



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 412

[CMS-1781-F]

RIN 0938-AV04

Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2024 and Updates to the IRF Quality Reporting Program

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule updates the prospective payment rates for inpatient rehabilitation facilities (IRFs) for Federal fiscal year (FY) 2024. As required by statute, this final rule includes the classification and weighting factors for the IRF prospective payment system's case-mix groups and a description of the methodologies and data used in computing the prospective payment rates for FY 2024. It also rebases and revises the IRF market basket to reflect a 2021 base year. It also confirms when IRF units can become excluded and paid under the IRF PPS. This rule also includes updates for the IRF Quality Reporting Program (QRP).

DATES: *Effective date:* These regulations are effective on October 1, 2023.

Applicability dates: The updated IRF prospective payment rates are applicable for IRF discharges occurring on or after October 1, 2023, and on or before September 30, 2024 (FY 2024).

FOR FURTHER INFORMATION CONTACT: Kim Schwartz, (410) 786-2571, for general information.

Catie Cooksey, (410) 786-0179, for information about the IRF payment policies and payment rates.

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SUPPLEMENTARY INFORMATION:

Availability of Certain Information Through the Internet on the CMS Website

The IRF prospective payment system (IRF PPS) Addenda along with other supporting documents and tables referenced in this final rule are available through the Internet on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS>.

We note that prior to 2020, each rule or notice issued under the IRF PPS has included a detailed reiteration of the various regulatory provisions that have affected the IRF PPS over the years. That discussion, along with detailed background information for various other aspects of the IRF PPS, is now available on the CMS Website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS>.

I. Executive Summary

A. Purpose

This final rule updates the prospective payment rates for IRFs for FY 2024 (that is, for discharges occurring on or after October 1, 2023, and on or before September 30, 2024) as required under section 1886(j)(3)(C) of the Social Security Act (the Act). As required by section 1886(j)(5) of the Act, this final rule includes the classification and weighting factors for the IRF PPS's case-mix groups (CMGs), and a description of the methodologies and data used in computing the prospective payment rates for FY 2024. It also rebases and revises the IRF market basket to reflect a 2021 base year. It also confirms when an IRF unit can be excluded and paid under the IRF PPS. This final rule includes several updates to the IRF QRP for the FY 2025 IRF QRP and FY 2026 IRF QRP. This final rule will add two new measures to the IRF QRP, remove three measures from the IRF QRP, and modify one measure in the IRF QRP. This final rule also finalizes the public reporting schedule of four measures. In addition, this final rule includes a summary of the comments received on Centers for Medicare and Medicaid Services'

(CMS') update on our efforts to close the health equity gap and on the request for information on principles CMS would use to select and prioritize IRF QRP quality measures in future years.

B. Summary of Major Provisions

In this final rule, we use the methods described in the FY 2023 IRF PPS final rule (87 FR 47038) to update the prospective payment rates for FY 2024 using updated FY 2022 IRF claims and the most recent available IRF cost report data, which is FY 2021 IRF cost report data. It also rebases and revises the IRF market basket to reflect a 2021 base year. It also modifies the regulation governing when an IRF unit can be excluded and paid under the IRF PPS.

Beginning with the FY 2025 IRF QRP, IRFs will be required to submit data on a modified version of the COVID-19 Vaccination Coverage among Healthcare Personnel measure and the Discharge Function Score measure. Beginning with the FY 2025 IRF QRP, IRFs will no longer be required to submit data on the Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function, the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (CBE #2633), and the IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (CBE #2634) measures.

Beginning with the FY 2026 IRF QRP, IRFs will be required to submit data on the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure. This final rule also adopts policies to begin public reporting of the Transfer of Health Information to the Patient-Post-Acute Care (PAC) and Transfer of Health Information to the Provider-PAC measures, the Discharge Function Score measure, and the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure. Finally, we provide a summary of the comments received from interested parties on principles for selecting and prioritizing IRF QRP quality measures and concepts as well as a summary of the comments received on our continued efforts to close the health equity gap.

C. Summary of Impact

TABLE 1: Cost and Benefit

Provision Description	Transfers/Costs
FY 2024 IRF PPS payment rate update	The overall economic impact of this final rule is an estimated \$355 million in increased payments from the Federal Government to IRFs during FY 2024.
FY 2025 through FY 2026 IRF QRP changes	The overall economic impact of this final rule is an estimated increase in cost to IRFs of \$31,412.56 beginning with the FY 2025 IRF QRP.

II. Background

A. Statutory Basis and Scope for IRF PPS Provisions

Section 1886(j) of the Act provides for the implementation of a per-discharge PPS for inpatient rehabilitation hospitals and inpatient rehabilitation units of a hospital (collectively, hereinafter referred to as IRFs). Payments under the IRF PPS encompass inpatient operating and capital costs of furnishing covered rehabilitation services (that is, routine, ancillary, and capital costs), but not direct graduate medical education costs, costs of approved nursing and allied health education activities, bad debts, and other services or items outside the scope of the IRF PPS. A complete discussion of the IRF PPS provisions appears in the original FY 2002 IRF PPS final rule (66 FR 41316) and the FY 2006 IRF PPS final rule (70 FR 47880) and we provided a general description of the IRF PPS for FYs 2007 through 2019 in the FY 2020 IRF PPS final rule (84 FR 39055 through 39057). A general description of the IRF PPS for FYs 2020 through 2023, along with detailed background information for various other aspects of the IRF PPS, is now available on the CMS Website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS>.

Under the IRF PPS from FY 2002 through FY 2005, the prospective payment rates were computed across 100 distinct CMGs, as described in the FY 2002 IRF PPS final rule (66 FR 41316). We constructed 95 CMGs using rehabilitation impairment categories (RICs), functional status (both motor and cognitive), and age (in some cases, cognitive status and age may not be a factor in defining a CMG). In addition, we constructed five special CMGs to account for very short stays and for patients who expire in the IRF.

For each of the CMGs, we developed relative weighting factors to account for a patient's

clinical characteristics and expected resource needs. Thus, the weighting factors accounted for the relative difference in resource use across all CMGs. Within each CMG, we created tiers based on the estimated effects that certain comorbidities would have on resource use.

We established the Federal PPS rates using a standardized payment conversion factor (formerly referred to as the budget-neutral conversion factor). For a detailed discussion of the budget-neutral conversion factor, please refer to our FY 2004 IRF PPS final rule (68 FR 45684 through 45685). In the FY 2006 IRF PPS final rule (70 FR 47880), we discussed in detail the methodology for determining the standard payment conversion factor.

We applied the relative weighting factors to the standard payment conversion factor to compute the unadjusted prospective payment rates under the IRF PPS from FYs 2002 through 2005. Within the structure of the payment system, we then made adjustments to account for interrupted stays, transfers, short stays, and deaths. Finally, we applied the applicable adjustments to account for geographic variations in wages (wage index), the percentage of low-income patients, location in a rural area (if applicable), and outlier payments (if applicable) to the IRFs' unadjusted prospective payment rates.

For cost reporting periods that began on or after January 1, 2002, and before October 1, 2002, we determined the final prospective payment amounts using the transition methodology prescribed in section 1886(j)(1) of the Act. Under this provision, IRFs transitioning into the PPS were paid a blend of the Federal IRF PPS rate and the payment that the IRFs would have received had the IRF PPS not been implemented. This provision also allowed IRFs to elect to bypass this blended payment and immediately be paid 100 percent of the Federal IRF PPS rate. The transition methodology expired as of cost reporting periods beginning on or after October 1, 2002 (FY 2003), and payments for all IRFs now consist of 100 percent of the Federal IRF PPS rate.

Section 1886(j) of the Act confers broad statutory authority upon the Secretary to propose refinements to the IRF PPS. In the FY 2006 IRF PPS final rule (70 FR 47880) and in correcting

amendments to the FY 2006 IRF PPS final rule (70 FR 57166), we finalized a number of refinements to the IRF PPS case-mix classification system (the CMGs and the corresponding relative weights) and the case-level and facility-level adjustments. These refinements included the adoption of the Office of Management and Budget's (OMB's) Core-Based Statistical Area (CBSA) market definitions; modifications to the CMGs, tier comorbidities; and CMG relative weights, implementation of a new teaching status adjustment for IRFs; rebasing and revising the market basket used to update IRF payments, and updates to the rural, low-income percentage (LIP), and high-cost outlier adjustments. Beginning with the FY 2006 IRF PPS final rule (70 FR 47908 through 47917), the market basket used to update IRF payments was a market basket reflecting the operating and capital cost structures for freestanding IRFs, freestanding inpatient psychiatric facilities (IPFs), and long-term care hospitals (LTCHs) (hereinafter referred to as the rehabilitation, psychiatric, and long-term care (RPL) market basket). Any reference to the FY 2006 IRF PPS final rule in this final rule also includes the provisions effective in the correcting amendments. For a detailed discussion of the final key policy changes for FY 2006, please refer to the FY 2006 IRF PPS final rule.

The regulatory history previously included in each rule or notice issued under the IRF PPS, including a general description of the IRF PPS for FYs 2007 through 2020, is available on the CMS Website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS>.

In late 2019,¹ the United States began responding to an outbreak of a virus named “SARS-CoV-2” and the disease it causes, which is named “coronavirus disease 2019” (abbreviated “COVID-19”). Due to our prioritizing efforts in support of containing and combatting the Public Health Emergency (PHE) for COVID-19, and devoting significant resources to that end, we published two interim final rules with comment period affecting IRF

¹ Patel A, Jernigan DB. Initial Public Health Response and Interim Clinical Guidance for the 2019 Novel Coronavirus Outbreak — United States, December 31, 2019–February 4, 2020. MMWR Morb Mortal Wkly Rep 2020;69:140–146. DOI <http://dx.doi.org/10.15585/mmwr.mm6905e1>.

payment and conditions for participation. The interim final rule with comment period (IFC) entitled, “Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency,” published on April 6, 2020 (85 FR 19230) (hereinafter referred to as the April 6, 2020 IFC), included certain changes to the IRF PPS medical supervision requirements at 42 CFR 412.622(a)(3)(iv) and 412.29(e) during the PHE for COVID–19. In addition, in the April 6, 2020 IFC, we removed the post-admission physician evaluation requirement at § 412.622(a)(4)(ii) for all IRFs during the PHE for COVID-19. In the FY 2021 IRF PPS final rule, to ease documentation and administrative burden, we also removed the post-admission physician evaluation documentation requirement at § 412.622(a)(4)(ii) permanently beginning in FY 2021.

A second IFC entitled, “Medicare and Medicaid Programs, Basic Health Program, and Exchanges; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency and Delay of Certain Reporting Requirements for the Skilled Nursing Facility Quality Reporting Program” was published on May 8, 2020 (85 FR 27550) (hereinafter referred to as the May 8, 2020 IFC). Among other changes, the May 8, 2020 IFC included a waiver of the “3-hour rule” at § 412.622(a)(3)(ii) to reflect the waiver required by section 3711(a) of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116-136, enacted on March 27, 2020). In the May 8, 2020 IFC, we also modified certain IRF coverage and classification requirements for freestanding IRF hospitals to relieve acute care hospital capacity concerns in States (or regions, as applicable) experiencing a surge during the PHE for COVID-19. In addition to the policies adopted in our IFCs, we responded to the PHE with numerous blanket waivers² and other flexibilities,³ some of which are applicable to the IRF PPS. CMS finalized these policies in the Calendar Year 2023 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems final rule with comment period

² CMS, “COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers,” (updated Feb. 19 2021) (available at <https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf>).

³ CMS, “COVID-19 Frequently Asked Questions (FAQs) on Medicare Fee-for-Service (FFS) Billing,” (updated March 5, 2021) (available at <https://www.cms.gov/files/document/03092020-covid-19-faqs-508.pdf>).

(87 FR 71748).

B. Provisions of the Patient Protection and the Affordable Care Act and the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) Affecting the IRF PPS in FY 2012 and Beyond

The Patient Protection and the Affordable Care Act (the Affordable Care Act or ACA) (Pub. L. 111–148) was enacted on March 23, 2010. The Health Care and Education Reconciliation Act of 2010 (Pub. L. 111-152), which amended and revised several provisions of the Patient Protection and Affordable Care Act, was enacted on March 30, 2010. In this final rule, we refer to the two statutes collectively as the “Affordable Care Act” or “ACA”.

The ACA included several provisions that affect the IRF PPS in FYs 2012 and beyond. In addition to what was previously discussed, section 3401(d) of the ACA also added section 1886(j)(3)(C)(ii)(I) of the Act (providing for a “productivity adjustment” for FY 2012 and each subsequent FY). The productivity adjustment for FY 2024 is discussed in section VI.D. of this final rule. Section 1886(j)(3)(C)(ii)(II) of the Act provides that the application of the productivity adjustment to the market basket update may result in an update that is less than 0.0 for a FY and in payment rates for a FY being less than such payment rates for the preceding FY.

Section 3004(b) of the ACA and section 411(b) of the MACRA (Pub. L. 114-10, enacted on April 16, 2015) also addressed the IRF PPS. Section 3004(b) of ACA reassigned the previously designated section 1886(j)(7) of the Act to section 1886(j)(8) of the Act and inserted a new section 1886(j)(7) of the Act, which contains requirements for the Secretary to establish a QRP for IRFs. Under that program, data must be submitted in a form and manner and at a time specified by the Secretary. Beginning in FY 2014, section 1886(j)(7)(A)(i) of the Act requires the application of a 2-percentage point reduction to the market basket increase factor otherwise applicable to an IRF (after application of paragraphs (C)(iii) and (D) of section 1886(j)(3) of the Act) for a FY if the IRF does not comply with the requirements of the IRF QRP for that FY. Application of the 2-percentage point reduction may result in an update that is less than 0.0 for a

FY and in payment rates for a FY being less than such payment rates for the preceding FY. Reporting-based reductions to the market basket increase factor are not cumulative; they only apply for the FY involved. Section 411(b) of the MACRA amended section 1886(j)(3)(C) of the Act by adding paragraph (iii), which required us to apply for FY 2018, after the application of section 1886(j)(3)(C)(ii) of the Act, an increase factor of 1.0 percent to update the IRF prospective payment rates.

C. Operational Overview of the Current IRF PPS

As described in the FY 2002 IRF PPS final rule (66 FR 41316), upon the admission and discharge of a Medicare Part A fee-for-service (FFS) patient, the IRF is required to complete the appropriate sections of a Patient Assessment Instrument (PAI), designated as the IRF-PAI. In addition, beginning with IRF discharges occurring on or after October 1, 2009, the IRF is also required to complete the appropriate sections of the IRF-PAI upon the admission and discharge of each Medicare Advantage (MA) patient, as described in the FY 2010 IRF PPS final rule (74 FR 39762) and the FY 2010 IRF PPS correction notice (74 FR 50712). All required data must be electronically encoded into the IRF-PAI software product. Generally, the software product includes patient classification programming called the Grouper software. The Grouper software uses specific IRF-PAI data elements to classify (or group) patients into distinct CMGs and account for the existence of any relevant comorbidities.

The Grouper software produces a five-character CMG number. The first character is an alphabetic character that indicates the comorbidity tier. The last four characters are numeric characters that represent the distinct CMG number. A free download of the Grouper software is available on the CMS website at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/Software.html>. The Grouper software is also embedded in the internet Quality Improvement and Evaluation System (iQIES) User tool available in iQIES at <https://www.cms.gov/medicare/quality-safety-oversight-general-information/iqies>.

Once a Medicare Part A FFS patient is discharged, the IRF submits a Medicare claim as a

Health Insurance Portability and Accountability Act of 1996 (HIPAA) (Pub. L. 104-191, enacted on August 21, 1996) -compliant electronic claim or, if the Administrative Simplification Compliance Act of 2002 (ASCA) (Pub. L. 107-105, enacted on December 27, 2002) permits, a paper claim (a UB-04 or a CMS-1450 as appropriate) using the five-character CMG number and sends it to the appropriate Medicare Administrative Contractor (MAC). In addition, once a MA patient is discharged, in accordance with the Medicare Claims Processing Manual, chapter 3, section 20.3 (Pub. 100-04), hospitals (including IRFs) must submit to their MAC an informational-only bill (type of bill (TOB) 111) that includes Condition Code 04. This will ensure that the MA days are included in the hospital's Supplemental Security Income (SSI) ratio (used in calculating the IRF LIP adjustment) for FY 2007 and beyond. Claims submitted to Medicare must comply with both ASCA and HIPAA.

Section 3 of the ASCA amended section 1862(a) of the Act by adding paragraph (22), which requires the Medicare program, subject to section 1862(h) of the Act, to deny payment under Part A or Part B for any expenses for items or services for which a claim is submitted other than in an electronic form specified by the Secretary. Section 1862(h) of the Act, in turn, provides that the Secretary shall waive such denial in situations in which there is no method available for the submission of claims in an electronic form or the entity submitting the claim is a small provider. In addition, the Secretary also has the authority to waive such denial in such unusual cases as the Secretary finds appropriate. For more information, see the "Medicare Program; Electronic Submission of Medicare Claims" final rule (70 FR 71008). Our instructions for the limited number of Medicare claims submitted on paper are available at <http://www.cms.gov/manuals/downloads/clm104c25.pdf>.

Section 3 of the ASCA operates in the context of the administrative simplification provisions of HIPAA, which include, among others, the requirements for transaction standards and code sets codified in 45 CFR part 160 and part 162, subparts A and I through R (generally known as the Transactions Rule). The Transactions Rule requires covered entities, including

covered healthcare providers, to conduct covered electronic transactions according to the applicable transaction standards. (See the CMS program claim memoranda at <http://www.cms.gov/ElectronicBillingEDITrans/> and listed in the addenda to the Medicare Intermediary Manual, Part 3, section 3600).

The MAC processes the claim through its software system. This software system includes pricing programming called the “Pricer” software. The Pricer software uses the CMG number, along with other specific claim data elements and provider-specific data, to adjust the IRF’s prospective payment for interrupted stays, transfers, short stays, and deaths, and then applies the applicable adjustments to account for the IRF’s wage index, percentage of low-income patients, rural location, and outlier payments. For discharges occurring on or after October 1, 2005, the IRF PPS payment also reflects the teaching status adjustment that became effective as of FY 2006, as discussed in the FY 2006 IRF PPS final rule (70 FR 47880).

D. Advancing Health Information Exchange

The Department of Health and Human Services (HHS) has a number of initiatives designed to encourage and support the adoption of interoperable health information technology and to promote nationwide health information exchange to improve health care and patient access to their digital health information.

To further interoperability in post-acute care settings, CMS and the Office of the National Coordinator for Health Information Technology (ONC) participate in the Post-Acute Care Interoperability Workgroup (PACIO) to facilitate collaboration with interested parties to develop Health Level Seven International® (HL7) Fast Healthcare Interoperability Resource® (FHIR) standards. These standards could support the exchange and reuse of patient assessment data derived from the post-acute care (PAC) setting assessment tools, such as the minimum data set (MDS), inpatient rehabilitation facility-patient assessment instrument (IRF-PAI), Long-Term Care Hospital (LTCH) continuity assessment record and evaluation (CARE) Data Set (LCDS),

outcome and assessment information set (OASIS), and other sources.^{4,5} The PACIO Project has focused on HL7 FHIR implementation guides for: functional status, cognitive status and new use cases on advance directives, re-assessment timepoints, and Speech, language, swallowing, cognitive communication and hearing (SPLASCH) pathology.⁶ We encourage PAC provider and health IT vendor participation as the efforts advance.

The CMS Data Element Library (DEL) continues to be updated and serves as a resource for PAC assessment data elements and their associated mappings to health IT standards such as Logical Observation Identifiers Names and Codes (LOINC) and Systematized Nomenclature of Medicine Clinical Terms (SNOMED).⁷ The DEL furthers CMS' goal of data standardization and interoperability. Standards in the DEL can be referenced on the CMS website and in the ONC Interoperability Standards Advisory (ISA). The 2023 ISA is available at https://www.healthit.gov/sites/isa/files/inline-files/2023%20Reference%20Edition_ISA_508.pdf.

We are also working with ONC to advance the United States Core Data for Interoperability (USCDI), a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange.⁸ We are collaborating with ONC and other Federal agencies to define and prioritize additional data standardization needs and develop consensus on recommendations for future versions of the USCDI. We are also directly collaborating with ONC to build requirements to support data standardization and alignment with requirements for quality measurement. ONC has launched the USCDI+ initiative to support the identification and establishment of domain specific datasets that build on the core USCDI foundation.⁹ The USCDI+ quality measurement domain currently being developed aims to support defining additional data specifications for quality measurement that harmonize, where

⁴ HL7 FHIR Release 4. Available at <https://www.hl7.org/fhir/>.

⁵ HL7 FHIR. PACIO Functional Status Implementation Guide. Available at <https://paciowg.github.io/functional-status-ig/>.

⁶ PACIO Project. Available at <http://pacioproject.org/about/>.

⁷ Centers for Medicare & Medicaid Services. Newsroom. Fact sheet: CMS Data Element Library Fact Sheet. June 21, 2018. Available at <https://www.cms.gov/newsroom/fact-sheets/cms-data-element-library-fact-sheet>.

⁸ USCDI. Available at <https://www.healthit.gov/isa/united-states-core-data-interoperability-uscdi>.

⁹ USCDI+. Available at <https://www.healthit.gov/topic/interoperability/uscdi-plus>.

possible, with other Federal agency data needs and inform supplemental standards necessary to support quality measurement, including the needs of programs supporting quality measurement for long-term and post-acute care.

The 21st Century Cures Act (Cures Act) (Pub. L. 114-255, enacted December 13, 2016) required HHS and ONC to take steps to promote adoption and use of electronic health record (EHR) technology.¹⁰ Specifically, section 4003(b) of the Cures Act required ONC to take steps to advance interoperability through the development of a Trusted Exchange Framework and Common Agreement aimed at establishing full network-to network exchange of health information nationally. On January 18, 2022, ONC announced a significant milestone by releasing the Trusted Exchange Framework¹¹ and Common Agreement Version 1.¹² The Trusted Exchange Framework is a set of non-binding principles for health information exchange, and the Common Agreement is a contract that advances those principles. The Common Agreement and the Qualified Health Information Network Technical Framework Version 1 (incorporated by reference into the Common Agreement) establish the technical infrastructure model and governing approach for different health information networks and their users to securely share clinical information with each other, all under commonly agreed to terms. The technical and policy architecture of how exchange occurs under the Common Agreement follows a network-of-networks structure, which allows for connections at different levels and is inclusive of many different types of entities at those different levels, such as health information networks, healthcare practices, hospitals, public health agencies, and Individual Access Services (IAS) Providers.¹³ On February 13, 2023, HHS marked a new milestone during an event at HHS

¹⁰ Sections 4001 through 4008 of Pub. L. 114-255. Available at <https://www.govinfo.gov/content/pkg/PLAW-114publ255/html/PLAW-114publ255.htm>.

¹¹ The Trusted Exchange Framework (TEF): Principles for Trusted Exchange (Jan. 2022). Available at https://www.healthit.gov/sites/default/files/page/2022-01/Trusted_Exchange_Framework_0122.pdf.

¹² Common Agreement for Nationwide Health Information Interoperability Version 1 (Jan. 2022). Available at https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.

¹³ The Common Agreement defines Individual Access Services (IAS) as “with respect to the Exchange Purposes definition, the services provided utilizing the Connectivity Services, to the extent consistent with Applicable Law, to

headquarters,¹⁴ which recognized the first set of applicants accepted for onboarding to the Common Agreement as Qualified Health Information Networks (QHINs). QHINs will be entities that will connect directly to each other to serve as the core for nationwide interoperability.¹⁵ For more information, we refer readers to <https://www.healthit.gov/topic/interoperability/trusted-exchange-framework-and-common-agreement>.

We invited providers to learn more about these important developments and how they are likely to affect IRFs.

III. Summary of Provisions of the Proposed Rule

In the FY 2024 IRF PPS proposed rule, we proposed to update the IRF PPS for FY 2024 and the IRF QRP for FY 2025 and FY 2026.

The proposed policy changes and updates to the IRF prospective payment rates for FY 2024 are as follows:

- Update the CMG relative weights and average length of stay values for FY 2024, in a budget neutral manner, as discussed in section IV. of the FY 2024 IRF PPS proposed rule (88 FR 20954 through 20959).
- Update the IRF PPS payment rates for FY 2024 by the market basket increase factor, based upon the most current data available, with a productivity adjustment required by section 1886(j)(3)(C)(ii)(I) of the Act, as described in section V. of the FY 2024 IRF PPS proposed rule

an Individual with whom the QHIN, Participant, or Subparticipant has a Direct Relationship to satisfy that Individual's ability to access, inspect, or obtain a copy of that Individual's Required Information that is then maintained by or for any QHIN, Participant, or Subparticipant." The Common Agreement defines "IAS Provider" as: "Each QHIN, Participant, and Subparticipant that offers Individual Access Services." See Common Agreement for Nationwide Health Information Interoperability Version 1, at 7 (Jan. 2022), https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.

¹⁴ "Building TEFCA," Micky Tripathi and Mariann Yeager, Health IT Buzz Blog. February 13, 2023. <https://www.healthit.gov/buzz-blog/electronic-health-and-medical-records/interoperability-electronic-health-and-medical-records/building-tefca>.

¹⁵ The Common Agreement defines a QHIN as "to the extent permitted by applicable SOP(s), a Health Information Network that is a U.S. Entity that has been Designated by the RCE and is a party to the Common Agreement countersigned by the RCE." See Common Agreement for Nationwide Health Information Interoperability Version 1, at 10 (Jan. 2022), https://www.healthit.gov/sites/default/files/page/2022-01/Common_Agreement_for_Nationwide_Health_Information_Interoperability_Version_1.pdf.

(88 FR 20959, 20973 through 20974).

- Rebase and revise the IRF market basket to reflect a 2021 base year, as discussed in section V. of the FY 2024 IRF PPS proposed rule (88 FR 20959 through 20973).

- Update the FY 2024 IRF PPS payment rates by the FY 2024 wage index and the labor-related share in a budget-neutral manner, as discussed in section V. of the FY 2024 IRF PPS proposed rule (88 FR 20974 through 20977).

- Describe the calculation of the IRF standard payment conversion factor for FY 2024, as discussed in section V. of the FY 2024 IRF PPS proposed rule (88 FR 20977).

- Update the outlier threshold amount for FY 2024, as discussed in section VI. of the FY 2024 IRF PPS proposed rule (88 FR 20980 through 20981).

- Update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs for FY 2024, as discussed in section VI. of the FY 2024 IRF PPS proposed rule (88 FR 20981).

- Describe the proposed modification to the regulation for IRF units to become excluded and paid under the IRF PPS as discussed in section VII. of the FY 2024 IRF PPS proposed rule (88 FR 20981 through 20984).

We also proposed updates to the IRF QRP and requested information in section VIII. of the FY 2024 IRF PPS proposed rule as follows:

- Modify the COVID-19 Vaccination Coverage among Healthcare Personnel measure beginning with the FY 2025 IRF QRP.

- Adopt the Discharge Function Score measure beginning with the FY 2025 IRF QRP.

- Remove 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 IRF QRP.

- Remove the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (NQF #2633) measure beginning with the FY 2025 IRF QRP.

- Remove the IRF Functional Outcome Measure: Change in Mobility Score for Medical

Rehabilitation Patients (NQF #2634) measure beginning with the FY 2025 IRF QRP.

- Adopt the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure beginning with the FY 2026 IRF QRP.

- Request information on principles for selecting and prioritizing IRF QRP quality measures and concepts.

- Provide an update on our continued efforts to close the health equity gap.

IV. Analysis of and Responses to Public Comments

We received 45 timely responses from the public, many of which contained multiple comments on the FY 2024 IRF PPS proposed rule (88 FR 20950). We received comments from various trade associations, inpatient rehabilitation facilities, individual physicians, therapists, clinicians, health care industry organizations, and health care consulting firms. The following sections, arranged by subject area, include a summary of the public comments that we received, and our responses.

A. General Comments on the FY 2024 IRF PPS Proposed Rule

In addition to the comments, we received on specific proposals contained within the proposed rule (which we address later in this final rule), commenters also submitted more general observations on the IRF PPS and IRF care generally.

Comment: We received several comments that were outside the scope of the FY 2024 IRF PPS proposed rule. Specifically, we received comments regarding the inclusion of recreational therapy in the IRF intensity of therapy requirement, disclosures of ownership and additional disclosable parties' information in the skilled nursing facility setting, the "low wage index policy," Medicare Advantage rules, waiving the "three-hour rule," and the IRF Review Choice Demonstration. We also received comments about making refinements to our measures to address the impact of COVID-19 and social determinants of health, to change the HCP COVID-19 measure specifications to annual data submission, and concerns of being inappropriately penalized for NHSN technical errors.

Response: We thank the commenters for bringing these issues to our attention and will take these comments into consideration for potential policy refinements or direct the comments to the appropriate subject matter experts.

V. Update to the Case-Mix Group (CMG) Relative Weights and Average Length of Stay (ALOS) Values for FY 2024

As specified in § 412.620(b)(1), we calculate a relative weight for each CMG that is proportional to the resources needed by an average inpatient rehabilitation case in that CMG. For example, cases in a CMG with a relative weight of 2, on average, will cost twice as much as cases in a CMG with a relative weight of 1. Relative weights account for the variance in cost per discharge due to the variance in resource utilization among the payment groups, and their use helps to ensure that IRF PPS payments support beneficiary access to care, as well as provider efficiency.

In the proposed rule, we proposed to update the CMG relative weights and ALOS values for FY 2024. Typically, we use the most recent available data to update the CMG relative weights and ALOS values. For FY 2024, we proposed to use the FY 2022 IRF claims and FY 2021 IRF cost report data. These data are the most current and complete data available at this time. Currently, only a small portion of the FY 2022 IRF cost report data are available for analysis, but the majority of the FY 2022 IRF claims data are available for analysis. We also proposed that if more recent data became available after the publication of the proposed rule and before the publication of the final rule, we would use such data to determine the FY 2024 CMG relative weights and ALOS values in the final rule.

We proposed to apply these data using the same methodologies that we have used to update the CMG relative weights and ALOS values each FY since we implemented an update to the methodology. The detailed CCR data from the cost reports of IRF provider units of primary acute care hospitals is used for this methodology, instead of CCR data from the associated primary care hospitals, to calculate IRFs' average costs per case, as discussed in the FY 2009

IRF PPS final rule (73 FR 46372). In calculating the CMG relative weights, we use a hospital-specific relative value method to estimate operating (routine and ancillary services) and capital costs of IRFs. The process to calculate the CMG relative weights for this final rule is as follows:

Step 1. We estimate the effects that comorbidities have on costs.

Step 2. We adjust the cost of each Medicare discharge (case) to reflect the effects found in the first step.

Step 3. We use the adjusted costs from the second step to calculate CMG relative weights, using the hospital-specific relative value method.

Step 4. We normalize the FY 2024 CMG relative weights to the same average CMG relative weight from the CMG relative weights implemented in the FY 2023 IRF PPS final rule (87 FR 47038).

Consistent with the methodology that we have used to update the IRF classification system in each instance in the past, we proposed to update the CMG relative weights for FY 2024 in such a way that total estimated aggregate payments to IRFs for FY 2024 are the same with or without the changes (that is, in a budget-neutral manner) by applying a budget neutrality factor to the standard payment amount. We note that, as we typically do, we updated our data between the FY 2024 IRF PPS proposed and final rules to ensure that we use the most recent available data in calculating IRF PPS payments. This updated data reflects a more complete set of claims for FY 2022 and additional cost report data for FY 2021. To calculate the appropriate budget neutrality factor for use in updating the FY 2024 CMG relative weights, we use the following steps:

Step 1. Calculate the estimated total amount of IRF PPS payments for FY 2024 (with no changes to the CMG relative weights).

Step 2. Calculate the estimated total amount of IRF PPS payments for FY 2024 by applying the changes to the CMG relative weights (as discussed in this final rule).

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2 to determine the budget neutrality factor of 1.0002 that would maintain the same total estimated aggregate payments in FY 2024 with and without the changes to the CMG relative weights.

Step 4. Apply the budget neutrality factor from step 3 to the FY 2024 IRF PPS standard payment amount after the application of the budget-neutral wage adjustment factor.

In section VI.G. of this final rule, we discuss the use of the existing methodology to calculate the standard payment conversion factor for FY 2024.

In Table 2, “Relative Weights and Average Length of Stay Values for Case-Mix Groups,” we present the CMGs, the comorbidity tiers, the corresponding relative weights, and the ALOS values for each CMG and tier for FY 2024. The ALOS for each CMG is used to determine when an IRF discharge meets the definition of a short-stay transfer, which results in a per diem case level adjustment.

TABLE 2: Relative Weights and Average Length of Stay Values for the Case-Mix Groups

CMG	CMG Description (M=motor, A=age)	Relative Weight				Average Length of Stay			
		Tier 1	Tier 2	Tier 3	No Comorbidity Tier	Tier 1	Tier 2	Tier 3	No Comorbidity Tier
0101	Stroke M >=72.50	0.9840	0.8414	0.7763	0.7348	9	10	9	9
0102	Stroke M >=63.50 and M <72.50	1.2601	1.0774	0.9941	0.9409	12	11	11	11
0103	Stroke M >=50.50 and M <63.50	1.6264	1.3907	1.2830	1.2144	14	14	14	13
0104	Stroke M >=41.50 and M <50.50	2.0857	1.7834	1.6454	1.5574	17	18	17	17
0105	Stroke M <41.50 and A >=84.50	2.5400	2.1718	2.0038	1.8966	24	21	20	20
0106	Stroke M <41.50 and A <84.50	2.9022	2.4816	2.2895	2.1671	25	25	23	22
0201	Traumatic brain injury M >=73.50	1.0814	0.8600	0.7832	0.7312	10	11	9	8
0202	Traumatic brain injury M >=61.50 and M <73.50	1.3878	1.1036	1.0051	0.9383	12	12	11	11
0203	Traumatic brain injury M >=49.50 and M <61.50	1.7187	1.3668	1.2447	1.1621	15	15	13	13
0204	Traumatic brain injury M >=35.50 and M <49.50	2.1379	1.7001	1.5483	1.4455	18	18	16	16
0205	Traumatic brain injury M <35.50	2.7326	2.1730	1.9790	1.8476	30	23	19	18
0301	Non-traumatic brain injury M >=65.50	1.2082	0.9506	0.8859	0.8275	10	10	10	9
0302	Non-traumatic brain injury M >=52.50 and M <65.50	1.5486	1.2184	1.1355	1.0606	13	13	12	12
0303	Non-traumatic brain injury M >=42.50 and M <52.50	1.8539	1.4586	1.3593	1.2697	15	15	14	13
0304	Non-traumatic brain injury M <42.50 and A >=78.50	2.1918	1.7245	1.6071	1.5011	19	17	16	15
0305	Non-traumatic brain injury M <42.50 and A <78.50	2.3908	1.8810	1.7530	1.6374	20	19	17	17
0401	Traumatic spinal cord injury M >=56.50	1.3571	1.0692	1.0384	0.9679	13	11	11	12
0402	Traumatic spinal cord injury M >=47.50 and M <56.50	1.7196	1.3548	1.3159	1.2265	16	15	14	13
0403	Traumatic spinal cord injury M >=41.50 and M <47.50	2.0713	1.6319	1.5849	1.4772	19	17	16	16
0404	Traumatic spinal cord injury M <31.50 and A <61.50	3.2583	2.5671	2.4932	2.3239	22	25	27	20
0405	Traumatic spinal cord injury M >=31.50 and M <41.50	2.6613	2.0967	2.0364	1.8980	21	22	22	20
0406	Traumatic spinal cord injury M >=24.50 and M <31.50 and A >=61.50	3.3419	2.6329	2.5572	2.3835	24	28	27	24
0407	Traumatic spinal cord injury M <24.50 and A >=61.50	4.4849	3.5334	3.4318	3.1986	44	36	33	35
0501	Non-traumatic spinal cord injury M >=60.50	1.2596	0.9985	0.9390	0.8577	12	11	10	10
0502	Non-traumatic spinal cord injury M >=53.50 and M <60.50	1.5508	1.2294	1.1561	1.0560	14	13	12	12
0503	Non-traumatic spinal cord injury M >=48.50 and M <53.50	1.7794	1.4107	1.3266	1.2117	16	14	14	13
0504	Non-traumatic spinal cord injury M >=39.50 and M <48.50	2.1413	1.6975	1.5963	1.4581	19	16	17	16
0505	Non-traumatic spinal cord injury M <39.50	3.0130	2.3886	2.2462	2.0517	28	25	23	21
0601	Neurological M >=64.50	1.3401	1.0161	0.9510	0.8567	11	10	10	9
0602	Neurological M >=52.50 and M <64.50	1.6602	1.2588	1.1781	1.0613	13	13	12	11
0603	Neurological M >=43.50 and M <52.50	1.9713	1.4946	1.3989	1.2601	15	14	14	13
0604	Neurological M <43.50	2.4621	1.8667	1.7472	1.5739	20	18	17	16
0701	Fracture of lower extremity M >=61.50	1.2031	0.9557	0.9124	0.8349	12	11	10	10

CMG	CMG Description (M=motor, A=age)	Relative Weight				Average Length of Stay			
		Tier 1	Tier 2	Tier 3	No Comorbidity Tier	Tier 1	Tier 2	Tier 3	No Comorbidity Tier
0702	Fracture of lower extremity M >=52.50 and M <61.50	1.4908	1.1842	1.1306	1.0345	13	13	12	12
0703	Fracture of lower extremity M >=41.50 and M <52.50	1.8376	1.4598	1.3937	1.2753	16	15	15	14
0704	Fracture of lower extremity M <41.50	2.2805	1.8116	1.7296	1.5826	18	18	18	16
0801	Replacement of lower-extremity joint M >=63.50	1.1836	0.9450	0.8786	0.8082	10	9	9	9
0802	Replacement of lower-extremity joint M >=57.50 and M <63.50	1.3462	1.0748	0.9992	0.9192	10	11	10	10
0803	Replacement of lower-extremity joint M >=51.50 and M <57.50	1.4961	1.1945	1.1105	1.0216	13	13	11	11
0804	Replacement of lower-extremity joint M >=42.50 and M <51.50	1.6858	1.3459	1.2513	1.1511	15	14	13	12
0805	Replacement of lower-extremity joint M <42.50	2.1040	1.6798	1.5617	1.4367	17	17	16	15
0901	Other orthopedic M >=63.50	1.2309	0.9485	0.8910	0.8136	11	10	10	9
0902	Other orthopedic M >=51.50 and M <63.50	1.5655	1.2064	1.1332	1.0348	14	12	12	11
0903	Other orthopedic M >=44.50 and M <51.50	1.8159	1.3994	1.3145	1.2004	15	14	14	13
0904	Other orthopedic M <44.5	2.1953	1.6917	1.5892	1.4512	19	17	16	15
1001	Amputation lower extremity M >=64.50	1.1998	0.9933	0.9080	0.8286	10	10	10	10
1002	Amputation lower extremity M >=55.50 and M <64.50	1.5279	1.2650	1.1564	1.0552	14	14	12	12
1003	Amputation lower extremity M >=47.50 and M <55.50	1.8004	1.4905	1.3626	1.2433	15	16	14	13
1004	Amputation lower extremity M <47.50	2.3361	1.9340	1.7680	1.6133	19	19	18	17
1101	Amputation non-lower extremity M >=58.50	1.2738	1.2738	1.0263	0.9729	12	14	11	10
1102	Amputation non-lower extremity M >=52.50 and M <58.50	1.4606	1.4606	1.1769	1.1156	13	16	12	11
1103	Amputation non-lower extremity M <52.50	2.0037	2.0037	1.6145	1.5304	17	18	16	13
1201	Osteoarthritis M >=61.50	1.3299	1.0296	0.9247	0.8605	12	11	10	10
1202	Osteoarthritis M >=49.50 and M <61.50	1.6836	1.3034	1.1707	1.0894	14	14	12	11
1203	Osteoarthritis M <49.50 and A >=74.50	2.1218	1.6426	1.4753	1.3729	17	17	17	14
1204	Osteoarthritis M <49.50 and A <74.50	2.2013	1.7042	1.5306	1.4244	18	18	16	15
1301	Rheumatoid other arthritis M >=62.50	1.3766	1.1049	0.9921	0.9182	10	11	10	10
1302	Rheumatoid other arthritis M >=51.50 and M <62.50	1.6431	1.3189	1.1842	1.0960	12	13	12	11
1303	Rheumatoid other arthritis M >=44.50 and M <51.50 and A >=64.50	1.8570	1.4906	1.3383	1.2387	13	12	15	12
1304	Rheumatoid other arthritis M <44.50 and A >=64.50	2.1954	1.7621	1.5822	1.4644	15	17	16	16
1305	Rheumatoid other arthritis M <51.50 and A <64.50	2.2065	1.7711	1.5902	1.4718	15	16	17	14
1401	Cardiac M >=68.50	1.1256	0.9099	0.8407	0.7768	10	10	9	9
1402	Cardiac M >=55.50 and M <68.50	1.4063	1.1368	1.0504	0.9705	12	12	11	11
1403	Cardiac M >=45.50 and M <55.50	1.7014	1.3753	1.2708	1.1742	15	14	13	12
1404	Cardiac M <45.50	2.1231	1.7162	1.5858	1.4651	18	17	16	15
1501	Pulmonary M >=68.50	1.2909	1.0412	1.0044	0.9516	13	10	10	10
1502	Pulmonary M >=56.50 and M <68.50	1.5272	1.2318	1.1883	1.1258	12	12	12	11
1503	Pulmonary M >=45.50 and M <56.50	1.8121	1.4616	1.4100	1.3358	15	14	13	13

CMG	CMG Description (M=motor, A=age)	Relative Weight				Average Length of Stay			
		Tier 1	Tier 2	Tier 3	No Comorbidity Tier	Tier 1	Tier 2	Tier 3	No Comorbidity Tier
1504	Pulmonary M <45.50	2.2346	1.8024	1.7386	1.6472	22	17	16	16
1601	Pain syndrome M >=65.50	1.1354	0.8523	0.8417	0.7736	10	10	9	10
1602	Pain syndrome M >=58.50 and M <65.50	1.4932	1.1209	1.1069	1.0174	9	11	12	11
1603	Pain syndrome M >=43.50 and M <58.50	1.7332	1.3011	1.2849	1.1810	10	13	13	13
1604	Pain syndrome M <43.50	2.1412	1.6074	1.5873	1.4590	11	15	17	15
1701	Major multiple trauma without brain or spinal cord injury M >=57.50	1.3697	1.0394	0.9843	0.8977	12	11	10	10
1702	Major multiple trauma without brain or spinal cord injury M >=50.50 and M <57.50	1.6534	1.2547	1.1881	1.0836	15	14	13	12
1703	Major multiple trauma without brain or spinal cord injury M >=41.50 and M <50.50	1.9589	1.4866	1.4077	1.2839	16	16	15	14
1704	Major multiple trauma without brain or spinal cord injury M >=36.50 and M <41.50	2.2563	1.7122	1.6214	1.4788	20	18	16	16
1705	Major multiple trauma without brain or spinal cord injury M <36.50	2.5847	1.9614	1.8574	1.6941	20	20	19	18
1801	Major multiple trauma with brain or spinal cord injury M >=67.50	1.0999	0.9202	0.8490	0.7684	11	11	10	9
1802	Major multiple trauma with brain or spinal cord injury M >=55.50 and M <67.50	1.3990	1.1704	1.0799	0.9774	14	13	12	11
1803	Major multiple trauma with brain or spinal cord injury M >=45.50 and M <55.50	1.7472	1.4617	1.3487	1.2207	13	16	14	14
1804	Major multiple trauma with brain or spinal cord injury M >=40.50 and M <45.50	2.0441	1.7101	1.5779	1.4282	19	18	16	16
1805	Major multiple trauma with brain or spinal cord injury M >=30.50 and M <40.50	2.4427	2.0435	1.8855	1.7066	22	23	19	18
1806	Major multiple trauma with brain or spinal cord injury M <30.50	3.5910	3.0042	2.7719	2.5089	38	32	29	24
1901	Guillain-Barré M >=66.50	1.2641	0.9028	0.8741	0.8392	12	12	11	10
1902	Guillain-Barré M >=51.50 and M <66.50	1.7885	1.2772	1.2367	1.1874	20	14	13	14
1903	Guillain-Barré M >=38.50 and M <51.50	2.5024	1.7871	1.7303	1.6613	25	19	19	18
1904	Guillain-Barré M <38.50	4.2456	3.0319	2.9356	2.8187	40	34	29	26
2001	Miscellaneous M >=66.50	1.1905	0.9557	0.8911	0.8082	11	10	10	9
2002	Miscellaneous M >=55.50 and M <66.50	1.4767	1.1855	1.1054	1.0025	13	12	12	11
2003	Miscellaneous M >=46.50 and M <55.50	1.7534	1.4075	1.3124	1.1903	15	14	13	13
2004	Miscellaneous M <46.50 and A >=77.50	2.0884	1.6765	1.5632	1.4177	18	17	16	15
2005	Miscellaneous M <46.50 and A <77.50	2.2394	1.7978	1.6763	1.5203	19	18	16	16
2101	Burns M >=52.50	1.5172	1.2785	1.1385	1.0176	17	15	12	11
2102	Burns M <52.50	2.4552	2.0690	1.8425	1.6468	24	21	18	18
5001	Short-stay cases, length of stay is 3 days or fewer	0.0000	0.0000	0.0000	0.1730	0	0	0	3
5101	Expired, orthopedic, length of stay is 13 days or fewer	0.0000	0.0000	0.0000	0.7794	0	0	0	8

CMG	CMG Description (M=motor, A=age)	Relative Weight				Average Length of Stay			
		Tier 1	Tier 2	Tier 3	No Comorbidity Tier	Tier 1	Tier 2	Tier 3	No Comorbidity Tier
5102	Expired, orthopedic, length of stay is 14 days or more	0.0000	0.0000	0.0000	1.8794	0	0	0	18
5103	Expired, not orthopedic, length of stay is 15 days or fewer	0.0000	0.0000	0.0000	0.8818	0	0	0	8
5104	Expired, not orthopedic, length of stay is 16 days or more	0.0000	0.0000	0.0000	2.3549	0	0	0	25

Generally, updates to the CMG relative weights result in some increases and some decreases to the CMG relative weight values. Table 2 shows how we estimate that the application of the revisions for FY 2024 would affect particular CMG relative weight values, which would affect the overall distribution of payments within CMGs and tiers. We note that, because we implement the CMG relative weight revisions in a budget-neutral manner (as previously described), total estimated aggregate payments to IRFs for FY 2024 are not affected as a result of the CMG relative weight revisions. However, the revisions affect the distribution of payments within CMGs and tiers.

TABLE 3: Distributional Effects of the Changes to the CMG Relative Weights

Percentage Change in CMG Relative Weights	Number of Cases Affected	Percentage of Cases Affected
Increased by 15% or more	65	0.0%
Increased by between 5% and 15%	1,195	0.4%
Changed by less than 5%	326,336	99.4%
Decreased by between 5% and 15%	599	0.2%
Decreased by 15% or more	0	0.0%

As shown in Table 3, 99.4 percent of all IRF cases are in CMGs and tiers that would experience less than a 5 percent change (either increase or decrease) in the CMG relative weight value as a result of the revisions for FY 2024. The changes in the ALOS values for FY 2024, compared with the FY 2023 ALOS values, are small and do not show any particular trends in IRF length of stay patterns.

We invited public comment on our proposed updates to the CMG relative weights and ALOS values for FY 2024.

The following is a summary of the public comments received on the proposed revisions to update the CMG relative weights and ALOS values for FY 2024 and our responses.

Comment: Commenters were generally supportive of the proposed updates to the relative weights and ALOS values and encouraged CMS to use the latest available data to update these values in the final rule. A few commenters expressed concern regarding reductions in certain relative weight values associated with traumatic spinal cord injury, major multiple traumas with brain or spinal cord injury, and Guillain-Barré. A few commenters also expressed concerns related to the increase of the ALOS for CMG 0404. These commenters noted that CMS did not propose a similar increase in reimbursement for this CMG and suggested the change may be due to distortions in the data rather than actual care changes.

Response: We appreciate these commenters' support for updating the relative weights and ALOS values for FY 2024. The CMG relative weights are updated each year in a budget neutral manner, thus leading to increases in some CMG relative weights and corresponding decreases in other CMG relative weights. We note that, as we typically do, we have updated our data between the FY 2024 IRF PPS proposed and this final rule to ensure that we use the most recent available data in calculating IRF PPS payments. The relative weights associated with these CMGs include both increases and decreases, and the variation for FY 2024 is similar to the typical year-to-year variation that we observe. The relative weight values are updated each year to ensure that the IRF case mix system is as reflective as possible of the current IRF population, thereby ensuring that IRF payments appropriately reflect the relative costs of caring for all types of IRF patients.

Additionally, the ALOS values are updated annually to be as reflective as possible of recent IRF utilization. The ALOS values are only used to determine which cases qualify for the short-stay transfer policy and are not used to determine payments for the non-short-stay transfer cases.

Comment: A commenter expressed concern that decreases to the CMG relative weights

and ALOS values do not reflect the medical complexity of the patients and suggested that CMS should revise the CMG relative weights and ALOS values to ensure adequate coverage and reimbursement for the services required to treat patients in IRF settings.

Response: We believe that these data accurately reflect the severity of the IRF patient population and the associated costs of caring for these patients in the IRF setting. The CMG relative weights are updated each year based on the most recent available data for the full population of IRF Medicare fee-for-service beneficiaries. This ensures that the IRF case mix system is as reflective as possible of changes in the IRF patient populations and the associated coding practices.

After consideration of the comments we received, we are finalizing our proposal to update the CMG relative weights and ALOS values for FY 2024, as shown in Table 2 of this final rule. These updates are effective for FY 2024, that is, for discharges occurring on or after October 1, 2023, and on or before September 30, 2024.

VI. FY 2024 IRF PPS Payment Update

A. Background

Section 1886(j)(3)(C) of the Act requires the Secretary to establish an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services for which payment is made under the IRF PPS. According to section 1886(j)(3)(A)(i) of the Act, the increase factor shall be used to update the IRF prospective payment rates for each FY.

Section 1886(j)(3)(C)(ii)(I) of the Act requires the application of a productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Thus, we proposed to update the IRF PPS payments for FY 2024 by a market basket increase percentage as required by section 1886(j)(3)(C) of the Act based upon the most current data available, with a productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act.

We have utilized various market baskets through the years in the IRF PPS. For a discussion of these market baskets, we refer readers to the FY 2016 IRF PPS final rule

(80 FR 47046).

In FY 2016, we finalized the use of a 2012-based IRF market basket, using Medicare cost report data for both freestanding and hospital-based IRFs (80 FR 47049 through 47068). In FY 2020, we finalized a rebased and revised IRF market basket to reflect a 2016 base year. The FY 2020 IRF PPS final rule (84 FR 39071 through 39086) contains a complete discussion of the development of the 2016-based IRF market basket. Beginning with FY 2024, we proposed to rebase and revise the IRF market basket to reflect a 2021 base year. In the following discussion, we provide an overview of the market basket and describe the methodologies used to determine the operating and capital portions of the 2021-based IRF market basket.

B. Overview of the 2021-Based IRF Market Basket

The 2021-based IRF market basket is a fixed-weight, Laspeyres-type price index. A Laspeyres price index measures the change in price, over time, of the same mix of goods and services purchased in the base period. Any changes in the quantity or mix of goods and services (that is, intensity) purchased over time relative to the base period are not measured.

The index itself is constructed in three steps. First, a base period is selected (for the proposed IRF market basket in the proposed rule, we proposed to use 2021 as the base period) and total base period costs are estimated for a set of mutually exclusive and exhaustive cost categories. Each category is calculated as a proportion of total costs. These proportions are called cost weights. Second, each cost category is matched to an appropriate price or wage variable, referred to as a price proxy. In almost every instance, these price proxies are derived from publicly available statistical series that are published on a consistent schedule (preferably at least on a quarterly basis). Finally, the cost weight for each cost category is multiplied by the level of its respective price proxy. The sum of these products (that is, the cost weights multiplied by their price index levels) for all cost categories yields the composite index level of the market basket in a given time period. Repeating this step for other periods produces a series of market basket levels over time. Dividing an index level for a given period by an index level for an

earlier period produces a rate of growth in the input price index over that timeframe.

As noted, the market basket is described as a fixed-weight index because it represents the change in price over time of a constant mix (quantity and intensity) of goods and services needed to provide IRF services. The effects on total costs resulting from changes in the mix of goods and services purchased subsequent to the base period are not measured. For example, an IRF hiring more nurses after the base period to accommodate the needs of patients would increase the volume of goods and services purchased by the IRF but would not be factored into the price change measured by a fixed-weight IRF market basket. Only when the index is rebased would changes in the quantity and intensity be captured, with those changes being reflected in the cost weights. Therefore, we rebase the market basket periodically so that the cost weights reflect recent changes in the mix of goods and services that IRFs purchase to furnish inpatient care between base periods.

C. Rebasing and Revising of the IRF PPS Market Basket

As discussed in the FY 2020 IRF PPS final rule (84 FR 39071 through 39086), the 2016-based IRF market basket cost weights reflect the 2016 Medicare cost report data submitted by both freestanding and hospital-based facilities.

Beginning with FY 2024, we proposed to rebase and revise the 2016-based IRF market basket cost weights to a 2021 base year reflecting the 2021 Medicare cost report data submitted by both freestanding and hospital-based IRFs. Below we provide a detailed description of our methodology used to develop the 2021-based IRF market basket. This proposed methodology is generally similar to the methodology used to develop the 2016-based IRF market basket.

We invited public comment on our proposed methodology for developing the 2021-based IRF market basket.

Comment: Many commenters supported the rebasing and revising of the IRF market basket from a 2016 base year to a 2021 base year as proposed. Some of these commenters encouraged CMS to focus greater attention on the costs and data needed to support payment

changes in the future.

Several commenters, while supporting moving forward with a 2021 base year, requested that CMS consider rebasing the IRF market basket to a later base year, such as 2022 or 2023, when the data become available, to more fully incorporate changes to IRF cost structures. One commenter stated that inflationary pressures and cost increases seem to have moderated somewhat during FY 2023 and therefore, using FY 2023 in future rulemaking would better align permanent changes that have occurred in more recent years. One commenter stated that they believe that using FY 2023 data, when available, may more accurately capture costs being incurred by IRFs and they requested that CMS update the IRF market basket cost weights with the most recently available data in the final rule.

Response: We appreciate the commenters' support to rebase and revise the IRF market basket. As discussed in section VI.A of this final rule, the market basket used to update IRF PPS payments has been periodically rebased and revised over the history of the IRF PPS to reflect more recent data on IRF cost structures. For the FY 2024 IRF PPS proposed rule, we proposed to rebase and revise the IRF market basket using 2021 Medicare cost reports, the most recent year of complete data available at the time of rulemaking, which showed an increase in the Compensation cost weight from 2016 to 2021. Data for 2022 and 2023 are incomplete at this time. Because complete 2022 IRF cost report data are currently unavailable, we believe it is more appropriate to update the base year cost weights to 2021 to reflect changes over this period rather than to delay the rebasing. It has been our longstanding practice to rebase the market basket on a regular basis to ensure it reflects the input cost structure of IRFs. As stated in the FY 2024 IRF PPS proposed rule (88 FR 20960), given the potential impact of the PHE on the Medicare cost report data, we will continue to monitor the Medicare cost report data as they become available and, if appropriate, propose any changes to the IRF market basket in future rulemaking.

We provide a summary of the more detailed public comments received on our proposed

methodology for developing the 2021-based IRF market basket and our responses in the following sections.

1. Development of Cost Categories and Weights for the 2021-Based IRF Market Basket

- a. Use of Medicare Cost Report Data

We proposed a 2021-based IRF market basket that consists of seven major cost categories and a residual derived from the 2021 Medicare cost reports (CMS Form 2552-10, OMB No. 0938-0050) for freestanding and hospital-based IRFs. The seven major cost categories are Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, Professional Liability Insurance (PLI), Home Office/Related Organization Contract Labor, and Capital. The residual category reflects all remaining costs not captured in the seven cost categories. The 2021 cost reports include providers whose cost reporting period began on or after October 1, 2020, and before October 1, 2021. As noted previously, the current IRF market basket is based on 2016 Medicare cost reports and, therefore, reflects the 2016 cost structure for IRFs. As described in the FY 2023 IRF PPS final rule (87 FR 47049 through 47050), we received comments on the FY 2023 IRF PPS proposed rule where interested parties expressed concern that the proposed market basket update was inadequate relative to input price inflation experienced by IRFs, particularly as a result of the COVID-19 PHE. These commenters stated that the PHE, along with inflation, has significantly driven up operating costs. Specifically, some commenters noted changes to the labor markets that led to the use of more contract labor, a trend that we verified in analyzing the Medicare cost reports through 2021. Therefore, we believe it is appropriate to incorporate more recent data to reflect updated cost structures for IRFs, and so we proposed to use 2021 as the base year because we believe that the Medicare cost reports for this year represent the most recent, complete set of Medicare cost report data available for developing the proposed IRF market basket at the time of this rulemaking. Given the potential impact of the PHE on the Medicare cost report data, we will continue to monitor these data going forward and any changes to the IRF market basket will be proposed in future

rulemaking.

Since our goal is to establish cost weights that are reflective of case mix and practice patterns associated with the services IRFs provide to Medicare beneficiaries, as we did for the 2016-based IRF market basket, we proposed to limit the cost reports used to establish the 2021-based IRF market basket to those from facilities that had a Medicare ALOS that was relatively similar to their facility ALOS. We believe that this requirement eliminates statistical outliers and ensures a more accurate market basket that reflects the costs generally incurred during a Medicare-covered stay. The Medicare ALOS for freestanding IRFs is calculated from data reported on line 14 of Worksheet S-3, part I. The Medicare ALOS for hospital-based IRFs is calculated from data reported on line 17 of Worksheet S-3, part I. We proposed to include the cost report data from IRFs with a Medicare ALOS within 15 percent (that is, 15 percent higher or lower) of the facility ALOS to establish the sample of providers used to estimate the 2021-based IRF market basket cost weights. We proposed to apply this ALOS edit to the data for IRFs to exclude providers that serve a population whose ALOS would indicate that the patients served are not consistent with an ALOS of a typical Medicare patient. We note that this is the same ALOS edit that we applied to develop the 2016-based IRF market basket. This process resulted in the exclusion of about nine percent of the freestanding and hospital-based IRF Medicare cost reports. Of those excluded, about 15 percent were freestanding IRFs and 85 percent were hospital-based IRFs. This ratio is relatively consistent with the universe of freestanding and hospital-based IRF cost reports where freestanding IRFs represent about 30 percent of the total.

We then proposed to use the cost reports for IRFs that met this ALOS edit requirement to calculate the costs for the seven major cost categories (Wages and Salaries, Employee Benefits, Contract Labor, Professional Liability Insurance, Pharmaceuticals, Home Office/Related Organization Contract Labor, and Capital) for the market basket. These are the same categories used for the 2016-based IRF market basket. Also, as described in section V.C.1.d. of the proposed rule, and as done for the 2016-based IRF market basket, we also proposed to use the

Medicare cost report data to calculate the detailed capital cost weights for the Depreciation, Interest, Lease, and Other Capital-Related cost categories. We note that we proposed to rename the Home Office Contract Labor cost category to the Home Office/Related Organization Contract Labor cost category to be more consistent with the Medicare cost report instructions.

