainable for the duration of the test. Robinson commented that specifying equilibrium for density as it applies to centrifugal housed or radial housed fans would create a need for laboratories to add climate control systems or increase the sizes of their existing laboratories to maintain a density equilibrium. If this is only meant as a measure of starting a test that may be acceptable, but for the duration of a test a 1 percent change in density is unlikely to be maintained particularly as testing a fan will take several hours or span over more than one day. (Robinson, No. 43 at p. 7) Additionally, Robinson commented that they do not see a need for a tight restriction on speed variation if the data can be corrected to a common condition. (Robinson, No. 43 at p. 10) In response, DOE notes that the purpose of setting a tolerance on fan speed is to ensure stability prior to testing, and prior to correcting to a common condition.

Of the variables listed in Table III–12, calculated ambient air density, which is a function of dry bulb temperature, wet bulb temperature and barometric pressure, impacts the fan's test environment. It is important to ensure that the lab environment is stable, while fan stability is being assessed. Calculated air density for fans and blowers that are not air circulating fans is determined from the dry bulb temperature at plane 0 (T_{d0}), the wet bulb temperature at plane 0 (T_{w0}), and the barometric pressure, where plane 0 is defined in Table 2 of AMCA 210–16 as the general test area. Regarding Robinson's comment that it may be difficult to maintain calculated air density within ±1 percent of the mean over the duration of the test, DOE clarifies that the air density tolerance proposed in the July 2022 NOPR applies only to the determination of fan stability and that section 6.2.4.1 of AMCA 210–16 includes temperature and pressure measurement requirements when environmental conditions are varying. DOE would not expect temperature, relative humidity, and barometric pressure to vary outside of the ranges listed above over the timeframe necessary to determine stability, even in a building without climate control. However, DOE notes that since air density is used to determine fan performance, air density must be captured during each test run.

Greenheck recommended not including additional equilibrium or stabilization procedures because once the dynamometer or calibrated motor is initially warmed up, no additional benefit is gained by waiting to stabilize. (Greenheck, No. 39 at . 6) To substantiate its position, Greenheck provided example test data for housed centrifugal fans at a constant rpm that showed no difference in brake horsepower versus airflow when the test was completed with cold bearings, warmed bearing or running each duty point for 5 minutes before taking the test measurement. (Greenheck, No. 39 at p. 7, Figure 2) Greenheck also provided a plot of energy use as a function of airflow for an axial fan using a calibrated motor. (Greenheck, No. 39 at p. 8, Figure 3) Although data values were not provided, Greenheck stated that all power readings within the usable portion of the fan curve are within 1 percent whether the motor was warmed up and data collected, the motor was warmed up and data was corrected to 1200 rpm, or the motor was warmed up and data was taken after running for 5 minutes. (Greenheck, No. 39 at p. 7, Figure 2)

Section 6.1.2 of AMCA 210–16 states that ''statistically stable conditions shall be established before each determination'' and that ''trial observations shall be made until steady readings are obtained.'' This section of AMCA 210–16 provides no provisions for determining stable readings and provides no requirements for evaluating if conditions are statistically stable. Comments from AMCA and fan and blower manufacturers suggest that there are multiple ways a manufacturer may verify that a fan under test is considered stable prior to testing. Based on the data provided by Greenheck, ensuring that the dynamometer or calibrated motor is warmed up may be sufficient to ensure fan stability during test. However, DOE notes that it is required to ensure that its test procedures are repeatable—ensuring repeatability becomes especially important if enforcement testing is warranted to evaluate compliance with any potential energy efficiency standards.

AMCA and Morrison stated that there is a need to ensure both equilibrium prior to testing and stability during testing, and that DOE did not sufficiently differentiate between the two. (AMCA No. 41 at pp. 28–30; Morrison, No. 42 at p. 7) In the following sections, DOE discusses the test stability requirements that it is adopting for fans and blowers that are not air circulating fans. DOE notes that the purpose of these stability provisions is to clarify section 6 of AMCA 210–16 to improve overall repeatability and reproducibility of the test procedure. DOE does not expect these requirements to obsolete historical testing completed by the industry.

In its comments, AMCA recommended using the same approach for determining stability of air circulating fans and fans and blowers that are not air circulating fans. Specifically, AMCA stated that all measured values will fluctuate over time, and recommended averaging these values over a 120-second duration to ensure test repeatability. (AMCA, No. 41 at p. 28) AMCA also commented that these fluctuations may trend upward or downward, or may fluctuate around an average value, and provided two examples, one where measured power increases with time over a measurement interval of 300 seconds, and the second where measured power varies, but does not increase over the same measurement interval. (AMCA, No. 41 at pp. 28–29) AMCA further recommended that instrument filtering should be used to minimize measurement fluctuations and provided examples of how a measurement instrument could be set up to do this. (AMCA, No. 41 at p. 29) AMCA also suggested that fan speed stability would be established when the averaged results from two successive readings differ by no more than 1 percent or 1 rpm, whichever is greater, and that electrical input power stability would be established when the averaged results from two successive readings differ by no more than 1 percent or 1 watt, whichever is greater. *Id.* DOE interprets AMCA's comments to suggest that filtered fan speed and input power or torque measurements should be averaged over 120-second intervals and that the average over this interval should be compared to previous 120-second intervals to determine whether these variables meet the tolerance requirements discussed above. (*See* AMCA, No. 41 at p. 29, recommendation 3) But AMCA also stated that fan stability occurs much more quickly for fans and blowers that are not air circulating fans since they are tested against pressure and in a duct or in a chamber. (AMCA, No. 41 at p. 29) Additionally, for fans and blowers that

are not air circulating fans, AMCA suggested a different time interval for determining the test measurement value, specifically taking the average over a 15 second interval, but increasing the averaging duration to 60 seconds if individual measurements fluctuate by more than ±2 percent of the average over the 15-second interval. (AMCA, No. 41 at p. 30) For testing, Morrison Products suggested a similar approach, but with shorter time intervals, specifically, test measurement values would be determined by averaging over 10 seconds; however, if individual measurements fluctuate by more than ±2 percent of the mean, the duration over which the average should be taken would increase to 30 seconds. (Morrison Products, No. 47 at p. 7)

DOE agrees with AMCA that determination of fan stability should be a comparison of averages over successive time durations. However, because DOE expects that fans and blowers that are not air circulating fans will reach stability more quickly than air circulating fans, it believes determining average input power and fan speed over 120-second intervals may filter the data too much and may unnecessarily increase the time to confirm equilibrium. Instead, DOE has determined that ensuring the average fan speed and average input power over successive 60-second data intervals (*i.e.,* average of data points collected at least every 5 seconds over 60 seconds) are within the tolerances listed in Table III–12 is appropriate for determining fan speed and input power equilibrium. The 60-second data interval is consistent with the interval recommended by AMCA as a secondary option if filtered measurements fluctuate by more than ±2 percent over a 15-second test interval. (AMCA, No. 41 at p. 30) While AMCA's suggestion was specific for testing, DOE believes that a consistent data collection interval for both equilibrium determination and testing reduces the complexity of the test procedure and reduces test procedure burden since the last sampling interval for determining equilibrium interval may be used as a test measurement.

In its comments, AMCA provided a figure showing input power trending upward over a 300-second measurement interval. (AMCA, No. 41 at p. 29, Figure 7) DOE understands this figure to suggest that comparing average values between successive data collection intervals may not capture instances where fan speed or input power are consistently trending upward or downward over time. Upward or downward trends in fan speed or input power over successive test intervals indicate that the fan system has not reached stability and that stability data must be collected over additional 60-second time intervals until data within the measured time intervals are no longer consistently increasing or decreasing. Comparing the slope of the individual data within each time interval, in addition to ensuring required tolerances are met, provides information on whether the measured value is stable, or consistently increasing or decreasing over time. For example, a positive slope calculated for three consecutive time intervals indicates a consistent upward trend in the measured variable suggesting that the fan has not reached stability and additional intervals must be run until a negative slope is achieved. As a second example, if a positive, negative, and positive slope are determined for fan speed and input power over three consecutive intervals, these variables are likely stable.

As such, DOE has determined to add further specificity to the stability requirements outlined in section 6.1.2 of AMCA 210–16. Specifically, stability will be evaluated and confirmed over at least three 60-second data collection intervals. DOE believes that at least three data collection intervals are necessary to ensure that slope is not consistently increasing or decreasing for each successive test duration. Fan speed and input power shall be monitored at least every 5 seconds over each 60-second data collection interval. The following two requirements must be met for a fan to be considered stable and for testing to commence:

(1) The average of fan speed from one data collection interval to the next must be within ±1 percent or 1 rpm, whichever is greater; and the average input power by reaction dynamometer, torque meter or calibrated motor must be ±4 percent, or the average input power by electrical meter must be ±2 percent of the mean or 1 watt, whichever is greater. These values are consistent with those proposed in the July 2022 NOPR; however, the interval over which average speed and average input power is determined, and the comparison between these intervals has been further clarified.

(2) The slope of fan speed and the slope of fan input power over 60 seconds from one data collection interval to the next shall not be trending upward or trending downward. Specifically, if the slope of 3 or more successive data collection intervals are all positive or all negative, additional data collection intervals must be run until a negative or positive slope, respectively, is achieved.

For testing (*i.e.,* after equilibrium has been verified), Morrison recommended sampling and statistically averaging test measurements over 10 seconds and that if filtered measurements fluctuate by more than 2 percent of the average value, the averaging time shall be increased to 30 seconds. (Morrison, No. 42 at p. 7) AMCA, as discussed previously, recommended statistically averaging test measurements over 15 seconds and if filtered measurements fluctuate by more than 2 percent of the average value, the averaging time would be increased to 60 seconds. (AMCA, No. 41 at p. 29–30)

First, DOE clarifies that the tolerances specified in Table III–12, excluding the air density tolerance, should be maintained throughout the test. Second, average values from two successive 60-second sampling intervals meet the tolerance requirements specified in Table III–12 (excluding air density). DOE expects that maintaining the same data collection requirements for equilibrium determination and testing (*i.e.,* 60 seconds) will simplify the test and ultimately reduce test burden, since the last equilibrium measurement could be used as a valid test point. However, DOE also recognizes that laboratories may be able to achieve the specified tolerance on fan speed and input power over a shorter time interval, as suggested by Morrison. Therefore, in this final rule, DOE is specifying only that the sampling interval to determine average test values should not exceed 60 seconds, consistent with the sampling interval used to determine equilibrium.

Regarding AMCA's comment on data filtering, or damping, DOE recognizes that data filtering helps reduce noise or measurement fluctuation. DOE's requirement that data taken every 5 seconds must be averaged over a 60-second duration effectively filters the data with a time constant of 5 seconds.

b. Air Circulating Fans

In the July 2022 NOPR, DOE discussed the equilibrium options considered by the AMCA 230 committee. At the time, the committee was considering choosing three or four of the following values to determine equilibrium: fan speed, system input power, barometric pressure, and load differential. The committee was also considering that these variables would need to meet a specified tolerance after at least 5 minutes of the fan running, with measurements taken at least every 5 seconds. 87 FR 44194, 44228.

Furthermore, DOE had tentatively determined that the ambient air density, extraneous airflow (*i.e.,* test room ventilation), system input voltage,

system input current, system input power, fan speed, load, and load differential would impact test results. *Id.* Therefore, DOE proposed that measurements of these values would need to fall within a specified tolerance window listed in Table III–13 prior to initiating a test for air circulating fans. *Id.* DOE also proposed that measurements for each of the variables would be taken at least every 5 seconds over at least 5 minutes, providing a minimum of 60 data points from which equilibrium can be verified. *Id.*

TABLE III–13—TOLERANCE REQUIREMENTS FOR MEASURED VARIABLES TO ESTABLISH STABILITY FOR AIR CIRCULATING FANS AS PROPOSED IN THE JULY 2022 NOPR

Variable	Equilibrium tolerance
Calculated air density	±1 percent of mean.
System input voltage	±2 percent of mean.
System input current	±2 percent of mean.
System input power	±2 percent of mean or 1 W, whichever is greater.
Fan speed	±1 percent of mean or 1 rpm, whichever is greater.
Load	±1 percent of mean.
Load differential	±1 percent of mean.

DOE proposed that air density, as determined from dry bulb temperature, dew point, and barometric pressure measured over at least 5 minutes, would remain within one percent of the mean air density to establish equilibrium prior to fan testing. *Id.* The system input voltage, system input current, system input power, load, and load differential tolerances for evaluating equilibrium that DOE proposed were two times the equipment accuracy tolerances specified in AMCA 230–15 and identical to those discussed by the AMCA 230 committee working group at the time. *Id.* Additionally, DOE proposed that fan speed would be within ±1 percent of the mean rpm or 1 rpm, whichever is highest over at least a 5-minute duration to establish equilibrium prior to testing. *Id.*

Furthermore, in the July 2022 NOPR, DOE discussed possibly prioritizing the variables such that equilibrium must always be demonstrated for a specific number of the highest priority variables. *Id.* Alternately, DOE discussed possibly specifying a subset of the variables proposed, similar to what had been discussed by the AMCA 230 committee at the time. *Id.*

DOE requested comment on its proposal for determining that an air circulating fan has reached equilibrium prior to initiating testing, on the minimum duration and maximum interval over which equilibrium would need to be verified, and on the variables it proposed. 87 FR 44194, 44228–44229.

As discussed, AMCA recommended using the same approach for determining stability of air circulating fans and fans and blowers that are not air circulating fans and AMCA's comments are summarized in the previous section. For air circulating fans, AMCA stated that the AMCA 230 committee proposed the following requirements for equilibrium that will be included in the next edition of AMCA 230: readings shall be recorded when both speed and electrical power have stabilized; readings shall be recorded at least 15 minutes after start-up; the averaged results from two successive readings of electrical input power shall differ by not more than 1 percent or 1 watt, whichever is greater; and the averaged results from two successive readings of fan speed shall differ by not more than 1 percent or 1 rpm, whichever is greater. (AMCA, No. 41 at p. 28, 30)

Greenheck recommended that DOE adopt the run-in period and filtering methodology in the latest revision of AMCA 230 and that DOE handle air circulating fans in a separate rulemaking. (Greenheck, No. 39 at p. 8)

In the July 2022 NOPR, DOE stated that should the revised version of AMCA 230 publish prior to the publication of any DOE test procedure final rule, DOE intends to revise its test procedure provisions in line with the latest AMCA 230 standard, provided the updates to the AMCA 230 standard are related to topics that DOE has discussed and for which DOE solicited comments. 87 FR 44194, 44228. Sections 7.1 and 7.3 of AMCA 230–23 include provisions for run-in and determination of fan stability prior to test, specifically:

(1) Run-in shall be conducted for no less than 15 minutes prior to the commencement of data collection;

(2) Ambient conditions shall be measured prior to startup and throughout the test, as specified;

(3) Load differential, measured electrical input power and fan speed measurements shall be averaged for a minimum of 120 seconds;

(4) Measured electrical input power stability is established when the averaged results from two successive readings differ by not more than 1 percent or 1 watt, whichever is greater; and

(5) Fan speed stability is established when the averaged results from two successive readings differ by not more than 1 percent or 1 rpm, whichever is greater.

Based on its review of AMCA 230–23, review of the comments received to the July 2022 NOPR, and additional evaluation of DOE test data for air circulating fans, DOE is generally adopting the fan stability provisions in AMCA 230–23, with additional clarification, as discussed below.

Regarding the determination of ambient conditions, DOE notes that AMCA 230–23 does not provide additional specifications for determining ambient conditions. Of the variables listed in Table III–13, input voltage and room air density, which is a function of dry bulb temperature, wet bulb temperature and barometric pressure, impact the fan's test environment. It is important to ensure that environmental stability is achieved to minimize changes that impact fan performance, and that stability is maintained during the test to ensure test repeatability. DOE proposed in the July 2022 NOPR that calculated air density must remain within ±1 percent of the mean and input voltage must remain within ±2 percent of the mean over a period of 5 minutes with data collected at least every 5 seconds. 87 FR 44194, 44228. DOE received no comments from stakeholders regarding stability determination or proposed tolerance criteria for either input voltage or room air density. Therefore, DOE is adopting the equilibrium tolerance criteria for input voltage and calculated air density as proposed in the July 2022 NOPR. However, based on comments received regarding determining fan stability (*i.e.,* fan speed and load differential) and the language in AMCA 230–23, DOE is instead requiring that input voltage and room air density must meet the specified tolerance requirements over the full duration of a test, including the time it takes to demonstrate fan stability. While DOE proposed that determining equilibrium over at least 5 minutes, DOE recognizes that achieving equilibrium and capturing test data will vary depending on the fan, and has therefore opted to not specify a minimum time requirement for data capture. Finally, as discussed for fans and blowers that are not air circulating fans, since air circulating fans may be tested in facilities without climate control, ambient condition data collection may start after the run-in period has been completed, but before commencement of stability testing. In summary, this final rule specifies that input voltage shall be captured at least every 5 seconds and shall not vary by more than ±2 percent over the duration of each test (including stability determination) and calculated air

density shall not vary by more than ±1 percent over the duration of each test (including stability determination).

AMCA 230–23 specifies that stability must be established for electrical input power and fan speed; however, DOE notes that section 7.2 of AMCA 230–23 requires reporting of load differential. Since measurement of load differential is a required value, and used in later calculations, DOE has determined that stability must also be demonstrated for load differential, in addition to electrical input power and fan speed. DOE notes that it proposed a tolerance of ±1 percent of the mean for load differential in the July 2022 NOPR. 87 FR 44194, 44228.

While AMCA's comments to the July 2022 NOPR are consistent with the language in AMCA 230–23, AMCA's comments additionally suggest that comparing average values between successive data collection intervals may not capture an upward or downward trend in fan speed, input power, or load differential. (AMCA, No. 41 at p. 29, Figure 7) A lab may observe an upward or downward trend in these variables over successive data collection intervals if the fan has not been run-in for enough time and/or is not at equilibrium.

To account for continuous upward or downward trends in slope over multiple 120-second measurement intervals, and to address AMCA's comment, DOE is adding further specificity to the stability requirements outlined in section 7.3 of AMCA 230–23. Specifically, stability will be evaluated and confirmed over at least three 120-second data collection intervals. The 120-second data collection interval is consistent with the provisions in section 7.3 of AMCA 230–23 for determining fan stability. However, AMCA 230–23 and AMCA's comments to the July 2022 NOPR do not recommend a minimum number of data collection intervals for determining stability. DOE believes that at least three data collection intervals are necessary to ensure a mix of positive and negative slopes calculated for the data collected over successive 120-second intervals. If the slope for each of three intervals either all increase or all decrease, the variable being measured is trending up or trending down, respectively, and the fan is not at equilibrium (see similar discussion in the previous section for fans and blowers that are not air circulating fans). While more than a minimum of three data collection intervals would provide greater assurance that fan speed, input power, and load are stable, DOE selected a minimum of three test intervals to minimize test burden, while still ensuring that a laboratory can validate that slopes are not consistently positive or negative. Additionally, DOE expects that if a fan is appropriately run-in prior to testing, laboratories should be able to demonstrate speed, input power and load stability with the minimum of three test intervals. Fan speed, input power, and load differential shall be monitored at least every 5 seconds over each 120-second data collection interval. The following two requirements must be met for a fan to be considered stable and for testing to commence:

(1) The average of fan speed from one data collection interval to the next must be within ±1 percent or 1 rpm, whichever is greater; the average fan input power from one data collection interval to the next must be ±1 percent or 1 watt, whichever is greater; and the average load differential from one data collection interval to the next must be ±1 percent. The tolerance requirements for fan speed and load differential are the same as those proposed in the July 2022 NOPR (see Table III–13); however, DOE has tightened its tolerance criteria for fan input power from ±2 percent of the mean or 1 W, whichever is greater, to ±1 percent of the mean or 1 W, whichever is greater, to be consistent with section 7.3 of AMCA 230–23.

(2) The slope of fan speed, input power, and load differential over 120 seconds from one data collection interval to the next shall not be monotonic. Specifically, if the slope of 3 or more successive data collection intervals are all positive or all negative, additional data collection intervals must be run until a negative or positive slope, respectively, is achieved.

16. Test Figures for Air Circulating Fans

In the July 2022 NOPR, DOE noted that AMCA 230–15 (with errata) describes the test set-up that can be used to test various categories of air circulating fans and specifies that air circulating fan heads and table fans, which correspond to unhoused ACFHs, must be tested according to test figures 2A, 2B1, and 2B2. AMCA 230–15 (with errata) and also specifies that box fans and personnel coolers, which are both housed ACFHs, must be tested using test figures 3A and 3B. DOE noted that the AMCA 230 committee reviewed the existing text figures and was considering revising the allowable test figures to reflect that housed air circulating fans could also be tested using test figures 2A, 2B1, and 2B2, and unhoused air circulating fans would be tested using figures 3A and 3B. 87 FR 44194, 44229.

In the July 2022 NOPR, DOE tentatively determined that test figures 2A, 2B1, 2B2, 3A and 3B are appropriate for all air circulating fans. As such, DOE proposed to specify that any test figures that are specified in AMCA 230–15 (with errata) can be used for testing air circulating fans. *Id.*

Since then, AMCA 230–23 became available and specifies that test figures 2A, 2B1, 2B2, 3A and 3B [89] are appropriate for all air circulating fan in section 6.1 of AMCA 230–23.

AMCA commented that AMCA 230–23 will include slight refinement of the test figures from the 2015 version. Nevertheless, stated AMCA, each test figure is applicable to the fans in the scope of AMCA 230, which means that figures 2A, 2B1, 2B2, 3A, and 3B are applicable to all air circulating fans. (AMCA, No. 41 at p. 27)

As proposed, DOE specifies that any test figures specified in AMCA 230–23 can be used for testing air circulating fans.

17. Location of External Airflow Measurement

In the July 2022 NOPR, DOE noted that section 8.1.2 of AMCA 230–15 (with errata) specifies that the air velocity in the test room, not generated by the test air circulating fan, shall not exceed 0.25 m/s (50 fpm) prior to, during, and after the test. Velocity measurements shall be taken immediately before and immediately after the test to ensure that this condition is met. In addition, AMCA 230–15 (with errata) specifies the location of the extraneous airflow measurement shall be directly under the center of the fan at an elevation of 1701.8 mm (67 in.) above the floor. DOE noted that this provision is only applicable to fans tested according to Figure 1 of AMCA 230–15 (with errata) and that there is no location specified for extraneous airflow measurement for fans tested according to Figures 2A, 2B1, 2B2, 3A and 3B. 87 FR 44194, 44234–44235.

In the July 2022 NOPR, DOE noted that the AMCA committee was considering adding the following provisions to specify the location of the extraneous airflow measurement and to move these provisions from section 8.1.2 of AMCA 230–15 (with errata) into each of the figures. For Figure 1 of AMCA 230–15, the location of extraneous airflow measurement would be directly under the center of the fan at an elevation of 1.7m (67 in.) above the floor. For figures 2A, 2B1, 2B2, 3A and 3B, the location of extraneous airflow measurement should be at the center of

[89] In AMCA 230–23. These figures were re-numbered 10.2A, 20.2B1, 10.2B2, 10.3A and 10.3B

the fan at a distance of 1.5m (5 ft) downstream of the fan impeller. DOE agreed that these additional specifications were necessary to ensure test procedure repeatability, and therefore proposed to add these additional provisions as considered by the AMCA 230 committee. 87 FR 44194, 44235.

AMCA commented that it supports the proposed location, adding that positions to measure extraneous airflow were added to AMCA 230 toward its revision. AMCA commented that the positions are the same as noted in the NOPR. (AMCA, No. 41 at p. 28)

Since publication of the July 2022 NOPR, the test figures of AMCA 230–23 have been updated to specify the positions to measure extraneous airflow as proposed. In this final rule, DOE is directly referencing the test figures in AMCA 230–23 which include the location of the extraneous airflow measurement as proposed.

18. Transducer Type Barometer

In the July 2022 NOPR, DOE noted that section 6.5.2.1 of AMCA 230–15 (with errata) specifies that transducer type barometers shall be calibrated for each test. DOE stated that the AMCA 230 committee was considering removing this requirement from the revised version. DOE noted that it was also considering not including this requirement as it may be sufficient to require that the barometer be calibrated against a mercury column barometer with a calibration that is traceable to National Institute of Standards and Technology (''NIST'') or other national physical measures recognized as equivalent by NIST, without having to repeat calibration before each test. 87 FR 44194, 44235.

AMCA commented that calibration of transducer-type barometers for each test should be removed. AMCA commented that mercury-column barometers are discouraged and have often been removed from labs for safety reasons, but that transducers are very stable and are calibrated annually. AMCA commented that the AMCA 230 technical committee proposed the following change to barometer calibration, which will be included in section 6.5.2.1 ''Calibration'' of the 2022 edition of AMCA 230: ''barometers shall be calibrated and calibration traceable to NIST or other national physical measures recognized as equivalent by NIST. Barometers shall be maintained in good condition. All equipment used to measure psychometric data shall be calibrated with uncertainties by an ISO 17025 accredited calibration laboratory.'' (AMCA, No. 41 at p. 30)

Robinson commented that it does not recommend adding a requirement to calibrate transducer-type barometers for each test. (Robinson, No. 43 at p. 10)

Since publication of the July 2022 NOPR, section 5.5.2.1 of AMCA 230–23 removed the requirement for calibration of transducer-type barometers for each test. As noted by AMCA, it is sufficient to require that the barometer be calibrated with a calibration that is traceable to National Institute of Standards and Technology (''NIST'') or other national physical measures recognized as equivalent by NIST, without having to repeat calibration before each test. DOE adopts to reference the provisions in section 5.5.2.1 of AMCA 230–23, and to not require calibration of transducer-type barometers for each test as recommended by Robinson.