Similar to the 2016-based IRF market basket major cost weights, for the majority of the 2021-based IRF market basket cost weights, we proposed to divide the 2021 costs for each cost category by the 2021 total Medicare allowable costs (routine, ancillary and capital) that are eligible for reimbursement through the IRF PPS (we note that we use total facility medical care costs as the denominator to derive both the PLI and Home Office/Related Organization Contract Labor cost weights). We next describe our proposed methodology for deriving the cost levels used to derive the 2021-based IRF market basket.

(1) Total Medicare Allowable Costs

For freestanding IRFs, we proposed that total Medicare allowable costs would be equal to the sum of total costs for the Medicare allowable cost centers as reported on Worksheet B, part I, column 26, lines 30 through 35, 50 through 76 (excluding 52 and 75), 90 through 91, and 93.

For hospital-based IRFs, we proposed that total Medicare allowable costs would be equal to the total costs for the IRF inpatient unit after the allocation of overhead costs (Worksheet B, part I, column 26, line 41) and a proportion of total ancillary costs reported on Worksheet B, part I, column 26, lines 50 through 76 (excluding 52 and 75), 90 through 91, and 93.

We proposed to calculate total ancillary costs attributable to the hospital-based IRF by first deriving an “IRF ancillary ratio” for each ancillary cost center. The IRF ancillary ratio is defined as the ratio of IRF Medicare ancillary costs for the cost center (as reported on Worksheet D–3, column 3 for hospital-based IRFs) to total Medicare ancillary costs for the cost center (equal to the sum of Worksheet D–3, column 3 for all relevant prospective payment systems (PPS) [that is, inpatient prospective payment system (IPPS), IRF PPS, inpatient psychiatric facilities (IPF) PPS and skilled nursing facility (SNF) PPS]). For example, if hospital-based IRF

Medicare physical therapy costs represent about 30 percent of the total Medicare physical therapy costs for the entire facility, then the IRF ancillary ratio for physical therapy costs would be 30 percent. We believe it is appropriate to use only a portion of the ancillary costs in the market basket cost weight calculations since the hospital-based IRF only utilizes a portion of the facility's ancillary services. We believe the ratio of reported IRF Medicare costs to reported total Medicare costs provides a reasonable estimate of the ancillary services utilized, and costs incurred, by the hospital-based IRF. We proposed that this IRF ancillary ratio for each cost center also be used to calculate Wages and Salaries and Capital costs, as described in section VI.C.1.a.(2) of this final rule.

Then for each ancillary cost center, we proposed to multiply the IRF ancillary ratio for the given cost center by the total facility ancillary costs for that specific cost center (as reported on Worksheet B, part I, column 26) to derive IRF ancillary costs. For example, the 30 percent IRF ancillary ratio for physical therapy cost center would be multiplied by the total ancillary costs for physical therapy (Worksheet B, part I, column 26, line 66). The IRF ancillary costs for each cost center are then added to total costs for the IRF inpatient unit after the allocation of overhead costs (Worksheet B, part I, column 26, line 41) to derive total Medicare allowable costs.

We proposed to use these methods to derive levels of total Medicare allowable costs for IRF providers. This is the same methodology used for the 2016-based IRF market basket. We proposed that these total Medicare allowable costs for the IRF will be the denominator for the cost weight calculations for the Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, and Capital cost weights. With this work complete, we then set about deriving cost levels for the seven major cost categories and then derive a residual cost weight reflecting all other costs not classified.

(2) Wages and Salaries Costs

For freestanding IRFs, we proposed to derive Wages and Salaries costs as the sum of

routine inpatient salaries (Worksheet A, column 1, lines 30 through 35), ancillary salaries (Worksheet A, column 1, lines 50 through 76 (excluding 52 and 75), 90 through 91, and 93), and a proportion of overhead (or general service cost centers in the Medicare cost reports) salaries. Since overhead salary costs are attributable to the entire IRF, we only include the proportion attributable to the Medicare allowable cost centers. We proposed to estimate the proportion of overhead salaries that are attributed to Medicare allowable costs centers by multiplying the ratio of Medicare allowable area salaries (Worksheet A, column 1, lines 30 through 35, 50 through 76 (excluding 52 and 75), 90 through 91, and 93) to total non-overhead salaries (Worksheet A, column 1, line 200 less Worksheet A, column 1, lines 4 through 18) times total overhead salaries (Worksheet A, column 1, lines 4 through 18). This is a similar methodology as used in the 2016-based IRF market basket.

For hospital-based IRFs, we proposed to derive Wages and Salaries costs as the sum of the following salaries attributable to the hospital-based IRF: inpatient routine salary costs (Worksheet A, column 1, line 41); overhead salary costs; ancillary salary costs; and a portion of overhead salary costs attributable to the ancillary departments.

(a) Overhead salary costs

We proposed to calculate the portion of overhead salary costs attributable to hospital-based IRFs by first calculating an IRF overhead salary ratio, which is equal to the ratio of total facility overhead salaries (as reported on Worksheet A, column 1, lines 4-18) to total facility noncapital overhead costs (as reported on Worksheet A, column 1 and 2, lines 4-18). We then proposed to multiply this IRF overhead salary ratio by total noncapital overhead costs (sum of Worksheet B, part I, columns 4 through 18, line 41, less Worksheet B, part II, columns 4 through 18, line 41). This methodology assumes the proportion of total costs related to salaries for the overhead cost center is similar for all inpatient units (that is, acute inpatient or inpatient rehabilitation).

(b) Ancillary salary costs

We proposed to calculate hospital-based IRF ancillary salary costs for a specific cost center (Worksheet A, column 1, lines 50 through 76 (excluding 52 and 75), 90 through 91, and 93) as salary costs from Worksheet A, column 1, multiplied by the IRF ancillary ratio for each cost center as described in section V.C.1.a.(1) of the proposed rule. The sum of these costs represents hospital-based IRF ancillary salary costs.

(c) Overhead salary costs for ancillary cost centers

We proposed to calculate the portion of overhead salaries attributable to each ancillary department (lines 50 through 76 (excluding 52 and 75), 90 through 91, and 93) by first calculating total noncapital overhead costs attributable to each specific ancillary department (sum of Worksheet B, part I, columns 4-18 less, Worksheet B, part II, column 26). We then identify the portion of these total noncapital overhead costs for each ancillary department that is attributable to the hospital-based IRF by multiplying these costs by the IRF ancillary ratio as described in section V.C.1.a.(1) of the proposed rule. We then sum these estimated IRF Medicare allowable noncapital overhead costs for all ancillary departments (cost centers 50 through 76, 90 through 91, and 93). Finally, we then identify the portion of these IRF Medicare allowable noncapital overhead costs that are attributable to Wages and Salaries by multiplying these costs by the IRF overhead salary ratio as described in section V.C.1.a.(2)(a) of the proposed rule. This is the same methodology used to derive the 2016-based IRF market basket.

(3) Employee Benefits Costs

Effective with the implementation of CMS Form 2552-10, we began collecting Employee Benefits and Contract Labor data on Worksheet S-3, part V.

For the 2021 Medicare cost report data, 54 percent of providers reported Employee Benefits data on Worksheet S-3, part V; particularly, approximately 57 percent of freestanding IRFs and 53 percent of hospital-based IRFs reported Employee Benefits data on Worksheet S-3, part V. For comparison, for 2016, about 45 percent of providers reported Employee Benefits data on Worksheet S-3, part V. Again, we continue to encourage all providers to report these

data on the Medicare cost report.

For freestanding IRFs, we proposed Employee Benefits costs would be equal to the data reported on Worksheet S-3, part V, column 2, line 2. We note that while not required to do so, freestanding IRFs also may report Employee Benefits data on Worksheet S-3, part II, which is applicable to only IPPS providers. Similar to the method for the 2016-based IRF market basket, for those freestanding IRFs that report Worksheet S-3, part II, data, but not Worksheet S-3, part V, we proposed to use the sum of Worksheet S-3, part II, lines 17, 18, 20, and 22, to derive Employee Benefits costs.

For hospital-based IRFs, we proposed to calculate total benefit costs as the sum of inpatient unit benefit costs, a portion of ancillary departments benefit costs, and a portion of overhead benefits attributable to both the routine inpatient unit and the ancillary departments. For those hospital-based IRFs that report Worksheet S-3, part V data, we proposed inpatient unit benefit costs be equal to Worksheet S-3, part V, column 2, line 4. Given the limited reporting on Worksheet S-3, part V, we proposed that for those hospital-based IRFs that do not report these data, we calculate inpatient unit benefits costs using a portion of benefits costs reported for Excluded areas on Worksheet S-3, part II. We proposed to calculate the ratio of inpatient unit salaries (Worksheet A, column 1, line 41) to total excluded area salaries (sum of Worksheet A, column 1, lines 20, 23, 40 through 42, 44, 45, 46, 94, 95, 98 through 101, 105 through 112, 114, 115 through 117, 190 through 194). We then proposed to apply this ratio to Excluded area benefits (Worksheet S-3, part II, column 4, line 19) to derive inpatient unit benefits costs for those providers that do not report benefit costs on Worksheet S-3, part V.

We proposed the ancillary departments benefits and overhead benefits (attributable to both the inpatient unit and ancillary departments) costs are derived by first calculating the sum of hospital-based IRF overhead salaries as described in section V.C.1.a.(2)(a) of the proposed rule, hospital-based IRF ancillary salaries as described in section V.C.1.a.(2)(b) of the proposed rule and hospital-based IRF overhead salaries for ancillary cost centers as described in section

V.C.1.a.(2)(c) of the proposed rule. This sum is then multiplied by the ratio of total facility benefits to total facility salaries, where total facility benefits is equal to the sum of Worksheet S-3, part II, column 4, lines 17-25, and total facility salaries is equal to Worksheet S-3, part II, column 4, line 1.

(4) Contract Labor Costs

Contract Labor costs are primarily associated with direct patient care services. Contract labor costs for other services such as accounting, billing, and legal are calculated separately using other government data sources as described in section V.C.1.c. of the proposed rule. To derive contract labor costs using Worksheet S-3, part V, data, for freestanding IRFs, we proposed Contract Labor costs be equal to Worksheet S-3, part V, column 1, line 2. As we noted for Employee Benefits, freestanding IRFs also may report Contract Labor data on Worksheet S-3, part II, which is applicable to only IPPS providers. For those freestanding IRFs that report Worksheet S-3, part II data, but not Worksheet S-3, part V, we proposed to use the sum of Worksheet S-3, part II, column 4, lines 11 and 13, to derive Contract Labor costs.

For hospital-based IRFs, we proposed that Contract Labor costs would be equal to Worksheet S-3, part V, column 1, line 4. For 2021 Medicare cost report data, 30 percent of providers reported Contract Labor data on Worksheet S-3, part V; particularly, approximately 56 percent of freestanding IRFs and 18 percent of hospital-based IRFs reported data on Worksheet S-3, part V. For comparison, for the 2016-based IRF market basket, about 26 percent of providers reported Contract Labor data on Worksheet S-3, part V. We continue to encourage all providers to report these data on the Medicare cost report.

Given the limited reporting on Worksheet S-3, part V, we proposed that for those hospital-based IRFs that do not report these data, we calculate Contract Labor costs using a portion of contract labor costs reported on Worksheet S-3, part II. We proposed to calculate the ratio of contract labor costs (Worksheet S-3, part II, column 4, lines 11 and 13) to PPS salaries (Worksheet S-3, part II, column 4, line 1 less the sum of Worksheet S-3, part II, column 4, lines

3, 401, 5, 6, 7, 701, 8, 9, 10 less Worksheet A, column 1, line 20 and 23). We then proposed to apply this ratio to total inpatient routine salary costs (Worksheet A, column 1, line 41) to derive contract labor costs for those providers that do not report contract labor costs on Worksheet S-3, part V.

(5) Pharmaceuticals Costs

For freestanding IRFs, we proposed to calculate pharmaceuticals costs using non-salary costs reported on Worksheet A, column 7, less Worksheet A, column 1, for the pharmacy cost center (line 15) and drugs charged to patients cost center (line 73).

For hospital-based IRFs, we proposed to calculate pharmaceuticals costs as the sum of a portion of the non-salary pharmacy costs and a portion of the non-salary drugs charged to patient costs reported for the total facility. We proposed that non-salary pharmacy costs attributable to the hospital-based IRF would be calculated by multiplying total pharmacy costs attributable to the hospital-based IRF (as reported on Worksheet B, part I, column 15, line 41) by the ratio of total non-salary pharmacy costs (Worksheet A, column 2, line 15) to total pharmacy costs (sum of Worksheet A, columns 1 and 2 for line 15) for the total facility. We proposed that non-salary drugs charged to patient costs attributable to the hospital-based IRF would be calculated by multiplying total non-salary drugs charged to patient costs (Worksheet B, part I, column 0, line 73 plus Worksheet B, part I, column 15, line 73 less Worksheet A, column 1, line 73) for the total facility by the ratio of Medicare drugs charged to patient ancillary costs for the IRF unit (as reported on Worksheet D-3 for hospital-based IRFs, column 3, line 73) to total Medicare drugs charged to patient ancillary costs for the total facility (equal to the sum of Worksheet D-3, column 3, line 73 for all relevant PPS (that is, IPPS, IRF, IPF and SNF).

(6) Professional Liability Insurance Costs

For freestanding and hospital-based IRFs, we proposed that Professional Liability Insurance (PLI) costs (often referred to as malpractice costs) would be equal to premiums, paid losses and self-insurance costs reported on Worksheet S-2, columns 1 through 3, line 118 – the

same data used for the 2016-based IRF market basket. For hospital-based IRFs, we proposed to assume that the PLI weight for the total facility is similar to the hospital-based IRF unit since the only data reported on this worksheet is for the entire facility, as we currently have no means to identify the proportion of total PLI costs that are only attributable to the hospital-based IRF.

However, when we derive the cost weight for PLI for both hospital-based and freestanding IRFs, we use the total facility medical care costs as the denominator as opposed to total Medicare allowable costs. For freestanding IRFs and hospital-based IRFs, we proposed to derive total facility medical care costs as the sum of total costs (Worksheet B, part I, column 26, line 202) less non-reimbursable costs (Worksheet B, part I, column 26, lines 190 through 201).

(7) Home Office/Related Organization Contract Labor Costs

For freestanding and hospital-based IRFs, we proposed to calculate the home office/related organization contract labor costs using data reported on Worksheet S-3, part II, column 4, lines 1401, 1402, 2550, and 2551. Similar to the PLI costs, these costs are for the entire facility. Therefore, when we derive the cost weight for Home Office/Related Organization Contract Labor costs, we use the total facility medical care costs as the denominator (reflecting the total facility costs less the non-reimbursable costs reported on lines 190 through 201). Our assumption is that the same proportion of expenses are used among each unit of the hospital.

(8) Capital Costs

For freestanding IRFs, we proposed that capital costs would be equal to Medicare allowable capital costs as reported on Worksheet B, part II, column 26, lines 30 through 35, 50 through 76 (excluding 52 and 75), 90 through 91, and 93.

For hospital-based IRFs, we proposed that capital costs would be equal to IRF inpatient capital costs (as reported on Worksheet B, part II, column 26, line 41) and a portion of IRF ancillary capital costs. We calculate the portion of ancillary capital costs attributable to the hospital-based IRF for a given cost center by multiplying total facility ancillary capital costs for the specific ancillary cost center (as reported on Worksheet B, part II, column 26) by the IRF

ancillary ratio as described in section V.C.1.a.(1) of the proposed rule. For example, if hospital-based IRF Medicare physical therapy costs represent 30 percent of the total Medicare physical therapy costs for the entire facility, then 30 percent of total facility physical therapy capital costs (as reported in Worksheet B, part II, column 26, line 66) would be attributable to the hospital-based IRF.

b. Final Major Cost Category Computation

After we derive costs for each of the major cost categories and total Medicare allowable costs for each provider using the Medicare cost report data as previously described, we proposed to address data outliers using the following steps. First, for the Wages and Salaries, Employee Benefits, Contract Labor, Pharmaceuticals, and Capital cost weights, we first divide the costs for each of these five categories by total Medicare allowable costs calculated for the provider to obtain cost weights for the universe of IRF providers. We then proposed to trim the data to remove outliers (a standard statistical process) by: (1) requiring that major expenses (such as Wages and Salaries costs) and total Medicare allowable operating costs be greater than zero; and (2) excluding the top and bottom 5 percent of the major cost weight (for example, Wages and Salaries costs as a percent of total Medicare allowable operating costs). We note that missing values are assumed to be zero consistent with the methodology for how missing values were treated in the 2016-based IRF market basket. After these outliers have been excluded, we sum the costs for each category across all remaining providers. We then divide this by the sum of total Medicare allowable costs across all remaining providers to obtain a cost weight for the 2021-based IRF market basket for the given category.

The proposed trimming methodology for the Home Office/Related Organization Contract Labor and PLI cost weights is slightly different than the proposed trimming methodology for the other five cost categories as described previously in this final rule. For these cost weights, since we are using total facility medical care costs rather than Medicare allowable costs associated with IRF services, we proposed to trim the freestanding and hospital-based IRF cost weights

separately.

For the PLI cost weight, for each of the providers, we first divide the PLI costs by total facility medical care costs to obtain a PLI cost weight for the universe of IRF providers. We then proposed to trim the data to remove outliers by: (1) requiring that PLI costs are greater than zero and are less than total facility medical care costs; and (2) excluding the top and bottom 5 percent of the major cost weight trimming freestanding and hospital-based providers separately. After removing these outliers, we are left with a trimmed data set for both freestanding and hospital-based providers. We then proposed to separately sum the costs for each category (freestanding and hospital-based) across all remaining providers. We next divide this by the sum of total facility medical care costs across all remaining providers to obtain both a freestanding cost weight and hospital-based cost weight. Lastly, we proposed to weight these two cost weights together using the Medicare allowable costs from the sample of freestanding and hospital-based IRFs that passed the PLI trim (59 percent for hospital-based and 41 percent for freestanding IRFs) to derive a PLI cost weight for the 2021-based IRF market basket.

For the Home Office/Related Organization Contract Labor cost weight, for each of the providers, we first divide the home office/related organization contract labor costs by total facility medical care costs to obtain a Home Office/Related Organization Contract Labor cost weight for the universe of IRF providers. We then proposed to trim only the top 1 percent of providers to exclude outliers while also allowing providers who have reported zero home office costs to remain in the Home Office/Related Organization Contract Labor cost weight calculations as not all providers will incur home office/relation organization contract labor costs. After removing these outliers, we are left with a trimmed data set for both freestanding and hospital-based providers. We then proposed to separately sum the costs for each category (freestanding and hospital-based) across all remaining providers. We next divide this by the sum of total facility medical care costs across all remaining providers to obtain a freestanding cost weight and hospital-based cost weight. Lastly, we proposed to weight these two cost weights

together using the Medicare allowable costs from the sample of freestanding and hospital-based IRFs that passed the Home Office/Related Organization Contract Labor cost weight trim (68 percent for hospital-based and 32 percent for freestanding IRFs) to derive a Home Office/Related Organization Contract Labor cost weight for the 2021-based IRF market basket.

Finally, we proposed to calculate the residual “All Other” cost weight that reflects all remaining costs that are not captured in the seven cost categories listed. See Table 4 for the resulting cost weights for these major cost categories that we obtain from the Medicare cost reports.

TABLE 4: Major Cost Categories as Derived from Medicare Cost Reports

Major Cost Categories	2021-Based IRF Market Basket (Percent)	2016-Based IRF Market Basket (Percent)
Wages and Salaries	46.6	47.1
Employee Benefits	11.6	11.3
Contract Labor	2.0	1.0
Professional Liability Insurance (Malpractice)	0.8	0.7
Pharmaceuticals	4.7	5.1
Home Office/Related Organization Contract Labor	5.4	3.7
Capital	8.6	9.0
All Other	20.4	22.2

*Total may not sum to 100 due to rounding.

As we did for the 2016-based IRF market basket, we proposed to allocate the Contract Labor cost weight to the Wages and Salaries and Employee Benefits cost weights based on their relative proportions under the assumption that contract labor costs are comprised of both wages and salaries and employee benefits. The Contract Labor allocation proportion for Wages and Salaries is equal to the Wages and Salaries cost weight as a percent of the sum of the Wages and Salaries cost weight and the Employee Benefits cost weight. For the proposed rule, the rounded percentage is 80 percent; therefore, we proposed to allocate 80 percent of the Contract Labor cost weight to the Wages and Salaries cost weight and 20 percent to the Employee Benefits cost weight. This allocation was 81/19 in the 2016-based IRF market basket (84 FR 39076). Table 5 shows the Wages and Salaries and Employee Benefit cost weights after Contract Labor cost weight allocation for both the 2021-based IRF market basket and 2016-based IRF market basket.

TABLE 5: Wages and Salaries and Employee Benefits Cost Weights After Contract Labor Allocation

Major Cost Categories	2021-Based IRF Market Basket	2016-Based IRF Market Basket
Wages and Salaries	48.2	47.9
Employee Benefits	11.9	11.4

The following is a summary of the public comments received on our proposed methodology for developing the major cost weights of the 2021-based IRF market basket and our responses.

Comment: A few commenters noted that their review of the market basket cost categories shows only modest increases, including with respect to labor and capital-related costs, despite their members experiencing much more significant actual increases in expenditures compared to 2016. One commenter requested that CMS consider increases in wages, salaries, benefits, and contract labor, among other categories, in its methodology.

One commenter supported the increase in proposed weights given the sustained labor increases and market challenges. However, the commenter stated that labor and supplies are significant stressors and requested CMS review pharmaceuticals and capital-related costs more closely before the final rule. The commenter stated that while they recognize that not all categories can increase, these components have all contributed to financial strain on the industry and stated that a decrease in their cost weights in the market basket does not reflect their current contribution to overall costs.

Response: As discussed previously, the major cost weights calculated from the Medicare cost reports for the 2021-based IRF market basket represent each cost category's share of total costs. Therefore, any changes in the cost weight from a prior base period will reflect the growth in the costs for that specific category relative to the growth in the costs for other categories. As a result, while costs for a particular category may have increased from 2016 to 2021 (such as capital-related costs as stated by the commenters), the Capital-Related cost weight would only increase if capital-related costs increased faster than the increase in total costs from 2016 to

2021. In response to the commenters' request that CMS consider increases in wages, salaries, benefits, and contract labor, among other categories, in its methodology, we believe that the proposed methodology to derive the major cost categories is detailed and robust. To allow for interested parties to evaluate this methodology, we have provided all of the detailed calculations and Medicare cost report fields so that commenters are able to replicate the methodology and provide specific comments on the derivation of these cost weights. We will continue to monitor the Medicare cost reports as new data becomes available for all of the major cost weights, including the categories mentioned by the commenter, and any changes to the IRF market basket will be proposed in future rulemaking.

We appreciate the commenter's request to review the pharmaceuticals and capital-related costs used in the proposed 2021-based IRF market basket more closely. We note that each of the cost weights in the market basket reflect a distribution and will change over time only when costs grow differently (either higher or lower) than other costs. The Pharmaceuticals cost weight in the 2021-based IRF market basket is 4.7 percent compared to the 2016-based IRF market basket with 5.1 percent. We examined the Medicare cost report data in more detail and found that the Pharmaceuticals cost weight decreased, in aggregate, for both urban and rural IRFs, government and for-profit IRFs, and for freestanding and hospital-based IRFs. The median Pharmaceuticals cost weight also decreased from 5.0 percent to 4.4 percent. Therefore, we believe that the proposed Pharmaceuticals cost weight is appropriate and reflects its share of overall costs.

The Capital-Related cost weight in the 2021-based IRF market basket is 8.6 percent compared to the 2016-based IRF market basket with 9.0 percent. We examined the Medicare cost report data in more detail and found that the Capital-Related cost weight decreased, in aggregate, for both urban and rural IRFs and for all ownership-types. The median Capital-Related cost weight also decreased from 8.8 percent to 8.1 percent. We note that both pharmaceuticals and capital-related costs per day increased from 2016 to 2021; however, they increased at a slower rate than total Medicare allowable costs per day (which is the denominator

in the cost weight calculation) resulting in slightly lower cost weights in 2021 compared to 2016. Therefore, we believe that the proposed Capital-Related cost weight is appropriate and reflects its share of overall costs.

Comment: A few commenters requested that CMS educate interested parties on the importance of reporting accurate and robust data on the Medicare cost reports. One commenter recognized that CMS is relying on the Medicare cost report data for the market basket cost weights, but noted that such data may not always be adequately recorded or prioritized for input. One commenter specifically noted that not all IRFs are properly reporting data for Employee Benefits and Contract Labor on the Medicare cost reports. The commenter stated that while all of their hospitals have reported these cost report line items, they urged CMS to emphasize their importance to ensure that the IRF sector understands the importance of accurately and fully reporting these line items to reduce data gaps for future updates.

Response: We recognize the commenters' concerns and reiterate that accurate and complete reporting of all data on the Medicare cost reports by IRFs help to ensure that the cost weights for the IRF market basket are reflective of the cost structure of IRFs. We also note that we analyze the Medicare cost report data to evaluate their representativeness; for example, we reweight the data reported by ownership type and urban/rural so that it reflects the universe of providers and compare it to the proposed cost weights that are based on reported data. Our analysis shows the proposed cost weights are representative across these dimensions. In addition, we also trim the data to eliminate outliers as described in section VI.C.1.b. of this final rule. As stated in the FY 2024 IRF PPS proposed rule (88 FR 20961) and previous IRF PPS rules, we continue to encourage all providers to report the Employee Benefits and Contract Labor data on the Medicare cost report. Going forward, we will continue to work with interested parties to communicate the importance of all providers filling out the Medicare cost report with accurate and complete data.

After consideration of the public comments, we are finalizing our methodology for

developing the major cost weights and therefore, we are finalizing these major cost weights as proposed.

c. Derivation of the Detailed Operating Cost Weights

To further divide the “All Other” residual cost weight estimated from the 2021 Medicare cost report data into more detailed cost categories, we proposed to use the 2012 Benchmark Input-Output (I-O) “Use Tables/Before Redefinitions/Purchaser Value” for North American Industry Classification System (NAICS) 622000, Hospitals, published by the Bureau of Economic Analysis (BEA). This data is publicly available at http://www.bea.gov/industry/io_annual.htm. For the 2016-based IRF market basket, we also used the 2012 Benchmark I-O data, the most recent data available at the time (84 FR 39076).

The BEA Benchmark I–O data are scheduled for publication every 5 years with the most recent data available for 2012. The 2012 Benchmark I–O data are derived from the 2012 Economic Census and are the building blocks for BEA’s economic accounts. Thus, they represent the most comprehensive and complete set of data on the economic processes or mechanisms by which output is produced and distributed.¹⁶ BEA also produces Annual I–O estimates; however, while based on a similar methodology, these estimates reflect less comprehensive and less detailed data sources and are subject to revision when benchmark data becomes available. Instead of using the less detailed Annual I–O data, we proposed to inflate the 2012 Benchmark I–O data forward to 2021 by applying the annual price changes from the respective price proxies to the appropriate market basket cost categories that are obtained from the 2012 Benchmark I–O data. We repeat this practice for each year. We then proposed to calculate the cost shares that each cost category represents of the inflated 2012 data. These resulting 2021 cost shares are applied to the All Other residual cost weight to obtain the detailed cost weights for the 2021-based IRF market basket. For example, the cost for Food: Direct Purchases represents 5.0 percent of the sum of the “All Other” 2012 Benchmark I–O Hospital

¹⁶ http://www.bea.gov/papers/pdf/IOmanual_092906.pdf.

Expenditures inflated to 2021; therefore, the Food: Direct Purchases cost weight represents 5.0 percent of the 2021-based IRF market basket's "All Other" cost category (20.4 percent), yielding a "final" Food: Direct Purchases cost weight of 1.0 percent in the 2021-based IRF market basket ($0.05 * 20.4 \text{ percent} = 1.0 \text{ percent}$).

Using this methodology, we proposed to derive seventeen detailed IRF market basket cost category weights from the 2021-based IRF market basket residual cost weight (20.4 percent). These categories are: (1) Electricity and Other Non-Fuel Utilities, (2) Fuel: Oil and Gas (3) Food: Direct Purchases, (4) Food: Contract Services, (5) Chemicals, (6) Medical Instruments, (7) Rubber and Plastics, (8) Paper and Printing Products, (9) Miscellaneous Products, (10) Professional Fees: Labor-Related, (11) Administrative and Facilities Support Services, (12) Installation, Maintenance, and Repair Services, (13) All Other Labor-Related Services, (14) Professional Fees: Nonlabor-Related, (15) Financial Services, (16) Telephone Services, and (17) All Other Nonlabor-Related Services.

We did not receive any comments on our methodology to use the BEA I-O data to derive the detailed operating cost weights. We are finalizing this methodology as we proposed. We note that we did receive one comment on the derivation of the Professional Fees: Labor-Related cost weight which we discuss in section VI.E. of this final rule.

d. Derivation of the Detailed Capital Cost Weights

As described in section V.C.1.b. of the proposed rule, we proposed a Capital-Related cost weight of 8.6 percent as obtained from the 2021 Medicare cost reports for freestanding and hospital-based IRF providers. We proposed to then separate this total Capital-Related cost weight into more detailed cost categories.

Using 2021 Medicare cost reports, we are able to group Capital-Related costs into the following categories: Depreciation, Interest, Lease, and Other Capital-Related costs. For each of these categories, we proposed to determine separately for hospital-based IRFs and freestanding IRFs what proportion of total capital-related costs the category represents.

For freestanding IRFs, using Medicare cost report data on Worksheet A-7 part III, we proposed to derive the proportions for Depreciation (column 9), Interest (column 11), Lease (column 10), and Other Capital-Related costs (column 12 through 14), which is similar to the methodology used for the 2016-based IRF market basket.

For hospital-based IRFs, data for these four categories are not reported separately for the hospital-based IRF; therefore, we proposed to derive these proportions using data reported on Worksheet A-7 for the total facility. We assumed the cost shares for the overall hospital are representative for the hospital-based IRF unit. For example, if depreciation costs make up 60 percent of total capital costs for the entire facility, we believe it is reasonable to assume that the hospital-based IRF would also have a 60 percent proportion because it is a unit contained within the total facility. This is the same methodology used for the 2016-based IRF market basket (84 FR 39077).

To combine each detailed capital cost weight for freestanding and hospital-based IRFs into a single capital cost weight for the 2021-based IRF market basket, we proposed to weight together the shares for each of the categories (Depreciation, Interest, Lease, and Other Capital-Related costs) based on the share of total capital costs each provider type represents of the total capital costs for all IRFs for 2021. Applying this methodology results in proportions of total capital-related costs for Depreciation, Interest, Lease and Other Capital-Related costs that are representative of the universe of IRF providers. This is the same methodology used for the 2016-based IRF market basket (84 FR 39077).

Lease costs are unique in that they are not broken out as a separate cost category in the 2021-based IRF market basket. Rather, we proposed to proportionally distribute these costs among the cost categories of Depreciation, Interest, and Other Capital-Related costs, reflecting the assumption that the underlying cost structure of leases is similar to that of capital-related costs in general. As was done under the 2016-based IRF market basket, we proposed to assume that 10 percent of the lease costs as a proportion of total capital-related costs represents overhead

and assign those costs to the Other Capital-Related cost category accordingly. We proposed to distribute the remaining lease costs proportionally across the three cost categories (Depreciation, Interest, and Other Capital-Related) based on the proportion that these categories comprise of the sum of the Depreciation, Interest, and Other Capital-Related cost categories (excluding lease expenses). This would result in three primary capital-related cost categories in the 2021-based IRF market basket: Depreciation, Interest, and Other Capital-Related costs. This is the same methodology used for the 2016-based IRF market basket (84 FR 39077). The allocation of these lease expenses is shown in Table 6.

Finally, we proposed to further divide the Depreciation and Interest cost categories. We proposed to separate Depreciation into the following two categories: (1) Building and Fixed Equipment and (2) Movable Equipment. We proposed to separate Interest into the following two categories: (1) Government/Nonprofit and (2) For-profit.

To disaggregate the Depreciation cost weight, we need to determine the percent of total Depreciation costs for IRFs that is attributable to Building and Fixed Equipment, which we hereafter refer to as the “fixed percentage.” For the 2021-based IRF market basket, we proposed to use slightly different methods to obtain the fixed percentages for hospital-based IRFs compared to freestanding IRFs.

For freestanding IRFs, we proposed to use depreciation data from Worksheet A-7 of the 2021 Medicare cost reports. However, for hospital-based IRFs, we determined that the fixed percentage for the entire facility may not be representative of the hospital-based IRF unit due to the entire facility likely employing more sophisticated movable assets that are not utilized by the hospital-based IRF. Therefore, for hospital-based IRFs, we proposed to calculate a fixed percentage using: (1) building and fixture capital costs allocated to the hospital-based IRF unit as reported on Worksheet B, part I, column 1, line 41, and (2) building and fixture capital costs for the top five ancillary cost centers utilized by hospital-based IRFs accounting for 78 percent of hospital-based IRF ancillary total costs: Physical Therapy (Worksheet B, part I, column 1, line

66), Drugs Charged to Patients (Worksheet B, part I, column 1, line 73), Occupational Therapy (Worksheet B, part I, column 1, line 67), Laboratory (Worksheet B, part I, column 1, line 60) and Clinic (Worksheet B, part I, column 1, line 90). We proposed to weight these two fixed percentages (inpatient and ancillary) using the proportion that each capital cost type represents of total capital costs in the 2021-based IRF market basket. We proposed to then weight the fixed percentages for hospital-based and freestanding IRFs together using the proportion of total capital costs each provider type represents. For both freestanding and hospital-based IRFs, this is the same methodology used for the 2016-based IRF market basket (84 FR 39077).

To disaggregate the Interest cost weight, we determined the percent of total interest costs for IRFs that are attributable to government and nonprofit facilities, which is hereafter referred to as the “nonprofit percentage,” as price pressures associated with these types of interest costs tend to differ from those for for-profit facilities. For the 2021-based IRF market basket, we proposed to use interest costs data from Worksheet A-7 of the 2021 Medicare cost reports for both freestanding and hospital-based IRFs. We proposed to determine the percent of total interest costs that are attributed to government and nonprofit IRFs separately for hospital-based and freestanding IRFs. We then proposed to weight the nonprofit percentages for hospital-based and freestanding IRFs together using the proportion of total capital costs that each provider type represents.

Table 6 provides the detailed capital cost share composition estimated from the 2021 IRF Medicare cost reports. These detailed capital cost share composition percentages are applied to the total Capital-Related cost weight of 8.6 percent calculated using the methodology described in section V.C.1.a.(8) of the proposed rule.

TABLE 6: Capital Cost Share Composition for the 2021-based IRF Market Basket

	Capital Cost Share Composition before Lease Expense Allocation	Capital Cost Share Composition after Lease Expense Allocation
Depreciation	48%	70%
Building and Fixed Equipment	30%	44%
Movable Equipment	18%	26%
Interest	10%	14%
Government/Nonprofit	5%	7%
For Profit	5%	7%
Lease	34%	-
Other Capital-Related Costs	8%	16%

*Detail may not add to total due to rounding.

We did not receive any comments on our proposed methodology for developing the detailed capital cost weights of the 2021-based IRF market basket. We are finalizing these detailed capital cost weights as proposed.

e. 2021-based IRF Market Basket Cost Categories and Weights

Table 7 compares the cost categories and weights for the 2021-based IRF market basket compared to the 2016-based IRF market basket.

TABLE 7: 2021-based IRF Market Basket Cost Weights Compared to 2016-based IRF Market Basket Cost Weights

Cost Category	2021-based IRF Market Basket Cost Weight	2016-based IRF Market Basket Cost Weight
Total	100.0	100.0
Compensation	60.1	59.4
Wages and Salaries	48.2	47.9
Employee Benefits	11.9	11.4
Utilities	1.4	1.4
Electricity and Other Non-Fuel Utilities	0.9	1.0
Fuel: Oil and Gas	0.5	0.4
Professional Liability Insurance	0.8	0.7
All Other Products and Services	29.1	29.5
All Other Products	11.4	12.5
Pharmaceuticals	4.7	5.1
Food: Direct Purchases	1.0	1.1
Food: Contract Services	1.2	1.2
Chemicals	0.4	0.4
Medical Instruments	2.5	2.9
Rubber and Plastics	0.4	0.4
Paper and Printing Products	0.6	0.6
Miscellaneous Products	0.8	0.8
All Other Services	17.7	17.0
Labor-Related Services	9.5	9.2
Professional Fees: Labor-Related	5.6	5.0
Administrative and Facilities Support Services	0.7	0.7
Installation, Maintenance, and Repair Services	1.5	1.6
All Other: Labor-Related Services	1.7	1.8
Nonlabor-Related Services	8.2	7.9
Professional Fees: Nonlabor-Related	5.9	5.4
Financial Services	0.9	0.9
Telephone Services	0.3	0.3
All Other: Nonlabor-Related Services	1.1	1.3
Capital-Related Costs	8.6	9.0
Depreciation	6.0	6.5
Building and Fixed Equipment	3.8	4.1
Movable Equipment	2.3	2.5
Interest Costs	1.2	1.5
Government/Nonprofit	0.6	0.9
For Profit	0.6	0.6
Other Capital-Related Costs	1.3	1.0

*Detail may not add to total due to rounding.

2. Selection of Price Proxies

After developing the cost weights for the 2021-based IRF market basket, we proposed to select the most appropriate wage and price proxies currently available to represent the rate of price change for each expenditure category. For the majority of the cost weights, we base the

price proxies on U.S. Bureau of Labor Statistics (BLS) data and group them into one of the following BLS categories:

- *Employment Cost Indexes.* Employment Cost Indexes (ECIs) measure the rate of change in employment wage rates and employer costs for employee benefits per hour worked. These indexes are fixed-weight indexes and strictly measure the change in wage rates and employee benefits per hour. ECIs are superior to Average Hourly Earnings (AHE) as price proxies for input price indexes because they are not affected by shifts in occupation or industry mix, and because they measure pure price change and are available by both occupational group and by industry. The industry ECIs are based on the NAICS and the occupational ECIs are based on the Standard Occupational Classification System (SOC).

- *Producer Price Indexes.* Producer Price Indexes (PPIs) measure the average change over time in the selling prices received by domestic producers for their output. The prices included in the PPI are from the first commercial transaction for many products and some services (<https://www.bls.gov/ppi/>).

- *Consumer Price Indexes.* Consumer Price Indexes (CPIs) measure the average change over time in the prices paid by urban consumers for a market basket of consumer goods and services (<https://www.bls.gov/cpi/>). CPIs are only used when the purchases are similar to those of retail consumers rather than purchases at the producer level, or if no appropriate PPIs are available.

We evaluated the price proxies using the criteria of reliability, timeliness, availability, and relevance:

- *Reliability.* Reliability indicates that the index is based on valid statistical methods and has low sampling variability. Widely accepted statistical methods ensure that the data were collected and aggregated in a way that can be replicated. Low sampling variability is desirable because it indicates that the sample reflects the typical members of the population. (Sampling variability is variation that occurs by chance because only a sample was surveyed rather than the

entire population.)

- *Timeliness.* Timeliness implies that the proxy is published regularly, preferably at least once a quarter. The market baskets are updated quarterly, and therefore, it is important for the underlying price proxies to be up-to-date, reflecting the most recent data available. We believe that using proxies that are published regularly (at least quarterly, whenever possible) helps to ensure that we are using the most recent data available to update the market basket. We strive to use publications that are disseminated frequently, because we believe that this is an optimal way to stay abreast of the most current data available.

- *Availability.* Availability means that the proxy is publicly available. We prefer that our proxies are publicly available because this will help ensure that our market basket updates are as transparent to the public as possible. In addition, this enables the public to be able to obtain the price proxy data on a regular basis.

- *Relevance.* Relevance means that the proxy is applicable and representative of the cost category weight to which it is applied. The CPIs, PPIs, and ECIs that we have selected to propose in this regulation meet these criteria. Therefore, we believe that they continue to be the best measure of price changes for the cost categories to which they would be applied.

Below is a detailed explanation of the price proxies we proposed for each cost category weight.

a. Price Proxies for the Operating Portion of the 2021-Based IRF Market Basket

(1) Wages and Salaries

We proposed to continue to use the ECI for Wages and Salaries for All Civilian workers in Hospitals (BLS series code CIU10262200000001) to measure the wage rate growth of this cost category. This is the same price proxy used in the 2016-based IRF market basket (84 FR 39080).

(2) Benefits

We proposed to continue to use the ECI for Total Benefits for All Civilian workers in Hospitals to measure price growth of this category. This ECI is calculated using the ECI for

Total Compensation for All Civilian workers in Hospitals (BLS series code CIU1016220000000I) and the relative importance of wages and salaries within total compensation. This is the same price proxy used in the 2016-based IRF market basket (84 FR 39080).

(3) Electricity and Other Non-Fuel Utilities

We proposed to continue to use the PPI Commodity Index for Commercial Electric Power (BLS series code WPU0542) to measure the price growth of this cost category (which we proposed to rename from Electricity to Electricity and Other Non-Fuel Utilities). This is the same price proxy used in the 2016-based IRF market basket (84 FR 39080).

(4) Fuel: Oil and Gas

Similar to the 2016-based IRF market basket, for the 2021-based IRF market basket, we proposed to use a blend of the PPI for Petroleum Refineries and the PPI Commodity for Natural Gas. Our analysis of the Bureau of Economic Analysis' 2012 Benchmark Input-Output data (use table before redefinitions, purchaser's value for NAICS 622000 [Hospitals]), shows that Petroleum Refineries expenses account for approximately 90 percent and Natural Gas expenses account for approximately 10 percent of Hospitals' (NAICS 622000) total Fuel: Oil and Gas expenses. Therefore, we proposed to use a blend of 90 percent of the PPI for Petroleum Refineries (BLS series code PCU324110324110) and 10 percent of the PPI Commodity Index for Natural Gas (BLS series code WPU0531) as the price proxy for this cost category. This is the same blend that was used for the 2016-based IRF market basket (84 FR 39080).

(5) Professional Liability Insurance

We proposed to continue to use the CMS Hospital Professional Liability Index to measure changes in PLI premiums. To generate this index, we collect commercial insurance premiums for a fixed level of coverage while holding non-price factors constant (such as a change in the level of coverage). This is the same proxy used in the 2016-based IRF market basket (84 FR 39080).

(6) Pharmaceuticals

We proposed to continue to use the PPI for Pharmaceuticals for Human Use, Prescription (BLS series code WPUSI07003) to measure the price growth of this cost category. This is the same proxy used in the 2016-based IRF market basket (84 FR 39080).

(7) Food: Direct Purchases

We proposed to continue to use the PPI for Processed Foods and Feeds (BLS series code WPU02) to measure the price growth of this cost category. This is the same proxy used in the 2016-based IRF market basket (84 FR 39080).

(8) Food: Contract Purchases

We proposed to continue to use the CPI for Food Away From Home (BLS series code CUUR0000SEFV) to measure the price growth of this cost category. This is the same proxy used in the 2016-based IRF market basket (84 FR 39080).

(9) Chemicals

Similar to the 2016-based IRF market basket, we proposed to use a four-part blended PPI as the proxy for the chemical cost category in the 2021-based IRF market basket. The blend is composed of the PPI for Industrial Gas Manufacturing, Primary Products (BLS series code PCU325120325120P), the PPI for Other Basic Inorganic Chemical Manufacturing (BLS series code PCU32518-32518-), the PPI for Other Basic Organic Chemical Manufacturing (BLS series code PCU32519-32519-), and the PPI for Other Miscellaneous Chemical Product Manufacturing (BLS series code PCU325998325998). For the 2021-based IRF market basket, we proposed to derive the weights for the PPIs using the 2012 Benchmark I-O data.

Table 8 shows the weights for each of the four PPIs used to create the blended Chemical proxy for the 2021 IRF market basket. This is the same blend that was used for the 2016-based IRF market basket (84 FR 39080).

TABLE 8: Blended Chemical PPI Weights

Name	2021-based IRF Weights	NAICS
PPI for Industrial Gas Manufacturing	19%	325120
PPI for Other Basic Inorganic Chemical Manufacturing	13%	325180
PPI for Other Basic Organic Chemical Manufacturing	60%	325190
PPI for Other Miscellaneous Chemical Product Manufacturing	8%	325998

(10) Medical Instruments

We proposed to use a blended price proxy for the Medical Instruments category, as shown in Table 9. The 2012 Benchmark I–O data shows the majority of medical instruments and supply costs are for NAICS 339112—Surgical and medical instrument manufacturing costs (approximately 56 percent) and NAICS 339113—Surgical appliance and supplies manufacturing costs (approximately 43 percent). Therefore, we proposed to use a blend of these two price proxies. To proxy the price changes associated with NAICS 339112, we proposed using the PPI for Surgical and medical instruments (BLS series code WPU1562). This is the same price proxy we used in the 2016-based IRF market basket. To proxy the price changes associated with NAICS 339113, we proposed to use a 50/50 blend of the PPI for Medical and surgical appliances and supplies (BLS series code WPU1563) and the PPI for Miscellaneous products, Personal safety equipment and clothing (BLS series code WPU1571). We proposed to include the latter price proxy as it would reflect personal protective equipment including but not limited to face shields and protective clothing. The 2012 Benchmark I–O data does not provide specific expenses for these products; however, we recognize that this category reflects costs faced by IRFs.

TABLE 9: Blended Medical Instruments PPI Weights

Name	2021-based IRF Weights	NAICS
PPI - Commodity - Surgical and medical instruments	56%	339112
PPI - Commodity - Medical and surgical appliances and supplies	22%	339113
PPI - Commodity - Miscellaneous products-Personal safety equipment and clothing	22%	

(11) Rubber and Plastics

We proposed to continue to use the PPI for Rubber and Plastic Products (BLS series code WPU07) to measure price growth of this cost category. This is the same proxy used in the 2016-based IRF market basket (84 FR 39081).

(12) Paper and Printing Products

We proposed to continue to use the PPI for Converted Paper and Paperboard Products (BLS series code WPU0915) to measure the price growth of this cost category. This is the same proxy used in the 2016-based IRF market basket (84 FR 39081).

(13) Miscellaneous Products

We proposed to continue to use the PPI for Finished Goods Less Food and Energy (BLS series code WPUFD4131) to measure the price growth of this cost category. This is the same proxy used in the 2016-based IRF market basket (84 FR 39081).

(14) Professional Fees: Labor-Related

We proposed to continue to use the ECI for Total Compensation for Private Industry workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same proxy used in the 2016-based IRF market basket (84 FR 39081).

(15) Administrative and Facilities Support Services

We proposed to continue to use the ECI for Total Compensation for Private Industry workers in Office and Administrative Support (BLS series code CIU2010000220000I) to measure the price growth of this category. This is the same proxy used in the 2016-based IRF market basket (84 FR 39081).

(16) Installation, Maintenance, and Repair Services

We proposed to continue to use the ECI for Total Compensation for Civilian workers in Installation, Maintenance, and Repair (BLS series code CIU1010000430000I) to measure the price growth of this cost category. This is the same proxy used in the 2016-based IRF market basket (84 FR 39081).

(17) All Other: Labor-Related Services

We proposed to continue to use the ECI for Total Compensation for Private Industry workers in Service Occupations (BLS series code CIU2010000300000I) to measure the price growth of this cost category. This is the same proxy used in the 2016-based IRF market basket (84 FR 39081).

(18) Professional Fees: Nonlabor-Related

We proposed to continue to use the ECI for Total Compensation for Private Industry workers in Professional and Related (BLS series code CIU2010000120000I) to measure the price growth of this category. This is the same proxy used in the 2016-based IRF market basket (84 FR 39081).

(19) Financial Services

We proposed to continue to use the ECI for Total Compensation for Private Industry workers in Financial Activities (BLS series code CIU201520A000000I) to measure the price growth of this cost category. This is the same proxy used in the 2016-based IRF market basket (84 FR 39081).

(20) Telephone Services

We proposed to continue to use the CPI for Telephone Services (BLS series code CUUR0000SEED) to measure the price growth of this cost category. This is the same proxy used in the 2016-based IRF market basket (84 FR 39081).

(21) All Other: Nonlabor-Related Services

We proposed to continue to use the CPI for All Items Less Food and Energy (BLS series code CUUR0000SA0L1E) to measure the price growth of this cost category. This is the same proxy used in the 2016-based IRF market basket (84 FR 39081).

The following is a summary of the public comments received on our proposed price proxies for the operating portion of the 2021-based IRF market basket and our responses.

Comment: A few commenters expressed concern that CMS's use of the IHS Global Inc.

(IGI) forecast for determining the market basket update does not capture the specialized nature of IRF costs. The commenters stated that IGI's general forecasts for hospital goods and services likely are not accounting for the fact that IRFs are providing more specialized services compared to other hospital settings such as specialized staff, equipment, and drugs.

Response: As described previously, the IRF market basket measures price changes (including changes in the prices for wages and salaries) over time and would not reflect increases in costs associated with changes in the volume or intensity of input goods and services until the market basket is rebased. In this final rule, we are rebasing and revising the current 2016-based IRF market basket to reflect a 2021 base year. As stated previously, we believe the 2021-based IRF market basket appropriately reflects IRF cost structures. To reflect expected price growth for each of the cost categories in the IRF market basket, we rely on impartial economic forecasts of the price proxies used in the market basket from IGI; as previously discussed, we use the best available price proxies that would measure expected price growth of the goods and services purchased by IRFs. We have consistently used the IGI economic price proxy forecasts in the market baskets used to update the IRF PPS payments since the implementation of the IRF PPS. For example, to measure price growth for IRF wages and salaries costs in the IRF market basket, since IRF-specific information is unavailable, we proposed to use the ECI for Wages and Salaries for All Civilian workers in Hospitals. We believe that this ECI is the best available price proxy to account for the occupational skill mix within IRFs. We note that we reviewed the Bureau of Labor Statistics Occupational Employment and Wage Statistics (OEWS) data for NAICS 622100 (General Medical and Surgical Hospitals) -- one of the primary data sources used to derive the weights for the ECI for Wages and Salaries for All Civilian workers in Hospitals -- and found that in 2021, the updated base year of the IRF market basket, approximately 56 percent of total estimated salaries (total employment multiplied by mean annual wage) for NAICS 622100 was attributed to Health Professional and Technical occupations, and approximately 20 percent was attributed to Health Service occupations.

Therefore, in the absence of an IRF-specific ECI, we believe that the highly skilled hospital workforce captured by the ECI for Wages and Salaries for All Civilian workers in Hospitals (inclusive of therapists, nurses, other clinicians, etc.) is a reasonable proxy for the compensation component of the IRF market basket. We would welcome any publicly available IRF-specific data that the commenters could provide regarding wage, benefits, or supplies prices.

Comment: One commenter encouraged CMS to explore other changes to the composition of the market basket to better capture evolving dynamics in the labor force. The commenter provided as an example that the ECI may no longer accurately capture the changing composition and cost structure of the hospital labor market given the large increases in short-term contract labor use and its growing costs.

Response: The purpose of the market basket is to measure the average change in the price of goods and services hospitals purchase in order to provide IRF medical services. We believe the ECI is an appropriate index to measure the price changes for Compensation costs as it holds occupational distribution constant. We note that the 2021-based IRF market basket cost weights show that contract labor costs account for about 3 percent of total compensation costs (reflecting employed and contract labor staff) for IRFs in 2021. In addition, an analysis of Medicare cost report data for IPPS hospitals shows that contract labor hours accounted for about 4 percent of total compensation hours (reflecting employed and contract labor staff) in 2021. Therefore, while we acknowledge that the ECI measures only reflect price changes for employed staff, we believe that the ECI for hospital workers is accurately reflecting the price change associated with the labor used to provide hospital care (as employed workers' hours account for 97 percent of hospital compensation hours). We will continue to monitor the trends in the ECI as well as the increased use of contract labor as a result of the PHE. We welcome any additional publicly available data that commenters can provide regarding alternative price indexes.

After consideration of the public comments, we are finalizing the price proxies for the operating portion of the 2021-based IRF market basket as proposed.

Table 11 lists all price proxies that we are finalizing for the 2021-based IRF market basket.

b. Price Proxies for the Capital Portion of the 2021-Based IRF Market Basket

(1) Capital Price Proxies Prior to Vintage Weighting

We proposed to continue to use the same price proxies for the capital-related cost categories in the 2021-based IRF market basket as were used in the 2016-based IRF market basket, which are provided in Table 11 and described below. Specifically, we proposed to proxy:

- Depreciation: Building and Fixed Equipment cost category by BEA's Chained Price Index for Nonresidential Construction for Hospitals and Special Care Facilities (BEA Table 5.4.4. Price Indexes for Private Fixed Investment in Structures by Type).

- Depreciation: Movable Equipment cost category by the PPI for Machinery and Equipment (BLS series code WPU11).

- Nonprofit Interest cost category by the average yield on domestic municipal bonds (Bond Buyer 20-bond index).

- For-profit Interest cost category by the iBoxx AAA Corporate Bond Yield index

- Other Capital-Related cost category by the CPI-U for Rent of Primary Residence (BLS series code CUUS0000SEHA).

We believe these are the most appropriate proxies for IRF capital-related costs that meet our selection criteria of relevance, timeliness, availability, and reliability. We also proposed to continue to vintage weight the capital price proxies for Depreciation and Interest to capture the long-term consumption of capital. This vintage weighting method is similar to the method used for the 2016-based IRF market basket (84 FR 39082) and is described below.

(2) Vintage Weights for Price Proxies

Because capital is acquired and paid for over time, capital-related expenses in any given year are determined by both past and present purchases of physical and financial capital. The

vintage-weighted capital-related portion of the 2021-based IRF market basket is intended to capture the long-term consumption of capital, using vintage weights for depreciation (physical capital) and interest (financial capital). These vintage weights reflect the proportion of capital-related purchases attributable to each year of the expected life of building and fixed equipment, movable equipment, and interest. We proposed to use vintage weights to compute vintage-weighted price changes associated with depreciation and interest expenses.

Capital-related costs are inherently complicated and are determined by complex capital-related purchasing decisions, over time, based on such factors as interest rates and debt financing. In addition, capital is depreciated over time instead of being consumed in the same period it is purchased. By accounting for the vintage nature of capital, we are able to provide an accurate and stable annual measure of price changes. Annual non-vintage price changes for capital are unstable due to the volatility of interest rate changes, and therefore, do not reflect the actual annual price changes for IRF capital-related costs. The capital-related component of the 2021-based IRF market basket reflects the underlying stability of the capital-related acquisition process.

The methodology used to calculate the vintage weights for the 2021-based IRF market basket is the same as that used for the 2016-based IRF market basket (84 FR 39082 through 39083) with the only difference being the inclusion of more recent data. To calculate the vintage weights for depreciation and interest expenses, we first need a time series of capital-related purchases for building and fixed equipment and movable equipment. We found no single source that provides an appropriate time series of capital-related purchases by hospitals for all of the above components of capital purchases. The early Medicare cost reports did not have sufficient capital-related data to meet this need. Data we obtained from the American Hospital Association (AHA) do not include annual capital-related purchases. However, we are able to obtain data on total expenses back to 1963 from the AHA. Consequently, we proposed to use data from the AHA Panel Survey and the AHA Annual Survey to obtain a time series of total expenses for

hospitals. We then proposed to use data from the AHA Panel Survey supplemented with the ratio of depreciation to total hospital expenses obtained from the Medicare cost reports to derive a trend of annual depreciation expenses for 1963 through 2020, which is the latest year of AHA data available. We proposed to separate these depreciation expenses into annual amounts of building and fixed equipment depreciation and movable equipment depreciation as determined earlier. From these annual depreciation amounts, we derive annual end-of-year book values for building and fixed equipment and movable equipment using the expected life for each type of asset category. While data is not available that is specific to IRFs, we believe this information for all hospitals serves as a reasonable alternative for the pattern of depreciation for IRFs.

To continue to calculate the vintage weights for depreciation and interest expenses, we also need to account for the expected lives for Building and Fixed Equipment, Movable Equipment, and Interest for the 2021-based IRF market basket. We proposed to calculate the expected lives using Medicare cost report data from Worksheet A-7 part III for freestanding and hospital-based IRFs. The expected life of any asset can be determined by dividing the value of the asset (excluding fully depreciated assets) by its current year depreciation amount. This calculation yields the estimated expected life of an asset if the rates of depreciation were to continue at current year levels, assuming straight-line depreciation. We proposed to determine the expected life of building and fixed equipment separately for hospital-based IRFs and freestanding IRFs, and then weight these expected lives using the percent of total capital costs each provider type represents. We proposed to apply a similar method for movable equipment. Using these methods, we determined the average expected life of building and fixed equipment to be equal to 25 years, and the average expected life of movable equipment to be equal to 12 years. For the expected life of interest, we believe vintage weights for interest should represent the average expected life of building and fixed equipment because, based on previous research described in the FY 1997 IPPS final rule (61 FR 46198), the expected life of hospital debt instruments and the expected life of buildings and fixed equipment are similar. We note

that for the 2016-based IRF market basket, the expected life of building and fixed equipment is 22 years, and the expected life of movable equipment is 11 years (84 FR 39082) using the 2016 Medicare cost report data for freestanding and hospital-based IRFs.

Multiplying these expected lives by the annual depreciation amounts results in annual year-end asset costs for building and fixed equipment and movable equipment. We then calculate a time series, beginning in 1964, of annual capital purchases by subtracting the previous year's asset costs from the current year's asset costs.

For the building and fixed equipment and movable equipment vintage weights, we proposed to use the real annual capital-related purchase amounts for each asset type to capture the actual amount of the physical acquisition, net of the effect of price inflation. These real annual capital-related purchase amounts are produced by deflating the nominal annual purchase amount by the associated price proxy as provided earlier in the proposed rule. For the interest vintage weights, we proposed to use the total nominal annual capital-related purchase amounts to capture the value of the debt instrument (including, but not limited to, mortgages and bonds). Using these capital-related purchase time series specific to each asset type, we proposed to calculate the vintage weights for building and fixed equipment, for movable equipment, and for interest.

The vintage weights for each asset type are deemed to represent the average purchase pattern of the asset over its expected life (in the case of building and fixed equipment and interest, 25 years, and in the case of movable equipment, 12 years). For each asset type, we used the time series of annual capital-related purchase amounts available from 2020 back to 1964. These data allow us to derive thirty-three 25-year periods of capital-related purchases for building and fixed equipment and interest, and 46 12-year periods of capital-related purchases for movable equipment. For each 25-year period for building and fixed equipment and interest, or 12-year period for movable equipment, we calculate annual vintage weights by dividing the capital-related purchase amount in any given year by the total amount of purchases over the

entire 25-year or 12-year period. This calculation is done for each year in the 25-year or 12-year period and for each of the periods for which we have data. We then calculate the average vintage weight for a given year of the expected life by taking the average of these vintage weights across the multiple periods of data. The vintage weights for the capital-related portion of the 2021-based IRF market basket and the 2016-based IRF market basket are presented in Table 10.