19. Reference Fan Electric Input Power Calculation for Air Circulating Fans

In the July 2022 NOPR, DOE proposed to rely on an FEI metric for air circulating fans. 87 FR 44194, 44237–44238. Section 4 of AMCA 214–21defines the FEI as the fan electrical input power of a reference fan (FEP_{ref}) divided by the fan electrical input power of the fan being rated at the same flow and total pressure conditions (FEP_{act}). Similar to how the FEP_{ref} of fans and blowers other than air circulating fans is calculated, DOE proposed to calculate the FEP_{ref} for air circulating fans based on:

- A reference fan shaft input power equation, used to calculate the reference fan shaft input power at a given duty point. This equation relies on a flow constant (Q_0) and a pressure constant (P_0), which represent how efficiency varies as a function of flow and pressure and an efficiency target, which was set to represent a market reference efficiency fan;
- A reference fan transmission efficiency equation, which calculates the reference fan transmission as a function of the reference shaft input power and represents a typical belt drive. *See* section 5.2 of AMCA 214–21; and
- A reference motor equation as described in section III.E.1 of this document.

DOE collected air circulating fan performance data from the BESS certification database [90] and performed regression analyses to determine the appropriate flow, pressure, and efficiency target constants for air circulating fans. DOE proposed to rely on the following constants: Q_0 = 3,210 CFM (rounded to the nearest 10); P_0 = 0 in.wg; and an efficiency target of 0.38 (38 percent). 87 FR 44194, 44231–44234.

In addition, DOE noted that it was considering using the term ''Air Circulating Fan FEI'' or ''ACFEI'' to differentiate the proposed FEI for air circulating fans from the FEI as it applies to fans and blowers that are not air circulating fans and from the CFEI as it applies to ceiling fans. 87 FR 44194, 44238

As noted in Section III.G of this document, DOE is not adopting the FEI or ACFEI as the metric for air circulating fans. Therefore, DOE is not opting to specify a calculation of FEP_{ref} for air circulating fans. Comments received on the air circulating fan FEI also relate to the metrics and are discussed in Section III.G of this document.

20. Rounding

As discussed in the July 2022 NOPR, AMCA 214–21 provides a method for calculating fan performance using the FEI metric; however, AMCA 214–21 does not provide normative rounding requirements for FEI. 87 FR 44194, 44234. DOE also discussed that it would consider referencing any rounding requirements in the updated version of AMCA 230, if those requirements were consistent with the rounding provisions that DOE proposed and solicited comments on in the July 2022 NOPR.[91] *Id.* DOE received no comments regarding standardization of rounding with the newest version of AMCA 230. DOE notes that AMCA 230–23 provides rounding provisions for blade span and tip speed but does not include rounding provisions in Section 8, calculations. While not discussed in the July 2022 NOPR, DOE notes that AMCA 230–15

[90] Data collected on March 22, 2022, included 507 models of air circulating fans with the following information: Manufacturer, Power Supply, Model Number, Style (*i.e.,* basket, box, panel, or tube), Size (in) (*i.e.,* impeller diameter), Guard configuration, Airflow (CFM), efficacy (CFM/W), Thrust (lbf), Input power (kW), Thrust Efficiency ratio (lbf/kW), 5D Centerline Velocity (fpm). *See bess.illinois.edu.*

[91] There is an error in section III.D.18 (Rounding) in the July 2022 NOPR. In the following sentence, it should have stated ''reporting'' instead of appurtenances, ''Should the revised version of AMCA 230 publish prior to the publication of any DOE test procedure final rule, DOE intends, after considering stakeholder feedback received in response to the proposals in this document, to revise the provisions related to appurtenances in line with the latest AMCA 230 standard, provided the updates in this standard are consistent with the provisions DOE is proposing in this NOPR, or the updates are related to topics that DOE has discussed and for which DOE has solicited comments to in this NOPR. Since the section title is ''rounding'', DOE has determined that, despite the error, and given that DOE received no comments the context of this sentence is clear.

also does not provide rounding requirements.

FEI is specified to the hundredths place in section 6.5.3.1.3 of ASHRAE 90.1–2019 (Fan Efficiency). Additionally, the DOE energy conservation standard for large diameter ceiling fans is the Ceiling Fan Energy Index (''CFEI''), where the CFEI metric is calculated according to AMCA 208–18, is specified to the hundredths place (*i.e.,* CFEI must be greater than or equal to 1.00 at high speed and 1.31 at 40 percent speed, or the nearest speed that is not less than 40 percent speed). 10 CFR 430.32.(s)(2)(ii). Additionally, Annex I of AMCA 214–21 (informative) specifies rounding the FEI to the hundredth place.

Therefore, in the July 2022 NOPR, DOE proposed rounding represented values of FEI to the hundredths place. *Id.* For consistency, DOE also proposed that represented values for FEP would be rounded to the hundredths place. *Id.*

How inputs to the calculation of FEI are rounded can impact the represented FEI (or FEP value). DOE reviewed the provisions related to rounding in the ceiling fans test procedure, which states that all measurements should be recorded at the resolution of the test instrumentation and that calculations shall be rounded to the number of significant digits present at the resolution of the test instrumentation. Section 3.1.1 of 10 CFR part 430, appendix U; 87 FR 44194, 44234.

In the July 2022 NOPR, DOE tentatively concluded that the rounding provisions in section 3.1.1 of 10 CFR part 430, appendix U are reasonable and that recording measurements at the resolution of the test instrumentation would provide sufficient significant digits for accurately calculating representative values of FEI and FEP. *Id.* Therefore, DOE proposed that all measurements would be recorded at the resolution of the test instrumentation and that calculations would be rounded to the number of significant digits present at the resolution of the test instrumentation. *Id.*

ebm-papst, New York Blower, AMCA, and Morrison agreed that rounding FEI to the hundredths place is reasonable. (ebm-papst, No. 31 at p. 11; New York Blower, No. 33 at p. 17, AMCA, No. 41 at p. 28; Morrison, No. 42 at p. 6). Additionally, New York Blower, AMCA and Morrison supported DOE's to round FEP to the nearest hundredth of a kW. (New York Blower, No. 33 at p. 17, AMCA, No. 41 at p. 28; Morrison, No. 42 at p. 6) AMCA and Morrison did, however, suggest that if the FEP is less than 1 kW, the value should be rounded to the nearest thousandth of a kW. (AMCA, No. 41 at p. 28; Morrison, No. 42 at p. 6) DOE received no comment on measurements being recorded at the resolution of the test instrument and calculations being rounded to the number of significant digits present at the resolution of the test instrument.

DOE is adopting the requirement to round the FEI to the nearest hundredths place. DOE considered stakeholder feedback on the rounding requirements for FEP and is specifying that FEP should be rounded to three significant digits. Therefore, if FEP is greater than 1 kW, the value would be rounded to the nearest hundredth of a kW and if the FEP is less than 1 kW, the value would be rounded to the nearest thousandth of a kW. DOE is additionally specifying that all measurements shall be recorded at the resolution of the test instrument and that calculations shall be rounded to the number of significant digits present at the resolution of the test instrument, consistent with its proposal in the July 2022 NOPR.

As discussed in detail in section III.G of this document, DOE is adopting an efficacy metric, reported in CFM/W, for air circulating fans. Although DOE discussed the possibility of adopting a CFM/W metric for air circulating fans in the July 2022 NOPR (87 FR 44194, 44234), DOE did not discuss or propose any rounding requirements for this metric. As such, DOE expects to propose rounding provisions for air circulating fans in a future certification rule.

F. Distinguishing Between Fans and Blowers and Air Circulating Fans

In the July 2022 NOPR, DOE noted that some manufacturers offer the same fan model with different mounting configurations. Depending on the mounting configuration, the same fan could either meet the definition of a fan tested per AMCA 210–15 or meet the definition of an air circulating fan and be tested per AMCA 230–15. DOE identified that air circulating fans with housing (*i.e.,* axial panel air circulating fans and box fans) can also be distributed in commerce as with brackets for mounting through a wall, ceiling, or other structure that separates the fan's inlet from its outlet and marketed as ''exhaust fans.'' In this case, DOE tentatively concluded these fans would be tested per AMCA 210–16 as they would meet the definition of an axial panel fan. DOE added that manufacturers who distribute these fans in commerce in both configurations and market the fans both for air circulation and exhaust applications typically test the fan using both AMCA 230–15 (with errata) and AMCA 210–16. DOE proposed that fan models that meet both the definition of an axial panel fan and the definition of an air circulating fan depending on the presence or absence of brackets for mounting through a wall, ceiling, or other structure that separates the fan's inlet from its outlet be tested according to both the test procedures for fans and blowers, excluding air circulating fans, and the test procedure for air circulating fans. 87 FR 44194, 44235.

AMCA commented that fan owners often apply fans differently from how manufacturers intended them to be used and that fan manufacturers did not have control over how panel fans are employed. AMCA noted that the presence or absence of brackets may not deter the use of a fan for the user's desired application. AMCA recommended that the criterion for the DOE-relevant test method is the fan nameplate information and coinciding technical marketing material and installation instructions. AMCA commented that if a fan is presented both as an air circulating fan and a fan and blower other than an air circulating fan by the manufacturer, then it shall be rated both ways, supported by both type of test reports. AMCA added that if a fan is a circulating panel fan, it should be required to be tested only as a circulating panel fan; if it is a panel fan, it should be required to be tested only as a panel fan; and if the fan can be used as either a circulating panel fan or a panel fan, it should be tested as both. (AMCA, No. 41 at pp. 30–31)

ebm-papst commented that the NOPR does not provide sufficient clarification of the distinguishing mounting features. Therefore, ebm-papst stated that an axial panel fan should be rated at least either as a ventilation fan or as a circulation fan. ebm-papst commented that rating of the same fan as per a second category should remain the choice of the fan suppliers, because they have to serve a diverse market with many unique fan selection criteria. (ebm-papst, No. 31 at p. 12)

The Efficiency Advocates commented in support of DOE's proposal that fans meeting the definition of both axial panel fans and air circulating fans be tested as both. The Efficiency Advocates commented that some manufacturers offer the same fan model with different mounting configurations. For example, stated the Efficiency Advocates, housed air circulating fans may also be sold with brackets for mounting through a wall or ceiling for use as an exhaust fan. The Efficiency Advocates added that this would reduce the potential for a loophole wherein a less efficient fan could be sold with different mounting configurations as a means of being

subject to a less stringent standard. (Efficiency Advocates, No. 32 at pp. 2–3)

DOE recognizes that manufacturers do not have control over how users ultimately decide to install their equipment. As a general matter, DOE's authority applies to products as manufactured and not at point of installation. (*See* generally 42 U.S.C. 6302.) DOE considers whether a fan is distributed in commerce with or without the presence or absence of brackets for mounting through a wall, ceiling, or other structure that separates the fan's inlet from its outlet. DOE requires that a fan that meets the definition of an axial panel fan and is distributed in commerce with components that enable it to be mounted through a wall, ceiling, or other structure that separates the fan's inlet from its outlet be tested in accordance with the test procedure for fans and blowers, excluding air circulating fans. DOE requires that a fan that meets the definition of an axial panel air circulating fan or box fan and is not distributed in commerce with components that enable it to be mounted through a wall, ceiling, or other structure that separates the fan's inlet from its outlet, be tested in accordance with the test procedure for air circulating fans. DOE requires that a fan that meets the definitions of both an axial panel fan and an air circulating fan (*i.e.,* axial panel air circulating fans and box fans) and is distributed in commerce with and without components that enable it to be mounted through a wall, ceiling, or other structure that separates the fan's inlet from its outlet be tested according to both the test procedures for fans and blowers, excluding air circulating fans, and the test procedure for air circulating fans.

In addition, AMCA commented that the current definitions used for certain air circulating fans, including axial panel fans, will lead to market confusion and the potential elimination of a significant number of products from the marketplace due to the product class assigned by DOE to the fan. AMCA provided an example of two essentially identical fans, except for the size of the fan. AMCA stated that per the current definitions, the first fan would be classified as an axial panel fan/air circulating axial panel fan and will likely remain available to consumers. However, AMCA commented that per the current DOE definitions, the second fan is a belt-driven ceiling fan, which requires the fan to meet the design requirements, including the capability of reverse operation and energy conservation standard, for ceiling fans. AMCA added that as Fan 2 is commonly applied, reversing the fan provides no benefit and the addition of the capability to reverse would reduce the efficiency of the fan at an added first cost to the consumer. In addition, stated AMCA, the second fan (assuming a common method of test) uses less energy to move the same volume of air, hence has a higher efficiency than Fan 1. AMCA finds it difficult to believe that consumers, retailers, and customs officials will be able to differentiate between DOE's axial panel Fan 1 and ceiling Fan 2. (AMCA, No. 41, p.31)

DOE notes that the requirement to include the capability of reversible action is not required for all ceiling fans s manufactured on or after January 1, 2007, and DOE included three exceptions for fans sold for industrial applications, fans sold for outdoor applications, and cases in which safety standards would be violated by the use of the reversible mode. 42 U.S.C. 6295(ff)(1)(A)(iii)) Further, as previously stated, the definition of ''fan and blower'' includes air circulating fans and excludes ceiling fans. Therefore, equipment that meets the definition of a ceiling fan would be excluded from the scope of equipment included under ''fan and blower.'' Any fan that is distributed in commerce with components that enable it to be suspended from a ceiling, and that meets the ceiling fan definition (*see* 10 CFR 430.2) in terms of being a non-portable device and for circulating air via the rotation of fan blades, is a ceiling fan. 87 FR 50396, 50402 (August 16, 2022). DOE will address any comments and concerns regarding the energy conservation standards for ceiling fans under a separate ceiling fan rulemaking.[92]

G. Metric

This section discusses the metrics adopted for fans and blowers other than air circulating fans and for air circulating fans.

1. Metric for Fans and Blowers Other Than Air Circulating Fans

AMCA 214–21 provides uniform methods to determine the FEP and FEI of a fan at a given duty point.[93] As explained, FEP describes the electrical input power of a fan in kW. AMCA 214–21 defines FEI as the ratio of the electrical input power of a reference fan to the electrical input power of the actual fan for which the FEI is calculated, both established at the same duty point. As stated, FEI is a dimensionless index for evaluating a fan's performance against a reference fan. Section 5 of AMCA 214–21 provides the equations to calculate the reference fan electrical input power as a function of airflow and pressure.

For fans other than circulating fans, the Working Group recommended using FEP as the primary fan metric and to allow using FEI for additional representation of energy use. The Working Group also recommended calculating FEI using the FEP of a fan that is exactly compliant with any future fan energy conservation standards. (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #6 at p. 5). The Working Group further recommended that the metric be evaluated at each operating point as specified by the manufacturer. (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendations #18 and #27 at pp. 10–11, 13–14). DOE explained that under this approach, for each basic model of fan, a manufacturer would have to determine the FEP of the fan at each operating point.

In the July 2022 NOPR, DOE also noted another metric called ''Fan Efficiency Grade'' or FEG, which is a numerical rating that represents the ratio of air power produced by the fan divided by the fan shaft power and is defined as a function of fan impeller diameter. FEG ratings are defined in discrete ''bands'' (*e.g.,* FEG 85, FEG 80, FEG 75, etc.) and are established in accordance with AMCA 205–12, ''Energy Efficiency Classification for Fans.'' [94] DOE noted that as defined in AMCA 205–12, the FEG rating is representative of only the maximum efficiency of the fan. As a result, depending on the actual operating conditions, a fan with a higher peak efficiency and FEG rating could consume more energy in a particular application than a fan with a lower peak efficiency and FEG rating. In addition, the FEG metric does not capture the performance of the motor, transmission, or motor controllers and does not differentiate among fans with motors, transmissions, and motor controllers with differing efficiency levels. DOE further noted that in its proposed regulation, the CEC is proposing to use

[92] *See* Docket No. EERE–2021–BT–STD–0011.

[93] As previously described, a duty point is characterized by a given airflow and pressure and has a corresponding operating speed. The collection of all duty points associated with a given speed is referred to as a ''fan curve.'' AMCA 214–21 provides methods to establish the FEP and FEI at any point within the operating range of the fan.

[94] *See* AMCA white paper available at: *www.amca.org/assets/resources/public/userfiles/file/Nospreads_FanEfficGrades.pdf*.

the FEI metric for fans and blowers.[95] Since the publication of the term sheet and of AMCA 214–21, a number of incentive programs and model energy codes and standards used in State energy codes rely on the FEI metric.[96] 87 FR 44194, 44237.

In the July 2022 NOPR, DOE proposed to apply FEI as the efficiency metric for fans and blowers. DOE stated that FEI would provide for evaluation of the efficiency of a fan or blower across a range of operating conditions, would capture the performance of the motor, transmission, or motor controllers (if any), and would allow for the differentiation of fans with motors, transmissions, and motor controllers with differing efficiency levels. In addition, the use of FEI would align with the industry test standard (AMCA 214–21) and drive better fan selections. 87 FR 44194, 44237.

In addition, DOE proposed that fan FEI would be evaluated in accordance with the DOE proposed test procedure at each of the fan's operating points within the range of air power and shaft input power proposed in scope (*i.e.,* at each duty point, as specified by the manufacturer within the range of air power and shaft input power in scope, *see* Section III.B.1 of this document). This approach is consistent with the term sheet recommendations and would require the determination of the FEI at each duty point as specified by the manufacturer. With this approach, the test procedure would not prescribe particular operating conditions at which the FEI is to be evaluated in order to calculate the FEI metric; instead, the FEI is determined at each duty point. Further, if DOE were to establish any potential energy conservation standards, compliance with that standard would be required at each duty point specified by the manufacturer within the range of air power and shaft input power proposed in scope (*i.e.,* operating range or ''bubble''), and for which the manufacturer publishes performance data. Manufacturers would not be allowed to publish performance data at non-compliant operating points. 87 FR 44194, 44237.

DOE further explained that in order to allow manufacturers to continue to publish performance data at any duty point, DOE also considered an alternative metric approach where the metric would be evaluated at set duty point(s) specified in the test procedure instead of having the FEI metric evaluated at each duty point as proposed. As a potential consideration, DOE provided an example of three duty points identified relative to the fan's BEP [97] at maximum speed and provided an example of a weighted average FEI metric (''WFEI'') established as the average FEI across all three duty points (*i.e.,* duty points of 100, 75, and 50 percent flow relative to BEP) and using a reference system curve in the case of multi- and variable-speed fans. DOE did not propose use of the WFEI metric in the July 2022 NOPR but requested comment on this alternative approach. 87 FR 44194, 44237–44238.

In response to the July 2022 NOPR, the CA IOUs commented in support of the proposed publication of the FEI and FEP at each duty point. (CA IOUs, No. 37 at p. 1)

ebm-papst stated support for the use of FEI for fans in the scope of this NOPR, other than air circulating fans. (ebm-papst, No. 31 at p. 12)

Greenheck commented that DOE should follow the recommendations of the term sheet, specifically in terms of the metric. (Greenheck, No. 39 at p. 2) Greenheck further recommended DOE utilize FEI as its efficiency metric as defined in AMCA 214–21 and required by ASHRAE 90. (Greenheck, No. 39 at p. 3)

Morrison commented that FEI is an appropriate metric to use in this proposed regulation for fans (that are not circulating fans). Morrison noted that ASHRAE and ICC energy codes, and States such as California, Oregon, and Florida, have adopted FEI in their State energy codes. The CEC is using FEI in its Title 20 regulation and that FEI is consistent with the term sheet. (Morrison, No. 42 at p. 7)

AMCA commented that FEI at maximum fan speed is the regulated metric for fans and blowers. AMCA commented that fan manufacturers and many other stakeholders have invested in determining and publishing FEI in lieu of FEG, FMEG,[98] and other efficiency metrics. (AMCA, No. 41 at p. 16) Further, AMCA commented that FEI is the most appropriate metric to use for a regulation for fans that are not air circulating fans. AMCA commented that FEI has been the metric used in ASHRAE and ICC energy codes since 2019, and States such as California, Oregon, and Florida have FEI in their State energy codes. AMCA further stated that the CEC is using FEI in its Title 20 regulation, which underwent extensive internal and public review—Title 20 is slated to take effect on Nov. 1, 2023.[99] AMCA further noted that the 2015 ASRAC term sheet has FEP as the regulatory metric and allowed for FEI to be used for marketing and other purposes. AMCA commented that since ASRAC, while code-change processes for ASHRAE 90.1, IECC, Title 20, and Title 24 were under way, industry and regulators agreed that FEI was a superior metric for regulating fans; hence these code/regulatory bodies settled on FEI and the AMCA 214 standard was developed around FEI as the regulatory metric. AMCA commented that the AMCA Certified Ratings Program evolved to certify manufacturer selection software ratings for FEI.[100] Also, stated AMCA, electric utility incentive programs have been developed around FEI for fans and blowers other than air circulating fans. AMCA also noted that for large-diameter ceiling fans, a derivative of FEI, Ceiling Fan Energy Index (CFEI), was developed to replace the average CFM/W metric DOE had previously used to regulate these products. (AMCA, No. 41 at pp. 31–32)

NEEA recommended that DOE establish the design point metric FEI as the regulatory metric for fans and blowers other than air circulating fans as it is an easy-to-understand rating (the higher the FEI value is, the better that fan is for a customer's specific application), accounts for one of the

[95] *See* Proposed regulatory language for Commercial and Industrial Fans and Blowers available in the following Docket: 22–AAER–01 at: *efiling.energy.ca.gov/Lists/DocketLog.aspx?docketnumber=22-AAER-01.*

[96] ANSI/ASHRAE/IES 90.1–2019, Energy Standard for Buildings Except Low-Rise Residential Buildings; ANSI/ASHRAE/ICC/USGBC/IES 189.1–2020, Standard for the Design of High-Performance; Green Buildings Except Low-Rise Residential Buildings; 2021 International Energy Conservation Code; 2021 International Green Construction Code; 2020 Florida Building Code: Energy Conservation; 2021 Oregon Energy Efficiency Specialty Code; 2022 California Building Energy Efficiency Standards (Title 24); incentive programs presently offered or under development by Seattle City Light, ComEd, and Xcel Energy *See* AMCA FEI Advocacy Brief available at: *www.amca.org/assets/resources/public/assets/uploads/0621-FEI_Advocacy_Brief_V3-20210715.pdf.*

[97] The BEP represents the flow and pressure values at which the fan total efficiency (ratio of total air power to fan shaft input power) is maximized when operating a given speed. Prior to the use of FEI, energy codes required selecting a fan with an efficiency within 10–15 percentage points of the BEP efficiency. *See* International Green Construction Code (2012); ANSI/ASHRAE/IES 90.1, Energy Standard for Buildings Except Low-Rise Residential Buildings (2013); ANSI/ASHRAE/USGBC/IES 189.1, Standard for the Design of High-Performance Green Buildings Except Low-Rise Residential Buildings (2014); International Energy Conservation Code (2015).

[98] DOE notes that FMEG refers to the Fan Motor Efficiency Grade metric used in Europe and determined in accordance with ISO 12759:2010, ''Fans—Efficiency classification for fans.''

[99] DOE notes that the CEC has since finalized its rulemaking. *See www.energy.ca.gov/rules-and-regulations/appliance-efficiency-regulations-title-20/appliance-efficiency-proceedings-11.*

[100] AMCA noted that a complete list of manufacturers with AMCA-certified ratings, is available at *www.amca.org/find-FEI.*

major drivers of fan energy use (fan sizing and specification) and will result in significant energy savings and better-sized fans for the end user. NEEA added that although FEI is a new metric, the fan market is ready and willing to adopt this metric for regulation as demonstrated by the development of an industry standard for FEI (AMCA 214–21), by manufacturers beginning to rate their fans using FEI, and by energy codes and utility incentive programs establishing requirements based on FEI. (NEEA, No. 36 at p. 2)

New York Blower stated support for AMCA's recommendations regarding the FEI metric. (New York Blower, No. 33 at p. 20) New York Blower added that FEI, as proposed in AMCA 214–21 provides a variety of utility, accurately represents efficiency, and provides energy consumption comparison between fans operating at the same duty point and that New York Blower is not aware of a better metric that represents energy consumption or the opportunity for energy savings. (*Id.* at p. 18)

In this final rule, DOE is applying FEI as the efficiency metric for fans and blowers other than air circulating fans. In addition, consistent with the term sheet recommendations, DOE is requiring that the FEI be evaluated in accordance with the DOE test procedure at each of the fan's operating points within the range of air power and shaft input power with thein scope (*i.e.,* at each duty point, as specified by the manufacturer within the range of air power and shaft input power in scope; *see* Section III.B.1 of this document). This approach requires the determination of the FEI at each duty point as specified by the manufacturer.

In response to the July 2022 NOPR, several stakeholders commented on the consideration of a WFEI metric for fans and blowers other than air circulating fans. The CA IOUs commented that while they support the proposed FEI metric, they equally support the concept of an alternate WFEI metric. However, the CA IOUs recommended revising the recommended alternative test points for fans without motor controllers because two of the points would fall in the unstable or stall operating region of the fan curve and provided illustrative examples (*i.e.,* the 75 percent and 50 percent of BEP airflow). Instead, the CA IOUS suggested a WFEI calculation using operating points based on pressure (*e.g.,* 80 and 60 percent of the BEP pressure). In addition, the CA IOUs suggested refining the definition of ''maximum speed.'' The CA IOUs commented that maximum speed is ambiguous and could refer to: (1) the maximum structural speed; (2) the maximum speed for which the manufacturer provides ratings; (3) the maximum speed the motor can sustain; (4) the maximum speed at which the motor controller allows the fan to operate; or (5) the maximum speed at which the fan can operate with a particular belt-drive transmission. The CA IOUs noted that interpreting maximum speed according to the last definition could provide an opportunity to evade any future standard as a manufacturer could certify performance at the speed resulting from operation with the fixed pulleys, which may incentivize some manufacturers to use a pulley set that results in a low speed or an adjustable pulley set to the lowest speed. The CA IOUs recommended the following framework to create a definition of maximum speed: (1) for bare shaft fans, the maximum speed shall be the maximum permitted speed of the fan as published by the manufacturer; (2) for fans sold with single-speed motors and direct-drive or flexible coupling transmissions, the certified speed shall be the speed achieved at each test point; [101] (3) for fans sold with single-speed motors and belt-drive transmissions, the fan shall be tested with a configuration that provides a speed the lesser of (a) the maximum speed that can be sustained by the motor or (b) the maximum structural speed published by the manufacturer; (4) for fans sold with a motor, speed controller, and direct-drive or flexible coupling transmissions, the tested point shall be the lesser of: (a) the maximum permitted speed of the fan as published by the manufacturer, (b) the maximum speed that can be sustained by the motor along the best efficiency curve, or (c) the maximum speed allowed by the controller and cannot be increased by a consumer; (5) for fans sold with a motor, speed controller, and belt-drive transmissions, the tested point shall be the lesser of: (a) the maximum permitted speed of the fan as published by the manufacturer, or (b) the maximum speed that can be sustained by the motor at its rated output along the best efficiency curve, using a transmission configuration that allows the motor to operate at its rated output. (CA IOUs, No. 37 at pp. 3–7)

ebm-papst commented that WFEI has no benefit over any of the other, much more deeply evaluated, fan efficiency metrics. In addition, ebm-papst stated opposition to the establishment of a reference system curve. ebm-papst commented that the fans it manufactures serve vastly different applications and this prevents usage of one or a few reference system curves for developing valid kWh predictions. (ebm-papst, No. 31 at p. 12)

Greenheck commented that the alternative WFEI metric would allow fan selections that use additional energy compared to a more energy-efficient fan for a given duty point and provided an illustrative example. (Greenheck, No. 39 at p. 4)

The CEC commented that a WFEI could result in an invalid representation of the efficiency range of the fan because it may reside in an area of operation where the fan stalls and is therefore not tested by manufacturers nor operated once installed. The CEC commented that when comparing the WFEI of two fans and assuming all three points to be used for the analysis reside in an area of operation where the fan will not stall, the WFEI generated will be heavily dependent on non-efficient operating conditions. Instead, the CEC recommended maintaining the FEI metric. (CEC, No. 30 at pp. 4–6)

NEEA commented against the use of WFEI as the regulatory metric as it does not align with the term sheet recommendation and would be an abrupt change to the current momentum behind FEI in the fan industry and energy codes. NEEA further noted some issues with the duty points considered for calculating the WFEI, which may be in the stall or surge region of the fan. NEEA also noted a lack of market information on the expected WFEI rating. NEEA further commented on the similarities between PEI (Pump Energy Index) and the WFEI metric and commented that while pump performance curves, which are used to calculate PEI, are readily available and did not represent an increase in burden for the industry to provide, fan manufacturers do not commonly publish performance data in this way, so there would be increased burden to produce these data, in addition to the testing required for certification. (NEEA, No. 36 at pp. 4–6)

Morrison commented that a WFEI metric would change the intent of the discussions and spirit of the ASRAC agreement and noted the following issues with such a metric: (1) WFEI is another version of FEG, which the Working Group rejected as a less than ideal metric for fans; (2) WFEI in most circumstances cannot be calculated using the points specified in the NOPR because some duty points may fall in the stall or surge region; (3) the WFEI for fixed-speed fans and variable-speed fans would have vastly differing values for the same fan and nothing related to their

[101] The CA IOUs noted that for many single-speed induction motor fans, the speed will change along the flow-pressure curve.

effect on energy use. Morrison further added that a FEG-style rating was considered by all involved in the ASRAC as inferior to the FEI rating method. Morrison added that the WFEI is an adjusted FEG and not at all like the FEI/FEP metrics proposed and agreed to in the term sheet. (Morrison, No. 42 at pp. 7–8)

Robinson commented on the unlikelihood that using a weighted average measure will result in the intended energy conservation sought by the proposed rule. Robinson added that the heavy industrial fan selection process includes several realities that may not be part of selection of a commercial fan. Robinson stated that heavy industrial process fans often operate on several data points and often require their own permitting process prior to installation. Robinson commented that heavy industrial process fans are subject to unique challenges in operation: they may have acid in the air stream; they may have rock product in the air stream; they may be subjected to high heat, etc. Robinson commented that the unique challenges of the operation of the HIP fan often drive fan selection more than the efficiency of the fan. Robinson commented that the understood, desired end result of implementing a weighted average measure is to force consumers to purchase more efficient fans. However, Robinson concluded, because of the factors described above (and others) it's unlikely that heavy industrial process operators will choose a specific fan type because of its efficiency rating alone. (Robinson, No. 43 at p. 4)

AHRI commented that DOE's consideration of an alternative metric, WFEI to replace Fan Energy Index (FEI)—the metric derived by industry test procedure AMCA 214–21—could constitute a proposal that is contradictory to the National Technology Transfer and Advancement Act of 1995 (NTTA), Public Law 104–113, and the Office of Management and Budget (OMB) Circular A–119, Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities. AHRI commented that both documents direct Federal agencies to adopt voluntary consensus standards unless they are inconsistent with applicable law or otherwise impracticable, as noted by DOE. (86 FR 70892, 70910, at fn 15 (Dec. 13, 2021)) AHRI commented that WFEI is a separate metric with a distinct calculation procedure that has not been evaluated by either fan manufacturers or their customers. (AHRI, No. 40 at p. 4) AHRI added that DOE has not presented supporting documentation that WFEI achieves the differentiation sought. (AHRI, No. 40 at p. 4) AHRI expressed its concern that the introduction of a WFEI metric did not undergo public comment in the October 2021 RFI. AHRI added that due to the lengthy history and complexity of commercial and industrial fans and the introduction of WFEI, stakeholders should be given additional time to review and ask DOE questions in order to provide meaningful comments that will assist DOE in this rulemaking process. (AHRI, No. 40 at p. 5) AHRI further commented that the proposed WFEI metric does not align with the term sheet and is not an appropriate metric. (*Id.* at p. 6)

AMCA commented that the WFEI was a deviation from the ASRAC term sheet which required the industry and advocates to expend time and resources to research and analyze a whole new metric (AMCA, No. 41 at p.2) AMCA added that there were numerous problems with using a WFEI metric. First, AMCA noted that the duty points considered in the NOPR to evaluate the WFEI would fall in regions where many fans would operate in stall or surge. Therefore, AMCA commented that if a weighted average value of BEP flow were used, different duty points would need to be chosen and noted that an optimal selection point for a backward-inclined fan typically is at 95 percent of peak pressure. In addition, AMCA commented that the considered WFEI metric would encourage fan designers to target higher efficiency at lower airflow, which would not result in energy savings. AMCA commented that fans are more often selected for operation at airflows greater than the BEP airflow and fan designers should be encouraged to improve efficiency at these greater airflows where fans are often applied. AMCA also included an example in Table 5 to illustrate how WFEI values for different sizes of the same fan model will remain approximately the same, which would drive fan selections toward the smaller, less-efficient sizes, which are less expensive. AMCA further identified additional issues with the potential consideration of a WFEI metric for fixed-speed fans and variable-speed fans related to the risk of having the duty points located in the stall/surge regions, as well as system effects and the noted that air-system curves are not necessarily quadratic parabolas through the origin due to filters, coils, and other devices which tend to introduce a linear component to the system resistance curve. Further, AMCA commented that it does not believe a WFEI would result in any net energy savings based on rating calculation. AMCA noted that the WFEI metric would assume the fan with a VFD will be selected because it has a higher rating than a fan without a VFD. However, AMCA commented, that would not guarantee the fan will be operated at varying speeds and if the fan is run at constant speed, the fan with the VFD will consume more energy because of additional drive losses in the VFD. Therefore, AMCA commented that the WFEI approach does not accurately reflect the presumed energy savings in application. In addition, AMCA commented that using a WFEI metric would change FEI from a duty-point metric to a product-based metric similar to FEG. AMCA noted the significant history revolving around the shortcomings of the FEG metric and how fans of similar FEG ratings can consume vastly different amounts of energy at specific duty points while a FEI metric would accommodate and identify these differences in energy consumption. (AMCA, No. 41 at pp. 32–34)

JCI stated that it shares AMCA's comments regarding the use of a new metric, weighted average (WFEI), versus the established FEP/FEI metrics which is also not in alignment with the 2015 term sheet. (JCI, No. 34 at p. 2)

New York Blower commented that the challenges of applying a product-based efficiency metric for fans (such as WFEI) because fans adapt to the system in which it is installed and the same fan can operate at high efficiency in one system and perform poorly in a different system. New York Blower commented that the FEI metric was developed to drive fan selections to peak efficiency and yield the greatest energy savings. (New York Blower, No. 33 at p. 2) New York Blower commented that the calculation of the WFEI would select duty points in the stall region for many fans. New York Blower added that they examined different ways to select duty points that could be combined into a WFEI metric and were unable to find an algorithm that could be employed across all fan categories without forcing selection of unacceptable duty points. Instead, New York Blower suggests that the BEP at maximum operating speed should be chosen as a single value to compute the WFEI. In addition, New York Blower commented that fans with variable speed drives would have an artificially high WFEI rating even if that fan is never operated away from a single speed and would allow less efficient fans marketed with a controller to remain in the market. New York Blower added that in the industrial market, a majority of applications are not operated

at or applied in a variable speed solution. Instead, there have seen an increase in cyclic activity in fans over the recent years (*i.e.,* the fans are being turned off when not operated). (New York Blower, No. 33 at p. 3) If DOE's intent is to promote variable speed drive installation, New York Blower commented that then either a direct credit to the required FEI performance requirement, or an installation credit at the time of calculations to overcome the insertion loss of the variable speed drive is appropriate. (New York Blower, No. 33 at p. 19) Finally, New York Blower commented that a product-based metric will, ultimately, result in product elimination from the market if efficiency requirements are raised high enough. Because of the vast performance range of a fan, New York Blower stated that it is unlikely the energy savings would be realized in proportion to the products eliminated from the market. Instead, New York Blower commented customers would lose utility from the loss of product availability. New York Blower commented on the complexity of implementing an application-based metric (such as FEI), acknowledging that a product-based metric (such as WFEI) is clearly an easier path to declaring an industry regulated. However, New York Blower recommended that DOE consider the value of saving energy be balanced with the urgency to complete a regulatory effort. (New York Blower, No. 33 at p. 4)

In the July 2022 NOPR, DOE did not propose to adopt the WFEI as the metric for fans and blowers other than air circulating fans. The WFEI metric was considered in the July 2022 NOPR in order to provide a potential alternative metric that would allow manufacturers to publish ratings at operating points with a potentially non-compliant FEI, should DOE establish energy conversation standards for fans and blowers other than air circulating fans. 87 FR 44194, 44237–44238. As noted by the CA IOUs, the CEC, Morrison, New York Blower and AMCA, the determination of such metric is challenging as some the operating points used in the calculation of the WFEI could fall in the stalling operating region of the fan. In addition, as highlighted by NEEA, Morrison, and AHRI such metric would not align with the term sheet recommendations. Further as stated by Greenheck, AMCA, New York Blower and Robinson, a fan with a higher WFEI may not necessarily result in less energy use. As noted previously, DOE establishes the FEI as the metric for fans and blowers other than air circulating fans, consistent with the term sheet recommendations and industry practice. Therefore, DOE is not adopting a definition of maximum speed and is not adopting to specify operating points for the calculation of the WFEI.

In response to the July 2022 NOPR, and regarding the ability to publish performance data for non-compliant duty points, the Efficiency Advocates commented that they continue to support the development of a fan efficiency metric and regulatory framework that drives better fan selections, but they encourage DOE to consider how this goal can be achieved while accommodating the potential need for manufacturers to show certain non-compliant operating points. The Efficiency Advocates commented that the original framework for improving fan selection was to limit the range of operating points, as shown in manufacturer literature and selection software, only to compliant operating points. They added that manufacturers have raised concerns regarding the need to show certain non-compliant operating points for safety reasons. Therefore, they encourage DOE to explore options for a regulatory framework for fans that would drive better fan selections, while accommodating the potential need for additional published information. For example, DOE could consider the feasibility of limiting fan selections returned in manufacturer selection software to those that are compliant at the specified operating point while allowing manufacturers to show certain non-compliant operating points (*e.g.,* in the high pressure, low airflow operating range) for those compliant fan selections. (Efficiency Advocates, No. 32 at p. 1)

Greenheck commented that it remained neutral on the topic of showing noncompliant points on the fan curve after a compliant fan is selected from a list of potential fan options. Greenheck added that this concept was not part of the proposed rulemaking and was suggested as an alternative to the flawed WFEI metric. Greenheck commented that the display of noncompliant points for safety or retrofit applications is an issue for the Energy Regulators, Advocates and built-up equipment manufacturers to discuss and determine the impact upon the industry and the potential value or burden of not showing those values. (Greenheck, No. 39 at p. 5)

NEEA recommended that DOE works together with stakeholders to determine the compliance, certification and enforcement approach for FEI. NEEA stated that NEEA and industry partners are in active collaboration to address DOE's concerns about compliance, certification and enforcement and expect to present additional comments with specific proposals after the comment period has closed. (NEEA, No. 36 at p. 3) NEEA commented in support of allowing manufacturers to publish non-compliant fan information stating that manufacturers need to be able to publish information on non-compliant installations of a fan to inform sizing. If this information is published, NEEA recommended that DOE provide direction on how manufacturers should make it clear that non-compliant fans should not be selected—such as different or grayed-out coloring for visual representations of fan performance. NEEA added that DOE could also require that manufacturer's selection software provide clear warnings and not allow the purchase of fans with FEI less than 1.0. (NEEA, No. 36 at p. 4) NEEA further commented that the process for compliance will be different for FEI compared to other regulated metrics. NEEA suggested two options: (1) Software compliance: Manufacturers could certify compliance of their selection software—the system a user interacts with when selecting a fan for purchase (NEEA noted that this recommendation aligned with Recommendation #26 of the term sheet); and (2) Compliant mapping: For each model, NEEA commented that DOE could require manufacturers to submit the operating conditions that resulted in a compliant FEI. These operating conditions could be organized in a ''compliant window'' or mapping similar to a fan operating curve; DOE could confirm that this window was correct when they review the CCMS submission. (NEEA, No. 36 at pp. 3–4)

In this final rule, DOE is not establishing energy conservation standards for fans and blowers and therefore this final rule would not result in any complaint window or non-complaint operating points as noted in Greenheck and NEEA's comments. DOE will consider issues related to representations and compliance to any potential energy conservation standard in a separate energy conservation standards rulemaking.[102]

2. Metric for Air Circulating Fans

In the July 2022 NOPR, DOE proposed to incorporate by reference AMCA 214–21 for air circulating fans, which relies on the FEP and FEI metrics (''wire-to-air metrics'') for air circulating fans. DOE also presented comments from AHRI,

[102] *See* rulemaking docket: EERE–2022–BT–STD–0002.

AMCA, ASAP, ACEEE, NRDC, and the CA IOUs in support of a FEI metric for air circulating fans.[103] Specifically, ASAP, ACEEE, NRDC cited advantages for FEI such as representativeness of energy use, straightforward interpretation by consumers, ability to account for efficiency differences between fans of the same diameter that deliver the same airflow, consistency with other fan metrics [104] while the CA IOUS mentioned the ability to account for air velocity.[105] [106] 87 FR 44194, 44236–44237.

In addition, to account for variations in fan speeds, DOE proposed the following, depending on the air circulating fan's speed capability: for single speed fans, DOE proposed that the FEI be evaluated at the single available speed and corresponding duty point. For multi-speed fans and variable speed fans, in the absence of data to characterize typical operating speeds, DOE proposed to calculate the FEI based on the weighted average FEI at each of the tested fan speeds, and that each speed be apportioned an equal weight. (*e.g.,* if the FEI is calculated at five speeds, each speed is given 20 percent in the calculation of the weighted average FEI). DOE tentatively determined that while DOE has not found data to characterize the field operating speeds of air circulating fans, a more representative FEI can be calculated by using a weighted average across multiple speeds and weighting all those speeds equally (when compared to calculating the efficiency at only high speed). DOE noted that it would still allow manufacturers to make representations of performance using CFM/W. 87 FR 44194, 44238.

DOE also stated that AMCA 230–15 provides methods to determine FEP of air circulating fans as well as efficacy (*i.e.,* amount of flow per unit of electrical input power produced in CFM/W) and overall efficiency (*i.e.,* amount of thrust per unit of electrical input power produced in lbf/W). *Id.* at 87 FR 44237. In the July 2022 NOPR, DOE indicated that it was aware that the AMCA 230 committee may consider specifying which metric to use in the updated version of AMCA 230 when evaluating the energy performance of air circulating fans. While the NOPR proposed to rely on FEI, DOE stated it was considering alternative metrics such as CFM/W, including weighted average CFM/W for multi- and variable-speed fans, as well as alternative weights for multi- and variable-speed fans. In addition, DOE discussed potentially using the abbreviation ''ACFEI'' (air circulating fan FEI) to distinguish this metric from the FEI specific to fans and blowers other than air circulating fans. 87 FR 44194, 44238–44239.

Since the publication of the July 2022 NOPR, AMCA 230–23 was published and section 7.2.4.1 includes revised provisions regarding test speeds to require testing at maximum speed only, with additional optional tests at lower speeds.

As discussed in section III.E.20 of this document, for the July 2022 NOPR, DOE collected air circulating fan performance data from the BESS certification database and performed regression analysis to determine the appropriate flow, pressure, and efficiency target constants for air circulating fans needed to calculate the FEI metric. DOE proposed to rely on the following constants: Q_0 = 3,210 CFM (rounded to the nearest 10); P_0 = 0 in. wg; and an efficiency target of 0.38 (38 percent). 87 FR 44194, 44230.

In response to the July 2022 NOPR, the Efficiency Advocates commented in support of using FEI as the metric for air circulating fans because it is both representative of energy usage and straightforward for purchasers to interpret (for example, a FEI of 1.1 represents about a 10 percent reduction in energy usage in comparison to an FEI of 1). Importantly, the Efficiency Advocates commented that the FEI accounts for inherent efficiency differences between fans of the same diameter that deliver different airflows. The Efficiency Advocates added that using FEI for air circulating fans would provide consistency with the other non-air circulating fans fan categories included within the scope of the proposed test procedure. In addition, the Efficiency Advocates commented in support of testing variable- and multi-speed air circulating fans at multiple, discrete speeds. They agree with DOE that testing and rating multi-speed fans at a range of speeds will better inform purchasers about fan efficiency across a range of operating speeds. They are also concerned that testing multi-speed air circulating fans only at high speed could result in lower ratings relative to single speed fans due to additional control losses. In other words, while a multi-speed fan may save energy in real-world applications, a rating only at high speed could make it appear less efficient than a comparable single speed fan. Thus, the Efficiency Advocates support DOE's proposal to test variable-/multi-speed fans at multiple speeds. (Efficiency Advocates, No. 32 at p. 2)

ebm-papst commented that FEI provides no benefit with ACFs. Instead, ebm-papst supports making CFM/W the regulated metric because this metric has served users of ACFs well. (ebm-papst, No. 31 at pp. 11, 13)

The CA IOUs commented that BESS Laboratories, an important certifying body for the agricultural fan market, uses a CFM/W metric. The CA IOUs commented that DOE used data from BESS Laboratories to inform its NOPR and similarly, many state utility programs use the BESS Laboratories data to provide rebates incentivizing farmers to use energy-efficient circulating fans. Although a FEI-based metric for circulating fans is likely superior, it would disrupt the market if CFM/W were not allowed to be used 180 days after the final publication of this rule. The CA IOUs recommended that DOE allow the publication of CFM/W and remove it in a future rulemaking (CA IOUs, No. 37 at p. 10) In addition, the CA IOUs commented that DOE should gather additional air circulating fan performance data to develop a new FEI-based metric. The CA IOUs noted that BESS certification database only represents a portion of the air circulating fan market. Specifically, the CA IOUs noted that the air circulating fans tested by BESS Laboratories are among the most efficient in the market and that manufacturers typically will only send their best-performing fans to qualify for utility rebates. The CA IOUs commented that the basis for the new equation should include sampling from the vastly larger air circulating fan market, including commodity fans sold in the retail market. For this reason, the CA IOUs recommended that DOE continue gathering information on the larger market and base the new metric on that data. (CA IOUs, No. 37 at p. 11)

AHRI commented that DOE did not provide data to characterize the field operating speeds of air circulating fans. However, DOE proposed that a more representative FEI can be calculated by using a weighted average across multiple speeds and weighting all those speeds equally (when compared to calculating the efficiency at only high speed) without offering substantiation of this conclusion. Further, AHRI commented that DOE also stated that CFM/W can continue to be used to represent performance of air circulating fan heads; however, this is absent in the proposed regulatory text. (AHRI, No. 40 at p. 4)

AMCA recommended efficacy (in CFM/W) as the regulated efficiency

[103] (AHRI, No. 10 at p. 2; AMCA, No. 6 at p. 9; ASAP, ACEEE, NRDC, No. 7 at p. 2; CA IOUs, No. 9 at p. 2).

[104] (ASAP, ACEEE, NRDC, No. 7 at p. 2).

[105] (CA IOUs, No. 9 at p. 2).

[106] See also (AHRI, No. 10 at p. 2; AMCA, No. 6 at p. 9).

metric for air circulating fans because air circulating fans are rated at only one volumetric flow rate (speed) at zero fan static pressure. AMCA commented that FEI does not add any advantages over simpler metrics for air circulating fans. (AMCA, No. 41 at p. 28) However, AMCA commented that users have for years selected and compared air circulating fans based on CFM/W ratings. AMCA commented that a change of the metric would cause confusion among many stakeholders. In addition, AMCA commented that requiring testing at multiple speeds would negate nearly all historical test data, provide an efficiency metric that confuses consumers, and create an inequitable market that rewards inefficient multiple speed fans that lack consumer utility. (AMCA, No. 41 at pp. 16–17) AMCA added that all considered air circulating-fan metrics (efficacy, thrust efficiency, and single-speed ACFEI) are based on measured fan thrust and fan air density and that legacy data of fully documented tests permit accommodation of future fan ratings as efficacy, thrust efficiency, or single-speed ACFEI these metrics can be calculated from raw test data. AMCA added that there would be little or no impact to the testing cost itself (only recalculation of ratings using the same test data are needed). However, any metric using blended or weighted ratings would invalidate all existing ACF ratings. Most air circulating fans would require new laboratory testing. (AMCA, No. 41 at p. 35) AMCA added that fan manufacturers must accommodate several distinct types of users, including agricultural markets, which generally do not seem to be well-considered in the fan rulemaking. For air circulating fans, the use of the FEI metric may be an issue for agricultural circulating fans (livestock cooling) because BESS labs has been using CFM/W for its certified ratings. These ratings also are used in agricultural electricity-savings incentive programs. However, AMCA commented that a switch to another metric would not be too difficult if historical test results could still be used for calculating new ratings. (AMCA, No. 41 at p. 36) Finally, AMCA commented that the upcoming AMCA 230 will not have an ACFEI metric in the standard. AMCA commented that if DOE ultimately adopts the ACFEI metric, then AMCA recommends using the following constants derived from analyses performed by the AMCA 230 committee: Q_0 = 0.2454 cubic meters per second (1,500 CFM); P_0 = 0.6719 Pa (0.0027 in. wg); and Fan Efficiency target of 38 percent. However, AMCA noted that there was insufficient analytical support for this metric at this time and that the current draft of AMCA 230 does not include ACFEI as a ratings metric. *Id.*

As noted by ebm-papst, the CA IOUs, and AMCA, the fan efficacy in CFM/W is the industry established metric and DOE has concerns over the readiness of an ACFEI metric. In addition, as stated by AMCA, there is insufficient analytical support and DOE acknowledges the uncertainty regarding the values of Q_0 and P_0 that should be used. Therefore, DOE concludes that, at this time, the advantages of the FEI or ACFEI metric identified in the July 2022 NOPR and discussed previously (*i.e.,* representativeness of energy use, straightforward interpretation by consumers, ability to account for efficiency differences between fans of the same diameter that deliver the same airflow, consistency with other fan metrics and ability to account for air velocity) are not significant enough to justify deviating from the established industry efficacy metric (CFM/W) given that the FEI or ACFEI metric have not yet been adopted by industry. In addition, the latest industry test procedure (AMCA 230–23) relies on an efficacy metric and does not rely on the FEI metric. Therefore, at this time, DOE is establishing an efficacy metric in CFM/W for air circulating fans.

In addition, given the uncertainty and lack of data regarding operation at speeds less than the maximum speed, as discussed in section III.E.14 of this document, DOE evaluates the efficacy metric at the highest speed (or ''maximum speed'') only for all air circulating fans regardless of their speed configuration.

H. Control Credit Approach for Fans and Blowers Other Than Air Circulating Fans

For fans and blowers other than air circulating fans, the Working Group recommended that the FEP of a fan with dynamic continuous control be calculated with an additional credit to offset the losses inherent to the control. (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #16 at p. 9)

As stated in the July 2022 NOPR, DOE analyzed the control credit in the European Commission Regulation No. EU 327/2011 and observed that the value of the credit is equivalent to about 5 to 10 percent of the fan electrical input power for a fan with controls with an electrical input power less than 5 kW, but that it decreases to 4 percent for fans at or above 5 kW. Since the term sheet publication, AMCA established the FEI calculation method in AMCA 214–21. DOE also reviewed the calculation of FEP for fans with variable speed controls in AMCA 214–21, which does not provide for any control credit (*i.e.,* motor controller credit). (*See* section 6.4.2 of AMCA 214–21.) In its proposed rulemaking for commercial and industrial fans and blowers, the CEC did not propose a credit when establishing the FEI of fans with controllers and did not specify a different minimum FEI level when proposing energy conservation standards for fans with a controller.[107] Instead, the CEC highlighted that fans with a controller will have a larger FEI-compliant performance capability compared to fans that are single speed.[108] 87 FR 44194, 44240.