TABLE 10: The 2021-Based IRF Market Basket and 2016-based IRF Market Basket Vintage Weights for Capital-Related Price Proxies

Year*	Building and Fixed Equipment		Movable Equipment		Interest	
	2021-based 25 years	2016-based 22 years	2021 based 12 years	2016-based 11 years	2021 based 25 years	2016 based 22 years
1	0.031	0.035	0.066	0.071	0.018	0.021
2	0.032	0.036	0.068	0.075	0.019	0.023
3	0.033	0.038	0.071	0.080	0.021	0.025
4	0.034	0.038	0.076	0.085	0.023	0.026
5	0.035	0.040	0.080	0.087	0.024	0.029
6	0.036	0.042	0.082	0.091	0.026	0.031
7	0.035	0.042	0.084	0.095	0.026	0.033
8	0.036	0.041	0.088	0.099	0.028	0.033
9	0.036	0.042	0.091	0.102	0.029	0.036
10	0.039	0.043	0.094	0.105	0.033	0.038
11	0.040	0.046	0.098	0.110	0.035	0.042
12	0.040	0.047	0.101	--	0.037	0.045
13	0.042	0.048	--	--	0.040	0.048
14	0.042	0.049	--	--	0.042	0.052
15	0.042	0.050	--	--	0.044	0.055
16	0.043	0.050	--	--	0.046	0.057
17	0.044	0.051	--	--	0.049	0.060
18	0.045	0.053	--	--	0.052	0.065
19	0.045	0.053	--	--	0.054	0.068
20	0.045	0.053	--	--	0.055	0.069
21	0.045	0.052	--	--	0.057	0.070
22	0.045	0.052	--	--	0.058	0.072
23	0.045	--	--	--	0.060	
24	0.045	--	--	--	0.061	
25	0.044	--	--	--	0.062	
Total	1.000	1.000	1.000	1.000	1.000	1.000

Note: Numbers may not add to total due to rounding.

* Year 25 is applied to the most recent data point when creating the vintage-weighted price proxies.

The process of creating vintage-weighted price proxies requires applying the vintage weights to the price proxy index where the last applied vintage weight in Table 10 is applied to the most recent data point. We have provided on the CMS website an example of how the vintage weighting price proxies are calculated, using example vintage weights and example price indices. The example can be found at <http://www.cms.gov/Research-Statistics-Data-and->

Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html

in the zip file titled “Weight Calculations as described in the IPPS FY 2010 Proposed Rule.”

We did not receive any comments on our proposed price proxies for the capital portion of the 2021-based IRF market basket. We are finalizing these price proxies as proposed.

c. Summary of Price Proxies of the 2021-based IRF Market Basket

Table 11 shows both the operating and capital price proxies that we are finalizing for the 2021-based IRF market basket.

TABLE 11: Price Proxies and Cost Weights for use in the 2021-based IRF Market Basket

Cost Description	Price Proxies	Weight
Total		100.0
Compensation		60.1
Wages and Salaries	ECI for Wages and Salaries for All Civilian workers in Hospitals	48.2
Employee Benefits	ECI for Total Benefits for All Civilian workers in Hospitals	11.9
Utilities		1.4
Electricity and Other Non-Fuel Utilities	PPI for Commercial Electric Power	0.9
Fuel: Oil and Gas	Blend of PPIs*	0.5
Professional Liability Insurance		0.8
Malpractice	CMS Hospital Professional Liability Insurance Premium Index	0.8
All Other Products and Services		29.1
All Other Products		11.4
Pharmaceuticals	PPI for Pharmaceuticals for Human Use, Prescription	4.7
Food: Direct Purchases	PPI for Processed Foods and Feeds	1.0
Food: Contract Services	CPI-U for Food Away From Home	1.2
Chemicals	Blend of PPIs*	0.4
Medical Instruments	Blend of PPIs*	2.5
Rubber and Plastics	PPI for Rubber and Plastic Products	0.4
Paper and Printing Products	PPI for Converted Paper and Paperboard Products	0.6
Miscellaneous Products	PPI for Finished Goods Less Food and Energy	0.8
All Other Services		17.7
Labor-Related Services		9.5
Professional Fees: Labor-Related	ECI for Total compensation for Private industry workers in Professional and related	5.6
Administrative and Facilities Support Services	ECI for Total compensation for Private industry workers in Office and administrative support	0.7
Installation, Maintenance & Repair Services	ECI for Total compensation for Civilian workers in Installation, maintenance, and repair	1.5
All Other: Labor-Related Services	ECI for Total compensation for Private industry workers in Service occupations	1.7
Nonlabor-Related Services		8.2
Professional Fees: Nonlabor-Related	ECI for Total compensation for Private industry workers in Professional and related	5.9
Financial services	ECI for Total compensation for Private industry workers in Financial activities	0.9
Telephone Services	CPI-U for Telephone Services	0.3
All Other: Nonlabor-Related Services	CPI-U for All Items Less Food and Energy	1.1
Capital-Related Costs		8.6
Depreciation		6.0
Fixed Assets	BEA chained price index for nonresidential construction for hospitals and special care facilities - vintage weighted (25 years)	3.8
Movable Equipment	PPI for machinery and equipment - vintage weighted (12 years)	2.3
Interest Costs		1.2
Government/Nonprofit	Average yield on domestic municipal bonds (Bond Buyer 20 bonds) - vintage weighted (25 years)	0.6
For Profit	Average Yield on iBoxx AAA Corporate Bonds – vintage weighted (25 years)	0.6
Other Capital-Related Costs	CPI-U for Rent of primary residence	1.3

Note: Totals may not sum to 100.0 percent due to rounding.

* Details on the series and weight for each price proxy used in the PPI blends is provided in section VI.C.2.

After consideration of public comments, we are finalizing the 2021-based IRF market basket as proposed.

D. FY 2024 Market Basket Update and Productivity Adjustment

1. FY 2024 Market Basket Update

For FY 2024 (that is, beginning October 1, 2023, and ending September 30, 2024), we proposed to use an estimate of the 2021-based IRF market basket increase percentage to update the IRF PPS base payment rate as required by section 1886(j)(3)(C)(i) of the Act. Consistent with historical practice, we proposed to estimate the market basket update for the IRF PPS based on IHS Global Inc.'s (IGI's) forecast using the most recent available data. IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets.

Based on IGI's fourth quarter 2022 forecast with historical data through the third quarter of 2022, the proposed 2021-based IRF market basket percentage increase for FY 2024 was 3.2 percent. Therefore, consistent with our historical practice of estimating market basket increases based on the best available data, we proposed a market basket increase percentage of 3.2 percent for FY 2024. We also proposed that if more recent data were subsequently available (for example, a more recent estimate of the market basket) we would use such data, if appropriate, to determine the FY 2024 update in the final rule.

Based on IGI's second quarter 2023 forecast with historical data through the first quarter of 2023, the 2021-based IRF market basket increase percentage for FY 2024 is 3.6 percent. Therefore, consistent with our historical practice of estimating market basket increases based on the best available data, we are finalizing a market basket increase percentage of 3.6 percent for FY 2024. For comparison, the current 2016-based IRF market basket is also projected to increase by 3.6 percent in FY 2024 based on IGI's second quarter 2023 forecast. Table 12 compares the 2021-based IRF market basket and the 2016-based IRF market basket percent changes. On average, the two indexes produce similar updates to one another, with the 4-year average historical growth rates (for FY 2019-FY 2022) of the 2021-based IRF market basket being equal to 3.2 percent compared to the 2016-based IRF market basket with 3.1 percent.

TABLE 12: The 2021-Based IRF Market Basket and 2016-Based IRF Market Basket Percent Changes, FY 2019 through FY 2026

	Fiscal Year (FY)	2021-Based IRF Market Basket Index Percent Change	2016-Based IRF Market Basket Index Percent Change
Historical data	FY 2019	2.4	2.3
	FY 2020	2.1	2.1
	FY 2021	2.8	2.7
	FY 2022	5.3	5.3
	Average 2019-2022	3.2	3.1
Forecast	FY 2023	4.9	4.8
	FY 2024	3.6	3.6
	FY 2025	3.1	3.1
	FY 2026	2.9	2.9
	Average 2023-2026	3.6	3.6

Note that these market basket percent changes do not include any further adjustments as may be statutorily required.

Source: IHS Global Inc. 2nd quarter 2023 forecast.

2. Productivity Adjustment

According to section 1886(j)(3)(C)(i) of the Act, the Secretary shall establish an increase factor based on an appropriate percentage increase in a market basket of goods and services.

Section 1886(j)(3)(C)(ii) of the Act then requires that, after establishing the increase factor for a FY, the Secretary shall reduce such increase factor for FY 2012 and each subsequent FY, by the productivity adjustment described in section 1886(b)(3)(B)(xi)(II) of the Act. Section

1886(b)(3)(B)(xi)(II) of the Act sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide, private nonfarm business multifactor productivity (as projected by the Secretary for the 10-year period ending with the applicable FY, year, cost reporting period, or other annual period) (the “productivity adjustment”). The U.S. Department of Labor’s Bureau of Labor Statistics (BLS) publishes the official measures of productivity for the U.S. economy. We note that previously the productivity measure referenced in section 1886(b)(3)(B)(xi)(II) of the Act, 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 above, 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-Dataand-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch>. In addition, in the FY 2022 IRF final rule (86 FR 42374), we noted that effective with FY 2022 and forward, CMS changed the name of this adjustment to refer to it as the productivity adjustment rather than the MFP adjustment.

Using IGI's fourth quarter 2022 forecast, the 10-year moving average growth of TFP for FY 2024 was projected to be 0.2 percent. Thus, in accordance with section 1886(j)(3)(C) of the Act, we proposed to calculate the FY 2024 market basket update, which is used to determine the applicable percentage increase for the IRF payments, using IGI's fourth quarter 2022 forecast of the proposed 2021-based IRF market basket. We proposed to then reduce this percentage increase by the estimated productivity adjustment for FY 2024 of 0.2 percentage point (the 10-year moving average growth of TFP for the period ending FY 2024 based on IGI's fourth quarter 2022 forecast). Therefore, the proposed FY 2024 IRF update was equal to 3.0 percent (3.2 percent market basket update reduced by the 0.2 percentage point productivity adjustment). Furthermore, we proposed that if more recent data became available after the publication of the proposed rule and before the publication of the final rule (for example, a more recent estimate of the market basket and/or productivity adjustment), we would use such data, if appropriate, to determine the FY 2024 market basket update and productivity adjustment in the final rule.

Using IGI's second quarter 2023 forecast, the 10-year moving average growth of TFP for FY 2024 is projected to be 0.2 percent. Thus, in accordance with section 1886(j)(3)(C) of the Act, we calculate the FY 2024 market basket update, which is used to determine the applicable percentage increase for the IRF payments, using IGI's second quarter 2023 forecast of the

2021-based IRF market basket. We then reduce this percentage increase by the estimated productivity adjustment for FY 2024 of 0.2 percentage point (the 10-year moving average growth of TFP for the period ending FY 2024 based on IGI's second quarter 2023 forecast). Therefore, the FY 2024 IRF update is equal to 3.4 percent (3.6 percent market basket update reduced by the 0.2 percentage point productivity adjustment).

For FY 2024, the Medicare Payment Advisory Commission (MedPAC) recommends that we reduce IRF PPS payment rates by 3 percent. As discussed, and in accordance with sections 1886(j)(3)(C) and 1886(j)(3)(D) of the Act, the Secretary proposed to update the IRF PPS payment rates for FY 2024 by a productivity-adjusted IRF market basket increase percentage of 3.0 percent. Section 1886(j)(3)(C) of the Act does not provide the Secretary with the authority to apply a different update factor to IRF PPS payment rates for FY 2024.

We invited public comment on our proposals for the FY 2024 market basket update and productivity adjustment.

The following is a summary of the public comments received on the proposed FY 2024 market basket update and productivity adjustment:

Comment: Several commenters supported the proposed payment update for FY 2024 and the use of the latest available data. Many commenters expressed concern that the FY 2024 payment update does not adequately factor in the effects of many challenges faced by IRFs such as the impact of the PHE, inflationary pressure, higher patient acuity, sequestration, increasing labor costs due to labor shortages, and other increased costs such as PPE, drugs, and supplies. One commenter expressed concern over the accuracy of the forecast underlying the proposed 3.2 percent market basket update for FY 2024.

A few commenters requested that CMS reexamine the forecasting approach or consider other methods and data sources to calculate the final rule market basket update that better reflects the rapidly increasing input prices and costs facing IRFs. One commenter requested that CMS discuss in the final rule how the agency will account for the increased costs to hospitals that are

not reflected in the recent market basket adjustments.

Response: We acknowledge and appreciate commenters' concerns regarding recent trends in inflation. We are required to update IRF PPS payments by the market basket update adjusted for productivity, as directed by section 1886(j)(3)(C) of the Act. Specifically, section 1886(j)(3)(C)(i) states that the increase factor shall be based on an appropriate percentage increase in a market basket of goods and services comprising services for which payment is made. In the FY 2024 IRF PPS proposed rule, we proposed to rebase and revise the current 2016-based IRF market basket to reflect a 2021 base year. See section VI.C. of this final rule for a description of this proposal, the comments received, and the final 2021-based IRF market basket. We believe the increase in the 2021-based IRF market basket adequately reflects the average change in the price of goods and services hospitals purchase in order to provide IRF medical services and is technically appropriate to use as the IRF payment update factor. The IRF market basket is a fixed-weight, Laspeyres-type index that measures the change in price over time of the same mix of goods and services purchased by IRFs in the base period. As we discussed in response to similar comments in the FY 2023 IRF PPS final rule, the IRF market basket update would reflect the prospective price pressures described by the commenters as increasing during a high inflation period (such as faster wage growth or higher energy prices) but would inherently not reflect other factors that might increase the level of costs, such as the quantity of labor used or any shifts between contract and staff nurses. We note that cost changes (that is, the product of price and quantities) would only be reflected when a market basket is rebased, and the base year weights are updated to a more recent time period. As stated previously, we are finalizing an IRF market basket that reflects a 2021 base year and therefore, any change in the cost structure for IRFs that occurred between 2016 and 2021 is now captured in the cost weights for this rebased market basket.

In response to the commenter's request that we reexamine the current forecasting approach for determining the IRF PPS market basket update, we provide the following

information. As stated previously, IGI is a nationally recognized economic and financial forecasting firm with which CMS contracts to forecast the components of the market baskets. At the time of the FY 2024 IRF PPS proposed rule, based on IGI's fourth quarter 2022 forecast with historical data through the third quarter of 2022, the 2021-based IRF market basket update was forecasted to be 3.2 percent for FY 2024, reflecting forecasted compensation price growth of 3.9 percent (by comparison, compensation price growth in the IRF market basket averaged 2.4 percent from 2013–2022). In the FY 2024 IRF PPS proposed rule, we proposed that if more recent data became available, we would use such data, if appropriate, to derive the final FY 2024 IRF market basket update for the final rule. For this final rule, we now have an updated forecast of the price proxies underlying the market basket that incorporates more recent historical data and reflects a revised outlook regarding the U.S. economy and expected price inflation for FY 2024. Based on IGI's second quarter 2023 forecast with historical data through the first quarter of 2023, we are projecting a FY 2024 IRF market basket update of 3.6 percent (reflecting forecasted compensation price growth of 4.3 percent) and a productivity adjustment of 0.2 percentage point. Therefore, for FY 2024 a final IRF productivity-adjusted market basket update of 3.4 percent (3.6 percent less 0.2 percentage point) will be applicable, compared to the 3.0 percent market basket update that was proposed.

We do acknowledge that FY 2022 compensation price growth for the 2016-based IRF market basket was higher (5.3 percent) than was forecasted at the time of the FY 2022 IRF PPS final rule (2.7 percent). We note that the lower projected FY 2024 IRF market basket percent increase relative to the FY 2022 historical increase and the FY 2023 projected increase reflects the expectation that wage and price pressures will lessen in FY 2024 relative to recent history.

Comment: Several commenters expressed concern about the continued application of the productivity adjustment to IRFs. The commenters noted that the PHE has resulted in further productivity challenges for IRFs and other healthcare providers. One commenter cited an article and data reporting declines in overall productivity in the economy and requested that CMS

consider these developments in the update to the productivity adjustment in the IRF PPS final rule. A few commenters requested that CMS carefully monitor the impact that these productivity adjustments will have on the rehabilitation hospital sector, provide feedback to Congress as appropriate, and reduce the productivity adjustment. One commenter requested that CMS explore ways to use its authority to offset or waive these adjustments. One commenter requested that CMS suspend at least temporarily the productivity adjustment that reduces the market basket update due to recent declines in hospital productivity. One commenter requested that CMS use its exceptions and adjustments authority under section 1886(j)(3)(A)(v) of the Act to remove the productivity adjustment for any fiscal year that was covered under PHE determination, that is, 2020 (0.4 percent), 2021 (0.0 percent), 2022 (0.7 percent), and 2023 (0.3 percent), from the calculation of the market basket for FY 2024 and any year thereafter.

Response: Section 1886(j)(3)(C)(ii)(I) of the Act requires the application of the productivity adjustment, described in section 1886(b)(3)(xi)(II), to the IRF PPS market basket increase factor. As required by statute, the FY 2024 productivity adjustment is derived based on the 10-year moving average growth in economy-wide productivity for the period ending FY 2024. We recognize the concerns of the commenters regarding the appropriateness of the productivity adjustment; however, we are required pursuant to section 1886(j)(3)(C)(ii)(I) to apply the specific productivity adjustment described here. In addition, with respect to providing feedback to Congress, we note that MedPAC annually monitors various factors for Medicare providers in terms of profitability and beneficiary access to care and reports the findings to Congress on an annual basis. MedPAC did a full analysis of payment adequacy for IRF providers in its March 2023 Report to Congress (<https://www.medpac.gov/document/march-2023-report-to-the-congress-medicare-payment-policy/>). MedPAC stated that given the positive payment adequacy indicators for IRFs, they recommended that the IRF base payment rate be reduced by 3 percent for FY 2024. Additionally, we note that we did not propose to use our authority under section 1886(d)(5)(I)(i) of the Act to remove or offset the application of the productivity

adjustment for FY 2024. As previously noted, we are required pursuant to section 1886(j)(3)(C)(ii)(I) of the Act to apply the productivity adjustment to the IRF PPS market basket increase factor.

Comment: A number of commenters requested that CMS deviate from its usual update and consider making one-time adjustments to the market basket update or applying a forecast error adjustment. One commenter stated CMS should apply a temporary payment adjustment or add-on payment to the IRF PPS in FY 2024 of 10 to 20 percent per discharge. Another commenter requested an adjustment to account for what the commenter described as CMS' "underpayment" of IRFs since 2020.

Response: As most recently discussed in the FY 2023 IRF PPS final rule, the IRF PPS market basket updates are set prospectively, which means that the market basket update relies on a mix of both historical data for part of the period for which the update is calculated and forecasted data for the remainder. For instance, the FY 2024 market basket update in this final rule reflects historical data through the first quarter of CY 2023 and forecasted data through the third quarter of CY 2024. While there is currently no mechanism to adjust for market basket forecast error in the IRF payment update, the forecast error for a market basket update is calculated as the actual market basket increase for a given year less the forecasted market basket increase. Due to the uncertainty regarding future price trends, forecast errors can be both positive and negative. In evaluating the difference between the forecast increase and later acquired actual data for the period from FY 2012 through FY 2020, we found the forecasted market basket updates for each payment year for IRFs were higher than the actual market basket updates. Therefore, we disagree with the suggestion that the FY 2024 base rates are too low based solely on the calculation of a forecast error over a short period of time (instead of considering forecast errors over longer periods). For this final rule, we have incorporated more recent historical data and forecasts to capture the price and wage pressures facing IRFs and believe it is the best available projection of inflation to determine the applicable percentage increase for the IRF

payments in FY 2024.

After consideration of public comments, we are finalizing a FY 2024 IRF productivity-adjusted market basket increase of 3.4 percent based on the most recent data available.

E. Labor-Related Share for FY 2024

Section 1886(j)(6) of the Act specifies that the Secretary is to adjust the proportion (as estimated by the Secretary from time to time) of inpatient rehabilitation facilities' costs that are attributable to wages and wage-related costs, of the prospective payment rates computed under section 1886(j)(3) of the Act for area differences in wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for such facilities. The labor-related share is determined by identifying the national average proportion of total costs that are related to, influenced by, or vary with the local labor market. We proposed to continue to classify a cost category as labor-related if the costs are labor-intensive and vary with the local labor market. As stated in the FY 2020 IRF PPS final rule (84 FR 39087), the labor-related share was defined as the sum of the relative importance of Wages and Salaries, Employee Benefits, Professional Fees: Labor-Related Services, Administrative and Facilities Support Services, Installation, Maintenance, and Repair Services, All Other: Labor-Related Services, and a portion of the Capital-Related Costs from the 2016-based IRF market basket.

Based on our definition of the labor-related share and the cost categories in the 2021-based IRF market basket, we proposed to include in the labor-related share for FY 2024 the sum of the FY 2024 relative importance 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 Capital-Related cost weight from the 2021-based IRF market basket.

Similar to the 2016-based IRF market basket (84 FR 39087), the 2021-based IRF market

basket includes two cost categories for nonmedical Professional Fees (including, but not limited to, expenses for legal, accounting, and engineering services). These are Professional Fees: Labor-Related and Professional Fees: Nonlabor-Related. For the 2021-based IRF market basket, we proposed to estimate the labor-related percentage of non-medical professional fees (and assign these expenses to the Professional Fees: Labor-Related services cost category) based on the same method that was used to determine the labor-related percentage of professional fees in the 2016-based IRF market basket.

As was done in the 2016-based IRF market basket (84 FR 39087), we proposed to determine the proportion of legal, accounting and auditing, engineering, and management consulting services that meet our definition of labor-related services based on a survey of hospitals conducted by us in 2008, a discussion of which can be found in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43850 through 43856). Based on the weighted results of the survey, we determined that hospitals purchase, on average, the following portions of contracted professional services outside of their local labor market:

- 34 percent of accounting and auditing services.
- 30 percent of engineering services.
- 33 percent of legal services.
- 42 percent of management consulting services.

We proposed to apply each of these percentages to the respective Benchmark I–O cost category underlying the professional fees cost category to determine the Professional Fees: Nonlabor-Related costs. The Professional Fees: Labor-Related costs were determined to be the difference between the total costs for each Benchmark I–O category and the Professional Fees: Nonlabor-Related costs. This is the same methodology that we used to separate the 2016-based IRF market basket professional fees category into Professional Fees: Labor-Related and Professional Fees: Nonlabor-Related cost categories (84 FR 39087).

Guidance/Guidance/Transmittals/Transmittals/r18p240i), the hospital Medicare Cost Report (CMS Form 2552-10, OMB No. 0938-0050) is collecting information on whether a hospital purchased professional services (for example, legal, accounting, tax preparation, bookkeeping, payroll, advertising, and/or management/consulting services) from an unrelated organization and if the majority of these expenses were purchased from unrelated organizations located outside of the main hospital's local area labor market. We encourage all providers to provide this information so we can potentially use in future rulemaking to determine the labor-related share.

In the 2021-based IRF market basket, nonmedical professional fees that are subject to allocation based on these survey results represent 4.0 percent of total costs (and are limited to those fees related to Accounting & Auditing, Legal, Engineering, and Management Consulting services). Based on our survey results, we proposed to apportion approximately 2.6 percentage points of the 4.0 percentage point figure into the Professional Fees: Labor-Related share cost category and the remaining 1.4 percentage point into the Professional Fees: Nonlabor-Related cost category.

In addition to the professional services listed, for the 2021-based IRF market basket, we proposed to allocate a proportion of the Home Office/Related Organization Contract Labor cost weight, calculated using the Medicare cost reports as stated previously in this final rule, into the Professional Fees: Labor-Related and Professional Fees: Nonlabor-Related cost categories. We proposed to classify these expenses as labor-related and nonlabor-related as many facilities are not located in the same geographic area as their home office, and therefore, do not meet our definition for the labor-related share, which requires the services to be purchased in the local labor market.

Similar to the 2016-based IRF market basket, we proposed for the 2021-based IRF market basket to use the Medicare cost reports for both freestanding IRF providers and hospital-based IRF providers to determine the home office labor-related percentages. The Medicare cost report requires a hospital to report information regarding its home office provider.

For the 2021-based IRF market basket, we proposed to start with the sample of IRF providers that passed the top 1 percent trim used to derive the Home Office/Related Organization Contract Labor cost weight as described in section V.C.1.b. of the proposed rule. Using information on the Medicare cost report, for freestanding and hospital-based providers separately, we first compare the location of the IRF with the location of the IRF's home office and classify an IRF based on whether its home office is located in the hospital facility's same Metropolitan Statistical Area. For both freestanding and hospital-based providers, we proposed to multiply each provider's Home Office/Related Organization Contract Labor cost weight (calculated using data from the total facility) by Medicare allowable total costs. We then calculate the proportion of Medicare allowable home office compensation costs that these IRFs represent of total Medicare allowable home office compensation costs. We proposed to multiply this percentage (45 percent) by the Home Office/Related Organization Contract Labor cost weight (5.4 percent) to determine the proportion of costs that should be allocated to the labor-related share. Therefore, we proposed to allocate 2.4 percentage points of the Home Office/Related Organization Contract Labor cost weight (5.4 percent times 45 percent) to the Professional Fees: Labor-Related cost weight and 3.0 percentage points of the Home Office/Related Organization Contract Labor cost weight to the Professional Fees: Nonlabor-Related cost weight (5.4 percent times 55 percent). For the 2016-based IRF market basket, we used a similar methodology (84 FR 39088) and determined that 42 percent of the 2016-based Home Office/Related Organization Contract Labor cost weight should be allocated to the labor-related share.

In summary, we apportioned 2.6 percentage points of the non-medical professional fees and 2.4 percentage points of the Home Office/Related Organization Contract Labor cost weight into the Professional Fees: Labor-Related cost category. This amount was added to the portion of professional fees that was identified to be labor-Related using the I-O data such as contracted advertising and marketing costs (approximately 0.6 percentage point of total costs) resulting in a Professional Fees: Labor-Related cost weight of 5.6 percent.

Comment: A few commenters supported the proposal to increase the labor-related share using data that better reflects increased labor costs as a percentage of IRFs' overall cost structure.

One commenter disagreed with CMS' proposal to exclude from the labor-related share the proportion of non-medical professional services fees presumed to have been purchased outside of the hospital's labor market. The commenter disagreed with CMS' assumption that services purchased from national firms are not affected by the local labor market. The commenter stated that when hospitals seek professional services, the services they are seeking (for example accounting, engineering, management consulting) typically are not so unique that they could only be provided by regional or national firms. The commenter stated that CMS' own survey data support this conclusion, as approximately 65 percent of these services are sourced from firms in the local market. The commenter stated that costs of services purchased from firms outside the hospital's labor market should be included with the labor-related share of costs.

The commenter requested that CMS provide evidence that pricing for professional services provided by regional and national firms to hospitals is offered in a national market that is not subject to geographic cost variation. The commenter requested that CMS restore the 1.4 percentage points it proposes to reclassify to Professional Services: Nonlabor-Related to the Professional Services: Labor-Related category, if the agency cannot produce strong evidence that prices for professional services provided by firms outside of a hospital's local labor market are homogenous.

Response: We disagree with the commenter and believe it is appropriate that a proportion of Accounting & Auditing, Legal, Engineering, and Management Consulting services costs purchased by hospitals should be excluded from the labor-related share. Section 1886(j)(6) of the Act specifies that the Secretary is to adjust the proportion (as estimated by the Secretary from time to time) of IRFs' costs that are attributable to wages and wage-related costs, of the prospective payment rates computed under section 1886(j)(3) of the Act for area differences in wage levels by a factor (established by the Secretary) reflecting the relative hospital wage level

in the geographic area of the rehabilitation facility compared to the national average wage level for such facilities.

The purpose of the labor-related share is to reflect the proportion of the national PPS base payment rate that is adjusted by the hospital's wage index (representing the relative costs of their local labor market to the national average). Therefore, we include a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market.

As acknowledged by the commenter and confirmed by the survey of hospitals conducted by CMS in 2008 (as stated previously in this final rule), professional services can be purchased from local firms as well as national and regional professional services firms. It is not necessarily the case, as asserted by the commenter, that these national and regional firms have fees that match those in the local labor market even though providers have the option to utilize those firms. That is, fees for services purchased from firms outside the local labor market may differ from those that would be purchased in the local labor market for any number of reasons (including but not limited to, the skill level of the contracted personnel, higher capital costs, etc.). As noted earlier in this section of this final rule, the definition for the labor-related share requires the services to be purchased in the local labor market; therefore, CMS' allocation of approximately 65 percent (2.6 percentage points of 4.0 percentage points) of the Professional Fees cost weight to Professional Fees: Labor-Related costs based on the 2008 survey results¹⁷ is consistent with the commenter's assertion that not all Professional Fees services are purchased in the local labor market. We believe it is reasonable to conclude that the costs of those Professional Fees services purchased directly within the local labor market are directly related to local labor market conditions and, thus, should be included in the labor-related share. The remaining approximately 35 percent of Professional Fees costs, which are purchased outside the local labor market, reflect different and additional factors outside the local labor market and,

¹⁷ The 65 percent is based on a survey conducted by CMS in 2008 as detailed in the FY 2010 IPPS/LTCH PPS final rule (74 FR 43850 through 43856). This was also used to determine the Professional Fees: Labor-related cost weight in the 2016-based IRF market basket.

thus, should be excluded from the labor-related share. In addition, we note the compensation costs of professional services provided by hospital employees (which would reflect the local labor market) are included in the labor-related share as they are included in the Wages and Salaries and Employee Benefits cost weights.

Therefore, for the reasons discussed, we believe our proposed methodology of continuing to allocate only a portion of Professional Fees to the Professional Fees: Labor-Related cost category is appropriate. As stated previously, effective for transmittal 18

([https://www.cms.gov/Regulations-and-](https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r18p240i)

[Guidance/Guidance/Transmittals/Transmittals/r18p240i](https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Transmittals/r18p240i)), the hospital Medicare Cost Report (CMS Form 2552-10, OMB No. 0938-0050) is collecting information on whether a hospital purchased professional services (for example, legal, accounting, tax preparation, bookkeeping, payroll, advertising, and/or management/consulting services) from an unrelated organization and if the majority of these expenses were purchased from unrelated organizations located outside of the main hospital's local area labor market. We encourage all providers to provide this information so we can potentially use in future rulemaking to determine the labor-related share.

Comment: One commenter disagreed with the assumption that home office compensation costs that occur outside of a hospital's labor market are not subject to geographic wage variation and stated that they do not believe that the proposed reclassification to the Professional Fees: Non-Labor-Related cost category is justified. The commenters stated that the proposed methodology fails to consider that the home office is essentially a part of the hospital, and thus the hospital, along with its home office, is operating in multiple labor markets. The commenters stated that the home office's portion of the hospital's labor costs should not be excluded from the labor-related share simply because they are not in the same labor market as the hospital.

The commenter conducted their own analysis of the Medicare cost report data showing that providers with a home office outside of their local labor market had a wage index both

below 1 as well as greater than 1. The commenter stated that those hospitals in a labor market with a wage index greater than 1 had mean home office average hourly wage costs that were greater than the mean home office average hourly wage costs of those hospitals in a labor market with a wage index less than 1. The commenter claimed that these data indicate that, contrary to CMS' assertion, home office salary, wage, and benefit costs for hospitals with home offices outside of their labor market are subject to geographic wage variation.

The commenter requested that CMS allocate the full 5.4 percentage points of the Home Office/Related Organization cost weight to the labor-related share.

Response: As previously stated, the purpose of the labor-related share is to determine the proportion of the national PPS base payment rate that is adjusted by the hospital's wage index (representing the relative costs of their local labor market to the national average). Therefore, we include a cost category in the labor-related share if the costs are labor intensive and vary with the local labor market.

As the commenter stated and as validated with the Medicare cost report, a hospital's home office can be located outside the hospital's local labor market. The proposed methodology for allocating 45 percent of the Home Office/Related Organization cost weight (reflecting compensation costs) is consistent with the intent of the statute to identify the proportion of costs likely to directly vary with the hospital's local labor market. Our methodology relies on the Medicare cost report data for hospitals reporting home office information to determine whether their home office is located in the same local labor market (which we define as the hospital's Metropolitan Statistical Area). As with professional services, we believe it is reasonable to conclude that costs of those home office services purchased directly within the local labor market are directly related to local labor market conditions while the remaining 55 percent of home office costs which are purchased outside the local labor market would reflect different and additional factors and, thus, should be excluded from the labor-related share.

Therefore, we believe our proposed methodology of continuing to allocate only a portion

of the Home Office/Related Organization cost weight into the Professional Fees: Labor-Related cost weight is appropriate. In addition, we would note that the compensation costs for hospital employees (which would reflect the local labor market) performing the same tasks as home office personnel are included in the labor-related share as they are included in the Wages and Salaries and Employee Benefits cost weights.

As stated previously, we proposed to include in the labor-related share the sum of the relative importance 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 Capital-Related cost weight from the 2021-based IRF market basket. The relative importance reflects the different rates of price change for these cost categories between the base year (2021) and FY 2024. Based on IGI's fourth quarter 2022 forecast for the proposed 2021-based IRF 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 70.3 percent. The portion of Capital-Related costs that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage applied to the 2016-based IRF market basket (84 FR 39088 through 39089). Since the relative importance of Capital-Related costs is 8.2 percent of the proposed 2021-based IRF market basket in FY 2024, we took 46 percent of 8.2 percent to determine the proposed labor-related share of Capital-Related costs for FY 2024 of 3.8 percent. Therefore, we proposed a total labor-related share for FY 2024 of 74.1 percent (the sum of 70.3 percent for the operating costs and 3.8 percent for the labor-related share of Capital-Related costs).

After consideration of public comments, we are finalizing the 2021-based IRF market basket labor-related cost categories and base year cost weights as proposed.

Based on IGI's second quarter 2023 forecast for the 2021-based IRF 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 70.3 percent. The portion of Capital-Related costs that is influenced by the local labor market is estimated to be 46 percent, which is the same percentage applied to the 2016-based IRF market basket (84 FR 39088 through 39089). Since the relative importance for Capital is 8.2 percent of the 2021-based IRF market basket in FY 2024, we took 46 percent of 8.2 percent to determine the labor-related share of Capital-Related costs for FY 2024 of 3.8 percent. Therefore, the total labor-related share for FY 2024 based on more recent data is 74.1 percent (the sum of 70.3 percent for the operating costs and 3.8 percent for the labor-related share of Capital-Related costs).

Table 13 shows the FY 2024 labor-related share using the 2021-based IRF market basket relative importance and the FY 2023 labor-related share using the 2016-based IRF market basket relative importance.

**TABLE 13: FY 2024 IRF Labor-Related Share and
FY 2023 IRF Labor-Related Share**

	FY 2024 Labor-Related Share ¹	FY 2023 Final Labor Related Share ²
Wages and Salaries	49.0	48.7
Employee Benefits	11.8	11.3
Professional Fees: Labor-related ³	5.5	4.9
Administrative and Facilities Support Services	0.7	0.8
Installation, Maintenance, and Repair Services	1.5	1.6
All Other: Labor-Related Services	1.8	1.9
Subtotal	70.3	69.2
Labor-related portion of Capital-Related costs (46%)	3.8	3.7
Total Labor-Related Share	74.1	72.9

¹ Based on the 2021-based IRF market basket, IHS Global, Inc. 2nd quarter 2023 forecast.

² Based on the 2016-based IRF market basket as published in the **Federal Register** (87 FR 47052).

³ Includes all contract advertising and marketing costs and a portion of accounting, architectural, engineering, legal, management consulting, and home office/related organization contract labor costs.

The FY 2024 labor-related share using the 2021-based IRF market basket is 1.2 percentage point higher than the FY 2023 labor-related share using the 2016-based IRF market basket. This higher labor-related share is primarily due to the incorporation of the 2021 Medicare cost report data, which increased the Compensation cost weight by approximately 0.8 percentage point compared to the 2016-based IRF market basket as shown in Tables 4 and 5.

F. Wage Adjustment for FY 2024

1. Background

Section 1886(j)(6) of the Act requires the Secretary to adjust the proportion of rehabilitation facilities’ costs attributable to wages and wage-related costs (as estimated by the Secretary from time to time) by a factor (established by the Secretary) reflecting the relative hospital wage level in the geographic area of the rehabilitation facility compared to the national average wage level for those facilities. The Secretary is required to update the IRF PPS wage index on the basis of information available to the Secretary on the wages and wage-related costs to furnish rehabilitation services. Any adjustment or updates made under section 1886(j)(6) of the Act for a FY are made in a budget-neutral manner.

In the FY 2023 IRF PPS final rule (87 FR 47054 through 47056) we finalized a policy to apply a 5-percent cap on any decrease to a provider’s wage index from its wage index in the

prior year, regardless of the circumstances causing the decline. Additionally, we finalized a policy that a new IRF would be paid the wage index for the area in which it is geographically located for its first full or partial FY with no cap applied because a new IRF would not have a wage index in the prior FY. Also, in the FY 2023 IRF PPS final rule, we amended the regulations at §412.624(e)(1)(ii) to reflect this permanent cap on wage index decreases. A full discussion of the adoption of this policy is found in the FY 2023 IRF PPS final rule.

For FY 2024, we proposed to maintain the policies and methodologies described in the FY 2023 IRF PPS final rule (87 FR 47038) related to the labor market area definitions and the wage index methodology for areas with wage data. Thus, we proposed to use the core based statistical areas (CBSAs) labor market area definitions and the FY 2024 pre-reclassification and pre-floor hospital wage index data. In accordance with section 1886(d)(3)(E) of the Act, the FY 2024 pre-reclassification and pre-floor hospital wage index is based on data submitted for hospital cost reporting periods beginning on or after October 1, 2019, and before October 1, 2020 (that is, FY 2020 cost report data).

The labor market designations made by the OMB include some geographic areas where there are no hospitals and, thus, no hospital wage index data on which to base the calculation of the IRF PPS wage index. We proposed to continue to use the same methodology discussed in the FY 2008 IRF PPS final rule (72 FR 44299) to address those geographic areas where there are no hospitals and, thus, no hospital wage index data on which to base the calculation for the FY 2024 IRF PPS wage index.

We invited public comment on our proposals regarding the Wage Adjustment for FY 2024.

The following is a summary of the public comments received on the proposals regarding the Wage Adjustment for FY 2024, with our responses:

Comment: Commenters stated support of the permanent 5-percent cap on wage index decreases. One commenter encouraged CMS to implement these caps in a non-budget neutral

manner to mitigate volatility caused by wage index shifts.

Response: We appreciate the commenters' support of the permanent cap on wage index decreases. As for budget neutrality, we do not believe that the permanent 5-percent cap policy for the IRF wage index should be applied in a non-budget-neutral manner. Any adjustment or updates made under section 1886(j)(6) of the Act for a FY must be made in a manner that assures that the aggregated payments under this subsection in the FY are not greater or less than those that would have been made in the year without such adjustments. In accordance with section 1186(j)(6) of the Act, our longstanding historical practice has been to implement updates to the wage index under the IRF PPS in a budget neutral manner. We refer readers to the FY 2023 IRF PPS final rule (87 FR 47054 through 47056) for a detailed discussion and for responses to these and other comments relating to the wage index cap policy.

Comment: One commenter encouraged CMS to release provider-level wage index tables in the final rule that would indicate what wage index value each IRF would receive, including whether or not the IRF would receive a capped wage index value, in order to avoid errors in the payment rates established by the MACs. Commenters also requested that CMS release the necessary wage index tables and data to enable IRFs to crosswalk the IPPS values after application of the low-wage index adjustment to the IRF PPS wage indices. These commenters also requested that CMS detail what data it believes is necessary to enable use of the post-reclassification and post-floor IPPS wage index data in the IRF PPS.

Response: The wage index tables for IRF PPS are provided at the CBSA level. The 5-percent cap policy is applied at the provider level. Hence, when the 5-percent cap is applicable, each IRF should work directly with its MAC to understand how the 5-percent cap is applied. MACs have more detailed information about the location of each IRF and the applicability of the 5-percent cap to each IRF's situation, and CMS has provided careful instructions to the MACs on applying the 5-percent cap policy (see publication 100-04 Medicare Claims Processing Manual, chapter 3). Further, we are unable to provide crosswalk tables or

data related to IPPS wage index policies. Data pertaining to the FY 2024 IPPS proposed rule is available at <https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps>. We do not have any additional data on this for the IRF PPS.

Comment: Commenters encouraged CMS to continue to reform the wage index policies. Commenters suggested that CMS revise the IRF wage index to adopt the IPPS policies such as geographic reclassification, rural floor, low wage adjustment, and the Outpatient PPS (OPPS) outmigration adjustments.

Response: We appreciate the commenters' suggestion to adopt the IPPS reclassification and rural floor policies, low wage, and the OPSS outmigration adjustments for the IRF wage index. The OPSS outmigration adjustment policy is a longstanding policy for that setting, and it should be noted that the wage index applied to the OPSS also includes the rural floor and any policies and adjustments applied to the IPPS wage index. As we do not have an IRF-specific wage index, we are unable to determine the degree, if any, to which these IPPS/OPSS policies under the IRF PPS would be appropriate. Data pertaining to any IPPS policies that are applied to the pre-reclassification/pre-floor wage index is available in the FY 2024 IPPS proposed rule at <https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps>. The rationale for our current wage index policies was most recently published in the FY 2022 IRF PPS final rule (86 FR 42377 through 42378) and fully described in the FY 2006 IRF PPS final rule (70 FR 47880, 47926 through 47928).

After consideration of the comments we received, we are finalizing our proposals regarding the Wage Adjustment for FY 2024.

2. Core-Based Statistical Areas (CBSAs) for the FY 2024 IRF Wage Index

The wage index used for the IRF PPS is calculated using the pre-reclassification and pre-floor inpatient PPS (IPPS) wage index data and is assigned to the IRF on the basis of the labor market area in which the IRF is geographically located. IRF labor market areas are delineated based on the CBSAs established by the OMB. The CBSA delineations (which were

implemented for the IRF PPS beginning with FY 2016) 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 2016 IRF PPS final rule (80 FR 47068 through 47076) for a full discussion of our implementation of the OMB labor market area delineations beginning with the FY 2016 wage index.

Generally, OMB issues major revisions to statistical areas every 10 years, based on the results of the decennial census. Additionally, OMB occasionally issues updates and revisions to the statistical areas in between decennial censuses to reflect the recognition of new areas or the addition of counties to existing areas. In some instances, these updates merge formerly separate areas, transfer components of an area from one area to another, or drop components from an area. On July 15, 2015, OMB issued OMB Bulletin No. 15–01, which provides minor updates to and supersedes OMB Bulletin No. 13–01 that was issued on February 28, 2013. The attachment to OMB Bulletin No. 15–01 provides detailed information on the update to statistical areas since February 28, 2013. The updates provided in OMB Bulletin No. 15-01 are 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 2018 IRF PPS final rule (82 FR 36250 through 36251), we adopted the updates set forth in OMB Bulletin No. 15–01 effective October 1, 2017, beginning with the FY 2018 IRF 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 2018 IRF PPS final rule. In the FY 2019 IRF PPS final rule (83 FR 38527), we continued to use the OMB delineations that were adopted beginning with FY 2016 to calculate the area wage indexes, with updates set forth in OMB Bulletin No. 15-01

that we adopted beginning with the FY 2018 wage index.

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 provide detailed information on the update to statistical areas since July 15, 2015, and are 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 2020 IRF PPS final rule (84 FR 39090 through 39091), we adopted the updates set forth in OMB Bulletin No. 17–01 effective October 1, 2019, beginning with the FY 2020 IRF wage index.

On April 10, 2018, OMB issued OMB Bulletin No. 18-03, which superseded the August 15, 2017 OMB Bulletin No. 17-01, and on September 14, 2018, OMB issued OMB Bulletin No. 18–04, which superseded the April 10, 2018 OMB Bulletin No. 18-03. These bulletins established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of this bulletin may be obtained at <https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf>.

To this end, as discussed in the FY 2021 IRF PPS proposed (85 FR 22075 through 22079) and final (85 FR 48434 through 48440) rules, we adopted the revised OMB delineations identified in OMB Bulletin No. 18-04 (available at <https://www.whitehouse.gov/wp-content/uploads/2018/09/Bulletin-18-04.pdf>) beginning October 1, 2020, including a 1-year transition for FY 2021 under which we applied a 5-percent cap on any decrease in an IRF’s wage index compared to its wage index for the prior fiscal year (FY 2020). The updated OMB delineations more accurately reflect the contemporary urban and rural nature of areas across the country, and the use of such delineations allows us to determine more accurately the appropriate wage index and rate tables to apply under the IRF PPS. OMB issued further revised CBSA delineations in OMB Bulletin No. 20-01, on March 6, 2020 (available on the web at

<https://www.whitehouse.gov/wp-content/uploads/2020/03/Bulletin-20-01.pdf>). However, we determined that the changes in OMB Bulletin No. 20-01 do not impact the CBSA-based labor market area delineations adopted in FY 2021. Therefore, CMS did not propose to adopt the revised OMB delineations identified in OMB Bulletin No. 20-01 for FY 2022 or 2023, and for these reasons CMS is likewise not making such a proposal for FY 2024.

3. IRF Budget-Neutral Wage Adjustment Factor Methodology

To calculate the wage-adjusted facility payment for the payment rates set forth in this final rule, we multiply the unadjusted Federal payment rate for IRFs by the FY 2024 labor-related share based on the 2021-based IRF market basket relative importance (74.1 percent) to determine the labor-related portion of the standard payment amount. (A full discussion of the calculation of the labor-related share appears in section VI.E. of this final rule.) We would then multiply the labor-related portion by the applicable IRF wage index. The wage index tables are available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRF-Rules-and-Related-Files.html>.

Adjustments or updates to the IRF wage index made under section 1886(j)(6) of the Act must be made in a budget-neutral manner. We calculate a budget-neutral wage adjustment factor as established in the FY 2004 IRF PPS final rule (68 FR 45689) and codified at § 412.624(e)(1), as described in the steps below. We use the listed steps to ensure that the FY 2024 IRF standard payment conversion factor reflects the update to the wage indexes (based on the FY 2020 hospital cost report data) and the update to the labor-related share, in a budget-neutral manner:

Step 1. Calculate the total amount of estimated IRF PPS payments using the labor-related share and the wage indexes from FY 2023 (as published in the FY 2023 IRF PPS final rule (87 FR 47038)).

Step 2. Calculate the total amount of estimated IRF PPS payments using the FY 2024 wage index values (based on updated hospital wage data and considering the permanent cap on wage index decreases policy) and the FY 2024 labor-related share of 74.1 percent.

Step 3. Divide the amount calculated in step 1 by the amount calculated in step 2. The resulting quotient is the FY 2024 budget-neutral wage adjustment factor of 1.0028.

Step 4. Apply the budget neutrality factor from step 3 to the FY 2024 IRF PPS standard payment amount after the application of the increase factor to determine the FY 2024 standard payment conversion factor.

We discuss the calculation of the standard payment conversion factor for FY 2024 in section VI.G. of this final rule.

We invited public comment on the proposed IRF wage adjustment for FY 2024.

We did not receive any comments on the proposed IRF budget-neutral wage adjustment factor methodology for FY 2024. Comments related to the budget neutral wage index cap policy are addressed in the Wage Adjustment section (VI.F) above.

We are finalizing our proposals regarding the IRF budget neutral wage adjustment factor methodology for FY 2024.

G. Description of the IRF Standard Payment Conversion Factor and Payment Rates for FY 2024

To calculate the standard payment conversion factor for FY 2024, as illustrated in Table 14, we begin by applying the increase factor for FY 2024, as adjusted in accordance with sections 1886(j)(3)(C) of the Act, to the standard payment conversion factor for FY 2023 (\$17,878). Applying the 3.4 percent increase factor for FY 2024 to the standard payment conversion factor for FY 2023 of \$17,878 yields a standard payment amount of \$18,486. Then, we apply the budget neutrality factor for the FY 2024 wage index (taking into account the permanent cap on wage index decreases policy), and labor-related share of 1.0028, which results in a standard payment amount of \$18,538. We next apply the budget neutrality factor for the CMG relative weights of 1.0002, which results in the standard payment conversion factor of \$18,541 for FY 2024.

We invited public comment on the proposed FY 2024 standard payment conversion factor.

We did not receive any comments on the FY 2024 standard payment conversion factor, and therefore, we are finalizing the revisions as proposed.

TABLE 14: Calculations to Determine the FY 2024 Standard Payment Conversion Factor

Explanation for Adjustment	Calculations	
Standard Payment Conversion Factor for FY 2023	\$17,878	
Market Basket Increase Factor for FY 2024 (3.6%), reduced by 0.2 percentage point for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act	x	1.034
Budget Neutrality Factor for the Updates to the Wage Index and Labor-Related Share	x	1.0028
Budget Neutrality Factor for the Revisions to the CMG Relative Weights	x	1.0002
FY 2024 Standard Payment Conversion Factor	=	\$18,541

After the application of the CMG relative weights described in section V. of this final rule to the FY 2024 standard payment conversion factor (\$18,541), the resulting unadjusted IRF prospective payment rates for FY 2024 are shown in Table 15.

TABLE 15: FY 2024 Payment Rates

CMG	Payment Rate Tier 1	Payment Rate Tier 2	Payment Rate Tier 3	Payment Rate No Comorbidity
0101	\$ 18,244.34	\$ 15,600.40	\$ 14,393.38	\$ 13,623.93
0102	\$ 23,363.51	\$ 19,976.07	\$ 18,431.61	\$ 17,445.23
0103	\$ 30,155.08	\$ 25,784.97	\$ 23,788.10	\$ 22,516.19
0104	\$ 38,670.96	\$ 33,066.02	\$ 30,507.36	\$ 28,875.75
0105	\$ 47,094.14	\$ 40,267.34	\$ 37,152.46	\$ 35,164.86
0106	\$ 53,809.69	\$ 46,011.35	\$ 42,449.62	\$ 40,180.20
0201	\$ 20,050.24	\$ 15,945.26	\$ 14,521.31	\$ 13,557.18
0202	\$ 25,731.20	\$ 20,461.85	\$ 18,635.56	\$ 17,397.02
0203	\$ 31,866.42	\$ 25,341.84	\$ 23,077.98	\$ 21,546.50
0204	\$ 39,638.80	\$ 31,521.55	\$ 28,707.03	\$ 26,801.02
0205	\$ 50,665.14	\$ 40,289.59	\$ 36,692.64	\$ 34,256.35
0301	\$ 22,401.24	\$ 17,625.07	\$ 16,425.47	\$ 15,342.68
0302	\$ 28,712.59	\$ 22,590.35	\$ 21,053.31	\$ 19,664.58
0303	\$ 34,373.16	\$ 27,043.90	\$ 25,202.78	\$ 23,541.51
0304	\$ 40,638.16	\$ 31,973.95	\$ 29,797.24	\$ 27,831.90
0305	\$ 44,327.82	\$ 34,875.62	\$ 32,502.37	\$ 30,359.03
0401	\$ 25,161.99	\$ 19,824.04	\$ 19,252.97	\$ 17,945.83
0402	\$ 31,883.10	\$ 25,119.35	\$ 24,398.10	\$ 22,740.54
0403	\$ 38,403.97	\$ 30,257.06	\$ 29,385.63	\$ 27,388.77
0404	\$ 60,412.14	\$ 47,596.60	\$ 46,226.42	\$ 43,087.43
0405	\$ 49,343.16	\$ 38,874.91	\$ 37,756.89	\$ 35,190.82
0406	\$ 61,962.17	\$ 48,816.60	\$ 47,413.05	\$ 44,192.47
0407	\$ 83,154.53	\$ 65,512.77	\$ 63,629.00	\$ 59,305.24
0501	\$ 23,354.24	\$ 18,513.19	\$ 17,410.00	\$ 15,902.62
0502	\$ 28,753.38	\$ 22,794.31	\$ 21,435.25	\$ 19,579.30
0503	\$ 32,991.86	\$ 26,155.79	\$ 24,596.49	\$ 22,466.13
0504	\$ 39,701.84	\$ 31,473.35	\$ 29,597.00	\$ 27,034.63
0505	\$ 55,864.03	\$ 44,287.03	\$ 41,646.79	\$ 38,040.57
0601	\$ 24,846.79	\$ 18,839.51	\$ 17,632.49	\$ 15,884.07
0602	\$ 30,781.77	\$ 23,339.41	\$ 21,843.15	\$ 19,677.56
0603	\$ 36,549.87	\$ 27,711.38	\$ 25,937.00	\$ 23,363.51
0604	\$ 45,649.80	\$ 34,610.48	\$ 32,394.84	\$ 29,181.68
0701	\$ 22,306.68	\$ 17,719.63	\$ 16,916.81	\$ 15,479.88
0702	\$ 27,640.92	\$ 21,956.25	\$ 20,962.45	\$ 19,180.66
0703	\$ 34,070.94	\$ 27,066.15	\$ 25,840.59	\$ 23,645.34
0704	\$ 42,282.75	\$ 33,588.88	\$ 32,068.51	\$ 29,342.99
0801	\$ 21,945.13	\$ 17,521.25	\$ 16,290.12	\$ 14,984.84
0802	\$ 24,959.89	\$ 19,927.87	\$ 18,526.17	\$ 17,042.89
0803	\$ 27,739.19	\$ 22,147.22	\$ 20,589.78	\$ 18,941.49
0804	\$ 31,256.42	\$ 24,954.33	\$ 23,200.35	\$ 21,342.55
0805	\$ 39,010.26	\$ 31,145.17	\$ 28,955.48	\$ 26,637.85
0901	\$ 22,822.12	\$ 17,586.14	\$ 16,520.03	\$ 15,084.96
0902	\$ 29,025.94	\$ 22,367.86	\$ 21,010.66	\$ 19,186.23
0903	\$ 33,668.60	\$ 25,946.28	\$ 24,372.14	\$ 22,256.62
0904	\$ 40,703.06	\$ 31,365.81	\$ 29,465.36	\$ 26,906.70
1001	\$ 22,245.49	\$ 18,416.78	\$ 16,835.23	\$ 15,363.07
1002	\$ 28,328.79	\$ 23,454.37	\$ 21,440.81	\$ 19,564.46
1003	\$ 33,381.22	\$ 27,635.36	\$ 25,263.97	\$ 23,052.03
1004	\$ 43,313.63	\$ 35,858.29	\$ 32,780.49	\$ 29,912.20
1101	\$ 23,617.53	\$ 23,617.53	\$ 19,028.63	\$ 18,038.54
1102	\$ 27,080.98	\$ 27,080.98	\$ 21,820.90	\$ 20,684.34
1103	\$ 37,150.60	\$ 37,150.60	\$ 29,934.44	\$ 28,375.15
1201	\$ 24,657.68	\$ 19,089.81	\$ 17,144.86	\$ 15,954.53
1202	\$ 31,215.63	\$ 24,166.34	\$ 21,705.95	\$ 20,198.57
1203	\$ 39,340.29	\$ 30,455.45	\$ 27,353.54	\$ 25,454.94
1204	\$ 40,814.30	\$ 31,597.57	\$ 28,378.85	\$ 26,409.80

CMG	Payment Rate Tier 1	Payment Rate Tier 2	Payment Rate Tier 3	Payment Rate No Comorbidity
1301	\$ 25,523.54	\$ 20,485.95	\$ 18,394.53	\$ 17,024.35
1302	\$ 30,464.72	\$ 24,453.72	\$ 21,956.25	\$ 20,320.94
1303	\$ 34,430.64	\$ 27,637.21	\$ 24,813.42	\$ 22,966.74
1304	\$ 40,704.91	\$ 32,671.10	\$ 29,335.57	\$ 27,151.44
1305	\$ 40,910.72	\$ 32,837.97	\$ 29,483.90	\$ 27,288.64
1401	\$ 20,869.75	\$ 16,870.46	\$ 15,587.42	\$ 14,402.65
1402	\$ 26,074.21	\$ 21,077.41	\$ 19,475.47	\$ 17,994.04
1403	\$ 31,545.66	\$ 25,499.44	\$ 23,561.90	\$ 21,770.84
1404	\$ 39,364.40	\$ 31,820.06	\$ 29,402.32	\$ 27,164.42
1501	\$ 23,934.58	\$ 19,304.89	\$ 18,622.58	\$ 17,643.62
1502	\$ 28,315.82	\$ 22,838.80	\$ 22,032.27	\$ 20,873.46
1503	\$ 33,598.15	\$ 27,099.53	\$ 26,142.81	\$ 24,767.07
1504	\$ 41,431.72	\$ 33,418.30	\$ 32,235.38	\$ 30,540.74
1601	\$ 21,051.45	\$ 15,802.49	\$ 15,605.96	\$ 14,343.32
1602	\$ 27,685.42	\$ 20,782.61	\$ 20,523.03	\$ 18,863.61
1603	\$ 32,135.26	\$ 24,123.70	\$ 23,823.33	\$ 21,896.92
1604	\$ 39,699.99	\$ 29,802.80	\$ 29,430.13	\$ 27,051.32
1701	\$ 25,395.61	\$ 19,271.52	\$ 18,249.91	\$ 16,644.26
1702	\$ 30,655.69	\$ 23,263.39	\$ 22,028.56	\$ 20,091.03
1703	\$ 36,319.96	\$ 27,563.05	\$ 26,100.17	\$ 23,804.79
1704	\$ 41,834.06	\$ 31,745.90	\$ 30,062.38	\$ 27,418.43
1705	\$ 47,922.92	\$ 36,366.32	\$ 34,438.05	\$ 31,410.31
1801	\$ 20,393.25	\$ 17,061.43	\$ 15,741.31	\$ 14,246.90
1802	\$ 25,938.86	\$ 21,700.39	\$ 20,022.43	\$ 18,121.97
1803	\$ 32,394.84	\$ 27,101.38	\$ 25,006.25	\$ 22,633.00
1804	\$ 37,899.66	\$ 31,706.96	\$ 29,255.84	\$ 26,480.26
1805	\$ 45,290.10	\$ 37,888.53	\$ 34,959.06	\$ 31,642.07
1806	\$ 66,580.73	\$ 55,700.87	\$ 51,393.80	\$ 46,517.51
1901	\$ 23,437.68	\$ 16,738.81	\$ 16,206.69	\$ 15,559.61
1902	\$ 33,160.58	\$ 23,680.57	\$ 22,929.65	\$ 22,015.58
1903	\$ 46,397.00	\$ 33,134.62	\$ 32,081.49	\$ 30,802.16
1904	\$ 78,717.67	\$ 56,214.46	\$ 54,428.96	\$ 52,261.52
2001	\$ 22,073.06	\$ 17,719.63	\$ 16,521.89	\$ 14,984.84
2002	\$ 27,379.49	\$ 21,980.36	\$ 20,495.22	\$ 18,587.35
2003	\$ 32,509.79	\$ 26,096.46	\$ 24,333.21	\$ 22,069.35
2004	\$ 38,721.02	\$ 31,083.99	\$ 28,983.29	\$ 26,285.58
2005	\$ 41,520.72	\$ 33,333.01	\$ 31,080.28	\$ 28,187.88
2101	\$ 28,130.41	\$ 23,704.67	\$ 21,108.93	\$ 18,867.32
2102	\$ 45,521.86	\$ 38,361.33	\$ 34,161.79	\$ 30,533.32
5001	\$ -	\$ -	\$ -	\$ 3,207.59
5101	\$ -	\$ -	\$ -	\$ 14,450.86
5102	\$ -	\$ -	\$ -	\$ 34,845.96
5103	\$ -	\$ -	\$ -	\$ 16,349.45
5104	\$ -	\$ -	\$ -	\$ 43,662.20

H. Example of the Methodology for Adjusting the Prospective Payment Rates

Table 16 illustrates the methodology for adjusting the prospective payments (as described in section VI. of this final rule). The following examples are based on two hypothetical Medicare beneficiaries, both classified into CMG 0104 (without comorbidities). The unadjusted prospective payment rate for CMG 0104 (without comorbidities) appears in Table 16.