Consistent with industry practice, DOE proposed to adopt the FEP and FEI calculation as specified in AMCA 214–21 and did not propose to develop a control credit for fans with a controller. As stated, EPCA requires the DOE test procedures be reasonably designed to produce test results, which reflect energy efficiency and energy use during a representative average use cycle and not be unduly burdensome to conduct. (42 U.S.C. 6314(a)(2)) To the extent use of a dynamic continuous control impacts the energy use characteristics of a fan or blower, the test procedure should account for such impact and appropriate consideration of any such impact would be part of the evaluation of potential energy conservation standards. *Id.*

AMCA supports DOE's proposal to not include a control credit in the test procedure. AMCA explained that the majority of AMCA members are not in the motor/controller business and frequently do not have influence over the choice of motor control. AMCA commented that should a credit be applied for motor controllers; it should be done at the efficiency-requirement level and not within the FEI calculation. (AMCA, No. 41 at p. 36)

Robinson commented that should DOE not include a credit, as it would cause differentiation from the European calculations and could impact the ability of U.S. manufacturers to compete against European or non-U.S. manufacturers. (Robinson, No. 43 at p. 11)

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[107] *See* Proposed regulatory language for Commercial and Industrial Fans and Blowers available in the following Docket: 22-AAER-01 at: *efiling.energy.ca.gov/Lists/DocketLog.aspx?docketnumber=22-AAER-01.*

[108] *See* Staff Report, pp. 36–37 for Commercial and Industrial Fans and Blowers available in the following Docket: 22-AAER-01 at: *efiling.energy.ca.gov/Lists/DocketLog.aspx?docketnumber=22-AAER-01.*

Morrison commented that variable frequency drive (''VFD'') control provides a good method to achieve part load operation dynamically in order to promote energy savings. Morrison stated that since the FEP calculation metric penalizes the use of VFDs, providing at a minimum an equivalent bonus factor is appropriate to gain back the losses in the calculation. Morrison commented that operating at part load saves significantly more energy than any other efficiency change. (Morrison, No. 42 at p. 8)

New York Blower commented against a credit in the FEP and FEI calculation for fans with a motor controller. However, in the context of a WFEI metric which overestimates energy savings obtained merely by selling the fan with a motor controller, New York Blower commented that a credit to cover an insertion loss of the motor controller would be more tolerable and representative of system performance than the energy consumption calculation as currently proposed in the WFEI. While not supported with much data, New York Blower commented that a 5 percent credit would be acceptable. New York Blower commented that based on limited published data, they estimate that motor controllers can operate at roughly 97 percent efficiency at optimal conditions. New York Blower further stated that a 5 percent credit would give the motor controller an additional 2 percent credit above typical insertion loss—which should be included in the FEI calculation—in the overall FEI representation. Again, New York Blower commented that they would accept criticism in their estimates from those more knowledgeable of the subject matter of motor controllers. New York Blower commented that they believe this proposal is reasonable in intent and execution considering the imposition of a WFEI metric. (New York Blower, No. 33 at pp. 20–21)

As stated previously, DOE is not adopting WFEI as the metric for fans and blowers. Consistent with industry practice, for fans and blowers other than air circulating fans, DOE is adopting the FEP and FEI metric as specified in AMCA 214–21 and is not including a control credit for fans with a motor controller. As stated, EPCA requires the DOE test procedures be reasonably designed to produce test results, which reflect energy efficiency and energy use during a representative average use cycle and not be unduly burdensome to conduct. (42 U.S.C. 6314(a)(2)) As stated by Morrison, the FEP calculation metric penalizes the use of VFDs, as it incorporates the losses from the VFD and appropriate consideration of any such impact would be part of the evaluation of potential energy conservation standards.

I. Alternative Energy Determination Method (AEDM)

For certain covered equipment, DOE permits the use of an AEDM subject to the requirements at 10 CFR 429.70. An AEDM is a mathematical model based on the covered equipment design, and mitigates the potential cost associated with having to physically test units. AEDMs are permitted in instances in which the model can reasonably predict the equipment's energy efficiency performance.

Although specific requirements vary by product or equipment, use of an AEDM entails development of a mathematical model that estimates energy efficiency or energy consumption characteristics of the basic model, as would be measured by the applicable DOE test procedure. 10 CFR 429.70(c)(1)(i). The AEDM must be based on engineering or statistical analysis, computer simulation or modeling, or other analytic evaluation of performance data. 10 CFR 429.70(c)(1)(ii). A manufacturer must validate an AEDM by demonstrating that its predicted efficiency performance of the evaluated equipment agrees with the performance as measured by actual testing in accordance with the applicable DOE test procedure. 10 CFR 429.70(c)(1)(iii). The validation procedure and requirements, including the statistical tolerance, number of basic models, and number of units tested, vary by product. 10 CFR 429.70.

Once developed, an AEDM may be used for representations of the performance of untested basic models in lieu of physical testing. The manufacturer, by using an AEDM, bears the responsibility and risk of the validity of the ratings, including cases where the manufacturer receives and relies on performance data for certain components from a component manufacturer.

AEDMs, when properly developed, can provide a straightforward and accurate means to predict the energy usage or efficiency characteristics of a basic model of a given covered product or equipment and reduce the burden and cost associated with testing. Where authorized by regulation, AEDMs enable manufacturers to rate and certify the compliance of their basic models by using the projected energy use or energy efficiency results derived from these simulation models in lieu of testing.

The Working Group recommended allowing the use of an AEDM to generate the represented values of FEP and FEI of a fan basic model. (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendations #23 through #25 at pp. 12–13)

As proposed in the July 2022 NOPR, DOE allows the use of an AEDM in lieu of testing to determine fan performance, which would mitigate the potential cost associated with having to physically test units. Comments received on this issue are discussed in the remainder of this section. 87 FR 44194, 44241.

1. Validation

Validation is the process by which a manufacturer demonstrates that an AEDM meets DOE's requirements for use as a certification tool by physically testing a certain number of basic models and comparing the test results to the output of the AEDM. Before using an AEDM, a manufacturer must validate the AEDM's accuracy and reliability as follows.

A manufacturer must select a minimum number of basic models from each validation class to which the AEDM applies. To validate an AEDM, the specified number of basic models from each validation class must be tested in accordance with the DOE test procedure and sampling plan in effect at the time those basic models used for validation are distributed in commerce. Testing may be conducted at a manufacturer's testing facility or a third-party testing facility. The resulting rating is directly compared to the result from the AEDM to determine the AEDM's validity. A manufacturer may develop multiple AEDMs per equipment category, and each AEDM may span multiple validation classes; however, the minimum number of basic models must be validated per equipment category for every AEDM that a manufacturer chooses to develop. An AEDM may be applied to any basic model within the applicable equipment category at the manufacturer's discretion. All documentation of testing, the AEDM results, and subsequent comparisons to the AEDM would be required to be maintained as part of both the test data underlying the certified rating and the AEDM validation package pursuant to 10 CFR 429.71.

The Working Group recommended that the AEDM be validated by the testing of at least two basic models, compliant with any potential energy conservation standards for each equipment class.[109] In addition, the

[109] DOE uses validation classes for AEDMs. While validation classes may not directly align with equipment classes, validation classes are consistent

Working Group recommended that if an AEDM was used to simulate a wire-to-air test method, then the basic models used to validate the AEDM had to be tested using the wire-to-air test method. (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #24 at p. 13).

In the July 2022 NOPR, DOE proposed to include fan and blower validation classes at 10 CFR 429.70(k) and to require that two basic models per validation class be tested using the relevant proposed test procedure. This number of basic models is consistent with the number of basic models required for most DOE-regulated equipment that utilize AEDMs. In addition, DOE proposed that at least one basic model selected for validation testing would be required to include a motor, or a motor and controller of each topology (*e.g.,* induction, permanent magnet, electronically commutated motor) included in the AEDM. DOE also proposed that if the AEDM is intended to represent the wire-to-air test method, then the testing of the basic models used to validate the AEDM must be performed according to the wire-to-air test method. Similarly, if the AEDM is intended to represent the fan shaft power test method, DOE proposed that the testing of the basic models used to validate the AEDM be performed according to the fan shaft power test method. 87 FR 44194, 44241.

Morrison commented that they continue to support the recommendation 24 of the term sheet and support a plan that has manufacturers using testing results from two units to prove an AEDM but using the sampling plan per Recommendation #23 of the ASRAC term sheet. The sampling plan should be removed from the AEDM validation testing requirements. (Morrison, No. 42 at p. 9)

AMCA commented that they support Working Group Recommendation #24. However, AMCA commented that Recommendation #24 varies from the NOPR in that the NOPR calls for the testing to be done compliant with the test procedure and sampling plan, which currently calls for two units per basic model. AMCA accepts testing two units to prove an AEDM but using the sampling plan per Recommendation #23 of the ASRAC term sheet. (AMCA, No. 41 at p. 37)

New York Blower commented that to require two units to validate an AEDM seems reasonable, but when the tests must be executed in accordance with a sampling requirement attached to it, the AEDM development processed appears overly complicated. (New York Blower, No. 33 at p. 21)

Robinson commented that the AEDM approach for fans and blowers is an imperative as testing costs will be overwhelming in the absence of an AEDM. Robinson commented that the requirement for two samples to validate an AEDM will preclude the term sheet agreement of using historical testing data which is developed from a single fan. (Robinson, No. 43 at p. 11)

DOE includes fan and blower validation classes at 10 CFR 429.70(m) and requires that two basic models per validation class be tested using the relevant proposed test procedure. As stated, the number of basic models is consistent with the number of basic models required for most DOE-regulated equipment that utilize AEDMs. In addition, DOE requires that at least one basic model selected for validation testing would be required to include a motor, or a motor and controller of each topology (*e.g.,* induction, permanent magnet, electronically commutated motor) included in the AEDM. DOE also requires that if the AEDM is intended to represent the wire-to-air test method, then the testing of the basic models used to validate the AEDM must be performed according to the wire-to-air test method. Similarly, if the AEDM is intended to represent the fan shaft power test method, DOE requires that the testing of the basic models used to validate the AEDM be performed according to the fan shaft power test method. In addition, as discussed in section III.J of this document, DOE requires testing at least one unit per basic model in accordance with the sampling plan per Recommendation #23 of the ASRAC term sheet.

DOE's proposed validation classes for fans and blowers are listed as follows: (1) centrifugal housed; (2) radial housed; (3) centrifugal inline; (4) centrifugal unhoused; (5) centrifugal PRV exhaust; (6) centrifugal PRV supply; (7) axial inline; (8) axial panel; (9) axial PRV; (10) unhoused ACFH; (11) air circulating axial panel fan; (12) box fan; (13) cylindrical air circulating fan; and (14) housed centrifugal air circulating fan. 87 FR 44194, 44241. Per the current draft of the revised AMCA 230 standard, AMCA recommends replacing the proposed validation classes (10) through (14) with ''(10) Air circulating fan heads.'' [110] Additionally, AMCA recommends an 11th class for laboratory exhaust fans that are not induced flow fans per its recommendation for the definition of safety fans and lab exhaust fans that are not induced flow fans.[111] (AMCA, No. 41 at p. 37)

DOE did not receive any comments related to the proposed validation classes (1) through (9) and is adopting them as proposed. Regarding laboratory exhaust fans, as stated previously (*see* section III.C.2 of this document), DOE is not including laboratory exhaust fans in the scope of the test procedure and therefore is not adding a validation class for this equipment. Regarding validation classes for air circulating fans, AMCA recommended using unique validation classes for all categories of air circulating fans. DOE has concerns that such an approach, keeping with the 2 basic models per validation class, would not allow development of a model that is sufficiently representative of impeller designs and housing configurations. In addition, AMCA did not provide supporting information other than stating consistency with AMCA 230–23 (which does not include AEDM requirements). Therefore, at this time, DOE is reducing the number of validation classes for air circulating fans by grouping all housed ACFHs with axial impellers (*i.e.,* air circulating axial panel fans, box fans, and cylindrical air circulating fans) under the same validation class (''axial housed ACFH'') and to establish the following validation classes: unhoused ACFH, axial housed ACFH, and housed centrifugal air circulating fan.

New York Blower estimated that three fans would need to be tested to support ratings for 12 sizes and that the performance of the remaining sizes could be estimated using an AEDM. New York Blower commented that once the AEDM inventory in the industry is created, maintenance would be

with equipment classes. DOE would propose equipment classes in a future energy conservation standards rulemaking for fans and blowers.

[110] In their comments, AMCA uses the acronym ACFH to designate air circulating fan heads. Air circulating fans includes both housed and unhoused ACFHs and DOE considers the term ACFH equivalent to air circulating fan.

[111] DOE notes that AMCA also noted that their recommended changes would alter the regulatory text as follows: (i) Select basic models. For each fan or blower validation class listed as follows: centrifugal housed fan; radial housed fan; centrifugal inline fan; centrifugal unhoused fan; centrifugal power roof ventilator exhaust fan; centrifugal power roof ventilator supply fan; axial inline fan; axial panel fan; axial centrifugal power roof ventilator fan; unhoused ACFH; air circulating axial panel fan; housed air circulating fan head; lab exhaust fan to which the AEDM is applied. (AMCA, No. 41 at p. 37) DOE notes that the draft regulatory text provided by AMCA and the comment do not align. In their comments, AMCA recommends replacing the proposed validation classes (10) through (14) with ''(10) Air circulating fan heads'' while in the regulatory text they recommend replacing the proposed validation classes (12) through (14) with ''(10) Air circulating fan heads.'' (AMCA, No. 41 at p. 37) DOE interprets that comment as taking precedent over the draft regulatory text provided as the validation classes listed by AMCA in the draft regulatory text provided do not match the comment otherwise.

lessened, but to get started would clearly take extensively longer than any compliance period currently proposed. New York Blower commented that having to document AEDMs and certify every size, on an annual basis, would be an incredible burden to the fan industry and result in added cost paid by consumers. (New York Blower, No. 33 at p. 5)

DOE is not establishing any certification requirements in this final rule; however, DOE notes that beginning 180 days after publication of this final rule, any voluntary representations of FEI for fans that are not air circulating fans or CFM/W for air circulating fans that are within the scope of this test procedure would be required to be based on the DOE test procedure. This requirement is further discussed in section III.L.

The Working Group recommended adding a tolerance of 5 percent to the results of the AEDM for the basic models used for validation of the AEDM. The Working Group recommended that the predicted FEP using the AEDM may not be more than five percent less than the FEP determined from the test according to the DOE test procedure for the basic models used to validate an AEDM. (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #25 at p. 13).

The Working Group recommendation would require that the FEP calculated by an AEDM must be greater than or equal to 95 percent of the FEP determined testing the basic models used to validate the AEDM. This is equivalent to requiring that the FEI determined using the FEP calculated by an AEDM must be less than or equal to 100/0.95 percent or approximately 105 percent of the FEI calculated using the FEP determined from testing the basic models used to validate the AEDM.[112]

In the July 2022 NOPR, DOE proposed to apply the 5 percent tolerance to the FEI because FEI is the proposed metric. DOE proposed that the FEI calculated by an AEDM must be less than or equal to 105 percent of the FEI determined from the test of the basic models used to validate the AEDM. 87 FR 44194, 44241.

In response to the July 2022 NOPR, Robinson requested clarification on whether there is a positive margin on the AEDM for predicted FEP. (Robinson, No. 43 at p. 11) DOE notes that there is a positive margin, as stated in the previous paragraph.

DOE did not receive any additional comments on this proposal and therefore is requiring that the FEI calculated by an AEDM must be less than or equal to 105 percent of the FEI determined from the test of the basic models used to validate the AEDM. For air circulating fans, DOE is applying a 5 percent tolerance as proposed, but to the adopted efficacy metric in CFM/W.

2. Additional AEDM Requirements

In the July 2022 NOPR, consistent with provisions for other commercial and industrial equipment, DOE proposed to require that, if requested by DOE, a manufacturer must perform at least one of the following activities: (1) conduct a simulation before a DOE representative to predict the performance of particular basic models of the equipment to which the AEDM was applied; (2) provide analysis of previous simulations conducted by the manufacturer; or (3) conduct certification testing of basic model(s) selected by DOE. 87 FR 44194, 44241–44242.

In addition, DOE proposed that when making representations of values other than FEI (*e.g.,* FEP, fan shaft power) for a basic model that relies on an AEDM, all other representations would be required to be based on the same AEDM results used to generate the represented value of FEI. *Id.* at 87 FR 44242.

In response to the July 2022 NOPR, Robinson commented that it objects to the requirement of providing copies of AEDM calculations because the Robinson companies are privately held. (Robinson, No. 43 at p.11) DOE notes that manufacturers initially must certify whether basic model performance was determined with an AEDM or not. If DOE has questions on the AEDM used for a given basic model, DOE contacts the manufacturer for this information. DOE considers all AEDM data provided by manufacturers to be confidential. These data would not be publicly available. Additionally, DOE notes that use of an AEDM and AEDM representations are voluntary.

DOE did not receive any additional comments on these issues and requires that when making representations of values other than FEI (*e.g.,* FEP, fan shaft power) or efficacy (as applicable) for a basic model that relies on an AEDM, all other representations would be required to be based on the same AEDM results used to generate the represented value of FEI or efficacy.

3. AEDM Verification Testing

In the July 2022 NOPR, consistent with the provisions for certain commercial and industrial equipment, DOE proposed to include provisions related to AEDM verification testing for fans and blowers in 10 CFR 429.70(k), including: (1) selection of units from retail if available, or otherwise from a manufacturer, (2) independent, third-party testing if available, or otherwise at a manufacturer's facility, (3) testing performed without manufacturer representatives on site, (4) testing in accordance with the DOE test procedure, any active test procedures, any guidance issued by DOE, and lab communication with the manufacturer only if DOE organizes it, (5) notification of manufacturer if a model tests worse than its certified rating by an amount exceeding a 5 percent tolerance with opportunity for the manufacturer to respond, (6) potential finding of the rating for the model to be invalid, and (7) specifications regarding when a manufacturer's use of an AEDM may be restricted due to prior invalid represented values and how a manufacturer could regain the privilege of using an AEDM for rating. 87 FR 44194, 44242. DOE did not receive any comments related to these proposals and DOE is adopting these provisions as proposed.

4. Engineered-To-Order

In response to the July 2022 NOPR, New York Blower requested clarification regarding engineered-to-order products. Specifically, New York Blower requested clarification regarding what defines a product as an engineered-to-order product and whether that would impact sampling and AEDM requirements. New York Blower commented that engineered-to-order better describes custom fans which contain a design, but no distinct sizes. New York Blower commented that the sizes are dynamically created when the customer provides the specification and the fan is then designed and built once, for a single use. New York Blower requested clarification on whether this type of product is required to follow the sampling and testing requirements. New York Blower recommended that custom fan designs be certified at a single size and that at the time of order, the data from the tested size would be rescaled through an AEDM, built, and shipped. New York Blower further recommended that the certification of the original tested fan would be carried to the designed fan and no further sampling or testing would be required. New York Blower commented that this is how

[112] The FEI is equal to the reference FEP (FEP_{ref}) divided by the FEP of the actual fan. Therefore, if the FEP calculated using the AEDM (FEP–AEDM) is greater than or equal to 95 percent of the FEP (FEP-test) determined through testing, the FEP_{ref}/FEP–AEDM is less than or equal to 1/0.95 * FEP_{ref}/FEP-test.

custom fans have been designed for as long as the affinity laws have been understood. New York Blower noted that such approach would conflict with the definition of the basic model as each instance of the custom fan design is likely to consume a significantly different amount of energy from the tested fan and therefore would need to be considered a different basic model. In summary, New York Blower requested that DOE allow custom fan designs to be certified through a single certification for each design. (New York Blower, No. 33 at pp. 23–24)

As stated in section III.E of this document, DOE references section 8.2.1 of AMCA 214–21, ''Fan laws and other calculation methods for shaft-to-air testing,'' and section 8.2.3 of AMCA 214–21, ''Calculation to other speeds and densities for wire-to-air testing,'' as proposed in the July 2022 NOPR. (*See* 87 FR 44194, 44222.) Section 8.2.3 of AMCA 214–21 includes provisions which allow speed and size interpolations. In addition, as discussed in this section, DOE allows the use of AEDM in lieu of testing. For engineered-to-order equipment, manufacturers would have the option to determine the FEI of the engineered-to-order basic model through physical testing, application of the fan laws (in accordance with the test procedure), or application of an AEDM. Manufacturers would be required to certify the basic model.

As discussed in section III.C.7 of this document, with regards to custom fans for which a single made-to-order fan is manufactured, general sampling requirements for all covered equipment at 10 CFR 429.11(b), and § 429.11(b)(2) provides provisions for sampling when only one unit of a basic model is produced.[113] In accordance with these provisions, a single engineered-to-order product must be tested to ensure it complies with the standard. To reduce testing burden, DOE is adopting AEDM provisions that would allow certification using such AEDM, in lieu of testing (*i.e.,* physical testing or application of the fan laws as in accordance with the test procedure) and would apply to any basic model, including made-to-order products. Certification would be based on the test results of the one unit, or the AEDM ratings for the model.

J. Sampling Plan

DOE provides sampling provisions for determining represented values of energy use or energy efficiency of a covered product or equipment. *See* generally, 10 CFR part 429. These sampling provisions provide uniform statistical methods that require testing a sample of units that is large enough to account for reasonable manufacturing variability among individual units of a basic model, or variability in the test methodology, such that the test results for the overall sample will be reasonably representative of the efficiency of that basic model.

The general sampling requirement currently applicable to all covered products and equipment provides that a sample of sufficient size must be randomly selected and tested and that, unless otherwise specified, a minimum of two units must be tested to certify a basic model. 10 CFR 429.11. This minimum is implicit in the requirement to calculate a mean—an average—which requires at least two values. Manufacturers can increase their sample size to narrow the margin of error. The design of the sampling plan is intended to determine an accurate assessment of product or equipment performance, within specified confidence limits, without imposing an undue testing or economic burden on manufacturers. Different samples from the same population will generate different values for the sample average. An interval estimate quantifies this uncertainty in the sample estimate by computing lower and upper confidence limits (''LCL'' and ''UCL'') of an interval (centered on the average of the sample) which will, with a given level of confidence, contain the population average. Instead of a single estimate for the average of the population (*i.e.,* the average of the sample), a confidence interval generates a lower and upper limit for the average of the population. The interval estimate gives an indication of how much uncertainty there is in the estimate of the average of the population.[114] Confidence limits are expressed in terms of a confidence coefficient. For covered equipment and products, the confidence coefficient typically ranges from 90 to 99 percent.[115] The confidence coefficient 97.5 percent, for example, means that if an infinite number of samples are collected, and the confidence interval computed, 97.5 percent of these intervals would contain the average of the population: *i.e.,* although the average of the entire population is not known, there is a high probability (97.5 percent confidence level) that it is greater than or equal to the LCL and less than or equal to the UCL.

To ensure that the represented value of efficiency is no greater than the population average, the sampling plans for determination of the represented value typically consist of testing a representative sample to ensure that . . . (ii) Any represented value of energy efficiency[116] . . . shall be no greater than the lower of (A) the average of the sample () or (B) the lower XX confidence limit of the true mean divided by K, where the values for XX and K vary with product or equipment type. XX, the confidence limit, typically ranges from 90 to 99 percent, while K, an adjustment factor, typically ranges from 0.9 to 0.99. The specific values for XX and K for a particular product or equipment are selected based on an expected level of variability in product performance and measurement uncertainty. 10 CFR 429.14 through 10 CFR 429.66. Requiring that the represented value be less than or equal to the LCL would ensure that the represented value of efficiency is no greater than the population average. DOE divides the LCL by K to provide additional tolerance to account for variability in product performance and measurement uncertainty.[117] The comparison with the average of the sample further ensures that if LCL divided by K is greater than , the represented value is established using the average of the sample. In addition, DOE relies on a one-sided confidence limit to provide the option for manufacturers to rate more conservatively.

The Working Group recommended that a represented value of FEP of a basic model be based on a minimum of one test, where the represented value of FEP must be less than or equal to any energy conservation standard level, and greater than or equal to the tested value of FEP.[118] The Working Group did not

[113] Section 429.11(b)(2) specifies that if only one unit of the basic model is produced, that unit must be tested, and the test results must demonstrate that the basic model performs at or better than the applicable standard(s). If one or more units of the basic model are manufactured subsequently, compliance with the default sampling and representations provisions is required.

[114] NIST/SEMATECH e-Handbook of Statistical Methods, *www.itl.nist.gov/div898/handbook/eda/section3/eda352.htm.*

[115] Part 429 in 10 CFR outlines sampling plans for certification testing for product or equipment covered by EPCA.

[116] Or any other metric for which the consumer will favor a higher value, such as FEI.

[117] For example, if DOE expects that the variability for measured performance is within a margin of 3 percent, DOE will use a K value of 0.97. *See* for example 79 FR 32019, 32037 (June 3, 2014).

[118] DOE notes that this requirement can be converted into the FEI metric as follows: the represented value of FEI of the basic model must be based on a minimum of one test, where the represented value of FEI must be greater than or

Continued

provide recommendations to address a situation in which a manufacturer chooses to increase their test sample size. (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #23 at p. 12) The Petitioners also requested that manufacturers be allowed to establish FEP and FEI ratings of a fan basic model based on testing of a single unit. (Docket No. EERE–2020–BT–PET–0003, The Petitioners, No. 1.3 at p. 8)

In the July 2022 NOPR, DOE proposed that a minimum sample size of two units would be used when making representations of FEP, FEI, and fan shaft power, as applicable. This proposal is consistent with the statistical sampling requirements in place for other commercial and industrial equipment regulated by DOE.[119] 87 FR 44194, 44243. In addition, DOE proposed that the FEI be rounded to the nearest hundredth. *Id.* at 87 FR 44243.

AMCA commented that a 2-sample test was a deviation from the ASRAC term sheet, which required the industry and advocates to expend time and resources to research and analyze the implication of losing the historical record of fan tests. (AMCA, No. 41 at p. 2) AMCA commented that sample sizes of one unit must be allowed, as stipulated in Recommendation #23 of the term sheet. AMCA further cited the example of commercial packaged boilers as a covered product for which DOE allows a single unit sample (10 CFR 429.60). AMCA commented that, if DOE does not allow a single unit sample, much of the historical data for the fan industry would be eliminated. AMCA added that the industry does not have the financial or logistical resources to retest all products with two-sample tests. In addition, AMCA commented that AMCA 214–21 defines how to calculate the FEP and FEI at a single duty point or point of operation which consists of values of flow rate, pressure, power, and density. AMCA noted that the proposed statistics included in the NOPR imply FEP and FEI values can be averaged over multiple tests. However, AMCA commented that when considering multiple samples, the tests would have to have an identical number of sampled duty points and each duty point would have to be at the same flow, pressure, and density.[120] AMCA commented that while tests can be corrected to have all data points represented at the same density, it is highly unlikely each collected data point will be at the same flow and pressure. AMCA commented that there is no known methodology to combine multiple sets of test data to compute an expected mean value of performance [121] and commented that DOE would need to provide some methodology. AMCA added that the proposed statistics would function accurately under the following conditions: (1) A single value of performance (metric) was derived from the test (for example, the WFEI); or (2) The value from the test was captured at some specific operating condition that is repeatable across tests (for example at BEP). AMCA commented that the proposed test procedure is such that historical data would not pass the current test-procedure requirements and requiring two units to be tested will double the expense for manufacturers and lead to excessive testing burden. AMCA commented that units that are built for test cannot be placed back into stock and sold as new or offered for sale and all tested units would be an unrecoverable expense. AMCA commented that in addition to the costs, the time required to test two units of every basic model would span well beyond the compliance time period and could exceed 10 years. Instead, AMCA recommended to follow the guidelines of AMCA 214 and allow a single test where the FEP and FEI is calculated at each duty point (corrected to uniform speed and density as appropriate), and this data becomes the basis for the efficiency values presented in the market. (AMCA, No. 41 at pp. 38–40)

JCI and Morrison commented in support of AMCA's comments regarding the proposed sampling plan. (JCI, No. 34 at p. 2; Morrison, No. 42 at pp. 9–12)

NEEA recommends DOE work with AMCA to understand the burden associated with testing two units to certify a basic model and clarify DOE's stance on allowing the use of historic testing to be used in certifying fans. (NEEA, No. 36 at p. 3)

New York Blower commented that the sampling and statistics built into 10 CFR parts 429 and 431 will function as expected for a product-based metric. However, New York Blower added that the FEI metric is designed to be applicable to an entire fan performance envelope (flow, pressure, density, and power) and that there is no agreed upon methodology that allows for the combining of two or more fan curves into a representation of performance for a population. (New York Blower, No. 33 at p. 3) New York Blower added that requiring two-sample testing will double the costs of testing compared to creating ratings for a series of sizes within a product line from a single test. (New York Blower, No. 33 at p. 5)

New York Blower further commented that for a product-based metric where statistical representation of a population is required, a two sample minimum is appropriate. New York Blower added that a two-sample minimum could impose significant restrictions on the manufacturer, by amplifying any deviation between samples to predict population performance. New York Blower commented that a Weighted Average FEI value could be calculated from a single test. Presuming this would represent minimum energy consumption or maximum efficiency of the population of products would require the manufacturer to estimate any deviations from future samples and incorporate it in the ratings calculation. While not statistically supportable, it would be a method to create ratings and certify products from a single test. (New York Blower, No. 33 at p. 22)

Robinson commented that the two-sample minimum causes great concern for heavy industrial processing fans. Robinson commented that heavy industrial processing fans are uniquely designed and engineered for each installation and application. The material and parts are ordered specific to the job and only after the engineering and drawing of the individual product are complete. The NOPR indicates that the DOE would attempt to require two of each fan to be built to test its efficiency. Considering the number of heavy industrial processing fans and blowers sold in a year, Robinson commented that this will add a significant time and financial burden even if it were possible to design an AEDM. In the case of custom engineered equipment, Robinson stated that an accurate AEDM will be difficult and expensive to develop, requiring significant engineering expertise. (Robinson, No. 43 at pp. 3–4)

In addition, Robinson requested clarifications regarding the sampling process and noted that it is not unusual for a custom fan manufacturer to not

equal to any energy conservation standard and less than or equal to the tested value of FEI.

[119] The general sampling requirement currently applicable to all covered products and equipment provides that a sample of sufficient size must be randomly selected and tested to ensure compliance and that, unless otherwise specified, a minimum of two units must be tested to certify a basic model as compliant. *See* 10 CFR 429.11.

[120] At a given density, each duty point is defined as a value of pressure and flow at a given speed, and the test procedure provides methods to determine the electrical or FEP at that duty point.

[121] AMCA commented that AMCA 211 provides a method of comparing fan-performance data to a reference rating and an interpolation method for estimating performance between two sets of performance data but does not provide a method of combining more than one set of test data to provide average prediction of performance. (AMCA, No. 41 at p. 39)

make a particular size for years depending on the needs of the market. Robinson commented it was their understanding that one test would be required to certify a design as custom fan manufacturers would have historical design data available regarding the original design. Robinson commented that the definition of basic models and varying full width size classes suggests that an extraordinary amount of testing would need to be conducted to certify basic models. (Robinson, No. 43 at p. 12)

Greenheck commented that the proposed two-test requirement is disruptive and an extreme burden to the industry. Greenheck commented that the fan test procedure and certified ratings program (''CRP''), developed by AMCA and utilized by the fan industry, requires a single-sample precertification test and recurring surveillance audits. Greenheck commented that a two-sample requirement will not focus the industry on development of higher efficiency products and support energy savings. Instead, it will eliminate currently available fan performance data and shackle manufacturers with years of recertification of existing products. Greenheck commented that the improved accuracy of two-sample testing provides no value or energy savings for products already following the AMCA CRP program. Greenheck recommended that DOE accept AMCA CRP historical data and allow single unit performance data following AMCA 210 and AMCA 211 moving forward. (Greenheck, No. 39 at pp. 2–3)

AHRI commented that the Working Group explicitly recommended that a represented value of a basic model be based on a minimum of one test, where the tested value must be less than the represented value. AHRI commented that this was deemed appropriate by the Working Group after lengthy discussion about the substantial burden retesting on the industry. AHRI commented that the ratings and sampling methods embodied in AMCA Publication 211, ''Certified Ratings Program Product Rating Manual for Fan Air Performance,'' have long been used and have been offered for regulatory purposes. AHRI does not support DOE's proposal that a minimum sample size of two units would be used when making representations of FEP, FEI, and BHP, as applicable, be required when that was explicitly recommended against by the cognizant Working Group. AHRI added that DOE has offered no data or analysis that the agreed upon methodology would be insufficient or deviate substantially from current practices. (AHRI, No. 40 at p. 7)

ebm-papst commented that they were unable to see through the complexities and important nuances of the AEDM and the statistical procedures that the NOPR proposed to implement. Instead, ebm-papst recommended adoption of AMCA 211 certification program into this fan rulemaking. (ebm-papst, No. 31 at p. 13)

Rheem commented that having multiple samples can be beneficial (Public Meeting Transcript, No 42 at pp. 85–86)

For fans and blowers other than air circulating fans, DOE is following the recommendation of the Working Group (Docket No. EERE–2013–BT–STD–0006, No. 179, Recommendation #23 at p. 12) and providing the option to test a minimum of one unit, where the tested value must be less than the represented value. If, however, a fan manufacturer chooses to certify compliance of a basic model based on the test result of a single unit, DOE notes that it may consider using a minimum sample size of one unit for enforcement testing, and if a single unit of this fan basic model does not meet the applicable Federal energy conservation standard, the fan basic model will be considered non-compliant. If a manufacturer chooses to certify compliance of a basic model based on the test result of a sample of more than one unit, DOE may consider performing enforcement testing based on a sample of more than one unit. As discussed in section III.K, DOE is not adopting enforcement provisions in this document and will address enforcement provisions in a future energy conservations standards rulemaking.

As stated, the Working Group did not provide recommendations to address a situation in which a manufacturer chooses to increase their test sample size, specifically in terms of the methodology to use when averaging the FEI of two or more duty points, which may not be exactly at the same flow and pressure due to testing variations. To address the situation where a manufacturer may choose to increase the test sample, DOE adds provisions to clarify how to perform the average FEI calculation: for each speed and flow value for which the manufacturer chooses to make a representation, the average FEI is the average of the FEI determined by each test and the duty point is defined as the value of speed, flow, and average of the pressures determined by each test. DOE notes that AMCA 214–22 provides methods to convert performance data from one speed to another speed (*see* Annex G and Annex H of AMCA 214–22 as well as section 7.9.1 of AMCA 210–216), as well as interpolation methods to determine the performance along the fan curve (*i.e.,* at any flow value) at a given speed.[122] Therefore, separate test results can be converted to the same flow and speed. The remaining pressure value would then be averaged to provide the average duty point pressure.

Regarding the use of historical test data, DOE understands that manufacturers of fans and blowers likely have historical test data which were developed with methods consistent with the DOE test procedure being adopted in this final rule. DOE does not expect manufacturers to regenerate all of the historical test data unless the rating resulting from the historical methods, which is based on the same methodology being adopted in this final rule, would no longer be valid.

Regarding the use of AMCA 211–22, DOE develops its own certification, compliance, and enforcement provisions and will consider the provisions in AMCA 211–22 to the extent possible in a separate certification-focused rulemaking.

AHAM commented that deviation from an agreed-upon term sheet diminished the value of participating in ASRAC negotiations and could result in reduced interest in participating in such negotiations in the future. AHAM stated that stakeholders from all perspectives (*e.g.,* manufacturers, efficiency advocates, States, and utilities) and DOE alike see value in that process. AHAM commented that they are a strong supporter of negotiated standards—both through the ASRAC process and through ''private'' negotiations among stakeholders with various points of view. (AHAM, No. 35 at p. 9)

AMCA commented that, DOE always reserves and retains the right to diverge from the ASRAC consensus, but in the interest of encouraging future participation in a process generally acknowledged to be a classic example of good regulatory policy and practice, DOE last-minute divergence in fundamental ways from the ASRAC consensus (especially where that consensus has been used as a guide for the more rapidly developed related regulation in California) will only serve as a disincentive for future parties to participate in ASRAC negotiations. (AMCA No. 41 at p. 3)

DOE notes that the adopted provisions to allow a sample of at least one unit aligns with the term sheet. As noted throughout the notice, DOE aligned with the recommendations of

[122] Sections 7.13.1 and 7.13.2 of AMCA 214–22 state: ''If needed, duty points between laboratory tested points (determinations), are obtained by fitting a cubic polynomial based on the four closest determinations.''

the term sheet except on the metric (FEI vs. FEP), where DOE aligned with the latest industry standard. *See* section III.G.1 of this document. DOE established the ASRAC in an effort to further improve DOE's process of establishing energy efficiency standards for certain appliances and commercial equipment. ASRAC allows DOE to use negotiated rulemaking as a means to engage all interested parties, gather data, and attempt to reach consensus on establishing energy-efficiency standards.

For air circulating fans, DOE did not receive any comments specific to the sampling plan. For air circulating fans, the metric is evaluated at a single operating point (*i.e.,* maximum speed, *See* Section III.G.2 of this document) and each basic model's performance is represented by a single rating. This metric approach is different from the one used for fans blowers other than air circulating fans where the metric is evaluated at each of the fan's operating points within the range of air power and shaft input power in scope (*i.e.,* at each duty point, as specified by the manufacturer within the range of air power and shaft input power in scope; *see* Section III.B.1 of this document) and requires the determination of the FEI at each duty point as specified by the manufacturer, resulting in multiple FEI ratings for the same basic model. For this reason, DOE believe it is appropriate to allow a minimum of one unit for fans and blowers other than air circulating fans, and to require a minimum of two units for air circulating fans. Thus, DOE is requiring a minimum of two units, as proposed in the July 2022 NOPR. As noted, a minimum of two units is consistent with the statistical sampling requirements in place for other commercial and industrial equipment regulated by DOE.[123]

K. Enforcement Provisions

In the July 2022 NOPR, DOE proposed to add specific enforcement testing provisions for fans and blowers at 10 CFR 429.110 and proposed that DOE would use an initial sample size of not more than four units and would determine compliance based on the arithmetic mean of the sample. This is similar to existing enforcement testing provisions for pumps and HVACR equipment. DOE also proposed to add product-specific enforcement provisions for fans and blowers other than air circulating fans to specify that: (1) geometric similarity of two or more fans will be verified by requiring that the manufacturer provides all fan design dimensions as described in Annex K of AMCA 214–21; and (2) DOE will test each fan basic model according to the test method (specified by the manufacturer in any certification report (*i.e.,* based on section 6.1, 6.2, 6.3, or 6.4 of AMCA 214–21). 87 FR 44194, 44243.

DOE did not receive any comments specific to this issue. In this final rule, DOE is not adopting enforcement provisions as proposed in the July 2022 NOPR. At this time, DOE has not established any energy conservation standards for fans and blowers and will consider establishing enforcement provisions as part of any future energy conservation standards rulemaking.

L. Effective and Compliance Dates

The effective date for the adopted test procedure will be 30 days after publication of this final rule in the **Federal Register**. EPCA prescribes that all representations of energy efficiency and energy use, including those made on marketing materials and product labels, for certain equipment, including fans and blowers, must be made in accordance with an amended test procedure, beginning 180 days after publication of the final rule in the **Federal Register**. (42 U.S.C. 6314(d)(1)) EPCA provides an allowance for individual manufacturers to petition DOE for an extension of the 180-day period if the manufacturer may experience undue hardship in meeting the deadline. (42 U.S.C. 6314(d)(2)) To receive such an extension, petitions must be filed with DOE no later than 60 days before the end of the 180-day period and must detail how the manufacturer will experience undue hardship. (*Id.*)

AMCA commented that if DOE's test procedure results in a comprehensive need for industry testing, there would not be sufficient throughput to meet, for example, a 180-calendar-day deadline. In actuality, it would likely take years for industry to retest everything. (AMCA No. 41, at p. 40)

JCI stated that it shares AMCA's comments regarding the 180-day compliance window between rule finalization and the effective date which is not possible for a product sector being regulated for the first time under the proposed NOPR requirements; either the proposed test procedures need to be revised or the time period needs to be extended to 6 years. (JCI, No. 34 at p. 2)

DOE understands that manufacturers of fans and blowers likely have historical test data which were developed with methods consistent with the DOE test procedure being adopted in this final rule. DOE notes that it does not expect manufacturers to regenerate all of the historical test data, unless the rating resulting from the historical methods, which is based on the same methodology being adopted in this final rule, would no longer be valid. EPCA provides a 180-day timeline for all representations regarding energy consumption or the cost of energy consumed by fans and blowers to be made according to the DOE test procedure. (42 U.S.C. 6314(d)(1)) This is a statutory requirement and not a timeline chosen by DOE.

AHRI commented that once the test procedure is finalized, fan manufacturers will have 180 days to comply with the new procedure. AHRI commented that this is an unrealistic timeline. AHRI commented that component fans that were once available for a product's full operating range may no longer be available and OEMs will not have the information about market availability of new component fans until well after the motor has been tested and certified. AHRI added that after assessing the availability on the market, OEMs may have to redesign equipment to accommodate for a different motor size, which could also negatively impact performance and efficiency. AHRI stated that redesign and testing take years to complete, and the information required for this equipment assessment will not be available until after fan manufacturers are actually complying with the test procedure. (AHRI, No. 40 at p. 9) AHRI added detailed descriptions and estimates of the costs to incorporate a redesigned fan into an OEM equipment. (AHRI, No. 40 at pp. 9–10)

As discussed previously, EPCA prescribes that all representations for fans and blowers must be made in accordance with an amended test procedure, beginning 180 days after publication of the final rule in the **Federal Register**. (42 U.S.C. 6314(d)(1)) At this time, DOE is not adopting energy conservation standards for fans and blowers, and the test procedure would not impact the availability of current models. The test procedure does not set any energy conservation standards and does not result in any non-compliant fans.

M. Test Procedure Costs and Impacts

As previously discussed, DOE is establishing a test procedure for fans and blowers at 10 CFR part 431, subpart J and a new appendix A and appendix

[123] The general sampling requirement currently applicable to all covered products and equipment provides that a sample of sufficient size must be randomly selected and tested to ensure compliance and that, unless otherwise specified, a minimum of two units must be tested to certify a basic model as compliant. *See* 10 CFR 429.11.

B. Additionally, DOE is (1) adopting through reference the test methods in AMCA 214–21 and AMCA 230–23, with certain modifications; (2) adopting through reference certain test procedure provisions in AMCA 210–16; and (3) specifying FEP and FEI, based on AMCA 214–21, and CFM/W, based on AMCA 230–23, as the relevant metrics. DOE is also adding section 69 to 10 CFR part 429, which adds fan and blower sampling requirements and provisions related to determining represented values, and is adding paragraph (n) to 10 CFR 429.70, which specifies alternative efficiency determination method requirements. DOE has determined that the test procedure would impact testing costs as discussed in the following paragraphs.

By adopting industry standards, DOE has determined that the test procedure in this final rule would be reasonably designed to produce test results that reflect energy efficiency and energy use of fans and blowers during a representative average use cycle and that would not be unduly burdensome for manufacturers to conduct. In the July 2022 NOPR, DOE presented costs associated with performing testing according to the proposed test procedure at third-party testing facilities (*i.e.,* facilities that are not operated by the manufacturer whose product is being tested). 87 FR 44194, 44243.

In the July 2022 NOPR, DOE assumed that both AMCA and non-AMCA members could test products at the AMCA testing facilities, with non-AMCA member costs being double the cost of AMCA members. 87 FR 44194, 44243. DOE has since learned that it is uncommon for the AMCA testing facility to test non-AMCA member products. In the July 2022 NOPR, DOE had estimated that 40 percent of fan manufacturers are not AMCA members. *Id.*

In the July 2022 NOPR, DOE had expected that manufacturers could have substantial initial capital costs if they established a test laboratory capable of testing to the proposed test procedure; however, DOE had anticipated that the cost to perform a test would be less for in-house testing than for third-party testing. *Id.* In other words, DOE had expected that over the lifetime of a new test laboratory, the initial capital costs would be less than the total cost of third-party testing.

In the July 2022 NOPR, DOE provided estimated costs for testing fans at third-party laboratories; however, based on stakeholder comments, DOE anticipates that the cost to perform a test would be less for in-house testing than for third-party testing. *Id.* DOE requested feedback on its assumption that it would cost an average of $4,200 to test one fan for both general fans and air circulating fans. DOE also requested feedback on the method described for estimating manufacturer per-model testing costs of general fans and air circulating fans. Additionally, DOE requested feedback and data on the total testing costs per basic model for testing at third-party facilities and on third-party laboratory testing costs (other than AMCA). *Id.*

AMCA commented that testing for air circulating fans per AMCA 230 would cost $1,420 per fan with an added cost of $350 per fan speed. (AMCA, No. 41 at p. 35) Additionally, AMCA provided an estimated cost of $6,300 to test a general fan. (AMCA, No. 41 at p. 40) New York Blower commented that the third-party testing costs were reasonable. (New York Blower, No. 33 at p. 22). AMCA, New York Blower, and Morrison commented that DOE did not consider the cost to ship fans to third-party facilities in its estimated test costs. (AMCA, No. 41 at p. 40; New York Blower, No. 33 at p. 22; Morrison, No. 42 at p. 12).

AMCA also commented that BESS Labs traditionally tests circulating fans; however, AMCA's policy is not to report on other organizations' pricing, so it did not provide details on BESS Labs and its testing programs. (AMCA, No. 41 at p. 40). JCI commented that there are limited laboratory facilities available for testing. (JCI, No. 34 at p. 1) DOE recognizes that third-party testing is currently not widely available and is not aware of any third-party testing facilities that can accommodate both general fans and air circulating fans aside from AMCA's testing facilities; therefore, DOE has updated its cost estimates to recognize that some fan manufacturers may need to build a test lab to test and certify fans according to the DOE test procedure.

Based on DOE's additional evaluation, and from stakeholder comments, in this final rule, DOE presents costs for building an in-house test facility to obtain representative efficiency values for fans and blowers according to the test procedure. As such, DOE has assumed that the in-house facilities would be connected to or within reasonable distance to the manufacturer production facility to eliminate the need to ship fans to the test lab. DOE has worked to minimize testing burden while maintaining the rigor of the test procedure is this final rule by: (1) requiring a minimal certification sample size of one unit per basic model, reduced from a minimum of two proposed in the July 2022 NOPR (87 FR 44194, 44243); (2) requirements for testing with appurtenances is now consistent with AMCA 210–16 and AMCA 230–23, which allows manufacturers to use historical data; (3) clarifying the definition of a basic model that was proposed in the July 2022 NOPR (87 FR 44194, 44213); and (4) allowing the use of AEDMs in lieu of testing. DOE addresses cumulative costs and burden and discusses its estimated test costs in detail in the following sections. Ultimately, DOE has determined that the costs to conduct the test procedure in this final rule do not outweigh the benefits and that the text procedure is not unduly burdensome for manufacturers to conduct.

1. Cumulative Costs and Burden

In response to the July 2022 NOPR, stakeholders commented that cumulative testing costs and burden would be significant based on the proposed test procedure.

Morrison commented that they estimate testing to take from 3 to 5 years and would require expanding lab operation and personnel. (Morrison, No. 42 at p. 12) Morrison additionally stated that they would need to test each of their thousands of basic models two times. *Id.* Additionally, Morrison stated that by dedicating more time to testing, they would not be able to dedicate as much time to customer development or research and design. *Id.* AMCA commented that it would take longer than 180 days, and most likely years, for the industry to retest all fans, either at a third-party lab or at an in-house laboratory. (AMCA, No. 41 at pp. 40–41) AMCA also stated that the amount of time required to test fans is dependent on the number of basic models. *Id.* JCI stated that they expect the cumulative test cost to be in the tens of millions of dollars and to take 6 years to complete. (JCI, No. 34 at p.1) AHRI commented that it would likely take fan manufacturers longer than 180 days after the test procedure is finalized to begin certifying fans. (AHRI, No. 40 at pp. 9–11) New York Blower commented that the cumulative testing burden would be significant when the number of basic models, samples, and appurtenances are considered. (New York Blower, No. 33 at p. 4)

New York Blower additionally commented that the proposed test procedure would not allow manufacturers to use historical test data and that manufacturers need to use historical test data to comply with standards in time. (New York Blower, No. 33 at p. 4)

DOE understands the comments from stakeholders to be in response to DOE's

proposal in the July 2022 NOPR to require a minimum of two samples to rate a basic model. 87 FR 44194, 44243. Additionally, DOE recognizes that the concerns over test costs and burden may be in response to DOE's proposals for testing with appurtenances (87 FR 44194, 44226), testing air circulating fans at multiple speeds (87 FR 44194, 44227), and DOE's consideration of a WFEI metric for fans and blowers that are not air circulating fans (87 FR 44194, 44237–44238) in the July 2022 NOPR.

In response to stakeholder concerns regarding cumulative test costs and burden, DOE is providing the option to test a minimum of one unit, rather than two units, for rating and certification (see Section III.J). As discussed in section III.E.12, DOE is aligning the provisions for testing with appurtenances with industry test standards AMCA 214–21 and AMCA 230–23. Finally, DOE is requiring that air circulating fans be tested at a single speed, as discussed in section III.E.14 of this document. As a result, DOE expects that manufacturers may use historical test results and the cumulative test cost and the time required to test products will be substantially decreased.

Furthermore, DOE notes that the deadline for manufacturers to comply with the test procedure 180 days after it is published is for voluntary representations, which is further discussed in section III.L of this document. If DOE were to set standards for general fans and air circulating fans, certification based on the sampling plan discussed in section III.J would be required on the compliance date of the standard, which could be between 3 and 5 years after the publication date of the energy conservation standards final rule.

JCI commented that the cost of testing was underestimated and that DOE did not consider the cost of building prototypes for test. (JCI, No. 34 at p. 1) Robinson stated that DOE did not consider the cost of building a custom fan in duplicate to test (Robinson, No. 43 at p. 12). The test procedure that DOE is adopting is non-destructive, meaning that test does not alter the operation and performance of the fan; therefore, DOE does not see a reason for that a prototype or duplicate fan needs to be produced solely for testing DOE is not including the cost of the fan in its updated test procedure cost estimates.

2. Estimated Costs for Building and Testing of Fans and Blowers Other Than Air Circulating Fans at an In-House Facility

a. Capital Costs

In the maximum-burden case where a fan manufacturer would be required to construct a test lab from scratch, manufacturers would be required to make capital outlays to acquire or build a testing facility and purchase test equipment. DOE has estimated costs for fans based on the AMCA 210–16 industry standard that DOE is referencing in this final test procedure. DOE estimated minimum and maximum costs, then used these two values to determine an average cost.

To estimate the costs to build an in-house testing facility, DOE assumed a single-story building built in the U.S. using 2022 costs. DOE estimated test facility square footage by using information from manufacturers and by evaluating outlet duct setups in AMCA 210–16, with length and width buffers applied. DOE estimated an average floor area of 3,450 square feet.[124] Using this average square footage value, DOE estimated a one-time building cost for warehouse and storage to be $321,000.[125]

DOE has identified that the test structure to test in accordance with AMCA 210–16 would consist of a traverse pitot duct and a main chamber. DOE has estimated that the average one-time cost for the traverse pitot duct and the main chamber would be $1,800.

The test procedure for fans and blowers other than air circulating fans, which aligns with AMCA 210–16, requires pressure, flow, power, and air density to be measured or calculated by equipment with specific calibrations and accuracies. The cost of this test equipment is considered as a one-time cost. The pressure measurement requires a manometer and a pitot-static tube. DOE has estimated the average cost of a manometer to be $590 and the average cost of a pitot-static tube to be $290. Flow can also be measured with the pitot-static tube. According to AMCA 210–16, power can be determined indirectly or directly. The indirect determination of power requires force or torque measurements by either a reaction dynamometer or torque meter, respectively, and power is calculated using equations in AMCA 210–16. The direct measurement of power requires either a calibrated motor or an electric meter. DOE has assumed that a testing facility would have all equipment necessary to determine power either directly or indirectly (*i.e.,* a reaction dynamometer, torque meter, calibrated motor and electric meter) to provide testing flexibility. This assumption is also the most conservative. DOE has estimated the average costs of a reaction dynamometer to be $5,700, a torque meter to be $1,600, a calibrated motor to be $1,700, and an electric meter to be $9,700. The air density is calculated using measurements of air temperature with a thermometer and pressure with a barometer. DOE has estimated the average costs of a thermometer to be $600 and a barometer to be $330. In sum, DOE has estimated that the cost to acquire all of the necessary test equipment to perform the general fans test procedure is, on average, $20,500.