Example: One beneficiary is in Facility A, an IRF located in rural Spencer County,

Indiana, and another beneficiary is in Facility B, an IRF located in urban Harrison County, Indiana. Facility A, a rural non-teaching hospital has a Disproportionate Share Hospital (DSH) percentage of 5 percent (which would result in a LIP adjustment of 1.0156), a wage index of 0.8347, and a rural adjustment of 14.9 percent. Facility B, an urban teaching hospital, has a DSH percentage of 15 percent (which would result in a LIP adjustment of 1.0454 percent), a wage index of 0.8793, and a teaching status adjustment of 0.0784.

To calculate each IRF's labor and non-labor portion of the prospective payment, we begin by taking the unadjusted prospective payment rate for CMG 0104 (without comorbidities) from Table 16. Then, we multiply the labor-related share for FY 2024 (74.1 percent) described in section VI.E. of this final rule by the unadjusted prospective payment rate. To determine the non-labor portion of the prospective payment rate, we subtract the labor portion of the Federal payment from the unadjusted prospective payment.

To compute the wage-adjusted prospective payment, we multiply the labor portion of the Federal payment by the appropriate wage index located in the applicable wage index table. This table is available on the CMS website at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/InpatientRehabFacPPS/IRF-Rules-and-Related-Files.html>.

The resulting figure is the wage-adjusted labor amount. Next, we compute the wage-adjusted Federal payment by adding the wage-adjusted labor amount to the non-labor portion of the Federal payment.

Adjusting the wage-adjusted Federal payment by the facility-level adjustments involves several steps. First, we take the wage-adjusted prospective payment and multiply it by the appropriate rural and LIP adjustments (if applicable). Second, to determine the appropriate amount of additional payment for the teaching status adjustment (if applicable), we multiply the teaching status adjustment (0.0784, in this example) by the wage-adjusted and rural-adjusted amount (if applicable). Finally, we add the additional teaching status payments (if applicable) to the wage, rural, and LIP-adjusted prospective payment rates. Table 16 illustrates the components

of the adjusted payment calculation.

TABLE 16: Example of Computing the FY 2024 IRF Prospective Payment

Steps		Rural Facility A (Spencer Co., IN)		Urban Facility B (Harrison Co., IN)	
1	Unadjusted Payment		\$ 28,875.75		\$ 28,875.75
2	Labor-Related Share	X	0.741	X	0.741
3	Labor Portion of Payment	=	\$ 21,396.93	=	\$21,396.93
4	CBSA-Based Wage Index	X	0.8347	X	0.8793
5	Wage-Adjusted Amount	=	\$ 17,860.02	=	\$18,814.32
6	Non-Labor Amount	+	\$ 7,478.82	+	\$7,478.82
7	Wage-Adjusted Payment	=	\$25,338.84	=	\$26,293.14
8	Rural Adjustment	X	1.149	X	1.000
9	Wage- and Rural-Adjusted Payment	=	\$29,114.32	=	\$26,293.14
10	LIP Adjustment	X	1.0156	X	1.0454
11	Wage-, Rural- and LIP-Adjusted Payment	=	\$29,568.51	=	\$27,486.85
12	Wage- and Rural-Adjusted Payment		\$29,114.32		\$26,293.14
13	Teaching Status Adjustment	X	0	X	0.0784
14	Teaching Status Adjustment Amount	=	\$0.00	=	\$2,061.38
15	Wage-, Rural-, and LIP-Adjusted Payment	+	\$ 29,568.51	+	\$27,486.85
16	Total Adjusted Payment	=	\$ 29,568.51	=	\$29,548.23

Thus, the adjusted payment for Facility A would be \$29,568.51, and the adjusted payment for Facility B would be \$29,548.23.

VII. Update to Payments for High-Cost Outliers under the IRF PPS for FY 2024

A. Update to the Outlier Threshold Amount for FY 2024

Section 1886(j)(4) of the Act provides the Secretary with the authority to make payments in addition to the basic IRF prospective payments for cases incurring extraordinarily high costs. A case qualifies for an outlier payment if the estimated cost of the case exceeds the adjusted outlier threshold. We calculate the adjusted outlier threshold by adding the IRF PPS payment for the case (that is, the CMG payment adjusted by all of the relevant facility-level adjustments) and the adjusted threshold amount (also adjusted by all of the relevant facility-level adjustments). Then, we calculate the estimated cost of a case by multiplying the IRF's overall CCR by the Medicare allowable covered charge. If the estimated cost of the case is higher than the adjusted outlier threshold, we make an outlier payment for the case equal to 80 percent of the difference between the estimated cost of the case and the outlier threshold.

In the FY 2002 IRF PPS final rule (66 FR 41362 through 41363), we discussed our

rationale for setting the outlier threshold amount for the IRF PPS so that estimated outlier payments would equal 3 percent of total estimated payments. For the FY 2002 IRF PPS final rule, we analyzed various outlier policies using 3, 4, and 5 percent of the total estimated payments, and we concluded that an outlier policy set at 3 percent of total estimated payments would optimize the extent to which we could reduce the financial risk to IRFs of caring for high-cost patients, while still providing for adequate payments for all other (non-high cost outlier) cases.

Subsequently, we updated the IRF outlier threshold amount in the FYs 2006 through 2023 IRF PPS final rules and the FY 2011 and FY 2013 notices (70 FR 47880, 71 FR 48354, 72 FR 44284, 73 FR 46370, 74 FR 39762, 75 FR 42836, 76 FR 47836, 76 FR 59256, 77 FR 44618, 78 FR 47860, 79 FR 45872, 80 FR 47036, 81 FR 52056, 82 FR 36238, 83 FR 38514, 84 FR 39054, 85 FR 48444, 86 FR 42362, and 87 FR 47038, respectively) to maintain estimated outlier payments at 3 percent of total estimated payments. We also stated in the FY 2009 final rule (73 FR 46370 at 46385) that we would continue to analyze the estimated outlier payments for subsequent years and adjust the outlier threshold amount as appropriate to maintain the 3 percent target.

To update the IRF outlier threshold amount for FY 2024, we proposed to use FY 2022 claims data and the same methodology that we used to set the initial outlier threshold amount in the FY 2002 IRF PPS final rule (66 FR 41362 through 41363), which is also the same methodology that we used to update the outlier threshold amounts for FYs 2006 through 2023. The outlier threshold is calculated by simulating aggregate payments and using an iterative process to determine a threshold that results in outlier payments being equal to 3 percent of total payments under the simulation. To determine the outlier threshold for FY 2024, we estimated the amount of FY 2024 IRF PPS aggregate and outlier payments using the most recent claims available (FY 2022) and the proposed FY 2024 standard payment conversion factor, labor-related share, and wage indexes, incorporating any applicable budget-neutrality adjustment

factors. The outlier threshold is adjusted either up or down in this simulation until the estimated outlier payments equal 3 percent of the estimated aggregate payments. Based on an analysis of the preliminary data used for the proposed rule, we estimated that IRF outlier payments as a percentage of total estimated payments would be approximately 2.3 percent in FY 2023.

Therefore, we proposed to update the outlier threshold amount from \$12,526 for FY 2023 to \$9,690 for FY 2024 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2024.

We note that, as we typically do, we updated our data between the FY 2024 IRF PPS proposed and final rules to ensure that we use the most recent available data in calculating IRF PPS payments. This updated data includes a more complete set of claims for FY 2022. Based on our analysis using this updated data, we estimate that IRF outlier payments as a percentage of total estimated payments are approximately 2.5 percent in FY 2023. Therefore, we will update the outlier threshold amount from \$12,526 for FY 2023 to \$10,423 for FY 2024 to account for the increases in IRF PPS payments and estimated costs and to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2024.

The following is a summary of the public comments received on the proposed update to the FY 2024 outlier threshold amount and our responses.

Comment: Commenters were supportive of the update to the outlier threshold for FY 2024; however, some commenters recommended that CMS implement a new methodology to set the outlier fixed loss amount using a 3-year average approach to promote stability in the outlier threshold value. One commenter suggested that changes in the outlier threshold should be limited to no more than plus or minus the market basket amount in any given year.

Response: We thank the commenters for their suggestions regarding the outlier threshold. We appreciate the suggestion to modify the outlier threshold methodology to use a 3-year average; however, it has been our long-standing practice to utilize the most recent full fiscal year of data to update the prospective payment rates and determine the outlier threshold amount,

as this data is generally considered to be the best overall predictor of experience in the upcoming fiscal year. Additionally, we do not believe it would be appropriate to limit changes in the outlier threshold to changes in the market basket as constraining adjustments to the outlier threshold may result in a threshold that generates outlier payments above or below the 3 percent target. We appreciate the commenters' suggestions and will take them into consideration as we continue to consider revisions to our outlier threshold methodology in future rulemaking.

Comment: Commenters suggested that CMS should consider policies to better target outlier payments, such as placing a cap on the amount of outlier payments any IRF could receive, lowering the 3 percent outlier pool, and including historical outlier reconciliation dollars in the outlier projections. Additionally, commenters encouraged CMS to monitor the increasing concentration of outlier payments and provide additional information on outlier payments for the public.

Response: We appreciate the various suggestions regarding the outlier threshold methodology. As most recently discussed in the FY 2023 IRF PPS Final Rule (87 FR 47038) our outlier policy is intended to reimburse IRFs for treating extraordinarily costly cases. Any future consideration given to imposing a limit on outlier payments or adjusting the outlier threshold to account for historical outlier reconciliation dollars would need to be carefully assessed and take into consideration the effect on access to IRF care for certain high-cost populations. We continue to believe that maintaining the outlier pool at 3 percent of aggregate IRF payments optimizes the extent to which we can reduce financial risk to IRFs of caring for highest-cost patients, while still providing for adequate payments for all other non-outlier cases. We appreciate the commenters' suggestions for refinements to the outlier methodology as well as the suggested areas of analysis and will take them into consideration as we continue to assess our outlier threshold methodology. We will continue to monitor our outlier policy to ensure it continues to compensate IRFs appropriately.

After consideration of the comments received and considering the most recent available

data, we are finalizing the outlier threshold amount of \$10,423 to maintain estimated outlier payments at approximately 3 percent of total estimated aggregate IRF payments for FY 2024.

B. Update to the IRF Cost-to-Charge Ratio Ceiling and Urban/Rural Averages for FY 2024

CCRs are used to adjust charges from Medicare claims to costs and are computed annually from facility-specific data obtained from MCRs. IRF specific CCRs are used in the development of the CMG relative weights and the calculation of outlier payments under the IRF PPS. In accordance with the methodology stated in the FY 2004 IRF PPS final rule (68 FR45692 through 45694), we proposed to apply a ceiling to IRFs' CCRs. Using the methodology described in that final rule, we proposed to update the national urban and rural CCRs for IRFs, as well as the national CCR ceiling for FY 2024, based on analysis of the most recent data available. We apply the national urban and rural CCRs in the following situations:

- New IRFs that have not yet submitted their first MCR.
- IRFs whose overall CCR is in excess of the national CCR ceiling for FY 2024, as discussed below in this section.
- Other IRFs for which accurate data to calculate an overall CCR are not available.

Specifically, for FY 2024, we proposed to estimate a national average CCR of 0.487 for rural IRFs, which we calculated by taking an average of the CCRs for all rural IRFs using their most recently submitted cost report data. Similarly, we proposed to estimate a national average CCR of 0.398 for urban IRFs, which we calculated by taking an average of the CCRs for all urban IRFs using their most recently submitted cost report data. We apply weights to both of these averages using the IRFs' estimated costs, meaning that the CCRs of IRFs with higher total costs factor more heavily into the averages than the CCRs of IRFs with lower total costs. For this final rule, we have used the most recent available cost report data (FY 2021). This includes all IRFs whose cost reporting periods begin on or after October 1, 2020, and before October 1, 2021. If, for any IRF, the FY 2021 cost report was missing or had an "as submitted" status, we used data from a previous FY's (that is, FY 2004 through FY 2020) settled cost report

for that IRF. We do not use cost report data from before FY 2004 for any IRF because changes in IRF utilization since FY 2004 resulting from the 60 percent rule and IRF medical review activities suggest that these older data do not adequately reflect the current cost of care. Using updated FY 2021 cost report data for this final rule, we estimate a national average CCR of 0.491 for rural IRFs, and a national average CCR of 0.402 for urban IRFs.

In accordance with past practice, we proposed to set the national CCR ceiling at 3 standard deviations above the mean CCR. Using this method, we proposed a national CCR ceiling of 1.45 for FY 2024. This means that, if an individual IRF's CCR were to exceed this ceiling of 1.45 for FY 2024, we will replace the IRF's CCR with the appropriate proposed national average CCR (either rural or urban, depending on the geographic location of the IRF). We calculated the proposed national CCR ceiling by:

Step 1. Taking the national average CCR (weighted by each IRF's total costs, as previously discussed) of all IRFs for which we have sufficient cost report data (both rural and urban IRFs combined).

Step 2. Estimating the standard deviation of the national average CCR computed in step 1.

Step 3. Multiplying the standard deviation of the national average CCR computed in step 2 by a factor of 3 to compute a statistically significant reliable ceiling.

Step 4. Adding the result from step 3 to the national average CCR of all IRFs for which we have sufficient cost report data, from step 1.

We also proposed that if more recent data become available after the publication of this proposed rule and before the publication of the final rule, we would use such data to determine the FY 2024 national average rural and urban CCRs and the national CCR ceiling in the final rule. Using the updated FY 2021 cost report data for this final rule, we estimate a national average CCR ceiling of 1.48, using the same methodology.

We invited public comment on the proposed update to the IRF CCR ceiling and the

urban/rural averages for FY 2024.

We did not receive any comments on the proposed revisions to the IRF CCR ceiling and the urban/rural averages for FY 2024. Consistent with the methodology outlined in the proposed rule, and using the most recent cost report data, we are finalizing a national average urban CCR at 0.402, the national average rural CCR at 0.491, and the national average CCR ceiling at 1.48 for FY 2024.

VIII. Modification to the Regulation for Excluded Inpatient Rehabilitation Facility Units Paid Under the IRF PPS

A. Background

Under current regulation, to be excluded from the IPPS, and to be paid under the IRF PPS or the IPF PPS, an IRF or IPF unit of a hospital must meet a number of requirements under § 412.25. Both this regulation and the policies applying to excluded units (which include excluded IRF units and excluded IPF units) have been in effect since before both the IRF PPS and IPF PPS were established, as discussed in the following paragraphs of this section. Before the IRF PPS and the IPF PPS were established, excluded units were paid based on their costs, as reported on their Medicare cost reports, subject to certain facility-specific cost limits. These cost-based payments were determined separately for operating and capital costs. Thus, under cost-based payments, the process of allocating costs to an IRF or IPF unit for reimbursement created significant administrative complexity. This administrative complexity necessitated strict regulations that allowed hospitals to open a new IPPS-excluded unit only at the start of a cost reporting period.

In the January 3, 1984, final rule (49 FR 235), CMS (then known as the Health Care Financing Administration) established policies and regulations for hospitals and units subject to and excluded from the IPPS. In that rule, we explained that section 1886(d) of the Act requires that the prospective payment system apply to inpatient hospital services furnished by all hospitals participating in the Medicare program except those hospitals or units specifically

excluded by the law. We further explained our expectation that a hospital's status (that is, whether it is subject to, or excluded from, the prospective payment system) would generally be determined at the beginning of each cost reporting period. We also stated that this status would continue throughout the period, which is normally 1 year. Accordingly, we stated that changes in a hospital's (or unit's) status that result from meeting or failing to meet the criteria for exclusion would be implemented only at the start of a cost reporting period. However, we also acknowledged that under some circumstances involving factors external to the hospital, status changes could be made at times other than the beginning of the cost reporting period. For example, a change in status could occur if a hospital is first included under the prospective payment system and, after the start of its cost reporting period, is excluded because of its participation in an approved demonstration project or State reimbursement control program that begins after the hospital's cost reporting period has begun.

In the FY 1993 IPPS final rule (57 FR 39798 through 39799), we codified our longstanding policies regarding when a hospital unit can change its status from not excluded to excluded. We explained in that final rule that since the inception of the prospective payment system for operating costs of hospital inpatient services in October 1983, certain types of specialty-care hospitals and hospital units have been excluded from that system under section 1888(d)(1)(B) of the Act. We noted that these currently include psychiatric and rehabilitation hospitals and distinct part units, children's hospitals, and long-term care hospitals. We further explained that section 6004(a)(1) of the Omnibus Budget Reconciliation Act of 1989, (Pub. L. 101-239, enacted December 19, 1989) amended section 1886(d)(1)(B) of the Act to provide that certain cancer hospitals are also excluded. We noted that the preamble to the January 3, 1984 final rule implementing the prospective payment system for operating costs (49 FR 235) stated that the status of a hospital or unit (that is, whether it is subject to, or excluded from, the prospective payment system) will be determined at the beginning of each cost reporting period. We noted that that same 1984 final rule also provided that changes in a

hospital's or unit's status that result from meeting or failing to meet the criteria for exclusion will be implemented prospectively only at the start of a cost reporting period, that is, starting with the beginning date of the next cost reporting period (49 FR 243). However, we noted that this policy was not set forth in the regulations. In the FY 1993 final rule, we stated that we proposed revising §§ 412.22 and 412.25 to specify that changes in the status of each hospital or hospital unit would be recognized only at the start of a cost reporting period. We stated that except in the case of retroactive payment adjustments for excluded rehabilitation units described in § 412.30(c), any change in a hospital's or unit's compliance with the exclusion criteria that occurs after the start of a cost reporting period would not be considered until the start of the following period. We noted that this policy would also apply to any unit that is added to a hospital during the hospital's cost reporting period. We also stated that we proposed revising § 412.25(a) to specify that as a requirement for exclusion, a hospital unit must be fully equipped and staffed, and be capable of providing inpatient psychiatric or rehabilitation care, as of the first day of the first cost reporting period for which all other exclusion requirements are met. We explained that a unit that meets this requirement would be considered open regardless of whether there are any inpatients in the unit.

In the same FY 1993 IPPS final rule, we responded to commenters who objected to this policy, stating that it unnecessarily penalizes hospitals for factors beyond their control, such as construction delays, that it discourages hospitals from making changes in their programs to meet community needs, or that it can place undue workload demands on regulatory agencies during certain time periods. In response, we explained that we believed that regulatory agencies, hospitals, and the public generally would benefit from policies that are clearly stated, can be easily understood by both hospitals and intermediaries, and can be simply administered. We stated that recognizing changes in status only at the beginning of cost reporting periods is consistent with these goals, while recognizing changes in the middle of cost reporting periods would introduce added complexity to the administration of the exclusion provisions. Therefore,

we did not revise the proposed changes based on these comments.

In the FY 2000 IPPS final rule (64 FR 41531 through 41532), we amended the regulations at § 412.25(c) to allow a hospital unit to change from excluded to not excluded at any time during the cost reporting period. We explained the statutory basis and rationale for this change in the FY 2000 IPPS proposed rule (64 FR 24740), and noted that a number of hospitals suggested that we consider a change in our policy to recognize, for purposes of exclusion from the IPPS, reductions in number of beds in, or entire closure of, units at any time during a cost reporting period. In that FY 2000 IPPS proposed rule, we explained that hospitals indicated that the bed capacity made available as a result of these changes could be used, as they need them, to provide additional services to meet patient needs in the acute care part of the hospital that is paid under the IPPS. We further explained that we evaluated the concerns of the hospitals and the effect on the administration of the Medicare program and the health care of beneficiaries of making these payment changes. As a result of that evaluation, we stated that we believed it was reasonable to adopt a more flexible policy in recognition of hospitals' changes in the use of their facilities. However, we noted that whenever a hospital establishes an excluded unit within the hospital, our Medicare fiscal intermediary would need to be able to determine costs of the unit separately from costs of the part of the hospital paid under the prospective payment system. At that time, we stated that the proper determination of costs ensured that the hospital was paid the correct amount for services in each part of the facility, and that payments under the IPPS did not duplicate payments made under the rules that were applicable to excluded hospitals and units, or vice versa. For this reason, we stated that we did not believe it would be appropriate to recognize, for purposes of exclusion from the IPPS, changes in the bed size or status of an excluded unit that are so frequent that they interfere with the ability of the intermediary to accurately determine costs. Moreover, we explained that section 1886(d)(1)(B) of the Act authorizes exclusion from the IPPS of specific types of hospitals and units, but not of specific admissions or stays, such as admissions for rehabilitation or psychiatric care, in a hospital paid

under the IPPS. We stated that without limits on the frequency of changes in excluded units for purposes of proper Medicare payment, there was the potential for some hospitals to adjust the status or size of their excluded units so frequently that the units would no longer be distinct entities and the exclusion would effectively apply only to certain types of care.

In the FY 2012 IRF PPS final rule (76 FR 47870), we began further efforts to increase flexibilities for excluded IPF and IRF units. In that rule, we explained that cost-based reimbursement methodologies that were in place before the IPF PPS and IRF PPS meant that the facilities' capital costs were determined, in part, by their bed size and square footage. Changes in the bed size and square footage would complicate the facilities' capital cost allocation. Thus, the regulations at § 412.25 limited the situations under which an IRF or IPF could change its bed size and square footage. In the FY 2012 IRF PPS final rule, we revised § 412.25(b) to enable IRFs and IPFs to more easily adjust to beneficiary changes in demand for IRF or IPF services and improve beneficiary access to these services. We believed that the first requirement (that beds can only be added at the start of a cost reporting period) was difficult, and potentially costly, for IRFs and IPFs that were expanding through new construction because the exact timing of the end of a construction project is often difficult to predict.

In that same FY 2012 IRF PPS final rule, commenters suggested that CMS allow new IRF units or new IPF units to open and begin being paid under their respective IRF PPS or IPF PPS at any time during a cost reporting period, rather than requiring that they could only begin being paid under the IRF PPS or the IPF PPS at the start of a cost reporting period. In response, we stated that we believed that this suggestion was outside the scope of the FY 2012 IRF PPS proposed rule (76 FR 24214) because we did not propose any changes to the regulations in § 412.25(c). However, we stated that we would consider this suggestion for possible inclusion in future rulemaking. Within the FY 2018 IRF PPS proposed rule (82 FR 20690, 20742 through 20743), CMS published a request for information (RFI) on ways to reduce burden for hospitals, physicians, and patients; improve the quality of care; decrease costs; and ensure that patients and

their providers and physicians are making the best health care choices possible. In response to the RFI, we received comments from IRF industry associations, State and national hospital associations, industry groups representing hospitals, and individual IRF providers. One of the comments we received in response to the RFI suggested allowing new IRF units to become excluded and be paid under the IRF PPS at any time during the cost reporting period, rather than only at the start of a cost reporting period, which the commenter believed would increase flexibility and eliminate a policy that may impose higher costs for providers while harmonizing an IRF payment system versus the IPPS payment system across all new IRF units.

B. Current Challenges Related to Excluded Hospital Units (§ 412.25(c)(1) and (c)(2))

Currently, under § 412.25(c)(1), a hospital can only start being paid under the IRF PPS or the IPF PPS for services provided in an excluded unit at the start of a cost reporting period. Specifically, § 412.25(c) limits when the status of hospital units may change for purposes of exclusion from the IPPS, as specified in § 412.25(c)(1) and § 412.25(c)(2). Section 412.25(c)(1) states that the status of a hospital unit may be changed from not excluded to excluded only at the start of the cost reporting period. If a unit is added to a hospital after the start of a cost reporting period, it cannot be excluded from the IPPS before the start of a hospital's next cost reporting period. Under § 412.25(c)(2), the status of a hospital unit may be changed from excluded to not excluded at any time during a cost reporting period, but only if the hospital notifies the fiscal intermediary and the CMS Regional Office in writing of the change at least 30 days before the date of the change, and maintains the information needed to accurately determine costs that are or are not attributable to the excluded unit. A change in the status of a unit from excluded to not excluded that is made during a cost reporting period must remain in effect for the rest of that cost reporting period.

In recent years, interested parties, such as hospitals, have written to CMS to express concerns about what they see as the unnecessary restrictiveness of the requirements of § 412.25(c). Based on this feedback, we continued to explore opportunities to reduce burden for

providers and clinicians, while keeping patient-centered care a priority. For instance, we considered whether this regulation might create unnecessary burden for hospitals and could potentially delay necessary rehabilitation beds from opening and being paid under the IRF PPS. As we continued to review and reconsider regulations to identify ways to improve policy, we recognized that the requirement at § 412.25(c)(1) that hospital units can only be excluded at the start of a cost reporting period, may be challenging to meet and potentially costly for facilities under some circumstances, for example, those that are expanding through new construction. Hospitals have indicated it is often difficult to predict the exact timing of the end of a construction project and construction delays may hamper a hospital's ability to have the construction of an excluded unit completed exactly at the start of a cost reporting period, which hospitals stated can lead to significant revenue loss if they are unable to be paid under the IRF PPS or IPF PPS until the start of the next cost reporting period.

As discussed, the requirements of § 412.25(c) were established to manage the administrative complexity associated with cost-based reimbursement for excluded IRF and IPF units. Today, however, because IRF units are paid under the IRF PPS, and IPF units are paid under the IPF PPS, cost allocation is not used for payment purposes. Because advancements in technology since the inception of the IRF PPS and IPF PPS have simplified the cost reporting process and enhanced communication between providers, CMS, and Medicare contractors, we are reconsidering whether it is necessary to continue to allow hospital units to become excluded only at the start of a cost reporting period.

C. Changes to Excluded Hospital Units (§ 412.25(c)(1) and (c)(2))

We are committed to continuing to transform the health care delivery system—and the Medicare program—by putting additional focus on patient-centered care and working with providers, physicians, and patients to improve outcomes, while meeting relevant health care priorities and reducing burden.

In response to the need for availability of inpatient rehabilitation beds we are finalizing

changes to § 412.25(c) to allow greater flexibility for hospitals to open excluded units, while minimizing the amount of effort Medicare contractors would need to spend administering the regulatory requirements. Although we are cognizant that there is a need for rehabilitative health services and support for providers along a continuum of care, including a robust investment in community-based rehabilitative services, this rule is focused on inpatient rehabilitation facility settings.

We note that § 412.25(c) applies to both IRFs and IPFs; therefore, revisions to § 412.25(c) will also affect IPFs in similar ways. Readers should refer to the FY 2024 IPF PPS final rule for discussion of revisions to § 412.25(c) and unique considerations applicable to IPF units.

As discussed, the current requirements of § 412.25(c)(1) were originally established to manage the administrative complexity associated with cost-based reimbursement for excluded IPF and IRF units. Because IPF and IRF units are no longer paid under cost-based reimbursement, but rather under the IPF PPS and IRF PPS respectively, we believe that the restriction that limits an IPF or IRF unit to being excluded only at the start of a cost reporting period is no longer necessary.

We amended our regulations in the FY 2012 IRF PPS final rule to address a regulation that similarly was previously necessary for cost-based reimbursement, but was not material to payment under the IRF PPS and IPF PPS. In that final rule, we explained that under cost-based payments, the facilities' capital costs were determined, in part, by their bed size and square footage. Changes in the bed size and square footage would complicate the facilities' capital cost allocation. We explained that under the IRF PPS and IPF PPS, however, a facility's bed size and square footage were not relevant for determining the individual facility's Medicare payment. Therefore, we believed it was appropriate to modify some of the restrictions on a facility's ability to change its bed size and square footage. Accordingly, we relaxed the restrictions on a facility's ability to increase its bed size and square footage. Under the revised requirements that we

adopted in the FY 2012 IRF PPS final rule in § 412.25(b), an IRF or IPF can change (either increase or decrease) its bed size or square footage one time at any point in a given cost reporting period as long as it notifies the CMS Regional Office at least 30 days before the date of the proposed change, and maintains the information needed to accurately determine costs that are attributable to the excluded units.

Similarly, in the case of the establishment of a new excluded IPF and IRF units, we do not believe that the timing of the establishment of the new unit is material for determining the individual facility's level of Medicare payment under the IRF PPS or IPF PPS. We believe it would be appropriate to allow a unit to become excluded at any time in the cost reporting year. However, we also believe it is important to minimize the potential administrative complexity associated with units changing their excluded status.

Accordingly, we amend the requirements currently in regulation at § 412.25(c)(1) to allow a hospital to open a new IRF unit anytime within the cost reporting year, as long as the hospital notifies the CMS Regional Office and Medicare Administrative Contractor (MAC) in writing of the change at least 30 days before the date of the change. Additionally, if a unit becomes excluded during a cost reporting year, this change would remain in effect for the rest of that cost reporting year. We maintain the current requirements of § 412.25(c)(2), which specify that, if an excluded unit becomes not excluded during a cost reporting year, the hospital must notify the MAC and the CMS Regional Office in writing of the change at least 30 days before the change, and this change would remain in effect for the rest of that cost reporting year. Finally, we consolidate the requirements for § 412.25(c)(1) and § 412.25(c)(2) into a new § 412.25(c)(1) that would apply to IRF units and specify the requirements for an IRF unit to become excluded or not excluded.

We believe this will provide IRFs greater flexibility when establishing an excluded unit at a time other than the start of a cost reporting period.

As noted, we proposed an identical policy for inpatient psychiatric units of hospitals in § 412.25(c)(2) in the FY 2024 IPF PPS proposed rule.

We proposed discrete regulation text for each of the hospital unit types (that is, IRF units and IPF units) to solicit comment on issues that might affect one hospital unit type and not the other. However, we stated that we may consider adopting one consolidated regulation text for both IRF and IPF units in either the IRF or IPF final rules for both unit types if we finalize both of our proposals. We requested public comments on finalizing a consolidated provision that would pertain to both IRF and IPF units.

The following is a summary of the public comments received on finalizing a consolidated provision that would pertain to both IRF and IPF units and our responses.

Comment: Commenters expressed broad support for the revision to the excluded hospital unit regulation at § 412.25(c). Many commenters stated that amending the excluded unit regulation improves access to critical rehabilitative services. One commenter appreciated CMS' recognition that the prior policy at § 412.25(c) created burden and complexity when attempting to open a new IRF unit amid construction, State agencies and certificate of need constraints, sometimes resulting in missing the start of the new cost reporting period.

Response: We appreciate the commenters' support of the modification to the excluded unit regulation allowing the opening of a new IRF unit to occur at any time during the cost reporting period. We agree with the commenters that the proposed amendments to § 412.25(c) will reduce burden and complexity and make it easier to open a new IRF unit.

After consideration of the comments we received, we are finalizing the consolidated provision that pertains to both IRF and IPF units. The amendments to § 412.25(c) for this consolidated provision will be finalized in the IPF final rule published elsewhere in this issue of the **Federal Register**.

IX. Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP)

A. Background and Statutory Authority

The Inpatient Rehabilitation Facility Quality Reporting Program (IRF QRP) is authorized by section 1886(j)(7) of the Act, and it applies to freestanding IRFs, as well as inpatient rehabilitation units of hospitals or Critical Access Hospitals (CAHs) paid by Medicare under the IRF PPS. Section 1886(j)(7)(A)(i) of the Act requires the Secretary to reduce by 2 percentage points the annual increase factor for discharges occurring during a fiscal year (FY) for any IRF that does not submit data in accordance with the IRF QRP requirements set forth in subparagraphs (C) and (F) of section 1886(j)(7) of the Act. 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 of the Act, to solicit input from certain groups regarding the selection of quality and efficiency measures for the IRF QRP. We have codified our program requirements in our regulations at § 412.634.

In the FY 2024 IRF PPS proposed rule, we proposed to adopt two new measures, remove three existing measures, and modify one existing measure. Second, we sought information on principles we could use to select and prioritize IRF QRP quality measures in future years. Third, we provided an update on our efforts to close the health equity gap. Finally, we proposed to begin public reporting of four measures.

B. General Considerations Used for the Selection of Measures for the IRF QRP

For a detailed discussion of the considerations we use for the selection of IRF QRP quality, resource use, or other measures, we refer readers to the FY 2016 IRF PPS final rule (80 FR 47083 through 47084).

1. Quality Measures Currently Adopted for the FY 2024 IRF QRP

The IRF QRP currently has 18 measures for the FY 2024 IRF QRP, which are listed in Table 17. For a discussion of the factors used to evaluate whether a measure should be removed from the IRF QRP, we refer readers to § 412.634(b)(2).

TABLE 17: Quality Measures Currently Adopted for the FY 2024 IRF QRP

Short Name	Measure Name & Data Source
Inpatient Rehabilitation Facility – Patient Assessment Instrument (IRF-PAI) Assessment-Based Measures	
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)
Application of Functional Assessment	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	IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients
Discharge Mobility Score	IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients
Change in Self-Care	IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients
Discharge Self-Care Score	IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients
DRR	Drug Regimen Review Conducted With Follow-Up for Identified Issues–Post Acute Care (PAC) Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP)
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 Outcome Measure
CDI	National Healthcare Safety Network (NHSN) Facility-wide Inpatient Hospital-onset <i>Clostridium difficile</i> 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 IRF	Medicare Spending Per Beneficiary (MSPB)–Post Acute Care (PAC) IRF QRP
DTC	Discharge to Community–PAC IRF QRP
PPR 30 day	Potentially Preventable 30-Day Post-Discharge Readmission Measure for IRF QRP
PPR Within Stay	Potentially Preventable Within Stay Readmission Measure for IRFs

C. Overview of IRF QRP Quality Measure Proposals

In the FY 2024 IRF PPS proposed rule, we proposed to adopt two new measures, remove three existing measures, and modify one existing measure for the FY 2025 IRF QRP and the FY 2026 IRF QRP. Beginning with the FY 2025 IRF QRP we proposed to (1) modify the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) measure, (2) adopt the Discharge Function Score measure,¹⁸ which we specified under sections 1886(j)(7)(F) and 1899B(c)(1) of the Act, and (3) remove three current measures: (i) the Application of Percent of Long-Term Care Hospital (LTCH) Patients with an Admission and Discharge Functional Assessment and a

¹⁸ 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 Inpatient Rehabilitation Facilities (IRFs) Technical Report. <https://www.cms.gov/files/document/irf-discharge-function-score-technical-report-february-2023.pdf>.

Care Plan That Addresses Function measure, (ii) the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients measure, and (iii) the IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients measure.

We proposed to add one new measure beginning with the FY 2026 IRF QRP, the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date measure, which we are specifying under sections 1886(j)(7)(F) and 1899B(d)(1) of the Act.

1. IRF QRP Quality Measures Beginning with the FY 2025 IRF QRP

a. Modification of the COVID-19 Vaccination Coverage Among Healthcare Personnel (HCP) Measure Beginning with the FY 2025 IRF QRP

(1) Background

On January 31, 2020, the Secretary 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 “coronavirus disease 2019” (COVID-19).¹⁹ Subsequently, in the FY 2022 IRF PPS final rule (86 FR 42385 through 42396), we adopted the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP COVID-19 Vaccine) measure for the IRF QRP. The HCP COVID-19 Vaccine measure requires each IRF to submit data on the number of healthcare personnel (HCP) eligible to work in the IRF for at least one day during the reporting period, excluding persons with contraindications to the COVID-19 vaccine, who have received a complete vaccination course against SARS-CoV-2 (86 FR 42389 through 42396).

Since that time, COVID-19 has continued to spread domestically and around the world with more than 103.8 million cases and 1.1 million deaths in the United States as of March 21, 2023.²⁰ 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

¹⁹ U.S. Department of Health and Human Services, Office of the Assistant Secretary for Preparedness and Response. Determination that a Public Health Emergency Exists. January 31, 2020. <https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx>.

²⁰ Centers for Disease Control and Prevention. COVID Data Tracker. March 21, 2023. <https://covid.cdc.gov/covid-data-tracker/#datatracker-home>.

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, 2023.²¹ The Department of Health and Human Services (HHS) let the PHE expire on May 11, 2023. However, HHS stated that the public health response to COVID-19 remains a public health priority with a whole-of-government approach to combatting the virus, including through vaccination efforts.²²

In the FY 2022 IRF PPS final rule (86 FR 42386 through 42396) and in the Revised Guidance for Staff Vaccination Requirements,²³ we stated that 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 IRFs through quality measurement in order to protect healthcare workers, patients, and caregivers, and to help sustain the ability of IRFs to continue serving their communities after the PHE. At the time we issued the FY 2022 IRF PPS final rule where we adopted the HCP COVID-19 Vaccine measure, the Food and Drug Administration (FDA) had issued emergency use authorizations (EUAs) for COVID-19 vaccines manufactured by Pfizer-BioNTech,²⁴ Moderna,²⁵ and Janssen.²⁶ The populations for which all three vaccines were authorized at that time included individuals 18 years of age and older. Shortly following the publication of the FY 2022 IRF PPS final rule on August 23, 2021, the FDA issued an approval for the Pfizer-BioNTech vaccine, marketed as Comirnaty.²⁷ The FDA

²¹ U.S. Department of Health and Human Services. Office of the Assistant Secretary for Preparedness and Response. Renewal of Determination that a Public Health Emergency Exists. February 9, 2023.

<https://aspr.hhs.gov/legal/PHE/Pages/COVID19-9Feb2023.aspx>.

²² U.S. Department of Health and Human Services. Fact Sheet: COVID-19 Public Health Emergency Transition Roadmap. February 9, 2023. <https://www.hhs.gov/about/news/2023/02/09/fact-sheet-covid-19-public-health-emergency-transition-roadmap.html>.

²³ 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>.

²⁴ Food and Drug Administration. FDA Takes Key Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for First COVID-19 Vaccine. December 11, 2020. <https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fight-against-covid-19-issuing-emergency-use-authorization-first-covid-19>.

²⁵ Food and Drug Administration. FDA Takes Additional Action in Fight Against COVID-19 By Issuing Emergency Use Authorization for Second COVID-19 Vaccine. December 18, 2020. <https://www.fda.gov/news-events/press-announcements/fda-takes-additional-action-fight-against-covid-19-issuing-emergency-use-authorization-second-covid>.

²⁶ Food and Drug Administration. FDA Issues Emergency Use Authorization for Third COVID-19 Vaccine. February 27, 2021. <https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-third-covid-19-vaccine>.

²⁷ Food and Drug Administration. FDA Approves First COVID-19 Vaccine. August 23, 2021. <https://www.fda.gov/news-events/press-announcements/fda-approves-first-covid-19-vaccine>.

issued approval for the Moderna vaccine, marketed as Spikevax, on January 31, 2022²⁸ and an EUA for the Novavax vaccine, on July 13, 2022.²⁹ The FDA also issued EUAs for single booster doses of the then authorized COVID-19 vaccines. As of November 19, 2021,^{30,31,32} 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 2022.³³ The FDA first authorized the use of a booster dose of bivalent or “updated” COVID-19 vaccines from Pfizer-BioNTech and Moderna in August 2022.³⁴

(a) Measure Importance

In the FY 2022 IRF PPS final rule (86 FR 42401), we acknowledged that we were still learning how effective the vaccines were against new variants of the virus that cause COVID-19. While the impact of COVID-19 vaccines on asymptomatic infection and transmission is not yet fully known, there are now robust data available across multiple populations on COVID-19 vaccine effectiveness against severe illness, hospitalization, and death. Two-dose COVID-19 vaccines from Pfizer-BioNTech and Moderna were found to be 88 percent and 93 percent effective against hospitalization for COVID-19, respectively, over 6 months for adults over age

²⁸ Food and Drug Administration. Coronavirus (COVID-19) Update: FDA Takes Key Action by Approving Second COVID-19 Vaccine. January 21, 2022. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine>.

²⁹ Food and Drug Administration. Coronavirus (COVID-19) Update: FDA Authorizes Emergency Use of Novavax COVID-19 Vaccine, Adjuvanted. July 13, 2022. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-emergency-use-novavax-covid-19-vaccine-adjuvanted>.

³⁰ Food and Drug Administration. FDA Authorizes Booster Dose of Pfizer-BioNTech COVID-19 Vaccine for Certain Populations. September 22, 2021. <https://www.fda.gov/news-events/press-announcements/fda-authorizes-booster-dose-pfizer-biontech-covid-19-vaccine-certain-populations>.

³¹ Food and Drug Administration. Coronavirus (COVID-19) Update: FDA Takes Additional Actions on the Use of a Booster Dose for COVID-19 Vaccines. October 20, 2021. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-additional-actions-use-booster-dose-covid-19-vaccines>.

³² Food and Drug Administration. Coronavirus (COVID-19) Update: FDA Expands Eligibility for COVID-19 Vaccine Boosters. November 19, 2021. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-expands-eligibility-covid-19-vaccine-boosters>.

³³ Food and Drug Administration. Coronavirus (COVID-19) Update: FDA Authorizes Second Booster Dose of Two COVID-19 Vaccines for Older and Immunocompromised Individuals. March 29, 2022. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-second-booster-dose-two-covid-19-vaccines-older-and>.

³⁴ 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. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use>.

18 without immunocompromising conditions.³⁵ 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.³⁶ Real-world studies of population-level vaccine effectiveness indicated similarly high rates of efficacy 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 2021.³⁷ Vaccines have also been highly effective in real-world conditions at preventing COVID-19 in HCP with up to 96 percent efficacy for fully vaccinated HCP, including those at risk for severe infection and those in racial and ethnic groups disproportionately affected by COVID-19.³⁸ Overall, data demonstrate that COVID-19 vaccines are effective and prevent severe disease, hospitalization, and death.

As SARS-CoV-2 persists and evolves, our COVID-19 vaccination strategy must remain responsive. When we adopted the HCP COVID-19 Vaccine measure in the FY 2022 IRF PPS final rule, we stated that the need for additional/booster doses of COVID-19 vaccines had not been established and no additional doses had been recommended (86 FR 42390). We also stated that we believed the numerator was sufficiently broad to include potential future additional/booster doses as part of a “complete vaccination course” and that the measure was sufficiently specified to address boosters (86 FR 42390). Since we adopted the HCP COVID-19 Vaccine measure in the FY 2022 IRF PPS final rule, new variants of SARS-CoV-2 have

³⁵ Self WH, Tenforde MW, Rhoads JP, et al. 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. *MMWR Morb Mortal Wkly Rep* 2021;70:1337-1343. doi: 10.15585/mmwr.mm7038e1.
https://cdc.gov/mmwr/volumes/70/wr/mm7038e1.htm?s_cid=mm7038e1_w.

³⁶ Scobie HM, Johnson AG, Suthar AB, et al. Monitoring Incidence of COVID-19 Cases, Hospitalizations, and Deaths, by Vaccination Status – 13 U.S. Jurisdictions, April 4-July 17, 2021. *MMWR Morb Mortal Wkly Rep* 2021;70:1284-1290. doi: 10.15585/mmwr.mm7037e1. <https://www.cdc.gov/mmwr/volumes/70/wr/mm7037e1.htm>.

³⁷ Fowlkes A, Gaglani M, Groover K, et al. 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. *MMWR Morb Mortal Wkly Rep* 2021;70:1167-1169. doi: 10.15585/mmwr.mm7034e4. <https://www.cdc.gov/mmwr/volumes/70/wr/mm7034e4.htm>.

³⁸ Pilishvili T, Gierke R, Fleming-Dutra KE, et al. Effectiveness of mRNA Covid-19 Vaccine among U.S. Health Care Personnel. *N Engl J Med*. 2021 Dec 16;385(25):e90. doi: 10.1056/NEJMoa2106599. PMID: 34551224; PMCID: PMC8482809. <https://pubmed.ncbi.nlm.nih.gov/34551224/>.

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 Centers for Disease Control and Prevention (CDC) because it spreads more easily than earlier variants.³⁹ 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.⁴⁰ 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 that are more than 6 months removed from receipt of their primary series.⁴¹ The FDA issued EUAs for booster doses of two bivalent COVID-19 vaccines, one from Pfizer-BioNTech⁴² and one from Moderna⁴³ 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.⁴⁴ COVID-19 booster doses are associated with a greater reduction in infections among HCP 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 HCP who received booster doses of the COVID-19 vaccine.^{45,46}

³⁹ Centers for Disease Control and Prevention. COVID-19: Variants. <https://www.cdc.gov/coronavirus/2019-ncov/variants/index.html>.

⁴⁰ Food and Drug Administration. COVID-19 Bivalent Vaccines. <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-bivalent-vaccines>.

⁴¹ Chalkias S, Harper C, Vrbicky K, et al. A Bivalent Omicron-Containing Booster Vaccine Against COVID-19. *N Engl J Med*. 2022 Oct 6;387(14):1279-1291. doi: 10.1056/NEJMoa2208343. PMID: 36112399; PMCID: PMC9511634.

⁴² Food and Drug Administration. Pfizer-BioNTech COVID-19 Vaccines. <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/pfizer-biontech-covid-19-vaccines>.

⁴³ Food and Drug Administration. Moderna COVID-19 Vaccines. <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/moderna-covid-19-vaccines>.

⁴⁴ Food and Drug Administration. Coronavirus (COVID-19) Update: FDA Authorizes Moderna, Pfizer-BioNTech Bivalent COVID-19 Vaccines for Use as a Booster Dose. August 31, 2022. <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-moderna-pfizer-biontech-bivalent-covid-19-vaccines-use>.

⁴⁵ Oster Y, Benenson S, Nir-Paz R, Buda I, Cohen MJ. 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. <https://pubmed.ncbi.nlm.nih.gov/35143997/>.

⁴⁶ Prasad N, Derado G, Acharya Nanduri S, et al. Effectiveness of a COVID-19 Additional Primary or Booster

We believe that vaccination remains the most effective means to prevent the severe consequences of COVID-19, including severe illness, hospitalization, and death. Given the availability of vaccine efficacy data, EUAs issued by the FDA for bivalent boosters, the continued presence of SARS-CoV-2 in the United States, and variance among rates of booster dose vaccination, it is important to update the specifications of the HCP COVID-19 Vaccine measure to refer to HCP who receive primary series and additional/booster doses in a timely manner. Given the persistent spread of COVID-19, we continue to believe that monitoring and surveillance of vaccination rates among HCP is important and provides patients, beneficiaries, and their caregivers with information to support informed decision making. We proposed to modify the HCP COVID-19 Vaccine measure to replace the term “complete vaccination course” with the term “up to date” in the HCP vaccination definition. We also proposed to update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID-19 vaccines, including additional/booster doses, beginning with the FY 2025 IRF QRP.

(b) Measure Testing

The CDC conducted beta testing of the proposed modified HCP COVID-19 Vaccine measure by assessing if the collection of information on additional/booster doses received by HCP was feasible, as information on receipt of additional/booster doses is required for determining if HCP are up to date with the current COVID-19 vaccination recommendations. Feasibility was assessed by calculating the proportion of facilities that reported additional/booster doses of the COVID-19 vaccine. The assessment was conducted in various facility types, including IRFs, using vaccine coverage data for the first quarter of calendar year (CY) 2022 (January - March), which was reported through the CDC’s National Healthcare Safety Network (NHSN). Feasibility of reporting additional/booster doses is evident by the fact

that 63.9 percent of IRFs reported vaccination additional/booster dose coverage data to the NHSN for the first quarter of 2022.⁴⁷ Additionally, HCP COVID-19 Vaccine measure scores calculated using January 1 - March 31, 2022 data had a median of 20.3 percent and an interquartile range of 8.9 to 37.7 percent, indicating a measure performance gap as there are clinically significant differences in additional/booster dose vaccination coverage rates among IRFs.⁴⁸

(2) Competing and Related Measures

Section 1886(j)(7)(D)(i) of the Act and section 1899B(e)(2)(A) of the Act require that, absent an exception under section 1886(j)(7)(D)(i) and section 1899B(e)(2)(B) of the Act, measures specified under section 1899B of the Act must 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 1886(j)(7)(D)(i) of the Act and section 1899B(e)(2)(B) of the Act permit 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 current version of the HCP COVID-19 Vaccine measure recently received endorsement by the CBE on July 26, 2022 under the name “Quarterly Reporting of COVID-19 Vaccination Coverage Among Healthcare Personnel.”⁴⁹ However, this measure received endorsement based on its specifications depicted in the FY 2022 IRF PPS final rule (86 FR 42386 through 42396) and does not capture information about whether HCP are up to date with their COVID-19 vaccinations. The proposed modification of this measure utilizes the term up to date in the HCP vaccination definition and updates the numerator to specify the time frames

⁴⁷ National Quality Forum. Measure Applications Partnership (MAP) Post-Acute Care/Long-Term Care: 2022-2023 Measures Under Consideration (MUC) Cycle Measure Specifications. December 1, 2022. <https://mmshub.cms.gov/sites/default/files/map-pac-muc-measure-specifications-2022-2023.pdf>.

⁴⁸ National Quality Forum. Measure Applications Partnership (MAP) Post-Acute Care/Long-Term Care: 2022-2023 Measures Under Consideration (MUC) Cycle Measure Specifications. December 1, 2022. <https://mmshub.cms.gov/sites/default/files/map-pac-muc-measure-specifications-2022-2023.pdf>.

⁴⁹ Partnership for Quality Measurement. Quarterly Reporting of COVID-19 Vaccination Coverage among Healthcare Personnel. July 26, 2022. <https://p4qm.org/measures/3636>.

within which an HCP is considered up to date with recommended COVID-19 vaccines. We were unable to identify any measures endorsed or adopted by a consensus organization for IRFs that captured information on whether HCP are up to date with their COVID-19 vaccinations, and we found no other feasible and practical measure on this topic.

Therefore, after consideration of other available measures, we found that the exception under sections 1886(j)(7)(D)(ii) and 1899B(e)(2)(B) of the Act applies and proposed the modified measure, HCP COVID-19 Vaccine beginning with the FY 2025 IRF QRP. The CDC, the measure developer, is pursuing CBE endorsement for the modified version of the measure and is considering an expedited review process as the current version of the measure has already received endorsement.

(3) Measure Applications Partnership (MAP) Review

We refer readers to the FY 2022 IRF PPS final rule (86 FR 42387 through 42388) for more information on the initial review of the HCP COVID-19 Vaccine measure by the Measure Applications Partnership (MAP).

The 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 the Medicare program, including our quality reporting programs. This allows interested parties to provide recommendations to the Secretary on the measures included on the list. We included an updated version of the HCP COVID-19 Vaccine measure on the MUC List, entitled “List of Measures under Consideration for December 1, 2022”⁵⁰ for the 2022-2023 pre-rulemaking cycle for consideration by the MAP. Interested parties submitted three comments during the pre-rulemaking process on the proposed modifications of the HCP COVID-19 Vaccine measure, and support was mixed. One commenter noted the importance for HCP to be vaccinated against COVID-19 and supported measurement and reporting as an

⁵⁰ Centers for Medicare & Medicaid Services. Overview of the List of Measures Under Consideration for December 1, 2022. CMS.gov. <https://mmshub.cms.gov/sites/default/files/2022-MUC-List-Overview.pdf>.

important strategy to help healthcare organizations assess their performance in achieving high rates of up to date vaccination of their HCP, while also noting that the measure would provide valuable information to the government as part of its ongoing response to the pandemic. This commenter also recommended the measure be used for internal quality improvement purposes rather than being publicly reported on Care Compare. Finally, this commenter also suggested that the measure should be stratified by social risk factors. However, two commenters supported less specific criteria for denominator and numerator inclusion. Specifically, one such commenter did not support the inclusion of unpaid volunteers in the measure denominator and found the measure's denominator to be unclear. Two commenters expressed concerns regarding burden of data collection, data lag, staffing challenges, and reportedly "high rates of providers contesting penalties tied to the existing HCP COVID-19 Vaccine measure adopted in the FY 2022 IRF PPS final rule." One commenter recommended that the measure be recharacterized as a surveillance measure given what they referred to as a tenuous relationship between collected data and quality of care provided by IRFs. Finally, all three commenters raised concern about the difficulty of defining up to date for purposes of the measure.

Shortly after publication of the MUC List, several MAP workgroups met to provide input on the modification we proposed for the current HCP COVID-19 Vaccine measure. First, the MAP Health Equity Advisory Group convened on December 6-7, 2022. The MAP Health Equity Advisory Group questioned whether the measure excludes patients with contraindications to FDA authorized or approved COVID-19 vaccines, and whether the measure will be stratified by demographic factors. The measure developer (that is, the CDC) confirmed that HCP with contraindications to the vaccines are excluded from the measure denominator and responded that the measure will not be stratified by demographic factors since the data are submitted at an aggregate rather than an individual level.

The MAP Rural Health Advisory Group met on December 8-9, 2022, during which a few members expressed concerns about data collection burden, given that small rural hospitals may

not have employee health software. The measure developer acknowledged the challenge of getting adequate documentation and emphasized their goal is to ensure the measures do not present a burden on the provider. The measure developer also noted that the model used for the HCP COVID-19 Vaccine measure is based on the Influenza Vaccination Coverage among HCP measure (CBE #0431), and it intends to utilize a similar approach to the modified HCP COVID-19 Vaccine measure if vaccination strategy becomes seasonal. The measure developer acknowledged that if COVID-19 becomes seasonal, the measure model could evolve to capture seasonal vaccination.

Next, the MAP Post-Acute Care/Long-Term Care (PAC/LTC) workgroup met on December 12, 2022, and provided input on the modification we proposed for the HCP COVID-19 Vaccine measure. The MAP PAC/LTC workgroup noted that the previous version of the measure received endorsement from the CBE (CBE #3636),⁵¹ and that the CDC intends to submit the updated measure for endorsement. The PAC/LTC workgroup voted to support the staff recommendation of conditional support for rulemaking pending testing indicating the measure is reliable and valid, and endorsement by the CBE.

Following the PAC/LTC workgroup meeting, a public comment period was held in which interested parties commented on the PAC/LTC workgroup's preliminary recommendations, and the MAP received three comments. Two supported the proposed modification of the HCP COVID-19 Vaccine measure, one of which strongly supported the vaccination of HCP against COVID-19. Although these commenters supported the measure, one commenter recommended seeking CBE⁵² endorsement for the updated measure and encouraged CMS to monitor any unintended consequences from the measure. Two commenters raised concerns with the measure's specifications. Specifically, one noted the denominator included a

⁵¹ Partnership for Quality Measurement. Quarterly Reporting of COVID-19 Vaccination Coverage among Healthcare Personnel. July 26, 2022. <https://p4qm.org/measures/3636>.

⁵² We emphasize that any references to NQF in the proposed rule were intended to refer to the CBE contracted by CMS at that time.

broad number of HCP, and another recommended a vaccination exclusion or exception for sincerely held religious beliefs. Finally, one commenter raised issues related to the time lag between data collection and public reporting on Care Compare and encouraged CMS to provide information as to whether the measure is reflecting vaccination rates accurately and encouraging HCP vaccination.

The MAP Coordinating Committee convened on January 24-25, 2023, during which the proposed measure was placed on the consent calendar and received a final recommendation of conditional support for rulemaking pending testing indicating the measure is reliable and valid, and endorsement by the CBE. We refer readers to the final MAP recommendations, titled *2022-2023 MAP Final Recommendations*.⁵³

(4) Quality Measure Calculation

The HCP COVID-19 Vaccine measure is a process measure developed by the CDC to track COVID-19 vaccination coverage among HCP in facilities such as IRFs. The HCP COVID-19 Vaccine measure is a process measure and is not risk-adjusted.

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.⁵⁴ We believe it is necessary to allow IRFs to include all HCP within the facility in the reporting because all HCP would have access to and may interact with IRF patients. IRFs report the following four categories of HCP to NHSN; the first three are included in the measure denominator:

- 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.
- Licensed independent practitioners (LIPs): This includes physicians (MD, DO),

⁵³ ⁵³ Measure Applications Partnership. 2022-2023 MAP Final Recommendations. <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>.

⁵⁴ Centers for Disease Control and Prevention. Contraindications and precautions. <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications>.

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 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.

- 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.

- Other contract personnel: Contract personnel are defined as persons providing care, treatment, or services at the facility through a contract who do not fall into any of the above-mentioned 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 HCP COVID-19 Vaccine measure.

The denominator excludes denominator-eligible individuals with contraindications as defined by the CDC.⁵⁵ We did not propose any 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 would refer to the definition of up to date as of the first day of the quarter, which can be found at <https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf>. For the purposes of NHSN surveillance, individuals would have been considered up to date during the Quarter 4 CY 2022 reporting period (surveillance period September 26, 2022 - December 25, 2022) for the IRF QRP if they meet one of the following criteria in place at the time:

⁵⁵ Centers for Disease Control and Prevention. Contraindications and precautions. <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#contraindications>.

1. Individuals who received an updated bivalent⁵⁶ booster dose, or
- 2a. Individuals who received their last booster dose less than 2 months ago, or
- 2b. Individuals who completed their primary series⁵⁷ less than 2 months ago.

We refer readers to <https://www.cdc.gov/nhsn/pdfs/nqf/covid-vax-hcpccoverage-rev-2023-508.pdf> for more details on the measure specifications.⁵⁸

While we did not propose any changes to the data submission or reporting process for the HCP COVID-19 Vaccine measure, we proposed that for purposes of meeting FY 2025 IRF QRP compliance, IRFs would report HCP who are up to date beginning in quarter four of CY 2023. Under the data submission and reporting process, IRFs would collect the numerator and denominator for the modified HCP COVID-19 Vaccine measure for at least one self-selected week during each month of the reporting quarter. IRFs would submit the data to the NHSN Healthcare Personnel Safety (HPS) Component before the quarterly deadline. If an IRF submits more than 1 week of data in a month, the CDC would use the most recent week's data to calculate the measure. Each quarter, the CDC would calculate a single quarterly COVID-19 HCP vaccination coverage rate for each IRF, which would be calculated by taking the average of the data from the three weekly rates submitted by the IRF for that quarter. Beginning with the FY 2026 IRF QRP, we proposed that IRFs would be required to submit data for the entire calendar year.

We also proposed that public reporting of the modified version of the HCP COVID-19 Vaccine measure would begin by the September 2024 Care Compare refresh or as soon as technically feasible.

We invited public comment on our proposal to modify the HCP COVID-19 Vaccine

⁵⁶ The updated (bivalent) Moderna and Pfizer-BioNTech boosters target the most recent Omicron subvariants. The updated (bivalent) boosters were recommended by the CDC on September 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.

⁵⁷ 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.

⁵⁸ We highlight that the hyperlink included in the FY 2024 IRF PPS proposed rule has been retired as the CDC has uploaded a new measure specification document to the NHSN. Therefore, the hyperlink has been updated in this FY 2024 IRF PPS final rule.

measure beginning with the FY 2025 IRF QRP. The following is a summary of the comments we received on our proposal to modify the HCP COVID-19 Vaccine measure beginning with the FY 2025 IRF QRP and our responses.

Comment: Several commenters supported our proposal to modify the numerator definition for the HCP COVID-19 Vaccine measure and to update the numerator to specify the time frames within which an HCP is considered up to date with recommended COVID-19 vaccines. One of these commenters said they continue to believe COVID-19 vaccination among HCP in all healthcare settings is the most effective infection prevention tool to protect staff, patients, and visitors against severe illness, hospitalization, and death. Another one of these commenters stated they recognized that vaccinations play a critical role in the nation's strategy to counter the spread of COVID-19, but still encouraged CMS to continue to monitor the measure.

Response: We thank the commenters for their support. We agree that 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 IRFs, in order to protect HCP, patients, and caregivers, and to help sustain the ability of HCP in each of these care settings to continue serving their communities. We will continue to monitor all measures to identify any concerning trends as part of our routine monitoring activities to regularly assess measure performance, reliability, and reportability for all data submitted for the IRF QRP.