In total, DOE has estimated the average capital cost of building an in-house testing facility for fans as $343,300. DOE notes that some fan manufacturers have indicated they already have existing facilities and equipment to test general fans according to AMCA 210–16, which DOE references in this final test procedure.

b. Annual Costs

DOE has estimated annual costs for operating a testing facility, which include utilities and equipment calibration. DOE has estimated that the annual utilities costs would be $8,000,[126] based on the average floor area discussed in the previous section. Equipment would need to be calibrated

[124] DOE used the AMCA 2012 general fans database to estimate the maximum diameter of a general fan. DOE then used the maximum diameter to determine the floor area necessary to build a main chamber and ductwork in accordance with the test set-ups in AMCA 210–16 with a buffer of 5 times the estimated area. DOE calculated the average floor area to be 6,500 square feet, which DOE then used as the maximum square footage value. DOE used 400 square feet as the minimum floor area, which DOE determined from communication with manufacturers. DOE calculated the average of these two values to estimate an average floor area of 3,450 square feet ((6,500 + 400) ÷ 2 = 3,450).

[125] DOE estimated the building cost for warehouse and storage based on the RSMeans Facilities Construction Cost Data (2011). DOE then used the Federal Reserve Economic Data's ''Producer Price Index by Industry: Fan, Blower, Air Purification Equipment Manufacturing'' to account for inflation to 2022 prices. (*https://fred.stlouisfed.org/series/PCU333413333413*)

[126] DOE estimated the commercial utility costs to be $0.1122/kWh using data from EIA's ''2021 Average Monthly Bill'' and commercial utility use to be 20.70 kWh/square foot using EIA's ''2018 Commercial Buildings Energy Consumption Survey'' (*www.eia.gov/electricity/sales_revenue_price/pdf/table5_b.pdf; https://www.eia.gov/consumption/commercial/data/2018/pdf/CBECS%202018%20CE%20Release%202%20Flipbook.pdf*). DOE then calculated total average commercial utility costs to be $8,000 ($0.1122/kWh × 20.70 kWh/square foot × 3,450 square feet = $8,013).

each year, which DOE has estimated to be $21,500 [127] based on 2016 calibration price lists from the National Institute of Standards and Technology (''NIST'').

In total, DOE has estimated the annual cost of operating an in-house testing facility for general fans as approximately $29,500.

c. Testing Costs

This final rule includes requirements regarding the sampling plan and representations for covered fans at subpart B of 10 CFR part 429. The sampling plan requirements require a minimum sample size of one unit per general fan basic model be tested when determining representative values of FEI, as well as other fan performance metrics.

Fan test costs include the cost of labor to set-up, test, and disassemble the fan. DOE estimated that it would take an average of 4 hours to set-up and disassemble a general fan and 2 hours to test a general fan, resulting in a total of 6 hours of labor per test. DOE has also assumed that a mechanical engineering technician would set-up and perform the testing. Based on wage and salary data from the Bureau of Labor Statistics (''BLS''), DOE has estimated a fully burdened hourly mechanical engineering technician wage of $43.[128] DOE has calculated the total cost of labor for testing a general fan to be approximately $260 per basic model, assuming one fan is tested per basic model.

d. AEDM Costs

As previously discussed, an AEDM is a mathematical model developed by a manufacturer that estimates the energy efficiency or energy consumption characteristics of a basic model as measured by the applicable DOE test procedure. Before using an AEDM, a fan manufacturer must validate the AEDM's accuracy and reliability by physically testing two basic models and comparing the test results to the output of the AEDM (see discussion in III.I.3 of this document).

In the July 2022 NOPR, DOE assumed a mechanical engineer would develop and validate a new AEDM. 87 FR 44194, 44243. DOE estimated that it would take 24 labor hours per validation class for an engineer to develop and validate an AEDM using existing simulation tools. *Id.* 87 FR at 44243–44244. DOE assumed a mechanical technician would implement an AEDM once it is developed. *Id.* DOE estimated that it would take a mechanical technician 1 hour to determine the representative values necessary to certify a basic model using an AEDM. *Id.*

In response to the July 2022 NOPR, several stakeholders commented that DOE underestimated the time it would take to develop an AEDM and to develop certified ratings from that AEDM. AMCA provided a list of steps required to validate an AEDM and estimated that it would take 56 working hours to develop an AEDM and 24 working hours to develop certified ratings. (AMCA, No. 41 at . 42) New York Blower commented that it would take between 100 and 200 working hours to develop an AEDM and 3 hours to develop certified ratings because using computational fluid dynamics to estimate fan performance is complex. (New York Blower, No. 33 at p. 23) Robinson suggested that it would take on the order of several days to weeks to develop an AEDM (Robinson, No. 43 at p. 12) Morrison commented that it would take at least 80 working hours to develop an AEDM. (Morrison, No. 42 at p. 13) Additionally, the same stakeholders commented that the development of certified ratings from an AEDM would need to be done by a mechanical engineer, not a mechanical technician. (AMCA, No. 41 at . 42; New York Blower, No. 33 at p. 23; Robinson, No. 43 at p. 12; Morrison, No. 42 at p. 12)

After considering stakeholder comments, DOE has updated the costs to develop, validate, and implement an AEDM. DOE used the values provided in stakeholder comments to estimate the labor hours required to develop, validate, and implement an AEDM. Additionally, DOE has updated its estimates to reflect stakeholder comments that a mechanical engineer would be required to complete all stages of the AEDM.

For this final rule, DOE assumes a mechanical engineer would develop, validate, and implement a new AEDM. Based on wage and salary data from the BLS, DOE estimated the fully burdened hourly mechanical engineering wage to be approximately $66.[129] Considering the values provided in stakeholder comments, DOE estimates an average of 128 labor hours per validation class for an engineer to develop and validate an AEDM for general fans using existing simulation tools. Therefore, DOE estimates the cost of a fully burdened mechanical engineer as approximately $8,500 per validation class. As discussed in section III.J.1, testing of two basic models is required to validate an AEDM for a specific validation class while one unit must be tested per basic model in order to validate an AEDM. Therefore, two physical tests on two different basic models are required for validation of a AEDM for general fans. As discussed previously, DOE estimates the labor cost per test to be $260. Therefore, the total estimated manufacturer labor cost to develop and validate an AEDM for a single validation class is estimated to be $9,020 which is the cost to perform one test on two basic models ($520) plus the fully burdened cost of a mechanical engineer's time to develop and validate the AEDM ($8,500).

DOE also assumes a mechanical engineer will implement an AEDM once it is developed. Using the values provided in stakeholder comments, DOE estimates that it would take a mechanical engineer an average of 14 labor hours to determine the representative values necessary to certify a basic model using an AEDM. Therefore, the estimated cost to implement an AEDM to develop certified ratings is $950 per basic model.

In response to the July 2022 NOPR, AMCA and Robinson commented that not all manufacturers have the simulation tools necessary to validate and implement an AEDM. (AMCA, No. 41 at . 42; Robinson, No. 43 at pp. 11–12) DOE acknowledges that computational fluid dynamics (''CFD'') software is necessary to validate and implement an AEDM for fans and blowers and has concluded that the cost to purchase the software should be included as an AEDM one-time cost.

[127] DOE estimated the NIST calibration fee from *www.nist.gov/system/files/documents/2016/10/31/FeeSchedule-2016.pdf.* However, this catalog does not list calibration prices for the following equipment: manometer, pitot-static tube, and barometer; therefore, DOE used similar thermodynamic and mechanical type instruments that measure velocity of airflow and pressure from NIST.

[128] DOE estimated the hourly wage using data from BLS's ''Occupational Employment and Wages, May 2021'' publication. DOE used the ''Mechanical Engineering Technologies and Technicians'' mean hourly wage of $30.47 to estimate the hourly wage rate (*www.bls.gov/oes/current/oes173027.htm*). Last accessed on April 3, 2023. DOE then used BLS's ''Employer Costs for Employee Compensation—December 2022'' to estimate that wages and salary account for approximately 70.5 of employer labor costs for private industry workers. (*www.bls.gov/news.release/pdf/ecec.pdf*). Last accessed on April 3, 2023. Therefore, DOE estimated a fully-burdened labor rate of $43 ($30.47 ÷ 0.705 = $43.21).

[129] DOE estimated the hourly wage using data from BLS's ''Occupational Employment and Wages, May 2021'' publication. DOE used the ''Mechanical Engineers'' mean hourly wage of $46.64 to estimate the hourly wage rate (*www.bls.gov/oes/current/oes172141.htm*). Last accessed on April 3, 2023. DOE then used BLS's ''Employer Costs for Employee Compensation—December 2022'' to estimate that wages and salary account for approximately 70.5 percent of employer labor costs for private industry workers. (*www.bls.gov/news.release/pdf/ecec.pdf*). Last accessed on April 3, 2023. Therefore, DOE estimated a fully-burdened labor rate of $66 ($46.64 ÷ 0.705 = $66.16).

Robinson estimated that the investment in hardware and software would be on the order of $125,000. (Robinson, No. 43 at p. 11)DOE reviewed CFD prices online and found a CFD free of cost,[130] so used $0 as its minimum CFD cost and the estimate from Robinson as the maximum cost for CFD software. DOE averaged these two values to determine an average CFD software cost of $62,500. DOE estimated the cost of a workstation with the necessary system requirements to run CFD software to be $3,000, with a minimum of $1,000 and a maximum of $5,000; however, DOE notes that many CFD software packages are cloud-and license-based. DOE has estimated the average cost of CFD software and compatible hardware to be $65,500 (62,500 + 3,000 = 65,500).

3. Estimated Costs for Building and Testing Air Circulating Fans at an In-House Facility

In response to the July 2022 NOPR, DOE only received comment from AMCA containing cost estimates for testing air circulating fans at a third-party laboratory. To estimate the costs for testing air circulating fans, DOE used the comment received, its own testing experience with these fans, information provided by manufacturers during interviews, and in some cases made assumptions relative to the values estimated for general fans.

a. Capital Costs

In the maximum-burden case where ACF manufacturers would have to construct a test lab from scratch, manufacturers would be required to make capital outlays to acquire or construct a test facility and purchase test equipment. DOE has estimated its test costs for ACFs based on the AMCA 230–23 industry standard that DOE is referencing in this final rule. DOE estimated a minimum and maximum costs, then used these two values to determine an average cost.

To estimate building costs of an in-house testing facility, DOE assumed a single-story building in the U.S. using 2022 costs. DOE estimated test facility square footage by using information from manufacturers and by evaluating standard setups in AMCA 230–23, with length and width buffers applied. DOE estimated an average floor area 315 square feet.[131] Using this average square footage value, DOE has estimated one-time building cost for warehouse and storage to be $29,300.

DOE has identified that the test structure to test in accordance with AMCA 230–23 would consist of a lever arm and a test station. DOE has estimated that the average one-time cost for the lever arm and the test station would be $400.

The test procedure for ACFs, which aligns with AMCA 230–23, requires thrust, power, and air density to be measured or calculated by equipment with specific calibrations and accuracies. The cost of this test equipment is considered as a one-time cost. According to the test procedure, thrust can be measured with a load cell or standard weights. DOE has assumed that a testing facility should be equipped with both equipment types to accommodate various testing configurations and to take a conservative approach. DOE has estimated the cost of a load cell to be $1,500 and a set of standard weights to be $1,300. The power measurement is taken directly from an electric meter, which DOE has estimated to cost $9,700. The air density is calculated using measurements of air temperature with a thermometer and pressure with a barometer. DOE has estimated the costs of a thermometer to be $600 and a barometer to be $330. In sum, DOE has estimated that the cost to acquire all the necessary test equipment to perform the ACF test procedure is, on average, $13,430.

In total, DOE has estimated the capital cost of building an in-house testing facility for ACFs, on average, as $43,130. DOE notes that some fan manufacturers have indicated they already have existing facilities and equipment to test ACFs according to AMCA 230–23, which DOE references in this final test procedure.

b. Annual Costs

DOE has estimated annual costs for operating a testing facility, which include utilities and equipment calibration. DOE has estimated that the annual utilities costs would be $730,[132] based on the average floor area discussed in the previous section. Equipment would need to be calibrated each year, which DOE has estimated to be $16,600 based on 2016 calibration price lists from NIST.[133]

In total, DOE has estimated the annual cost of operating an in-house testing facility for ACFs as approximately $17,330.

c. Testing Costs

This final rule includes requirements regarding the sampling plan and representations for covered air circulating fans at subpart B of 10 CFR part 429. The sampling plan requires a minimum sample size of one unit per ACF basic model be tested when determining representative values of CFM/W, as well as other general fan performance metrics. Test costs include the cost of labor to set-up, test, and disassemble the fan. DOE estimated that it would take an average of 4 hours to set-up and disassemble a fan and 2 hours to test a fan, resulting in a total of 6 hours of labor per test. DOE has also assumed that a mechanical engineering technician would set-up and perform the testing. Based on wage and salary data from the BLS, DOE has estimated a fully burdened mechanical engineering technician wage of $44 per hour.[134] DOE has calculated the total cost of labor for testing an ACF to be approximately $260 per basic model.

d. AEDM Costs

As discussed previously in section III.M.2.d of this document, DOE assumes that a mechanical engineer would develop, validate, and implement a new AEDM. Based on wage and salary data from the BLS, DOE estimated the fully burdened mechanical engineering wage to be approximately $66 per

[130] *openfoam.org/*

[131] DOE used its air circulating fan database to estimate the average and maximum diameter of an ACF to be 40 inches and 61 inches, respectively. DOE then used these diameters to determine the floor area necessary to build a test structure for each fan in accordance with the test set-ups in AMCA 230–23 with a buffer of 1.2. DOE calculated the average floor area to be 180 square feet and the maximum floor area to be 430 square feet. DOE then took the average of these two values to estimate that the average floor area would be 315 square feet ((180 + 430) ÷ 2 = 315).

[132] DOE estimated the commercial utility costs to be $0.11/kWh using data from EIA's ''2021 Average Monthly Bill'' and commercial utility use to be 20.70 kWh/square foot using EIA's ''2018 Commercial Buildings Energy Consumption Survey'' (*www.eia.gov/electricity/sales_revenue_price/pdf/table5_b.pdf; www.eia.gov/consumption/commercial/data/2018/ppt/CBECS%202018%20C&E%20Flipbook.ppt*). DOE then calculated total average commercial utility costs to be $730 ($0.1122/kWh × 20.70 kWh/square foot × 315 square feet = $731).

[133] DOE estimated the NIST calibration fee from *www.nist.gov/system/files/documents/2016/10/31/FeeSchedule-2016.pdf.* However, this catalog does not list calibration prices for barometers; therefore, DOE used pricing for similar thermodynamic instruments.

[134] DOE estimated the hourly wage using data from BLS's ''Occupational Employment and Wages, May 2021'' publication. DOE used the ''Mechanical Engineering Technologies and Technicians'' mean hourly wage of $30.47 to estimate the hourly wage rate (*www.bls.gov/oes/current/oes173027.htm*). Last accessed on April 3, 2023. DOE then used BLS's ''Employer Costs for Employee Compensation—December 2022'' to estimate that wages and salary account for approximately 70.5 percent of employer labor costs for private industry workers. (*www.bls.gov/news.release/pdf/ecec.pdf*). Last accessed on April 3, 2023. Therefore, DOE estimated a fully-burdened labor rate of $43 ($30.47 ÷ 0.705 = $43.21).

hour.[135] Since product lines for air circulating fans are less complex than those for general fans, DOE also estimates that it would take roughly half the time to develop an AEDM for ACFs than it would to develop an AEDM for general fans; therefore, DOE assumed 62 labor hours per validation class for an engineer to develop and validate an AEDM for ACFs fans using existing simulation tools. Therefore, DOE estimates the cost of a fully burdened mechanical engineer as approximately $4,100 per validation class. As discussed in section III.I.1, testing of two basic models is required to validate an AEDM for a specific validation class. One unit must be tested per basic model in order to validate an AEDM. Therefore, two physical tests on two different basic models are required for validation of an ACF AEDM. As discussed in the previous section, DOE estimates the labor cost per test to be $260. Therefore, the total estimated manufacturer labor cost to develop and validate an AEDM for a single validation class is estimated to be $4,620, which is the cost to perform one test on two basic models ($520) plus the fully burdened cost of a mechanical engineer's time to develop and validate the AEDM ($4,100).

DOE also assumes a mechanical engineer would implement an AEDM once it is developed. DOE estimates that it would take a mechanical engineer 7 labor hours to determine the representative values necessary to certify a basic model using an AEDM. Therefore, the estimated cost to implement an AEDM to develop certified ratings for ACFs is $460 per basic model.

Additionally, DOE acknowledges that computational fluid dynamics software is necessary to validate and implement an AEDM and has concluded that the cost to purchase the software should be included as a one-time cost to use AEDMs. Software and hardware requirements and estimated cost are expected to be similar to that estimated for general fans (*i.e.,* $63,000).

[135] DOE estimated the hourly wage using data from BLS's ''Occupational Employment and Wages, May 2021'' publication. DOE used the ''Mechanical Engineers'' mean hourly wage of $46.64 to estimate the hourly wage rate (*www.bls.gov/oes/current/oes172141.htm*). DOE then used BLS's ''Employer Costs for Employee Compensation—June 2022'' to estimate that wages and salary account for approximately 70.5 percent of employer labor costs for private industry workers. (*www.bls.gov/news.release/pdf/ecec.pdf*). Last accessed on April 3, 2023. Therefore, DOE estimated a fully-burdened labor rate of $66 ($46.64 ÷ 0.705 = $66.16).

e. Voluntary Representations

Manufacturers of fans included within the scope of the test procedure adopted in this final rule would not be required to test fans and blowers in accordance with the DOE test procedure until the compliance date of a final rule adopting new energy conservation standards for fans and blowers. If manufacturers are currently reporting FEI for fans and blowers that are not air circulating fans or CFM/W for air circulating fans, they would need to ensure that the product is tested using the DOE test procedure and any representations in their marketing materials disclose the results of such test.[136] Although DOE is not requiring manufacturers to report FEI for fans and blowers that are not air circulating fans or CFM/W for air circulating fans prior to the compliance date of any new efficiency standards, DOE is assuming that manufactures may incur additional costs to remove or add FEI or CFM/W to their marketing materials to effect voluntary representations prior to the compliance date and independent of any new efficiency standards.

DOE anticipates that manufacturers currently making voluntary representations would update their online selection software, online catalogs, and product labels to remove or update efficiency representations in accordance with the DOE test procedure. DOE assumes that manufacturers would only need to update future print marketing materials, rather than create new materials as a result of the test procedure. DOE estimates that this effort would consist of no more than an hour of time for a graphic designer, along with two hours of time for a web developer, and one hour for a mechanical engineering technician—for a cost of approximately $195.01—per manufacturer.[137] If manufacturers decide to voluntarily test their products to provide an updated representation, manufacturers would incur the previously estimated testing costs along with this marketing materials related cost.

[136] If manufacturers voluntarily make representations regarding the FEI of fans and blowers that are not air circulating fans or CFM/W of air circulating fans, they would be required to test according to the DOE test procedure. *See* 42 U.S.C 6314(d)(1)

[137] Graphic designer salary of $28.83 per hour, web developer salary of $39.09 per hour, and mechanical technician salary of $29.07 per hour. Wages account for 70.5 percent of employer labor costs. DOE estimated the hourly wage using data from BLS's ''Occupational Employment and Wages, May 2021'' publication for each occupation (*www.bls.gov/oes/current/oes172141.htm*). Last accessed on April 3, 2023. DOE then used BLS's ''Employer Costs for Employee Compensation—December 2022'' to estimate that wages and salary account for approximately 70.5 percent of employer labor costs for private industry workers. (*www.bls.gov/news.release/pdf/ecec.pdf*). Last accessed on April 3, 2023. ($28.83 + $39.09 * 2 + $30.47)/0.705 = $195.01.

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866 and 13563

Executive Order (''E.O.'')12866, ''Regulatory Planning and Review,'' as supplemented and reaffirmed by E.O. 13563, ''Improving Regulation and Regulatory Review, 76 FR 3821 (Jan. 21, 2011) and E.O. 14094, ''Modernizing Regulatory Review,'' 88 FR 21879 (April 11, 2023), requires agencies, to the extent permitted by law, to (1) propose or adopt a regulation only upon a reasoned determination that its benefits justify its costs (recognizing that some benefits and costs are difficult to quantify); (2) tailor regulations to impose the least burden on society, consistent with obtaining regulatory objectives, taking into account, among other things, and to the extent practicable, the costs of cumulative regulations; (3) select, in choosing among alternative regulatory approaches, those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity); (4) to the extent feasible, specify performance objectives, rather than specifying the behavior or manner of compliance that regulated entities must adopt; and (5) identify and assess available alternatives to direct regulation, including providing economic incentives to encourage the desired behavior, such as user fees or marketable permits, or providing information upon which choices can be made by the public. DOE emphasizes as well that E.O. 13563 requires agencies to use the best available techniques to quantify anticipated present and future benefits and costs as accurately as possible. In its guidance, the Office of Information and Regulatory Affairs (''OIRA'') in the Office of Management and Budget (''OMB'') has emphasized that such techniques may include identifying changing future compliance costs that might result from technological innovation or anticipated behavioral changes. For the reasons stated in the preamble, this final regulatory action is consistent with these principles.

Section 6(a) of E.O. 12866 also requires agencies to submit ''significant regulatory actions'' to OIRA for review. OIRA has determined that this final

regulatory action does not constitute a ''significant regulatory action'' under section 3(f) of E.O. 12866. Accordingly, this action was not submitted to OIRA for review under E.O. 12866.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of a final regulatory flexibility analysis (FRFA) for any final rule where the agency was first required by law to publish a proposed rule for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the DOE rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's website: *www.energy.gov/gc/office-general-counsel.* DOE reviewed this final rule under the provisions of the Regulatory Flexibility Act and the procedures and policies published on February 19, 2003.

DOE has determined that the only non-voluntary costs imposed by this test procedure would be changes to marketing materials for companies currently making efficiency representations—constituting $195.01 per manufacturer as estimated previously. This cost is not expected to differ between small and large manufacturers. The testing costs estimated previously would either be imposed following possible new energy conservation standards on covered fans and blowers or voluntarily undertaken by manufacturers. As such, DOE has concluded that there would not be significant economic impact on small entities as a result of this test procedure. Still, although such is not currently required, DOE has recently conducted a focused inquiry into small business manufacturers of the fans and blowers covered by this rulemaking in relation to the test procedure related costs that would be imposed as a result of possible future energy conservation standards.

DOE used the Small Business Administration (SBA) size standards to determine whether any small entities would be subject to the requirements of the proposed rule. The small business size standards are listed by North American Industry Classification System (''NAICS'') code as well as by industry description and are available at *www.sba.gov/document/support--table-size-standards.* Manufacturing commercial and industrial fans and blowers is classified under NAICS 333413, ''Industrial and Commercial Fan and Blower and Air Purification Equipment Manufacturing.'' The SBA sets a threshold of 500 employees or fewer for an entity to be considered as a small business for this category. DOE used a combination of publicly available information and a private stakeholder database to create a list of potential manufacturers. DOE additionally referenced manufacturer lists for similar products derived from Compliance Certification Database.[138] Once DOE created a list of potential manufacturers, DOE used market research tools to determine whether any met the SBA's definition of a small entity, based on the total number of employees for each company including parent, subsidiary, and sister entities.

Based on DOE's analysis, over 200 companies potentially selling commercial and industrial fans and blowers covered by this proposed test procedure were identified. DOE screened out companies that do not meet the small entity definition and additionally screened out companies that are largely or entirely foreign owned and operated. Of the identified companies, 51 were further identified as a potential small business manufacturing commercial and industrial fans and blowers. Through a review of each business' respective website DOE established that 20 of the 51 businesses were distinct OEMs directly producing covered equipment. Below is a discussion of the various potential testing costs associated with these small manufacturers and potential future energy conservation standards for fans and blowers.

1. Creation of Testing Facility—General Fans

DOE does not expect costs for a test facility to differ between large and small businesses. As outlined in section III.M of this document, DOE estimated the capital investment for a new general fan testing facility and equipment to be $343,300 along with approximately $8,000 in yearly utility costs and $21,500 in yearly calibration costs.

2. AEDM Creation and Testing Costs—General Fans

DOE likewise does not expect that general fan per model in-house testing costs or AEDM creation costs would differ between large and small manufacturers. As outlined in section III.M, DOE estimated the average total labor cost of testing a covered general fan to be $260 per model (Which will need to be done for two basic models per validation class) and approximately $8,700 to develop the AEDM for a validation class—for a total of $9,220.

Due to the lack of a model database and the large number of potential small businesses, DOE reviewed the websites and, where available, the product catalogs of each of the small businesses manufacturers. While detailed product information was not availiable for three of the sampled small businesses, DOE identified, maximally, 2,709 models of commercial and industrial fans and blowers that are covered by the proposed test procedure across the remaining 17 small businesses. The number of models identified ranged from 7 to 636 across the applicable manufacturers, for an average of 159 and a median of 40 models per manufacturer. Across all 20 small business manufacuters, DOE estimates that 65 AEDMs would be required—with manufacturers offering between one and six of the general fans categories covered by this rulemaking, for a median value of two. Accordingly, DOE has estimated that total unit testing and AEDM creation costs would be $599,300 for all small businesses.

3. Creation of Testing Facility—Air Circulating Fans

DOE does not expect costs for a test facility for air circulating fans to differ between large and small businesses. As outlined in section III.M of this document, DOE estimated the capital investment for a new air circulating fans testing facility and equipment to be $43,130 on average, along with approximately $730 in yearly utility costs and $16,660 in yearly calibration costs.