Comment: Several commenters were concerned that the measure has not undergone full reliability and validity testing, and they believe the CBE endorsement process will allow a full evaluation of a range of issues affecting measure reliability, accuracy, and feasibility. Two of these commenters, however, stated that the current version of the HCP COVID-19 Vaccine measure has not had a holistic evaluation to determine whether it is working as intended since it never went through a CBE endorsement process and is relatively new to the CMS quality reporting programs.

Response: We refer commenters to section IX.C.1.a.2. of this final rule where we point out that the current version of the HCP COVID-19 Vaccine measure received endorsement by the CBE on July 26, 2022, under the name “Quarterly Reporting of COVID-19 Vaccination Coverage among Healthcare Personnel.”⁵⁹ However, this measure received endorsement based on its specifications in the FY 2022 IRF PPS final rule (86 FR 42386 through 42396). Even though the current, endorsed version does not capture information about whether HCP are up to date with their COVID-19 vaccinations, we believe its endorsement speaks to the quality of the measure design as we proposed that many components of the measure remain intact in this modified version. Since we were unable to identify any CBE-endorsed measures for IRFs that captured information on whether HCP are up to date with their COVID-19 vaccinations, and we found no other feasible and practical measure on this topic, we find the modification to the HCP COVID-19 Vaccine measure reasonable for IRF QRP adoption and implementation. The CDC, the measure developer, is pursuing CBE endorsement for the modified version of the measure.

In terms of measure testing, as mentioned in section IX.C.1.a.1.b. of this final rule, we reiterate that the CDC conducted beta testing of the modified HCP COVID-19 Vaccine measure and concluded that the collection of information on additional/booster doses received by HCP was feasible with 63.9 percent of IRFs reported vaccination additional/booster dose coverage data to the NHSN for the first quarter of 2022. Additionally, the measure score displayed a performance gap indicating clinically significant differences in additional/booster dose vaccination coverage rates among IRFs. We will continue to monitor all our measures to identify any concerning trends as part of our routine monitoring activities to regularly assess measure performance, reliability, and reportability for all data submitted for the IRF QRP.

Comment: Several commenters opposed the proposed modifications to the HCP COVID-19 Vaccine measure. The most frequently cited reasons were that the COVID-19 PHE ended on

⁵⁹ Partnership for Quality Measurement. Quarterly Reporting of COVID-19 Vaccination Coverage among Healthcare Personnel. July 26, 2022. <https://p4qm.org/measures/3636>.

May 11, 2023, and subsequently CMS removed the staff vaccination requirement under the Hospital Conditions of Participation (CoP) at § 482.42(g) established by the Omnibus COVID-19 Health Care Staff Vaccination Interim Final Rule (86 FR 61555). Two of these commenters questioned why the HCP COVID-19 Vaccine measure would still be used as a metric for quality of care in the IRF QRP at the same time CMS is removing the requirement that covered providers and suppliers establish policies and procedures for staff vaccination for COVID-19 and removing the COVID-19 vaccination requirements from the hospital conditions of participation. One of these commenters suggested that if CMS plans to require providers report staff vaccination status, it would be more appropriate to implement the requirement through the CoPs rather than the IRF QRP. One of these commenters highlighted that facilities will no longer have any Federal authority to require staff to receive any COVID-19 vaccines and demand vaccination status from staff. One commenter suggested the proposed revision to the measure would be inconsistent with Federal and State mandates which require only a primary vaccination series, and since the PHE is ending, many (if not all) of these mandates are being lifted. They point out that the Federal and State mandates did not extend the HCP vaccination requirement to include the bivalent booster or any other booster. Given the Administration's announcement that the COVID-19 PHE has ended, they believe the need for HCP to be up to date with vaccinations will be diminished, and the benefit of this measure may be compromised.

Response: We appreciate the commenters' feedback, but disagree. We continue to believe that it is important to measure vaccination status regardless of whether the COVID-19 PHE is in effect. We also believe this measure continues to align with our goals to promote wellness and disease prevention. Under CMS' Meaningful Measures Framework 2.0, the HCP COVID-19 Vaccine measure addresses the quality priorities of "Immunizations" and "Public Health" through the Meaningful Measures Area of "Wellness and Prevention."⁶⁰ Under the

⁶⁰ Centers for Medicare & Medicaid Services. June 17, 2022. Meaningful Measures 2.0: Moving from Measure Reduction to Modernization. <https://www.cms.gov/medicare/meaningful-measures-framework/meaningful-measures-20-moving-measure-reduction-modernization>.

National Quality Strategy, the measure addresses the goal of Safety under the priority area Safety and Resiliency.⁶¹ While we removed vaccination requirements from the Hospital CoP at the end of the PHE as discussed previously, we note that the reporting requirements of the IRF QRP for the proposed modified version of the HCP COVID-19 Vaccine measure are distinct from those cited by the commenter. Specifically, the IRF QRP is a pay-for-reporting program, and therefore the inclusion of this measure does not require that HCP actually receive these additional/booster vaccine doses. The Administration's continued response to COVID-19 is not fully dependent on the emergency declaration for the COVID-19 PHE, and even beyond the end of the COVID-19 PHE, we will continue to work to protect individuals and communities from the virus and its worst impacts by supporting access to COVID-19 vaccines, treatments, and tests.⁶²

Comment: One commenter requested that CMS clarify whether the elimination of vaccine "mandates" will impact the adoption or use of the proposed HCP COVID-19 Vaccine measure.

Response: We clarify that the vaccination requirements under § 482.42(g) (which have now been lifted), are separate from IRF QRP requirements to report HCP COVID-19 vaccination data. Even though the PHE has ended and vaccination requirements have been lifted, CMS intends to encourage ongoing COVID-19 vaccination through use of its quality reporting programs (88 FR 36487). One way to encourage patient safety and COVID-19 vaccination is through adoption of the modified up to date numerator definition of the HCP COVID-19 Vaccine measure. Despite the White House's announcement,⁶³ the IRF QRP still requires data submission of the HCP COVID-19 Vaccine measure to the NHSN for IRFs to remain in

⁶¹ Centers for Medicare & Medicaid Services. May 1, 2023. CMS National Quality Strategy. <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/cms-quality-strategy>.

⁶² U.S. Department of Health and Human Services. May 9, 2023. Fact Sheet: End of the COVID-19 Public Health Emergency. <https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html#:~:text=That%20means%20with%20the%20COVID,the%20expiration%20of%20the%20PHE.>

⁶³ The White House. May 1, 2023. The Biden-Harris Administration Will End COVID-19 Vaccination Requirements for Federal Employees, Contractors, International Travelers, Head Start Educators, and CMS-Certified Facilities. <https://www.whitehouse.gov/briefing-room/statements-releases/2023/05/01/the-biden-administration-will-end-covid-19-vaccination-requirements-for-federal-employees-contractors-international-travelers-head-start-educators-and-cms-certified-facilities/>.

compliance with the IRF QRP. However, since the IRF QRP is a pay-for-reporting program, HCP COVID-19 vaccination is not mandated by this measure.

Comment: A number of commenters expressed concerns with the evolving nature of the measure's up to date numerator definition, and believe that the reliability and validity of the measure may be negatively impacted if the up to date definition were to change frequently. Several of these commenters raised concerns with the potential inaccuracy of the measure since the term up to date could be revised between reporting periods or in the middle of a reporting period. One of these commenters suggested the definition will quickly and frequently become outdated, and another commenter believes the science is still emerging and it is too soon to adopt a revised definition for the HCP COVID-19 vaccine. Finally, several commenters believed that the current specifications are flawed given the lack of a stable definition of the up to date numerator definition.

Response: We recognize that the up to date COVID-19 vaccination definition may evolve due to the changing nature of the virus. Since the adoption of the current version of the measure, the public health response to COVID-19 has necessarily adapted to respond to the changing nature of the virus's transmission and community spread. As mentioned in the FY 2022 IRF PPS final rule (86 FR 42362), we received several public comments during the current measure's pre-rulemaking process encouraging us to continue to update the measure as new evidence on COVID-19 continues to arise and we stated our intention to continue to work with partners including FDA and CDC to consider any updates to the measure in future rulemaking as appropriate. We believe that the proposed modification to this measure aligns with our responsive approach to COVID-19 and will continue to support vaccination as the most effective means to prevent the worst consequences of COVID-19, including severe illness, hospitalization, and death.

In response to the commenter's concerns that the up to date numerator definition may evolve, we refer commenters to section IX.C.1.a.4. of this final rule where we explained that

providers would refer to the definition of up to date as the first day of the quarter, which can be found at the following CDC NHSN webpage:

<https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf>. The CDC notes that this aforementioned document will be updated quarterly to reflect any changes as COVID-19 guidance evolves, and notes that providers should use the definitions for the reporting period associated with the reporting weeks included in data submission. At the beginning of each reporting period and before collecting or submitting data on this modified measure, IRFs must refer to the aforementioned document to determine the then-applicable definition of up to date to apply when collecting data on the vaccination status of HCP for that quarterly reporting period. As such, the up to date vaccination definition during a particular reporting period would not change, and each provider will be measured against the same criteria within the same quarter. If the requirements do change from one quarter to the next, IRFs would have the up to date definition at the beginning of the quarter (using the aforementioned CDC NHSN webpage) and have a minimum of 3 weeks to assess whether their HCP meet the definition of up to date before submitting HCP COVID-19 Vaccine measure data during the self-selected week of a corresponding month. We will continue to monitor all measures to identify any concerning trends as part of our routine monitoring activities to regularly assess measures performance, reliability, and reportability for all data submitted for the IRF QRP.

Comment: Several commenters also suggested that the proposed modification to the measure numerator would be administratively burdensome due to the time it will take to (1) stay abreast of the current definition of up to date and (2) track whether their HCP met that definition at a time when IRFs are dealing with workforce issues. One commenter stated that given the current workforce shortage, adding more requirements on the healthcare workforce and health care systems will only exacerbate the situation. Another commenter said that healthcare facilities that are currently voluntarily reporting data to the CDC using the new up to date definition find the collection process quite administratively burdensome. Many commenters

were concerned that frequent changes to the definition of up to date would increase administrative burden for IRFs because they would have to alter their data collection processes to ensure that they report the proper data on HCP vaccination.

Response: We appreciate commenters' concerns regarding the reporting of the measure, but disagree that the proposed up to date numerator definition for the HCP COVID-19 Vaccine measure may exacerbate workforce shortages. We believe that the risks associated with COVID-19 warrant direct attention, especially because HCP are working directly with, and in close proximity to, patients. IRFs have been reporting the current version of the measure since the measure's initial data submission period (October 1, 2021 through December 31, 2021), and we believe that there has been sufficient time to allocate the necessary resources required to report this measure. We note that for purposes of NHSN surveillance, the CDC used the up to date numerator definition during the Quarter 4 2022 surveillance period (September 26, 2022 through December 25, 2022) (88 FR 20905) and IRFs have been successfully reporting the measure in alignment with the proposed modifications.

The CDC provides frequent communications and education to support IRFs' understanding of the latest guidelines. CDC posts an updated document approximately 2 weeks before the start of a new reporting quarter. If there are any changes to the definition, forms, etc., CDC will host a webinar in the 1-2 weeks before the beginning of a new reporting quarter. If IRFs have any concerns they would like to address with CMS regarding the data submission of this measure, they can voice their concerns during CMS' Hospitals Open Door Forums (ODFs). For more information on ODFs and to sign up for email notifications, we refer readers to the following CMS webpage: https://www.cms.gov/outreach-and-education/outreach/opendoorforums/odf_hospitals.

Comment: One commenter questioned whether HCP without booster(s) would be mandated to get booster(s) if the proposed measure were adopted. Two commenters were concerned that because the proposed reporting requirements are inconsistent with internal, State,

and Federal policies for vaccination, it will lead to inaccurate reporting.

Response: The current HCP COVID-19 Vaccine measure in the IRF QRP does not require HCP to receive a COVID-19 vaccine and the proposed modification to the measure numerator definition would not mandate HCP to receive an additional/booster dose under the up to date definition for this measure. It is an IRF's responsibility to determine its own personnel policies. The HCP COVID-19 Vaccine measure only requires reporting of vaccination rates for an IRF to successfully participate in the IRF QRP. As we have described previously, the CDC posts an updated document approximately 2 weeks before the start of a new reporting quarter. If there are any changes to the definition, forms, etc., CDC will host a webinar in the 1-2 weeks before the beginning of a new reporting quarter. It is the IRF's responsibility to accurately report vaccination status of HCP in accordance with this measure's specifications.

Comment: One commenter noted that the CDC's vaccination guidance suggests that some individuals with certain risk factors should consider receiving an additional booster dose within four months of receiving their first bivalent dose. Yet, the commenter noted that IRFs usually do not have routine access to data to know which of their HCP may need an additional booster. The commenter was concerned that, in order to collect accurate data, IRFs would have to obtain permission to inquire and attain information on each individual HCP's underlying health risk factors and a mechanism to keep the data fully secure. As a result, they express concern that the resource intensiveness of collecting data under the CDC's current definitions for the HCP COVID-19 Vaccine measure may outweigh its value.

Response: IRFs have been engaging with their staff since October 1, 2022 when the data collection for the HCP COVID-19 Vaccine measure began. This proposed modification to the HCP COVID-19 Vaccine measure should not require any changes to how IRFs currently engage with their staff and administer a comprehensive vaccine administration strategy. Specifically, we note that considerations for individuals with certain risk factors, such as those who are immunocompromised, are not impacted by the modification proposed to this measure as these

considerations are present with the primary vaccination series for the current HCP COVID-19 Vaccine measure. As emphasized in the CDC NHSN “COVID-19 Vaccination Modules: Understanding Key Terms and Up to Date Vaccination” webpage <https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf> referred to in section IX.C.1.a.4. of this final rule, the NHSN surveillance definition for up to date is currently the same for all HCP regardless of immunocompromised status.

Comment: One commenter acknowledged that even though the proposed modification to this measure does not mandate HCP become up to date with their COVID-19 vaccine, it may affect how providers approach vaccination requirements for their workforce. They are concerned that entry-level workers will choose to work in other areas of commerce without similar COVID-19 vaccination requirements.

Response: We clarify that the HCP COVID-19 Vaccine measure does not require providers to adopt mandatory vaccination policies, and note that it is an IRFs’ responsibility to determine its own personnel policies. The proposed modified HCP COVID-19 Vaccine measure would only require reporting of HCP vaccination rates, which would then be publicly reported on CMS’ Care Compare website. We believe that the risks associated with COVID-19 warrant direct attention, especially because HCP are working directly with, and in close proximity to, patients. To support a comprehensive vaccine administration strategy, we encourage IRFs to voluntarily engage in the provision of appropriate and accessible education and vaccine-offering activities. Many IRFs across the country are educating staff, patients, and patients’ representatives, participating in vaccine distribution programs, and voluntarily reporting up to date vaccine administration.

Comment: One commenter questioned whether the measure would be a comparison of the number of HCP with a primary series only and the number of HCP with a primary series and booster doses.

Response: We interpret the commenter’s response as asking whether the measure would

compare an IRF's HCP's primary series vaccination rate to an IRF's performance on the modified version of the HCP COVID-19 Vaccine measure. The modification to the HCP COVID-19 Vaccine measure does not make a comparison between the two HCP groups. Rather, the measure assesses the ratio between the number of HCP who are considered up to date on their COVID-19 vaccinations with the total number of HCP eligible to work in the facility for at least one day during the reporting period.

Comment: Several commenters did not support the HCP COVID-19 quality measure since it does not exclude HCP who choose not to receive up to date vaccinations due to personal or religious beliefs. Four of these commenters suggested we align the measure's exclusion criteria with the Hospital Conditions of Participation (CoPs) requirement from the interim final rule "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination" (86 FR 61555), which allowed exclusions for religious exemptions.⁶⁴ One of these commenters recommended that CMS develop an additional exclusion for this measure to account for sincerely held religious beliefs in order to align with Office of Civil Rights guidance.

Additionally, one commenter noted that even though the current version of the HCP COVID-19 Vaccine measure excludes persons with medical contraindications from the measure's denominator, they believe that the exclusion may be inconsistently applied among IRFs and other healthcare settings.

Response: We acknowledge that individual HCP may have sincerely held religious beliefs, observances, or practices that would prevent them from receiving a vaccine. However, we want to reiterate that neither the current version nor the proposed modified version of the measure mandate that HCP be up to date on their COVID-19 vaccination. The HCP COVID-19

⁶⁴ Conditions of Participation requirements from the interim final rule "Medicare and Medicaid Programs; Omnibus COVID-19 Health Care Staff Vaccination" (86 FR 61555) are no longer in effect due to the "Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID-19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs-IID) To Provide COVID-19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID-19 Testing Requirements" final rule (88 FR 36485).

Vaccine measure only requires reporting of vaccination rates for successful IRF QRP participation.

With respect to the comment about exclusions being inconsistently applied, CMS has multiple processes in place to ensure reported patient data are accurate. State agencies conduct standard certification surveys for IRFs, and accuracy and completeness of the IRF-PAI are among the regulatory requirements that surveyors evaluate during surveys.⁶⁵ Additionally, the IRF-PAI process has multiple regulatory requirements. Our regulations at § 412.606(b) require that (1) the assessment accurately reflects the patient’s status, (2) a clinician appropriately trained to perform a patient assessment using the IRF-PAI conducts or coordinates each assessment with the appropriate participation of health professionals, and (3) the assessment process includes direct observation, as well as communication with the patient.⁶⁶ We take the accuracy of IRF-PAI assessment data very seriously, and routinely monitor the IRF QRP measures' performance, and will take appropriate steps to address any such issues, if identified, in future rulemaking.

Comment: One commenter suggested the measure needs to be restructured given the variation among States as to what information can be requested of staff and can be conditions of employment. These variations would make the ability to create any national average invalid. Another commenter suggested that without a regular cadence of boosters or a defined COVID-19 “season,” similar to influenza, modifying the definition of up to date is premature.

Response: We acknowledge the commenter's concern regarding how State laws may impact an IRF’s ability to collect data regarding HCP COVID-19 vaccination status in order to report on this measure, and note that these Federal requirements would remain regardless of fluctuating State requirements. We believe, however, that IRFs obtaining information on HCP COVID-19 vaccination status is important for determining reasonable measures to protect the

⁶⁵ Center for Medicare and Medicaid Services. September 6, 2022. Hospitals.

<https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcompliance/hospitals>.

⁶⁶ 42 CFR 412.606 <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-412/subpart-P/section-412.606>.

health and safety of not only the patients whom the IRF serves, but other staff working within the facility. We clarify that the HCP COVID-19 Vaccine measure does not require providers to adopt mandatory vaccination policies. In addition, we recognize that the up to date COVID-19 vaccination definition may evolve due to the changing nature of the virus. Since the adoption of the current version of the measure, the public health response to COVID-19 has necessarily adapted to respond to the changing nature of the virus's transmission and community spread. As mentioned in the FY 2022 IRF PPS final rule (86 FR 42362), we received several public comments during the measure's pre-rulemaking process encouraging us to continue to update the measure as new evidence on COVID-19 continues to arise and we stated our intention to continue to work with partners including FDA and CDC to consider any updates to the measure in future rulemaking as appropriate. We believe that the proposed measure modification aligns with the Administration's responsive approach to COVID-19 and will continue to support vaccination as the most effective means to prevent the worst consequences of COVID-19, including severe illness, hospitalization, and death.

Comment: One commenter suggested CMS would be able to obtain the same information by examining community levels of COVID-19 vaccination.

Response: This measure reports the vaccination rate among the HCPs 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. We disagree that facility-level HCP vaccination information can be obtained by examining community levels of COVID-19 vaccinations since facility-level rates could vary within the same community.

Comment: A number of commenters raised concerns about the frequency and manner of data submission. Commenters noted that if the CDC revises the up to date definition in the middle of a reporting period, the data reported by providers will no longer be an accurate reflection of the facility. One commenter recommended CMS should adopt a "fixed definition of vaccine coverage" for calculating measure performance. Commenters noted that, without a

single consistent resource for reporting instructions when the definition of up to date is revised, the risk of inaccurate reporting increases.

Response: In response to the commenters' concerns that the up to date numerator definition may change during the reporting period, we refer commenters to section IX.C.1.a.4. of this final rule where we discuss how providers should refer to the definition of up to date as of the first day of the quarterly reporting period, which can be found at the following CDC NHSN webpage: <https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf>. The CDC notes that this aforementioned document will be updated quarterly to reflect any changes as COVID-19 guidance evolves, and notes that providers should use the definitions for the reporting period associated with the reporting weeks included in data submission. As such, the up to date vaccination definition that would be applicable during a particular reporting period should not change, which addresses the commenter's concern that there be a single consistent resource for reporting instructions when the definition of up to date is revised. If the requirements do change from one quarter to the next, IRFs would have the up to date definition at the beginning of the quarter (using the aforementioned CDC NHSN webpage), and have a minimum of 3 weeks to assess whether their HCP meet the definition of up to date before submitting HCP COVID-19 Vaccine measure data during the self-selected week of a corresponding month. IRFs would determine the up to date definition at the beginning of the quarter (using the aforementioned CDC NHSN webpage) and would have a minimum of 3 weeks to determine whether their staff are up to date on vaccinations before submitting HCP COVID-19 Vaccine measure data during the self-selected week of a corresponding month.

We interpret the commenter's recommendation to adopt a "fixed definition of vaccine coverage" as maintaining only one version of an up to date definition indefinitely. We thank the commenter for the suggestion. However, we note that in section IX.C.1.a.1.a of this final rule that as SARS-CoV-2 evolves, our COVID-19 vaccination strategy must remain responsive. When we adopted the HCP COVID-19 Vaccine measure in the FY 2022 IRF PPS final rule, we

stated that the need for additional/booster doses of COVID-19 vaccines had not been established and no additional doses had been recommended (86 FR 42390). To address the new variants of COVID-19, vaccine manufacturers have developed bivalent vaccines, which have been shown to increase immune responses to SARS-CoV-2 variants. We continue to believe that vaccination remains the most effective means to prevent severe consequences of COVID-19 and feel it is important to update the specifications of the HCP COVID-19 Vaccine measure to reflect most recent guidance that explicitly specifies for HCP to receive primary series and additional/booster doses in a timely manner.

Comment: One commenter questioned if retroactive assessment of data will be required if the up to date definition were to change during the reporting period.

Response: If the definition of up to date changes from one quarter to the next, IRFs would not have to submit data retroactively.

Comment: One commenter suggested that if the measure continues to be included in the IRF QRP, CMS should reduce the burden of gathering data from all personnel captured within the measure's denominator population.

Response: We did not propose changes to the measure denominator and disagree that the denominator criteria should be loosened. We emphasize that any HCP working in the facility for at least one working day during the reporting period, meeting denominator eligibility criteria, may come into contact with IRF patients, increasing the risk for HCP to patient transmission of infection. Therefore, we believe the measure as proposed has the potential to generate actionable data on up to date HCP COVID-19 vaccination rates that can be used to target quality improvement among IRF providers, including increasing up to date HCP COVID-19 vaccination coverage in IRFs, while also promoting patient safety and increasing the transparency of quality of care in the IRF setting.

Comment: Two commenters recommended that the HCP COVID-19 Vaccine measure's reporting requirements should align more closely to those of the HCP Influenza Vaccine

measure. One commenter notes that the HCP Influenza Vaccine measure does not require providers to track and report whether HCP receive up to date vaccinations. A few commenters suggested CMS consider limiting the reporting requirement to at least one week for each quarter and to work with the CDC to move toward a version of the measure that may be reported annually. One of the commenters who suggested annual reporting was generally supportive of the modification to the measure. Another commenter questioned if HCP without booster vaccinations will be mandated to receive boosters, and if booster vaccinations will be required annually or seasonally like the influenza vaccine.

Response: As we stated in the FY 2024 IRF PPS proposed rule (88 FR 20950), the measure developer (the CDC) 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 for the HCP COVID-19 Vaccine measure if vaccination strategy becomes seasonal. Neither the current nor proposed modified versions of the HCP COVID-19 Vaccine measure mandate that HCPs receive an up to date COVID-19 vaccine.

Comment: Six commenters expressed concerns with the delay between data submission via the NHSN and public reporting on Care Compare, emphasizing that the up to date numerator definition may change between the time when data are submitted and when data are publicly reported. One commenter points out that it may mean that HCP who counted as up to date in a given quarter may no longer be up to date in the next quarter and CMS needs to clearly communicate what publicly reported data reflect.

Response: We thank the commenters for expressing their concerns about the data lag between data submission and public reporting. We clarify that, as mentioned in the FY 2022 IRF PPS final rule (86 FR 42496 through 42497), we revised our public reporting policy for this measure to use quarterly reporting, which allows the most recent quarter of data to be displayed, as opposed to an average of four rolling quarters. Additionally, the public display schedule of the HCP COVID-19 Vaccine measure aligns with IRF QRP public display policies finalized in

the FY 2017 IRF PPS final rule (81 FR 52055), which allows IRFs to submit their IRF QRP data up to 4.5 months after the end of the reporting quarter. A number of administrative tasks must then occur in sequential order between the time IRF QRP data are submitted and reported in Care Compare to ensure the validity of data and to allow IRFs sufficient time to appeal any determinations of non-compliance with our requirements for the IRF QRP. We believe this reporting schedule, outlined in section IX.C.1.a.4. of this final rule is reasonable, and expediting this schedule may establish undue burden on providers and jeopardize the integrity of the data.

Additionally, CMS does communicate the time periods that publicly reported data reflect. This information can be retrieved through the Care Compare site (<https://www.medicare.gov/care-compare/>) through “View Quality Measures,” and then clicking on “Get current data collection period.”

Comment: One commenter believed the delay between when the information is collected and when it is actually publicly reported could cause confusion and damage the public’s trust and confidence in the quality of care delivered in their community if the rate of up to date healthcare personnel vaccination is “low” due to the data lag. Another commenter noted that changing CDC definitions is challenging for health care professionals, and they do not believe that this information can be articulated in a manner for patients to fully digest in order to make meaningful health care decisions.

Response: While we acknowledge that an IRF’s percentage of HCP who are up to date with their COVID-19 vaccination could change if the CDC modifies its guidance, each provider will be measured against the same criteria within the same quarter, and the guideline for each quarter will be shared through the CDC website ahead of each quarter at the following NHSN webpage: <https://www.cdc.gov/nhsn/pdfs/hps/covidvax/UpToDateGuidance-508.pdf>. If the requirements do change from one quarter to the next, IRFs would have the up to date definition at the beginning of the quarter and have a minimum of 3 weeks to assess whether their HCP meet the definition of up to date before submitting HCP COVID-19 Vaccine measure data during the

self-selected week of a corresponding month.

We also believe patients will be able to understand what changes to the up to date definition mean on Care Compare. We note that the public has been using the information displayed on Care Compare for the current HCP COVID-19 Vaccine measure since it was first publicly reported in 2022. CMS works closely with its Office of Communications and consumer groups when onboarding measures to the Care Compare websites, and we will do the same with the modified HCP COVID-19 Vaccine measure to ensure that the measure description on Care Compare is clear and understandable for the general public.

Comment: One commenter requested that CMS account for how CMS will publicly report the HCP COVID-19 Vaccine measure when the up to date definition in the numerator changes. They provide as example using CDC data where in the population greater than or equal to 65 years old, 94.3 percent have completed the primary series (the current measure numerator definition), while only 42.6 percent have received a booster dose (the proposed measure numerator definition). This commenter does not believe that the two numbers should be trended and compared over time given that they are different definitions of vaccination.

Response: We thank the commenter for the question, and we clarify that only one FY quarter of data is publicly reported at a time and the provider's performance is compared with its peers using data collected from the same FY quarter, and thus subject to the same definitions as set forth in the measure's guidelines. While the measure is only publicly reported one FY quarter at a time, we review measure trends as part of our routine monitoring activities and will exercise caution when monitoring measure trends especially during time periods when the CDC guidelines may change.

Comment: One commenter inquired about if and where the HCP COVID-19 Vaccine measure will be reported. This commenter also inquired about if facilities with more up to date vaccinations will get higher star-ratings. Additionally, this commenter questioned if there will be additional reimbursement for collecting up to date vaccination rates of HCP. Lastly, the

commenter inquired about how information about HCP vaccine percentages will be aggregated.

Response: We thank the commenter for their questions. As mentioned in section IX.C.1.a.4. of this final rule, the HCP COVID-19 Vaccine measure will be publicly reported on Care Compare beginning with the September 2024 Care Compare refresh. Additionally, we will make available to IRFs a preview of their performance on the HCP COVID-19 Vaccine measure on the IRF Provider Preview Report, which will be issued approximately 3 months prior to displaying the measure on Care Compare. In terms of star-ratings, the IRF QRP is not a part of the Hospital Quality Star Rating program. Furthermore, we reiterate that the IRF QRP is a pay-for-reporting program. Therefore, IRFs will only be financially penalized under the IRF QRP if they fail to comply with measure data submission requirements. There will not be additional reimbursement for collecting up to date vaccination rates of HCP or reimbursement based on HCP COVID-19 Vaccine measure performance. In response to the commenter's question about how percentages of HCP who are up to date with their COVID-19 vaccination will be aggregated, each quarter the CDC will calculate a single quarterly HCP COVID-19 vaccination coverage rate for each facility, by taking the average of the data from the three weekly rates submitted by the facility for that quarter. If more than 1 week of data are submitted for the month, the most recent submitted week of the month will be used. We refer readers to the following CDC NHSN webpage for additional information:

<https://www.cdc.gov/nhsn/pdfs/hps/covidvax/protocol-hcp-508.pdf>

After careful consideration of the public comments we received, we are finalizing our proposal to modify the HCP COVID-19 Vaccine measure beginning with the FY 2025 IRF QRP as proposed.

b. Discharge Function Score Measure Beginning with the FY 2025 IRF QRP

(1) Background

IRFs provide rehabilitation therapy in a resource-intensive inpatient hospital environment to patients with complex nursing, medical management, and rehabilitation needs, who require

and can reasonably be expected to benefit from the multidisciplinary care provided in an IRF. Patients tend to have neurological conditions such as stroke, spinal cord injury, and brain injury; degenerative conditions including multiple sclerosis; congenital deformities; amputations; burns; active inflammatory conditions; severe or advanced osteoarthritis; or knee and hip joint replacements.⁶⁷ In 2019, the most common condition treated by IRFs was stroke, which accounted for about one-fifth of IRF cases.⁶⁸ For stroke patients, rehabilitation has been shown to be the most effective way to reduce stroke-associated motor impairments. Addressing these impairments is crucial as functional deficits affect patients' mobility, their capabilities in daily life activities, and their participation in society, which can lead to a lower quality of life.⁶⁹

Section 1886(j)(7)(F)(ii) 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 post-acute care (PAC) settings, including IRFs. To satisfy this requirement, we adopted the Application of 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) measure for the IRF QRP in the FY 2016 IRF PPS final rule (80 FR 47100 through 47111). While this 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 out⁷⁰ and proposed to remove it in section VIII.C.1.c. of the proposed rule. While there are other outcome measures

⁶⁷ 42 CFR 412.29.

⁶⁸ 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.

⁶⁹ Hatem SM, Saussez G, Della Faille M, Prist V, Zhang X, Dispa D, Bleyenheuft Y. Rehabilitation of Motor Function After Stroke: A Multiple Systematic Review Focused on Techniques to Stimulate Upper Extremity Recovery. *Front Hum Neurosci.* 2016 Sep 13;10:442. doi: 10.3389/fnhum.2016.00442. PMID: 27679565; PMCID: PMC5020059.

⁷⁰ Centers for Medicare & Medicaid Services. 2022 Annual Call for Quality Measures Fact Sheet, p. 10. <https://www.cms.gov/files/document/mips-call-quality-measures-overview-fact-sheet-2022.pdf>.

addressing functional status⁷¹ that can reliably distinguish performance among providers in the IRF QRP, these outcome measures are not cross-setting in nature because they rely on functional status items not collected in all PAC settings. In contrast, a cross-setting functional outcome measure would align measure specifications 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.⁷² 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.^{73,74,75} Nonetheless, evidence suggests that physical functional abilities, including mobility and self-care, are modifiable predictors of patient

⁷¹ The measures include: Change in Self-Care Score for Medical Rehabilitation Patients (Change in Mobility for Medical Rehabilitation Patients, Discharge Self-Care Score for Medical Rehabilitation Patients), Discharge Mobility Score for Medical Rehabilitation Patients.

⁷² 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.

⁷³ 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.

⁷⁴ 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.

⁷⁵ 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.

outcomes across PAC settings, including functional recovery or decline after post-acute care,^{76,77,78,79} rehospitalization rates,^{80,81,82} discharge to community,^{83,84} and falls.⁸⁵

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 IRF care may include optimizing functional improvement, returning to a previous level of independence, or avoiding institutionalization. Several studies have reported that IRF care can improve patients' motor function at discharge for patients with various diagnoses, including traumatic

⁷⁶ Deutsch A, Palmer L, Vaughan M, Schwartz C, McMullen T. Inpatient Rehabilitation Facility Patients' Functional Abilities and Validity Evaluation of the Standardized Self-Care and Mobility Data Elements. *Arch Phys Med Rehabil.* 2022 Feb 11:S0003-9993(22)00205-2. doi: 10.1016/j.apmr.2022.01.147. Epub ahead of print. PMID: 35157893.

⁷⁷ 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.

⁷⁸ Alcusky M, Ulbricht CM, Lapane KL. Postacute Care Setting, Facility Characteristics, and Poststroke Outcomes: A Systematic Review. *Arch Phys Med Rehabil.* 2018;99(6):1124-1140.e9. doi: 10.1016/j.apmr.2017.09.005. PMID: 28965738; PMCID: PMC5874162.

⁷⁹ 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.

⁸⁰ 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.

⁸¹ 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.

⁸² 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.

⁸³ Minor M, Jaywant A, Togliola J, Campo M, O'Dell MW. Discharge Rehabilitation Measures Predict Activity Limitations in Patients with Stroke Six Months after Inpatient Rehabilitation. *Am J Phys Med Rehabil.* 2021 Oct 20. doi: 10.1097/PHM.0000000000001908. Epub ahead of print. PMID: 34686630.

⁸⁴ 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.

⁸⁵ Hoffman GJ, Liu H, Alexander NB, Tinetti M, Braun TM, Min LC. Posthospital Fall Injuries and 30-Day Readmissions in Adults 65 Years and Older. *JAMA Netw Open.* 2019 May 3;2(5):e194276. doi: 10.1001/jamanetworkopen.2019.4276. PMID: 31125100; PMCID: PMC6632136.

brain injury and stroke.^{86,87,88,89} While patients generally improve in all functional domains at IRF discharge, evidence has shown that a significant number of patients continue to exhibit deficits in the domains of fall risk, gait speed, and cognition, suggesting the need for ongoing treatment. Assessing functional status as a health outcome in IRFs can provide valuable information in determining treatment decisions throughout the care continuum, such as the need for rehabilitation services and discharge planning,^{90,91,92,93} as well as provide information to consumers about the effectiveness of rehabilitation and other IRF 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 IRF's quality of care.^{94,95}

⁸⁶ Evans E, Krebill C, Gutman R, Resnik L, Zonfrillo MR, Lueckel SN, Zhang W, Kumar RG, Dams-O'Connor K, Thomas KS. Functional Motor Improvement during Inpatient Rehabilitation among Older Adults with Traumatic Brain Injury. *PM R*. 2022 Apr;14(4):417-427. doi: 10.1002/pmrj.12644. PMID: 34018693; PMCID: PMC8606011.

⁸⁷ Kowalski RG, Hammond FM, Weintraub AH, Nakase-Richardson R, Zafonte RD, Whyte J, Giacino JT. Recovery of Consciousness and Functional Outcome in Moderate and Severe Traumatic Brain Injury. *JAMA Neurol*. 2021;78(5):548-557. doi: 10.1001/jamaneurol.2021.0084. PMID: 33646273; PMCID: PMC7922241.

⁸⁸ Li CY, Karmarkar A, Kuo YF, Haas A, Ottenbacher KJ. Impact of Self-Care and Mobility on One or More Post-Acute Care Transitions. *J Aging Health*. 2020;32(10):1325-1334. doi: 10.1177/0898264320925259. PMID: 32501126; PMCID: PMC7718286.

⁸⁹ O'Dell MW, Jaywant A, Frantz M, Patel R, Kwong E, Wen K, Taub M, Campo M, Togliola J. Changes in the Activity Measure for Post-Acute Care Domains in Persons With Stroke During the First Year After Discharge From Inpatient Rehabilitation. *Arch Phys Med Rehabil*. 2021 Apr;102(4):645-655. doi: 10.1016/j.apmr.2020.11.020. PMID: 33440132.

⁹⁰ Harry M, Woehrle T, Renier C, Furcht M, Enockson M. Predictive Utility of the Activity Measure for Post-Acute Care '6-Clicks' Short Forms on Discharge Disposition and Effect on Readmissions: A Retrospective Observational Cohort Study. *BMJ Open*. 2021;11:e044278. doi: 10.1136/bmjopen-2020-044278. PMID: 33478966; PMCID: PMC7825271.

⁹¹ Chang FH, Lin YN, Liou TH, Lin JC, Yang CH, Cheng HL. Predicting Admission to Post-Acute Inpatient Rehabilitation in Patients with Acute Stroke. *J Rehabil Med*. 2020 Sep 28;52(9):jrm00105. doi: 10.2340/16501977-2739. PMID: 32924065.

⁹² 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;101(4):pzab043. doi: 10.1093/ptj/pzab043. PMID: 33517463.

⁹³ Covert S, Johnson JK, Stilphen M, Passek S, Thompson NR, Katzan I. Use of the Activity Measure for Post-Acute Care "6 Clicks" Basic Mobility Inpatient Short Form and National Institutes of Health Stroke Scale to Predict Hospital Discharge Disposition After Stroke. *Phys Ther*. 2020 Aug 31;100(9):1423-1433. doi: 10.1093/ptj/pzab102. PMID: 32494809.

⁹⁴ 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.

⁹⁵ 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.

We proposed to adopt the Discharge Function Score (DC Function) measure⁹⁶ in the IRF QRP beginning with the FY 2025 IRF QRP. This assessment-based outcome measure evaluates functional status by calculating the percentage of IRF patients who meet or exceed an expected discharge function score. We also proposed that this measure would replace the topped-out Application of Functional Assessment/Care Plan cross-setting process measure. Like the Application of Functional Assessment/Care Plan cross-setting process measure, the proposed DC Function measure is calculated using standardized patient assessment data from the IRF Patient Assessment Instrument (IRF-PAI).

The DC Function measure supports our current priorities. Specifically, the measure aligns with the Streamline Quality Measurement domain in CMS's Meaningful Measures 2.0 Framework in two ways. First, the proposed outcome measure could further CMS's objective to prioritize outcome measures by replacing the current cross-setting process measure (see section VIII.C.1.c. of the proposed rule). 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; existing functional outcome measures do not use a set of cross-setting assessment items. Second, this measure would add no additional provider burden since it would be calculated using data from the IRF-PAI that IRFs are already required to collect.

The proposed DC Function measure would also follow a calculation approach similar to the existing functional outcome measures, which are endorsed by the CBE, with some modifications.⁹⁷ Specifically, the measure (1) considers two dimensions of function⁹⁸ (self-care

⁹⁶ Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report.

<https://www.cms.gov/files/document/irf-discharge-function-score-technical-report-february-2023.pdf>.

⁹⁷ The existing measures are the IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients measure (Discharge Self-Care Score), and the Inpatient Rehabilitation Facility (IRF) Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients measures (Discharge Mobility Score).

⁹⁸ 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.

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 lead to less accurate measure performances.

(b) Measure Testing

The measure development contractor used FY 2019 data to conduct testing 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 VIII.C.1.b.(3) of the proposed rule). Validity was assessed for the measure performance, the risk adjustment model, face validity, and statistical imputation models. Validity testing of measure performance entailed determining Spearman's rank correlations between the proposed measure's performance for providers with 20 or more stays and the performance of other publicly reported IRF quality measures. Results indicated that the proposed DC Function measure captures the intended outcome based on the directionalities and strengths of correlation coefficients and are further detailed below in Table 18.

TABLE 18: Spearman’s Rank Correlation Results of DC Function Measure with Publicly Reported IRF Quality Measures

Measure – Long Name	Measure – Short Name	ρ
Discharge to Community–PAC IRF QRP	Discharge to Community	0.25
IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients	Change in Self-Care Score	0.82
IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients	Change in Mobility Score	0.86
IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients	Discharge Self-Care Score	0.85
IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients	Discharge Mobility Score	0.88

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.⁹⁹ The ratios of observed-to-predicted discharge function score across eligible stays, by deciles of expected functional capabilities, ranged from 0.99 to 1.01. 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 VIII.C.1.b.(3) of the proposed rule). Lastly, validity testing of the measure’s statistical imputation models indicated that the models demonstrate good discrimination and produce more precise and accurate estimates of function scores for items with missing scores when compared to the current imputation approach implemented in IRF QRP functional outcome measures, specifically the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients measure (Change in Self-Care Score), the IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients measure (Change in Mobility Score), the IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients measure

⁹⁹ “Expected functional capabilities” is defined as the predicted discharge function score.

(Discharge Self-Care Score), and the IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients measure (Discharge Mobility Score).

Reliability and reportability testing also yielded results that support the proposed DC Function measure's scientific acceptability. Split-half testing revealed the proposed measure's excellent reliability, indicated by an intraclass correlation coefficient value of 0.95.

Reportability testing indicated high reportability (98 percent) of IRFs meeting the public reporting threshold of 20 eligible stays. For additional measure testing details, we refer readers to the document titled *Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report*.¹⁰⁰

(2) Competing and Related Measures

Section 1886(j)(7)(D)(i) of the Act and section 1899B(e)(2)(A) of the Act require that, absent an exception under section 1886(j)(7)(D)(i) and 1899B(e)(2)(B) of the Act, measures specified under section 1886(j)(7)(D)(ii) of the Act and section 1899B of the Act must be endorsed by the 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 1886(j)(7)(D)(ii) of the Act and section 1899B(e)(2)(B) of the Act permit 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 IRFs and (2) satisfy the requirement of the Act to develop and implement standardized quality measures from the quality measure domain of functional status, cognitive function, and changes in function and cognitive function across the PAC settings. While the

¹⁰⁰ *Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report*.
<https://www.cms.gov/files/document/irf-discharge-function-score-technical-report-february-2023.pdf>.

Application of Functional Assessment/Care Plan measure assesses both functional domains and satisfies the Act's requirement, this current cross-setting process measure is not endorsed by a consensus organization and the performance on the Application of Functional Assessment/Care Plan measure among IRFs is so high and unvarying that this current measure does not offer meaningful distinctions in performance. Additionally, after review of other measures, we were unable to identify any measures endorsed or adopted by a consensus organization for IRFs that meet the aforementioned requirements. While the IRF QRP includes CBE endorsed outcome measures addressing functional status,¹⁰¹ they each assess a single domain of function, and are not cross-setting in nature because they rely on functional status items not collected in all PAC settings.

Therefore, after consideration of other available measures, we found that the exceptions under sections 1886(j)(7)(D)(ii) and 1899B(e)(2)(B) of the Act apply and proposed to adopt the DC Function measure beginning with the FY 2025 IRF QRP. We intend to submit the proposed measure to the CBE for consideration of endorsement when feasible.

(3) Interested Parties and Technical Expert Panel (TEP) Input

In our development and specification of this measure, we employed a transparent process in which we sought input from interested parties and national experts and engaged in a process that allowed for pre-rulemaking input in accordance with section 1890A of the Act. To meet this requirement, we provided the following opportunities for input from interested parties: a patient and family/caregiver advocates (PFA) focus group, two TEPs, and public comments through a request for information (RFI).

First, the measure development contractor convened a PFA focus group, 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

¹⁰¹ The measures include: Change in Self-Care Score for Medical Rehabilitation Patients Change in Mobility Score for Medical Rehabilitation Patients, Discharge Self-Care Score for Medical Rehabilitation Patients, and Discharge Mobility Score for Medical Rehabilitation Patients.

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 for the DC Function measure 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 IRF QRP. The TEPs consisted of interested parties with a diverse range of expertise, including IRF and PAC subject matter knowledge, clinical expertise, patient and family perspectives, and measure development experience. The TEPs supported the proposed measure concept and provided 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 the currently adopted Discharge Mobility Score and Discharge Self-Care Score measures, or one that is modeled after the currently adopted Change in Mobility Score and Change in Self-Care Score measures. 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' concepts for the development of the 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. Lastly, 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 we applied their 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)¹⁰² and *Technical Expert Panel (TEP) for Cross-Setting Function Measure Development Summary Report* (January 2022 TEP)¹⁰³ 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 IRFs through an RFI in the FY 2023 IRF PPS proposed rule (87 FR 20244). Commenters were supportive of a cross-setting functional outcome measure that is inclusive of both self-care and mobility items, but also

¹⁰² *Technical Expert Panel (TEP) for the Refinement of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) Function Measures Summary Report* (July 2021 TEP) is available at <https://mmshub.cms.gov/sites/default/files/TEP-Summary-Report-PAC-Function.pdf>.

¹⁰³ *Technical Expert Panel (TEP) for Cross-Setting Function Measure Development Summary Report* (January 2022 TEP) is available at <https://mmshub.cms.gov/sites/default/files/PAC-Function-TEP-Summary-Report-Jan2022-508.pdf>.

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 47070).

(4) Measure Applications Partnership (MAP) Review

Our pre-rulemaking process includes making publicly available a list of quality and efficiency measures, called the MUC List, that the Secretary is considering adopting for use in the Medicare program, including our quality reporting programs. This allows multi-interested parties to provide recommendations to the Secretary on the measures included on the list.

We included the DC Function measure under the IRF QRP in the publicly available MUC List for December 1, 2022.¹⁰⁴ After the MUC List was published, the CBE convened MAP received four comments from interested parties in the industry on the 2022 MUC List. Two commenters were supportive of the measure and two were not. Among the commenters in support of the measure, one commenter stated that function scores are the most meaningful outcome measure in the IRF setting, as they not only assess patient outcomes but also can be used for clinical improvement processes. Additionally, this commenter noted the measure's good reliability and validity and that the measure is feasible to implement. The second commenter supported including the measure in the IRF QRP measures we propose through rulemaking.

Commenters not in support of the measure raised the following concerns: the need for more detailed measure specifications, the complexity of calculating the expected discharge score, the measure's validity and usability, and the differences in denominator populations across PAC settings. We were able to address these concerns during the MAP PAC/LTC workgroup meeting held on December 12, 2022. Specifically, we clarified that the technical reports include detailed measure specifications, and that expected discharge scores are calculated by risk-adjusting the observed discharge scores (see section VIII.C.1.b.(5) of the proposed rule). We also noted that

¹⁰⁴ 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>.

the measure exhibits good validity (see section VIII.C.1.b(1)(b) of the proposed rule) and clarified that the wide range of expected scores does not indicate poor validity and is consistent with the range of observed scores. We also pointed out that the measure is highly usable since it is similar in design and complexity to existing function measures and its data elements are already in use. Lastly, we explained that the denominator population in each measure setting represents the assessed population within the setting and the measure satisfies the requirement of the Act for a cross-setting measure in the functional status domain.

Shortly after, several CBE convened MAP workgroups met to provide input on the proposed DC Function measure. First, the MAP Health Equity Advisory Group convened on December 6-7, 2022. The MAP Health Equity Advisory Group did not share any health equity concerns related to the implementation of the DC Function measure, and only requested clarification regarding measure specifications from the measure steward. The MAP Rural Health Advisory Group met on December 8-9, 2022, during which two of its members provided support for the DC Function measure and other MAP Rural Health Advisory Group members did not express rural health concerns regarding the measure.

The MAP PAC/LTC workgroup met on December 12, 2022 and provided input on the proposed 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 VIII.C.1.b.(5) of the proposed rule). Therefore, we believe that these scores cannot be “gamed” by reporting less-ambitious functional goals. We also pointed out that the measure is highly usable as it is similar in design and complexity to existing function measures and that the data elements used in this measure are already in use on the IRF-PAI submitted by IRFs. Lastly, we clarified that the DC Function measure is intended to supplement, rather than replace, existing IRF QRP measures for self-care and mobility and implements improvements on the existing Discharge Self-Care Score

and Discharge Mobility Score measures that make the proposed measure more valid and harder to game.

The MAP PAC/LTC workgroup went on to discuss several concerns with the DC Function measure, including (1) whether the measure is cross-setting due to denominator populations that differ among 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 of section 1886(j)(7) 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 measure exhibits good validity and clarified that the wide range of expected scores does not indicate poor validity and 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 MAP PAC/LTC workgroup's preliminary recommendation, the CBE received two comments in support of the MAP PAC/LTC workgroup's preliminary recommendation of conditional support for rulemaking. One commenter recommended the DC Function measure under the condition that the measure be reviewed and refined such that its implementation supports patient autonomy and results in care that aligns with patients' personal functional goals. The second commenter provided support for the DC Function 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: (1) the measure utilizes different patient populations in each setting-specific denominator, (2) the risk-adjustment models use setting-specific covariates, and (3) using a single set of cross-setting Section GG self-care and mobility function items in our standardized patient assessment instruments is not appropriate since the items may not be relevant given the differences in each PAC resident/patient population.

Finally, the MAP Coordinating Committee workgroup convened on January 24-25, 2023. At this meeting, one interested party indicated their lack of support for the PAC/LTC workgroup's preliminary recommendation. The commenter expressed concern that the proposed DC Function measure competes with existing self-care and mobility measures in the IRF QRP. We noted that we monitor measures to determine whether they meet any measure removal factors, set forth in 42 CFR § 413.360(b)(2), and when identified, we may remove such measures through the rulemaking process. We 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. The MAP Coordinating Committee members expressed support for our review of existing measures for potential removal, as well as for the proposed DC Function measure, favoring the implementation of a single, standardized function measure across PAC settings. The Coordinating Committee unanimously upheld the workgroup recommendation of conditional support for rulemaking. We refer readers to the final MAP recommendations titled *2022-2023 MAP Final Recommendations*.¹⁰⁵

(5) Quality Measure Calculation

The proposed DC Function measure is an outcome measure that estimates the percentage of IRF patients who meet or exceed an expected discharge score during the reporting period. The proposed measure's numerator is the number of IRF stays with an observed discharge function

¹⁰⁵ 2022-2023 MAP Final Recommendations. <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>.

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 IRF stay. Risk adjustment controls for patient characteristics such as admission function score, age, and clinical conditions. The denominator is the total number of IRF stays with an IRF-PAI 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 Inpatient Rehabilitation Facilities (IRFs) Technical Report*.¹⁰⁶

The proposed DC Function 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 IRF patients. Currently, functional outcome measures in the IRF 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, this proposed DC Function measure’s statistical imputation allows missing values (that is, 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 the construction of the discharge score and the admission score.

¹⁰⁶ Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report.
<https://www.cms.gov/files/document/irf-discharge-function-score-technical-report-february-2023.pdf>.

Relative to the current simple imputation method, this statistical imputation approach increases precision and accuracy and reduces the bias in estimates of missing item values. We refer readers to the *Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report*¹⁰⁷ for measure specifications and additional details.

We invited public comment on our proposal to adopt the DC Function measure, beginning with the FY 2025 IRF QRP. The following is a summary of the public comments received on our proposal to adopt the DC Function measure, beginning with the FY 2025 IRF QRP, and our responses:

Comment: Two commenters supported the addition of the DC Function measure to the IRF QRP. One of these commenters agreed that the measure is a significant improvement upon existing function measures and notes the measure's potential to demonstrate the value of maintenance therapy. While supportive of the measure, one commenter believes the data sources for certain risk adjustment covariates, such as the Brief Interview of Mental Status (BIMS) to assess cognitive function, can be improved upon and urges CMS to closely monitor the appropriateness of the risk model used to estimate expected discharge scores. Another commenter noted that the measure does not impose additional provider burden, is an outcome measure rather than a process measure, and implements an imputation approach that improves upon the method used in the currently adopted Discharge Self-Care Score, Discharge Mobility Score, Change in Self-Care Score, and Change in Mobility Score measures. Both commenters encouraged continual evaluation of the imputation methodology for validity and any unintended negative consequences.

Response: We thank the commenters for their support of the proposed measure and agree that the measure improves upon existing function measures implemented in the IRF QRP. We reevaluate measures implemented in the IRF QRP on an ongoing basis to ensure they have

¹⁰⁷ *Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report.*
<https://www.cms.gov/files/document/irf-discharge-function-score-technical-report-february-2023.pdf>

strong scientific acceptability and appropriately capture the care provided by IRFs. This monitoring includes the appropriateness and performance of both the risk models and imputation models used to calculate the measure. We also agree that the accuracy of the expected discharge function score is vital to the measure's performance but disagree that the data sources for cognitive function are flawed. As described in the FY 2019 IRF PPS final rule (83 FR 38544) and the FY 2020 proposed rule (84 FR 17294-17295), the cognitive items including the expression of ideas and wants, understanding verbal and non-verbal content, and the Brief Interview of Mental Status (BIMS) items have been thoroughly tested and have been shown to be valid. The reliability of these cognitive items was tested in the IRF setting through kappa statistics. Results indicated that most kappa values were above 0.60, which indicates strong reliability.¹⁰⁸

Comment: One commenter who supported the measure requested a simplified overview of the risk adjustment methodology, as this would enable clinicians to provide more meaningful feedback in future years and also serve to alleviate clinician fear associated with an unknown measurement of the quality of care they provide.

Response: We agree that it is important for clinicians to understand the proposed quality measure, and thus provided detailed specifications to ensure transparency with respect to the measure's calculation, including the risk adjustment methodology. At a high level, the 'expected' discharge score is calculated by risk-adjusting the observed discharge score (that is, the sum of individual function item values at discharge) for admission functional status, age, and clinical characteristics using an ordinary least squares linear regression model. The model intercept and risk adjustor coefficients are determined by running the risk adjustment model on all eligible IRF stays. For more detailed measure specifications, we direct readers to the document titled *Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs)*

¹⁰⁸ *The Development and Testing of the Continuity Assessment Record and Evaluation (CARE) Item Set: Final Report on Reliability Testing Volume 2 of 3* <https://www.cms.gov/files/document/development-and-testing-continuity-assessment-record-and-evaluation-care-item-set-final-report.pdf>

Comment: One commenter supported the proposed adoption of the DC Function measure, noting its importance as a patient-centered measure. However, this commenter strongly encouraged CMS to submit the measure for CBE endorsement.

Response: We thank the commenter for their support and agree it is an important patient-centered measure. We intend to submit the proposed measure to the CBE for consideration of endorsement when feasible.

Comment: One commenter supported the proposed measure as it captures both self-care and mobility items and encouraged the review and refinement of the measure as needed. However, this commenter preferred separate quality measures for self-care and mobility to ensure each setting is able to capture the items most relevant to its patient population needs and goals and use the measures to determine meaningful quality improvement activities.

Response: We thank the commenter for their support and agree with the importance of capturing both self-care and mobility items in the proposed measure, and for this reason, the Discharge Self-Care Score and Discharge Mobility Score measures are not proposed for removal. As with all other measures, we will routinely monitor this measure to ensure the measure maintains strong scientific acceptability and utility to PAC settings.

Comment: Several commenters did not support the adoption of this proposed measure because it lacks CBE endorsement or has not undergone the CBE endorsement process. Three of these commenters noted that the CBE endorsement process provides information on whether or not the measure provides valuable information that can be used to inform improvements in care. Two other commenters pointed out that the measure received a MAP recommendation of “conditional support for rulemaking pending endorsement by a consensus-based entity” and believe there should be a discussion about competing measures, since the Discharge Self-Care

¹⁰⁹ *Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report.*
<https://www.cms.gov/files/document/irf-discharge-function-score-technical-report-february-2023.pdf>.

Score and Discharge Mobility Score measures in the IRF QRP are CBE endorsed.

Response: We direct readers to section IX.C.1.b.(2) of this final rule, where we discuss this topic in detail. Despite the current absence of CBE endorsement for this measure, we still believe it is important to adopt the DC Function measure into the IRF QRP because, unlike the Discharge Self-Care Score and Discharge Mobility Score measures, the DC Function measure relies on functional status items collected on the IRF-PAI and in all PAC settings, satisfies requirement of a cross-setting quality measure set forth in sections 1886(j)(7)(F)(ii) and 1899B(c)(1)(A) of the Act, and assesses both domains of function. We also direct readers to section IX.C.1.b.(2) of this final rule, where we discuss measurement gaps that the DC Function measure fills in relation to competing and related measures. We also acknowledge the importance of the CBE endorsement process and plan to submit the proposed measure for CBE endorsement in the future. We direct readers to section IX.C.1.b.(1)(b) of this final rule, and the technical report for detailed measure testing results demonstrating that the measure provides meaningful information which can be used to improve quality of care, and to the TEP report summaries^{110,111} which detail TEP support for the proposed measure concept.

Comment: A few commenters oppose the adoption of this proposed measure, claiming that it is duplicative of the Discharge Self-Care Score and Discharge Mobility Score currently in the IRF QRP. They believe the adoption of the proposed measure will create confusion among clinicians, patients, and payers who review publicly displayed quality measure information. Two of these commenters added that if the DC Function Score measure is adopted, then the Discharge Self-Care Score and Discharge Mobility Score measures should be removed.

Response: We disagree that the proposed measure is duplicative of the Discharge Self-Care Score and Discharge Mobility Score measures and believe all three measures add value to

¹¹⁰ 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://mms-test.battelle.org/sites/default/files/TEP-Summary-Report-PAC-Function.pdf>.

¹¹¹ 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>.

the IRF QRP measure set. As discussed in section IX.C.1.b.(2) of this final rule, the Discharge Self-Care Score and Discharge Mobility Score measures are not cross-setting because they rely on functional status items not collected in all PAC settings and thus do not satisfy requirement of a cross-setting quality measure set forth in sections 1886(j)(7)(F)(ii) and 1899B(c)(1)(A) of the Act. In contrast, the DC Function measure does include functional status items collected in each of the four PAC settings. Moreover, the DC Function measure captures information that is distinct from the Discharge Self-Care Score and Discharge Mobility Score measures.

Specifically, the DC Function measure considers both dimensions of function (utilizing a subset of self-care and mobility GG items in the IRF-PAI), while the Discharge Self-Care Score and Discharge Mobility Score measures each consider one dimension of function (utilizing all self-care or mobility GG items, respectively). We intend for IRFs to use information from the DC Function measure and the Discharge Self-Care Score and Discharge Mobility Score measures when assessing functional areas that may be opportunities for improvement.

Comment: Several commenters opposed the proposed DC Function measure because it combines self-care and mobility items collected on the IRF-PAI. Five of these commenters expressed a preference toward the Discharge Self-Care Score and Discharge Mobility Score measures currently adopted in the IRF QRP because they reflect the two dimensions of function separately. These five commenters believe a composite measure may disadvantage certain patient populations. The same commenters suggested that patients with limited function in their lower extremities may have more difficulty improving mobility while a patient with limited function in their upper extremities may have more difficulty improving self-care.

Response: The DC Function measure is intended to summarize several cross-setting functional assessment items while meeting the requirements of sections 1886(j)(7)(F) and 1899B(c)(1)(A) of the Act. We agree with the commenters that the individual Discharge Self-Care Score and Discharge Mobility Score measures will continue to be useful to assess care quality in these dimensions, and for this reason, these two measures are not proposed for

removal. Providers will be able to use information from both the DC Function measure and the Discharge Self-Care Score and Discharge Mobility Score measures when determining which functional areas may be opportunities for improvement. Moreover, we disagree that patients with lower functional performance on either self-care or mobility items will be disadvantaged in the proposed measure calculations. For each stay included in measure calculations, the observed function score is compared to the expected discharge score, which is adjusted to account for clinical characteristics, admission functional status, and demographic characteristics of the patient. Risk adjustment creates an individualized expectation for discharge function score for each stay that controls for these factors and ensures that each stay is measured against an expectation that is calibrated to the patient's individual circumstances when determining the numerator for each IRF.