4. AEDM Creation and Testing Costs—Air Circulating Fans

DOE likewise does not expect that air circulating fans per model in-house testing costs or AEDM creation costs would differ between large and small manufacturers. As outlined in section III.M of this document, DOE estimated the average total labor cost of testing a covered general fan to be $260 per model (Which will need to be done for two basic models per validation class) and approximately $4,100 to develop the AEDM for a validation class—for a total of $4,620.

Out of the 20 small business manufacturers identified, four produce

[138] U.S. Department of Energy Compliance Certification Database, available at *www.regulations.doe.gov/certification-data/products.html.*

covered air circulating fans in addition to general fans. The number of models offered range from four to 30 and each of these small businesses only offers one validation category of air circulating fan. Accordingly, all four small businesses would incur an aggregate additional $18,480 in testing and AEDM creation costs.

5. Total Costs

Total potential costs to the identified small businesses would be approximately $7,244,000 and the average cost would be approximately $381,260. 16 of the small businesses would also incur an average of $8,000 in yearly utility costs and $21,500 in yearly calibration costs and four of small businesses would incur around $8,730 in yearly utility costs and $38,160 in yearly calibration costs. DOE was able to find annual revenue estimates for 19 of the small businesses. Estimated one-time testing costs as a pecentage of estimated annual revenue range widely—from less than one 0.4 percent to 44.6 percent—for an average of approximately 7.7 percent. Additionally, Manufacturers would not be required to test their products according to the DOE test procedure unless and until possible new energy conservation standards are established. Manufacturers would need to test their products according to the DOE test procedure if they wish to make representations about efficiency in their marketing material—as mentioned previously, updating marketing materials is expected to cost $195.01.

6. Certification Statement

As noted previously, almost no non-voluntary costs are anticipated as a result of this rulemaking—since testing would not be required unless and until new energy conservation standards are established for covered fans and blowers. Based on the de minimis cost impacts, DOE certifies that this final rule does not have a ''significant economic impact on a substantial number of small entities,'' and determined that the preparation of a FRFA is not warranted. DOE will transmit a certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the Small Business Administration for review under 5 U.S.C. 605(b).

C. Review Under the Paperwork Reduction Act of 1995

Although no energy conservation standards have been established for fans and blowers as of the publication of this final rule, manufacturers of fans and blowers would need to certify to DOE that their products comply with any potential future applicable energy conservation standards. To certify compliance, manufacturers must first obtain test data for their equipment according to the DOE test procedures, including any amendments adopted for those test procedures. DOE has established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including fans and blowers. (*See* generally 10 CFR part 429.) The collection-of-information requirement for the certification and recordkeeping is subject to review and approval by OMB under the Paperwork Reduction Act (''PRA''). This requirement has been approved by OMB under OMB control number 1910–1400. Public reporting burden for the certification is estimated to average 35 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

Certification data will be required for fans and blowers; however, DOE is not establishing certification or reporting requirements for fans and blowers in this final rule. Instead, DOE may consider proposals to establish certification requirements and reporting for fans and blowers under a separate rulemaking regarding appliance and equipment certification. DOE will address changes to OMB Control Number 1910–1400 at that time, as necessary.

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

D. Review Under the National Environmental Policy Act of 1969

In this final rule, DOE establishes test procedure amendments that it expects will be used to develop and implement future energy conservation standards for fans and blowers. DOE has determined that this rule falls into a class of actions that are categorically excluded from review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and DOE's implementing regulations at 10 CFR part 1021. Specifically, DOE has determined that adopting test procedures for measuring energy efficiency of consumer products and industrial equipment is consistent with activities identified in 10 CFR part 1021, appendix A to subpart D, A5 and A6. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

E. Review Under Executive Order 13132

Executive Order 13132, ''Federalism,'' 64 FR 43255 (August 4, 1999), imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have federalism implications. The Executive order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. DOE examined this final rule and determined that it will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this final rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297(d)) No further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

Regarding the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' 61 FR 4729 (Feb. 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; (3) provide a clear legal standard for affected conduct rather than a general standard; and (4) promote simplification and burden reduction. Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation (1) clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct

while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in sections 3(a) and 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (''UMRA'') requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a regulatory action resulting in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820; also available at *www.energy.gov/gc/office-general-counsel.* DOE examined this final rule according to UMRA and its statement of policy and determined that the rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of $100 million or more in any year, so these requirements do not apply.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This final rule will not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

DOE has determined, under Executive Order 12630, ''Governmental Actions and Interference with Constitutionally Protected Property Rights'' 53 FR 8859 (March 18, 1988), that this regulation will not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). Pursuant to OMB Memorandum M–19–15, Improving Implementation of the Information Quality Act (April 24, 2019), DOE published updated guidelines which are available at *www.energy.gov/sites/prod/files/2019/12/f70/DOE%20Final%20Updated%20IQA%20Guidelines%20Dec%202019.pdf.* DOE has reviewed this final rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use,'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OMB, a Statement of Energy Effects for any significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that (1) is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA as a significant energy action. For any significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use if the regulation is implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

This regulatory action is not a significant regulatory action under Executive Order 12866. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

L. Review Under Section 32 of the Federal Energy Administration Act of 1974

Under section 301 of the Department of Energy Organization Act (Pub. L. 95–91; 42 U.S.C. 7101), DOE must comply with section 32 of the Federal Energy Administration Act of 1974, as amended by the Federal Energy Administration Authorization Act of 1977. (15 U.S.C. 788; ''FEAA'') Section 32 essentially provides in relevant part that, where a proposed rule authorizes or requires use of commercial standards, the notice of proposed rulemaking must inform the public of the use and background of such standards. In addition, section 32(c) requires DOE to consult with the Attorney General and the Chairman of the Federal Trade Commission (''FTC'') concerning the impact of the commercial or industry standards on competition.

The modifications to the test procedure for fans and blowers adopted in this final rule incorporates testing methods contained in certain sections of the following commercial standards: AMCA 214–21, AMCA 210–16, AMCA 230–23, AMCA 240–15, ISO 5801:2017, ISO 80079–36:2016, and UL 705. DOE has evaluated these standards and is unable to conclude whether it fully complies with the requirements of section 32(b) of the FEAA (*i.e.,* whether it was developed in a manner that fully provides for public participation, comment, and review.) DOE has consulted with both the Attorney General and the Chairman of the FTC about the impact on competition of using the methods contained in these standards and has received no comments objecting to their use.

M. Congressional Notification

As required by 5 U.S.C. 801, DOE will report to Congress on the promulgation of this rule before its effective date. The report will state that it has been determined that the rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

N. Description of Materials Incorporated by Reference

In this final rule, DOE incorporates by reference the following test standards:

AMCA 214–21 is an industry-accepted test procedure that provides methods to determine fan electrical shaft power and/or electrical power, flow, and pressure and calculate the fan energy index (FEI) and is applicable to product sold in North America. AMCA 214–21 specifies testing conducted in accordance with other industry-accepted test procedures (also proposed for incorporation by reference). The test procedure established by this final rule references various sections of AMCA 214–21 that address test setup, test conduct, and calculation of the FEI for fans and blowers other than air circulating fans.

AMCA 210–16 and AMCA 230–23 are industry-accepted test procedures that provides methods of tests for fans and blowers other than air circulating fans, and air circulating fans, respectively, in the United States. These methods are referenced in AMCA 214–21.

AMCA 240–15 is an industry-accepted test procedure that provides definitions and methods of tests for positive pressure ventilator.

Copies of AMCA 214–21, AMCA 210–16, AMCA 230–23, and AMCA 240–15, may be purchased from AMCA International at 30 West University Drive, Arlington Heights, IL 60004–1893, or by going to *www.amca.org.*

ISO 5801:2017 is the industry-accepted test procedure that provides methods of tests for fans and blowers that are not air circulating fans, internationally.

ISO 80079–36:2016, specifies the method and requirements for design, construction, testing and marking of non-electrical equipment intended for use in potentially explosive atmospheres.

Copies of ISO 5801:2017 and ISO 80079–36:2016 may be purchased from International Organization for Standardization, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland, or by going to *www.iso.org.*

UL 705–22 provides safety requirements for power ventilators.

Copies of UL 705–2022 can be obtained from UL, 333 Pfingsten Road, Northbrook, IL, 60062 or *www.shopulstandards.com.*

V. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this final rule.

List of Subjects

10 CFR Part 429

Administrative practice and procedure, Confidential business information, Energy conservation, Household appliances, Imports, Intergovernmental relations, Reporting and recordkeeping requirements, Small businesses.

10 CFR Part 431

Administrative practice and procedure, Confidential business information, Energy conservation test procedures, Incorporation by reference, and Reporting and recordkeeping requirements.

Signing Authority

This document of the Department of Energy was signed on April 20, 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 April 20, 2023.

Treena V. Garrett,

Federal Register Liaison Officer, U.S. Department of Energy.

For the reasons stated in the preamble, DOE amends parts 429 and 431 of Chapter II of Title 10, Code of Federal Regulations as set forth below:

PART 429—CERTIFICATION, COMPLIANCE, AND ENFORCEMENT FOR CONSUMER PRODUCTS AND COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 1. The authority citation for part 429 continues to read as follows:

Authority: 42 U.S.C. 6291–6317; 28 U.S.C. 2461 note.

§ 429.11 [Amended]

■ 2. Section 429.11 is amended in paragraphs (a) and (b)(1) by removing ''429.68'' and adding in its place ''429.69''.

■ 3. Add § 429.69 to subpart B to read as follows:

§ 429.69 Fans and blowers.

(a) *Determination of represented values of fans and blowers other than air circulating fans.* A manufacturer must determine the represented values for each basic model, either by testing in conjunction with the applicable sampling provisions or by applying an AEDM as set forth in this section and in § 429.70(n). Manufacturers must update represented values to account for any change in the applicable motor standards in Table 5 of § 431.25 of this chapter and certify amended values as of the next annual certification (as applicable).

(1) *Testing.* (i) If the represented values for a given basic model are determined through testing, a sample of at least one unit must be selected and the requirements of § 429.11 apply.

(ii) If only one unit is tested, at each duty point characterized by a flow and speed value, any represented value of fan electrical input power (''FEP''), fan shaft input power, or other measure of energy consumption of a basic model for which consumers would favor lower values shall be greater than or equal to the tested value. Represented values must be rounded to the nearest hundredth.

(iii) If only one unit is tested, at each duty point characterized by a flow and speed value, any represented value of fan electrical input power (''FEI''), or other measure of energy consumption of a basic model for which consumers would favor higher values shall be less than or equal to the tested value. Represented values must be rounded to the nearest hundredth.

(iv) If more than one unit is tested, at each duty point characterized by a flow and speed value, any represented value of fan electrical input power (''FEP''), fan shaft input power, or other measure of energy consumption of a basic model for which consumers would favor lower values shall be greater than or equal to the higher of:

(A) The mean of the sample, where

$$\bar{x} = \frac{1}{n}\sum_{i=1}^{n} x_i$$

Where is $\bar{x}$ the sample mean; n is the number of samples, and x_i is the i^{th} sample. Or,

(B) The upper 95 percent confidence limit (UCL) of the true mean divided by 1.05, where:

$$UCL = \bar{x} + t_{0.95}\left(\frac{s}{\sqrt{n}}\right)$$

and $\bar{x}$ is the sample mean; s is the sample standard deviation; n is the number of samples; and $t_{0.95}$ is the t statistic for a 95 percent one-tailed confidence interval with n-1 degrees of freedom (from appendix A of subpart B of this part). Represented values must be rounded to the nearest hundredth.

(v) If more than one unit is tested, any represented value of the fan energy index (''FEI''), or other measure of energy consumption of a basic model for which consumers would favor higher values shall be less than or equal to the lower of:

(A) The mean of the sample, where

$$\bar{x} = \frac{1}{n}\sum_{i=1}^{n} x_i$$

Where $\bar{x}$ is the sample mean; n is the number of samples, and x_i is the i^{th} sample. Or,

(B) The lower 95 percent confidence limit (LCL) of the true mean divided by 0.95, where:

$$LCL = \bar{x} - t_{0.95}\left(\frac{s}{\sqrt{n}}\right)$$

and $\bar{x}$ is the sample mean; s is the sample standard deviation; n is the number of samples; and $t_{0.95}$ is the t statistic for a 95 percent one-tailed confidence interval with n-1 degrees of freedom (from appendix A of subpart B of this part). Represented values must be rounded to the nearest hundredth.

(vi) At each duty point characterized by a flow and speed value, the representative value of static or total pressure of a basic model of must be the mean of the tested static or total pressure for each tested unit. If only one unit is tested, the representative value of static or total pressure at the duty point of a basic model is the tested value.

(2) *Alternative efficiency determination methods.* In lieu of testing, the represented values for a basic model must be determined through the application of an AEDM pursuant to the requirements of § 429.70(n) and the provisions of this section, where: the represented values of any basic model used to validate an AEDM must be calculated under paragraph (b)(1) of this section.

(b) *Determination of represented values for air circulating fans.* A manufacturer must determine the represented values for each basic model, either by testing in conjunction with the applicable sampling provisions or by applying an AEDM as set forth in this section and in § 429.70(n).

(1) *Testing.* (i) If the represented values for a given basic model are determined through testing, the requirements of § 429.11 apply.

(ii) Any represented value of fan electrical input power (''W_E''), or other measure of energy consumption of a basic model for which consumers would favor lower values shall be greater than or equal to the higher of:

(A) The mean of the sample, where

$$\bar{x} = \frac{1}{n}\sum_{i=1}^{n} x_i$$

Where $\bar{x}$ is the sample mean; n is the number of samples, and x_i is the i^{th} sample. Or,

(B) The upper 95 percent confidence limit (UCL) of the true mean divided by 1.05, where:

$$UCL = \bar{x} + t_{0.95}\left(\frac{s}{\sqrt{n}}\right)$$

and $\bar{x}$ is the sample mean; s is the sample standard deviation; n is the number of samples; and $t_{0.95}$ is the t statistic for a 95 percent one-tailed confidence interval with n-1 degrees of freedom (from appendix A of subpart B of this part). Represented values must be rounded to the nearest hundredth.

(iii) Any represented value of efficacy (Eff_{circ}) or other measure of energy consumption of a basic model for which consumers would favor higher values shall be less than or equal to the lower of:

(A) The mean of the sample, where

$$\bar{x} = \frac{1}{n}\sum_{i=1}^{n} x_i$$

Where $\bar{x}$ is the sample mean; n is the number of samples, and x_i is the i^{th} sample. Or,

(B) The lower 95 percent confidence limit (LCL) of the true mean divided by 0.95, where:

$$LCL = \bar{x} - t_{0.95}\left(\frac{s}{\sqrt{n}}\right)$$

and $\bar{x}$ is the sample mean; s is the sample standard deviation; n is the number of samples; and $t_{0.95}$ is the t statistic for a 95 percent one-tailed confidence interval with n-1 degrees of freedom (from appendix A of subpart B of this part). Represented values must be rounded to the nearest hundredth.

(2) *Alternative efficiency determination methods.* In lieu of testing, the represented values for a basic model must be determined through the application of an AEDM pursuant to the requirements of § 429.70(n) and the provisions of this section, where: the represented values of any basic model used to validate an AEDM must be calculated under paragraph (b)(1) of this section.

■ 4. Amend § 429.70 is amended by:

■ a. In paragraph (a), removing ''429.65'' and, adding its place, ''429.69''; and

■ b. Adding paragraph (n).

The additions reads as follows:

§ 429.70 Alternative methods for determining energy efficiency or energy use.

* * * * *

(n) *Alternative efficiency determination method (AEDM) for fans and blowers.* (1) *Criteria an AEDM must satisfy.* A manufacturer is not permitted to apply an AEDM to a basic model of fan or blower to determine represented values pursuant to this section unless:

(i) The AEDM is derived from a mathematical model that estimates the energy use characteristics of the basic model as measured by the applicable DOE test procedure and accurately represents the performance characteristics of that basic model;

(ii) The AEDM is based on engineering or statistical analysis, computer simulation or modeling, or other analytic evaluation of actual performance data; and

(iii) The manufacturer has validated the AEDM in accordance with paragraph (n)(2) of this section.

(2) *Validation of an AEDM.* Before using an AEDM, the manufacturer must validate the AEDM's accuracy and reliability by comparing the simulated FEI, or simulated efficacy, as applicable, to the tested FEI or tested efficacy, as applicable (determined by testing), as follows.

(i) *Select basic models.* For each fan or blower validation class listed as follows: centrifugal housed fan; radial housed fan; centrifugal inline fan; centrifugal unhoused fan; centrifugal power roof ventilator exhaust fan; centrifugal power roof ventilator supply fan; axial inline fan; axial panel fan; axial centrifugal power roof ventilator fan; unhoused ACFH; axial housed ACFH; and housed centrifugal air circulating fan to which the AEDM is applied, a manufacturer must select at least two basic models compliant with any energy conservation standards in subpart J of part 431 of this chapter. In addition, at least one basic model selected for validation testing should include a motor, or a motor and controller if the AEDM is applied to a basic model with a motor or to a basic model with a motor and controller.

(ii) *Apply the AEDM* to the selected basic models. Using the AEDM,

calculate the simulated FEI, or efficacy, as applicable, for each of the selected basic models.

(iii) *Testing.* Test a sample of units of each of the selected basic models in accordance with 10 CFR 431.174 and determine the FEI or efficacy, as applicable, in accordance with § 429.69(a)(1) and (b)(1) as applicable.

(iv) *Compare.* The simulated FEI or simulated efficacy, as applicable, for each basic model must be less than or equal to 105 percent of the FEI or efficacy, as applicable, determined in paragraph (n)(2)(iii) of this section through testing.

(v) *Additional AEDM requirements.* When making representations of values other than FEI (*e.g.,* FEP, fan shaft power) or efficacy (as applicable) for a basic model that relies on an AEDM, all other representations are required to be based on the same AEDM results used to generate the represented value of FEI or efficacy.

(3) *Verification of an AEDM*—(i) *Periodic review*s. Each manufacturer must periodically select basic models representative of those to which it has applied an AEDM. The manufacturer must select a sufficient number of basic models to ensure the AEDM maintains its accuracy and reliability. For each basic model selected for verification: subject at least one unit to testing in accordance with 10 CFR 431.174. The provisions in paragraph (n)(2)(iv) of this section must be met.

(ii) *Inspection records.* Each manufacturer that has used an AEDM under this section must have available for inspection by the Department of Energy records showing:

(A) The method or methods used to develop the AEDM;

(B) The mathematical model, the engineering or statistical analysis, computer simulation or modeling, and other analytic evaluation of performance data on which the AEDM is based;

(C) Complete test data, equipment information, and related information that the manufacturer has generated or acquired pursuant to paragraphs (n)(2) and (3) of this section; and

(D) The calculations used to determine the simulated FEI or simulated weighted-average FEI, as applicable, of each basic model to which the AEDM was applied.

(iii) *Simulations.* If requested by the Department, the manufacturer must:

(A) Conduct simulations to predict the performance of particular basic models of electric motors specified by the Department;

(B) Provide analyses of previous simulations conducted by the manufacturer; and/or

(C) Conduct testing of basic models selected by the Department.

PART 431—ENERGY EFFICIENCY PROGRAM FOR CERTAIN COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 5. The authority citation for part 431 continues to read as follows:

Authority: 42 U.S.C. 6291–6317; 28 U.S.C. 2461 note.

■ 6. Section 431.172 is revised to read as follows:

§ 431.172 Definitions.

Air circulating axial panel fan means an axial housed air circulating fan head without a cylindrical housing or box housing that is mounted on a panel, orifice plate or ring.

Air circulating fan means a fan that has no provision for connection to ducting or separation of the fan inlet from its outlet using a pressure boundary, operates against zero external static pressure loss, and is not a jet fan.

Air circulating fan discharge area: area of a circle having a diameter equal to the blade tip diameter.

Air circulating fan outlet area means the gross inside area measured at the plane of the outlet opening.

Air-cooled steam condenser means a device for rejecting heat to the atmosphere through the indirect condensing of steam inside air-cooled finned tubes.

Axial inline fan means a fan with an axial impeller and a cylindrical housing with or without turning vanes.

Axial panel fans means an axial fan, without cylindrical housing, that includes a panel, orifice plate, or ring with brackets for mounting through a wall, ceiling, or other structure that separates the fan's inlet from its outlet.

Basic model, with respect to fans and blowers, means all units of fans and blowers manufactured by one manufacturer, having the same primary energy source, and having essentially identical electrical, physical, and functional (*e.g.,* aerodynamic) characteristics that affect energy consumption. In addition:

(1) All variations of blade pitches of an adjustable-pitch axial fan may be considered a single basic model; and

(2) All variations of impeller widths and impeller diameters of a given full-width impeller and full-diameter impeller centrifugal fan may be considered a single basic model.

Box fan means an axial housed air circulating fan head without a cylindrical housing that is mounted on a panel, orifice plate or ring and is mounted in a box housing.

Centrifugal housed fan means a fan with a centrifugal or mixed flow impeller in which airflow exits into a housing that is generally scroll-shaped to direct the air through a single fan outlet. A centrifugal housed fan does not include a radial impeller.

Centrifugal inline fan means a fan with a centrifugal or mixed flow impeller in which airflow enters axially at the fan inlet and the housing redirects radial airflow from the impeller to exit the fan in an axial direction.

Centrifugal unhoused fan means a fan with a centrifugal or mixed flow impeller in which airflow enters through a panel and discharges into free space. Inlets and outlets are not ducted. This fan type also includes fans designed for use in fan arrays that have partition walls separating the fan from other fans in the array.

Cross-flow fan means a fan or blower with a housing that creates an airflow path through the impeller in a direction at right angles to its axis of rotation and with airflow both entering and exiting the impeller at its periphery. Inlets and outlets can optionally be ducted.

Cylindrical air circulating fan means an axial housed air circulating fan head with a cylindrical housing that is not a Positive Pressure Ventilator as defined in AMCA 240–15 (incorporated by reference, see § 431.173).

Evaporative field erected closed-circuit cooling tower means a structure which rejects heat to the atmosphere through the indirect cooling of a process fluid stream to a lower temperature by partial evaporation of an external recirculating water flow.

Evaporative field erected open-circuit cooling tower means a structure which rejects heat to the atmosphere through the direct cooling of a water stream to a lower temperature by partial evaporation.

Fan or *blower* means a rotary bladed machine used to convert electrical or mechanical power to air power, with an energy output limited to 25 kilojoule (kJ)/kilogram (kg) of air. It consists of an impeller, a shaft and bearings and/or driver to support the impeller, as well as a structure or housing. A fan or blower may include a transmission, driver, and/or motor controller.

Fan static air power means the static power delivered to air by the fan or blower; it is proportional to the product of the fan airflow rate, the fan static pressure and the compressibility coefficient and is calculated in accordance with section 7.8.1 of AMCA 210–16 (incorporated by reference, see § 431.173), using static pressure instead of total pressure.

Fan total air power means the total power delivered to air by the fan or blower; it is proportional to the product of the fan airflow rate, the fan total pressure and the compressibility coefficient and is calculated in accordance with section 7.8.1 of AMCA 210–16 (incorporated by reference, see § 431.173).

Field erected air-cooled (dry) cooler means a structure which rejects heat to the atmosphere from a fluid, either liquid, gas or a mixture thereof, flowing through an air-cooled internal coil.

Field erected evaporative condenser means a structure which rejects heat to the atmosphere through the indirect condensing of a refrigerant in an internal coil by partial evaporation of an external recirculating water flow.

Full-diameter impeller means maximum impeller diameter with which a given fan or blower basic model is distributed in commerce.

Full-width impeller means the maximum impeller width with which a given fan or blower basic model is distributed in commerce.

Housed air circulating fan head means an air circulating fan with an axial or centrifugal impeller, and a housing.

Housed centrifugal air circulating fan means a housed air circulating fan head with a centrifugal or radial impeller in which airflow exits into a housing that is generally scroll shaped to direct the air through a single, narrow fan outlet.

Induced flow fan means a type of laboratory exhaust fan with a nozzle and windband; the fan's outlet airflow is greater than the inlet airflow due to induced airflow. All airflow entering the inlet exits through the nozzle. Airflow exiting the windband includes the nozzle airflow plus the induced airflow.

Jet fan means a fan designed and marketed specifically for producing a high velocity air jet in a space to increase its air momentum. Jet fans are rated using thrust. Inlets and outlets are not ducted but may include acoustic silencers.

Packaged air-cooled (dry) cooler means a device which rejects heat to the atmosphere from a fluid, either liquid, gas or a mixture thereof, flowing through an air-cooled internal coil.

Packaged evaporative closed-circuit cooling tower means a device which rejects heat to the atmosphere through the indirect cooling of a process fluid stream in an internal coil to a lower temperature by partial evaporation of an external recirculating water flow.

Packaged evaporative condenser means a device which rejects heat to the atmosphere through the indirect condensing of a refrigerant in an internal coil by partial evaporation of an external recirculating water flow.

Packaged evaporative open-circuit cooling tower means a device which rejects heat to the atmosphere through the direct cooling of a water stream to a lower temperature by partial evaporation.

Power roof ventilator means a fan with an internal driver and a housing to prevent precipitation from entering the building. It has a base designed to fit over a roof or wall opening, usually by means of a roof curb.

Radial-housed fan means a fan with a radial impeller in which airflow exits into a housing that is generally scroll-shaped to direct the air through a single fan outlet. Inlets and outlets can optionally be ducted.

Safety Fan means:

(1) A reversible axial fan in cylindrical housing that is designed and marketed for use in ducted tunnel ventilation that will reverse operation under emergency ventilation conditions;

(2) A fan for use in explosive atmospheres tested and marked according to the English version of ISO 80079–36:2016 (incorporated by reference, see § 431.173);

(3) An electric-motor-driven-Positive Pressure Ventilator as defined in AMCA 240–15 (incorporated by reference, see § 431.173);

(4) A fan bearing a listing for ''Power Ventilators for Smoke Control Systems'' in compliance with UL 705 (incorporated by reference, see § 431.173); or

(5) A laboratory exhaust fan designed and marketed specifically for exhausting contaminated air vertically away from a building using a high-velocity discharge.