Comment: Several commenters stated that the DC Function measure has not been tested, such as testing for reliability, validity, or feasibility.

Response: We direct readers to section IX.C.1.b.(1)(b) of this final rule, where we discuss extensively the testing of the proposed DC Function measure. Testing demonstrated good validity for the measure performance, the risk adjustment model, face validity, and statistical imputation models; excellent reliability; and high reportability. The proposed measure would be calculated using data from the IRF-PAI that are already reported to the Medicare program for payment and quality reporting purposes and are therefore feasible to implement and require no additional provider burden. Additionally, we direct readers to section IX.C.1.b.(1)(b) of this final rule and to the Discharge Function Score for IRFs Technical Report¹¹² for detailed measures testing results that support that the measure provides meaningful information which

¹¹² Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report.
<https://www.cms.gov/files/document/irf-discharge-function-score-technical-report-february-2023.pdf>.

can be used to improve quality of care, as well as the TEP report summaries^{113,114} which detail TEP support for the proposed measure concept.

Comment: Several commenters oppose the adoption of the DC Function measure because they do not believe it is appropriate or accurate for CMS to override the clinical judgement of the clinicians who are treating the patient by using statistical imputation to impute a value to a data element when an ANA code is used. Two of these commenters noted that the ANA codes allow clinicians to use their professional judgement when certain activities should not or could not be safely attempted by the patient, which may be due to medical reasons. Additionally, two of these commenters stated that among some patients not able to attempt certain self-care and mobility tasks at the time of admission, the use of ANA codes decreases significantly at the time of discharge, which they believe reflect the functional outcomes achieved during their IRF stay. One of these commenters additionally noted that a patient who cannot attempt an activity due to medical or safety concerns is considered dependent for that activity at that time.

Response: We acknowledge that the ANA codes allow clinicians to use their professional judgement when certain activities should not or could not be attempted safely by the patient and that there may be medical reasons that a patient cannot safely attempt a task. We note that we did not propose any changes to the coding guidance for using ANA codes, and we would not expect IRF coding practices to change. However, we want to clarify that utilizing statistical imputation to calculate a quality measure does not override the clinical judgement of clinicians who are expected to continue determining whether certain activities can be safely attempted by patients at the time of admission and discharge and utilize that information to determine appropriate goals and treatment interventions for their IRF patients. Rather, statistical

¹¹³ Technical Expert Panel (TEP) for the Refinement of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) Function Measures Summary Report (July 2021 TEP) is available at <https://mms-test.battelle.org/sites/default/files/TEP-Summary-Report-PAC-Function.pdf>.

¹¹⁴ Technical Expert Panel (TEP) for Cross-Setting Function Measure Development Summary Report (January 2022 TEP) is available at <https://mmshub.cms.gov/sites/default/files/PAC-Function-TEP-Summary-Report-Jan2022-508.pdf>.

imputation is a component in measure calculation of reported data and improves upon the imputation approach currently implemented in the Change in Mobility Score, Change in Self-Care Score, Discharge in Mobility Score, and Discharge in Self-Care Score measures. In these currently adopted measures, ANA codes are always imputed to 1 (dependent) when calculating the measure scores, regardless of a patient's own clinical and functional information. However, the imputation approach implemented in the proposed DC Function measure uses each patient's available functional and clinical information to estimate each ANA value had the item been completed. Testing demonstrates that, relative to the current simple imputation method, the statistical imputation approach used in this DC Function measure increases precision and accuracy and reduces bias in estimates of missing item values.

Comment: Two commenters stated that clinicians do not have the autonomy to choose whether walk items or wheelchair items are the most appropriate choice for the patient at discharge. To illustrate this point, these commenters provided an example to show how the measure logic may not be equitable for walk patients versus wheelchair patients. The example states that if a patient walks 10 feet dependently because a second helper assists with a wheelchair due to poor balance and will use a wheelchair full time after discharge, then the patient's risk-adjusted expected outcomes would be based on their ability to walk, since a score was coded for Walk 10 feet on admission or discharge.

Response: We disagree that clinicians do not have the autonomy to choose whether walk or wheelchair items should be assessed for a patient at discharge. Clinicians are expected to use their clinical judgement when determining whether certain activities can be safely attempted by the patients when completing the IRF-PAI, reporting ANA codes in measure data, and utilizing the assessment data to determine appropriate goals for their IRF patients. With respect to the example provided, we would like to point out that the use of walk and wheelchair items in the calculation of measure outcomes is similar to that of the existing Discharge Mobility measure: namely, wheelchair items are used only if walk items were coded as ANA at both admission and

discharge, in order to maximize the use of walk item scores whenever they are available, including for patients who are scored on both walk and wheelchair items. Both the DC Function and Discharge Mobility Score measures would use the information about the patient's dependent walking at admission. The Discharge Mobility measure would then impute the lowest score ("dependent") to the ANA walking items at discharge, while the DC Function measure may impute a higher score to those items, based on the clinical and functional covariates for that patient.

Comment: Some commenters expressed concerns regarding the bootstrapping samples used during the development of the DC Function measure imputation model because they believe these samples are not representative of the full IRF population. These commenters believe the validity testing of the proposed DC Function imputation model is not accurate because the models are built using only the functional abilities of patients who had no Section GG items on the IRF-PAI coded ANA, and they believe this comprises a small percentage of the IRF population and exhibits clinical, demographic, and functional characteristics that likely differ from those of the entire IRF population. As such, two of these commenters stated that these imputation models should not be imposed on patients who had ANA assessments, as doing so could lead to unfair penalization of IRF providers treating certain patient populations and performance scores that are not representative of true functional gains achieved by patients during an IRF stay. Another one of four commenters further suggested that the current model of imputing ANA patients as dependent on that functional item is likely more representative of a patient's functional capabilities than the statistical imputation approach, as a patient who is unable to complete an activity would be viewed as "dependent" for purposes of that activity's assessment at that time. This same commenter recommended for CMS to release more demographic data of the patient population that the bootstrapping model utilizes to understand if this population is truly representative of IRF patients.

Response: We would like to clarify that bootstrapping samples were used only to

determine validity of the imputation models; to develop the imputation models themselves, all stays without ANAs for each single item were used. As an example, when estimating the imputation model for GG0130A admission scores, all stays without ANAs for GG0130A at admission (>95 percent of eligible stays) were used. In other words, rather than using the relatively small subset of stays without any ANAs across all GG items, we used much larger subsets without ANAs on a given item. In fact, measure calculations using FY 2021 data utilized 89-100 percent of stays in each of the discharge imputation models and in each of the non-walk/wheelchair admission imputation models. The percentage of stays in the walk/wheelchair admission imputation models ranges from around 45 percent to 73 percent, which is expected as these items have higher rates of skips based on the CMS guidance for coding the IRF-PAI. Given that 89-100 percent of samples are utilized in almost all the imputation models, the imputation models are, in fact, built upon samples that are representative of the IRF population. Furthermore, the imputation methodology builds upon the risk-adjustment methodology which has been in place for multiple years for existing measures. Risk adjustment creates an individualized expectation for the discharge function score for each stay that controls for clinical, demographic, and function characteristics to ensure that each stay is measured against an expectation that is calibrated to the patient's individual circumstances. Similarly, imputation creates an individualized prediction for each GG item value for each stay based on clinical, demographic, and function characteristics to ensure that each imputed value is calibrated to the patient's individual circumstances. Lastly, testing has indicated that discharge functional abilities of patients with ANA codes at admission tended to be higher than those coded as dependent at admission. Treating ANAs and dependent scores equivalently, as is done in the Discharge Self-Care Score and Discharge Mobility Score measures, may disadvantage patients who were truly scored as dependent at admission. Statistical imputation allows the DC Function measure to address this bias.

Comment: Two commenters advocated for the release of more data and methodology

pertaining to the statistical imputation approach. One commenter stated that this is the first time CMS is implementing a quality measure score with imputed data and that the report is unclear in how walk versus wheelchair patients are accounted for in this measure when there is an ANA code. This commenter shared results of an analysis they conducted on their own data which indicated that the sample of patients without an ANA can range from over 60 percent to over 90 percent depending on how the model handles dashes and ANA codes for walk and wheelchair patients, and this wide discrepancy shows the complexity of developing this measure and in verifying its results. The other commenter noted that the statistical imputation approach may falsely elevate overall discharge scores, and thus encouraged oversight and reporting related to the frequency of use of ANA codes on discharge.

Response: We remind commenters that the four functional outcome measures currently used in the IRF QRP are calculated using imputed data. The current imputation approach in these four measures is to recode all ANA codes to 1 (dependent) for purposes of calculating the measure scores, regardless of a patient's reason for receiving IRF care, their demographics, or their clinical and functional characteristics. In contrast, the imputation approach of the proposed DC Function measure uses each patient's available primary reason for IRF care, their demographics, and their functional and clinical information to estimate each ANA value had the item been completed. Testing demonstrates that, relative to the current simple imputation method, the statistical imputation approach increases precision and accuracy and reduces bias in estimates of missing item values. Additionally, we are unsure which report is being referenced and direct readers to the document titled *Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report* for more detailed measure specifications.¹¹⁵

We cannot respond to the findings of the analyses performed by the commenter since we do not have sufficient information. However, our analyses of FY 2021 data have indicated that

¹¹⁵ *Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report*.
<https://www.cms.gov/files/document/irf-discharge-function-score-technical-report-february-2023.pdf>.

around 89-100 percent of stays are used in each of the discharge imputation models and in each of the non-walk/wheelchair admission imputation models. The percentage of stays in the walk/wheelchair admission imputation models range from around 45 percent to 73 percent, which is expected as these items have higher rates of skips based on the CMS guidance in the IRF-PAI.

Lastly, we disagree that the statistical imputation approach may falsely elevate overall discharge scores. The statistical imputation approach will in fact reflect more accurate performance scores, as indicated by testing results presented pertaining to statistical imputation, compared to the current simple imputation method.

Comment: A few commenters stated that under the statistical imputation methodology, a patient's functional status could be recoded at a higher level based on "the most likely score" of other, completely unrelated functional items (for example, oral hygiene and the ability to go up and down steps) and reliance on completely unrelated functional items to impute function scores is not clinically or statistically appropriate.

Response: We disagree that using a full set of clinical characteristics and functional items is not appropriate. The imputation models for the proposed DC Function measure use a similar set of covariates as the risk adjustment model for the Discharge Self-Care Score and Discharge Mobility Score measures which IRFs have been reporting since FY 2016. In addition to these covariates, the proposed DC Function measure's model adds the available information from all available Section GG functional items on the IRF-PAI. While less-related functional variables are generally less correlated with a given item's score, and thus carry less weight in terms of how much they influence the imputed value, they still contribute to the overall model performance by improving overall model fit and reducing estimation error.

Comment: A few commenters suggested that CMS be more involved with clinicians in discussions surrounding the assessment and coding of patients rather than using an imputation approach if there is concern that ANA codes are not truly reflective of patients' functional

abilities. One of these commenters also urged CMS to provide additional coding guidance for ANA use for the GG items in order to better standardize and reduce the use of ANA codes.

Response: We engaged with PAC providers on more than one occasion. As described in section IX.C.1.b.(3) of this final rule, our measure development contractor convened two TEPs to obtain expert clinician input on the development of the measure. The TEPs consisted of interested parties with a diverse range of expertise, including IRF and other PAC subject matter knowledge, clinical expertise, and measure development experience in PAC settings. As described in the PAC QRP Functions TEP Summary Report – March 2022,¹¹⁶ panelists agreed that the recode approach used in the currently implemented Discharge Self-Care Score, Discharge Mobility Score, Change in Self-Care Score, and Change in Mobility Score measures could be improved upon and reiterated that not all ANAs reflect dependence on a function activity. Based on the extensive testing results presented to the TEP, a majority of panelists favored the statistical imputation over alternative methodologies and an imputation method that is more accurate over one that is simpler.

Additionally, CMS continually provides training resources to providers to give guidance about how to code functional items,¹¹⁷ including the use of ANA codes.

Comment: One commenter believed self-care and mobility items in the IRF-PAI can be reported as a zero, resulting in the proposed imputation approach producing errors or needing to be recoded to a different measure; while another commenter sought clarification on measure calculations and stated that the DC Function measure calculates a risk adjusted ratio of observed to expected scores at discharge for all patients over 18 years old that do not meet exclusion criteria. While they supported the risk adjustment method, this commenter warned that it may give different results than the “alternative standardization risk-adjustment model.”

¹¹⁶ Technical Expert Panel (TEP) for Cross-Setting Function Measure Development, January 26-27, 2022 Summary Report. <https://mmshub.cms.gov/sites/default/files/PAC-Function-TEP-Summary-Report-Jan2022-508.pdf>. Page 20.

¹¹⁷ Centers for Medicare & Medicaid Services. Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP) Training. <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/irf-quality-reporting/irf-quality-reporting-training>.

Response: The DC Function measure’s items are neither recoded to 0 nor recoded in another measure but are recoded to a value between 1 and 6. The imputation approach is similar in complexity to the DC Function measure’s risk adjustment approach, which is modeled after the approach in the currently adopted Discharge Self-Care Score, Discharge Mobility Score, Change in Self-Care Score, and Change in Mobility Score measures. Please reference section IX.C.1.b.(5) of this final rule for more information on the proposed imputation approach.

We agree that it is important for clinicians to understand the proposed quality measure, and thus provided detailed specifications to ensure transparency with respect to the measure’s calculation, including the risk-adjustment methodology. To clarify, the DC Function measure score is not a ratio. The measure is constructed by calculating the number of IRF stays where the expected score is higher than the observed score out of total stays. At a high level, the “expected” discharge score is calculated by risk-adjusting the observed discharge score (that is, the sum of individual function item values at discharge) for admission functional status, age, and clinical characteristics using an ordinary least squares linear regression model. The model intercept and risk adjustor coefficients are determined by running the risk adjustment model on all eligible IRF stays. For more detailed measure specifications, we direct readers to the document titled Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report.¹¹⁸

Also, we are unsure of the “alternative standardization risk-adjustment model” this commenter references and would like to clarify that the proposed risk adjustment model has undergone validity testing, showing 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.¹¹⁹

Comment: One commenter stated that there is no minimum number of eligible stays from

¹¹⁸ *Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report.*
<https://www.cms.gov/files/document/irf-discharge-function-score-technical-report-february-2023.pdf>.

¹¹⁹ “Expected functional capabilities” is defined as the predicted discharge function score.

which to base the imputation method, potentially invalidating results.

Response: We would like to clarify that imputation models are estimated using the entire population of eligible stays, and thus sample size is not a concern. For additional measure testing details, we refer readers to the document titled *Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report*.¹²⁰

Comment: One commenter expressed concern with the proposed statistical imputation approach utilized in the DC Function measure and suggested it might lead to this measure score varying significantly from the Discharge Self-Care Score and Discharge Mobility Score measures' scores.

Response: The DC Function measure captures information that is distinct from the Discharge Self-Care Score and Discharge Mobility Score measures. Specifically, the DC Function measure considers both dimensions of function (utilizing a subset of self-care and mobility GG items), while the Discharge Self-Care Score and Discharge Mobility Score measures each consider one dimension of function (utilizing all self-care and mobility GG items, respectively). For these same reasons, we expect to see differences in outcome percentages among these three measures for reasons unrelated to the imputation approach used.

Comment: Two commenters believe the measure's imputed and risk-adjusted expected values will complicate clinicians' ability to review and validate information used for public reporting. Another commenter stated that the statistical imputation approach is a very complex calculation and understanding how performance is impacted may be difficult for both IRFs and the public. This commenter urges CMS to continuously evaluate this method and its impact impacts across the PAC settings.

Response: The proposed measure uses methods that are similar in complexity to CBE-endorsed functional outcome measures that have been adopted in the PAC QRP for several years

¹²⁰ *Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report*.
<https://www.cms.gov/files/document/irf-discharge-function-score-technical-report-february-2023.pdf>.

and will be similarly specified. As such, understanding performance should be no more difficult than understanding the currently adopted Discharge Self-Care Score, Discharge Mobility Score, Change in Self-Care Score, and Change in Mobility Score measures. As with all other measures, we will routinely monitor this measure's performance, including the statistical imputation approach, to ensure the measure remains valid and reliable.

Comment: One commenter requested that CMS provide more clarity on its imputation approach to recoding, specifically contrasting it with a Rasch analysis used in the PAC PPS prototype, to ensure transparency and clinical meaningfulness.

Response: The Rasch analysis in the PAC PPS prototype produces a single value to which every single ANA is recoded for a given item across all patients and settings. By contrast, under the imputation approach for the DC Function measure, we estimate a different recode value for each patient, based on their clinical comorbidities, codes on all other GG items, and setting. We believe our approach accounts for several likely effects: setting-specific coding guidance and practice differences; function scores being correlated with clinical comorbidities; and functional scores for a given GG item being correlated with functional codes on other GG items, particularly on “adjacent” (similar) items. Therefore, we believe recoding ANAs based on patients’ specific clinical risk and using all available GG item scores (codes) is a more valid approach. For more detailed measure specifications, we direct readers to the document titled *Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report*.¹²¹

Comment: Two commenters expressed concern that the proposed measure numerator is not wholly attributed to a facility’s quality of care and that the calculation of the “expected” discharge score is opaque, resulting in difficulty for providers to determine the score for which they are striving. These commenters further noted that functional goals are not based on statistical regression and are identified via individual-specific goals related to function,

¹²¹ *Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report*.
<https://www.cms.gov/files/document/irf-discharge-function-score-technical-report-february-2023.pdf>.

independence, and overall health.

Response: We agree with the commenter that functional goals are identified for each patient as a result of an individual assessment and clinical decisions, rather than statistics. However, we want to remind commenters that the DC Function measure is not calculated using the goals identified in clinical process. The “expected” discharge score is calculated by risk-adjusting the observed discharge score (that is, the sum of individual function item values at discharge) for admission functional status, age, and clinical characteristics using an ordinary least squares linear regression model. The model intercept and risk adjustor coefficients are determined by running the risk adjustment model on all eligible IRF stays. For more detailed measure specifications, we direct readers to the document titled *Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report*.¹²² The risk-adjustment model for this measure controls for clinical, demographic, and function characteristics to ensure that the score fully reflects a facility’s quality of care.

Comment: One commenter opposed the adoption of the proposed measure because this commenter has significant concern with the current calculations of the “expected” discharge score for the proposed measure. This commenter stated that there are identified discrepancies in the way that CMS calculates an “expected” discharge score for the existing Discharge Self-Care Score and Discharge Mobility Score measures, calculations are complex, and calculations of the “expected” discharge value for multiple separate function items is unclear. As a result, this commenter believed it is premature to implement an expanded discharge function score measure and doing so will result in serious implementation burdens and technical challenges.

Response: This commenter noted discrepancies in the way “expected” discharge scores for current functional outcome measures are calculated but did not provide additional information regarding the discrepancies to which they were referring. CMS is unaware of any

¹²² *Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report*.
<https://www.cms.gov/files/document/irf-discharge-function-score-technical-report-february-2023.pdf>.

discrepancies and would require further details in order to respond to these concerns.

Nonetheless, we believe the proposed measure's calculations of the "expected" discharge score has strong scientific acceptability based on measure testing results, as previously discussed. As with all other measures, we will routinely monitor this measure's performance, including the issue raised about the calculation of "expected" discharge scores, to ensure the measure remains valid and reliable.

We would also like to clarify that the "expected" discharge score is not calculated for each function item separately. Instead, the "expected" discharge score is calculated by risk-adjusting the observed discharge score, which is the sum of individual function item (observed) values at discharge. For more detailed measure specifications, we direct readers to the document titled *Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report*.¹²³

Comment: Several commenters disagreed with language in the proposed rule that characterized items coded with an ANA code (codes 07, 09, 10, and 88), a dash (-), and a skip (^) as "missing" data since CMS provides distinct guidance and specifications for each code's use. Specifically, these commenters stated that ANA codes represent clinical information that the patient was incapable of performing a task for reasons specified by CMS in the IRF-PAI manual and thus are not considered "missing data"; because these ANA codes represent clinical information, three of these commenters stated that imputation of these ANA codes based on other function activities would not improve the precision of the score.

Response: We agree that ANA codes, a dash, and a skip have different meanings when used on the IRF-PAI. To clarify, the use of the term "missing" data refers to codes that are not coded 01, 02, 03, 04, 05, or 06 which represent the amount of (or lack of) helper assistance a patient needs to complete a functional activity. ANA codes, a dash, and a skip are considered

¹²³ *Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report*.
<https://www.cms.gov/files/document/irf-discharge-function-score-technical-report-february-2023.pdf>.

“missing” in the context of the measure calculations since the observed discharge score is the sum of 01-06 values from functional assessment items included in the observed discharge score. Utilizing statistical imputation to calculate the observed discharge score does not disregard the clinical information represented by ANA codes. Rather, statistical imputation is a component in measure calculation of reported data and improves upon the imputation approach currently implemented in the Change in Mobility Score, Change in Self-Care Score, Discharge in Mobility Score, and Discharge in Self-Care Score measures. In these measures, ANA codes are always imputed to 1 (dependent) when calculating the measure scores, regardless of a patient’s own clinical and functional information. The imputation approach implemented in the proposed DC Function measure uses each patient’s available functional and clinical information, including ANA codes on other functional assessment items, to estimate each ANA value had the item been completed. Testing demonstrates that, relative to the current simple imputation method, the statistical imputation approach in used this DC Function measure increases precision and accuracy, while reducing bias in estimates of missing item values.

Comment: Several commenters raised concerns about the extent to which the measure can be considered a cross-setting measure, and its utility for comparing performance across settings. Some of these commenters believe that calculating a cross-setting function measure with different populations across PAC settings will not be meaningful in characterizing patients or comparing their outcomes across the different PAC settings, and may lead to inaccurate comparisons for patients, caregivers, Medicare Advantage plans, Medicaid managed care plans, and other interested parties. The same commenters also stated that CMS should work with interested parties to standardize data so that interested parties can differentiate patients’ abilities and disabilities in a wide range of functional levels across the PAC spectrum.

Response: We acknowledge that the measure denominators differ across PAC settings. However, as clarified during the MAP PAC/LTC workgroup discussed in section IX.C.1.b.(4) of this final rule, the denominator population in each measure setting is the population included in

the respective setting's quality reporting program, as stated in the FY 2023 IRF PPS final rule (87 FR 47082 and 87 FR 47074) and the FY 2018 SNF PPS final rule (82 FR 36598). Moreover, we would like to clarify that cross-setting measures do not necessarily suggest that facilities can be compared across settings. Instead, these measures are intended to compare providers within a specific setting while standardizing measurement of function across settings. The proposed measure does just this, by aligning measure specifications across settings and including the use of a common set of standardized functional assessment data elements. This alignment satisfies the requirements of section 1886(j)(7)(F)(i) of the Act for a cross-setting measure in the functional status domain specified under section 1899B(c)(1) of the Act.

Comment: One commenter requested the rationale as to why confidence intervals were not calculated and reported for the expected function scores and utilized in determining meaningful differences between the observed and expected function score. This commenter also stated that the minimum clinical difference in discharge function scores that indicates a change is meaningful to patient progress has not been identified.

Response: The proposed DC Function measure uses the same approach in determining whether an observed discharge score is different than its associated expected discharge score as the currently adopted Discharge Self-Care Score and Discharge Mobility Score measures that are CBE endorsed. Specifically, the DC Function measure reports the proportion of a given provider's stays where observed discharge function score matches or exceeds expected discharge function score. The measure score is a continuous variable with values between 0 and 100, allowing for intuitive interpretation and comparisons. Our TEP supported that patients and families are more likely to understand a measure that expresses functional outcome as a simple proportion of patients who meet expectation for their discharge functional status, rather than units of change in a scoring system that is unfamiliar to most Care Compare website users (the primary audience for this measure). Measure scores based on statistical significance of differences between observed and expected values (based on confidence intervals) place

providers in broad categories, such as ‘No different than national average,’ which do not allow more granular provider comparisons for the public reviewing the measure’s data on Care Compare. Given the excellent reliability of the DC Function measure, we believe that reporting provider scores as broad categories is not warranted.

Comment: One commenter noted the variability in median scores and believed this range suggests the measure may not be valid, and that the variability may be problematic when making comparisons among providers.

Response: First, we would like to clarify that median scores are not used in the calculation of this measure. While we would require additional information regarding the median scores referenced in this comment to provide a more complete response, we acknowledge that the measure has a large range of average expected discharge scores, as calculated for each provider. This range is consistent with the range of observed discharge scores, indicating that the measure is capturing the range of patient’s functional abilities, and thus, in fact, supports the validity of the measure.

Comment: One commenter noted that intrinsic to the discharge scores are the associated admission scores, and suggested an analysis of this measure to assess the variability in initial admission function scores between hospitals for similar types of patients as differences may account for the gaps in the observed discharge function scores.

Response: We acknowledge that the observed gap in discharge function scores may be due to variability in the initial admission function scores; nevertheless, the admission function scores are included as covariates in the risk adjustment model and thus are accounted for in the calculations of the expected discharge function scores.

Comment: One commenter questioned CMS’ characterization of the adjusted R-squared value of 0.65 for the proposed DC Function measure’s risk adjustment model. This commenter believed a value of 0.65 suggests moderate, rather than “good” model discrimination. This commenter suggested CMS should address the ability of the risk adjustment model to make

predictions by comparing R-squared values of the “training” and “validation” sets and reporting “predicted R-squared” values.

Response: We want to clarify that the adjusted R-squared for the DC Function measure, as reported in the Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report,¹²⁴ was 0.51. We believe that this value indicates “good” model discrimination, and it is comparable to those of the Discharge Self-Care Score and Discharge Mobility Score measures (0.48-0.50). Additionally, because the measure model uses all available data, the concepts of “training” and “validation” sets (and any related “predicted R-squared”) are not applicable. Rather, adjusted R-squared values capture model fit for the risk-adjustment model.

Comment: Two commenters expressed concern that the measure performance may not adequately demonstrate the advancement in functional ability a patient has gained across the mobility and self-care domains during their IRF stay. One of these commenters believed that upper body dressing and lower body dressing are better indicators of patient functional success at discharge than items currently included in the DC Function measure, and the rationale for selecting certain function items to be captured in this measure seem to be based solely on ensuring cross-setting applicability and less on the accuracy of an “expected” function score.

Response: We acknowledge that the cross-setting applicability was a motivating factor in determining function items captured in the proposed DC Function measure, and upper body dressing and lower body dressing function items were not available across settings. Nonetheless, the proposed DC Function measure does reflect the progress of patients across both the mobility and self-care domains. As stated in section IX.C.1.b.(3) of this final rule, the TEP supported the inclusion of both functional domains as self-care items impact mobility items and are clinically relevant to function. Additionally, the proposed measure is meant to supplement, rather than

¹²⁴ *Discharge Function Score for Inpatient Rehabilitation Facilities (IRFs) Technical Report.*
<https://www.cms.gov/files/document/irf-discharge-function-score-technical-report-february-2023.pdf>.

replace, the Discharge Self-Care Score and Discharge Mobility Score measures which implement the remaining self-care and mobility function items not captured in the DC Function measure. High correlations between the proposed measure and the Discharge Self-Care Score and Discharge Mobility Score measures (0.85 and 0.88, respectively) demonstrate that these three measures capture related but distinct aspects of provider care in relation to patients' function. The TEP understood these aforementioned considerations and supported the inclusion of the function items included in the proposed measure.

Comment: Two commenters (one in support of this proposed measure, and one opposed) raised concerns that the measure does not account for cognition and communication. One commenter urged CMS to consider alternative assessments that better incorporate cognition and communication into the measure calculation. The other commenter similarly raised concerns that Section GG items in the IRF-PAI insufficiently capture all elements of function and do not adequately capture the outcomes required for safety and independence.

Response: We agree that cognition and communication are critically important and related to the safety and independence of patients. Although not directly assessed for the purpose of measure calculation, this measure does indirectly capture a facility's ability to impact a patient's cognition and communication to the extent that these factors are correlated to improvements in self-care and mobility. That said, we agree that communication and cognition are important to assess directly, and facilities currently do so through completion of the BIMS, CAM©, and items BB0700-BB0800 in the IRF-PAI. Additionally, CMS regularly assesses the measures in the IRF QRP for measurement gaps, and as described in section IX.D of this final rule, specifically identified cognitive improvement as a possible gap and sought feedback about how to best assess this clinical dimension. CMS will use this feedback as well as discussion with technical experts and empirical analyses to determine how to measure communication and cognition.

Comment: Two commenters expressed concern regarding the validity or completeness of

reported functional assessment data. One of these commenters recommended that CMS improve providers' reporting of functional assessment data before adopting this measure, as the inconsistency of PAC providers' recording of this information raises concerns about publicly reporting this measure and using this measure for payment. This commenter provided the example that some providers code patient function in response to payment incentives. Although there are currently no payment implications for this measure, this commenter noted that differential coding practices and profitability by case type across IRFs may contribute to differential profitability. Additionally, this commenter stated that the current imputation approach used in existing measures in the IRF QRP recodes any ANA code to the most or second most dependent level which would lead to a lower motor score and raise Medicare payment for the stay.

Response: We acknowledge that the coding of GG items may be affected by payment and quality reporting considerations and are actively monitoring IRF coding practices. The imputation approach implemented in the currently adopted Discharge Self-Care Score and Discharge Mobility Score measures, which recodes any ANA code to the most dependent level, can exacerbate these incentives, particularly with respect to function at admission. We would like to point out that statistical imputation used in the proposed DC Function measure reduces these incentives by using all available relevant information to assign the most likely score, ranging from most to least dependent, to each GG item. We acknowledge the importance of utilizing valid assessment data and will continue to monitor this potential data validity concern and will reconsider the measure's implementation in the quality reporting program, if needed.

CMS has multiple processes in place to ensure reported patient data are accurate. State agencies conduct standard certification surveys for IRFs, and accuracy and completeness of the IRF-PAI are among the regulatory requirements that surveyors evaluate during surveys.¹²⁵

¹²⁵ Center for Medicare and Medicaid Services. September 6, 2022. Hospitals. <https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcompliance/hospitals>.

Additionally, the IRF-PAI process has multiple regulatory requirements. Our regulations at § 412.606(b) require that (1) the assessment accurately reflects the patient's status, (2) a clinician appropriately trained to perform a patient assessment using the IRF-PAI conducts or coordinates each assessment with the appropriate participation of health professionals, and (3) the assessment process includes direct observation, as well as communication with the patient.¹²⁶ We take the accuracy of IRF-PAI assessment data very seriously, and routinely monitor the IRF QRP measures' performance, and will take appropriate steps to address any such issues, if identified, in future rulemaking.

We note that the potential consequences of submitting false data and information in the IRF-PAI, including the potential for civil liability under the False Claims Act (31 U.S.C. §§ 3729 to 3733) for knowingly presenting a false or fraudulent claim to the government for payment, provide strong incentives for providers to ensure that the data submitted in the IRF-PAI are accurate.

Comment: One commenter raised concerns about the measure, noting that IRFs are allowed to have 5 percent of the IRF-PAI data incomplete.

Response: We interpret the comment as referring to the 95 percent completion threshold for the Annual Increase Factor (AIF) update. IRFs must submit 95 percent of their assessments with 100 percent of the required data elements to avoid the 2 percent penalty.¹²⁷ As with all our IRF QRP measures, we will continue to monitor this measure to identify any concerning trends as part of our routine monitoring activities to regularly assess measure performance, reliability, and reportability for all data submitted for the IRF QRP.

Comment: One commenter believes that self-care and mobility items are not tracked across PAC settings, creating inconsistent reporting and undue burden on IRFs, and stating that

¹²⁶ 42 CFR 412.606 <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-412/subpart-P/section-412.606>.

¹²⁷ § 412.634(f) Requirements under the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP). <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-412/subpart-P/section-412.634>.

IRFs are held to different standards compared to other settings.

Response: In addition to the IRF, the items in the DC Function measure are collected and tracked across the SNF, LTCH and Home Health setting. Therefore, we do not believe IRFs are held to a higher standard as it relates to collecting this information.

After careful consideration of the public comments we received, we are finalizing our proposal to adopt the DC Function measure as an assessment-based outcome measure beginning with the FY 2025 IRF QRP.

c. Removal of the Application of Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan That Addresses Function Beginning with the FY 2025 IRF QRP

We proposed to remove 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 from the IRF QRP beginning with the FY 2025 IRF QRP. Section 412.634(b)(2) of our regulations specifies eight factors we consider for measure removal from the IRF QRP, and 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 IRFs is so high and unvarying that meaningful distinctions in improvements in performance can no longer be made.¹²⁸ 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.C.1.b. of the 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 below.

¹²⁸ For more information on the factors CMS uses to base decisions for measure removal, we refer readers to § 412.634(b)(2) Subpart P – Requirements under the Inpatient Rehabilitation Facility (IRF) Quality Reporting Program (QRP). <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-412/subpart-P/section-412.634>.

In regard to removal factor one, the Application of Functional Assessment/Care Plan measure has become topped out, with average performance rates reaching nearly 100 percent over the past 3 years (ranging from 99.8 percent to 99.9 percent during CYs 2019-2021).^{129,130,131} For the 12-month period of third quarter of CY 2020 through second quarter of CY 2021 (July 1, 2020 through June 30, 2021), IRFs had an average score for this measure of 99.8 percent, with nearly 80 percent of IRFs scoring 100 percent,¹³² and for CY 2021, IRFs had an average score of 99.9 percent, with nearly 78 percent of IRFs scoring 100 percent.¹³³ 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 among IRFs.

In regard to measure removal factor six, the proposed DC Function measure is more strongly associated with desired patient functional outcomes than this current process measure, the Application of Functional Assessment/Care Plan measure. As described in section VIII.C.b.(1)(b) of the proposed rule, the DC Function measure has the predictive ability to distinguish patients with low expected functional capabilities from those with high expected functional capabilities.¹³⁴ We have 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 statutory requirements 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, this process measure, the Application of Functional Assessment/Care Plan measure which measures only whether a functional assessment is completed, and a functional goal is included in

¹²⁹ Centers for Medicare & Medicaid Services. Inpatient Rehabilitation Facilities Data Archive, 2021, Annual Files National Data 07-21. <https://data.cms.gov/provider-data/archived-data/inpatient-rehabilitation-facilities>.

¹³⁰ Centers for Medicare & Medicaid Services. Inpatient Rehabilitation Facilities Data Archive, 2022, Annual Files National Data 04-22. <https://data.cms.gov/provider-data/archived-data/inpatient-rehabilitation-facilities>.

¹³¹ Centers for Medicare & Medicaid Services. Inpatient Rehabilitation Facilities Data Archive, 2022, Annual Files National Data 09-22. <https://data.cms.gov/provider-data/archived-data/inpatient-rehabilitation-facilities>.

¹³² Centers for Medicare & Medicaid Services. Inpatient Rehabilitation Facilities Data Archive, 2022, Annual Files Provider Data 04-22. <https://data.cms.gov/provider-data/archived-data/inpatient-rehabilitation-facilities>.

¹³³ Centers for Medicare & Medicaid Services. Inpatient Rehabilitation Facilities Data Archive, 2022, Annual Files Provider Data 09-22. <https://data.cms.gov/provider-data/archived-data/inpatient-rehabilitation-facilities>.

¹³⁴ “Expected functional capabilities” is defined as the predicted discharge function score.

the care plan, is no longer necessary, and can be replaced with a measure that evaluates the IRF's outcome of care on a patient's function.

Because the Application of Functional Assessment/Care Plan measure meets measure removal factors one and six under § 412.634(b)(2), we proposed to remove it from the IRF QRP beginning with the FY 2025 IRF QRP. We also proposed that public reporting of the Application of Functional Assessment/Care Plan measure would end by the September 2024 Care Compare refresh or as soon as technically feasible when public reporting of the proposed DC Function measure would begin (see section VIII.G.3. of the proposed rule).

Under our proposal, IRFs 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) on the IRF-PAI beginning with patients admitted on October 1, 2023. We would remove the items for Self-Care Discharge Goals (that is, GG0130, Column 2) and Mobility Discharge Goals (that is, GG0170, Column 2) with the next release of the IRF-PAI. Under our proposal, these items would not be required to meet IRF QRP requirements beginning with the FY 2025 IRF QRP.

We invited public comment on our proposal to remove the Application of Functional Assessment/Care Plan measure from the IRF QRP beginning with the FY 2025 IRF QRP. The following is a summary of the public comments received on our proposal and our responses:

Comment: Several commenters supported the removal of the Application of Functional Assessment/Care Plan measure, along with the requirement to submit the associated goal items (that is, the Self-Care Discharge Goals and Mobility Discharge Goals), stating that the measure lacks variation in performance and is no longer meaningful, and noted its removal will reduce burden. Three of these commenters noted that the measure's removal should not be tied to the adoption of the DC Function measure because the measure is topped out and is no longer representative of meaningful distinctions in improvements and performance.

Response: We thank the commenters for their support to remove the Application of Functional Assessment/Care Plan measure and the removal of the GG items from the IRF-PAI

and agree that the measure provides limited value given the lack of variation. With respect to the commenters' request that we not tie this measure removal proposal to the adoption of the DC Function measure, we would like to clarify that a cross-setting measure of function is required to meet the requirements set forth in sections 1886(j)(7)(F)(i) and 1899B(c)(1)(A) of the Act. Thus, the removal of this measure is inherently dependent on the adoption of a new measure that would also meet the requirements of sections 1886(j)(7)(F)(i) and 1899B(c)(1)(A) of the Act.

Comment: One commenter supported the removal of the Application of Functional Assessment/Care Plan measure, but also noted that it is important and integral to set and track individual patient functional goals for a patient's care plan.

Response: We thank the commenter for their support to remove the Application of Functional Assessment/Care Plan measure from the IRF QRP. Additionally, we agree that it is critically important that facilities continue to set and track patient functional goals, even after the measure is removed. While CMS will not require the assessment or reporting of, items associated with this measure, IRFs have the option to continue collection within their own health records to meet patient needs.

After consideration of the public comments we received, we are finalizing our proposal to remove the Application of Functional Assessment/Care Plan measure from the IRF QRP beginning with the FY 2025 IRF QRP as proposed.

d. Removal of the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients and Removal of the IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients Beginning with the FY 2025 IRF QRP

We proposed to remove the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (Change in Self-Care Score) and the IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (Change in Mobility Score) measures from the IRF QRP beginning with the FY 2025 IRF QRP. Section 412.634(b)(2) of our regulations specifies eight factors we consider for measure removal from

the IRF QRP. We proposed removal of these measures because they satisfy measure removal factor eight: the costs associated with a measure outweigh the benefits of its use in the IRF QRP.

Measure costs are multifaceted and include costs associated with implementing and maintaining the measures. On this basis, we proposed to remove these measures for two reasons. First, the costs to IRFs associated with tracking similar or duplicative measures in the IRF QRP outweigh any benefit that might be associated with the measures. Second, the costs to CMS associated with program oversight of the measures, including measure maintenance and public display, outweigh the benefit of information obtained from the measures. We discuss each of these in more detail below.

We adopted the Change in Self-Care Score and Change in Mobility Score measures in the FY 2016 IRF PPS final rule (80 FR 47112 through 47118) under section 1886(j)(7)(D)(ii) of the Act because the measures meet the functional status, cognitive function, and changes in function and cognitive function domain under section 1899B(c)(1) of the Act. Two additional measures addressing the functional status, cognitive function, and changes in function and cognitive function domain were adopted in the same program year: the IRF Functional Outcome Measure: Discharge Self-Care Score for Medical Rehabilitation Patients (Discharge Self-Care Score) and the IRF Functional Outcome Measure: Discharge Mobility Score for Medical Rehabilitation Patients (Discharge Mobility Score) measures. Given that the primary goal of rehabilitation is improvement in functional status, IRF clinicians have traditionally assessed and documented individual patients' functional status at admission and discharge to evaluate the effectiveness of the rehabilitation care provided.

We proposed to remove the Change in Self-Care Score and Change in Mobility Score measures because we believe the IRF costs associated with tracking duplicative measures outweigh any benefit that might be associated with the measures. Since the adoption of these measures in 2016, we have been monitoring the data and found that the scores for the two self-care functional outcome measures, Change in Self-Care Score and Discharge Self-Care Score,

are very highly correlated in IRF settings (0.97).¹³⁵ Similarly, in the monitoring data, we have found that, the scores for the two mobility score measures, Change in Mobility Score and Discharge Mobility Score, are very highly correlated in IRF settings (0.98).¹³⁶ The high correlation between these measures suggests that the Change in Self-Care Score and Discharge Self-Care Score and the Change in Mobility Score and the Discharge Mobility Score measures provide almost identical information about this dimension of quality to IRFs and are therefore duplicative.

Our proposal to remove the Change in Self-Care Score and the Change in Mobility Score measures is supported by feedback received from the TEP convened for the Refinement of LTCH, IRF, SNF/NF, and HH Function Measures. As described in section VIII.C.1.b(3) of the proposed rule, the TEP panelists were presented with analyses that demonstrated the “Change in Score” and “Discharge Score” measure sets are highly correlated and do not appear to measure unique concepts, and they subsequently articulated that it would be sensible to retire either the “Change in Score” or “Discharge Score” measure sets for both self-care and mobility. Based on responses to the post-TEP survey, the majority of panelists (nine out of 12 respondents) suggested that only one measure is necessary. Of those nine respondents, six preferred retaining the “Discharge Score” measures over the “Change in Score” measures.¹³⁷

Additionally, we proposed to remove the Change in Self-Care Score and Change in Mobility Score measures because the program oversight costs outweigh the benefit of information that CMS, IRFs, and the public obtain from the measures. We must engage in

¹³⁵ Acumen, LLC and Abt Associates. 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, July 14-15, 2021: Summary Report. February 2022. <https://mmshub.cms.gov/sites/default/files/TEP-Summary-Report-PAC-Function.pdf>.

¹³⁶ Acumen, LLC and Abt Associates. 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: July 14-15, 2021: Summary Report. February 2022. <https://mmshub.cms.gov/sites/default/files/TEP-Summary-Report-PAC-Function.pdf>.

¹³⁷ Acumen, LLC and Abt Associates. 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, July 14-15, 2021: Summary Report. February 2022. <https://mmshub.cms.gov/sites/default/files/TEP-Summary-Report-PAC-Function.pdf>.

various activities when administering the QRPs, such as monitoring measure results, producing provider preview reports, and ensuring the accuracy of the publicly reported data. Because these measures essentially provide the same information to IRFs and consumers as the Discharge Self-Care Score and Discharge Mobility Score measures, the costs to CMS associated with measure maintenance and public display outweigh the benefit of information obtained from the measures.

Because these measures meet the criteria for measure removal factor eight, we proposed to remove the Change in Self-Care Score and Change in Mobility Score measures from the IRF QRP beginning with the FY 2025 IRF QRP. We also proposed that public reporting of the Change in Self-Care Score and the Change in Mobility Score measure would end by the September 2024 Care Compare refresh or as soon as technically feasible.

We invited public comment on our proposal to remove the Change in Self-Care Score and Change in Mobility Score measures from the IRF QRP beginning with the FY 2025 IRF QRP.

The following is a summary of the public comments received on our proposal to remove the Change in Self-Care Score and Change in Mobility Score measures from the IRF QRP beginning with the FY 2025 IRF QRP and our responses.

Comment: Several commenters expressed their support for the removal of the Change in Self-Care Score and the Change in Mobility Score measures, noting that these measures are duplicative of other measures and that their removal will reduce costs to IRFs and to CMS.

Response: We thank the commenters for their support of the removal of the measures and agree, based on the testing we presented in the proposed rule, that the Change in Self-Care Score and Change in Mobility Score measures are duplicative of the Discharge Self-Care Score and Discharge Mobility Score measures.

Comment: Several commenters did not agree with the removal of the Change in Self-Care Score and Change in Mobility Score measures because they believe these measures provide more information than the Discharge Self-Care Score and the Discharge Mobility Score

measures. Specifically, some commenters stated that capturing the amount of change patients experience is more valuable than capturing whether patients meet or exceed an expected amount of change during their stay. One commenter noted that the greater variability in performance of the Change in Self-Care Score and Change in Mobility Score measures offers significantly greater opportunity to differentiate IRF performance, compared to the analogous Discharge Self-Care Score and Discharge Mobility Score measures.

Response: We appreciate the perspective of the commenters and understand that there are advantages and disadvantages to retiring the Change in Self-Care Score and Change in Mobility Score versus the Discharge Self-Care Score and Discharge in Mobility Score measures. We weighed the tradeoffs of these measures in consultation with a TEP, comprised of 15 panelists with diverse perspectives and areas of expertise, including IRF representation.¹³⁸ The majority of the TEP favored the retirement of the Change in Self-Care Score and Change in Mobility Score measures because they believed the Discharge Self-Care Score and Discharge in Mobility Score measures better capture a patient's relevant functional abilities. We agree that it is important for facilities to track the amount of change that occurs over the course of a stay for its patients and would like to point out that the removal of the Change in Self-Care Score and Change in Mobility Score measures does not preclude IRFs' abilities in this regard. However, we also believe that the Change in Self-Care Score and Change in Mobility Score measures are not intuitive to interpret for the primary audience of Care Compare, as the unit of change, and what constitutes a meaningful change, are unfamiliar to the vast majority of users, particularly prospective or current patients and their caregivers. This is in contrast to the Discharge Self-Care Score and Discharge Mobility Score measures, which are presented as a simple proportion. Additionally, as noted in section VII.C.1.b.1.b of this final rule, the correlations between the

¹³⁸ Acumen, LLC and Abt Associates. 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, July 14–15, 2021: Summary Report. February 2022. <https://mmshub.cms.gov/sites/default/files/TEP-Summary-Report-PAC-Function.pdf>.

Change in Self-Care Score and Discharge Self-Care Score measures and Change in Mobility Score and Discharge Mobility Score measures are very high (Spearman correlation: 0.97-0.98), indicating the measures capture almost identical concepts and lead to very similar rankings.¹³⁹ As such, the testing does not support the claim that the Change in Self-Care Score and Change in Mobility Score measures provide significantly more information on which to compare facilities, as the relative rankings of facilities are very similar between the Change in Self-Care Score and Discharge Self-Care Score measures and the Change in Mobility Score and Discharge Mobility Score measures. Given the TEP's recommendation, the more intuitive interpretation, and the very high correlations, we believe there is more value in retiring the Change in Self-Care Score and Change in Mobility Score measures and retaining the Discharge Self-Care Score and Discharge Mobility Score measures.

Comment: Two commenters raised concerns that the methodology used to calculate the Discharge Self-Care Score and Discharge Mobility Score measures does not account for functional abilities at admission in the way that the Change in Self-Care Score and Change in Mobility Score measures being proposed for removal do. One of these commenters requested that CMS clarify the extent to which these remaining Discharge Self-Care Score and Discharge Mobility Score measures would account for change in patients' function over time, as well as patient heterogeneity. Relatedly, another commenter noted that patients with higher discharge scores at the end of their IRF stay may include many patients who were admitted with high scores initially, and therefore, the quality and value of the IRF's care can be potentially misunderstood. These commenters also raised concerns about unintended consequences that could be introduced through the removal of the Change in Self-Care Score and Change in Mobility Score measures, such as the cherry-picking of patients or creating limited access to

¹³⁹ Acumen, LLC and Abt Associates. 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: July 14–15, 2021: Summary Report. February 2022. <https://mmshub.cms.gov/sites/default/files/TEP-Summary-Report-PAC-Function.pdf>.

services for those with lower functional status. One of these commenters urged CMS to carefully evaluate whether the removal of the Change in Self-Care Score and Change in Mobility Score measures could lead to such unintended consequences.

Response: We appreciate that measures of functional outcomes must account for patient case-mix to ensure fair and meaningful comparisons across facilities. Accordingly, the Discharge Self-Care Score and Discharge Mobility Score measures that would remain in the IRF QRP do in fact account for functional abilities at admission, as well as other relevant demographic and clinical characteristics (see, for example, *Inpatient Rehabilitation Facility Quality Reporting Program Measure Calculations and Reporting User's Manual v4.0*).¹⁴⁰ Specifically, the expected discharge scores, which patients must meet or exceed to meet for the measures' numerators are predicted using the patients' observed admission function scores plus the same clinical comorbidities and demographic characteristics as the corresponding Change in Self-Care Score and Change in Mobility Score measures. Given that the Discharge Self-Care Score and Discharge Mobility Score measures do account for functional abilities at admission, among other relevant clinical characteristics that can impact functional improvement, we do not anticipate that the removal of the Change in Self-Care Score and Change in Mobility Score measures will increase any incentive to cherry-pick patients or block access to care. We take the appropriate access to care in IRFs very seriously, and routinely monitor the performance of measures in the IRF QRP, including performance gaps across IRFs. We will continue to monitor closely whether any proposed changes to the IRF QRP have unintended consequences on access to care for high-risk patients. Should we find any unintended consequences, we will take appropriate steps to address these issues in future rulemaking.

Comment: One commenter stated that they do not support the removal of the Change in Self-Care Score and Change in Mobility Score measures, stating that these measures assess

¹⁴⁰ Centers for Medicare & Medicaid Services. Inpatient Rehabilitation Facility Quality Reporting Program Measure Calculations and Reporting User's Manual Version 4.0. October 2022. <https://www.cms.gov/files/document/irf-quality-measure-calculations-and-reporting-users-manual-v40.pdf>.

patients who meet or exceed a specific risk-adjusted goal, and as such are representative of IRF care as a whole.

Response: We agree that there is value in assessing the extent to which patients meet or exceed an expected level of function, where the expected level of function accounts for a patient's own case mix. However, we would like to point out that this is exactly what the Discharge Self-Care Score and Discharge Mobility Score measures assess (which would be retained in the IRF QRP), as opposed to the Change in Self-Care and Change in Mobility Measure, which measure the risk-adjusted change in function between admission and discharge.

After consideration of the public comments we received, we are finalizing our proposal to remove the Change in Self-Care Score and Change in Mobility Score measures from the IRF QRP beginning with the FY 2025 IRF QRP as proposed.

2. IRF QRP Quality Measure Beginning with the FY 2026 IRF QRP

a. COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure Beginning with the FY 2026 IRF QRP

(1) Background

COVID-19 has been and continues to be a major challenge for PAC facilities, including IRFs. The Secretary first declared COVID-19 a PHE on January 31, 2020. As of March 23, 2023, the U.S. has reported 103,957,053 cumulative cases of COVID-19, and 1,123,613 total deaths due to COVID-19.¹⁴¹ 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.¹⁴² Older adults, in general, are prone to both acute and chronic infections owing to reduced immunity, and are a high-risk population.¹⁴³

¹⁴¹ Centers for Disease Control and Prevention. COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker/#cases_totalcases.

¹⁴² 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>.

¹⁴³ Lekamwasam R, Lekamwasam S. Effects of COVID-19 pandemic on health and wellbeing of older people: a comprehensive review. *Ann Geriatr Med Res*. 2020 Sep;24(3):166-172.doi: 10.4235/agmr.20.0027. PMID: 32752587; PMCID: PMC7533189.

Adults age 65 and older comprise over 75 percent of total COVID-19 deaths despite representing 13.4 percent of reported cases.¹⁴⁴ COVID-19 has impacted older adults' access to care, leading to poorer clinical outcomes, as well as taking a serious toll on their mental health and well-being due to social distancing.¹⁴⁵

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.¹⁴⁶ Initial studies showed the efficacy of FDA-approved or authorized COVID-19 vaccines in preventing COVID-19. Prior to the emergence of the Delta variant of the virus, vaccine effectiveness against COVID-19-associated hospitalization among adults aged 65 and older was 91 percent for those who were fully vaccinated with an mRNA vaccine (Pfizer-BioNTech or Moderna), and 84 percent for those receiving a viral vector vaccine (Janssen). Adults aged 65 and older who were fully vaccinated with an mRNA COVID-19 vaccine had a 94 percent reduction in risk of COVID-19 hospitalization while those who were partially vaccinated had a 64 percent reduction in risk.¹⁴⁷ 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.¹⁴⁸

More recently, since the emergence of the Omicron variants and availability of booster doses, multiple studies have shown that while vaccine effectiveness has waned, protection is

¹⁴⁴ Centers for Disease Control and Prevention. Demographic trends of COVID-19 cases and deaths in the US reported to CDC. COVID Data Tracker. <https://covid.cdc.gov/covid-data-tracker/#demographics>.

¹⁴⁵ 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>.

¹⁴⁶ Chalkias S, Harper C, Vrbicky K, et al. A Bivalent Omicron-Containing Booster Vaccine Against COVID-19. *N Engl J Med*. 2022 Oct 6;387(14):1279-1291. doi: 10.1056/NEJMoa2208343. PMID: 36112399; PMCID: PMC9511634.

¹⁴⁷ 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>.

¹⁴⁸ Grannis SJ, Rowley EA, Ong TC, et al. 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.org/10.15585/mmwr.mm7037e2.

higher among those receiving booster doses than among those only receiving the primary series.^{149,150,151} CDC data show that, among people age 50 and older, those who have received both a primary vaccination series and booster doses have a lower risk of hospitalization and dying from COVID-19 than their non-vaccinated counterparts.¹⁵² Additionally, a second vaccine booster dose has been shown to reduce risk of severe outcomes related to COVID-19, such as hospitalization or death.¹⁵³ Early evidence also demonstrates that the bivalent boosters, specifically aimed to provide better protection against disease caused by Omicron subvariants, have been quite effective, and underscores the role of up to date vaccination protocols in effectively countering the spread of COVID-19.^{154,155}

(a) Measure Importance

Despite the availability and demonstrated effectiveness of COVID-19 vaccinations, significant gaps continue to exist in vaccination rates.¹⁵⁶ As of March 22, 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

¹⁴⁹ 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.

¹⁵⁰ 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 Apr 21;386(16):1532-1546. doi: 10.1056/NEJMoa2119451. PMID: 35249272; PMCID: PMC8908811.

¹⁵¹ 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 Sep 1;5(9):e2232760. doi: 10.1001/jamanetworkopen.2022.32760. <https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2796615>. PMID: 36136332; PMCID: PMC9500552.

¹⁵² Centers for Disease Control and Prevention. Rates of laboratory-confirmed COVID-19 hospitalizations by vaccination status. COVID Data Tracker. February 9, 2023. <https://covid.cdc.gov/covid-data-tracker/#covidnet-hospitalizations-vaccination>.

¹⁵³ 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>.

¹⁵⁴ Chalkias S, Harper C, Vrbicky K, et al. A bivalent omicron-containing booster vaccine against COVID-19. *N Engl J Med.* 2022 Oct 6;387(14):1279-1291. doi: 10.1056/NEJMoa2208343. PMID: 36112399; PMCID: PMC9511634.

¹⁵⁵ Tan, S.T., Kwan, A.T., Rodríguez-Barraquer, I. et al. Infectiousness of SARS-CoV-2 breakthrough infections and reinfections during the Omicron wave. *Nat Med* 29, 358–365 (2023). <https://doi.org/10.1038/s41591-022-02138-x>.

¹⁵⁶ Centers for Disease Control and Prevention. COVID Data Tracker: COVID-19 vaccinations in the United States. https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-people-booster-percent-pop5.

booster).¹⁵⁷ 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.¹⁵⁸ Variations are also present when examining vaccination rates by race, gender, and geographic location.¹⁵⁹ 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.¹⁶⁰ Disparities have been found in vaccination rates between rural and urban areas, with lower vaccination rates found in rural areas.^{161,162} Data show that 55.2 percent of the eligible population in rural areas have completed the primary vaccination series, as compared to 66.5 percent of the eligible population in urban areas.¹⁶³ 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 a

¹⁵⁷ 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>.

¹⁵⁸ 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/>.

¹⁵⁹ 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 Mar 4;71:335-340. doi: 10.15585/mmwr.mm7109a2. PMID: 35239636; PMCID: PMC8893338.

¹⁶⁰ Centers for Disease Control and Prevention. COVID Data Tracker: Trends in demographic characteristics of people receiving COVID-19 vaccinations in the United States. <https://covid.cdc.gov/covid-data-tracker/#vaccination-trends>.

¹⁶¹ 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 Mar 4;71:335-340. doi: 10.15585/mmwr.mm7109a2. PMID: 35239636; PMCID: PMC8893338.

¹⁶² Sun Y, Monnat SM. Rural-urban and within-rural differences in COVID-19 vaccination rates. *J Rural Health*. 2022 Sep;38(4):916-922. doi: 10.1111/jrh.12625. PMID: 34555222; PMCID: PMC8661570

¹⁶³ Centers for Disease Control and Prevention. COVID Data Tracker. COVID-19 Vaccination Equity. <https://covid.cdc.gov/covid-data-tracker/#vaccination-equity>.

booster dose.¹⁶⁴

We proposed to adopt the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID-19 Vaccine) measure for the IRF QRP beginning with the FY 2026 IRF QRP. The proposed measure has the potential to increase COVID-19 vaccination coverage of patients in IRFs, as well as prevent the spread of COVID-19 within the IRF patient population. The proposed Patient/Resident COVID-19 Vaccine measure would also support the goal of CMS's 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 publicly reported on Care Compare and would provide patients, including those who are at high risk for developing serious complications from COVID-19, and their caregivers, with valuable information they can consider when choosing an IRF. The proposed Patient/Resident COVID-19 Vaccine measure would also facilitate patient care and care coordination during the hospital discharge planning process. For example, a discharging hospital, in collaboration with the patient and family, could use this proposed measure's publicly reported information on Care Compare to coordinate care and ensure patient preferences are considered in the discharge plan. Additionally, the proposed Patient/Resident COVID-19 Vaccine measure would be an indirect measure of IRF action. Since the patient's COVID-19 vaccination status would be reported at discharge from the IRF, if a patient is not up to date with their COVID-19 vaccination per applicable CDC guidance at the time they are admitted, the IRF has the opportunity to educate the patient and provide information on why they should become up to date with their COVID-19 vaccination. IRFs may also choose to administer the vaccine to the patient prior to their discharge from the IRF or coordinate a follow-up visit for the patient to obtain the vaccine at their physician's office or local pharmacy.

¹⁶⁴ Centers for Disease Control and Prevention. COVID-19 Vaccination Equity. COVID Data Tracker. <https://covid.cdc.gov/covid-data-tracker/#vaccination-equity>.

(b) Item Testing

The measure development contractor conducted testing of the proposed standardized patient/resident COVID-19 vaccination coverage assessment item for the proposed Patient/Resident COVID-19 Vaccine measure using patient scenarios, draft guidance manual coding instructions, and cognitive interviews to assess IRFs' comprehension of the item and the associated guidance. A team of clinical experts assembled by our measure development contractor developed these patient scenarios to represent the most common scenarios that IRFs would encounter. The results of the item testing demonstrated that IRFs that used the draft guidance manual coding instructions had strong agreement (that is, 84 percent) with the correct responses, supporting its reliability. The testing also provided information to improve both the item itself and the accompanying guidance.