Unhoused air circulating fan head means an air circulating fan without a housing, having an axial impeller with a ratio of fan-blade span (in inches) to maximum rate of rotation (in revolutions per minute) less than or equal to 0.06. The impeller may or may not be guarded.

■ 7. Section 431.173 is added to read as follows:

§ 431.173 Materials incorporated by reference.

(a) Certain material is incorporated by reference into this subpart with the approval of the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, DOE must publish a document in the **Federal Register** and the material must be available to the public. All approved incorporation by reference (IBR) material is available for inspection at DOE, and at the National Archives and Records Administration (NARA). Contact DOE at: the U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, 1000 Independence Ave. SW, EE–5B, Washington, DC 20585, (202) 586–9127, *Buildings@ee.doe.gov*, *https://www.energy.gov/eere/buildings/building-technologies-office.* For information on the availability of this material at NARA, visit *www.archives.gov/federal-register/cfr/ibr-locations.html* or email: *fr.inspection@nara.gov.* The material may be obtained from the sources in the following paragraphs of this section.

(b) *AMCA.* Air Movement and Control Association International, Inc., 30 West University Drive, Arlington Heights, IL 60004–1893; (847) 394–0150; *www.amca.org.*

(1) ANSI/AMCA Standard 21016 (''AMCA 210–16''), *Laboratory Methods of Testing Fans for Certified Aerodynamic Performance Rating,* ANSI-approved August 26, 2016; IBR approved for § 431.172; appendix A to this subpart. (Co-published as ASHRAE 51–16).

(2) ANSI/AMCA Standard 214–21 (''AMCA 214–21''), *Test Procedure for Calculating Fan Energy Index (FEI) for Commercial and Industrial Fans and Blowers,* ANSI-approved March 1, 2021; IBR approved for § 431.174; appendix A to this subpart.

(3) ANSI/AMCA Standard 230–23 (''AMCA 230–23''), *Laboratory Methods of Testing Air Circulating Fans for Rating and Certification,* ANSI-approved February 10, 2023. IBR approved for appendix B to this subpart.

(4) ANSI/AMCA Standard 240–15 (''AMCA 240–15''), *Laboratory Methods of Testing Positive Pressure Ventilators for Aerodynamic Performance Rating,* ANSI-approved May 9, 2015; IBR approved for § 431.172.

(c) *ISO.* International Organization for Standardization, Chemin de Blandonnet 8, CP 401, 1214 Vernier, Geneva, Switzerland; *www.iso.org.*

(1) ISO 5801:2017(E) (''ISO 5801:2017''), *Fans—Performance testing using standardized airways,* Third Edition, approved September 2017; IBR approved for appendix A to this subpart.

(2) ISO 80079–36:2016, *Explosive atmospheres—Part 36: Non-electrical equipment for explosive atmospheres—Basic method and requirements,* Edition 1.0, February 2016; IBR approved for § 431.172.

(d) *UL.* Underwriters Laboratories, 333 Pfingsten Road, Northbrook,

Illinois, 60062; *www.shopulstandards.com.*

(1) UL 705, *Standard for Safety for Power Ventilators,* Edition 7, July 19, 2017 (including revisions through August 19, 2022); IBR approved for § 431.172.

(2) [Reserved].

■ 8. Section 431.174 is added to read as follows:

§ 431.174 Test Procedure for fans or blowers.

(a) *Scope for fans and blowers other than air circulating fans.* A fan or blower, other than an air circulating fan is subject to the test procedure in this section if it meets the following criteria:

(1) Is a centrifugal housed fan; radial housed fan; centrifugal inline fan; centrifugal unhoused fan; centrifugal power roof ventilator exhaust fan; centrifugal power roof ventilator supply fan; axial inline fan; axial panel fan; or axial centrifugal power roof ventilator fan;

(2) Is not:

(i) A radial housed unshrouded fan with blade diameter at tip less than 30 inches or a blade width of less than 3 inches;

(ii) A safety fan;

(iii) An induced flow fan;

(iv) A jet fan;

(v) A cross-flow fan;

(vi) A fan manufactured exclusively to be powered by internal combustion engines;

(vii) A fan that create a vacuum of 30 inches water gauge or greater;

(viii) A fan that is designed and marketed to operate at or above 482 degrees Fahrenheit (250 degrees Celsius); or

(ix) A fan and blower embedded in the equipment listed in paragraph (a)(3) of this section;

(3) Is not an embedded fan subject to the following exclusions:

(i) The test procedure in this section does not apply to fans or blowers that are embedded in:

(A) Single phase central air conditioners and heat pumps rated with a certified cooling capacity less than 65,000 British thermal units per hour (''Btu/h'') cooling capacity, that are subject to DOE's energy conservation standard at 10 CFR 430.32(c);

(B) Three phase, air-cooled, small commercial packaged air-conditioning and heating equipment rated with a certified cooling capacity less than 65,000 Btu/h cooling capacity, that are subject to DOE's energy conservation standard at § 431.97(b);

(C) Transport refrigeration (*i.e.,* Trailer refrigeration, Self-powered truck refrigeration, Vehicle-powered truck refrigeration, Marine/Rail container refrigerant);

(D) Vacuum cleaners;

(E) Heat Rejection Equipment: Packaged evaporative open-circuit cooling towers; Evaporative field-erected open-circuit cooling towers; Packaged evaporative closed-circuit cooling towers; Evaporative field-erected closed-circuit cooling towers; Packaged evaporative condensers; Field-erected evaporative condensers; Packaged air-cooled (dry) coolers; Field-erected air-cooled (dry) cooler; Air-cooled steam condensers; Hybrid (water saving) versions of all of the previously listed equipment that contain both evaporative and air-cooled heat exchange sections;

(F) Air curtains; and

(G) Direct expansion-dedicated outdoor air system that are subject to any of DOE's test procedures in appendix B to subpart F of this part.

(ii) The test procedure in this section does not apply to supply or condenser fans or blowers that are embedded in:

(A) Air-cooled commercial package air conditioners and heat pumps (''CUAC,'' ''CUHP'') with a certified cooling capacity between 5.5 ton (65,000 Btu/h) and 63.5 ton (760,000 Btu/h) that are subject to DOE's energy conservation standard at § 431.97(b);

(B) Water-cooled and evaporatively-cooled commercial air conditioners that are subject to DOE's energy conservation standard at § 431.97(b);

(C) Water-source heat pumps that are subject to DOE's energy conservation standard at § 431.97(b);

(D) Single package vertical air conditioners and heat pumps that are subject to DOE's energy conservation standard at § 431.97(d);

(E) Packaged terminal air conditioners (''PTAC'') and packaged terminal heat pumps (PTHP) that are subject to DOE's energy conservation standard at § 431.97(c);

(F) Computer room air conditioners that are subject to DOE's energy conservation standard at § 431.97(e); and

(G) Variable refrigerant flow multi-split air conditioners and heat pumps that are subject to DOE's energy conservation standard at § 431.97(f); and

(4) In addition, the test procedure is only applicable to fan or blower duty points with the following characteristics, measured or calculated in accordance with the test procedure set forth in appendix A of this subpart:

(i)(A) Fan shaft input power equal to or greater than 1 horsepower; or

(B) Fan electrical input power equal to or greater than 0.89 kW; and

(ii)(A) Fan static air power equal to or less than 150 horsepower for fans using a static pressure basis fan energy index (''FEI'') in accordance with the required test configuration listed in table 7.1 of AMCA 214–21 (incorporated by reference, see § 431.173); or

(B) Fan total air power equal to or less than 150 horsepower for fans using a total pressure basis FEI in accordance with the required test configuration listed in table 7.1 of AMCA 214–21;

(b) *Scope for air circulating fans.* The test procedure in this section applies to all air circulating fans with input power greater than or equal to 125W at maximum speed.

(c) *Testing and calculations for fans and blowers other than air circulating fans.* Determine the FEI, the fan electrical input power (''FEP''), and fan shaft power (as applicable) at each duty point, as specified by the manufacturer, using the test procedure set forth in appendix A of this subpart.

(d) *Testing and calculations for air circulating fan.* Determine the FEI and the fan electrical input power (''FEP'') or the weighted-average FEI and weighted-average FEP as applicable, using the test procedure set forth in appendix B of this subpart.

■ 9. Add appendix A to subpart J of part 431 to read as follows:

Appendix A to Subpart J of Part 431—Uniform Test Method for the Measurement of Energy Consumption of Fans and Blowers Other Than Air Circulating Fans

After October 30, 2023, any representations made with respect to energy use or efficiency of fans and blowers subject to testing pursuant to § 431.174 must be made in accordance with this appendix. Any optional representations of fan energy index in the optional test configuration listed in table 7.1 of AMCA 214–21 ($FEI_{optional}$) must be accompanied by a representation of fan energy index in the required test configuration listed in table 7.1 of AMCA 214–21 (FEI).

0. Incorporation by Reference

In § 431.173, DOE incorporated by reference the entire standard for AMCA 210–16, AMCA 214–21, and ISO 5801:2017; however, only enumerated provisions of those documents are applicable as follows. In cases where there is a conflict, the language of this appendix takes precedence over those documents.

0.1 AMCA 210–16:

(a) Section 3, ''Definitions/Units of Measure/Symbols'';

(b) Section 4, ''Instruments and Methods of Measurement'' ;

(c) Section 5, ''Test Setups and Equipment'';

(d) Section 6, ''Observation and Conduct of Test'';

(e) Section 7, ''Calculations'' excluding Section 7.9.2, ''Conversion to other rotational speeds and air densities with compressible

flow'' and Section 7.9.3, ''Conversion formulae for new densities and new rotational speeds'';

0.2. AMCA 214–21:

(a) Section 2, ''References (Normative),'' as referenced in section 2.2 of this appendix;

(b) Section 3, ''Definitions,'' as referenced in section 1 of this appendix;

(c) Section 4, ''Calculation of the FEI for a Single Duty Point,'' as referenced in section 2.6 of this appendix;

(d) Section 5, ''Reference Fan Electrical Power (FEP_{ref}),'' as referenced in section 2.6 of this appendix;

(e) Section 6.1, ''Wire-to-Air Testing at the Required Duty Point,'' as referenced in section 2.2 of this appendix;

(f) Section 6.2, ''Calculated Ratings Based on Wire-to-Air Testing,'' as referenced in section 2.2 of this appendix;

(g) Section 6.3, ''Bare Shaft Fans,'' as referenced in section 2.2 of this appendix;

(h) Section 6.4, ''Fans with Polyphase Regulated Motor'', excluding Section 6.4.1.4, ''Requirements for the VFD, if included'' and Section 6.4.2.4, ''Combined motor-VFD efficiency'' as referenced in section 2.2 of this appendix;

(i) Section 7, ''Testing,'' as referenced in sections 2.2 and 2.3 of this appendix;

(j) Section 8, ''Rating Development'', excluding Section 8.2.2, ''Separate Fan and Motor Tests'' and Section 8.3, ''Appurtenances'' as referenced in section 2.2 of this appendix;

(k) Annex D, ''Motor Performance Constants (Normative),'' as referenced in section 2.2 of this appendix;

(l) Annex E, ''Calculation Methods for Fans Tested Shaft-to-Air,'' as referenced in section 2.2 of this appendix;

(m) Annex G, ''Wire-to-Air Measurement—Calculation to Other Speeds and Densities (Normative),'' as referenced in section 2.2 of this appendix;

(n) Annex J, ''Other data and calculations to be retained,'' as referenced in section 2.2 of this appendix; and

(o) Annex K, ''Proportionality and Dimensional Requirements (Normative),'' as referenced in section 2.2 of this appendix.

0.3. ISO 5801:2017:

(a) Section 3, ''Terms and Definitions'';

(b) Section 4, ''Symbols, Abbreviated Terms and Subscripts'';

(c) Section 5, ''General'';

(d) Section 6, ''Test Configurations'';

(e) Section 7, ''Carrying out the Test'';

(f) Section 8, ''Airways for Duct Configuration'';

(g) Section 9, ''Standardized Test Chambers'';

(h) Section 10, ''Various Component Parts for a Laboratory Setup'';

(i) Section 11, ''Standard Test Configurations'';

(j) Section 12, ''Measurements'';

(k) Section 13, ''Reference Conditions'';

(l) Section 15, ''Calculations'';

(m) Section 16, ''Fan Characteristic Curves''; and

(n) Section 17, ''Uncertainty Analysis''.

1. Definitions

The definitions applicable to this appendix are defined in § 431.172 and in section 3, ''Definitions,'' of AMCA 214–21. In cases where there is a conflict, the definitions in § 431.172 take precedence over AMCA 214–21.

2. Test Procedure for Fans and Blowers Other Than Air Circulating Fans

2.1. General.

This section describes the test procedure for fans and blowers other than air circulating fans. In cases where there is a conflict, the provisions in this appendix take precedence over AMCA 214–21. Where AMCA 214–21 refers to Annex A, ''Polyphase Regulated Motor Efficiencies (Normative),'' of AMCA 214–21, Table 5 of § 431.25 must be used instead.

2.2. Testing

2.2.1. General.

The fan electrical input power (FEP_{act}) in kilowatts must be determined at every duty point specified by the manufacturer in accordance with one of the test methods listed in Table 1, and the following sections of AMCA 214–21: Section 2, ''References (Normative)''; Section 7, ''Testing,'' including the referenced provisions to AMCA 210–16 and ISO 5801:2017 as listed in sections 2.2.2 and 2.2.3 of this appendix; Section 8.1, ''Laboratory Measurement Only'' (as applicable); and Annex J, ''Other data and calculations to be retained.''

TABLE 1 TO APPENDIX A TO SUBPART J OF PART 431

Driver	Motor controller present?	Transmission configuration?	Test method	Applicable section(s) of AMCA 214–21
Electric motor	Yes or No	Any	Wire-to-air	6.1 ''Wire-to-Air Testing at the Required Duty Point''.
Electric motor	Yes or No	Any	Calculation based on Wire-to-air testing.	6.2 ''Calculated Ratings Based on Wire to Air Testing'' (references Section 8.2.3, ''Calculation to other speeds and densities for wire-to-air testing,'' and Annex G, ''Wire-to-Air Measurement—Calculation to Other Speeds and Densities (Normative)'').
Regulated polyphase motor	No	Direct drive, V-belt drive, flexible coupling or synchronous belt drive.	Shaft-to-air	6.4 ''Fans with Polyphase Regulated Motors,'' (references Annex D, ''Motor Performance Constants (Normative)'')*.
None or non-electric	No	None	Shaft-to-air	Section 6.3, ''Bare Shaft Fans''.
Regulated polyphase motor	No	Direct drive, V-belt drive, flexible coupling or synchronous belt drive.	Calculation based on Shaft-to-air testing.	Section 8.2.1, ''Fan laws and other calculation methods for shaft-to-air testing'' (references Annex D, ''Motor Performance Constants (Normative),'' Annex E, ''Calculation Methods for Fans Tested Shaft-to-Air,'' and Annex K, ''Proportionality and Dimensional Requirements (Normative)'').
None or non-electric	No	None	Calculation based on Shaft-to-air testing.	Section 8.2.1, ''Fan laws and other calculation methods for shaft-to-air testing'' (references Annex E, ''Calculation Methods for Fans Tested Shaft-to-Air,'' and Annex K, ''Proportionality and Dimensional Requirements (Normative)'').

*Excluding Section 6.4.1.4, ''Requirements for the VFD, if included'' and Section 6.4.2.4, ''Combined motor-VFD efficiency.''

Testing must be performed in accordance with the required test configuration listed in table 7.1 of AMCA 214–21. The following values must be determined in accordance with this appendix at each duty point specified by the manufacturer: fan airflow in cubic feet per minute; fan air density; fan total pressure in inches of water gauge for fans using a total pressure basis FEI in accordance with Table 7.1 of AMCA 214–21; fan static pressure in inches of water gauge for fans using a static pressure basis FEI in atcordance with table 7.1 of AMCA 214–21; fan speed in revolutions per minute; and fan shaft input power in horsepower for fans tested in accordance with sections 6.3, 6.4 or 6.5 of AMCA 214–21.

In addition, if applying the equations in Section E.2 of Annex E of AMCA 214–21 for compressible flows, the compressibility coefficients must be included in the equations as applicable.

All measurements must be recorded at the resolution of the test instrumentation and calculations must be rounded to the number of significant digits present at the resolution of the test instrumentation.

In cases where there is a conflict, the provisions in AMCA 214–21 take precedence over AMCA 210–16 and ISO 5801:2017. In addition, the provisions in this appendix apply.

2.2.2 Power Roof Ventilators

Centrifugal Power Roof Ventilators that are both supply and exhaust must be tested in both supply and exhaust configurations as listed in table 7.1 of AMCA 214–21.

2.2.3 Embedded Fans

Embedded fans that are not manufactured in a standalone configuration must be tested in a standalone configuration. If some components of the bare shaft fan are not removable without causing irreversible damage to the equipment into which the fan is embedded, testing must be performed using additional fan components, except for the fan impeller, that are geometrically identical to that of the fan embedded inside the larger piece of equipment for testing.

2.3. Power Supply

Any wire-to-air testing must be conducted at the supply frequency, phase, and voltages specified in this section. The frequency and voltage must be selected in accordance with section 7.8. of AMCA 214–21. Fans and blowers rated for operation for single- or multi-phase power supply must be tested with single- or multi-phase electricity, respectively. Fans and blowers, capable of operating with single- and multi-phase power supply, must be tested using multi-phase electricity.

2.4. Stability Conditions.

The following conditions must be met to establish system stability prior to collecting test data:

(a) Barometric pressure, dry bulb temperature and wet bulb temperature in the general test area must be captured at least every five seconds after the run-in period is completed and the ambient air density calculated from these values shall not vary by more than ±1 percent during verification of fan speed and fan input power stability.

(b) After the fan has been run-in, record the fan speed in rpm and the input power (in pound-force, pound-force-in, or watts) at least every 5 seconds for at least three 60-second intervals. Readings shall be made simultaneously. Repeat these measurements over 60-second intervals until:

(1) The average fan speed from the last 60-second interval varies by less than the absolute value of 1 percent or 1 rpm, whichever is greater, when compared to the average fan speed measured during the previous 60-second test interval;

(2) The average input power from the last 60-second interval varies by less than the absolute value of 1 percent, whichever is greater, compared to the average input power measured during the previous 60-second test interval; and

(3) The slopes calculated from the individual data collected for fan speed and input power during at least three 60-second sampling intervals include both positive and negative values (*e.g.,* two positive and one negative slope value or one positive and two negative slope values). If three positive or three negative slopes are determined in succession, additional sampling intervals are required until slopes from three successive sampling intervals include both positive and negative values.

2.5. Sampling Intervals for Testing.

A test measurement must meet the following conditions:

(a) The sampling interval over which average test values are determined shall not exceed 60 seconds;

(b) The average fan speed from the most recent 60-second interval varies by less than the absolute value of 1 percent or 1 rpm, whichever is greater, when compared to the average fan speed measured during the previous 60-second test interval; and

(c) the average input power from the last 60-second interval by reaction dynamometer, torque meter or calibrated motor must be ±4 percent, or the average input power by electrical meter must be ±2 percent of the mean or 1 watt, whichever is greater, compared to the average input power measured during the previous 60-second test interval.

2.6. FEI calculation

The FEI must be determined at every duty point in accordance with Section 4, ''Calculation of the FEI for a single duty point,'' and Section 5, ''Reference Fan Electrical Power (FEP_{ref})'' of AMCA 214–21. In addition, the FEI must be rounded to the nearest hundredths place; FEP must be rounded to three significant figures; and all measurements must be recorded at the resolution of the test instrument.

■ 10. Add appendix B to subpart J of part 431 to read as follows:

Appendix B to Subpart J of Part 431—Uniform Test Method for the Measurement of Energy Consumption of Air Circulating Fans

After October 30, 2023, any representations made with respect to energy use or efficiency of air circulating fans subject to testing pursuant to § 431.174 must be made in accordance with this appendix. Any optional representations of air circulating fan efficacy at speeds less than the air circulating fan's maximum speed must be accompanied by a representation of the air circulating fan efficacy at maximum speed.

0. Incorporation by Reference

In § 431.173, DOE incorporated by reference the entire standard for AMCA 230–23; however, only enumerated provisions of those documents are applicable as follows. In cases where there is a conflict, the language of this appendix takes precedence over those documents.

0.1 AMCA 230–23:

(a) Section 4, ''Definitions/Units of Measurement/Symbols,'' as referenced in section 1 and 2.2.2 of this appendix;

(b) Section 5, ''Instruments and Methods of Measurement,'' as referenced in section 2.2.2 of this appendix;

(c) Section 6, ''Equipment and Setup,'' as referenced in section 2.2.2 of this appendix;

(d) Section 7, ''Observations and Conduct of Test,'' as referenced in section 2.2.2 of this appendix;

(e) Section 8, ''Calculations,'' as referenced in section 2.2.2 of this appendix; and

(f) Section 9, ''Report and Results of Test,'' as referenced in section 2.2.2 of this appendix.

1. Definitions

The definitions applicable to this appendix are defined in § 431.172 and in Section 4, ''Definitions/Units of Measurement/Symbols,'' of AMCA 230–23. In cases where there is a conflict, the definitions in § 431.172 take precedence over AMCA 230–23.

2. Test Procedure for Air Circulating Fans

2.1. General

This section describes the test procedure for air circulating fans.

2.2. Testing

2.2.1. General

The air circulating fan efficacy (Eff_{circ}) in cubic feet per minute (''CFM'') per watt (''W'') (''CFM/W'') at maximum speed must be determined in accordance with the applicable sections of AMCA 230–23 as listed in section 2.2.2 of this appendix. In addition, testing must be conducted in accordance with the provisions in sections 2.3 through 2.5 of this appendix. Optional testing speeds lower than maximum speed is permitted. Speeds less than maximum speeds must be expressed at a percentage of maximum speed (*e.g.,* 50 percent) and the air circulating fan efficacy at lower speed must include the speed percentage in its subscript (*e.g.,* $Eff_{circ,50}$).

All measurements must be recorded at the resolution of the test instrumentation and calculations must be rounded to the number of significant digits of the resolution of the test instrumentation.

2.2.2. AMCA 230–23, Applicable Sections.

The following sections of AMCA 230–23 are applicable: Section 4, ''Definitions/Unit of Measurement/Symbols''; Section 5, ''Instruments and Methods of Measurement''; Section 6, ''Instruments and Methods of Measurement''; Section 7, ''Observations and Conduct of Test''; Section 8, ''Calculations''; and Section 9, ''Report and Results of Test.''

2.3. Air circulating fans without motors

Air circulating fans distributed in commerce without an electric motor must be tested using an electric motor as recommended in the manufacturer's catalogs or distributed in commerce with the air circulating fan. If more than one motor is available in manufacturer's catalogs or distributed in commerce with the air circulating fan, testing must be conducted using the least efficient motor capable of running the fan at the fan's maximum allowable speed.

2.4. Power Supply.

The test must be conducted at the frequency, phase, and voltages specified in this section.

2.4.1. Frequency.

Air circulating fans rated for operation with only 60 Hz power supply must be tested with 60 Hz electricity. Air circulating fans capable of operating with 50 Hz and 60 Hz electricity must be tested with 60 Hz electricity.

2.4.2. Phase.

Air circulating fans rated for operation for single- or multi-phase power supply must be tested with single- or multi-phase power electricity, respectively. Air circulating fans, capable of operating with single- and multi-phase power supply, must be tested using multi-phase electricity.

2.4.3. Voltage.

Select the supply voltage as follows:

(a) For air circulating fans tested with single-phase electricity, the supply voltage must be:

(1) 120 V if the air circulating fan's minimum rated voltage is 120 V or the lowest rated voltage range contains 120 V,

(2) 240 V if the air circulating fan's minimum rated voltage is 240 V or the lowest rated voltage range contains 240 V, or

(3) The air circulating fan's minimum rated voltage (if a voltage range is not given) or the mean of the lowest rated voltage range, in all other cases.

(b) For air circulating fans tested with multi-phase electricity, the supply voltage must be

(1) 240 V if the air circulating fan's minimum rated voltage is 240 V or the lowest rated voltage range contains 240 V, or

(2) The air circulating fan's minimum rated voltage (if a voltage range is not given) or the mean of the lowest rated voltage range, in all other cases.

2.5. Stability Conditions.

In addition to the test requirements specified in sections 7.1 and 7.3 of AMCA 230–23, the following conditions must be met to establish system stability prior to collecting test data:

(a) Test voltage shall be captured at least every five seconds and shall not vary by more than +/−1 percent during each test. Barometric pressure, dry bulb temperature and wet bulb temperature in the general test area for calculation of air density must be captured at least every five seconds and the calculated ambient air density shall not vary by more than +/−1 percent during each test.

(b) After a run-in time of at least 15 minutes, record the fan speed in rpm, the input power in watts, and load differential in pound-force for at least 3 120-second intervals. Repeat these measurements over additional 120-second intervals until:

(1) The average fan speed of the last 120-second interval varies by less than the absolute value of 1 percent or 1 rpm, whichever is greater, when compared to the average fan speed measured during the previous 120-second test interval;

(2) The average input power of the last 120-second interval varies by less than the absolute value of 1 percent or 1 watt, whichever is greater, compared to the average input power measured during the previous 120-second test interval;

(3) The average load differential of the last 120-second interval varies by less than the absolute value of 1 percent, whichever is greater, compared to the average load differential during the previous 120-second test interval; and

(4) The slopes calculated from the individual data collected for fan speed, input power, and load differential during at least three 120-second intervals include both positive and negative values (*e.g.,* two positive and one negative value or one positive and two negative values). If three positive or three negative slopes are determined in succession, additional sampling intervals are required until slopes from three successive intervals include both positive and negative values.

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When a date falls on a weekend or holiday, the next Federal business day is used. (See 1 CFR 18.17)

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