(2) Competing and Related Measures

Sections 1886(j)(7)(D)(i) and 1899B(e)(2)(A) of the Act require that, absent an exception under sections 1886(j)(7)(D)(ii) and 1899B(e)(2)(B) of the Act, measures specified under section 1886(j)(7)(D)(i) of the Act and section 1899B of the Act must 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, sections 1886(j)(7)(D)(ii) and 1899B(e)(2)(B) of the Act permit 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 endorsed and adopted measures, we were unable to identify any measures endorsed or adopted by a consensus organization for IRFs focused on capturing COVID-19 vaccination coverage of IRF patients. We found only one related measure addressing COVID-19 vaccination, the COVID-19 Vaccination Coverage among Healthcare Personnel measure, adopted for the FY 2023 IRF QRP (86 FR 42385 through 42396), which captures the percentage

of HCP who receive a complete COVID-19 primary vaccination course.

Therefore, after consideration of other available measures that assess COVID-19 vaccination rates among IRF patients, we believe the exceptions under sections 1886(j)(7)(D)(ii) and 1899B(e)(2)(B) of the Act apply. We intend to submit the proposed measure for consideration of endorsement by the CBE when feasible.

(3) Interested Parties and Technical Expert Panel (TEP) Input

First, the measure development contractor 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 IRF action, would be most helpful in patient and family/caregiver decision-making. Next, TEP meetings were 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 IRF setting without denominator exclusions was an important goal. We considered the TEP's recommendations, and we applied the 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 MMS Hub.¹⁶⁵

To seek input on the importance, relevance, and applicability of a patient/resident COVID-19 vaccination coverage measure, we also solicited public comments in an RFI for publication in the FY 2023 IRF PPS proposed rule (87 FR 47038).¹⁶⁶ Comments were generally

¹⁶⁵ *Technical Expert Panel (TEP) for the Development of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) COVID-19 Vaccination-Related Items and Measures Summary Report.*

<https://mmshub.cms.gov/sites/default/files/COVID19-Patient-Level-Vaccination-TEP-Summary-Report-NovDec2021.pdf>.

¹⁶⁶ 87 FR 20218.

positive on the concept of a measure addressing COVID-19 vaccination coverage among IRF patients. Some commenters included caveats with their support and requested further details regarding measure specifications and CBE endorsement. In addition, commenters voiced concerns regarding the evolving recommendations related to boosters and the definition of “up to date,” as well as whether an IRF length of stay would allow for meaningful distinctions among IRFs (87 FR 47071).

(4) Measure Applications Partnership (MAP) Review

The 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 list. The Patient/Resident COVID-19 Vaccine measure was included on the publicly available 2022 MUC List for the IRF QRP.¹⁶⁷

After the MUC List was published, the MAP received five comments from interested parties. Commenters were mostly supportive of the measure and recognized the importance of patients’ 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 that patient engagement is critical at this stage of the pandemic, while another noted the criteria for inclusion in the numerator and denominator provide flexibility for the measure to remain relevant to current circumstances. Another commenter anticipated minimal implementation challenges since healthcare providers are already asking for patients’ COVID-19 vaccination status at intake. Commenters who were not supportive of the measure raised several issues, including that the measure does not capture quality of care, concern about the evolving definition of the term “up to date,” that data

¹⁶⁷ Centers for Medicare & Medicaid Services. (2022). Overview of the List of Measures Under Consideration for December 1, 2022. <https://mmshub.cms.gov/sites/default/files/2022-MUC-List-Overview.pdf>.

collection would be burdensome, that administering the vaccine could impact the IRF treatment plan, and that a measure only covering one quarter may not be meaningful.

Subsequently, several MAP workgroups met to provide input on the proposed measure. First, the MAP Health Equity Advisory Group convened on December 6, 2022. One MAP Health Equity Advisory Group member noted that the percentage of true contraindications for the COVID-19 vaccine is low, and the lack of exclusions on the measure is reasonable in order to minimize variation in what constitutes a contraindication.¹⁶⁸ Similarly, the MAP Rural Health Advisory Group met on December 8, 2022, and requested clarification of the term “up to date” and noted concerns with the perceived level of burden for collection of data.¹⁶⁹

Next, the MAP PAC/LTC workgroup met on December 12, 2022. The MAP PAC/LTC workgroup’s voting members raised concerns brought up in public comments, such as provider actionability, lack of denominator exclusions, requirements for assessing patient vaccination status, evolving COVID-19 vaccination recommendations, and data reporting frequency for this measure. Additionally, MAP PAC/LTC workgroup members noted the potential inability of IRFs to administer the vaccine due to the shorter average length of stay as compared to other PAC settings. In response to workgroup member feedback, we noted that the intent of the Patient/Resident COVID-19 Vaccine measure would be to promote transparency of data for patients to make informed decisions regarding care and is not intended to be a measure of IRF action. We also explained that this measure does not have exclusions for patient refusal since this measure was intended to report raw rates of vaccination, and this information is important for consumer choice. Additionally, we believe that PAC providers, including IRFs, are in a unique position to leverage their care processes to increase vaccination coverage in their settings to protect patients and prevent negative outcomes. We also noted that collection of these data

¹⁶⁸ CMS Measures Management System (MMS). Measure Implementation: Pre-rulemaking MUC Lists and MAP reports. <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>.

¹⁶⁹ CMS Measures Management System (MMS). Measure Implementation: Pre-rulemaking MUC Lists and MAP reports. <https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports>.

will not require additional documentation or proof of vaccination. We clarified that the Patient/Resident COVID-19 Vaccine measure would include the definition of up to date, so the measure would consider future changes in the CDC guidance regarding COVID-19 vaccination. We also clarified that the measure would continue to be a quarterly measure similar to the existing HCP COVID-19 Vaccine measure, as CDC has not determined whether COVID-19 is, or will be, a seasonal disease like influenza. Finally, we noted that the average 12-day length of stay at IRFs is generally longer than patient stays at acute care hospitals. Given that health care is a continuum and every contact along the continuum provides an opportunity to encourage vaccination, IRFs have sufficient time to act on the patient's vaccination status. However, the MAP PAC/LTC workgroup reached a 60 percent consensus on the vote of "Do not support for rulemaking" for this measure.¹⁷⁰

The MAP received four comments from industry commenters in response to the MAP PAC/LTC workgroup's recommendations. Interested parties generally understood the importance of COVID-19 vaccinations in preventing the spread of COVID-19, although a majority of commenters did not recommend the inclusion of the proposed Patient/Resident COVID-19 Vaccine measure for the IRF QRP and raised several concerns. Specifically, commenters were concerned about vaccine hesitancy and providers' inability to influence results based on factors outside of their control. Commenters also noted that the measure has not been fully tested and encouraged CMS to monitor the measure for unintended consequences and ensure that the measure has meaningful results. One commenter raised concerns on whether patients' vaccination information would be easily available to IRFs as well as potential limitations with patients recounting vaccination status. One commenter was in support of the measure and provided recommendations for CMS to consider adding an exclusion for medical contraindications and submitting the measure for CBE endorsement.

¹⁷⁰ CMS Measures Management System (MMS). Measure Implementation: Pre-rulemaking MUC Lists and MAP reports. https://mmshub.cms.gov/measure-lifecycle/measure-implementation/pre-rulemaking/lists-and-reports_

Finally, the MAP Coordinating Committee convened on January 24, 2023, and noted concerns which were previously discussed in the MAP PAC/LTC workgroup, such as potential disruption to patient therapy due to vaccination and acuity of patients in the IRF setting. However, a MAP Coordinating Committee member noted that a patient's potential inability to complete rehabilitation was not a valid reason to withhold support of this measure, and that, because these patients have a high acuity, they are more vulnerable to COVID-19, further emphasizing the need to vaccinate them. MAP Coordinating Committee members also raised concerns discussed previously during the MAP PAC/LTC workgroup, including the shorter IRF length of stay and excluding medical contraindications from the denominator.

The MAP Coordinating Committee recommended three mitigation strategies for the Patient/Resident COVID-19 Vaccine measure: (i) reconsider exclusions for medical contraindications, (ii) complete reliability and validity measure testing, and (iii) seek CBE endorsement. The MAP Coordinating Committee ultimately reached 81 percent consensus on its voted recommendation of "Do not support with potential for mitigation." Despite the MAP Coordinating Committee's vote, we believe it is still important to propose the Patient/Resident COVID-19 Vaccine measure for the IRF QRP. As we stated in section VIII.C.2.a.(3) of the 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*.¹⁷¹

(5) Quality Measure Calculation

¹⁷¹ 2022-2023 MAP Final Recommendations. <https://mmshub.cms.gov/sites/default/files/2022-2023-MAP-Final-Recommendations-508.xlsx>

The proposed Patient/Resident COVID-19 Vaccine measure is an assessment-based process measure that reports the percent of stays in which patients in an IRF are up to date on their COVID-19 vaccinations per the CDC’s latest guidance.¹⁷² This measure has no exclusions and is not risk adjusted.

The numerator for the proposed measure would be the total number of IRF stays in the denominator in which patients are up to date with their COVID-19 vaccination per CDC’s latest guidance. The denominator for the proposed measure would be the total number of IRF stays discharged during the reporting period.

The data source for the proposed Patient/Resident COVID-19 Vaccine measure is the IRF-PAI for IRF patients. For more information about the proposed data submission requirements, we refer readers to section VIII.F.3. of the proposed rule. For additional technical information about this proposed measure, we refer readers to the draft measure specifications document titled *COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date Draft Measure Specifications*.¹⁷³ available on the IRF QRP Measures and Technical Information webpage.

We invited public comments on the proposal to adopt the Patient/Resident COVID-19 Vaccine measure beginning with the FY 2026 IRF QRP. The following is a summary of the public comments received on our proposal and our responses.

Comment: One commenter supported the measure noting it does not add significant burden.

Response: We thank the commenter for their support.

A number of commenters did not support the proposal to adopt the Patient/Resident COVID-19 Vaccine measure to the IRF QRP for various reasons. The following is a summary

¹⁷² The definition of “up to date” may change based on CDC’s latest guidelines and is available on the CDC webpage, “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 March 2, 2023).

¹⁷³ COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date Draft Measure Specifications. <https://www.cms.gov/files/document/patient-resident-covid-vaccine-draft-specs.pdf>.

of these public comments received on our proposal and our responses.

Comment: One commenter agreed with CMS's proposed justification that the measure has the potential to drive COVID-19 vaccination uptake among IRF patients and prevent the spread of COVID-19 in the IRF population and agreed that the measure could help empower consumers in making decisions about their care. Despite this, they still urged CMS to ensure that measures are appropriately specified and adequately tested and validated prior to implementation. This commenter also noted that, unlike the proposed HCP COVID-19 Vaccine measure, the specifications for this Patient/Resident COVID-19 Vaccine measure solely reference the definition of up to date as described on CDC's "Stay Up to Date" website. Even though this definition more accurately reflects the most current Advisory Committee on Immunization Practices (ACIP) recommendation, the commenter urged CMS to ensure that this approach to specifying measures is valid and will not serve to cause confusion or reporting challenges in the future.

However, several commenters did not support the proposal due to the measure not being fully tested for reliability and validity, and one commenter noted that even CMS stated that the measure would need to be tested for reliability and validity once enough data were collected. One commenter said it was unclear whether it is feasible for PAC facilities to collect and report information for the proposed measure. Another one of these commenters suggested CMS "rushed through" the validation process to add the measure to the IRF QRP as soon as possible because there is no support showing the measure is practical or feasible. Some commenters also encouraged CMS to delay implementation of the measure in the IRF QRP until the measure had been fully tested.

Response: We are pleased that the commenter agrees with CMS's proposed rationale that the measure has the potential to drive COVID-19 vaccination uptake among IRF patients, prevent the spread of COVID-19 in the IRF population, and empower consumers in making decisions about their care.

We also acknowledge the concerns brought up regarding the measure not being tested yet and commenters' reasons for not supporting the measure. However, we have tested the item proposed for the IRF-PAI to capture data for this measure and its feasibility and appropriateness. Since a COVID-19 vaccination item does not yet exist within the IRF-PAI, we developed clinical vignettes to test item-level reliability of a draft Patient/Resident COVID-19 Vaccine item for the IRF-PAI. The clinical vignettes were a proxy for patient records with the most common and challenging cases providers would encounter, similar to the approach that CMS uses to train providers on all new assessment items, and the results demonstrated strong agreement (that is, 84 percent).

Validity testing has not yet been completed, since the COVID-19 vaccination item does not yet exist on the IRF-PAI. However, the Patient/Resident COVID-19 Vaccine measure was constructed based on prior use of similar items, such as the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) for the IRF QRP and LTCH QRP.¹⁷⁴ We have used these types of patient/resident vaccination assessment items in the calculation of vaccination quality measures in our PAC QRPs and intend to conduct reliability and validity testing for this specific Patient/Resident COVID-19 Vaccine measure once the COVID-19 vaccination item has been added to the IRF-PAI and we have collected sufficient data.

Additionally, we solicited feedback from our TEP on the proposed assessment item and its feasibility. No concerns were raised by the TEP regarding obtaining information required to complete the new COVID-19 vaccination item.¹⁷⁵

Comment: Several commenters did not support the measure and cited the CBE's MAP 2022-2023 review cycle where the MAP failed to reach consensus, and ultimately did not

¹⁷⁴ 78 FR 47859 and 77 FR 53257.

¹⁷⁵ Technical Expert Panel (TEP) for the Development of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) COVID-19 Vaccination-Related Items and Measures Summary Report. <https://mmshub.cms.gov/sites/default/files/COVID19-Patient-Level-Vaccination-TEP-Summary-Report-NovDec2021.pdf>.

recommend the measure for rulemaking. One commenter said they were deeply concerned about the proposal to add the Patient/Resident COVID-19 Vaccine measure because it appeared as though CMS disregarded the recommendations of the MAP. Several of the commenters noted that the MAP is a multi-stakeholder panel of experts representing providers, patients, and payers, and encouraged CMS to address the MAP's concerns about the measure, including adding exclusions in the measure, conducting measure testing, and submitting the measure for CBE endorsement prior to adopting it in the IRF QRP.

Response: As part of the pre-rulemaking process, HHS takes into consideration the recommendations of the MAP in selecting candidate quality and efficiency measures. HHS selects candidate measures and publishes proposed rules in the **Federal Register**, which allows for public comment and further consideration before a final rule is issued. If the CBE under contract with CMS has not endorsed a candidate measure, then HHS must publish a rationale for the use of the measure described in section 1890(b)(7)(B) of the Act in the notice. The MAP Coordinating Committee recommended three mitigation strategies for the Patient/Resident COVID-19 Vaccine measure: (i) reconsider exclusions for medical contraindications, (ii) complete reliability and validity measure testing, and (iii) seek CBE endorsement. We would like to reiterate that this measure is intended to promote transparency of data for patients/caregivers to make informed decisions for selecting facilities, providing potential patients and their caregivers with an important piece of information regarding vaccination rates as part of their process of identifying providers they would want to seek care from. As we stated in section IX.C.2.a.(3) of this final 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 intend to add a new item to the IRF-PAI assessment tool to collect this information. We will then conduct measure testing once sufficient data on the COVID-19 vaccination item are collected through the IRF-PAI and plan to submit the measure

for CBE endorsement when it is technically feasible to do so.

Comment: A few commenters believe the adoption of a patient-level measure of COVID-19 vaccination status might quickly become topped out due to lack of meaningful improvement in the vaccination rate, comparing it to the Percent of Residents of Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (CBE #0680) that was removed from the IRF QRP measure set in the FY 2019 IRF PPS final rule (83 FR 38514). One of these commenters also stated that IRF performance on this proposed measure will fail to show meaningful distinctions in improvements since 94.3 percent of the United States population at least 65 years of age had completed their primary series as of May 2023.

Response: We do not believe this measure is at risk of being retired early. The Patient/Resident COVID-19 Vaccine measure reports the percentage of patients in an IRF who are up to date on their COVID-19 vaccinations per the CDC's latest guidance, rather than capturing the rates of primary vaccination series only. Because the measure reflects an up to date vaccination status, it minimizes the potential for topping out. We believe that continued monitoring of up to date vaccination among patients will remain an important tool to minimize severe illness, hospitalization, and death in PAC facilities. Additionally, we believe there is substantial room for improvement in measure performance. As of May 2023, while the vaccination rates among people 65 and older were high for the primary vaccination series (94.3 percent), the vaccination rates were lower for the first booster dose (73.9 percent among those who received a primary series) and even lower for the second booster dose (60.4 percent among those who received a first booster).¹⁷⁶

Comment: A few commenters were concerned that the Yes/No response options for the COVID-19 vaccination item in the IRF-PAI may be unreliable and lead to inaccurate and inconsistent reporting of data. One of these commenters noted that they are also concerned that

¹⁷⁶ Centers for Disease Control and Prevention. COVID-19 vaccination age and sex trends in the United States, national and jurisdictional. May 11, 2023. <https://data.cdc.gov/Vaccinations/COVID-19-Vaccination-Age-and-Sex-Trends-in-the-Uni/5i5k-6cmh>.

a self-reported up to date answer might not be accurate, which could lead to incorrect timing for the next dosage or inaccurate reporting overall. Two of these commenters said that it is unlikely most patients would have an understanding of the CDC's specific definition of up to date when answering a yes/no question for the patient assessment, which could also lead to potentially inaccurate data.

Response: We disagree with the commenters. The results of the item testing conducted to test the COVID-19 vaccination item supported the use of a Patient-level COVID-19 Vaccination Coverage measure item. When the item was tested as drafted in the measure specifications with Yes/No response options, overall agreement for IRFs was 84 percent. Across all provider types, those who used the CDC website, or the guidance manual and the CDC website had the highest percent agreement (100 percent and 88 percent, respectively). We also believe the provision of two response options helps alleviate provider burden of providing additional details and information regarding the patient's vaccination status. Our TEP panelists indicated that they generally prefer items with less information in order to reduce IRFs' burden and that the nuance provided by the "more information" options could add additional burden and potential confusion.¹⁷⁷ Additionally, coding guidance for this item would allow providers to use all sources of information available to obtain the vaccination data, such as patient interviews, medical records, proxy response, and vaccination cards provided by the patient or their caregivers.¹⁷⁸ As with any other assessment item on the IRF-PAI, we expect IRF providers to work closely with the patient to obtain the most accurate response to the assessment question.

Comment: A few commenters were concerned that the measure does not provide response options for patients who refuse to answer, refuse the vaccination, or are excluded due to medical contraindications or closely held religious beliefs. Another commenter urged CMS to

¹⁷⁷ Technical Expert Panel (TEP) for the Development of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) COVID-19 Vaccination-Related Items and Measures Summary Report. <https://mmshub.cms.gov/sites/default/files/COVID19-Patient-Level-Vaccination-TEP-Summary-Report-NovDec2021.pdf>.

¹⁷⁸ COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date Draft Measure Specifications. <https://www.cms.gov/files/document/patient-resident-covid-vaccine-draft-specs.pdf>.

consider adding an exclusion for medical contraindications, while still another noted that CMS has failed to address the recommendations of the CBE to explore adding medical exemptions to the measure.

Response: We understand and thank the commenters for their recommendations about adding exclusions to the measure. Our measure development contractor convened a focus group of PFAs as well as a TEP that included interested parties from every PAC setting, to solicit input on patient/resident COVID-19 vaccination measures and assessment items. The PFAs told us that a measure capturing raw vaccination rates would be most helpful in patient and family/caregiver decision-making. Our TEP agreed that developing a measure to report the rate of vaccination without denominator exclusions was an important goal.¹⁷⁹ Based on this feedback, we believe excluding patients/residents with contraindications from the measure would distort the intent of the measure of providing raw COVID-19 patient vaccination rates, while making the information more difficult for patients/caregivers to interpret, and therefore we did not include any exclusions.

Comment: Several commenters were concerned regarding the lack of a well-defined definition of up to date, and the burden it poses on providers to collect this data. One commenter said the “moving target definition” contributes to concerns about the reliability of the data collected. One commenter believed that the current specifications are flawed since the current numerator specifications refers the end user to a website outlining when primary and additional/booster dose(s) are recommended and stated that this lack of a well-defined set of specifications could negatively impact the reliability and validity of the measure.

Response: The up to date concept is not new to providers and is currently in use by Nursing Home facilities for the short-stay and long-stay Percent of Residents Assessed and

¹⁷⁹ Technical Expert Panel (TEP) for the Development of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) COVID-19 Vaccination-Related Items and Measures Summary Report. <https://mmshub.cms.gov/sites/default/files/COVID19-Patient-Level-Vaccination-TEP-Summary-Report-NovDec2021.pdf>.

Appropriately Given the Pneumococcal Vaccine and Percent of Residents Who Received the Pneumococcal Vaccine measures. Beyond the historical use of this concept, ensuring that standards of care are up to date according to the relevant authorities remains a widespread goal for all providers. We believe that IRF providers should be staying current on the latest care guidelines for COVID-19 vaccination as part of best practice. Further, the IRF-PAI Guidance Manual will indicate how to code the item and providers could access the CDC website at any time to find the definition of up to date. The CDC has published FAQs that clearly state the definition of up to date.¹⁸⁰ In fact, when we tested the COVID-19 vaccination item, there was strong agreement with the correct responses when facilities used the available guidance, and rates of correct responses increased when facilities accessed the CDC website. Across all provider types, those who used the CDC website, or the guidance manual and the CDC website, had the highest percent agreement (100 percent and 88 percent respectively).

Comment: One commenter noted that some patient stays may overlap between the period when new additional/booster dose(s) become available and/or the definition of up to date changes and requested clarification on how providers should account for such “bridge” cases.

Response: Given this assessment item is completed at discharge, providers would code the item using guidance in place at the time of the patient’s discharge. As previously discussed, this measure does not mandate or require patients to be up to date with their COVID-19 vaccination. IRFs are successfully able to report the measure, and comply with the IRF QRP requirements, irrespective of the number of patients who have been vaccinated.

Comment: Another commenter was concerned regarding the uncertainty about the seasonality of COVID-19, future vaccination schedules, and how often new versions of a COVID-19 vaccine will be available.

Response: Beyond the historical use of the concept of up to date, ensuring that standards

¹⁸⁰ Centers for Disease Control and Prevention. Frequently Asked Questions. May 15, 2023. <https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html>.

of care are up to date according to the relevant authorities remains a widespread goal for all providers. As the SARS-CoV-2 virus mutates, this vaccination measure takes a forward-thinking approach to ensure that PAC patients are protected in the event of COVID-19 infection. Given that CDC guidelines may change over time in response to the virus, we believe the use of up to date will actually be simpler for facilities since it ensures that the measure specifications, item responses, and accompanying item guidance would not have to continually change.

Additionally, CMS regularly reviews its measures as part of the measure maintenance process, and will re-specify the measure in the future, if needed, based on any changes to guidelines.

A number of commenters were concerned about the burden this measure places on providers and listed several types of burden including difficulty with data collection and keeping up with the definition of up to date. The following is a summary of those comments and our responses.

Comment: Two commenters believe the proposed measure will pose unique challenges due to patients' different comorbidities and preexisting conditions that may impact which vaccine recommendation applies to them, and they believe that complying with the CDC guidelines may be challenging and time consuming for IRFs, especially if CDC revises its guidance. One of the commenters also noted that given the potential that there could be audits related to the COVID-19 vaccine measures, that increased time, personnel and financial resources would be required to collect and report the required data for these measures, and they believe those resources would be better utilized for direct patient care and other quality improvement activities that more closely align with the primary mission of IRFs.

Response: We disagree that this measure, if finalized, would take time away from patient care. We believe PAC providers should be assessing whether patients are up to date with COVID-19 vaccination as a part of their care, and even if they do not administer the vaccine, they can coordinate follow-up care for the patient to obtain the vaccine elsewhere. During our item testing, we heard from providers that they are routinely inquiring about COVID-19

vaccination status when admitting patients. CMS is committed to providing Medicare beneficiaries with high quality health care and therefore, routinely performs audits and reviews to ensure the standard of IRF care is maintained. We believe providers need to exercise due diligence as they stay abreast of standards of care and new evidence, as it becomes available. We believe IRFs consider vaccination essential to patient safety and quality care.

Gathering information about a patient's vaccination status is an important part of developing and administering a comprehensive plan of care. Rather than taking time away from patient care, providers will be documenting information they are likely already collecting through the course of providing care to the patients. We would remind providers that IRFs are currently required to meet the IRF QRP requirements as authorized by section 1886(j)(7) of the Act, and it applies to freestanding IRFs, as well as inpatient rehabilitation units of hospitals or Critical Access Hospitals (CAHs) paid by Medicare under the IRF PPS.

Comment: Two commenters believe that, as the CDC updates eligibility requirements for the latest versions of the COVID-19 vaccine, keeping track of eligibility and what is considered up to date will be difficult for IRFs. One of these commenters stated that data infrastructure would be needed to capture the non-static definition of up to date to reassess vaccine status with each new revision of the reporting definition, and this would result in a heavy burden on data collection, analysis, and reporting programs.

Response: We recognize that the up to date COVID-19 vaccination definition may evolve due to the changing nature of the virus, but we are also confident in IRFs' ability to understand these changes as they have been at the front lines of managing COVID-19 since the beginning of the pandemic. The public health response to COVID-19 has necessarily adapted to respond to the changing nature of the virus's transmission and community spread. As mentioned in the FY 2022 IRF PPS final rule (86 FR 42386), we received several public comments during the HCP COVID-19 Vaccine measure's pre-rulemaking process encouraging us to continue to evaluate the new evidence on COVID-19 as it continues to arise and we stated our intention to continue to

work with partners, including FDA and CDC. We believe that the proposed measure aligns with the Administration's responsive approach to COVID-19 and will continue to support vaccination as the most effective means to prevent the worst consequences of COVID-19, including severe illness, hospitalization, and death. However, IRFs can choose how they want to manage tracking CDC information.

Comment: A few commenters noted that collecting this information would be especially burdensome in cases where patients are unable or unwilling to provide the necessary information. One of these commenters also stated that patients will have cognitive, communication, and memory deficits that will cause barriers to appropriate communication and understanding of their vaccination status.

Response: As noted in the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date Draft Measure Specifications,¹⁸¹ providers will be able to use multiple sources of information available to obtain the vaccination data, such as patient interviews, medical records, proxy response, and vaccination cards provided by the patient or their caregivers. Therefore, coding of this item in the IRF-PAI would not be limited to a patient's oral response. As with any assessment item, we will also publish coding guidance and instructions to further assist providers in collection of these data.

Comment: Commenters did not support the measure stating that IRFs do not typically administer vaccines and it would be an undue burden for rehabilitation units to store, provide, and report the administration of the COVID-19 vaccine.

Response: This measure does not require IRF providers to administer the vaccine to the patients. While we know of no current indications of shortages or delays for the COVID-19 vaccines in IRF facilities and believe that facilities should be able to administer the vaccine if a patient is agreeable to receiving the vaccination, IRFs do not have to administer the vaccine

¹⁸¹ COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date Draft Measure Specifications. <https://www.cms.gov/files/document/patient-resident-covid-vaccine-draft-specs.pdf>.

themselves. They can arrange for the patient to obtain the vaccine outside of their facility or can work with community pharmacies to obtain vaccines.

Several commenters did not support the measure as they do not think it is a measure of quality of care due to a lack of correlation between the vaccine uptake of patients and the quality of care a patient can expect when being admitted for a stay at an IRF and the inability of IRFs to affect the results. Commenters disagreed with CMS's statement in the proposed rule (86 FR 21000) that "PAC providers, including IRFs, are in a unique position to leverage their care processes to increase vaccination coverage in their setting to protect patients and prevent negative outcomes." One commenter expressed significant logistical and clinician concerns with the proposal and its ability to quantify quality of care. They gave several reasons, which we address below.

Comment: Two commenters noted that IRFs do not have immediate or ongoing access to COVID-19 vaccines and/or booster dose(s) and will have difficulty reporting and demonstrating improvement on this measure.

Response: While we believe facilities should be able to administer the vaccine if a patient is agreeable to receiving the vaccination, this measure does not require IRFs to administer the vaccine themselves. There are no current indications that there are vaccine shortages or delays for the COVID-19 vaccines in PAC facilities. However, IRFs can arrange for the patient to obtain the vaccine outside of their facility or can work with community pharmacies to obtain vaccines. We would also like to point out that the number of patients who have been vaccinated by an IRF does not impact an IRF's ability to successfully report the measure to comply with the requirements of the IRF QRP.

Comment: Several commenters believe it is often infeasible or inappropriate to offer vaccination for patients due to length of stay, ability to manage side effects and medical contraindications, or other logistical challenges to gathering information from a patient who may have received care from multiple proximal providers. One commenter said that administering

the vaccine could cause a readmission back to acute care or delay the patient's course of rehabilitation and extend their length of stay beyond the average time frame for which they receive payment. Therefore, these things would make it difficult for IRFs to manage and potentially improve their performance on this measure.

Response: We understand concerns about PAC length of stay or effect of the vaccine on patient care. We believe providers should use clinical judgement to determine if a patient is eligible to receive the vaccination and avoid harm to the patient. It is the responsibility of the IRFs to determine when a patient is ready for discharge, keeping in mind patient's health and safety, which may necessitate a longer length of stay.

However, we also believe that vaccination for high-risk populations, such as those in IRFs, is of paramount importance, and regardless of length of stay, a provider has the opportunity to educate the patient and provide information on why they should become up to date with COVID-19 vaccination, if they are not up to date at the time they are admitted. We believe vaccines can be scheduled at times that prevent or minimize disruptions with the patient treatment plan. For example, the vaccine could be given on a weekend or prior to discharge if the patient chooses to receive it. We would also like to point out that this measure does not mandate patients to be up to date with their COVID-19 vaccine. The number of patients who have been vaccinated in an IRF does not impact an IRF's ability to successfully report the measure to comply with the requirements of the IRF QRP.

Comment: Other commenters said that most patients who are interested in receiving a vaccine have already received it from the referring hospital, long-term care hospital, skilled nursing facility or other setting where the patient received care prior to admission to the IRF, and therefore they did not think this measure would have an impact on the vaccination rates.

Response: This measure is intended to provide the percent of patients who are up to date with their COVID-19 vaccination in an IRF at the time of discharge. This measure promotes transparency of raw data regarding COVID-19 vaccination rates for patients/caregivers to make

informed decisions for selecting facilities. Irrespective of the patient's vaccination status, this measure will provide potential patients and their caregivers with an important piece of information regarding vaccination rates as part of their process of identifying providers they would want to seek care from, alongside other measures available on Care Compare, to make an informed, comprehensive decision. Additionally, we believe IRF providers would benefit in such situations where patients have already been vaccinated prior to admission, given this would mean the patient is up to date and reduce IRF burden to educate or vaccinate the patient.

Comment: Several commenters list other factors affecting patient vaccination status outside of the IRF's control such as patient refusals and other cultural or religious reasons for a patient not receiving vaccination. One commenter believes COVID-19 vaccinations are still highly influenced by the political environment and political beliefs of patients/residents and their families. Therefore, they believe the percentage of patients who are vaccinated within an IRF will reflect the political leanings of the region in which the facility is located, and IRFs will not be able to influence this. Commenters noted that patients/residents may choose to forgo vaccination despite a provider's best efforts to encourage vaccination among their patients/residents. One commenter stated that patients retain their right to decline a vaccine when they are admitted to an IRF and they believe patient acceptance of a vaccine does not measure an IRF's quality of care.

Response: We appreciate providers' commitment to ensuring that patients are educated and encouraged to receive vaccinations, and we acknowledge that individual patients have a choice regarding whether to receive a COVID-19 vaccine or additional/booster dose(s), despite provider efforts. However, it is also true that patients and family/caregivers have choices about selecting PAC providers, and it is our intention to empower them with the information they need to make an informed decision by publicly reporting the data we receive from IRFs on this measure. We understand that despite provider efforts, there may be instances where a patient chooses not to be vaccinated, and we want to remind IRFs that this measure does not mandate

that patients be up to date with their COVID-19 vaccine. The number of patients who have been vaccinated in an IRF does not impact an IRF's ability to successfully report the measure to comply with the requirements of the IRF QRP.

Comment: One commenter said that even if the measure is intended to give patients and families information to make decisions about care, the lack of IRF access in many areas may reduce the impact of having IRFs collect this information. Several commenters believe the IRF's rate of vaccination will generally mirror the current COVID-19 vaccination rate in an IRF's local community, which they do not believe is a reflection of an IRF's quality as a provider nor would it provide relevant or useful information through public reporting.

Response: As described in section IX.C.2.a.(3) of this final rule, the measure development contractor convened TEP meetings to solicit feedback on the development of patient/resident COVID-19 vaccination measures. Analyses showed considerable variation in COVID-19 vaccination rates among nursing homes by State and within State. Further, States with the lowest complete vaccination rates also show wider within-State variations in vaccination rates among nursing homes.¹⁸² The TEP panelists indicated that the presence of disparities in vaccination rates makes the patient-level vaccination measure meaningful to develop, and they broadly agreed that the vaccination gaps identified for nursing homes were also likely present within other PAC settings, including IRFs.¹⁸³ Therefore, we believe that the information this measure will provide will still be valuable to potential IRF patients and their caregivers who have geographic limitations while seeking care. Additionally, this measure will provide potential patients and their caregivers with an important piece of information regarding vaccination rates as part of their process of identifying IRF providers they would want to seek care from,

¹⁸² Technical Expert Panel (TEP) for the Development of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) COVID-19 Vaccination-Related Items and Measures Summary Report. <https://mmshub.cms.gov/sites/default/files/COVID19-Patient-Level-Vaccination-TEP-Summary-Report-NovDec2021.pdf>.

¹⁸³ Technical Expert Panel (TEP) for the Development of Long-Term Care Hospital (LTCH), Inpatient Rehabilitation Facility (IRF), Skilled Nursing Facility (SNF)/Nursing Facility (NF), and Home Health (HH) COVID-19 Vaccination-Related Items and Measures Summary Report. <https://mmshub.cms.gov/sites/default/files/COVID19-Patient-Level-Vaccination-TEP-Summary-Report-NovDec2021.pdf>.

alongside other measures available on Care Compare to make a comprehensive decision.

Comment: Several commenters raised concerns about unintended consequences of receiving the vaccine during an IRF stay and believe they would interfere with a patient's therapy. They believe that scheduling a COVID-19 vaccine during a patient's relatively short length of stay, 12-13 days on average, could mean they have to forego several days of therapy they would otherwise need and be entitled to. One commenter noted that providers may have concerns that the side effects of a vaccine can interfere with or cause confusion while a patient is being diagnosed or treated during their hospitalization, and that the side effects of a vaccine like COVID-19 could delay needed intense therapy treatment. One commenter noted that the known side-effects of the COVID-19 vaccine per the CDC, "pain, redness, swelling at the injection site, tiredness, headache, muscle pain, chills, fever, and nausea," are contradictory to participating in intensive therapy, at least 3 hours a day, 5 days a week.

Response: We understand and acknowledge commenters' concerns about potential side effects of COVID-19 vaccination on patient participation in IRF care and activities. However, vaccines can be scheduled at times that prevent or minimize disruptions to the patient treatment plan. For example, if an IRF is concerned about a patient's ability to perform in 3 hours of therapy a day, the vaccine could be given on a weekend or prior to discharge. We support an IRF's use of clinical judgement to determine if a patient is eligible to receive the vaccination and if a patient chooses to receive one, to work with the patient to schedule the appropriate time to administer the vaccine. We also want to remind IRFs that they do not have to administer the COVID-19 vaccine. The number of patients who have been vaccinated in an IRF does not impact an IRF's ability to successfully report the measure to comply with the requirements of the IRF QRP

Comment: One commenter pointed to the concerns raised by the MAP and other interested parties and believes CMS should consider the potential impacts of its approach on vaccination efforts. They caution that as providers are endeavoring to follow the vaccine

guidelines and gain patient trust, this measure—as constructed—has the potential to adversely impact patient-provider relationships, trust, and provider performance.

Response: We disagree with the commenter. We believe the proposed measure will 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,” and the PFAs we met with agreed that a measure capturing raw vaccination rates would be most helpful in patient and family/caregiver decision-making. Additionally, we take the appropriate access to care in IRFs very seriously, and routinely monitor the QRP measures' performance, including performance gaps across IRFs. We intend to monitor closely whether any proposed change to the IRF QRP has unintended consequences on access to care for high risk patients. Should we find any unintended consequences, we will take appropriate steps to address these issues in future rulemaking.

Comment: Several commenters did not support adoption of this measure in light of the Administration’s announcement of the end of the COVID-19 PHE on May 11, 2023. One of these commenters commended CMS for recognizing the burden of such a requirement included in the Hospital Conditions of Participation and working to remove it, but now questions the “juxtaposition” of proposing a vaccine uptake measure as a metric for quality of care. Another one of these commenters said that the end of the PHE will make it more challenging for patients to stay informed on the most recent guidance from the CDC. Finally, one of these commenters also brought up concerns about CDC’s recent recommendations that individuals aged 65 and over “may” receive an additional dose of the updated vaccines.

Response: Despite the announcement of the end of the COVID-19 PHE, many people continue to be affected by COVID-19, particularly seniors, people who are immunocompromised, and people with disabilities. As mentioned in the End of COVID-19

Public Health Emergency Fact Sheet,¹⁸⁴ our response to the spread of SARS-CoV-2, the virus that causes COVID-19, remains a public health priority. Even beyond the end of the COVID-19 PHE, we will continue to work to protect Americans from the virus and its worst impacts by supporting access to COVID-19 vaccines, treatments, and tests, including for people without health insurance. Given the continued impacts of COVID-19, we believe it is important to promote patient vaccination and education, which this measure aims to achieve. Accordingly, we are aligning our approach with those for other infectious diseases, such as influenza by encouraging ongoing COVID-19 vaccination.¹⁸⁵ Further, published coding guidance will indicate how to code the item taking into account CDC guidelines, and providers could access the CDC website at any time to find the definition of up to date. Lastly, this measure as proposed for the IRF QRP is not associated with the PHE declaration, or the Conditions of Participation. This measure is being proposed to address CMS's priority to empower consumers to make informed health care choices through patient-directed quality measures and public transparency, as with previous vaccination measures.

Comment: Two commenters noted that the draft item does not provide response options for patients who refuse to answer, refuse the vaccination, or are excluded due to medical contraindications or closely held religious beliefs. One commenter said that if CMS does add the measure to the IRF QRP, they must allow IRFs to report that they could not determine the patient's vaccination status. This commenter also noted that the CBE's MAP Health Equity Advisory Group "expressed concerns about vaccine hesitancy due to cultural norms," and that if CMS adopts the proposed Patient/Resident COVID-19 Vaccine measure, IRFs should be able to report that they were unable to determine if a patient was vaccinated. Another commenter

¹⁸⁴ U.S. Department of Health and Human Services. Fact Sheet: End of the COVID-19 Public Health Emergency. May 9, 2023. <https://www.hhs.gov/about/news/2023/05/09/fact-sheet-end-of-the-covid-19-public-health-emergency.html>.

¹⁸⁵ Medicare and Medicaid Programs; Policy and Regulatory Changes to the Omnibus COVID-19 Health Care Staff Vaccination Requirements; Additional Policy and Regulatory Changes to the Requirements for Long-Term Care (LTC) Facilities and Intermediate Care Facilities for Individuals With Intellectual Disabilities (ICFs-IID) To Provide COVID-19 Vaccine Education and Offer Vaccinations to Residents, Clients, and Staff; Policy and Regulatory Changes to the Long Term Care Facility COVID-19 Testing Requirements. (88 FR 36487).

suggested that having a single yes or no item on the IRF-PAI without any requirements for documentation or validation of vaccination status would amount to a mere checkmark in a box with no evidence that it leads to improved quality of care.

Response: We thank commenters for their recommendations about adding additional response options to the item for exclusions. However, as we have stated previously, the PFAs convened for our TEP told us that a measure capturing raw vaccination rates would be most helpful in patient and family/caregiver decision-making. The TEP agreed that developing a measure to report the rate of vaccination without denominator exclusions was an important goal. Based on this feedback, we believe excluding patients/residents with contraindications from the measure would distort the intent of the measure of providing raw COVID-19 patient vaccination rates, while making the information more difficult for patients/caregivers to interpret, and hence did not include any exclusions.

CMS has multiple processes in place to ensure reported patient data are accurate. State agencies conduct standard certification surveys for IRFs, and accuracy and completeness of the IRF-PAI are among the regulatory requirements that surveyors evaluate during surveys.¹⁸⁶ Additionally, the IRF-PAI process has multiple regulatory requirements. Our regulations at § 412.606(b) require that (1) the assessment accurately reflects the patient's status, (2) a clinician appropriately trained to perform a patient assessment using the IRF-PAI conducts or coordinates each assessment with the appropriate participation of health professionals, and (3) the assessment process includes direct observation, as well as communication with the patient.¹⁸⁷ We take the accuracy of IRF-PAI assessment data very seriously, and routinely monitor the IRF QRP measures' performance, and will take appropriate steps to address any such issues, if identified, in future rulemaking.

¹⁸⁶ Centers for Medicare & Medicaid Services. Hospitals. September 6, 2022.

<https://www.cms.gov/medicare/provider-enrollment-and-certification/certificationandcompliance/hospitals>.

¹⁸⁷ 42 CFR 412.606 <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-412/subpart-P/section-412.606>.

We note that the potential consequences of submitting false data and information in the IRF-PAI, including the potential for civil liability under the False Claims Act (31 U.S.C. §§ 3729 to 3733) for knowingly presenting a false or fraudulent claim to the government for payment, provide strong incentives for providers to ensure that the data submitted in the IRF-PAI are accurate.

Comment: One commenter noted that the intent of the measure as proposed was unclear. This commenter referred to CMS' comment in the FY 2024 IRF PPS proposed rule that the “intent of the Patient/Resident COVID-19 Vaccine measures would be to promote transparency of data for patients to make informed decisions regarding care and is not intended to be a measure of IRF action.” However, the commenter disagreed with this rationale, referencing the RFI in section VIII.D. of the proposed rule, Principles for Selecting and Prioritizing IRF QRP Quality Measures and Concepts under Consideration for Future Years. The commenter believes the proposed measure fails to qualify for the first proposed principle for selecting and prioritizing IRF QRP quality measure concepts under consideration for future years, “actionability.”

Response: As stated in section VIII.D.2. of the proposed rule, to address actionability, IRF QRP measures should focus on structural elements, healthcare processes, and outcomes of care that have been demonstrated, such as through clinical evidence or other best practices, to be amenable to improvement and feasible for IRFs to implement. As stated previously, we believe this Patient/Resident COVID-19 Vaccine measure is an indirect measure of provider action. Providers have the opportunity to engage and educate patients on the benefits and importance of COVID-19 vaccination, especially in the IRF setting where patients are at higher risk of contracting COVID-19. Additionally, once collected these data will be available on the patient-level reports for IRF providers, which will further help providers decide on actions such as patient education and steps they can take to increase vaccination in their facility.

After consideration of the public comments we received, we are finalizing our proposal to adopt the Patient/Resident COVID-19 Vaccine measure as an assessment-based measure

beginning with the FY 2026 IRF QRP as proposed.

D. Principles for Selecting and Prioritizing IRF QRP Quality Measures and Concepts under Consideration for Future Years – Request for Information (RFI)

1. Solicitation of Comments

In the proposed rule, we invited general comments on the principles for identifying IRF QRP measures, as well as additional comments about measurement gaps, and suitable measures for filling these gaps. Specifically, we solicited comment on the following questions:

- Principles for Selecting and Prioritizing 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?

- IRF 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 IRF QRP measures that have not been identified in this RFI?

- Measures and Measure Concepts Recommended for Use in the IRF QRP

- ++ Are there measures that you believe are either currently available for use, or that could be adapted or developed for use in the IRF QRP program to assess performance in the areas of (1) cognitive functioning, (2) behavioral and mental health, (3) patient experience and patient satisfaction, (4) chronic conditions, (5) pain management, or (6) other areas not mentioned in this RFI?

CMS also sought input on data available to develop measures, approaches for data

collection, perceived challenges or barriers, and approaches for addressing challenges. We received several comments in response to this RFI, which are summarized below.

Comments on Principles for Selecting and Prioritizing QRP Measure:

A few commenters expressed support for the measure selection and prioritization criteria identified by CMS in the RFI in the proposed rule, as well as those espoused through the National Quality Strategy and the “Universal Foundation” of quality measures. One commenter indicated that principles for measure selection and prioritization identified by CMS in the RFI are consistent with the principles inherent in the CMS Measure Management System and recommended that MMS measure development principles be integrated into the IRF QRP principles. The same commenter suggested that clearly delineated processes are required in order to guide the application of these principles.

One commenter recommended that CMS consider the extent to which measures offer a well-rounded assessment of performance, are complementary, and demonstrate the patient’s journey.

Several commenters expressed concern about the addition of measures to the QRP and specifically requested that CMS consider the administrative burden associated with measure reporting. To reduce administrative burden, commenters suggested that CMS consider opportunity costs, and remove measures that are not tied to strategic quality improvement aims.

In addition to administrative burden, other criteria that commenters suggested be considered as part of CMS’ guiding principles, included: whether the measure is endorsed by a CBE; the extent to which the measure focuses on a salient healthcare issue; the measure’s technical specifications, reliability and validity, implementation feasibility, and electronic availability of data.

One commenter requested that CMS clearly explain how measures selected for development meet the set criteria used.

Comments on Principles for Selecting and Prioritizing QRP Measures and Measures and

Measure Concepts Recommended for Use in the IRF QRP

Although several commenters agreed with CMS on the presence of measurement gaps in the IRF QRP, particularly in the domain of cognitive functioning, one commenter stated that even if intended to fill a gap, additional measures to the IRF QRP could not be justified given the present administrative burden on IRFs. The commenter recommended that CMS continually evaluate whether measures are necessary and remove those that are deemed unnecessary. Another commenter indicated that CMS should neither add quality measures to the IRF QRP nor attempt to fill gaps until IRFs receive financial assistance for EHR systems.

Comments on Cognitive Function

Several commenters supported the introduction of cognitive measures for future QRP measure sets, with one commenter indicating that cognitive function measures would provide additional context concerning IRF efficacy.

Multiple commenters did not support the use of the CAM[®] or BIMS as a source of data for use in measuring cognitive function. One commenter stated that neither the CAM[®] nor BIMS provide clinical value to inform rehabilitation care planning or outcomes, including the change in cognitive functioning from admission to discharge. Commenters indicated that the BIMS was not developed as a tool to screen for the presence or absence of cognitive impairment and that it only captures selected elements of cognition, such as attention, short-term memory and verbal interaction, rather than executive functioning, judgement, reasoning, and higher-level cognitive functions. Commenters further stated that the BIMS scale shows low sensitivity identifying cognitive deficits that affect community placement.

Other concerns about the BIMS for use in development of measures of cognitive functioning included the lack of physician buy-in for the BIMS, variation in the reliability of scoring, and limited utility of the BIMS for measuring and risk-adjusting patient cognition and communication.

Although one commenter indicated that the proprietary nature of cognitive functioning

instruments and administrative burden posed a challenge to adopting a cognitive assessment instrument, several commenters encouraged CMS to pursue alternative data sources and measures of cognitive functioning. Suggestions of ways to assess cognition included the Functional Independence Measure™ (FIM™) and patient-reported outcome measures. Another commenter encouraged CMS to select measures that are reliable, feasible, valid, and that are, or could be, endorsed by a consensus organization.

Comments on Behavioral and Mental Health

Commenters voiced appreciation for CMS interest in addressing behavioral and mental health issues through the development of quality measures for the IRF QRP. Other commenters cited potential challenges to the adoption of behavioral and mental health measures. One commenter indicated that it would be difficult for IRFs to offer psychological services given the 3-hour therapy per day requirement.¹⁸⁸ Another commenter indicated that such measures would not be relevant for the IRF setting, since patients with a severe behavioral or mental health impairment would be unlikely to participate in therapy, and inpatient rehabilitation would not be an appropriate setting. Should CMS still seek to develop behavioral and mental health quality measures, the commenter suggested consideration of the Patient Health Questionnaire (PHQ)-2 through PHQ-9, which are required for completion of the IRF-PAI.

One commenter suggested that CMS consider adoption of measures that evaluate psychosocial functioning. One commenter recommended that behavioral and mental health measures capture rehabilitative services, such as therapeutic recreation, that support activities that the patient is expected to enjoy post-hospitalization.

Comments on Patient Experience and Patient Satisfaction

A few commenters expressed support for the adoption of measures derived from patient experience surveys, including the IRF Experience of Care (EOC) survey. One commenter

¹⁸⁸ § 412.622(a)(3)(ii) Subpart P – Prospective Payment for Inpatient Rehabilitation Hospitals and Rehabilitation Units; Basis of payment.

expressed preference for the use of the IRF EOC survey over the CoreQ Short Stay Discharge Survey (CoreQ survey) to measure patient experience, indicating that the IRF EOC survey addresses essential assessment areas (for example, goal setting, communications with staff, respect and privacy received, ability to obtain assistance when needed, cleanliness of the facility), whereas the CoreQ survey provides a more limited assessment and lacks the depth to drive quality improvement. Should CMS decide to use the CoreQ survey, the commenter recommended that CMS allow the fielding of supplemental questions, such as items from the IRF EOC survey. Regardless of which tool is used, the commenter urged CMS to ensure the reliability and validity of the measure and composites, subject the measure for review by a CBE, and to pursue the Consumer Assessment of Healthcare Providers and Services (CAHPS) trademark.

One commenter, who did not support the inclusion of a patient experience or satisfaction measure in the IRF QRP, indicated that the administrative and financial costs associated with data collection, particularly for smaller, hospital-based IRFs, would be too high. The commenter further indicated that information gathered from these items would not be meaningful.

Comments on Chronic Condition and Pain Management

One commenter indicated that, because pain is an inherent part of intensive rehabilitation therapy, rather than measuring whether pain exists or whether level of pain was assessed, a more meaningful pain measure would assess the extent to which IRF staff are responsive to and help manage patients' pain. The commenter suggested that the use of a patient-reported outcome measure would provide more meaningful information than a process measure of pain and would not increase burden to the IRF. Another commenter expressed concern about unintended consequences associated with measures related to pain management.

Comments on Other Measurement Gaps

Some commenters believe measurement gaps to exist in areas not identified in the RFI. Other measures and measurement concepts identified by commenters included health equity;

care for degenerative cognitive conditions; IRF workforce safety culture, engagement, and burnout; and measures of quality of life, such as the World Health Organization Quality of Life (WHOQOL) assessment and the Comprehensive Evaluation in Recreational Therapy for Physical Disabilities (CERT-Phys Dis).

Response: We appreciate the input provided by commenters. While we will not be responding to specific comments submitted in response to this RFI in this final rule, we intend to use this input to inform our future measure development efforts.

E. Health Equity Update

1. Background

In the FY 2023 IRF PPS proposed rule (87 FR 20247 through 20254), we included an RFI entitled “*Overarching Principles for Measuring Equity and Healthcare Quality Disparities Across CMS Quality Programs.*” We define health equity as “the attainment of the highest level of health for all people, where everyone has a fair and just opportunity to attain their optimal health regardless of race, ethnicity, disability, sexual orientation, gender identity, socioeconomic status, geography, preferred language, or other factors that affect access to care and health outcomes.”¹⁸⁹ 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*¹⁹⁰ are in line with Executive Order 13985, “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government.”¹⁹¹ The goals included in the

¹⁸⁹ Centers for Medicare & Medicaid Services. Health Equity. October 3, 2022. <https://www.cms.gov/pillar/health-equity>.

¹⁹⁰ Centers for Medicare & Medicaid Services. CMS Framework for Health Equity 2022–2032. April 2022. <https://www.cms.gov/files/document/cms-framework-health-equity-2022.pdf>.

¹⁹¹ 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.whitehouse.gov/briefing->

CMS Framework for Health Equity serve to further advance health equity, expand coverage, and improve health outcomes for the more than 170 million individuals supported by our programs, and set a foundation and priorities for our work, including: strengthening our infrastructure for assessment, creating synergies across the health care system to drive structural change, and identifying and working to eliminate barriers to CMS-supported benefits, services, and coverage. The CMS Framework for Health Equity outlines the approach CMS will use to promote health equity for enrollees, mitigate health disparities, and prioritize CMS's commitment to expanding the collection, reporting, and analysis of standardized data.¹⁹²

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).¹⁹³ 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, regulations, oversight strategies, and quality improvement initiatives.

A goal of the NQS is to address persistent disparities that underlie our healthcare system. Racial disparities, 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.¹⁹⁴ 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 2020.¹⁹⁵ Therefore, we

room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.

¹⁹² Centers for Medicare and Medicaid Services. The Path Forward: Improving Data to Advance Health Equity Solutions. <https://www.cms.gov/files/document/path-forward-the-data-paper.pdf>. July 11, 2023.

¹⁹³ Centers for Medicare and Medicaid Services. CMS National Quality Strategy? <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Value-Based-Programs/CMS-Quality-Strategy>.

¹⁹⁴ 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>.

¹⁹⁵ Agency for Healthcare Research and Quality. 2022 National Healthcare Quality and Disparities Report. November 2022. <https://www.ahrq.gov/research/findings/nhqrdr/nhqrdr22/index.html>.

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 IRF PPS final rule (87 FR 47072 through 47073) for a summary of the public comments and suggestions CMS received in response to the health equity RFI. In the proposed rule, we said we would take these comments into account as we continue to work to develop policies, quality measures, and measurement strategies on this important topic.

2. Anticipated Future State

We are committed to developing approaches to meaningfully incorporate the advancement of health equity into the IRF 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.¹⁹⁶ Measure stratification by CMS is important for better understanding the differences in health outcomes from across different patient population groups according to specific demographic and SDOH variables. For example, when pediatric measures over the past two decades are stratified by race, ethnicity, and income, they show that outcomes for children in the lowest income households and for Black and Hispanic children have improved faster than outcomes for children in the highest income households or for White children, thus narrowing an important health disparity.¹⁹⁷ This analysis and comparison of the SDOH items in the

¹⁹⁶ 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>.

¹⁹⁷ 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>.

assessment instruments support our desire to understand the benefits of measure stratification. Hospital providers receive such information in their confidential feedback reports (CFRs) and we think this learning opportunity would benefit PAC providers. The goals of the CFR are to provide IRFs with their results so they can compare certain quality measures stratified by dual eligible status and race and ethnicity. The process is meant to increase providers' awareness of their data. We will solicit feedback from IRFs for future enhancements to the CFRs.

In the proposed rule, we said that we are considering whether health equity measures we have adopted for other settings, such as hospitals,¹⁹⁸ could be adopted in PAC settings. We said we were exploring ways to incorporate SDOH elements into the measure specifications. For example, we could consider a future health equity measure like screening for social needs and interventions using our current SDOH data items of preferred language, interpreter services, health literacy, transportation, and social isolation. With 30 percent to 55 percent of health outcomes attributed to SDOH,¹⁹⁹ a measure capturing and addressing SDOH could encourage IRFs 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 IRF. These SDOH data items assess health literacy, social isolation, transportation problems, and preferred language (including need for or want of an interpreter). We also see value in aligning SDOH data items according to existing health information technology (IT) vocabulary and codes sets where applicable and appropriate such as those included in the Office of the National Coordinator for Health Information (ONC) United

¹⁹⁸ Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2023 Rates; Quality Programs and Medicare Promoting Interoperability Program Requirements for Eligible Hospitals and Critical Access Hospitals; Costs Incurred for Qualified and Non-Qualified Deferred Compensation Plans; and Changes to Hospital and Critical Access Hospital Conditions of Participation. 87 FR 49202 through 49215.

¹⁹⁹ World Health Organization. Social Determinants of Health. https://www.who.int/health-topics/social-determinants-of-health#tab=tab_1.

States Core Data for Interoperability (USCDI)²⁰⁰ across all care settings as we develop future health equity quality measures under our IRF QRP statutory authority. This would further the NQS' goal of aligning quality measures across our programs as part of the Universal Foundation.²⁰¹

Although we did not directly solicit feedback to our update, we did receive some public comments, which we summarize.

Comment: Several commenters responded to our update on the continuing efforts to advance health equity. One commenter encouraged CMS to consider data collection reports as a starting point, and also a structural measure that is based on health equity priorities, similar to what has been adopted in other Medicare quality reporting programs.

Two commenters supported the idea of measure stratification by certain SDOH, and one requested this information on all claims-based measures. Both commenters emphasized that any additional stratification of quality measures, including social risk factors and SDOH, would be of value to PAC providers, including IRFs.

One commenter also noted that receiving patient-level data for claims-based measures on a more frequent basis would enable them to make better informed decisions. This commenter referenced the Hospital Inpatient Quality Reporting (IQR) Program which provides reports with patient-level data to hospitals and urged CMS to provide IRFs with the same level of detail in their quality data. They also noted that while having the measures stratified by SDOH would be helpful, they believe having it in a timely manner could have a more meaningful impact on equity and quality of care.

We received some comments on other data points that may be useful in identifying and addressing health disparities. One commenter suggested focusing efforts on social risk factors

²⁰⁰ United States Core Data for Interoperability (USCDI), <https://www.healthit.gov/isa/united-states-core-data-interopability-uscdi>.

²⁰¹ 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.

that are of sufficient granularity to drive appropriate interventions at the individual level. Another commenter noted that while it is important to still try to understand differences by race and ethnicity to identify and address disparities that might stem from racism and social and economic inequities, they recommended against making generalizations about differences in health and health care simply based on race and ethnicity and to instead conduct more in-depth evaluations of underlying social and economic drivers of health. This commenter suggested that CMS incentivize the collection and analysis of data on factors such as, but not limited to, disability status, veteran status, primary or preferred language, health literacy, food security, transportation access, housing stability, social support after discharge from an IRF, and a person's access to care. This same commenter, however, pointed out that any program must account for the fact that there are many contributors to health inequities, including personal factors, many of which are outside the control of IRFs. They encouraged CMS to have ongoing engagement with interested parties to best understand structural and socioeconomic barriers to health and to monitor for any unintended consequences. Finally, this commenter urged CMS to focus on improving care coordination as patients move between settings. However, another commenter requested CMS consider what is already being collected by providers prior to adding additional data collection requirements.

One commenter encouraged CMS to thoughtfully consider the appropriate data collection of SDOH factors before attempting to report the data, given the resources required to implement new items in the electronic medical record. They pointed to the current work underway by the Office of Management and Budget (OMB) seeking feedback about combining race and ethnicity questions (88 FR 5375).

One commenter recommended CMS consider including SDOH in new quality measures and in IRF payment and suggested it could be accomplished through the use of ICD-10 Z-codes as indicators of the additional resources required to care for patients.

Response: We thank all the commenters for responding to our update on this important

CMS priority. We will take your recommendations into consideration in our future work on health equity.

F. Form, Manner, and Timing of Data Submission under the IRF QRP

1. Background

We refer readers to the regulatory text at § 412.634(b)(1) for information regarding the current policies for reporting IRF QRP data.

2. Reporting Schedule for the IRF-PAI Assessment Data for the Discharge Function Score Measure Beginning with the FY 2025 IRF.

As discussed in section VIII.C.1.b. of the proposed rule, we proposed to adopt the Discharge Function Score (DC Function) measure beginning with the FY 2025 IRF QRP. We proposed that IRFs would be required to report these IRF-PAI assessment data related to the DC Function measure beginning with patients discharged on October 1, 2023, for purposes of the FY 2025 IRF QRP. Starting in CY 2024, IRFs would be required to submit data for the entire calendar year beginning with the FY 2026 IRF QRP. Because the DC Function measure is calculated based on data that are currently submitted to the Medicare program in the IRF-PAI, there would be no new burden associated with data collection for this measure.

We invited public comments on our proposal.

We did not receive any comments on this proposed revision, and therefore, we are finalizing the revisions as proposed.

3. Reporting Schedule for the Data Submission of IRF-PAI Assessment Data for the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date Quality Measure Beginning with the FY 2026 IRF QRP

As discussed in section VIII.C.2.a. of the proposed rule, we proposed to adopt the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID-19 Vaccine) measure beginning with the FY 2026 IRF QRP. We proposed that IRFs would be required to report the IRF-PAI assessment data related to the Patient/Resident COVID-

19 Vaccine measure beginning with patients discharged on October 1, 2024, for purposes of the FY 2026 IRF QRP. Starting in CY 2025, IRFs would be required to submit data for the entire CY beginning with the FY 2027 IRF QRP.

We also proposed to add a new item to the IRF-PAI in order for IRFs to report this measure. Specifically, a new item would be added to the IRF-PAI discharge assessment to collect information on whether a patient is up to date with their COVID-19 vaccine at the time of discharge from the IRF. 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.²⁰²

We invited public comments on our proposal. The following is a summary of the public comments received on our proposal to require IRFs to report a new IRF-PAI assessment data item for the Patient/Resident COVID-19 Vaccine measure beginning with patients discharged on October 1, 2024, and our responses.

Comment: One commenter stated that this proposed measure has the potential to increase COVID-19 vaccination coverage of patients in IRFs, as well as prevent the spread of COVID-19 within the IRF patient population. However, given that the patient's COVID-19 vaccination status was proposed to be collected at discharge from the IRF rather than upon admission, they believe the opportunity is lost.

Response: We believe that during a patient stay, IRFs have the opportunity to educate the patient and provide information on why they should become up to date, if a patient is not up to date with their vaccine at the time they are admitted. This is particularly important for patients in IRFs, who tend to be at higher risk for serious complications from COVID-19. If the patient is agreeable, the patient may receive the necessary vaccine to become up to date any time during their IRF stay prior to discharge.

Comment: One commenter noted that IRFs have been reporting COVID-19 vaccination

²⁰² *COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date*. Draft Measure Specifications. <https://www.cms.gov/files/document/patient-resident-covid-vaccine-draft-specs.pdf>.

and infection data to both State departments of health and the CDC's National Healthcare Safety Network (NHSN) and introducing a new IRF-PAI item would create the potential for duplicative reporting.

Response: Currently, as part of the IRF QRP, we do not collect COVID-19 vaccination data for patients. CMS only collects COVID-19 vaccination data for healthcare personnel via the NHSN. Therefore, addition of an IRF-PAI item for the purposes of collecting patient COVID-19 vaccination data would not lead to duplicative reporting at the Federal level.

Comment: One commenter noted that the draft specifications for this measure do not specify what the preferred source would be, or how facilities should deal with conflicting information from different sources (for example, the patient responding that they are vaccinated, but the medical record suggesting they are not).

Response: As described in the Draft Technical Specifications,²⁰³ providers will be able to use all sources of information available to obtain the vaccination data, such as patient interviews, medical records, proxy response, and vaccination cards provided by the patient or their caregivers. As with any assessment item in the IRF-PAI, we will also publish coding guidance and instructions to further aid providers in collection of this data, including coding in situations with conflicting information.

After consideration of the public comments we received, we are finalizing our proposal to require IRFs to report a new IRF-PAI assessment data item for the Patient/Resident COVID-19 Vaccine measure beginning with patients discharged on October 1, 2024 for the FY 2026 IRF QRP as proposed.

G. Policies Regarding Public Display of Measure Data for the IRF QRP

1. Background

Section 1886(j)(7)(E) of the Act requires the Secretary to establish procedures for making

²⁰³ COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date Draft Measure Specifications.
<https://www.cms.gov/files/document/patient-resident-covid-vaccine-draft-specs.pdf>.

the IRF QRP data available to the public after ensuring that IRFs have the opportunity to review their data prior to public display. For a more detailed discussion about our policies regarding public display of IRF QRP measure data and procedures for the IRF's opportunity to review and correct data and information, we refer readers to the FY 2017 IRF PPS final rule (81 FR 52045 through 52048).

2. Public Reporting of the Transfer of Health (TOH) Information to the Provider – Post-Acute Care (PAC) Measure and TOH Information to the Patient – PAC Measure Beginning with the FY 2025 IRF QRP

We proposed to begin publicly displaying data for the measures, TOH Information to the Provider – PAC Measure (TOH – Provider) and 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 IRF PPS final rule (84 FR 39099 through 39107). In response to the COVID-19 PHE, we issued an interim final rule (85 FR 27595 through 27596), which delayed the compliance date for the collection and reporting of the TOH – Provider and TOH – Patient measures to October 1st of the year that is at least one full FY after the end of the COVID-19 PHE. Subsequently, the CY 2022 Home Health PPS Rate Update final rule (86 FR 62381 through 62386) revised the compliance date for the collection and reporting of the TOH – Provider and TOH – Patient measures under the IRF QRP to October 1, 2022. Data collection for these two assessment-based measures in the IRF QRP began with patients discharged on or after October 1, 2022.

We proposed to publicly display four rolling quarters of the data we receive for these two assessment-based measures, initially using data on discharges from January 1, 2023, through December 31, 2023 (Quarter 1 2023 through Quarter 4 2023); and to begin publicly reporting data on these measures with the September 2024 refresh of Care Compare, or as soon as technically feasible. To ensure the statistical reliability of the data, we proposed that we would

not publicly report an IRF's performance on a measure if the IRF had fewer than 20 eligible cases in any four consecutive rolling quarters for that measure. IRFs that have fewer than 20 eligible cases would be distinguished with a footnote that states, "The number of cases/patient stays is too small to publicly report."

We invited public comment on our proposal for the public display of the TOH – Provider and TOH – Patient assessment-based measures. The following is a summary of the public comments received on the proposal to publicly report these measures and our responses.

Comment: Several commenters supported the proposal to publicly report the Transfer of Health Information to the Provider-PAC Measure and the Transfer of Health Information to the Patient-PAC Measure beginning with the September 2024 Care Compare refresh or as soon as technically feasible. One commenter believes the additional attention and focus on the transfer of health information would improve internal and external processes for patients and caregivers. Another commenter suggested stratification of the data would add value to consumers and providers.

Response: We thank the commenters for their support and agree that the information will provide helpful information to consumers about an IRF's internal and external processes related to transfer of important health information. We also appreciate the suggestion for stratifying the data, and we will use this input to inform our future public reporting refinements.

Comment: One commenter was not supportive of the proposal, saying that the reporting requirement would be duplicative of information IRFs are already required to collect and the measures would be redundant.

Response: We want to clarify that the proposal would add no additional reporting requirements to the IRF QRP. IRFs began collecting the Transfer of Health information data elements for all patients discharged beginning October 1, 2022. In section IX.G.2 of this final rule, we proposed using data collected from January 1, 2023 through December 31, 2023 for the inaugural display of the measures on Care Compare beginning September 2024 or as soon as

technically feasible.

Comment: One commenter said they valued the public reporting of metrics that reflect the quality of care a patient received in an IRF but encouraged CMS to delay reporting of the TOH-Patient and TOH-Provider measures until 2025, using discharges from January 1, 2024 through December 31, 2024 (Quarter 1, 2024 through Quarter 4, 2024), given their recent adoption into the IRF QRP.

Response: We disagree with the commenter. While the TOH-Patient and TOH-Provider measures original data collection start date was October 1, 2020, we delayed the collection of the measures due to the COVID-19 PHE. As the commenter noted, CMS revised the data collection to begin October 1, 2022, and while we have received some questions about the new data items on the IRF-PAI through our IRF QRP helpdesk, the number of questions have been minimal. Neither have there been any reported problems with the implementation of these items. The inaugural reporting period we proposed, January 1, 2023 through December 31, 2023 (Quarter 1, 2023 through Quarter 4, 2023) is consistent with our public reporting proposals for other new IRF QRP measures. We do not agree that IRFs need more time to adjust for these measures.

As a result of the public comments, we are finalizing our proposal to begin publicly displaying data for the measures: (1) Transfer of Health (TOH) Information to the Provider – Post-Acute Care (PAC) Measure (TOH-Provider); and (2) TOH Information to the Patient – PAC Measure (TOH-Patient) beginning with the September 2025 Care Compare refresh or as soon as technically feasible.

3. Public Reporting of the Discharge Function Score Measure Beginning with the FY 2025 IRF QRP

We proposed to begin publicly displaying data for the Discharge Function Score (DC Function) measure beginning with the September 2024 refresh of Care Compare, or as soon as technically feasible, using data collected from January 1, 2023 through December 31, 2023

(Quarter 1 2023 through Quarter 4 2023). We proposed that an IRF's DC Function measure score would be displayed based on four quarters of data. Provider preview reports would be distributed to IRFs in June 2024, or as soon as technically feasible. Thereafter, an IRF's DC Function measure score would be publicly displayed based on four quarters of data and updated quarterly. To ensure the statistical reliability of the data, we proposed that we would not publicly report an IRF's performance on the measure if the IRF had fewer than 20 eligible cases in any quarter. IRFs 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 report."

We invited public comment on the proposal for the public display of the DC Function assessment-based measure beginning with the September 2024 refresh of Care Compare, or as soon as technically feasible. The following is a summary of the public comments received on our proposal and our responses.

Comment: One commenter provided support to publicly report the DC Function measure.

Response: We thank the commenter for their support to publicly report the proposed measure.

Comment: One commenter recommended that CMS specify when results will be provided to IRFs for their review, that CMS provide more patient-specific data, and clarify whether CMS uses results for "judgement or quality improvement or both." This commenter suggests CMS report "comparative stratified functional status based on key risk factors at discharge" to assist IRF improvements.

Response: CMS plans to publicly display the DC Function measure score quarterly, based on four quarters of data. We refer readers to section IX.F.2 of this final rule for information about when the proposed DC Function measure will be publicly reported. Specifically, we proposed to begin publicly displaying data for the DC Function measure beginning with the September 2024 refresh of Care Compare, or as soon as technically feasible, using data collected from January 1, 2023, through December 31, 2023 (Quarter 1 2023 through

Quarter 4 2023). Provider preview reports would be distributed to IRFs in June 2024, or as soon as technically feasible. Thereafter, an IRF's DC Function measure score would be publicly displayed based on four quarters of data and updated quarterly.

In regards to patient-specific data, IRFs can review key aspects of this measure, such as who did and did not meet the numerator criteria, in their own patient-level quality measure reports. In terms of the intended use of this measure, as with all QRPs, this measure will help inform Medicare beneficiaries and their caregivers when selecting IRF care and can be used by IRFs to monitor their own performance and improve care quality. Finally, we thank the commenter for their suggestion that CMS provide performance results stratified by key risk factors and will consider the feasibility of adding stratified performance scores to the provider preview report at a later date.

Comment: One commenter expressed concern that IRFs with eligible stays requiring imputation during the first quarter of the measure period will not know the imputed values for their patients until the entire 12-month measure target period ends. Additionally, this commenter believes that after the first 12-month period ends and a new quarter begins, changes in imputed values from the first year will not be reflected in measure scores. The same commenter expressed concern for the inclusion of new IRFs in the proposed measure calculations, believing these IRFs will be excluded from the measure until they have a full 12 months of data.

Response: New IRFs will not need 12 full months of data to receive scores but will receive scores with the following quarterly update. We propose to use data collected from January 1, 2023, through December 31, 2023 (Quarter 1 2023 through Quarter 4 2023) for the first scores published. Therefore, IRFs will not need to wait 12 months for results. Also, because scores will be updated quarterly, results will consider new information provided that will impact scores from previous quarters.

After consideration of the public comments we received, we are finalizing our proposal to begin publicly displaying data for the DC Function measure beginning with the September 2024

Care Compare refresh or as soon as technically feasible.

4. Public Reporting of the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date Measure Beginning with the FY 2026 IRF QRP

We proposed to begin publicly displaying data for the COVID-19 Vaccine: Percent of Patients/Residents Who are Up to Date (Patient/Resident COVID-19 Vaccine) measure beginning with the September 2025 refresh of Care Compare, or as soon as technically feasible, using data collected for Q4 2024 (October 1, 2024 through December 31, 2024). We proposed that an IRF's percent of patients who are up to date, as reported under the Patient/Resident COVID-19 Vaccine measure, would be displayed based on one quarter of data. Provider preview reports would be distributed to IRFs in June 2025 for data collected in Q4 2024, or as soon as technically feasible. Thereafter, the percent of IRF patients who are up to date with their COVID-19 vaccinations would be publicly displayed based on one quarter of data updated quarterly. To ensure the statistical reliability of the data, we proposed that we would not publicly report an IRF's performance on the measure if the IRF had fewer than 20 eligible cases in any quarter. IRFs 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 report."

We invited public comment on the proposal for the public display of the Patient/Resident COVID-19 Vaccine measure beginning with the September 2025 refresh of Care Compare, or as soon as technically feasible. The following is a summary of the public comments received and our responses.

Comment: Several commenters questioned the value of reporting only one quarter of data, since community vaccination rates vary over time and as definitions update.

Response: We believe it is important to make the most up to date data available to patients and their caregivers, which will support them in making essential decisions about their health care. We proposed the measure to be publicly reported on a rolling quarterly basis in order to align with the existing HCP COVID-19 Vaccine measure. This means the information would

be updated quarterly with only the most recent data, such that the measure would be consumed as the most recent quarter of data refreshed. We believe averaging over 12 months would result in the dilution of the most recent and potentially more meaningful information, as opposed to the proposed method of reporting, which would result in publishing information that is more up to date and would not affect the data collection schedule established for submitting assessment data.

Comment: We received comments on whether the public reporting of the measure would be meaningful or useful to consumers. One commenter said that as with most publicly reported data, there is a generous lag time from when the vaccine is administered, the data gathered and submitted, and their eventual display online.

Response: The data will be posted on Care Compare as soon as technically feasible, and therefore having a one quarter reporting period reduces the lag following the data submission deadline. We believe this mitigates concerns that the data would not reflect 'recent' information to consumers.

Comment: Another commenter expressed concern about the impact of publicly reporting the data due to the fact that potential patients may infer that a lower vaccination rate implies the facility has a certain political viewpoint on vaccinations, and that could influence their decision to choose the facility.

Response: It is true that individual patients can make their own inference regarding the rates displayed publicly, and a provider may or may not be able to influence that. However, per 1899B(g) of the Act, CMS is statutorily obligated to publicly report IRF performance on the IRF QRP quality measures. This measure will provide potential patients and their caregivers with an important piece of information regarding vaccination rates as part of their process of identifying providers they would want to seek care from, alongside other measures available on Care Compare to make a comprehensive decision.

After consideration of the public comments we received, we are finalizing our proposal to begin publicly displaying data for the Patient/Resident COVID-19 measure beginning with the September 2025 Care Compare refresh or as soon as technically feasible.

X. Provisions of the Final Regulations

In the final rule, we are adopting the provisions set forth in the FY 2024 IRF PPS proposed rule (88 FR 20950), specifically:

- We will update the CMG relative weights and average length of stay values for FY 2024, in a budget neutral manner, as discussed in section V. of this final rule.
- We will update the IRF PPS payment rates for FY 2024 by the market basket increase factor, based upon the most current data available, with a productivity adjustment required by section 1886(j)(3)(C)(ii)(I) of the Act, as described in section VI. of this final rule.
- We will rebase and revise the IRF market basket to reflect a 2021 base year, as discussed in section VI. of this final rule.
- We will update the FY 2024 IRF PPS payment rates by the FY 2024 wage index and the labor-related share in a budget-neutral manner, as discussed in section VI. of this final rule.
- We will calculate the IRF standard payment conversion factor for FY 2024, as discussed in section VI. of final rule.
- We will update the outlier threshold amount for FY 2024, as discussed in section VII. of this final rule.
- We will update the cost-to-charge ratio (CCR) ceiling and urban/rural average CCRs for FY 2024, as discussed in section VII. of this final rule.
- We will modify the regulation for IRF units to become excluded and paid under the IRF PPS as discussed in section VIII. of this final rule.
- We are also adopting updates to the IRF QRP in section IX. of this final rule as follows:

++ We are adopting the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up

to Date (Patient/Resident COVID-19 Vaccine) measure.

++ We are adopting the Discharge Function Score (DC Function) measure.

++ We are modifying the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) (HCP COVID-19 Vaccine) measure.

++ We are removing the Application of 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) measure.

++ We are removing the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (Change in Self-Score) measure.

++ We are removing the IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (Change in Mobility Score) measure.

XI. Collection of Information Requirements

Under the Paperwork Reduction Act 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 Paperwork Reduction Act 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.

This final rule refers to associated information collections that are not discussed in the regulation text contained in this document.

A. Requirements for Updates Related to the IRF QRP Beginning with the FY 2025 IRF QRP

An IRF that does not meet the requirements of the IRF QRP for a fiscal year will receive a 2-percentage point reduction to its otherwise applicable annual increase factor for that fiscal year.

We believe that the burden associated with the IRF QRP is the time and effort associated with complying with the requirements of the IRF QRP. In section VIII.C. of the proposed rule, we proposed to modify one measure, adopt three new measures, and remove three measures from the IRF QRP.

As stated in section VIII.C.1.a. of the proposed rule, we proposed that IRFs submit data on one modified quality measure, the COVID-19 Vaccination Coverage among Healthcare Personnel (HCP) (HCP COVID-19 Vaccine) measure beginning with the FY 2025 IRF QRP. The data is collected through the Centers for Disease Control and Prevention (CDC's) National Health Safety Network (NHSN). IRFs currently utilize the NHSN for purposes of meeting other IRF QRP requirements, including the current HCP COVID-19 Vaccine measure. IRFs will continue to submit the HCP COVID-19 Vaccine measure data to CMS through the NHSN. The burden associated with the HCP COVID-19 Vaccine measure is accounted for under the CDC's information collection request currently approved under OMB control number 0920-1317 (expiration date: January 31, 2024). Because we did not propose any updates to the form, manner, and timing of data submission for this HCP COVID-19 Vaccine measure, there will be no increase in burden associated with the proposal and refer readers to the FY 2022 IRF PPS final rule (86 FR 42399 through 42400) for these policies.

In section VIII.C.1.b. of the proposed rule, we proposed to adopt the Discharge Function Score (DC Function) measure beginning with the FY 2025 IRF QRP. This assessment-based quality measure will be calculated using data from the IRF Patient Assessment Instrument (IRF-PAI) that are already reported to CMS for payment and quality reporting purposes, and the burden is accounted for in the information collection request currently approved under OMB

control number 0938-0842 (expiration date: August 31, 2025). There will be no additional burden for IRFs associated with the DC Function measure since it does not require collection of new data elements.

In section VIII.C.1.c. of the proposed rule, we also proposed to remove 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 beginning with the FY 2025 IRF QRP. We believe that the removal of the Application of Functional Assessment/Care Plan measure will result in a decrease of 18 seconds (0.3 minutes or 0.005 hours) of clinical staff time at admission beginning with the FY 2025 IRF QRP. We believe the IRF-PAI item affected by 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 item based on past IRF burden calculations in conjunction with expert opinion. 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 45 percent; PT 45 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' (BLS) May 2021 National Occupational Employment and Wage Estimates.²⁰⁴ To account for overhead and fringe benefits, we doubled the hourly wage. These amounts are detailed in Table 19.

²⁰⁴ U.S. Bureau of Labor Statistics' (BLS) May 2021 National Occupational Employment and Wage Estimates. https://www.bls.gov/oes/current/oes_nat.htm.

TABLE 19: 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

We estimated that the burden and cost for IRFs for complying with requirements of the FY 2025 IRF QRP would decrease under our proposal. Specifically, we believe that there will be a 0.005 hour decrease in clinical staff time to report data for each IRF-PAI completed at admission. Using data from calendar year 2021, we estimated 511,938 admission assessments from 1,133 IRFs annually. This equates to a decrease of 2,560 hours in burden at admission for all IRFs (0.005 hour × 511,938 admissions). Given 0.135 minutes of occupational therapist time at \$86.04 per hour, 0.135 minutes of physical therapist time at \$89.34 per hour, 0.015 minutes registered nurse time at \$79.56 per hour, 0.0075 minutes of licensed vocational nurse time at \$49.86 per hour, and 0.0075 minutes of speech language pathologist time at \$82.52 per hour to complete an average of 454 IRF-PAI admission assessments per IRF per year, we estimate the total cost will be decreased by \$194.79 (\$220,697.60 total reduction/1,133 IRFs) per IRF annually, or \$220,697.60 for all IRFs annually based on the proposed removal of the Application of Functional Assessment/Care Plan measure.

In section VIII.C.1.d. of the proposed rule, we proposed to remove the IRF Functional Outcome Measure: Change in Self-Care Score for Medical Rehabilitation Patients (Change in Self-Care Score) and the IRF Functional Outcome Measure: Change in Mobility Score for Medical Rehabilitation Patients (Change in Mobility Score) measures beginning with the FY 2025 IRF QRP. While these assessment-based quality measures were proposed for removal, the

data elements used to calculate the measures will still be collected by IRFs for payment and quality reporting purposes, specifically for other quality measures under the IRF QRP.

Therefore, we believe that the proposal to remove the Change in Self-Care Score and Change in Mobility Score measures will not decrease burden for IRFs.

In section VIII.C.2.a. of the proposed rule, we proposed to adopt the COVID-19 Vaccine: Percent of Patients/Residents Who Are Up to Date (Patient/Resident COVID-19 Vaccine) measure beginning with the FY 2026 IRF QRP. The proposed measure will be collected using the IRF-PAI. One data element will be added to the IRF-PAI at discharge in order to allow for collection of the Patient/Resident COVID-19 Vaccine measure, and we believe will result in an increase of 0.3 minutes of clinical staff time at discharge. We believe that the additional Patient/Resident COVID-19 Vaccine measure's data element will be completed equally by registered nurses and licensed vocational nurses. Mean hourly wages for these staff are detailed in Table 19. However, individual IRFs determine the staffing resources necessary. Using data from CY 2021, we estimated a total of 779,274 discharges on all patients regardless of payer from 1,133 IRFs annually. This equates to an increase of 3,896 hours in burden for all IRFs ($0.005 \text{ hour} \times 779,274 \text{ admissions}$). Given 0.15 minutes of registered nurse time at \$79.56 per hour and 0.15 minutes of licensed vocational nurse time at \$49.86 per hour to complete an average of 691 IRF-PAI discharge assessments per IRF per year, we estimate that the total cost of complying with the IRF QRP requirements will be increased by \$222.52 [$(\$64.71/\text{hr} \times 3,896 \text{ hours})/1,133 \text{ IRFs}$] per IRF annually, or \$252,110.16 ($\$64.71/\text{hr} \times 3,896 \text{ hours}$) for all IRFs annually based on the adoption of the Patient/Resident COVID-19 Vaccine measure. The information collection request approved under OMB control number 0938-0842 (expiration date: August 31, 2025) will be revised and sent to OMB for approval.

In summary, under OMB control number 0938-0842, the changes to the IRF QRP will result in a burden addition of \$27.73 per IRF ($\$31,412.56/1,133 \text{ IRFs}$). The total cost increase

related to this information collection is approximately \$31,412.56 and is summarized in Table 20.

TABLE 20: Change in Burden Associated with OMB Control Number 0938-0842

Quality Measure	Per IRF		All IRFs	
	Change in annual burden hours	Change in annual cost	Change in annual burden hours	Change in annual cost
Change in Burden associated with removal of the Application of Functional Assessment/Care Plan measure beginning with the FY 2025 IRF QRP	-2.26	-\$ 194.79	-2,560	-\$ 220,697.60
Change in Burden associated with adoption of the Patient/Resident COVID-19 Vaccine measure beginning with the FY 2026 IRF QRP	+3.44	+\$ 222.52	+3,896	+\$ 252,110.16
Total Change in burden for the IRF QRP associated with 0938-0842	1.18	\$ 27.73	1,336	\$ 31,412.56

We invited public comments on the proposed information collection requirements.

The following is a summary of the public comments received on the proposed revisions and our responses:

Comment: One commenter noted their disappointment that CMS continues to add and modify IRF QRP requirements while IRFs are still facing operational challenges related to the COVID-19 pandemic. They said the proposed modification to the HCP COVID-19 Vaccine measure beginning with the FY 2025 IRF QRP will add to their administrative burden and compliance costs. They also stated that the net effect of the removal of three current measures, the addition of two new measures, and the modification of one measure did not reduce any administrative burden associated with the IRF QRP.

Response: We acknowledge that the net effect of our policies finalized in this final rule is an increase of \$27.73 per IRF per year. However, despite the operational challenges imposed by the COVID-19 pandemic, we must maintain our commitment to quality of care for all patients. In this final rule, we have sought to strike an appropriate balance between maintaining our commitment to quality of care with the impact on IRFs. The result is a reduction of the IRF

QRP measure set from 18 to 17. We will continue to assess the IRF QRP measure set and use our Meaningful Measures Framework and measure removal criteria to guide decisions about future changes.

Comment: Two commenters stated the estimate of 18 seconds or 0.3 minutes of clinical staff time at discharge underestimates the burden of clinical staff to collect the Patient/Resident COVID-19 Vaccine measure. One of these commenters estimated the time required by a clinician to document a single item in the electronic medical record is around 7 seconds. This commenter also suggested the collection of the information from the patient to complete the data element will likely take far more than the remaining estimated 11 seconds, particularly due to the confusing nature and ongoing changes to the definition of “up to date,” as well as the time necessary to conduct a patient interview, reconcile information provided by the patient, review the medical records, or contact a proxy for the information. The commenter stated that CMS’ estimate does not account for the time needed to modify their electronic medical record system or to train staff for this measure. The other commenter suggested that the clinician type included in the burden estimate for the Patient/Resident COVID-19 Vaccine measure was not inclusive of the range of staff type that would need to receive an estimated hour of training. The commenter stated the training costs should be considered as a part of the burden estimate for completing the item.

Response: The 18 seconds (0.3 minutes) estimated for this item is based on past IRF burden calculations and represents the time it takes to encode the IRF-PAI. As the commenter pointed out in their example, the patient must be assessed, and information gathered. After the patient assessment is completed, the IRF-PAI is coded with the information and submitted to the Internet Quality Improvement and Evaluation System (iQIES), and it is these steps (after the patient assessment) that the estimated burden and cost captures. Finally, as we stated in section X.A. of this final rule, our assumptions for staff type were based on the categories generally necessary to perform an assessment, and subsequently encode it, which is consistent with past

collection of information estimates.²⁰⁵ While we acknowledge that some IRFs may train and utilize other personnel, our estimates are based on the categories of personnel necessary to complete the IRF-PAI.

Comment: We received comments about the burden estimate for the DC Function Score measure. One commenter opposed the adoption of this measure given the growing burden of administering the IRF QRP, workforce shortages, and financial pressures. Two other commenters suggested that the measure's adoption will require software updates to implement and monitor the measure's complex calculations prior to CMS publishing results, as well as additional training and education for clinical and administrative personnel. One of these commenters recommended CMS should consider these costs because they impact the values presented in the FY 2024 IRF PPS proposed rule. Another commenter observed IRFs will still need to educate and train their clinicians on the new measure, incorporate discussion of this measure into their interdisciplinary team meetings, and create a solution that will calculate imputation values and the risk-adjusted expected discharge function score values in order to manage performance.

Response: CMS continually looks for opportunities to minimize burden associated with collection of the IRF-PAI for information users through strategies that simplify collection and submission requirements. As discussed in sections IX.C.1.b. and X.A. of this final rule, this measure is modeled after the currently adopted Discharge Mobility Score and Discharge Self-Care Score measures, and we are not proposing changes to the number of items required or the reporting frequency of the items reported in the IRF-PAI for this DC Function measure. IRFs have been collecting the data elements used in the calculation of the DC Function measure since FY 2017. At that time, we standardized the collection instructions across all IRFs, ensuring that all instructions and notices are written in plain language, and by providing step-by-step examples for completing the IRF-PAI. CMS provides a dedicated help desk to support users and respond

²⁰⁵ FY 2016 IRF PPS proposed rule (80 FR 23390).

to questions about the data collection. Additionally, a dedicated IRF QRP webpage houses multiple modes of tools, such as instructional videos, case studies, user manuals, and frequently asked questions which support understanding of the items collected for the DC Function measure and the IRF-PAI generally, and these can be used by current users and assist new users of the IRF-PAI. CMS utilizes a listserv to facilitate outreach to users, such as communicating timely and important new material(s), and we will use those outreach resources when providing training and information about the new DC Function measure. CMS creates data collection specifications for IRF electronic health record (EHR) software with ‘skip’ patterns associated with the Quality Indicator items used for the DC Function measure to ensure the IRF-PAI is limited to the minimum data required to meet quality reporting requirements. These specifications are available free of charge to all IRFs and their technology partners. Further, these minimum requirements are standardized for all users of the IRF-PAI assessment forms. Finally, CMS calculates this measure for IRFs, and provides IRFs with various resources to review and monitor their own performance on this measure, including a free internet-based system through which users can access on-demand reports for feedback on the collection of the IRF-PAI associated with their facility.

After considering the public comments received, and for the reasons outlined in this section of the final rule and our comment responses, we are finalizing the revisions as proposed.

XII. Regulatory Impact Analysis

A. Statement of Need

This final rule updates the IRF prospective payment rates for FY 2024 as required under section 1886(j)(3)(C) of the Act and in accordance with section 1886(j)(5) of the Act, which requires the Secretary to publish in the **Federal Register** on or before August 1 before each FY, the classification and weighting factors for CMGs used under the IRF PPS for such FY and a description of the methodology and data used in computing the prospective payment rates under the IRF PPS for that FY. This final rule also implements section 1886(j)(3)(C) of the Act, which

requires the Secretary to apply a productivity adjustment to the market basket increase factor for FY 2012 and subsequent years.

Furthermore, this final rule adopts policy changes to the IRF QRP under the statutory discretion afforded to the Secretary under section 1886(j)(7) of the Act. We are finalizing updates to the IRF QRP requirements beginning with the FY 2025 IRF QRP and FY 2026 IRF QRP. We are finalizing a modification to a current measure in the IRF QRP which we believe will encourage healthcare personnel to remain up to date with the COVID-19 vaccine, resulting in fewer cases, less hospitalizations, and lower mortality associated with the virus. We are finalizing the adoption of two new measures: one measure to maintain compliance with the requirements of section 1899B of the Act and replace the current cross-setting process measure with a measure that is more strongly associated with desired patient functional outcomes; and a second measure that supports the goals of CMS Meaningful Measures Initiative 2.0 to empower consumers with tools and information as they make healthcare choices as well as assist IRFs to leverage their care processes to increase vaccination coverage in their settings to protect residents and prevent negative outcomes. We are finalizing the removal of three measures from the IRF QRP as they meet the criteria specified at § 412.634(b)(2) for measure removal.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094 entitled “Modernizing Regulatory Review” (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches

that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). The Executive Order 14094 entitled “Modernizing Regulatory Review” (hereinafter, the Modernizing E.O.) amends section 3(f)(1) of Executive Order 12866 (Regulatory Planning and Review). The amended 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 \$200 million or more in any 1 year (adjusted every 3 years by the Administrator of OIRA for changes in gross domestic product), or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, territorial, 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) raise legal or policy issues for which centralized review would meaningfully further the President’s priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case.

A regulatory impact analysis (RIA) must be prepared for major rules with significant regulatory action/s and/or with significant effects as per section 3(f)(1) (\$200 million or more in any 1 year). We estimate the total impact of the policy updates described in this final rule by comparing the estimated payments in FY 2024 with those in FY 2023. This analysis results in an estimated \$355 million increase for FY 2024 IRF PPS payments. Additionally, we estimate that costs associated with updating the reporting requirements under the IRF QRP result in an estimated \$31,783,532.15 additional cost in FY 2026 for IRFs. Based on our estimates, OMB’s Office of Information and Regulatory Affairs has determined this rulemaking is significant per section 3(f)(1) as measured by the \$200 million or more in any 1 year, and hence also a major rule under Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (also

known as the Congressional Review Act). Accordingly, we have prepared an RIA that, to the best of our ability, presents the costs and benefits of the rulemaking.

C. Anticipated Effects

1. Effects on IRFs

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 IRFs and most other providers and suppliers are small entities, either by having revenues of \$8.0 million to \$41.5 million or less in any 1 year depending on industry classification, or by being nonprofit organizations that are not dominant in their markets. (For details, see the Small Business Administration's final rule that set forth size standards for health care industries, at 65 FR 69432 at https://www.sba.gov/sites/default/files/2019-08/SBA%20Table%20of%20Size%20Standards_Effective%20Aug%202019%2C%202019_Rev.pdf, effective January 1, 2017 and updated on August 19, 2019.) Because we lack data on individual hospital receipts, we cannot determine the number of small proprietary IRFs or the proportion of IRFs' revenue that is derived from Medicare payments. Therefore, we assume that all IRFs (an approximate total of 1,133 IRFs, of which approximately 50 percent are nonprofit facilities) are considered small entities and that Medicare payment constitutes the majority of their revenues. HHS generally uses a revenue impact of 3 to 5 percent as a significance threshold under the RFA. As shown in Table 21, we estimate that the net revenue impact of the final rule on all IRFs is to increase estimated payments by approximately 4.0 percent. The rates and policies set forth in this final rule will not have a significant impact (not greater than 4 percent) on a substantial number of small entities. The estimated impact on small entities is shown in Table 21. MACs are not considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a

significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. As shown in Table 21, we estimate that the net revenue impact of this final rule on rural IRFs is to increase estimated payments by approximately 3.6 percent based on the data of the 135 rural units and 12 rural hospitals in our database of 1,133 IRFs for which data were available. We estimate an overall impact for rural IRFs in all areas between 2.0 percent and 6.2 percent. As a result, we anticipate that this final rule will not have a significant impact on a substantial number of small entities.

Section 202 of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-04, enacted March 22, 1995) (UMRA) 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 is approximately \$177 million. This final rule does not mandate any requirements for State, local, or tribal governments, or for the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it issues 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. As stated, this final rule will not have a substantial effect on State and local governments, preempt State law, or otherwise have a federalism implication.

2. Detailed Economic Analysis

This final rule will update the IRF PPS rates contained in the FY 2023 IRF PPS final rule (87 FR 47038). Specifically, this final rule will update the CMG relative weights and ALOS values, the wage index, and the outlier threshold for high-cost cases. This final rule will apply a productivity adjustment to the FY 2024 IRF market basket increase factor in accordance with section 1886(j)(3)(C)(ii)(I) of the Act. Further, this final rule rebases and revises the IRF market

basket to reflect a 2021 base year. We are also modifying the regulation governing when IRF units can be excluded and paid under the IRF PPS.

We estimate that the impact of the changes and updates described in this final rule would be a net estimated increase of \$355 million in payments to IRFs. The impact analysis in Table 21 of this final rule represents the projected effects of the updates to IRF PPS payments for FY 2024 compared with the estimated IRF PPS payments in FY 2023. We determine the effects by estimating payments while holding all other payment variables constant. We use the best data available, but we do not attempt to predict behavioral responses to these changes, and we do not make adjustments for future changes in such variables as number of discharges or case-mix.

We note that certain events may combine to limit the scope or accuracy of our impact analysis, because such an analysis is future-oriented and, thus, susceptible to forecasting errors because of other changes in the forecasted impact time period. Some examples could be legislative changes made by the Congress to the Medicare program that would impact program funding, or changes specifically related to IRFs. Although some of these changes may not necessarily be specific to the IRF PPS, the nature of the Medicare program is such that the changes may interact, and the complexity of the interaction of these changes could make it difficult to predict accurately the full scope of the impact upon IRFs.

In updating the rates for FY 2024, we are implementing the standard annual revisions described in this final rule (for example, the update to the wage index and market basket increase factor used to adjust the Federal rates). We are also reducing the FY 2024 IRF market basket increase factor by a productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act. We estimate the total increase in payments to IRFs in FY 2024, relative to FY 2023, would be approximately \$355 million.

This estimate is derived from the application of the FY 2024 IRF market basket increase factor, as reduced by a productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act, which yields an estimated increase in aggregate payments to IRFs of \$305 million.

However, there is an estimated \$50 million increase in aggregate payments to IRFs due to the update to the outlier threshold amount. Therefore, we estimate that these updates would result in a net increase in estimated payments of \$355 million from FY 2023 to FY 2024.

The effects of the updates that impact IRF PPS payment rates are shown in Table 21. The following updates that affect the IRF PPS payment rates are discussed separately below:

- The effects of the update to the outlier threshold amount, from approximately 2.5 percent to 3.0 percent of total estimated payments for FY 2024, consistent with section 1886(j)(4) of the Act.
- The effects of the annual market basket update (using the 2021-based IRF market basket) to IRF PPS payment rates, as required by sections 1886(j)(3)(A)(i) and (j)(3)(C) of the Act, including a productivity adjustment in accordance with section 1886(j)(3)(C)(ii)(I) of the Act.
- The effects of applying the budget-neutral labor-related share and wage index adjustment, as required under section 1886(j)(6) of the Act, accounting for the permanent cap on wage index decreases when applicable.
- The effects of the budget-neutral changes to the CMG relative weights and ALOS values under the authority of section 1886(j)(2)(C)(i) of the Act.
- The total change in estimated payments based on the FY 2024 payment changes relative to the estimated FY 2023 payments.

3. Description of Table 21

Table 21 shows the overall impact on the 1,133 IRFs included in the analysis.

The next 12 rows of Table 21 contain IRFs categorized according to their geographic location, designation as either a freestanding hospital or a unit of a hospital, and by type of ownership; all urban, which is further divided into urban units of a hospital, urban freestanding hospitals, and by type of ownership; and all rural, which is further divided into rural units of a hospital, rural freestanding hospitals, and by type of ownership. There are 986 IRFs located in

urban areas included in our analysis. Among these, there are 648 IRF units of hospitals located in urban areas and 338 freestanding IRF hospitals located in urban areas. There are 147 IRFs located in rural areas included in our analysis. Among these, there are 135 IRF units of hospitals located in rural areas and 12 freestanding IRF hospitals located in rural areas. There are 459 for-profit IRFs. Among these, there are 424 IRFs in urban areas and 35 IRFs in rural areas. There are 571 non-profit IRFs. Among these, there are 480 urban IRFs and 91 rural IRFs. There are 103 government-owned IRFs. Among these, there are 82 urban IRFs and 21 rural IRFs.

The remaining four parts of Table 21 show IRFs grouped by their geographic location within a region, by teaching status, and by DSH patient percentage (PP). First, IRFs located in urban areas are categorized for their location within a particular one of the nine Census geographic regions. Second, IRFs located in rural areas are categorized for their location within a particular one of the nine Census geographic regions. In some cases, especially for rural IRFs located in the New England, Mountain, and Pacific regions, the number of IRFs represented is small. IRFs are then grouped by teaching status, including non-teaching IRFs, IRFs with an intern and resident to average daily census (ADC) ratio less than 10 percent, IRFs with an intern and resident to ADC ratio greater than or equal to 10 percent and less than or equal to 19 percent, and IRFs with an intern and resident to ADC ratio greater than 19 percent. Finally, IRFs are grouped by DSH PP, including IRFs with zero DSH PP, IRFs with a DSH PP less than 5 percent, IRFs with a DSH PP between 5 and less than 10 percent, IRFs with a DSH PP between 10 and 20 percent, and IRFs with a DSH PP greater than 20 percent.

The estimated impacts of each policy described in this rule to the facility categories listed are shown in the columns of Table 21. The description of each column is as follows:

- Column (1) shows the facility classification categories.
- Column (2) shows the number of IRFs in each category in our FY 2024 analysis file.
- Column (3) shows the number of cases in each category in our FY 2024 analysis file.
- Column (4) shows the estimated effect of the adjustment to the outlier threshold

amount.

- Column (5) shows the estimated effect of the update to the IRF labor-related share and wage index, in a budget-neutral manner.

- Column (6) shows the estimated effect of the update to the CMG relative weights and ALOS values, in a budget-neutral manner.

- Column (7) compares our estimates of the payments per discharge, incorporating all of the policies reflected in this final rule for FY 2024 to our estimates of payments per discharge in FY 2023.

The average estimated increase for all IRFs is approximately 4.0 percent. This estimated net increase includes the effects of the IRF market basket update for FY 2024 of 3.4 percent, which is based on a IRF market basket increase factor of 3.6 percent, less a 0.2 percentage point productivity adjustment, as required by section 1886(j)(3)(C)(ii)(I) of the Act. It also includes the approximate 0.6 percent overall increase in estimated IRF outlier payments from the update to the outlier threshold amount. Since we are making the updates to the IRF wage index, labor-related share and the CMG relative weights in a budget-neutral manner, they will not be expected to affect total estimated IRF payments in the aggregate. However, as described in more detail in each section, they will be expected to affect the estimated distribution of payments among providers.

TABLE 21: IRF Impact for FY 2024 (Columns 4 through 7 in percentage)

Facility Classification	Number of IRFs	Number of Cases	Outlier	FY 2024 Wage Index and Labor-Related Share	CMG Weights	Total Percent Change ¹
(1)	(2)	(3)	(4)	(5)	(6)	(7)
Total	1,133	385,653	0.6	0.0	0.0	4.0
Urban unit	648	137,080	1.0	0.0	0.0	4.5
Rural unit	135	16,844	0.9	-0.4	0.0	3.9
Urban hospital	338	226,579	0.2	0.0	0.0	3.7
Rural hospital	12	5,150	0.2	-0.8	0.1	2.8
Urban For-Profit	424	221,988	0.3	0.0	0.0	3.7
Rural For-Profit	35	8,209	0.4	-0.7	0.0	3.1
Urban Non-Profit	480	123,128	0.9	0.1	0.0	4.4

Facility Classification	Number of IRFs	Number of Cases	Outlier	FY 2024 Wage Index and Labor-Related Share	CMG Weights	Total Percent Change ¹
Rural Non-Profit	91	11,642	1.0	-0.3	0.0	4.0
Urban Government	82	18,543	1.0	0.0	0.0	4.5
Rural Government	21	2,143	0.6	-0.5	0.0	3.4
Urban	986	363,659	0.5	0.0	0.0	4.0
Rural	147	21,994	0.7	-0.5	0.0	3.6
Urban by region						
Urban New England	29	13,450	0.4	-0.2	0.0	3.6
Urban Middle Atlantic	118	40,542	0.7	0.5	0.0	4.7
Urban South Atlantic	170	81,632	0.5	0.1	0.0	4.0
Urban East North Central	164	43,093	0.6	-0.5	0.0	3.5
Urban East South Central	55	25,607	0.2	-0.1	0.0	3.5
Urban West North Central	77	21,080	0.6	0.1	0.0	4.1
Urban West South Central	201	87,094	0.3	0.3	0.0	4.0
Urban Mountain	77	27,560	0.5	-1.0	0.0	2.8
Urban Pacific	95	23,601	1.2	0.3	0.0	5.0
Rural by region						
Rural New England	5	1,054	0.8	-2.3	0.2	2.0
Rural Middle Atlantic	10	1,048	1.1	-0.5	0.0	4.1
Rural South Atlantic	15	3,957	0.3	0.2	0.0	3.9
Rural East North Central	24	2,939	0.6	-0.6	0.0	3.4
Rural East South Central	21	3,453	0.3	-0.6	0.0	3.0
Rural West North Central	20	2,374	1.2	-0.5	-0.1	4.0
Rural West South Central	43	6,423	0.8	-0.5	0.0	3.7
Rural Mountain	6	461	1.7	-0.1	0.0	4.9
Rural Pacific	3	285	3.1	-0.3	0.0	6.2
Teaching status						
Non-teaching	1,030	341,160	0.5	-0.1	0.0	3.9
Resident to ADC less than 10%	58	32,410	0.7	0.3	0.0	4.4
Resident to ADC 10%-19%	33	10,675	1.1	0.6	0.0	5.2
Resident to ADC greater than 19%	12	1,408	1.4	0.7	-0.1	5.5
Disproportionate share patient percentage (DSH PP)						
DSH PP = 0%	49	6,136	0.7	0.5	0.0	4.6
DSH PP <5%	137	60,402	0.4	0.4	0.0	4.1
DSH PP 5%-10%	233	92,942	0.4	0.0	0.0	3.9
DSH PP 10%-20%	415	150,180	0.6	-0.1	0.0	3.8
DSH PP greater than 20%	299	75,993	0.8	-0.1	0.0	4.2

¹This column includes the impact of the updates in columns (4), (5), and (6) above, and of the IRF market basket update for FY 2024 of 3.6 percent, reduced by 0.2 percentage point for the productivity adjustment as required by section 1886(j)(3)(C)(ii)(I) of the Act. Note, the products of these impacts may be different from the percentage changes shown here due to rounding effects.

4. Impact of the Update to the Outlier Threshold Amount

The estimated effects of the update to the outlier threshold adjustment are presented in column 4 of Table 21.

For the FY 2024 proposed rule, we used preliminary FY 2022 IRF claims data and based on that preliminary analysis, we estimated that IRF outlier payments as a percentage of total

estimated IRF payments would be 2.3 percent in FY 2023. As we typically do between the proposed and final rules each year, we updated our FY 2022 IRF claims data to ensure that we are using the most recent available data in setting IRF payments. Therefore, based on an updated analysis of the most recent IRF claims data for this final rule, we estimate that IRF outlier payments as a percentage of total estimated IRF payments are 2.5 percent in FY 2023. Thus, we are adjusting the outlier threshold amount in this final rule to maintain total estimated outlier payments equal to 3 percent of total estimated payments in FY 2024.

The impact of this update to the outlier threshold amount (as shown in column 4 of Table 21) is to increase estimated overall payments to IRFs by 0.6 percentage point. We do not estimate that any group of IRFs would experience a decrease in payments from this proposed update.

5. Impact of the Wage Index, Labor-Related Share, and Wage Index Cap

In column 5 of Table 21, we present the effects of the budget-neutral update of the wage index and labor-related share, taking into account the permanent 5 percent cap on wage index decreases, when applicable. The changes to the wage index and the labor-related share are discussed together because the wage index is applied to the labor-related share portion of payments, so the changes in the two have a combined effect on payments to providers. As discussed in section VI.E. of this final rule, we update the FY 2024 labor-related share from 72.9 percent in FY 2023 to 74.1 percent in FY 2024. In aggregate, we do not estimate that these updates will affect overall estimated payments to IRFs. However, we do expect these updates to have small distributional effects. We estimate the largest decrease in payment from the update to the CBSA wage index and labor-related share to be a 2.3 percent decrease for IRFs in the Rural New England region and the largest increase in payment to be a 0.5 percent increase for IRFs in the Urban Middle Atlantic Region.

6. Impact of the Update to the CMG Relative Weights and ALOS Values

In column 6 of Table 21, we present the effects of the budget-neutral update of the CMG

relative weights and ALOS values. In the aggregate, we do not estimate that these updates will affect overall estimated payments of IRFs. However, we do expect these updates to have small distributional effects, with the largest effect being an increase in payments of 0.2 percent to IRFs in the Rural New England region.

7. Effects of Modification of the Regulation for Excluded IRF Units Paid Under the IRF PPS

As discussed in section VIII. of this final rule, we are amending the regulation text at § 412.25(c)(1) in this final rule.

We do not anticipate a financial impact associated with the modification of the regulation for excluded IRF units paid under the IRF PPS because an IRF unit would simply be opening on a different date (in the middle of a cost reporting period) than they otherwise would have (at the start of a cost reporting period). Although this modification to the regulatory requirements significantly reduces the burden of opening new IRF units and reduces IRF's construction costs, we do not believe that it will significantly affect IRF payments.

In response to the need for availability of inpatient rehabilitation beds we are implementing changes to § 412.25(c) to allow greater flexibility for hospitals to open excluded units, while minimizing the amount of effort that Medicare contractors would need to spend administering the regulatory requirements. We believe this change will provide IRFs greater flexibility when establishing an excluded unit at a time other than the start of a cost reporting period.

8. Effects of Requirements for the IRF QRP Beginning with FY 2025

In accordance with section 1886(j)(7)(A) of the Act, the Secretary must reduce by 2 percentage points the annual market basket increase factor otherwise applicable to an IRF for a fiscal year if the IRF does not comply with the requirements of the IRF QRP for that fiscal year. In section IX.A. of the proposed rule, we discussed the method for applying the 2 percentage point reduction to IRFs that fail to meet the IRF QRP requirements.

As discussed in section IX.C.1.a. of this final rule, we are finalizing the proposal to

modify one measure in the IRF QRP beginning with the FY 2025 IRF QRP, the HCP COVID-19 Vaccine measure. We believe that the burden associated with the IRF QRP is the time and effort associated with complying with the non-claims-based measures requirements of the IRF QRP. 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 January 31, 2024).

As discussed in section IX.C.1.b. of this final rule, we are finalizing the proposal for IRFs to collect data on one new quality measure, the DC Function measure, beginning with assessments completed on October 1, 2023. However, the measure utilizes data items that IRFs already report to CMS for payment and quality reporting purposes, and therefore the burden is accounted for in the PRA package approved under OMB control number 0938-0842 (expiration August 31, 2025).

As discussed in section IX.C.1.c. of this final rule, we are finalizing the proposal to remove the Application of Functional Assessment/Care Plan measure, from the IRF QRP, and this proposal would result in a decrease of 0.3 minutes of clinical staff time beginning with admission assessments completed on October 1, 2023. The proposed decrease in burden will be accounted for in a revised information collection request under OMB control number (0938-0842), and we provided impact information. We believe the data element for this quality measure is completed by occupational therapists (45 percent of the time or 0.135 minutes), physical therapists (45 percent of the time or 0.135 minutes), registered nurses (5 percent of the time or 0.015 minutes), licensed practical and vocational nurses (2.5 percent of the time or 0.0075 minutes), or by speech-language pathologists (2.5 percent of the time or 0.0075 minutes). 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' (BLS) May 2021 National Occupational Employment and Wage Estimates.²⁰⁶ To account for overhead and fringe benefits, we doubled the hourly wage. These amounts are detailed in Table 22.

TABLE 22: 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

With 511,938 admissions from 1,133 IRFs annually, we estimated an annual burden decrease of 2,560 fewer hours (511,938 admissions x .005 hours) and a decrease of \$220,697.60 [2,560 hours x \$86.21/hr]. For each IRF we estimated an annual burden decrease of 2.26 hours (2,560 hours/1,133 IRFs) at a savings of \$194.79 (\$220,697.60/1,133 IRFs).

As discussed in section IX.C.1.d. of this final rule, we are finalizing the removal of two additional measures from the IRF QRP, the Change in Self-Care Score and Change in Mobility Score measures, beginning with assessments completed on October 1, 2023. However, the data items used in the calculation of this measure are used for other payment and quality reporting purposes, and therefore there is no change in burden associated with this proposal.

9. Effects of Requirements for the IRF QRP Beginning with FY 2026

As discussed in section IX.C.2.a. of this final rule, we are finalizing the adoption of the Patient/Resident COVID-19 Vaccine measure, beginning with the FY 2026 IRF QRP. We estimated this measure would result in an increase of 0.3 minutes of clinical staff time beginning with discharge assessments completed on October 1, 2024. Although the increase in burden will be accounted for in a revised information collection request under OMB control number

²⁰⁶ U.S. Bureau of Labor Statistics' (BLS) May 2021 National Occupational Employment and Wage Estimates. https://www.bls.gov/oes/current/oes_nat.htm.

0938-0842, we provided impact information. We estimated the data element for this quality measure would be completed by registered nurses (50 percent of the time or 0.15 minutes) or by licensed practical and vocational nurses (50 percent of the time or 0.15 minutes). 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' (BLS) May 2021 National Occupational Employment and Wage Estimates.²⁰⁷ To account for overhead and fringe benefits, we doubled the hourly wage. These amounts are detailed in Table 22. With 779,274 discharges on all patients regardless of payer from 1,133 IRFs annually, we estimated an annual burden increase of 3,896 hours (779,274 discharges x 0.005 hours) and an increase of \$252,110.16 (\$64.71/hr x 3,896 hours). For each IRF, we estimated an annual burden increase of 3.44 hours (3,896 hours/1,133 IRFs) at an additional cost of \$222.52 (\$252,110.16/1,133 IRFs).

In summary, under OMB control number 0938-0842, the changes to the IRF QRP will result in an estimated increase in programmatic burden for 1,133 IRFs. The total burden increase is approximately \$31,412.56 for all IRFs and \$27.73 per IRF and is summarized in Table 23.

²⁰⁷ U.S. Bureau of Labor Statistics' (BLS) May 2021 National Occupational Employment and Wage Estimates. https://www.bls.gov/oes/current/oes_nat.htm.

TABLE 23: Estimated IRF QRP Program Impacts for FY 2025 and FY 2026

Quality Measure	Per IRF		All IRFs	
	Change in annual burden hours	Change in annual cost	Change in annual burden hours	Change in annual cost
Change in Burden associated with removal of the Application of Functional Assessment/Care Plan measure beginning with the FY 2025 IRF QRP	-2.26	-\$ 194.79	-2,560	-\$ 220,697.60
Change in Burden associated with the adoption of the Patient/Resident COVID-19 Vaccine measure beginning with the FY 2026 IRF QRP	+3.44	+\$ 222.52	+3,896	+\$ 252,110.16
Total increase in burden for the IRF QRP finalized in this rule	1.18	\$ 27.73	1,336	\$ 31,412.56

We invited public comments on the overall impact of the IRF QRP proposals for FY 2025 and FY 2026.

We did not receive any comments on the proposed revisions and therefore, we are finalizing the revisions as proposed.

D. Alternatives Considered

The following is a discussion of the alternatives considered for the IRF PPS updates contained in this final rule.

Section 1886(j)(3)(C) of the Act requires the Secretary to update the IRF PPS payment rates by an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services.

We proposed to adopt a market basket increase factor for FY 2024 that is based on a rebased and revised market basket reflecting a 2021 base year. We considered the alternative of continuing to use the 2016-based IRF market basket without rebasing to determine the market basket increase factor for FY 2024. However, we typically rebase and revise the market baskets for the various PPS every 4 to 5 years so that the cost weights and price proxies reflect more recent data. Therefore, we believe it is more technically appropriate to use a 2021-based IRF market basket since it allows for the FY 2024 market basket increase factor to reflect a more up-

to-date cost structure experienced by IRFs.

As noted previously in this final rule, section 1886(j)(3)(C) of the Act requires the Secretary to update the IRF PPS payment rates by an increase factor that reflects changes over time in the prices of an appropriate mix of goods and services included in the covered IRF services and section 1886(j)(3)(C)(ii)(I) of the Act requires the Secretary to apply a productivity adjustment to the market basket increase factor for FY 2024. Thus, in accordance with section 1886(j)(3)(C) of the Act, we are updating the IRF prospective payments in this final rule by 3.4 percent (which equals the 3.6 percent estimated IRF market basket increase factor for FY 2024 reduced by a 0.2 percentage point productivity adjustment as determined under section 1886(b)(3)(B)(xi)(II) of the Act (as required by section 1886(j)(3)(C)(ii)(I) of the Act)).

We considered maintaining the existing CMG relative weights and average length of stay values for FY 2024. However, in light of recently available data and our desire to ensure that the CMG relative weights and average length of stay values are as reflective as possible of recent changes in IRF utilization and case mix, we believe that it is appropriate to update the CMG relative weights and average length of stay values at this time to ensure that IRF PPS payments continue to reflect as accurately as possible the current costs of care in IRFs.

We considered maintaining the existing outlier threshold amount for FY 2024. However, analysis of updated FY 2023 data indicates that estimated outlier payments would be less than 3 percent of total estimated payments for FY 2024, unless we updated the outlier threshold amount. Consequently, we are adjusting the outlier threshold amount in this final rule to maintain estimated outlier payments at 3 percent of estimated aggregate payments in FY 2024.

We considered not modifying the regulation governing when IRF units can be excluded and paid under the IRF PPS. However, we believe that amending the regulation would provide hospitals greater flexibility when establishing an IRF.

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 IRF QRP Program, the COVID-19

pandemic has exposed the importance of implementing infection prevention strategies, including the promotion of COVID-19 vaccination for HCP and patients/residents. We believe these measures would 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 IRFs as well as provide data to patients and caregivers through transparency of data. Therefore, these measures have the potential to generate actionable data on COVID-19 vaccination rates.

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 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 cross-setting process measure (that is, the Application of Functional Assessment/Care Plan measure) with an outcome 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 removal of the Application of Functional Assessment/Care Plan measure meets measure removal factors one and six, and no longer provides meaningful distinctions in improvements in performance. Finally, the removal of the Change in Self-Care Score and Change in Mobility Score measures meets measure removal factor eight, and the costs associated with these measures outweigh the benefits of their use in the program. Therefore, no alternatives were considered.

E. Regulatory Review Costs

If regulations impose administrative costs on private entities, such as the time needed to read and interpret this final 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 the FY 2024 IRF PPS proposed rule will be the number of reviewers of this year's final rule. We acknowledge that this assumption may understate or overstate the costs of reviewing this final rule. It is possible that not all commenters reviewed the FY 2024 IRF PPS proposed rule in detail, and it is also possible that some reviewers chose not to comment on the FY 2024 proposed rule. For these reasons, we thought that the number of commenters would be a fair estimate of the number of reviewers of this final rule.

We also recognize that different types of entities are in many cases affected by mutually exclusive sections of this final rule, and therefore, for the purposes of our estimate we assume that each reviewer reads approximately 50 percent of the rule.

Using the national mean hourly wage data from the May 2022 BLS for Occupational Employment Statistics (OES) for medical and health service managers (SOC 11-9111), we estimate that the cost of reviewing this rule is \$123.06 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 3 hours for the staff to review half of this final rule. For each reviewer of the rule, the estimated cost is \$369.18 (3 hours x \$123.06). Therefore, we estimate that the total cost of reviewing this regulation is \$16,613.10 (\$369.18 x 45 reviewers).

F. Accounting Statement and Table

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 24 we have prepared an accounting statement showing the classification of the expenditures associated with the provisions of this final rule. Table 24 provides our best estimate of the increase in Medicare

payments under the IRF PPS as a result of the updates presented in this final rule based on the data for 1,133 IRFs in our database.

TABLE 24: Accounting Statement: Classification of Estimated Expenditure

	Category	Transfers
Change in Estimated Transfers from FY 2023 IRF PPS to FY 2024 IRF PPS	Annualized Monetized Transfers	\$355 million
	From Whom to Whom?	Federal Government to IRF Medicare Providers
Estimated Costs Associated with the FY 2025 and FY 2026 IRF QRP	Annualized monetized cost in FY 2025 and FY 2026 for IRFs due to new quality reporting program requirements	\$31,412.56
Estimated Costs Associated with Review Cost for FY 2024 IRF PPS	Cost associated with regulatory review cost	\$16,613.10

G. Conclusion

Overall, the estimated payments per discharge for IRFs in FY 2024 are projected to increase by 4.0 percent, compared with the estimated payments in FY 2023, as reflected in column 7 of Table 21.

IRF payments per discharge are estimated to increase by 4.0 percent in urban areas and 3.6 percent in rural areas, compared with estimated FY 2023 payments. Payments per discharge to rehabilitation units are estimated to increase 4.5 percent in urban areas and 3.9 percent in rural areas. Payments per discharge to freestanding rehabilitation hospitals are estimated to increase 3.7 percent in urban areas and 2.8 percent in rural areas.

Overall, IRFs are estimated to experience a net increase in payments as a result of the policies in this final rule. The largest payment increase is estimated to be a 6.2 percent increase for IRFs located in the Rural Pacific region. The analysis above, together with the remainder of this preamble, provides an RIA.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by OMB.

Chiquita Brooks-LaSure, Administrator of the Centers for Medicare & Medicaid Services, approved this document on July 24, 2023.

Xavier Becerra,

Secretary,

Department of Health and Human Services.

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